RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 201]

Long-Term Care Nursing Facilities

The Department of Health (Department), after consultation with the Health Policy Board, amends §§ 201.1—201.3 (relating to applicability; requirements; and definitions), to read as set forth in Annex A. This is the first of four final-form rulemaking packages for long-term care nursing facilities being promulgated by the Department.

The contents for the four final-form rulemaking packages are as follows:

Rulemaking 1—General Applicability and Definitions

§ 201.1. Applicability.

§ 201.2. Requirements.

§ 201.3. Definitions.

§ 211.12. Nursing services. (Withdrawn on final-form.)

Rulemaking 2—General Operation and Physical Requirements

§ 201.23. Closure of facility.

Chapter 203. Application of Life Safety Code for Long-Term Care Nursing Facilities. (Reserved on final-form.)

Chapter 204. Physical Environment and Equipment Standards for Construction, Alteration or Renovation of Long-Term Care Nursing Facilities after July 1, 2023.

Chapter 205. Physical Environment and Equipment Standards for Long-Term Care Nursing Facilities Construction, Alteration or Renovation Approved before July 1, 2023.

§ 207.4. Ice containers and storage. (Reserved on final-form.)

Rulemaking 3—Applications for Ownership, Management and Changes of Ownership; Health and Safety

§ 201.12. Application for license of a new facility or change in ownership.

§ 201.12a. Notice and opportunity to comment. (New section on final-form.)

§ 201.12b. Evaluation of application for license of a new facility or change in ownership. (Section renumbered on final-form.)

§ 201.13. Issuance of license for a new facility or change in ownership.

§ 201.13a. Regular license. (New section on final-form.)

§ 201.13b. Provisional license. (New section on final-form.)

§ 201.13c. License renewal. (Section renumbered on final-form.)

§ 201.14. Responsibility of licensee.

§ 201.15. Restrictions on license.

§ 201.15a. Enforcement. (New section on final-form.)

§ 201.15b. Appeals. (New section on final-form.)

§ 201.17. Location.

§ 201.22. Prevention, control and surveillance of tuberculosis (TB).

§ 209.1. Fire department service. (Reserved on final-form.)

§ 209.7. Disaster preparedness. (Reserved on final-form.)

§ 209.8. Fire drills. (Reserved on final-form.)

§ 211.1. Reportable diseases.

Rulemaking 4—Qualifications, Training, Job Duties, Recordkeeping, Program Standards and Resident Rights and Services

§ 201.18. Management.

§ 201.19. Personnel records.

§ 201.20. Staff development.

§ 201.21. Use of outside resources.

§ 201.24. Admission policy.

§ 201.25. Discharge policy. (Reserved on final-form.)

§ 201.26. Resident representative.

§ 201.29. Resident rights.

§ 201.30. Access requirements. (Reserved on final-form.)

§ 201.31. Transfer agreement.

§ 207.2. Administrator's responsibility. (Reserved on final-form.)

§ 209.3. Smoking.

§ 211.2. Medical director.

§ 211.3. Verbal and telephone orders.

§ 211.4. Procedure in event of death.

§ 211.5. Medical records.

§ 211.6. Dietary services.

§ 211.7. Physician assistants and certified registered nurse practitioners.

§ 211.8. Use of restraints.

§ 211.9. Pharmacy services.

§ 211.10. Resident care policies.

§ 211.11. Resident care plan. (Reserved on final-form.)

§ 211.12. Nursing services. (Consolidated amendments on final-form.)

§ 211.15. Dental services.

§ 211.16. Social services.

§ 211.17. Pet therapy.

Comments on Multiple Packages; Stakeholder Engagement

The Department received comments during the public comment periods of all four proposed rulemaking packages expressing concern with the Department's decision to divide the long-term care nursing facility regulations into separate rulemakings. As provided previously, the Department divided the regulatory packages as follows: Rulemaking 1—General Applicability and Definitions; Rulemaking 2—General Operation and Physical Requirements; Rulemaking 3—Applications for Ownership, Management and Changes of Ownership; Health and Safety; and Rulemaking 4—Qualifications, Training, Job Duties, Recordkeeping, Program Standards and Resident Rights and Services.

Although the Department intended to provide succinct areas for review and comment, commentators expressed some difficulty in reviewing sections of the regulations without the context of the remaining regulatory chapters and concern that multiple regulatory packages may lead to a lack of clarity and confusion for the regulated community and the public. Commentators also requested that the Department consider comments on all four proposed rulemaking packages outside of the 30-day comment period for each proposed package, or that the Department withdraw or resubmit all four proposed rulemaking packages as one package with an additional 30-day comment period. The Department also received comments regarding concern related to recent engagement with stakeholders, given that the Long-Term Care Work Group (LTC Work Group) last formally met in 2018 and was disbanded during the start of the novel coronavirus (COVID-19) pandemic.

In commenting on proposed Rulemaking 1, the Independent Regulatory Review Commission (IRRC) acknowledged the Department's authority to promulgate regulations as it deems appropriate. However, IRRC requested the Department consider the regulated community's comments and the requests regarding the separate rulemakings. IRRC specifically asked the Department to explain why its approach in dividing the amendments into multiple packages was reasonable. IRRC also asked that the Department ensure that amendments be consistent across the packages, and that the interrelation and any impacts between the packages be clearly presented for the regulated community.

In commenting on proposed Rulemaking 2, IRRC again echoed concerns that separate rulemakings have the potential consequence of inconsistencies and errors across the four packages. IRRC inquired whether having multiple regulatory packages is in the public interest, whether it protects the public health, safety and welfare, and whether it is reasonable and lacks ambiguity. IRRC asked whether it was in the public interest or reasonable to expect the regulated community to hold multiple proposed regulations simultaneously in mind while reviewing a proposed regulation. IRRC also asked the Department to: (1) identify in this final-form preamble any provisions which assume approval of Rulemaking 1 as final-form; (2) cross-reference these provisions to the relevant provisions in Rulemaking 1; and (3) explain the impact if Rulemaking 1 is not approved before or at the same time as Rulemaking 2. IRRC recommended that the Department deliver each of the four individual packages as final-form rulemakings on the same day. In addition, IRRC, in its comment for proposed Rulemaking 3 and Rulemaking 4 expressed the same concerns as in the previous proposed rulemakings, but additionally suggested that the Department consider issuing an Advance Notice of Final Rulemaking to assist in reaching consensus.

Response

At the outset, the Department recognized that the changes to the long-term care nursing facility regulations would be numerous and complex, whether presented in one giant package or in multiple packages. A large, single package would have been unwieldy and would likely have been presented around the date that the fourth regulatory package was completed and submitted (May 11, 2022). A later publication date would have resulted in less opportunity for comments, less time for the commentators to study the material and deliberate, and less time for necessary and valuable stakeholder engagement. Further, the regulated community's input throughout this process informed the administration and legislature's investment in this year's budget. As such, the decision was made to continue with the changes in smaller, separate, more digestible packages. As provided previously, the Department initially decided to divide the proposed amendments to the six regulatory chapters under Subpart C (relating to long-term care facilities) into multiple packages to allow the public and interested parties a greater opportunity to thoroughly examine and digest the distinct proposed regulatory amendments over a longer period of time. In dividing these six chapters over four rulemakings, the public and interested parties would be permitted to provide more detailed comments and allow the Department to focus more closely on comments, provide a thoroughly considered response to questions and comments, and tailor the remaining proposed packages based on additional public and stakeholder input.

Further, in response to these public comments, the Department has considered all public comments and IRRC's comments across all four proposed rulemakings before drafting the four final-form rulemakings. In addition, based on comments received, the Department is submitting all four final-form rulemakings to IRRC, the legislative standing committees and the public commentators together on the same day. The drafting and submitting of all four final-form rulemakings together at the end of the last public comment periods allows interested parties and the public to vet and comment on each package separately, as well as in relation to the other packages. Throughout this process, the Department has continued to accept and review comments and be available to meet with stakeholders. If a commentator believed that a proposed amendment in Rulemaking 4 did not align with a proposed amendment in Rulemaking 1, the commentator could submit a comment to that effect for consideration by the Department during the public comment period for the proposed Rulemaking 4.

The Department did, in fact, take into consideration comments received on proposed Rulemakings 1 and 2, when drafting proposed Rulemakings 3 and 4. This is evidenced by the proposal to expressly include text from the Centers for Medicare & Medicaid (CMS), State Operations Manual, Appendix PP into the text of the regulation. See for example, proposed Rulemaking 4, proposed § 201.29(o) (relating to resident's rights). This inclusion of specific text was based on comments received by commentators and IRRC in proposed Rulemaking 1. The Department also consolidated the total number of proposed packages from five to four packages in response to both public and IRRC comments received in proposed Rulemaking 1.

In addition to considering comments on the four proposed packages during and outside of the four public comment periods, the Department met with stakeholders on four occasions following the receipt of public comments to discuss their concerns and to gain additional insight into comments that were received. The first of these meetings, for proposed Rulemakings 1 and 2, occurred on December 15, 2021. Representatives from the American Association of Retired Persons (AARP), Alzheimer's Association—Delaware Valley and Greater Pennsylvania Chapters, Center for Advocacy for the Rights & Interests of the Elderly (CARIE), Community Legal Services, LeadingAge, Pennsylvania Health Care Association (PHCA), Pennsylvania Coalition of Affiliated Healthcare & Living Communities (PACAH), and SEIU Healthcare Pennsylvania (SEIU) attended that meeting. The second meeting, for proposed Rulemaking 3 occurred on June 8, 2022. Representatives from AARP, Alzheimer's Associa-

tion, CARIE, Community Legal Services, LeadingAge, PHCA Pennsylvania Health Law Project and SEIU again attended that stakeholder meeting. The Department explicitly stressed to stakeholders during this June 8, 2022, meeting that it would be considering comments on all proposed rulemakings, and that it would welcome any additional comments or feedback that stakeholders might have after the meeting regarding proposed amendments to the various regulatory chapters. The Department also indicated in a press release on proposed Rulemaking 4, issued on June 3, 2022, that it would be considering comments on all four proposed rulemakings before submitting final-form regulations. The third meeting with stakeholders, for proposed Rulemaking 4, occurred on August 3, 2022. Present at that meeting were representatives from AARP, Alzheimer's Association, CARIE, PHCA, Pennsylvania Health Funders Collaborative (PHFC) and SEIU. The Department held the fourth meeting on August 17, 2022. At this meeting, the Department presented stakeholders with an overview of the changes that were made from the proposed rulemakings to the final-form rulemakings in response to their comments, on all four rulemakings, and provided them with an opportunity to comment and provide feedback on the final-form regulations. Present at that meeting were representatives from the Alzheimer's Association, CARIE, Community Legal Services, County Commissioners Association, Disability Rights, LeadingAge, PHCA, PHFC and SEIU.

After consideration of all comments received on the four proposed packages, the Department firmly supports its decision in splitting the six long-term care nursing facility chapters into multiple packages. While the Department appreciates the comments and suggestion for one consolidated package, one is not needed at this stage due to the public, the regulated community, and advocates' full and continued opportunity to offer input on all of the long-term care nursing facilities' regulations, throughout the four separate public comment periods, the first of which occurred over a year ago, as well as during the stakeholder meetings that occurred from 2021 through August 2022. In addition, as mentioned previously, at the meeting on August 17, 2022, the Department provided stakeholders an overview of the changes that were adopted on all four rulemakings, to ensure that stakeholders fully understand all amendments. At that meeting, the Department also permitted stakeholders the opportunity to further comment on the final-form amendments and incorporated this feedback into the final-form regulations. Finally, as previously noted, splitting the regulations into multiple, separate packages benefited the public, the regulated community and advocates because it allowed the Department to incorporate their feedback as it moved forward with the drafting of subsequent packages, which promoted the public interest, health, safety and welfare by improving the overall quality of the proposed regulations.

The Department has, in each of the four final-form preambles, discussed and responded to all comments received on the contents of the four proposed rulemakings, regardless of when the comment was received. The Department has added cross-references, as appropriate, where comments received on one package relate to another package to further aid in the review of the four packages together in their entirety. For example, in proposed Rulemaking 1, the Department received comments requesting that staff, other than nursing personnel, be considered when determining whether a facility has met the minimum number of direct resident care hours in § 211.12(i) (relating to nursing services). In response to this comment, the types of individuals required for the minimum number of direct resident care hours was intentionally addressed in proposed Rulemaking 4 and generated additional comments during that proposed rulemaking's public comment period. The Department has, therefore, indicated in § 211.12(i) of the preamble for this final-form rulemaking, that it received comments on this topic and provided a cross-reference to the more in-depth discussion of this topic in the preamble for final-form Rulemaking 4. Further, to provide additional clarity and readability, the Department moved the proposed language relating to direct resident care hours from proposed Rulemaking 1 to final-form Rulemaking 4. Finally, the Department has noted where one rulemaking assumes the approval of another rulemaking. Through this extended review and public comment process, the Department has been transparent in its proposals and has responded to these comments throughout each rulemaking.

Background and Need for Amendments

The percentage of adults 65 years of age or older in this Commonwealth is increasing. In 2010, approximately 15% of Pennsylvanians were 65 years of age or older. In 2017, this number increased to 17.8%. In 2020, just under 20% of the population in Pennsylvania was 65 years of age or older. For every 10 individuals under 25 years of age lost in Pennsylvania since 2010, the State gained 21 persons 65 years of age or older. This Commonwealth also has a higher percentage of older adults when compared to other states. In 2017, this Commonwealth ranked fifth in the Nation in the number (2.2 million) of older adults and seventh in percentage (17.8%). The increase in older Pennsylvanians is expected to continue. It has been estimated that by 2030, there will be 38 older Pennsylvanians (65 years of age or older) for every 100-working age Pennsylvanians (15 years of age to 64 years of age). Penn State Harrisburg, Pennsylvania State Data Center (July 2018). Population Characteristics and Change: 2010 to 2017 (Research Brief). Retrieved from https://pasdc.hbg.psu.edu/data/research-briefs/pa-population-estimates; Penn State Harrisburg, Pennsylvania State Data Center (June 2022). Trends in Pennsylvania's Population by Age (Research Brief). Retrieved from https://pasdc.hbg.psu.edu/sdc/pasdc_files/researchbriefs/June_2022.pdf.

As the number of older Pennsylvanians increases, the number of those needing long-term care nursing will also increase. It has been estimated that an individual turning 65 years of age today has an almost 70% chance of needing some type of long-term services or support during the remainder of their lifetime; 20% will need long-term care support for longer than 5 years. More people use long-term care services at home and for longer; however, approximately 35% utilize nursing facilities for this type of care. Administration for Community Living. (February 2020). How Much Care Will You Need? Retrieved from https://acl.gov/ltc/basic-needs/how-much-care-will-you-need. Approximately 72,000 individuals reside in the 682 long-term care nursing facilities currently licensed by the Department.

The COVID-19 pandemic highlighted the vulnerability of older adults, with a larger percentage of deaths occurring in individuals 65 years of age and older. Centers for Disease Control and Prevention (CDC). Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC. Retrieved from https://covid.cdc.gov/covid-data-tracker/#demographics. See also, CDC. COVID-19 Weekly Cases and Deaths per 100,000 Population by Age, Race/Ethnicity and Sex, United States,

March 1, 2020—June 25, 2022. Retrieved from https://covid.cdc.gov/covid-data-tracker/#demographicsovertime. Further, it is estimated that deaths of residents in long-term care facilities accounted for at least 34% of all COVID-19 deaths in the United States during the time that the CDC tracked this data. https://covidtracking.com/analysis-updates/what-we-know-about-the-impact-of-the-pandemic-on-our-most-vulnerable-community. In this Commonwealth alone, there have been approximately 11,443 confirmed deaths of residents in long-term care nursing facilities since January 2020. AARP (September 15, 2022). AARP Nursing Home COVID-19 Dashboard Fact Sheets. Retrieved from https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-states.html.

The repercussions of the COVID-19 pandemic have reached far beyond the direct, physical effects of contracting the COVID-19 virus. Lockdowns intended to protect vulnerable residents at the beginning of the COVID-19 pandemic led to social isolation and loneliness because residents were prevented from having in-person contact with their loved ones. This led to an increase in depression and anxiety, cognitive decline and in some cases, physical deterioration, among residents who were already fearful of contracting the virus. Levere, M., Rowan, P., & Wysocki, A. (2021). "The Adverse Effects of the COVID-19 Pandemic on Nursing Home Resident Well-Being." *Journal of the American Medical Directors Association*, 22(5), 948-954.e2. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7980137/. Nursing service personnel, who were already stressed before the pandemic, incurred additional stress from, among other things, shortages in personal protective equipment (PPE), limited access to COVID-19 testing supplies, fear of contracting COVID-19 while at work and spreading it to others, concern for residents under their care, lack of public support and recognition, and an increase in workloads due to the additional protective measures needed to prevent spread of COVID-19 and other nursing service personnel leaving the workforce. White, E.M., Wetle, T.F., Reddy, A. & Baier, R.R. (2021). "Front-line Nursing Home Staff Experiences During the COVID-19 Pandemic." *Journal of the American Medical Directors Association*, 22(1), 199—203. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7685055/.

The Department's long-term care nursing facilities regulations have not been updated since 1999, with the last significant update occurring in 1997 after the 1996 amendment to the Health Care Facilities Act (HCFA or act) (35 P.S. §§ 448.101—448.904b). Since that time, there have been substantial changes in the means of delivering care and providing a safe environment for residents in long-term care nursing facilities, with the COVID-19 pandemic further highlighting the need for change. The Department has been attempting to complete this much needed reform since before the COVID-19 pandemic, in late 2017. At that time, the Department sought assistance and advice from members of the LTC Work Group. The Department worked with the LTC Work Group regularly in 2018. The members of the LTC Work Group were drawn from a diverse background and included representatives from urban and rural long-term care facilities and various stakeholder organizations and consumer groups that work in the area of resident care and delivery of services. The LTC Work Group members consisted of representatives from the following organizations: American Institute of Financial Gerontology; Baker Tilly Virchow Krause, LLP; Berks Heim and Rehabilitation; Fulton County Medical Center; Garden Spot Community; HCR ManorCare; Inglis House; Landis Communities; Leading Age; Legg Consulting Services; LIFE Pittsburgh; Luzerne County Community College; The Meadows at Blue Ridge; Mennonite Home, Lutheran Senior Life Passavant Community; PA Coalition of Affiliated Healthcare and Living Communities; Pennsylvania Home Care Association; University of Pittsburgh; and Valley View Nursing Home. The following State agencies participated: the Department of Aging; the Department of Human Services (DHS); and the Department of Military and Veteran's Affairs (DMVA).

The members of the LTC Work Group met regularly during 2018 with the LTC Work Group's primary focus being the simplification and modernization of the existing long-term care regulations. After these discussions were complete, the Department reviewed the recommendations of the LTC Work Group and consulted with other potentially impacted agencies in 2019 and 2020. In 2020, 2021 and 2022, the Department continued its efforts to draft amendments to the long-term care nursing facility regulations while also handling the day-to-day challenges of protecting the residents of those facilities, who were being hit the hardest by the COVID-19 pandemic.

As discussed previously, in response to concerns raised by IRRC and commentators, the Department ramped up its communications with stakeholders by holding the first of four stakeholder meetings, beginning in December 2021, to address comments received on proposed Rulemaking 1 and Rulemaking 2. The Department held a second meeting with stakeholders in June 2022 after the public comment and IRRC comment periods ended for proposed Rulemaking 3, and a third stakeholder meeting in August 2022 after the public and IRRC comment periods ended for proposed Rulemaking 4. The Department held a fourth stakeholder meeting on August 17, 2022, to provide an overview of changes from the proposed rulemakings to these final-form rulemakings and permitted stakeholders to provide additional feedback and comments on amendments during this meeting.

The discussions with stakeholders and the comments received on the four proposed rulemakings have made it abundantly clear that amendments to the current long-term care nursing facility regulations are desperately needed and must not be delayed any longer. Commentators expressed in comments to all four groups that they were pleased to see the Department updating these regulations. The comments in support of amending the regulations can generally be summarized as follows:

- Amendments are long overdue.
- Revisions to existing regulations are urgently needed.
- COVID-19 had a devastating impact on facilities and highlighted the need for revisions.
- Regulations need to be updated to provide additional protections to residents.

Unfortunately, while commentators agree for the most part that an update to the regulations is needed, they do not agree on the extent of the update needed. Some commentators strongly argued that the Department's proposed amendments do not go far enough in protecting residents, while other commentators strongly argued that the Department's proposed amendments go too far and result in a fiscal impact. The Department has considered all comments it received both in favor of and against the proposed amendments and has responded to those comments. In considering those comments and balancing the competing interests of the parties in this regulatory review process, the Department has made revisions from the proposed rulemakings to these final-form rulemak-

ings. The Department has also provided explanations to comments received in the preambles for each of these four final-form rulemakings, as explained more fully in the preceding text.

Public Comments

In response to proposed Rulemaking 1, the Department received comments from 486 public commentators; 13 legislative comment letters, including comments from individual legislative members, a joint letter from 17 legislative members, and a letter from the House Democratic members of the Women's Health Caucus; 14 form letters; and comments from IRRC. These comments are discussed in further detail as follows.

In addition, a joint legislative hearing regarding proposed Rulemaking 1 was held on September 15, 2021, by the Senate Health and Human Services and Aging and Youth Committees. The Department participated in the hearing and provided testimony and a commitment to continue working with stakeholders to address workforce challenges in the long-term care industry. The Department maintains this commitment and will continue to engage with stakeholders to provide guidance and technical assistance as the regulations are implemented and commits to continued engagement with stakeholders and other agencies to support ongoing workforce development in the long-term care industry.

Description of Amendments/Summary of Comments and Responses

§ 201.1. Applicability

This section is unchanged from the proposed rulemaking to this final-form rulemaking. As explained on the proposed rulemaking, the phrases "profit and nonprofit" and "which provide either skilled nursing care or intermediate nursing care, or both, within the facilities under the act" are deleted from the current regulation. The phrase "as defined in section 802.1 of the act (35 P.S. § 448.802a)" is added after the term "long-term care nursing facilities" to clarify that this subpart applies to all long-term care nursing facilities as defined by the act. The act applies to all long-term care nursing facilities regardless of whether the facility is designated as a profit or nonprofit. In addition, the definition of a long-term care nursing facility under the act is more descriptive than what is presently provided for in this section of the regulations. The direct reference to the definition of "long-term care nursing facility" adds clarity and promotes consistency in the application of the act and in the application and scope of this subpart to long-term care nursing facilities.

A commentator questioned whether the language in this section needs to be more clearly stated to indicate that the regulations apply to applicants for licensure as well as those who already own or operate long-term care nursing facilities. Although the Department appreciates this comment, the licensure standards for health and safety apply to facilities and needs no further clarification. The Department, therefore, declines to make this amendment.

Commentators also expressed concern that under the proposed amendment, the three private-pay facilities licensed by the Department will be subject to Federal requirements pertaining to the conditions of participation for Medicare or Medical Assistance (MA) even though those facilities purposely do not participate in those programs. These comments more accurately pertain to § 201.2 and are discussed more fully as follows.

§ 201.2. Requirements

Subsection (a)

Subsection (a) is revised from the proposed rulemaking to this final-form rulemaking, in response to public comments. The Department had proposed to move the existing language in § 201.2 into subsection (a) with amendments. Specifically, the Department proposed to delete the exceptions to the Federal requirements that are currently listed in this section and to expand the existing citation to the Federal requirements to incorporate the Federal requirements for long-term care nursing facilities at 42 CFR Part 483, Subpart B (relating to requirements for long term care facilities) in their entirety. In this final-form rulemaking, however, the Department adds an exception to the incorporation of the Federal requirements for 42 CFR 483.1 (relating to basis and scope) based on the review and consideration of public comments. The reason for this exception is explained more fully as follows.

Commentators, in proposed Rulemaking 1, were generally supportive of the LTC Work Group's recommendation to simplify and modernize the existing Departmental regulations by expanding the incorporation of the Federal requirements. However, many commentators expressed concern that the Department's intent to apply the minimum Federal long-term care facility standards and certification requirements would negatively impact the three licensed facilities that do not participate in Medicare or MA. In proposed Rulemaking 4, certain commentators again expressed support for the Department's decision to incorporate the Federal requirements, while others expressed concern over the incorporation of the Federal requirements. These commentators expressed both general, overarching concerns with the incorporation of the Federal requirements, as well as specific concerns related to various sections in the Department's regulations. In contrast, other commentators expressed concern if the private-pay facilities might be excluded from the proposed expansion to incorporate all the Federal minimum standards and certification requirements.

The Department responds to both the general, overarching comments and the application of § 201.2 to the private-pay facilities in further detail as follows, addressing similar comments that were submitted in response to both proposed Rulemakings 1 and 4. Comments related to the impact of the incorporation of the Federal regulations on specific sections of the Department's regulations will also be addressed in the specific sections as follows.

General concerns regarding § 201.2

One commentator to proposed Rulemaking 1 suggested adding the phrase, "and thereby requires long-term care facilities to comply with" after the words "incorporates by reference" and before the citation to 42 CFR Part 483, Subpart B. As defined by *Black's Law Dictionary*, incorporation by reference is "a method of making a secondary document part of a primary document by including in the primary document a statement that the secondary document should be treated as if it were contained in the primary one." The addition of the language proposed by the commentator is redundant and unnecessary, and the Department declines to include it. The same commentator questioned why the Department is referencing and incorporating the 1998 version of the Federal requirements. In response to this question, the Department notes it is not incorporating the 1998 version but is instead deleting the outdated reference to the 1998 version as indicated, on

proposed, by brackets before and after the following language, "42 CFR 483.1—483.75 (relating to requirements for long-term care facilities) revised as of October 1, 1998."

Comments ranged from asserting that the Federal requirements were the bare minimum and not stringent enough to protect health and safety; to conversely asserting that requiring private-pay facilities to adhere to these Federal standards would have a significant and negative programmatic and fiscal impact. Specifically, commentators stated in response to proposed Rulemaking 4 that the Department is over-relying on Federal requirements and asserted that deleting certain provisions in existing State regulations in exchange for Federal requirements will have a deleterious effect. Commentators asserted that the Department was adopting the bare minimum requirements and suggested that the Department further strengthen or enhance these requirements at the State level. Some commentators also requested that the Department add the verbatim text of the Federal requirements into the State regulations or cross-reference the Federal requirements and then expand or strengthen these requirements.

In response to these comments, the Department generally notes that the Federal minimum standards and certification requirements for long-term care facilities were adopted "to enforce requirements from the perspective of quality of care and life for long term care residents." 54 FR 5316 (February 2, 1989). These Federal regulations were comprehensively amended in 2016 to "achieve broad-based improvements both in the quality of health care. . .and in patient safety, while at the same time reducing procedural burdens on providers," with subsequent amendments; the most recent amendments occurring on August 4, 2021. See 81 FR 68688 (October 4, 2016); 86 FR 42524 (August 4, 2021). Since the Department's adoption of the 1998 regulations 23 years ago, there have been expanded requirements for emergency preparedness; quality assurance and infection control; abuse, neglect and exploitation protections; and admission and discharge protections, among others, to ensure the health and safety of residents. The Federal requirements now focus more on person-centered care as well, with expanded requirements for resident rights, resident assessment, and quality of life and care for residents. The Department did not take the decision to incorporate the Federal requirements lightly, but rather, carefully, and thoroughly reviewed the Federal requirements for health and safety before deciding to incorporate them. Because the Federal requirements are comprehensive and balance patient safety with provider procedures, they provide an excellent baseline for ensuring the health, safety and welfare of residents, while balancing industry stakeholders' interests. The Department, in its review and consideration of public comments, determined that some of the Federal requirements were not as robust as needed, and therefore, where necessary, has retained and added requirements in this subpart that supplant the Federal requirements to further ensure the health and safety of residents.

The Department, however, declines to copy and paste the verbatim Federal requirements into State regulation as some commentators requested. Under 45 Pa.C.S. § 727 (relating to matter not required to be published), the Department shall omit the text of the *Code of Federal Regulations* when incorporated by reference in documents that are published in the *Pennsylvania Bulletin* and codified in the *Pennsylvania Code*. This is similarly prohibited under § 2.14(b) (relating to incorporation by reference) of the *Pennsylvania Code & Bulletin Style Manual* (*Style Manual*), as well, which the Department follows in drafting regulations.

Moreover, while the Department appreciates the desire to have all requirements in one place, 679 out of the 682 facilities licensed by the Department (99.56%) already participate in the Medicare or MA programs and thus, (1) are already required to meet these standards; and (2) are intimately familiar with the requirements in 42 CFR Part 483, Subpart B. Having the State requirements as a separate supplement to the Federal requirements is more efficient, convenient and accessible for the regulated community in understanding what is being required in addition to the minimum requirements for health and safety at the Federal level.

Application of § 201.2 to private-pay facilities

There are currently 682 facilities that are licensed by the Department. Approximately 72,000 individuals reside in these facilities. Out of these 682 facilities, all but three of these facilities (or 99.56%) participate in Medicare or MA, and thus, are already required to comply with the health safety requirements in 42 CFR Part 483, Subpart B. The three private-pay facilities have a combined capacity of 102 licensed beds of the approximate 72,000 residents. Further, these facilities had a reported, combined census reported of 79 residents for the Department's 2020-2021 annual report. Department of Health. (2021). *Nursing Home Reports*. Retrieved from: https://www.health.pa.gov/topics/HealthStatistics/HealthFacilities/NursingHomeReports/Pages/nursing-home-reports.aspx.

Although the three licensed private-pay facilities are not required to generally comply with the requirements under 42 CFR Part 483, Subpart B because they do not participate in Medicare or MA, under existing § 201.2 (which has been in place since 1999), private-pay facilities have been required to comply with some, but not all the Federal requirements in 42 CFR Part 483, Subpart B for licensure in this Commonwealth. Specifically, these facilities are presently required to comply with the Federal requirements, as they existed on October 1, 1998, except for specific provisions relating to resident rights, admission, transfer and discharge, resident assessment, nursing, physician and dental services, physical environment and administration, as delineated in existing paragraphs (1) through (10).

The Department proposed to expand the incorporation of the Federal requirements in § 201.2 to include all the Federal long-term care facility requirements at 42 CFR Part 483, Subpart B. The intent of this proposed expansion was to require all facilities, including private-pay facilities, to comply with all the Federal health and safety requirements, without exception. This initially seemed to be clear to the regulated community based on comments the Department received on proposed Rulemaking 1; however, comments received in response to proposed Rulemaking 4 suggested otherwise. Commentators to proposed Rulemaking 4 indicated they were concerned that the three private-pay facilities would be exempted from meeting these Federal standards.

Although not specifically expressed by commentators, upon further review, the Department believes this confusion may stem from the incorporation of 42 CFR 483.1, which sets forth the basis and scope for the Federal requirements and indicates that the Federal requirements pertain to facilities that participate in Medicare or MA. To clarify this issue and eliminate this confusion, the Department revises § 201.2 in this final-form rulemaking to expressly exclude 42 CFR 483.1, from the requirements

that facilities must comply with under State law. In addition, based on comments received regarding transmission of data and data set reporting to the CMS, the Department clarifies that the Federal standards for reporting of Minimum Data Set (MDS) reporting and the transmission of data to CMS are not required, unless a facility is participating in the Medicare or MA program.

In summary, with the promulgation of this regulation, all facilities licensed by the Department will be required to comply with the Federal requirements in 42 CFR Part 483, Subpart B, except for 42 CFR 483.1 and the data transmission and MDS reporting requirements, regardless of whether they participate in Medicare or MA, or are private-pay. Under subsection (b), however, a facility may apply for an exception to the requirements of Subpart C under §§ 51.31—51.34 (relating to exceptions). This includes the ability to apply for an exception to the incorporation of a specific Federal requirement. Specifically, all facilities, including private-pay facilities, may request an exception to subsection (a) under the exceptions process identified in §§ 51.31—51.34. To assist the Department in rendering decisions on requests for exceptions to subsection (a), a facility requesting such an exception is required to identify the specific Federal requirements to which it is seeking an exception, rather than broadly requesting an exception to all the Federal requirements.

Impact of § 201.2 on private-pay facilities

Commentators also expressed concern, in proposed Rulemaking 1, that private-pay facilities would incur additional costs from the expansion of § 201.2 to encompass all the Federal requirements. Specifically, commentators were concerned that these facilities would need to hire additional staff for positions, such as a grievance officer, and submit data using CMS software that they will need to purchase because they do not participate in Medicare or MA. Commentators were also concerned that facility staff would become bogged down by additional reporting, recordkeeping and other paperwork required under the Federal requirements. Commentators were concerned that these additional requirements would take away from the time these facilities spend caring for residents, and that additional costs from the added requirements would in turn be passed on to residents, who are paying out of their own pocket to receive care at these facilities.

As noted previously, the three private-pay facilities are already required under existing § 201.2 to comply with Federal requirements from 1998, unless a requirement is specifically exempted. IRRC asked the Department to amend this final-form preamble and Regulatory Analysis Form for Rulemaking 1 to provide a more detailed analysis of the impact on the private-pay facilities of Federal requirements that are being added by virtue of the expansion of § 201.2, including fiscal impact and reporting, recordkeeping and other paperwork requirements. IRRC also asked the Department to explain the reasonableness of these additional Federal requirements for private-pay facilities.

To identify which Federal requirements may potentially impact the three licensed private-pay facilities,[1] the Department first compared the Federal requirements that were adopted in existing § 201.2 to the present version of the Federal requirements to determine which sections have been updated or added since 1998. The Department then compared this list to its existing regulations to determine if the three private-pay facilities might already be complying with these additional requirements under State law. The Department identified the following sections as creating additional fiscal, reporting, recordkeeping, and paperwork requirements for the three private-pay facilities. The Department notes again that this list applies solely to the three private-pay facilities. These facilities make up only a small fraction of this Commonwealth's long-term care nursing facility residency, by having fewer than 100 residents (.1%). The remaining 679 facilities licensed by the Department are already required to comply with these requirements.

Private-pay fiscal impact—grievance officer

Some commentators asserted that the expansion of the incorporation of the Federal requirements would require private-pay facilities to hire additional staff. Specifically, these commentators asserted the incorporation of Federal requirements would require these facilities to hire a grievance officer. In 2016, CMS expanded and strengthened the residents' rights section under 42 CFR 483.10 (relating to resident rights). Provisions were added to ensure equal access to quality care, to prohibit discrimination and afford equal treatment, and to permit a resident representative to act on behalf of a resident. Visitation rights and a resident's ability to participate in care planning were also expanded. Subsection (j) of 42 CFR 483.10, pertaining to a resident's right to voice grievances, was expanded as well. Under 42 CFR 483.10(j)(4), a facility is required to establish a grievance policy to ensure prompt resolution of all grievances regarding resident rights. The policy must include among other things, identifying a grievance officer to oversee the grievance process, receive and track grievances, lead any necessary investigations at the facility, maintain confidentiality of the resident, issue written grievance decisions, and coordinate with Federal and State agencies as necessary. Although private-pay facilities are already required to meet certain Federal resident rights requirements, as commentators noted, the establishment of a grievance policy and designating a grievance officer would be a new requirement for these facilities. However, there is no requirement that the grievance officer be full-time or new personnel. As such, a facility may choose to assign the duties of the grievance officer, consistent with the needs of the facility, to a current employee of the facility in addition to other responsibilities. Further, it is likely that most facilities already have a process to address complaints that could be utilized or expanded upon to comply with this final-form rulemaking.

Moreover, any fiscal impact to these three facilities is vastly outweighed by the need for a properly managed process through which residents may assure their resident rights and voice grievances. The grievance officer plays a vital role in the oversight of this process and is necessary to ensure that grievances are properly managed and promptly resolved.

Private-pay fiscal impact—CMS reporting requirements

The existing regulations of the Department already incorporate many of the Federal requirements and the expansion to incorporate the remaining Federal requirements at 42 CFR Part 483, Subpart B will impact the three long-term care nursing facilities that do not participate in either the Medicare or MA Program. However, based on comments received, the Department is exempting facilities from complying with 42 CFR 483.1 and the

[1] All other facilities licensed by the Department participate in Medicare or MA and are already required to comply, under Federal law, with the Federal requirements. The expansion under State law to comply with these requirements is not expected to negatively impact these facilities unless they fail to comply with the requirements and have not sought an exception under §§ 51.31—51.34.

data transmission and MDS reporting requirements, unless the facility participates in the Medicare or MA programs.

Assuming that the three private-pay facilities have not updated any of their practices and procedures since 1998, it is anticipated that the maximum cost to each facility to incorporate current Federal health and safety standards would be approximately $67,862. This maximum estimate, adjusted for inflation, is based on the cost analysis from the Federal Department of Health and Human Services when it promulgated its comprehensive updates at 81 FR 68688 (October 4, 2016). A break-down of these potential costs, adjusted for inflation through the United States Bureau of Labor Statistics CPI Inflation Calculator at https://www.bls.gov/data/inflation_calculator.htm, are as follows:

Resident Rights (42 CFR 483.10 (relating to resident rights))	$13,020
Admission, Discharge, and Transfer Rights (42 CFR 483.15 (relating to admission, transfer, and discharge rights))	$230
Comprehensive Resident Centered Care Planning (42 CFR 483.21 (relating to comprehensive resident centered care planning))	$6,760
Nursing Services (42 CFR 483.35 (relating to nursing services))	$304
Food and Nutrition Services (42 CFR 483.60 (relating to food and nutrition services))	$145
Quality Assurance and Performance Improvement (42 CFR 483.75 (relating to quality assurance and performance improvement))	$3,926
Infection Control (42 CFR 483.80 (relating to infection control))	$23,318
Compliance and Ethics Program (42 CFR 483.85 (relating to compliance and ethics program))	$19,262
Training (42 CFR 483.95 (relating to training requirements))	$897
Total	$67,862

However, based on the Department's experience with facilities' compliance with existing regulatory requirements, these facilities already comply with various provisions, such as infection prevention and control measures, emergency preparedness and planning, food service safety and homelike environment requirements. Therefore, it is unlikely that the facilities would reach the maximum estimated costs.

In addition, a facility may apply for an exception to the requirements of Subpart C under §§ 51.31—51.34. This includes the ability to apply for an exception to the incorporation of a specific Federal requirement. Specifically, all facilities, including private-pay facilities, may request an exception under the process identified in §§ 51.31—51.34. To assist the Department in rendering decisions on requests for exceptions, a facility requesting an exception is required to identify the specific Federal requirements to which it is seeking an exception, rather than broadly requesting an exception to all of the Federal requirements.

Requiring all long-term care nursing facilities to comply with the minimum Federal health and safety standards for long-term care facilities is reasonable because it will increase health and safety standards, improve the survey process, create consistency and eliminate any confusion in the application of standards to long-term care nursing facilities, which will benefit all long-term care nursing facilities. Although there is anticipated to be a fiscal impact regarding incorporation of certain Federal standards for the three facilities that do not participate in Medicare or MA Programs, the cost of these health and safety standards is outweighed by the health and safety benefits for nursing facility residents. The benefit of this final-form rulemaking is consistent standards for licensure to ensure the health, safety and welfare of all residents of long-term care nursing facilities in this Commonwealth. To assist with implementation of this final-form rulemaking, the Department extends the effective date and will be providing technical assistance and outreach to the regulated community.

Private-pay other reporting, recordkeeping and paperwork requirements

Assuming that the three private-pay facilities have not updated any of their recordkeeping practices and procedures since 1998, it is anticipated the new paperwork requirements for the three private-pay facilities may include the following:

- Establishment of a grievance policy, receiving grievances and providing written responses under 42 CFR 483.10.
- Resident signature on care plan under 42 CFR 483.10.
- Notification to residents of charges under 42 CFR 483.10.
- Notice to residents of transfers or discharges, including updated notices of changes under 42 CFR 483.15.
- Discharge planning under 42 CFR 483.15.
- Quality assurance and performance improvement program and plan under 42 CFR 483.75.

In addition, based on comments received, the Department is exempting facilities from complying with 42 CFR 483.1 and the data transmission and MDS reporting requirements, unless the facility participates in Medicare or MA.

Subsection (b)

Subsection (b) is deleted from the proposed rulemaking to this final-form rulemaking. The Department had proposed, in subsection (b), to incorporate by reference Chapter 7 and Appendix PP—Guidance to Surveyors for Long-Term Care Facilities (Appendix PP) from the CMS State Operations Manual. Several commentators and IRRC, objected to the incorporation of Chapter 7 and Appendix PP of the State Operations Manual in this final-form rulemaking. Based on the comments received from commentators and IRRC, the language that was proposed in subsection (b) is deleted.

Subsection (c)

The Department did not receive any comments on this subsection. However, in this final-form rulemaking, the language in proposed subsection (c) is unchanged from the proposed rulemaking to this final-form rulemaking, and clarifies that a long-term care nursing facility may apply for an exception under §§ 51.31—51.34. As previously noted, this includes the ability of a facility to request an exception to a Federal standard under subsection (a).

Subsection (d)

Subsection (d) is deleted from the proposed rulemaking to this final-form rulemaking. The Department had proposed in subsection (d) to add language indicating that failure to comply with the requirements in 42 CFR Part 483, Subpart B would constitute a violation of this subpart, unless an exception is granted under §§ 51.31—51.34. Several commentators, as well as IRRC, expressed concern that this proposed provision was duplicative and unnecessary, and requested that it be deleted. After careful consideration, the Department agrees that this language is duplicative and deletes this language.

Several commentators expressed concern that the proposed language in subsection (d) would permit the Department to tag violations of Federal regulations as violations of the State regulations, which would result in duplicate fines from facilities being fined under both Federal and State regulations. As noted by IRRC, by virtue of the new language in subsection (a), failure to comply with the requirements of 42 CFR Part 483, Subpart B, is a violation of State regulation without the need for the language that was proposed in subsection (d). Contrary to comments received by the Department, existing subsection (a) already incorporated by reference various Federal requirements. In other words, facilities that participate in Medicare or MA were previously tagged, under Federal law, if they violated the Federal requirements and also tagged for violating the State requirements under subsection (a).

To the extent that commentators are concerned that private-pay facilities will be fined or penalized under both Federal law and State law for failure to comply with the Federal requirements, this is inaccurate. As stated previously, the three private-pay facilities do not participate in Medicare or MA and, as such, may not be fined or penalized under Federal Medicare and MA participation requirements. Also as mentioned previously, under State law, the private-pay facilities have been required to comply with certain provisions of the Federal requirements under existing subsection (a). They will be required now to comply with all provisions of those requirements moving forward, except for 42 CFR 483.1 and the data transmission and MDS reporting to CMS requirements, by virtue of the expansion of subsection (a). The impact of the expansion of subsection (a) on the three private-pay facilities is discussed more fully previously in this preamble. These facilities will not see an increase in fines or penalties unless they fail to comply with the requirements in subsection (a) and have not sought an exception to those requirements. As noted previously, the Department will be providing technical assistance and outreach to the regulated community to assist with implementation of this final-form rulemaking.

§ 201.3. Definitions

Subsection (a) is deleted from the proposed rulemaking to this final-form rulemaking. The Department had proposed to divide § 201.3 into two parts. In proposed subsection (a), the Department proposed to incorporate by reference all terms defined in 42 CFR Part 483, Subpart B and in Chapter 7 and Appendix PP of the State Operations Manual. In proposed subsection (b), the Department proposed to define only those terms not already defined by 42 CFR Part 483, Subpart B and in Chapter 7 and Appendix PP of the State Operations Manual.

Commentators generally supported the Department's adoption of the Federal definitions in 42 CFR Part 483, Subpart B, with a few exceptions. Some commentators and IRRC commented on the Department's reliance on the Federal definition for the term "abuse" as this term is also defined in State law in section 103 of the Older Adults Protective Services Act (OAPSA) (35 P.S. § 10225.103). Some commentators also commented on the Department's deletion of terms that contained education and experience qualifications. These concerns are addressed more specifically in the summary of each definition as follows.

In addition, some commentators and IRRC expressed concern regarding the location of various definitions. IRRC specifically commented: "If the Department intends to rely on Federal regulations to define certain terms, we ask the Department to incorporate by reference those terms or promulgate the text of those terms in the final-form regulations. If the Department intends to rely on definitions found in Federal guidance, we ask the Department to promulgate the text of those definitions in the final-form regulations."

By virtue of § 201.2(a), as amended, all definitions in 42 CFR Part 483, Subpart B are incorporated into the regulation. However, in response to the comments noted previously and for ease of reference and readability, the Department amends § 201.3, in this final-form rulemaking, to delete subsection (a) and to incorporate by reference relevant definitions from 42 CFR Part 483, Subpart B. The Department also amends § 201.3 to add the text of certain definitions to provide clarity and readability to the regulated community. The amendments to § 201.3 are described more fully as follows, with revisions from the proposed rulemaking to this final-form rulemaking expressly noted.

Definition of abuse

The definition of "abuse" is revised, from the proposed rulemaking to this final-form rulemaking. The Department had proposed to delete the definition of "abuse" because this term is defined in the Federal requirements at 42 CFR 483.5 (relating to definitions). Commentators and IRRC commented on the wholesale deletion of the definition of "abuse" from this section, with some commentators requesting that the definition of "abuse" be amended to incorporate both the Federal definition of abuse, and the definition of abuse from the OAPSA (35 P.S. §§ 10225.101—10225.5102). The Department reviewed the definition of "abuse" in both Federal regulation and in OAPSA and discerns no noticeable difference between the two definitions for purposes under Subpart C. In this final-form rulemaking, the Department retains the definition of "abuse" but replaces the current definition with a cross-reference to the citation of the Federal definition for consistency, in response to public comment and IRRC.

Commentators also requested that if the Department defers to the Federal definition of abuse, that the Department retain more specific definitions of abuse, such as "physical abuse" and "verbal abuse" in regulation, because these terms are incorporated in the Federal definition but not separately or specifically defined. The Department, in consideration and in response to these comments, retains these definitions as separately defined terms and moves the terms "verbal abuse," "sexual abuse," "physical abuse," "mental abuse," "involuntary seclusion" and "neglect" so that they appear in alphabetical order. Amendments to these definitions are described more specifically as follows.

Definition of act

The definition of "act" is unchanged from the proposed rulemaking to this final-form rulemaking. As explained

on the proposed rulemaking, the citation to HCFA in the definition of "act" is amended to reflect the proper citation that encompasses all provisions of the act.

Definitions of administration of drugs, drug administration and drug dispensing

The definitions for "administration of drugs," "drug administration" and "drug dispensing" remain unchanged from the proposed rulemaking to this final-form rulemaking. As explained on the proposed rulemaking, the terms "drug" and "drugs" are replaced with "medication" and "medications" in these definitions to reflect current terminology used to describe the process of administering medications to residents in long-term care nursing facilities. Due to these amendments, the definitions for "medication administration" and "medication dispensing" are moved so that they appear in alphabetical order.

Definition of administrator

The definition of "administrator" is revised from the proposed rulemaking to this final-form rulemaking. The Department had proposed to delete the definition of "administrator" because this term is defined in the Federal requirements for facilities. However, in response to comments received from commentators and IRRC, the definition of administrator is retained and amended by deleting the first sentence of the definition and adding a cross-reference to 42 CFR 483.70(d)(2) (relating to administration). The second sentence, requiring that the administrator be licensed and registered by the Department of State, is retained in response to concerns expressed by several commentators regarding the deletion of qualifications of individuals defined in the regulation.

Definition of alteration

The definition for "alteration" is deleted from the proposed rulemaking to this final-form rulemaking based on comments received in proposed Rulemaking 2. A new definition for "construction, alteration or renovation" is added in this final-form rulemaking, based on these comments. The term "construction, alteration or renovation" is defined as "the erection, building, remodeling, modernization, improvement, extension or expansion of a facility, or the conversion of a building or portion thereof to a facility. The term does not include part-for-part replacement or regular facility maintenance." This amendment is also discussed in the preamble for final-form Rulemaking 2 in Chapter 204.

Definitions of ambulatory resident and nonambulatory resident

The definitions for "ambulatory resident" and "nonambulatory resident" were proposed to be deleted and continue to be deleted in this final-form rulemaking, because the ordinary dictionary definition applies. The terms "ambulatory" and "nonambulatory" are understood to have their ordinary dictionary definitions when applied to describe a resident who can walk or not walk in a long-term care nursing facility. A commentator questioned the Department's decision to delete these definitions, indicating that it may be necessary to retain them with respect to requirements related to a facility's ability to evacuate residents. The Department may not define terms in regulation where the dictionary meanings for those terms apply. See § 2.11 (relating to definition section) of the *Style Manual*. The Department therefore declines to retain or amend these terms in response to this comment.

Request for definition of applicant

A commentator requested that the Department add a definition for the term "applicant." The commentator proposed that the term "applicant" be defined as, "the entity applying for licensure, whether initial licensure for a new facility or transfer of ownership licensure for an existing facility that would, if approved by the Department, be transferred to the new owner." This same commentator in proposed Rulemaking 2, questioned the use of the term "prospective licensee" that the Department proposed to retain in existing regulation. Several commentators also requested in proposed Rulemaking 3, that the Department add a definition for the term "person" to align with the act.

After careful consideration, the Department declines to add the term "applicant" to this regulation and instead uses the term "prospective licensee" in Subpart C. The Department also declines to add a definition for the term "prospective licensee." The term "licensee" is presently defined in § 201.3 as, "the individual, partnership, association or corporate entity including a public agency or religious or fraternal or philanthropic organization authorized to operate a licensed facility." The Department is not amending this definition in this final-form rulemaking. The term "prospective" is commonly understood and is defined as "relating to or effective in the future; likely to come about; likely to be or become" in Webster's dictionary. *Merriam-Webster*. "Prospective." Retrieved from https://www.merriam-webster.com/dictionary/prospective. As the term "prospective" is generally understood by its ordinary dictionary meaning, the Department does not believe it is necessary to include a separate definition for the term "prospective licensee." The Department, however, adds the term "person" to § 201.3 with a cross-reference to the act, in response to requests from commentators in proposed Rulemaking 3 to add this definition. The Department also in response to these comments amends sections in Rulemaking 3, on final-form, where applicable, to be consistent in the use of the terms "prospective licensee" and "person." The rationale for these amendments is explained further in the preamble for final-form Rulemaking 3 at § 201.12 (relating to application for license of a new facility or change in ownership).

Definition of audiologist

The definition for "audiologist" remains deleted from the proposed rulemaking to this final-form rulemaking because that term is not used in this subpart. Therefore, a definition is not necessary. The Department did not receive any comments regarding the proposed deletion of this definition.

Definition of authorized person to administer medications

The definition of "authorized person to administer medications" is amended in this final-form rulemaking to remove the term "drugs" for consistency in the use of only the term "medication" throughout all of the final-form rulemakings.

Definition of basement

The definition for "basement" continues to be retained in this final-form rulemaking without amendment. The Department did not receive any comments regarding the retention of this definition.

Definition of CRNP

The definition of "CRNP—certified registered nurse practitioner" continues to be retained in this final-form rulemaking without amendment. The Department did not receive any comments regarding the retention of this definition.

Definition of charge nurse

The definition of "charge nurse" is revised, from the proposed rulemaking to this final-form rulemaking. The Department had proposed to delete the definition of "charge nurse" on the proposed rulemaking because this term is defined in the Federal requirements for facilities. In response to comments received from commentators and IRRC, the definition of "charge nurse" is retained, on final-form, and amended by updating the definition to use "RN" and "LPN," as those are now defined terms, and removing the provision permitting waiver of the licensure requirement.

Definition of clinical laboratory

The definition of "clinical laboratory" is revised, from the proposed rulemaking to this final-form rulemaking. The Department had proposed to delete the definition of "clinical laboratory" on the proposed rulemaking because this term is defined in section 353 of the Clinical Laboratory Improvements Amendments of 1988 (CLIA) (42 U.S.C.A. § 263a). Specifically, laboratory services are covered under 42 CFR 483.50(a) (relating to laboratory, radiology, and other diagnostic services), with the term "clinical laboratory" defined under section 353(a) of CLIA. A facility that provides its own laboratory services or performs any laboratory tests directly must have a certificate under section 353 of CLIA. In response to comments from commentators and IRRC, the definition of "clinical laboratory" is retained, in this final-form rulemaking, and amended by deleting the current definition and adding a cross-reference to the updated definition of "clinical laboratory" in section 353 of CLIA.

Definition of clinical records

The definition of "clinical records" is deleted in this final-form rulemaking. The Department had proposed to retain this definition, but upon further review, it is not necessary to retain this definition because the Department has replaced the term "clinical records" with the term "medical records" throughout these final-form rulemakings to align with terminology used throughout the Federal requirements in 42 CFR Part 483, Subpart B. The term "medical records" is commonly understood by its ordinary dictionary meaning. Therefore, a definition is not needed.

Definition of controlled substance

The definition of "controlled substance" continues to be retained from the proposed rulemaking to this final-form rulemaking. The Department did not receive any comments regarding the retention of this definition.

Definition of corridor

The definition of "corridor" is revised from the proposed rulemaking to this final-form rulemaking. The Department replaces the word "patient's" with "resident's" before the words "sleeping quarters" at the request of a commentator. The Department agrees that the term "resident" more appropriately describes an individual who is admitted to a long-term care nursing facility.

Definition of Department

The definition of "Department" continues to be retained from the proposed rulemaking to this final-form rulemaking. The Department did not receive any comments regarding the retention of this definition.

Definitions of dietician, dietetic service supervisor and qualified dietician

The definitions of "dietitian" and "dietetic service supervisor" continue to be deleted but replaced, in this final-form rulemaking, with the definition of "qualified dietitian." The Department had proposed to delete the definitions of "dietitian" and "dietetic service supervisor" based on the Federal requirements.

Under the Federal requirements, a facility must employ sufficient staff with appropriate competencies and skills to carry out the functions of the food and nutrition service. This includes a "qualified dietitian or other clinically qualified nutrition professional" who is employed on either a full-time, part-time or consultant basis, and a "director of food and nutrition services" where a qualified dietitian or other clinically qualified nutrition professional is not employed full-time.

The Department received support from one commentator over the proposed deletion of the term "dietitian" because the term "qualified dietician" is defined in 42 CFR 483.60(a)(1). Further, in response to comments from commentators and IRRC, in this final-form rulemaking, the Department adds the term "qualified dietitian" with a cross-reference to 42 CFR 483.60(a)(1). In response to concerns raised by commentators regarding the deletion of qualifications for certain individuals in regulation, including the "dietitian," the Department notes that the qualifications for the "qualified dietitian or other clinically qualified nutrition professional" and the "director of food and nutrition services" are outlined in 42 CFR 483.60(a)(1).

Definition of director of nursing services

The definition of "director of nursing services" is revised, from the proposed rulemaking to this final-form rulemaking. The Department had proposed to delete the definition of "director of nursing services" in the proposed rulemaking because this term is defined in the Federal requirements for facilities. In response to comments received from commentators and IRRC, the definition of "director of nursing services" is retained, in this final-form rulemaking, and amended by deleting the current definition and adding a cross-reference to indicate that this individual is a registered nurse designated by a facility under 42 CFR 483.35(b)(2). The Department retains the qualifications of the registered nurse (RN) who serves in this capacity in response to commentators who expressed concern about the deletion of qualifications of certain individuals from regulation.

Definition of discharge

In this final-form rulemaking the Department adds the definition of "discharge" in response to comments received on proposed Rulemaking 4 to distinguish between a "transfer" and a "discharge." In this final-form rulemaking a "discharge" is defined as "[t]he movement of a resident from a bed in one certified facility to a bed in another certified facility or other location in the community, when return to the original facility is not expected."

Definition of drug or medication; medication

The term "drug" is removed from the definition of "drug or medication" from the proposed rulemaking to this final-form rulemaking for consistency in the use of the term "medication" throughout the final-form rulemakings. The definition of "medication" is moved so that it appears in alphabetical order, but otherwise remains the same.

Definition of elopement

The definition of "elopement" is revised, from the proposed rulemaking to this final-form rulemaking. The Department proposed to delete the definition of "elopement" in the proposed rulemaking. In response to comments from commentators and IRRC regarding ease of finding terms that are defined in the State Operations

Manual, the definition of "elopement" is retained, and amended, in this final-form rulemaking, to mirror the current definition in the State Operations Manual, that elopement occurs "when a resident leaves the premises or a safe area without authorization."

Definition of existing facility

The definition of "existing facility" remains deleted in this final-form rulemaking. This term is outdated and will no longer be used in this subpart. The Department did not receive any comments regarding the proposed deletion of this term.

Definition of exit or exitway

The definition of "exit or exitway" is revised, from the proposed rulemaking to this final-form rulemaking. The Department proposed to delete the definition of "exit" in the proposed rulemaking because this term is defined in the State Operations Manual. In response to comments received from commentators and IRRC, the definition of "exit" is retained and amended, in this final-form rulemaking, to mirror the current definition in the State Operations Manual, as "a means of egress which is lighted and has three components: an exit access (corridor leading to the exit), an exit (a door) and an exit discharge (door to the street or public way)."

Definition of exploitation

The definition of "exploitation" is added in this final-form rulemaking with a cross-reference to this definition in 42 CFR 483.5, in response to the request of commentators who requested that this definition be added.

Definition of facility

The definition of "facility" continues to be retained without amendment in this final-form rulemaking. The Department did not receive any comments regarding the retention of this definition.

Definition of full compliance and substantial compliance

To further aid the regulated community in understanding the criteria for a license, the Department adds a definition for "full compliance" and a definition for "substantial compliance." A facility will be in "full compliance" if they are in "total compliance." Further, as defined, a facility will be in "substantial compliance" if the requirements in paragraphs (1) and (2) of the definition are met. Under paragraph (1), any cited deficiencies must be, individually and in combined effect, of a minor nature such that neither the deficiencies nor efforts toward their correction will interfere with or adversely affect normal facility operations or adversely affect any resident's health or safety. Under paragraph (2), the facility must have implemented a plan of correction approved by the Department. These definitions are based on the definitions for "full compliance" and "substantial compliance" that exist for hospitals in § 101.92(b) (relating to regular license).

Definition of full-time

The definition of "full-time" is revised, from the proposed rulemaking to this final-form rulemaking. The Department proposed to delete the definition of "full-time" in the proposed rulemaking because this term is defined in the State Operations Manual. The State Operations Manual defines "full-time" as "working 35 or more hours a week." As there is no substantial difference between this definition and the current definition, the Department, in this final-form rulemaking, retains the current definition without amendment.

Definition of health care practitioner

The definition of "health care practitioner" from the act is revised from the proposed rulemaking to this final-form rulemaking. The Department had proposed the addition of this definition for consistency in the application of this term to long-term care nursing facilities and to recognize the range of health care professionals who provide care to residents in long-term care nursing facilities. In this final-form rulemaking, the definition for "health care practitioner" is moved so that it appears in alphabetical order in the list of definitions. A stylistic amendment is also made in this final-form rulemaking to remove language from the definition of "health care practitioner" indicating that the term "practitioner" when used as a standalone term is synonymous with those individuals defined as a "health care practitioner." The term "practitioner" is added as a separate term, in this final-form rulemaking, and defined as "a health care practitioner as defined in section 103 of the act."

Definition of interdisciplinary team

The definition of "interdisciplinary team" is revised, from the proposed rulemaking to this final-form rulemaking. The Department had proposed to delete the definition of "interdisciplinary team" in the proposed rulemaking because this term is defined in 42 CFR 483.21(b)(2)(ii). In response to comments from commentators and IRRC, the definition of "interdisciplinary team" is retained, in this final-form rulemaking, and amended by deleting the text of the current definition and adding a cross-reference to 42 CFR 483.21(b)(2)(ii).

Definition of intimidation

In response to public comment, a new definition for "intimidation" is added from the proposed rulemaking to this final-form rulemaking. Per requests from commentators, the Department adopts the definition of "intimidation" in section 103 of the OAPSA (35 P.S. § 10225.103), which defines "intimidation" as "an act or omission by any person or entity toward another person which is intended to, or with knowledge that the act or omission will, obstruct, impede, impair, prevent or interfere with the administration of [OAPSA] or any law intended to protect older adults from mistreatment."

Definition of involuntary seclusion

As previously noted, the definition of "involuntary seclusion" is retained in this final-form rulemaking, in response to public comment. The definition of "involuntary seclusion" is retained without amendment but moved from the definition of "abuse" so that it appears in alphabetical order in the list of definitions.

Definition of licensed practical nurse

The definition of "licensed practical nurse" is unchanged from the proposed rulemaking to this final-form rulemaking. The definition of "licensed practical nurse" is amended to add the acronym "LPN" and to include a citation to the regulations of the State Board of Nursing to describe more accurately an individual licensed in this capacity under the Practical Nurse Law (63 P.S. §§ 651—667.8). The Department did not receive any comments on this amendment.

Definition of licensee

The definition of "licensee" is retained without amendment in this final-form rulemaking. The Department did not receive any comments regarding the retention of this definition.

Definition of locked restraint

The definition of "locked restraint" remains deleted in this final-form rulemaking. The Department did not receive any comments regarding the proposed deletion of this definition.

Definition of long-term care ombudsman

The Department adds a definition for the term "long-term care ombudsman" in response to a request from a commentator. The Department declines to adopt the definition proposed by the commentator, however, which limits the definition to the "local" long-term care ombudsman. The Department instead defines "long-term care ombudsman" as "an individual at the State or local level who is responsible for carrying out the duties and functions under section 3058g of the State Long-Term Care Ombudsman Program (42 U.S.C.A. § 3058g)." The Department has chosen this broader definition to encompass both the local long-term care ombudsman and the State long-term care ombudsman.

Definition of medical record practitioner

The definition of "medical record practitioner" remains deleted in this final-form rulemaking. The Department proposed to delete this definition because it is outdated and will no longer be used in this subpart. The Department did not receive any comments regarding the proposed deletion of this definition.

Definition of mental abuse

As noted previously, the definition of "mental abuse" is retained, in this final-form rulemaking, but moved from the definition of "abuse" so that it appears in alphabetical order. The Department retains the existing definition without amendment based on concerns raised by commentators.

Definitions of misappropriation of resident property and mistreatment

In response to comments from commentators and IRRC requesting that Federal definitions be added to the regulation for clarity, definitions are also added in this final-form rulemaking for "misappropriation of resident property" and "mistreatment," with cross-references to these definitions in 42 CFR 483.5.

Definition of NFPA

The definition of "NFPA" is retained, without amendment, in this final-form rulemaking. The Department did not receive any comments on the proposed rulemaking regarding the retention of this definition.

Definition of neglect

As previously noted, the definition of "neglect" is retained, in this final-form rulemaking, based on comments from commentators. However, the definition is moved from the definition of "abuse" so that it appears in alphabetical order. The Department also replaces the current definition of "neglect" with a cross-reference to the definition of "neglect" under 42 CFR 483.5 to align with Federal requirements and in response to comments received from commentators and IRRC.

Definition of nonproprietary drug

The definition of "nonproprietary drug" remains deleted from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the use of the word "prescription" more accurately reflects the current terminology that is used. The existing definition of the word "prescription" is amended as follows: (1) the word "drugs" is replaced with the word "medications" to reflect current terminology; (2) the words "licensed medical" are replaced with the words "health care" before the word "practitioner" for consistency with the use and meaning of the term "health care practitioner" in this subpart; and (3) the word "his" is deleted to make the definition gender neutral. The Department did not receive any comments on the proposed rulemaking regarding this amendment.

Definition of nurse aide

The definition of "nurse aide" is revised, from the proposed rulemaking to this final-form rulemaking. The Department proposed to delete the definition of "nurse aide" in the proposed rulemaking because this term is defined in 42 CFR 483.5. In response to comments from commentators and IRRC, the definition of "nurse aide" is retained in this final-form rulemaking, and amended by adding a cross-reference to 42 CFR 483.5. Further, in response to commentators who expressed concern over the Department's deletion of qualifications from definitions, the Department retains these qualifications in the definition of "nurse aide" in this final-form rulemaking.

Definitions of nursing care and nursing service personnel

The definitions of "nursing care" and "nursing service personnel" are retained, without amendment in this final-form rulemaking. The Department did not receive any comments on the proposed rulemaking regarding the retention of these definitions.

Definitions of occupational therapist and occupational therapy assistant

The definitions of "occupational therapist" and "occupational therapy assistant" remain deleted from the proposed rulemaking to this final-form rulemaking. These terms are not used in this subpart, and therefore, a definition is not necessary. The Department did not receive any comments regarding the proposed deletion of these definitions.

Definition of person

The definition of "person" is added in this final-form rulemaking, with a cross-reference to the definition of this term in section 103 of the act (35 P.S. § 448.103), in response to public comment. Commentators requested that the Department add this definition in comment to proposed Rulemaking 3 for clarity in the use of this term in the regulations.

Definitions of pharmacist and pharmacy

The definitions of "pharmacist" and "pharmacy" are retained, without amendment, in this final-form rulemaking. The Department did not receive any comments on the proposed rulemaking with respect to the retention of these definitions.

Definition of physical abuse

As previously noted, the definition of "physical abuse" is retained in this final-form rulemaking in response to public comment. The definition of "physical abuse" is retained without amendment but moved from the definition of "abuse" so that it is in alphabetical order in the list of definitions.

Definitions of physical therapist and physical therapy assistant

The definitions of "physical therapist" and "physical therapy assistant" remain deleted from the proposed rulemaking to this final-form rulemaking. These terms are not used in this subpart, and therefore, a definition is

not necessary. The Department did not receive any comments regarding the proposed deletion of these terms.

Definition of physician assistant

The definition of "physician assistant" is retained, without amendment, in this final-form rulemaking. The Department did not receive any comments on the proposed rulemaking regarding the retention of this definition.

Definition of practice of pharmacy

The definition of "practice of pharmacy" remains deleted in this final-form rulemaking. This term is not used in this subpart, and a definition is not necessary. The Department did not receive any comments regarding the proposed deletion of this definition.

Definition of proprietary drug

The definition of "proprietary drug" remains deleted from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the definition of "proprietary drug" is replaced with the definition of "non-prescription medication." The shift from the use of the term "proprietary drug" to "non-prescription medication" reflects a change in terminology used in the long-term care nursing environment. The definition is also amended to reflect common usage of this term to refer to an over-the-counter medication that is purchased without a prescription. One commentator questioned the Department's proposal to replace the term "proprietary drug" with the term "non-prescription medication" because a proprietary drug is defined as "a drug that has a trade name and is protected by a patent brand-name drug" in The Free Dictionary at www.thefreedictionary.com. However, the term "proprietary drug" as defined in the Department's existing regulation, is "a drug which does not contain a quantity of a controlled substance *which can be purchased without a prescription and may be purchased from sources other than a pharmacy* and is usually sold under a patented or trade name" (Emphasis added). The term "non-prescription medication" more closely aligns with this existing definition and with the definition amended to, "an over-the-counter medication legally purchased without a prescription" is reflective of current terminology and understanding in the long-term care environment. The Department declines to retain or amend the term "proprietary drug" in response to this comment.

Definition of registered nurse

The definition of "registered nurse" is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the definition of "registered nurse" is amended for clarity. The acronym "RN" is added to the definition. A citation to the regulations of the State Board of Nursing is also added to describe more accurately an individual licensed in this capacity under The Professional Nursing Law (63 P.S. §§ 211—225.5). The Department did not receive any comments regarding this amendment.

Definition of resident

The definition of "resident" is retained in this final-form rulemaking without amendment. The Department did not receive any comments on the proposed rulemaking regarding the retention of this definition.

Definition of resident activities coordinator

The definition of "resident activities coordinator" remains deleted in this final-form rulemaking. In response to commentators requesting that this definition be retained, the Department is adding a definition for "qualified therapeutic recreation specialist" with a cross reference to 42 CFR 483.24(c) (relating to quality of life), which is similar to the current definition for "recreation activities coordinator." In response to concerns raised by commentators regarding the deletion of qualifications for certain individuals in the regulation, the Department notes that the Federal definition for "qualified therapeutic recreation specialist" in 42 CFR 483.24(c)(2) contains the qualifications for an individual who serves in this capacity. It is therefore not necessary to repeat those qualifications in the text of § 201.3.

Definitions of resident representative; responsible person

The definition of "resident representative" is added in this final-form rulemaking, with a cross-reference to 42 CFR 483.5, in response to comments received from commentators and IRRC. The term "resident representative" replaces the outdated term "responsible person" throughout the regulation to describe the types of individuals who may act on behalf of a resident. Because the term "responsible person" is outdated, the definition for "responsible person" remains deleted in this final-form rulemaking. A commentator requested that the Department expand this definition to include a prohibition on an employee of a facility serving as a resident representative for a resident. Although definitions should not contain substantive provisions, this comment is further addressed in final-form Rulemaking 4 in § 201.26 (relating to resident representative).

Definition of residential unit

The definition of "residential unit" remains deleted in this final-form rulemaking. As the Department explained in the proposed rulemaking this term is outdated and will no longer be used in this subpart. The Department did not receive any comments regarding the proposed deletion of this definition.

Definition of restraint

The definition of "restraint" is revised from the proposed rulemaking to this final-form rulemaking. The Department proposed to delete the definition of "restraint" because the term "restraint" is defined as including physical and chemical restraints, with the terms "physical restraint" and "chemical restraint" further defined in the State Operations Manual. In response to comments from commentators and IRRC, the term "restraint" is retained in this final-form rulemaking with the definitions for the terms "physical restraint" and "chemical restraint" amended to mirror the definitions in the State Operations Manual.

Definitions of serious bodily injury and serious physical injury

A commentator requested that the Department add definitions for "serious bodily injury" and "serious physical injury." The Department, in this final-form rulemaking, adds these terms with cross-references to the definitions in section 3 of the OAPSA (35 P.S. § 10225.103).

Definition of sexual abuse

As previously noted, the definition of "sexual abuse" is retained in this final-form rulemaking, in response to public comment. The Department retains the text of the existing definition but adds, the words "non-consensual contact of any type" to align with the Federal definition of "abuse" at 42 CFR 483.5.

Definition of skilled or intermediate care

The definition of "skilled or intermediate care" is deleted in this final-form rulemaking. The Department

proposed to delete this term because it is outdated. A commentator expressed concern that the deletion of this definition might impact MA eligibility tied to standards set forth in the definition. The Department consulted with DHS, who confirmed that the term "skilled or intermediate care" is outdated and that there would be no impact on MA eligibility if the Department deletes this term.

Definition of social worker

The definition of "social worker" continues to be deleted but is replaced in this final-form rulemaking with the definition for "qualified social worker." The Department proposed to delete the definition of "social worker" based on the Federal requirements. Under the Federal requirements, a social worker is referred to as a "qualified social worker" and is defined at 42 CFR 483.70(p) (relating to administration). In response to comments from commentators and IRRC, on this final-form rulemaking, the Department is replacing the definition of "social worker" with a definition for "qualified social worker" and cross-referencing the definition for this term in 42 CFR 483.70(p). In response to concerns raised by commentators regarding the deletion of qualifications for certain individuals in regulation, the Department notes that the Federal definition for "qualified social worker" in 42 CFR 483.70(p) contains the qualifications for an individual who serves in this capacity. It is therefore not necessary to repeat those qualifications in the text of § 201.3.

Definition of speech/language pathologist

The definition of "speech/language pathologist" remains deleted in this final-form rulemaking. As explained in the proposed rulemaking this term is not used in this subpart. Therefore, a definition is not necessary. The Department did not receive any comments regarding the proposed deletion of this definition.

Definition of transfer

In this final-form rulemaking the Department adds the definition of "transfer" in response to comments received on proposed Rulemaking 4 to distinguish between a "transfer" and a "discharge." In this final-form rulemaking a "transfer" is defined as "[t]he movement of a resident from a bed in one certified facility to a bed in another certified facility when the resident expects to return to the original facility."

Definition of verbal abuse

As previously noted, the definition of "verbal abuse" is retained in this final-form rulemaking in response to public comment. The definition of "verbal abuse" is retained with one grammatical edit but moved from the definition of "abuse" so that it is in alphabetical order in the list of definitions.

§ 211.12(i). Nursing services

Based on comments received, the Department is not amending this section in final-form Rulemaking 1. Instead, for ease of readability and responding to comments related to nursing services requirements being proposed in more than one rulemaking, the Department is amending this section, as a whole, in final-form Rulemaking 4. As such, the amendments on the proposed rulemaking are stricken in final-form Rulemaking 1.

On the proposed rulemaking, the Department amended subsection (i) to increase the minimum number of hours of direct care from 2.7 hours to 4.1 hours. The Department also added a provision to require facilities, during each shift in a 24-hour period, to have a sufficient number of nursing staff with the appropriate competencies and skill sets to provide nursing care and related services to: assure resident safety; and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.

As further provided in the preamble to final-form Rulemaking 4, the Department increased the direct resident care hours from 2.7 hours to 2.87 hours of minimum direct resident care for each resident during a 24-hour period, beginning July 1, 2023. The following year, July 1, 2024, the number of hours of minimum direct resident care for each resident, when totaled for the entire facility, will be increased to 3.2 hours of direct resident care for each resident.

The Department amends this requirement from the proposed rulemaking based on significant varying comments from commentators, IRRC and members of the legislature. Comments ranged from support of increasing direct resident care hours to opposition asserting concerns related to lack of funding for 4.1-hour requirement and staffing concerns, with additional comments requesting a delayed implementation. Many commentators strongly supported the increase, citing to research that shows that 4.1 hours is essential to ensure that residents receive quality care and indicating that an increase is long overdue. Commentators cited to many of the benefits that the Department noted on the proposed rulemaking, including health benefits to residents, fewer reports of abuse and higher job satisfaction for nursing service personnel. Some commentators also suggested that 4.1 hours is too low.

In contrast, commentators opposed to the increase asserted that a proposed increase to 4.1 hours is not realistic due to a workforce shortage. Commentators also indicated that facilities have had to resort to the use of agency staff, who are not as familiar with the needs of residents that are specific to the facility they are assigned to, and thus, are not able to provide the same high-quality care as nursing service personnel who work with the residents on a day-to-day basis. Commentators also expressed concern that rural communities may be more greatly impacted due to their smaller populations. Commentators also expressed concern that the increase would impact the poor and minorities who already have limited access to care. Other commentators pointed out that the regulated community is still reeling from the impacts of COVID-19 and indicated that they feel now is not the time to be making changes.

IRRC, in proposed Rulemaking 1, noted that commentators both supported and opposed the proposed increase to 4.1 direct care hours with specific examples related to the previously stated concerns. IRRC asked that the Department explain how this final-form regulation protects residents, while also addressing the impact of the minimum number of direct care hours on facilities, regardless of whether the Department retains or amends § 211.12(i). IRRC also asked if the Department sees any potential negative impact for residents if positions remain unfilled when the regulation goes into effect.

The Department carefully considered the varying comments in support of and in opposition to the increased direct resident care hours. In balancing the interests of consumers, advocates and industry stakeholders, in combination with the substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023 (see the act of July 11, 2022 (P.L. 540, No. 54) and the act of July 8, 2022 (No. 1A), known as the General Appropria-

tion Act of 2022), the Department amended this section in Rulemaking 4, as provided previously, with a graduated implementation date. The rate of 3.2 hours of direct resident care for each resident is comparable to surrounding states and similarly situated states: Delaware 3.28 hours; Maryland 3.00 hours; New York 3.50 hours; New Jersey 2.50 hours; District of Columbia 3.50—4.10 hours; Ohio 2.50 hours; Florida 3.6 hours; Rhode Island 3.58 hours; and West Virginia 2.25 hours. https://www.macpac.gov/publication/state-policies-related-to-nursing-facility-staffing/.

In addition, as further provided in Rulemaking 4, the Department deletes the words "during each shift" in response to concerns raised by commentators that this language is confusing. Specifically, commentators were concerned that this language, as drafted, could be construed to require the same number of nursing personnel at night when residents are sleeping as during the day when they are more active and need more care, and that facilities would be required to provide a total of 12.3 hours of direct care per day, rather than the proposed 4.1 hours of direct care. The Department agrees that the addition of "during each shift" is confusing. As such, the Department deletes the words "during each shift" in final-form Rulemaking 4 to alleviate this concern. In addition, during the public comment period for Rulemaking 4, the Department received further comments on this provision regarding the type of services included as "general nursing care." The Department has further addressed these comments in the preamble to Rulemaking 4.

Other comments

The Department received several other comments during the public comment period for proposed Rulemaking 1 that are unrelated to amendments proposed in that rulemaking. One commentator made several suggestions regarding oversight of rental payments, fees for services, depreciation and taxes assessed on facilities. The Department, however, does not have regulatory oversight of these areas and these comments are outside the scope of the rulemaking. However, the Department amends requirements for applications for licensure in final-form Rulemaking 3 to include submission of certain types of financial information. The types of financial information and reporting is discussed in more detail in the preamble for final-form Rulemaking 3.

One commentator indicated generally they would like to see future rulemakings address the need for greater LGBTQ inclusivity in facilities and make cultural sensitivity and competency trainings a requirement for facility administrators and frontline staff. The same commentator indicated they would like to see trainings regarding racial equity and implicit bias mandated as part of the staff development trainings in § 201.20 (relating to staff development). Although training and staff development is not addressed in this final-form rulemaking, the Department did receive similar comments to final-form Rulemaking 4. As further provided in the preamble to final-form Rulemaking 4, the Department amends § 201.20 to require annual in-service training on resident rights, including nondiscrimination and cultural competency.

One commentator asked whether the proposed increase in direct care hours will impact pharmacy technicians. The increase in direct care hours will impact nursing service personnel as explained in § 211.12(i) and in final-form Rulemaking 4 in § 211.12(f.1). Pharmacy technicians are not considered direct care providers for general nursing care and will not be impacted by this rulemaking under § 211.12(i).

One commentator asked if anything could be done to address the fact that facilities will only communicate with an agent of the facility under a power of attorney. The commentator expressed the need for alternative arrangements. As previously noted, the definition of "resident representative" is "as defined in 42 CFR 483.5." Under Federal regulations, the term resident representative includes individuals chosen by the resident to act on the resident's behalf and agents under power of attorney. As defined in 42 CFR 483.5, "resident representative" means any of the following:

> "(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;
>
> (2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;
>
> (3) Legal representative, as used in section 712 of the Older Americans Act; or.
>
> (4) The court-appointed guardian or conservator of a resident.
>
> (5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction."

One commentator indicated that the Department should consider temporary administration with the authority to handle care and operating procedures to improve quality in consistently poor performing facilities. Although this final-form rulemaking does not address temporary management, this issue is further discussed in the preamble to final-form Rulemaking 4. Under new § 201.15a (relating to enforcement), actions the Department may take to enforce include, but are not limited to, requiring a plan of correction, issuing a provisional license, revoking a license, appointing a temporary manager, limiting or suspending admissions to a facility, and assessing fines or civil monetary penalties.

One commentator requested that the regulations be amended to include the following requirements: (1) staff to wear name and position badges that are clearly visible to all; (2) staff to knock before entering a resident's room and introduce and announce themselves before entering the room; (3) that residents be able to place cameras in their rooms if their roommates agree; (4) facilities be open 24/7 to family and this be made clear when a resident is admitted; (5) facilities have a published process in place for residents and family members to submit care or treatment concerns and a timeframe in which to respond to them; (6) residents and family members be allowed to submit anonymous complaints to the local ombudsman for investigation and resolution. Another commentator requested that the regulations be amended to include the following requirements: (1) every doctor to be Board certified in geriatrics; (2) residents have the freedom to be transported to their primary care physician if they want; (3) doctors on staff meet with every new resident and family for at least 30 minutes on admission or within

1-2 days to assess the resident, review medications, answer questions and make recommendations; (4) doctors do a follow-up assessment a week later with the resident and family to review care and to answer questions; (5) a list of medications be provided to family members; (6) medical records and charts be available upon request; (7) residents be allowed to transfer to a different facility if they are not happy; (8) improved requirements for facility inspections and investigation complaints that involve different employees conducting inspections versus complaints; and (9) evaluation and inspection reports for facilities be published in local papers and any violations or citations highlighted.

Although this final-form rulemaking does not specifically address facility requirements, physician requirements, medical records, transfer agreement, facility inspections and surveys, grievances and resident rights, final-form Rulemaking 2, Rulemaking 3 and Rulemaking 4 address these various requirements.

Specifically, final-form Rulemaking 2 requires a facility to develop a closure plan, including a transfer and relocation plan of residents under § 201.23(c.4) (relating to closure of facility). Final-form Rulemaking 3 addresses inspection reports. Under § 201.14 (relating to responsibility of licensee) of final-form Rulemaking 3, a facility is required to have on file the most recent inspection reports. Upon requests, a facility is required to make the most recent report available to interested persons.

Final-form Rulemaking 4 also addresses transfers, transfer agreements and resident rights. Under § 201.29(c.2) of final-form Rulemaking 4, a resident has the rights set forth under 42 CFR 483.10, plus the additional rights under subsection (c.2). This includes the right to choose an attending physician, unless an alternative physician is needed to assure appropriate and adequate care. As previously noted in this final-form rulemaking, facilities are also required to establish a grievance policy in accordance with 42 CFR 483.10(j). In addition, further information regarding how to file a concern or complaint is available on the Department's web site at https://www.health.pa.gov/topics/facilities/nursing%20homes/Pages/Nursing%20Homes.aspx.

Final-form Rulemaking 4 also addresses transfer agreement under § 201.31 (relating to transfer agreement), which requires a transfer agreement between the facility and one or more hospitals.

Other commentators broadly suggested that the Department update requirements for infection prevention and control and emergency and pandemic preparedness planning. Requirements for infection prevention and control and emergency preparedness are addressed and further discussed in final-form Rulemaking 3. Commentators also broadly expressed support for updated application for licensure and change in ownership procedures to ensure a thorough evaluation of the applicant's experience, expertise and financial capacity to provide high quality of care. Requirements related to applications for licensure and changes in ownership are also addressed and further discussed in final-form Rulemaking 3. Finally, commentators broadly expressed support for improvements to requirements for residents' rights to protect all residents from discrimination or ill treatment. As previously provided, requirements related to resident rights are addressed and further discussed in final-form Rulemaking 4.

Comments on effective date

Some commentators, on proposed Rulemaking 1, urged the Department to make all four proposed rulemakings effective upon publication as final-form rulemakings, stating that these amendments are so long overdue that no phase-in period should be allowed. Other commentators, however, felt that the changes being proposed are too significant, and that the regulated community needs time to budget, plan and hire staff, particularly for the proposed increase in direct care hours. Some commentators suggested that the Department allow for a year or more for implementation of the regulations, while other commentators suggested a ramp-up period before all the regulations become effective. IRRC asked, in commenting on proposed Rulemaking 1, if the Department would consider a delayed implementation timetable for compliance. Commentators and IRRC also raised concerns in comments to proposed Rulemaking 3, regarding the Department's proposal to set the same effective date for all four final-form rulemakings. IRRC asked the Department to address these concerns and explain why this timeframe was reasonable.

In response to commentators and IRRC, the final-form rulemakings for all four regulatory packages will take effect on July 1, 2023, with the following exceptions. In final-form Rulemaking 3, § 201.12a(a), (b) and (c)(1) through (3), which require prospective licensees to provide written notice to certain individuals, shall take effect on February 1, 2023. Sections 201.12, 201.12b, 201.13c(b) and (c), and 201.12a(c)(4) and (d) shall take effect on October 31, 2023. In final-form Rulemaking 4, § 211.12(f.1)(3) and (i)(2) shall take effect on July 1, 2024. This will allow the regulated community a reasonable amount of time to adequately plan and initiate the staffing and budget changes necessary to achieve compliance.

Fiscal Impact and Paperwork Requirements

Fiscal impact

As previously provided, the Department participated in the Senate Health and Human Services and Aging and Youth Committees joint legislative hearing regarding this final-form rulemaking on September 15, 2021. Various stakeholders participated, including PHCA, AARP Pennsylvania, LeadingAge Pennsylvania, PACAH, SEIU Healthcare Pennsylvania and CARIE. During this hearing, there was much discussion about the proposed staffing increase from 2.7 hours to 4.1 hours of direct resident care and the related cost and staff concerns. Specifically, concerns were raised regarding stagnant MA rates since MA pays for 70% of all nursing home care. There were also comments regarding increased costs related to the increased staffing generally. During this hearing, stakeholder testimony provided that many facilities struggle to reach 3.3 hours of direct resident care. Resident advocates also expressed concerns with staff turnover and the need for greater transparency to understand how facilities are spending public funds. There was further testimony regarding staff burnout due to high demands of resident care, workers leaving the field and the need to address systemic underfunding of these services in the Commonwealth.

In response to the comments and concerns raised during this legislative hearing, throughout the public comment process, and in other discussions, the Governor's Fiscal Year (FY) 2022-2023 budget proposal proposed an MA rate increase of $190 million; $91 million in State funding to be matched with $99 million in Federal funds for the first 6 months of calendar year 2023 and a proposed $250 million one-time investment of American Rescue Plan Act (ARPA) (Pub.L. 117-2) funds in long-term living programs, including direct one-time funding for all

facilities to support their workforce and help them to hire more staff to meet the requirements of the forthcoming regulations. The funding was proposed to be provided to facilities in advance of the expected staffing increases to allow facilities to stabilize their existing workforce and recruit additional staff prior to the regulatory increases going into effect.

Following the Governor's budget proposal, industry stakeholders called for $294 million in MA funding in the Commonwealth's FY 2022-2023 budget. The FY 2022-2023 Appropriations Act signed by Governor Tom Wolf included bipartisan support for a historic increase in one-time and ongoing funding for facilities. As enacted, $147 million in State funding was appropriated to support implementation of the Department's regulations. Specifically, this funding will be used to support a 17.5% Medicaid rate increase beginning January 1, 2023, which allows facilities time to ramp up staffing to meet the direct care staffing hours required on July 1, 2023. Assuming Federal approval, these State funds will be matched with an additional $159 million in Federal funds, totaling $306 million in Medicaid funding for the first 6 months of calendar year 2023. Nursing facilities will also receive $131 million in one-time ARPA funding during FY 2022-2023. A detailed fiscal impact for the regulated community, the Commonwealth and local government is as follows:

Regulated community

The amendments will apply to all 682 long-term care nursing facilities licensed by the Department. These facilities provide health services to approximately 72,000 residents. This total includes 19 county-owned and operated facilities, 6 veterans' homes that are operated by DMVA, 654 privately-owned facilities that participate in Medicare or MA and 3 private-pay facilities that do not participate in Medicare or MA.

The existing regulations of the Department already incorporate many of the Federal requirements and the expansion to incorporate the remaining Federal requirements at 42 CFR Part 483, Subpart B will not impact the facilities that participate in the Medicare or MA programs. However, the three private-pay long-term care nursing facilities that do not participate in either the Medicare or MA Program will be impacted.

Assuming that the three private-pay facilities have not updated any of their practices and procedures since 1998, it is anticipated that the maximum cost to each facility to incorporate current Federal health and safety standards would be approximately $67,862. This maximum estimate, adjusted for inflation, is based on the cost analysis from the Federal Department of Health and Human Services when it promulgated its comprehensive updates at 81 FR 68688 (October 4, 2016). A break-down of these potential costs, adjusted for inflation through the United States Bureau of Labor Statistics CPI Inflation Calculator at https://www.bls.gov/data/inflation_calculator.htm, are as follows:

Resident Rights (42 CFR 483.10)	$13,020
Admission, Discharge, and Transfer Rights (42 CFR 483.15)	$230
Comprehensive Resident Centered Care Planning (42 CFR 483.21)	$6,760
Nursing Services (42 CFR 483.35)	$304
Food and Nutrition Services (42 CFR 483.60)	$145
Quality Assurance and Performance Improvement (42 CFR 483.75)	$3,926
Infection Control (42 CFR 483.80)	$23,318
Compliance and Ethics Program (42 CFR 483.85)	$19,262
Training (42 CFR 483.95)	$897
Total	$67,862

However, based on the Department's experience with facilities' compliance with existing regulatory requirements, these facilities already comply with various provisions, such as infection prevention and control measures, emergency preparedness and planning, food service safety, and homelike environment requirements. Therefore, it is unlikely that the facilities would reach the maximum estimated costs.

In addition, a facility may apply for an exception to the requirements of Subpart C under §§ 51.31—51.34. This includes the ability to apply for an exception to the incorporation of a specific Federal requirement. Specifically, all facilities, including private-pay facilities, may request an exception under the process identified in §§ 51.31—51.34. To assist the Department in rendering decisions on requests for exceptions, a facility requesting an exception is required to identify the specific Federal requirements to which it is seeking an exception, rather than broadly requesting an exception to all of the Federal requirements.

Further, based on comments received, the Department is exempting facilities from complying with 42 CFR 483.1 and the data transmission and MDS reporting requirements, unless the facility participates in the Medicare or MA programs

Requiring all long-term care nursing facilities to comply with the minimum Federal health and safety standard for long-term care facilities will increase health and safety standards, improve the survey process, create consistency and eliminate any confusion in the application of standards to long-term care nursing facilities, which will benefit all long-term care nursing facilities. Although there is anticipated to be a fiscal impact regarding incorporation of certain Federal standards for the three facilities that do not participate in Medicare or MA Programs, the cost of these health and safety standards is outweighed by the health and safety benefits for nursing facility residents. The benefit of this final-form rulemaking is consistent standards for licensure to ensure the health, safety and welfare of all residents of long-term care nursing facilities in this Commonwealth.

Commonwealth—Department

The amendments will not increase costs to the Department. The Department's surveyors perform the function of surveying and inspecting long-term care nursing facilities for compliance with both Federal and State regulations. The elimination of subsections that are outdated and duplicative of the Federal requirements will streamline the survey process for long-term care nursing facilities and provide consistency and congruency to the stakeholder industry. This, in turn, will reduce confusion in the application of the standards that apply to long-term care nursing facilities.

Commonwealth—DMVA

Of the 682 long-term care nursing facilities licensed by the Department, 6 facilities are veterans' homes that are

operated by the DMVA. These facilities are already required to comply with the Federal requirements and thus, are already required to comply with existing Federal health and safety standards.

The DMVA-operated licensed facilities will not incur any additional cost to align with the Federal requirements. As noted, these facilities are already required to comply with the Federal requirements.

Commonwealth—DHS

Although the provisions of this final-form rulemaking, which relate to incorporation of Federal health and safety standards and the updating of definitions, will not have a cost impact to DHS, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023, was enacted under the act of July 11, 2022 (P.L. 540, No. 54) and appropriated under the act of July 8, 2022, (No. 1A), known as the General Appropriations Act of 2022 (Act 2022-1A).

Local government

As previously mentioned, there are currently 19 county-owned long-term care nursing facilities, licensed by the Department. These facilities account for approximately 7.5% (6,524 beds) of licensed nursing facility beds across this Commonwealth. Allegheny County owns four of the nursing homes; the remaining homes are in the following 15 counties: Berks, Bradford, Bucks, Chester, Clinton, Crawford, Delaware, Erie, Indiana, Lehigh, Monroe, Northampton, Philadelphia, Warren and Westmoreland.

County-owned long-term care nursing facilities participate in Medicare or MA and thus, are already required to comply with the Federal requirements.

The county-owned licensed facilities will not incur any additional cost due to align with the Federal requirements. As noted, these facilities participate in Medicare or MA and thus, are already required to comply with the Federal requirements.

Residents of long-term care nursing facilities

Approximately 72,000 individuals that reside in the 682 long-term care nursing facilities licensed by the Department are affected by the amendments. Residents in private pay facilities are positively affected by the expansion of the Federal health and safety requirements.

Paperwork requirements

Assuming that the three private-pay facilities have not updated any of their recordkeeping practices and procedures since 1998, it is anticipated the new paperwork requirements for the three private-pay facilities may include the following:

- Establishment of a grievance policy, receiving grievances and providing written responses under 42 CFR 483.10.
- Resident signature on care plan under 42 CFR 483.10.
- Notification to residents of charges under 42 CFR 483.10.
- Notice to residents of transfers or discharges, including updated notices of changes under 42 CFR 483.15.
- Discharge planning under 42 CFR 483.15.
- Quality assurance and performance improvement program and plan under 42 CFR 483.75.

In addition, based on comments received, the Department is exempting facilities from complying with 42 CFR 483.1 and the data transmission and MDS reporting requirements, unless the facility participates in the Medicare or MA program.

Small Business Analysis

A commentator expressed concern that the Department did not identify and estimate the number of small businesses that will be subject to the regulation. This commentator indicated that many of its members are small businesses under the definition of "small business" in the Regulatory Review Act (71 P.S. §§ 745.1—745.14). IRRC asked the Department to calculate and address the economic impact of this final-form rulemaking on small businesses.

Under section 3 of the Regulatory Review Act (71 P.S. § 745.3) a small business is "defined in accordance with the size standards described by the United States Small Business Administration's Small Business Size Regulations under 13 CFR Ch. 1 Part 121 (relating to small business size regulations) or its successor regulation." Under 13 CFR 121.101 (relating to what are SBA size standards?), the Small Business Administration's (SBA) "size standards determine whether a business entity is small." Size standards are developed under the North America Industry Classification System (NAICS). The Department applied the NAICS standards to determine how many long-term care nursing facilities, licensed by the Department, are small businesses.

The Department conducted a search on the NAICS web site to find the NAICS code for long-term care nursing facilities. The NAICS code for nursing care facilities (skilled nursing facilities) is 623110. The Department looked this code up in the table located in 13 CFR 121.201 (relating to what size standards has SBA identified by North American Industry Classification System codes?) and determined that a long-term care nursing facility is a small business if it has $30 million or less in annual receipts. The Department then pulled the latest long-term care nursing facility cost report from CMS to determine the impact to facilities that participate in Medicare or MA. The latest cost report data from CMS is 2018. Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data. The Department applied current Federal Standards of Accounting to this data to determine each facility's annual receipts. Based on this analysis, the Department determined that 623 facilities that participate in Medicare or MA have $30 million or less in annual receipts. Although the data from CMS is from 2018, the Department believes that currently, at least the same number of facilities, if not more, would meet the definition of a small business. This analysis aligns with the Department's previous assumption that most long-term nursing facilities licensed by the Department meet the definition of a small business.

The Department also asked stakeholders during the meetings held in 2021 and 2022 for assistance in determining the impact to small businesses. The stakeholders were not able to provide the Department with specific information regarding how the Department's proposed regulations would impact small businesses. However, during the stakeholder meeting for Rulemakings 1 and 2, a stakeholder suggested that the Department search GuideStar, which provides financial information regarding nonprofit entities, to determine whether the three private-pay facilities are small businesses. The Department searched the GuideStar web site at https://www.guidestar.org/ for the three private-pay facilities that are

licensed by the Department. Based on this data, one of the private-pay facilities, Friends Home in Kennett/Linden Hall, meets the definition of a small business applying the NAICS standards. Another private-pay facility, Foulkeways at Gwynedd does not meet the definition of a small business based on its gross receipts. Data for the third private-pay facility, Dallastown Nursing Center, is not available on GuideStar, but for the purposes of this analysis, the Department assumes that Dallastown is a small business.

In sum, at least 91% of nursing facilities meet the definition of a small business. Consistent with the HCFA and function of licensure, the purpose of these regulatory amendments is to ensure the health, safety and welfare of all residents of long-term care nursing facilities in this Commonwealth by providing the minimum health and safety standards. Given that most facilities are a small business and the need for surveying for the health and safety of residents, the Department did not establish differing criteria for nursing facilities that are small businesses compared to the minority of facilities that are not small businesses. Further, in determining the minimum health and safety requirements, the Department considered the myriad of received comments, feedback from meetings and stakeholder groups and attempted to balance the interests between consumers and the stakeholder industry. The Department's responsibility to ensure that residents receive safe, quality care applies to all residents of long-term care nursing facilities in this Commonwealth, and it is critical that all residents of long-term care nursing facilities receive the same level of high-quality care, regardless of whether the facility they reside in is a small business.

Statutory Authority

Sections 601 and 803 of the HCFA (35 P.S. §§ 448.601 and 448.803) authorize the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the HCFA. Section 801.1 of the HCFA (35 P.S. § 448.801a) seeks to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities. The minimum standards are to assure safe, adequate and efficient facilities and services and to promote the health, safety and adequate care of patients or residents of those facilities. In section 102 of the HCFA (35 P.S. § 448.102), the General Assembly has found that a purpose of the HCFA is, among other things, to assure that citizens receive humane, courteous and dignified treatment. Finally, section 201(12) of the HCFA (35 P.S. § 448.201(12)) provides the Department with explicit authority to enforce its rules and regulations promulgated under the HCFA.

The Department also has the duty to protect the health of the people of this Commonwealth under section 2102(a) of the Administrative Code of 1929 (71 P.S. § 532(a)). The Department has general authority to promulgate regulations under section 2102(g) of the Administrative Code of 1929.

Effectiveness/Sunset Date

This final-form rulemaking will become effective on July 1, 2023. A sunset date will not be imposed. The Department will monitor the regulations and update them as necessary.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on July 21, 2021, the Department submitted a copy of the notice of proposed rulemaking, published at 51 Pa.B. 4074 (July 31, 2021), to IRRC and the Chairpersons of the Senate Health and Human Services Committee and the House Health Committee for review and comment.

Under section 5(c) of the Regulatory Review Act, the Department shall submit to IRRC, the Senate Health and Human Services Committee and the House Health Committee copies of comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the Senate Health and Human Services Committee, the House Health Committee, and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on October 27, 2022, the final-form rulemaking was deemed approved by the Senate Health and Human Services Committee and the House Heath Committee. Under section 5.1(e) of the Regulatory Review Act, IRRC met on October 28, 2022 and approved the final-form rulemaking.

Contact Person

Additional information regarding this final-form rulemaking may be obtained by contacting Ann Chronister, Director, Bureau of Long-Term Care Programs, 625 Forster Street, Room 526, Health and Welfare Building, Harrisburg, PA 17120, (717) 547-3131, RA-DHLTCRegs@pa.gov. Persons with a disability may submit questions in alternative format such as by audio tape, Braille or by using V/TT (717) 783-6514 or the Pennsylvania Hamilton Relay Service at (800) 654-5984 (TT). Persons who require an alternative format of this document may contact Ann Chronister at the previous address or telephone number so that necessary arrangements can be made.

Findings

The Department finds that:

(1) Public notice of intention to adopt the regulations adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), referred to as the Commonwealth Documents Law (CDL), and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law and all comments were considered in drafting this final-form rulemaking.

(3) The amendments made to this final-form rulemaking do not enlarge the original purpose of the proposed rulemaking as published under section 201 of the CDL.

(4) The adoption of the regulations is necessary and appropriate for the administration of the Health Care Facilities Act.

Order

The Department, acting under the authorizing statute, orders that:

(1) The regulations of the Department in 28 Pa. Code Chapter 201 are amended by amending §§ 201.1—201.3 as set forth in Annex A.

(*Editor's Note*: Proposed § 211.12 is not amended in this final-form rulemaking. See Rulemaking 4 for consolidated final-form amendments of § 211.12.)

(2) The Department shall submit this final-form rulemaking to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(3) The Department shall submit this final-form rulemaking to IRRC, the Senate Health and Human Services Committee and the House Health Committee as required by law.

(4) The Department shall certify this final-form rulemaking, as approved for legality and form, and shall deposit it with the Legislative Reference Bureau as required by law.

(5) This final-form rulemaking shall take effect on July 1, 2023.

DR. DENISE A. JOHNSON,
Acting Secretary

(*Editor's Note*: See 52 Pa.B. 7054 (November 12, 2022) for IRRC's approval order.)

Fiscal Note: 10-221. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

Subpart C. LONG-TERM CARE FACILITIES

CHAPTER 201. APPLICABILITY, DEFINITIONS, OWNERSHIP AND GENERAL OPERATION OF LONG-TERM CARE NURSING FACILITIES

GENERAL PROVISIONS

§ 201.1. Applicability.

This subpart applies to long-term care nursing facilities as defined in section 802.1 of the act (35 P.S. § 448.802a).

§ 201.2. Requirements.

(a) The Department incorporates by reference 42 CFR Part 483, Subpart B of the Federal requirements for long-term care facilities, (relating to requirements for long-term care facilities), as licensing regulations for long-term care nursing facilities, with the exception of 42 CFR 483.1 (relating to basis and scope) and the requirements under 42 CFR Part 483 Subpart B for the transmission of data and minimum data set (MDS) reporting to the Centers for Medicare & Medicaid Services (CMS) unless the facility is participating in the Medicare or Medical Assistance Program.

(b) A facility may apply for an exception to the requirements of this subpart under §§ 51.31—51.34 (relating to exceptions).

§ 201.3. Definitions.

The following words and terms, when used in this subpart, have the following meanings, unless the context clearly indicates otherwise:

Abuse—As defined in 42 CFR 483.5 (relating to definitions).

Act—The Health Care Facilities Act (35 P.S. §§ 448.101—448.904b).

Administration of medication—The giving of a dose of medication to a resident as a result of an order of a practitioner licensed by the Commonwealth to prescribe medications.

Administrator—As defined in 42 CFR 483.70(d)(2) (relating to administration). The administrator shall be currently licensed and registered by the Department of State under the Nursing Home Administrators License Act (63 P.S. §§ 1101—1114.2).

Authorized person to administer medications—Persons qualified to administer medications in facilities are as follows:

(i) Physicians and dentists who are currently licensed by the Bureau of Professional and Occupational Affairs, Department of State.

(ii) Registered nurses who are currently licensed by the Bureau of Professional and Occupational Affairs, Department of State.

(iii) Practical nurses who have successfully passed the State Board of Nursing examination.

(iv) Practical nurses licensed by waiver in this Commonwealth who have successfully passed the United States Public Health Service Proficiency Examination.

(v) Practical nurses licensed by waiver in this Commonwealth who have successfully passed a medication course approved by the State Board of Nursing.

(vi) Student nurses of approved nursing programs who are functioning under the direct supervision of a member of the school faculty who is present in the facility.

(vii) Recent graduates of approved nursing programs who possess valid temporary practice permits and who are functioning under the direct supervision of a professional nurse who is present in the facility. The permits shall expire if the holders of the permits fail the licensing examinations.

(viii) Physician assistants and registered nurse practitioners who are certified by the Bureau of Professional and Occupational Affairs.

Basement—A story or floor level below the main or street floor. If, due to grade differences, there are two levels qualifying as a street floor, a basement is a floor below the lower of the two street floors.

CRNP—certified registered nurse practitioner—A registered nurse licensed in this Commonwealth who is certified by the State Board of Nursing and the State Board of Medicine as a CRNP, under The Professional Nursing Law (63 P.S. §§ 211—225) and the Medical Practice Act of 1985 (63 P.S. §§ 422.1—422.45).

Charge nurse—A person designated by the facility who is experienced in nursing service administration and supervision and in areas such as rehabilitative or geriatric nursing or who acquires the preparation through formal staff development programs and who is licensed by the Commonwealth as one of the following:

(i) An RN.

(ii) An RN licensed by another state as an RN and who has applied for endorsement from the State Board of Nursing and has received written notice that the application has been received by the State Board of Nursing. This subparagraph applies for 1 year, or until Commonwealth licensure is completed, whichever period is shorter.

(iii) [Reserved].

(iv) An LPN designated by the facility as a charge nurse on the night tour of duty in a facility with a census of 59 or less in accordance with § 211.12 (relating to nursing services).

Clinical laboratory—As defined in 42 U.S.C.A. § 263a(a).

Construction, alteration or renovation—The erection, building, remodeling, modernization, improvement, extension or expansion of a facility, or the conversion of a building or portion thereof to a facility. The term does not include part-for-part replacement or regular facility maintenance.

Controlled substance—A drug, substance or immediate precursor included in Schedules I—V of the Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144).

Corridor—A passageway, hallway or other common avenue used by residents and personnel to travel between buildings or sections of the same building to reach a common exit or service area. The service area includes, but is not limited to, living room, kitchen, bathroom, therapy rooms and storage areas not immediately adjoining the resident's sleeping quarters.

Department—The Department of Health of the Commonwealth.

Director of nursing services—An RN designated by a facility under 42 CFR 483.35(b)(2) (relating to nursing services) and has 1 year of experience or education in nursing service administration and supervision, as well as additional education or experience in areas such as rehabilitative or geriatric nursing, and participates annually in continuing nursing education.

Discharge—The movement of a resident from a bed in one certified facility to a bed in another certified facility or other location in the community, when return to the original facility is not expected.

Elopement—When a resident leaves the premises or a safe area without authorization.

Exit or *exitway*—A means of egress which is lighted and has three components: an exit access (corridor leading to the exit), an exit (a door) and an exit discharge (door to the street or public way).

Exploitation—As defined in 42 CFR 483.5.

Facility—A licensed long-term care nursing facility as defined in Chapter 8 of the act (35 P.S. §§ 448.801—448.821).

Full-time—A minimum of a 35-hour work week.

Full compliance—Means total compliance.

Health care practitioner—As defined in section 103 of the act (35 P.S. § 448.103).

Interdisciplinary team—As defined in 42 CFR 483.21(b)(2)(ii) (relating to comprehensive person-centered care planning).

Intimidation—As defined in section 3 of the Older Adults Protective Services Act (35 P.S. § 10225.103).

Involuntary seclusion—Separation of a resident from other residents or from the resident's room or confinement with or without roommates against the resident's will, or the will of the resident's representative, excluding emergency or short term monitored separation from other residents for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs.

LPN—licensed practical nurse—A practical nurse licensed to practice under the Practical Nurse Law (63 P.S. §§ 651—667.8) and the regulations of the State Board of Nursing in 49 Pa. Code Chapter 21, Subchapter B (relating to practical nurses).

Licensee—The individual, partnership, association or corporate entity including a public agency or religious or fraternal or philanthropic organization authorized to operate a licensed facility.

Long-term care ombudsman—An individual at the State or local level who is responsible for carrying out the duties and functions under section 3058g of the State Long-Term Care Ombudsman Program (42 U.S.C.A. § 3058g).

Medication—A substance meeting one of the following qualifications:

(i) Is recognized in the official United States pharmacopeia, or official National formulary or a supplement to either of them.

(ii) Is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.

(iii) Is other than food and intended to affect the structure or a function of the human body or other animal body.

(iv) Is intended for use as a component of an article specified in subparagraphs (i), (ii) or (iii), but not including devices or their components, parts or accessories.

Medication administration—An act in which a single dose of a prescribed medication or biological is given to a resident by an authorized person in accordance with statutes and regulations governing the act. The complete act of administration entails removing an individual dose from a previously dispensed, properly labeled container, verifying it with the physician's orders, giving the individual dose to the proper resident and promptly recording the time and dose given.

Medication dispensing—An act by a practitioner or a person who is licensed in this Commonwealth to dispense medications under the Pharmacy Act (63 P.S. §§ 390-1—390-13) entailing the interpretation of an order for a medication or biological and, under that order, the proper selecting, measuring, labeling, packaging and issuance of the medication or biological for a resident or for a service unit of the facility.

Mental abuse—Includes humiliation, harassment, threats of punishment or deprivation.

Misappropriation of resident property—As defined in 42 CFR 483.5.

Mistreatment—As defined in 42 CFR 483.5.

NFPA—National Fire Protection Association.

Neglect—As defined in 42 CFR 483.5.

Non-prescription medication—An over-the-counter medication legally purchased without a prescription.

Nurse aide—An individual, as defined in 42 CFR 483.5, providing nursing or nursing-related services to residents in a facility who:

(i) Does not have a license to practice professional or practical nursing in this Commonwealth.

(ii) Does not volunteer services for no pay.

(iii) Has met the requisite training and competency evaluation requirements as defined in 42 CFR 483.35 (relating to nursing services).

(iv) Appears on the Commonwealth's Nurse Aide Registry.

(v) Has no substantiated findings of abuse, neglect or misappropriation of resident property recorded in the Nurse Aide Registry.

Nursing care—A planned program to meet the physical and emotional needs of the resident. The term includes procedures that require nursing skills and techniques applied by properly trained personnel.

Nursing service personnel—Registered nurses, licensed practical nurses and nurse aides.

Person—As defined in section 103 of the act.

Pharmacist—A person licensed by the State Board of Pharmacy to engage in the practice of pharmacy.

Pharmacy—A place properly licensed by the State Board of Pharmacy where the practice of pharmacy is conducted.

Physical abuse—Includes hitting, slapping, pinching and kicking. The term also includes controlling behavior through corporal punishment.

Physician assistant—An individual certified as a physician assistant by the State Board of Medicine under the Medical Practice Act of 1985, or by the State Board of Osteopathic Medical Examiners under the Osteopathic Medical Practice Act (63 P.S. §§ 271.1—271.18).

Practitioner—A health care practitioner as defined in section 103 of the act.

Prescription—A written or verbal order for medications issued by a health care practitioner in the course of professional practice.

Qualified dietician—As defined in 42 CFR 483.60(a)(1) (relating to food and nutrition services).

Qualified social worker—As defined in 42 CFR 483.70(p).

Qualified therapeutic recreation specialist—As defined in 42 CFR 483.24(c) (relating to quality of life).

RN—registered nurse—An individual licensed to practice professional nursing under The Professional Nursing Law and the regulations of the State Board of Nursing in 49 Pa. Code Chapter 21, Subchapter A (relating to registered nurses).

Resident—A person who is admitted to a licensed long-term care nursing facility for observation, treatment or care for illness, disease, injury or other disability.

Resident representative—As defined in 42 CFR 483.5.

Restraint—A restraint can be physical or chemical.

(i) A physical restraint includes any manual method, physical or mechanical device, equipment or material that is attached or adjacent to the resident's body, cannot be removed easily by the resident, and restricts the resident's freedom of movement or normal access to the resident's body.

(ii) A chemical restraint includes any medication that is used for discipline or convenience and not required to treat medical symptoms.

Serious bodily injury—As defined in section 3 of the Older Adults Protective Services Act.

Serious physical injury—As defined in section 3 of the Older Adults Protective Services Act.

Sexual abuse—Non-consensual contact of any type with a resident, including sexual harassment, sexual coercion or sexual assault.

Substantial compliance—

(i) cited deficiencies are, individually and in combined effect, of a minor nature such that neither the deficiencies nor efforts toward their correction will interfere with or adversely affect normal facility operations or adversely affect any resident's health or safety; and

(ii) the facility has implemented a plan of correction approved by the Department.

Transfer—The movement of a resident from a bed in one certified facility to a bed in another certified facility when the resident expects to return to the original facility.

Verbal abuse—Use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend or disability. Examples of verbal abuse include:

(i) Threats of harm.

(ii) Saying things to frighten a resident, such as telling a resident that the resident will never be able to see the resident's family again.

[Pa.B. Doc. No. 22-2016. Filed for public inspection December 23, 2022, 9:00 a.m.]

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CHS. 201, 203, 204, 205 AND 207]

Long-Term Care Nursing Facilities

The Department of Health (Department), after consultation with the Health Policy Board, amends §§ 201.23 and 207.4, Chapters 203 and 205, and adds Chapter 204 in Subpart C (relating to long-term care facilities), to read as set forth in Annex A. This is the second of four final-form rulemakings for long-term care nursing facilities being promulgated by the Department.

The contents for the four final-form rulemaking packages are as follows:

Rulemaking 1—General Applicability and Definitions

§ 201.1. Applicability.

§ 201.2. Requirements.

§ 201.3. Definitions.

§ 211.12. Nursing services. (Withdrawn on final-form.)

Rulemaking 2—General Operation and Physical Requirements

§ 201.23. Closure of facility.

Chapter 203. Application of Life Safety Code for Long-Term Care Nursing Facilities. (Reserved on final-form.)

Chapter 204. Physical Environment and Equipment Standards for Construction, Alteration or Renovation of Long-Term Care Nursing Facilities after July 1, 2023.

Chapter 205. Physical Environment and Equipment Standards for Long-Term Care Nursing Facilities Construction, Alteration or Renovation Approved before July 1, 2023.

§ 207.4. Ice containers and storage. (Reserved on final-form.)

Rulemaking 3—Applications for Ownership, Management and Changes of Ownership; Health and Safety

§ 201.12. Application for license of a new facility or change in ownership.

§ 201.12a. Notice and opportunity to comment (New section on final-form.)

§ 201.12b. Evaluation of application for license of a new facility or change in ownership. (Section renumbered on final-form.)

§ 201.13. Issuance of license for a new facility or change in ownership.

§ 201.13a. Regular license. (New section on final-form.)

§ 201.13b. Provisional license. (New section on final-form.)

§ 201.13c. License renewal. (Section renumbered on final-form.)

§ 201.14. Responsibility of licensee.

§ 201.15. Restrictions on license.

§ 201.15a. Enforcement. (New section on final-form.)

§ 201.15b. Appeals. (New section on final-form.)

§ 201.17. Location.

§ 201.22. Prevention, control and surveillance of tuberculosis (TB).

§ 209.1. Fire department service. (Reserved on final-form.)

§ 209.7. Disaster preparedness. (Reserved on final-form.)

§ 209.8. Fire drills. (Reserved on final-form.)

§ 211.1. Reportable diseases.

Rulemaking 4—Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services

§ 201.18. Management.

§ 201.19. Personnel records.

§ 201.20. Staff development.

§ 201.21. Use of outside resources.

§ 201.24. Admission policy.

§ 201.25. Discharge policy. (Reserved on final-form.)

§ 201.26. Resident representative.

§ 201.29. Resident rights.

§ 201.30. Access requirements. (Reserved on final-form.)

§ 201.31. Transfer agreement.

§ 207.2. Administrator's responsibility. (Reserved on final-form.)

§ 209.3. Smoking.

§ 211.2. Medical director.

§ 211.3. Verbal and telephone orders.

§ 211.4. Procedure in event of death.

§ 211.5. Medical records.

§ 211.6. Dietary services.

§ 211.7. Physician assistants and certified registered nurse practitioners.

§ 211.8. Use of restraints.

§ 211.9. Pharmacy services.

§ 211.10. Resident care policies.

§ 211.11. Resident care plan. (Reserved on final-form.)

§ 211.12. Nursing services. (Consolidated amendments on final-form.)

§ 211.15. Dental services.

§ 211.16. Social services.

§ 211.17. Pet therapy.

Comments on Multiple Packages; Stakeholder Engagement

The Department received comments during the public comment periods of all four proposed rulemaking packages expressing concern with the Department's decision to divide the long-term care nursing facility regulations into separate rulemakings. As previously provided, the Department divided the regulatory packages as follows: Rulemaking 1—General Applicability and Definitions; Rulemaking 2—General Operation and Physical Requirements; Rulemaking 3—Applications for Ownership, Management and Changes of Ownership; Health and Safety; and Rulemaking 4—Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services.

Although the Department intended to provide succinct areas for review and comment, commentators expressed some difficulty in reviewing sections of the regulations without the context of the remaining regulatory chapters and concern that multiple regulatory packages may lead to a lack of clarity and confusion for the regulated community and the public. Commentators also requested that the Department consider comments on all four proposed rulemaking packages outside of the 30-day comment period for each proposed package, or that the Department withdraw or resubmit all four proposed rulemaking packages as one package with an additional 30-day comment period. The Department also received comments regarding concern related to recent engagement with stakeholders, given that the Long-Term Care Work Group (LTC Work Group) last formally met in 2018 and was disbanded during the start of the novel coronavirus (COVID-19) pandemic.

In commenting on proposed Rulemaking 1, the Independent Regulatory Review Commission (IRRC) acknowledged the Department's authority to promulgate regulations as it deems appropriate. However, IRRC requested the Department to consider the regulated communities comments and the requests regarding the separate rulemakings. IRRC specifically asked the Department to explain why its approach in dividing the amendments into multiple packages was reasonable. IRRC asked whether it was in the public interest or reasonable to expect the regulated community to hold multiple proposed regulations simultaneously in mind while reviewing a proposed regulation. IRRC also asked that the Department ensure that amendments be consistent across the packages, and that the interrelation and any impacts between the packages be clearly presented for the regulated community.

In commenting on Rulemaking 2, IRRC again echoed concerns that separate rulemakings have the potential consequence of inconsistencies and errors across the four packages. IRRC inquired whether having multiple regulatory packages is in the public interest, whether it protects the public health, safety and welfare, and whether it is reasonable and lacks ambiguity. IRRC also asked the Department to: (1) identify in the final-form preamble any provisions which assume approval of Rulemaking 1 as final-form; (2) cross-reference these provisions to the relevant provisions in Rulemaking 1; and (3) explain the

impact if Rulemaking 1 is not approved before or at the same time as Rulemaking 2. IRRC recommended that the Department deliver each of the four individual packages as final-form rulemakings on the same day. In addition, IRRC, in its comment for proposed Rulemaking 3 and Rulemaking 4 expressed the same concerns as in the previous proposed rulemakings, but additionally suggested that the Department consider issuing an Advance Notice of Final Rulemaking to assist in reaching consensus.

Response

At the outset, the Department recognized that the changes to the long-term care nursing facility regulations would be numerous and complex, whether presented in one giant package or in multiple packages. A large single package would have been unwieldy and would likely have been presented around the date that the fourth regulatory package was completed and submitted (May 11, 2022). A later publication date would have resulted in less opportunity for comments, less time for the commentators to study the material and deliberate, and less time for necessary and valuable stakeholder engagement. Further, the regulated communities' input throughout this process informed the administration and legislature's investment in this year's budget. As such, the decision was made to continue with the changes in smaller, separate, more digestible packages. As provided previously, the Department initially decided to divide the proposed amendments to the six regulatory chapters under Subpart C into multiple packages to allow the public and interested parties a greater opportunity to thoroughly examine and digest the distinct proposed regulatory amendments over a longer period of time. In dividing these six chapters over four rulemakings, the public and interested parties would be permitted to provide more detailed comments and allow the Department to focus more closely on comments, provide a thoroughly considered response to questions and comments, and tailor the remaining proposed packages based on additional public and stakeholder input.

Further, in response to these public comments, the Department has considered all public comments and IRRC's comments across all four proposed rulemakings before drafting these four final-form rulemakings. In addition, based on comments received, the Department is submitting all four final-form rulemakings to IRRC, the legislative standing committees and the public commentators together on the same day. The drafting and submitting of all four final-form rulemakings together at the end of the last public comment periods allows interested parties and the public to vet and comment on each package separately, as well as in relation to the other packages. Throughout this process, the Department has continued to accept and review comments and be available to meet with stakeholders. If a commentator believed that a proposed amendment in Rulemaking 4 did not align with a proposed amendment in Rulemaking 1, the commentator could submit a comment to that effect for consideration by the Department during the public comment period for the proposed Rulemaking 4.

The Department did, in fact, take into consideration comments received on proposed Rulemakings 1 and 2, when drafting proposed Rulemakings 3 and 4. This is as evidenced by the proposal to expressly include text from the Centers for Medicare & Medicaid (CMS), State Operations Manual, Appendix PP into the text of the regulation. See for example, proposed Rulemaking 4 and proposed § 201.29(o) (relating to resident's rights). This inclusion of specific text was based on comments received by commentators and IRRC in proposed Rulemaking 1. The Department also consolidated the total number of proposed packages from five to four packages in response to both public and IRRC comments received in proposed Rulemaking 1.

In addition to considering comments on the four proposed packages during and outside of the four public comment periods, the Department met with stakeholders on four occasions following the receipt of public comments to discuss their concerns and to gain additional insight into comments that were received. The first of these meetings, for proposed Rulemakings 1 and 2, occurred on December 15, 2021. Representatives from the American Association of Retired Persons (AARP), Alzheimer's Association—Delaware Valley and Greater Pennsylvania Chapters, Center for Advocacy for the Rights & Interests of the Elderly (CARIE), Community Legal Services, LeadingAge, Pennsylvania Health Care Association (PHCA), Pennsylvania Coalition of Affiliated Healthcare and Living Communities (PACAH) and SEIU Healthcare Pennsylvania attended that meeting. The second meeting, for proposed Rulemaking 3 occurred on June 8, 2022. Representatives from AARP, Alzheimer's Association, CARIE, Community Legal Services, LeadingAge, PHCA, Pennsylvania Health Law Project (PHLP), and SEIU again attended that stakeholder meeting. The Department explicitly stressed to stakeholders during this June 8, 2022, meeting that it would be considering comments on all proposed rulemakings, and that it would welcome any additional comments or feedback that stakeholders might have after the meeting regarding proposed amendments to the various regulatory chapters. The Department also indicated in a press release on proposed Rulemaking 4, issued on June 3, 2022, that it would be considering comments on all four proposed rulemakings before submitting final-form rulemakings. The third meeting with stakeholders, for proposed Rulemaking 4, occurred on August 3, 2022. Present at that meeting were representatives from AARP, Alzheimer's Association, CARIE, PHCA, Pennsylvania Health Funders Collaborative (PHFC), and SEIU. The Department held the fourth meeting on August 17, 2022. At this meeting, the Department presented stakeholders with an overview of the changes that were made from the proposed rulemaking to the final-form rulemaking in response to their comments, on all four rulemakings, and provided them with an opportunity to comment and provide feedback on the final-form rulemakings. Present at that meeting were representatives from Alzheimer's Association, CARIE, Community Legal Services, County Commissioners Association of Pennsylvania (CCAP), Disability Rights, LeadingAge, PHCA, PHFC and SEIU.

After consideration of all comments received on the four proposed rulemaking packages, the Department firmly supports its decision in splitting the six long-term care nursing facility chapters into multiple packages. While the Department appreciates the comments and suggestion for one consolidated package, one is not needed at this stage due to the public, the regulated community and advocates full and continued opportunity to offer input on all the long-term care nursing facilities' regulations, throughout the four separate public comment periods, the first of which occurred over a year ago, as well as during the stakeholder meetings that occurred from 2021 through August 2022. In addition, as mentioned previously, at the meeting on August 17, 2022, the Department provided stakeholders an overview of the changes that were adopted on all four rulemakings, to ensure that

stakeholders fully understand all amendments. At that meeting, the Department also permitted stakeholders the opportunity to further comment on the final-form amendments and incorporated this feedback into these final-form rulemakings. Finally, as previously noted, splitting the regulations into multiple, separate packages benefited the public, regulated community and advocates because it allowed the Department to incorporate their feedback as it moved forward with the drafting of subsequent packages, which promoted the public interest, health, safety and welfare by improving the overall quality of the proposed rulemakings.

The Department has, in each of the four final-form rulemaking preambles, discussed and responded to all comments received on the contents of the four proposed rulemakings, regardless of when the comment was received. The Department adds cross-references, as appropriate, where comments received on one package relate to another package to further aid in the review of the four packages together in their entirety. For example, in proposed Rulemaking 1, the Department received comments requesting that staff, other than nursing personnel, be considered when determining whether a facility has met the minimum number of direct resident care hours in § 211.12(i) (relating to nursing services). In response to this comment, the types of individuals required for the minimum number of direct resident care hours was intentionally addressed in proposed Rulemaking 4 and generated additional comments during that proposed rulemaking's public comment period. The Department has, therefore, indicated in § 211.12(i) of the preamble for final-form Rulemaking 1, that it received comments on this topic and provided a cross-reference to the more in-depth discussion of this topic in the preamble for final-form Rulemaking 4. Further, to provide additional clarity and readability, the Department moved the proposed language relating to direct resident care hours from proposed Rulemaking 1 to final-form Rulemaking 4. Finally, the Department has noted where one rulemaking assumes the approval of another rulemaking. Through this extended review and public comment process, the Department has been transparent in its proposals and has responded to these comments through each final-form rulemaking.

Background and Need for Amendments

The percentage of adults 65 years of age or older in this Commonwealth is increasing. In 2010, approximately 15% of Pennsylvanians were 65 years of age or older. In 2017, this number increased to 17.8%. In 2020, just under 20% of the population in this Commonwealth was 65 years of age or older. For every 10 individuals under 25 years of age lost in this Commonwealth since 2010, the State gained 21 persons 65 years of age or older. This Commonwealth also has a higher percentage of older adults when compared to other states. In 2017, this Commonwealth ranked fifth in the Nation in the number (2.2 million) of older adults and seventh in percentage (17.8%). The increase in older Pennsylvanians is expected to continue. It has been estimated that by 2030, there will be 38 older Pennsylvanians (65 years of age or older) for every 100-working age Pennsylvanians (15 years of age to 64 years of age). Penn State Harrisburg, Pennsylvania State Data Center (July 2018). Population Characteristics and Change: 2010 to 2017 (Research Brief). Retrieved from https://pasdc.hbg.psu.edu/data/research-briefs/pa-population-estimates; Penn State Harrisburg, Pennsylvania State Data Center (July 2018). Trends in Pennsylvania's Population by Age (June 2022). (Research Brief). Retrieved from https://pasdc.hbg.psu.edu/sdc/pasdc_files/researchbriefs/June_2022.pdf.

As the number of older Pennsylvanians increases, the number of those needing long-term care nursing will also increase. It has been estimated that an individual turning 65 years of age today has an almost 70% chance of needing some type of long-term services or support during the remainder of their lifetime; 20% will need long-term care support for longer than 5 years. More people use long-term care services at home and for longer; however, approximately 35% utilize nursing facilities for this type of care. Administration for Community Living. (February 2020). How Much Care Will You Need? Retrieved from https://acl.gov/ltc/basic-needs/how-much-care-will-you-need. Approximately 72,000 individuals reside in the 682 long-term care nursing facilities currently licensed by the Department.

The COVID-19 pandemic highlighted the vulnerability of older adults, with a larger percentage of deaths occurring in individuals 65 years of age and older. Centers for Disease Control and Prevention (CDC). Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC. Retrieved from https://covid.cdc.gov/covid-data-tracker/#demographics. See also, CDC. COVID-19 Weekly Cases and Deaths per 100,000 Population by Age, Race/Ethnicity and Sex, United States, March 1, 2020—June 25, 2022. Retrieved from https://covid.cdc.gov/covid-data-tracker/#demographicsovertime. Further, it is estimated that at least a quarter of COVID-19 deaths occurred in long-term care nursing Further, it is estimated that deaths of residents in long-term care facilities accounted for at least 34% of all COVID-19 deaths in the United States during the time that the CDC tracked this data. https://covidtracking.com/analysis-updates/what-we-know-about-the-impact-of-the-pandemic-on-our-most-vulnerable-community. In this Commonwealth alone, there have been approximately 11,443 confirmed deaths of residents in long-term care nursing facilities since January 2020. AARP (September 15, 2022). AARP Nursing Home COVID-19 Dashboard Fact Sheets. Retrieved from https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-states.html.

The repercussions of the COVID-19 pandemic have reached far beyond the direct, physical effects of contracting the COVID-19 virus. Lockdowns intended to protect vulnerable residents at the beginning of the COVID-19 pandemic led to social isolation and loneliness because residents were prevented from having in-person contact with their loved ones. This led to an increase in depression and anxiety, cognitive decline and in some cases, physical deterioration, among residents who were already fearful of contracting the virus. Levere, M., Rowan, P., & Wysocki, A. (2021). "The Adverse Effects of the COVID-19 Pandemic on Nursing Home Resident Well-Being." *Journal of the American Medical Directors Association*, 22(5), 948-954.e2. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7980137/. Nursing service personnel, who were already stressed before the COVID-19 pandemic, incurred additional stress from, among other things, shortages in personal protective equipment (PPE), limited access to COVID-19 testing supplies, fear of contracting COVID-19 while at work and spreading it to others, concern for residents under their care, lack of public support and recognition, and an increase in workloads due to the additional protective measures needed to prevent spread of COVID-19 and other nursing service personnel leaving the workforce. White, E.M., Wetle, T.F., Reddy, A. & Baier, R.R. (2021). "Front-line Nursing Home Staff Experiences During the COVID-19 Pandemic." *Jour-*

nal of the American Medical Directors Association, 22(1), 199-203. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7685055/.

The Department's long-term care nursing facilities regulations have not been updated since 1999, with the last significant update occurring in 1997 after the 1996 amendment to the Health Care Facilities Act (the HCFA or act) (35 P.S. §§ 448.101—448.904b). Since that time, there have been substantial changes in the means of delivering care and providing a safe environment for residents in long-term care nursing facilities, with the COVID-19 pandemic further highlighting the need for change. The Department has been attempting to complete this much needed reform since before the COVID-19 pandemic, in late 2017. At that time, the Department sought assistance and advice from members of the LTC Work Group. The Department worked with the LTC Work Group regularly in 2018. The members of the LTC Work Group were drawn from a diverse background and included representatives from urban and rural long-term care facilities and various stakeholder organizations and consumer groups that work in the area of resident care and delivery of services. The LTC Work Group members consisted of representatives from the following organizations: American Institute of Financial Gerontology; Baker Tilly Virchow Krause, LLP; Berks Heim and Rehabilitation; Fulton County Medical Center; Garden Spot Community; HCR ManorCare; Inglis House; Landis Communities; Leading Age; Legg Consulting Services; LIFE Pittsburgh; Luzerne County Community College; The Meadows at Blue Ridge; Mennonite Home; Lutheran Senior Life Passavant Community; PACAH; Pennsylvania Home Care Association; University of Pittsburgh; and Valley View Nursing Home. The following State agencies participated: Department of Aging; the Department of Human Services (DHS); and the Department of Military and Veterans Affairs (DMVA).

The members of the LTC Work Group met regularly during 2018 with the LTC Work Group's primary focus being the simplification and modernization of the existing long-term care regulations. After these discussions were complete, the Department reviewed the recommendations of the LTC Work Group and consulted with other potentially impacted agencies in 2019 and 2020. In 2020, 2021 and 2022, the Department continued its efforts to draft amendments to the long-term care nursing facility regulations while also handling the day-to-day challenges of protecting the residents of those facilities, who were being hit the hardest by the COVID-19 pandemic.

As discussed previously, in response to concerns raised by IRRC and commentators, the Department ramped up its communications with stakeholders by holding the first of four stakeholder meetings, beginning in December 2021, to address comments received on proposed for Rulemaking 1 and this rulemaking. The Department held a second meeting with stakeholders in June 2022 after the public comment and IRRC comment periods ended for proposed Rulemaking 3, and a third stakeholder meeting in August 2022 after the public and IRRC comment periods ended for proposed Rulemaking 4. The Department held a fourth stakeholder meeting on August 17, 2022, to provide an overview of changes from the proposed rulemakings to these final-form rulemakings and permitted stakeholders to provide additional feedback and comments on amendments during this meeting.

The discussions with stakeholders and the comments received on the four proposed rulemakings have made it abundantly clear that amendments to the current long-term care nursing facility regulations are desperately needed and must not be delayed any longer. Commentators expressed in comments to all four groups that they were pleased to see the Department updating these regulations. The comments in support of amending the regulations can generally be summarized as follows:

- Amendments are long overdue.
- Revisions to existing regulations are urgently needed.
- COVID-19 had a devastating impact on facilities and highlighted the need for revisions.
- Regulations need to be updated to provide additional protection to residents.

Unfortunately, while commentators agree for the most part that an update to the regulations is needed, they do not agree on the extent of the update needed. Some commentators strongly argued that the Department's proposed amendments do not go far enough in protecting residents, while other commentators strongly argued that the Department's proposed amendments go too far and result in a fiscal impact. The Department has considered all comments it received both in favor of and against the proposed amendments and has responded to those comments. In considering those comments and balancing the competing interest of the parties in this regulatory review process, the Department has made revisions from the proposed rulemakings to these final-form rulemakings. The Department has also provided explanations to comments received in the preambles for each of the four final-form rulemakings, as explained previously.

Public Comments

In response to proposed Rulemaking 2, the Department received comments from 20 public commentators and comments from IRRC. These comments are discussed in further detail as follows.

Description of amendments / summary of comments and responses

Chapter 201. Applicability, Definitions, Ownership and General Operation of Long-Term Care Nursing Facilities

General comment(s)

A few commentators suggested that the Department add § 201.0 at the beginning of this chapter to provide enumerated purposes for the Department's regulation of long-term care nursing facilities. Commentators suggested that the proposed purpose section include the following purposes: (1) to enhance the health and welfare of citizens in this Commonwealth by making the health care and long-term services and supports delivery system responsive and adequate to the needs of its citizens; (2) to assure that new health care services and facilities are efficiently and effectively used; (3) to ensure that health care services and facilities meet and will continue to meet high quality standards; (4) to respect the right that all citizens have to receive quality, humane, courteous and dignified care; (5) to ensure nursing facility residents can maintain their individuality and make choices about how they want to live; (6) to foster responsible private operation and ownership of health care facilities; and (7) to encourage innovation and continuous development of improved methods of health care delivery to nursing home residents.

The Department appreciates this comment and agrees with the provision of quality services and care in an effective and efficient manner; however, this proposed

language is largely duplicative of the purpose statement set forth in statute under section 102 of the HCFA (35 P.S. § 448.102). Section 102 states in full:

> The General Assembly finds that the health and welfare of Pennsylvania citizens will be enhanced by the orderly and economical distribution of health care resources to prevent needless duplication of services. Such distribution of resources will be furthered by governmental involvement to coordinate the health care system. Such a system will enhance the public health and welfare by making the delivery system responsive and adequate to the needs of its citizens and assuring that new health care services and facilities are efficiently and effectively used; that health care services and facilities continue to meet high quality standards; and, that all citizens receive humane, courteous, and dignified treatment. In developing such a coordinated health care system, it is the policy of the Commonwealth to foster responsible private operation and ownership of health care facilities, to encourage innovation and continuous development of improved methods of health care and to aid efficient and effective planning using local health systems agencies. It is the intent of the General Assembly that the Department of Health foster a sound health care system which provides for quality care at appropriate health care facilities throughout the Commonwealth.

The language suggested by commentators for proposed § 201.0 is lifted directly from the purpose statement in the act with minimal changes. The Department follows the *Pennsylvania Code & Bulletin Style Manual* in drafting regulations. Under § 2.10 (relating to purpose section) of the *Pennsylvania Code & Bulletin Style Manual*, purpose statements should only be included in regulations when necessary. Since this language is duplicative, the Department declines to reproduce this language in this final-form rulemaking.

§ 201.23. Closure of facility

This section is amended from the proposed rulemaking to this final-form rulemaking. Although the Department retains the cross-reference at the beginning of this section to the closure requirements in 42 CFR 483.70(l) and (m) (relating to administration), the Department makes amendments to each subsection, described as follows.

Subsection (a)

Subsection (a) remains deleted from the proposed rulemaking to this final-form rulemaking. The Department proposed to delete subsection (a) as duplicative of Federal requirements for a facility to provide a 60-day notice of closure to the Department, and existing § 51.3(c) (relating to notification), which requires notice at least 60 days prior to a facility ceasing to provide an existing health care service or reducing its bed complement. Commentators requested that the Department retain this subsection, instead of deleting it because it provides for greater protections than the Federal requirements by requiring that notice be provided to the Department at least 90 days prior to closure, rather than 60 days as required by 42 CFR 483.70(l)(1)(i). Commentators were generally concerned that the reduction in the number of days' notice would negatively affect residents who need more time, not less, to prepare in the event of a facility closure. IRRC asked if the reduction from 90 days to 60 days affects notice to residents. IRRC asked the Department to explain the reasonableness and feasibility of reducing the notice timeframe, and how doing so protects the health, safety and welfare of residents, if the amendment from 90 days to 60 days affects residents.

Under existing § 201.23(a) (relating to closure of facility), facilities must provide notice to the Department at least 90 days prior to closure. However, there is no specific timeframe in which facilities must provide notice to residents. Instead, under existing requirements, notice to residents is required under existing § 201.23(b) and (c) within a "sufficient time" for an orderly transfer. After carefully considering public comments and IRRC's comments regarding the timing of and requirements for notice of a facility closure, the Department adds subsections (c.1), (c.2) and (c.3), to provide a specific timeframe to further protect residents, while addressing the realities surrounding closure of facilities. Subsections (c.1), (c.2) and (c.3) address the timing and communication of a facility closure plan as explained more fully as follows.

Subsection (b)

Subsection (b) remains deleted from the proposed rulemaking to this final-form rulemaking. The Department proposed to delete subsection (b), which requires the licensee of a facility to notify the resident or resident's responsible person of the closure of a facility, because under 42 CFR 483.70(l)(1), the administrator of a facility is required to give notice to certain agencies and individuals, including residents and their legal representatives or other responsible parties. Commentators requested that the Department not delete subsection (b) but instead improve it by requiring that notice be provided to residents and resident representatives not only in writing, but also in the manner that the resident and resident representatives prefer contact. Commentators also requested that language be added to require certain information to be included in the notice and that the notice be provided to certain individuals. In response to these comments, the Department adds subsections (c.3) and (c.4) to this final-form rulemaking, as explained more fully as follows.

Subsection (c)

Subsection (c) remains deleted from the proposed rulemaking to this final-form rulemaking. The Department proposed to delete this subsection, which requires a facility to give a resident or the resident's responsible person sufficient time to effectuate an orderly transfer. IRRC noted that the Department, in proposing to delete this section, relied on its proposed incorporation by reference of CMS' State Operations Manual, Appendix PP, in proposed Rulemaking 1, by indicating that it expected a facility's closure plan to include certain elements from Appendix PP that include addressing the orderly transfer of residents. IRRC asked the Department in comment to proposed Rulemaking 1 to delete the incorporation by reference of Appendix PP. IRRC asked in comment to this proposed rulemaking, "If Appendix PP is removed, how will that impact requirements for closure plans for facilities?" IRRC also requested that the Department clarify in this final-form rulemaking, the requirements for a facility closure plan.

In response to IRRC's comment on proposed Rulemaking 1, the Department has removed the incorporation of Appendix PP from the regulations. Further, in response to public comments, the Department has added provisions related to closure plan requirements because it provides greater protection to residents and greater clarity to the regulated community. To avoid the impact of having no closure plan requirements, the Department adds subsections (c.1)—(c.3).

Commentators also expressed concern over the deletion of subsection (c) because requiring a plan is not the same as ensuring an orderly transfer. The Department agrees that an orderly transfer is distinct from notice of a closure. Under 42 CFR 483.15(c)(7) (relating to admission, transfer, and discharge rights), a facility must also "provide and document sufficient preparation and orientation to residents *to ensure a safe and orderly transfer or discharge from the facility*" (emphasis added). This is already required of all facilities, including the three private-pay facilities, under the partial incorporation of the Federal requirements under existing § 201.2 (relating to requirements).

Subsection (c.1)

As noted previously, subsection (c.1) is added from the proposed rulemaking to this final-form rulemaking, at the request of commentators and IRRC. Under subsection (c.1), a facility will be required to develop a closure plan that includes the following:

(1) The identification of those who will be responsible for the daily operation and management of the facility during the closure process.

(2) The roles and responsibilities, and contact information, for the facility owner and the administrator or any replacement or temporary manager during the closure process.

(3) Assurance that no new residents will be admitted to the facility after the written notice of closure is provided under subsection (c.3).

(4) A plan for identifying and assessing available facilities to which residents can be transferred, taking into consideration each resident's individual best interests and resident's goals, preferences and needs regarding services, location and setting. This shall include:

(i) Interviewing each resident and resident representative, if applicable, to determine each resident's goals, preferences and needs.

(ii) Offering the opportunity, to each resident and resident representative, if applicable, to obtain information regarding options within the community.

(iii) Providing residents and resident representatives, if applicable, with information or access to information regarding providers and services.

(5) A plan for the communication and transfer of resident information, including medical records.

(6) Provisions for the ongoing operations and management of the facility, its residents and staff during the closure process, that include the following:

(i) Payment of salaries and expenses.

(ii) Continuation of appropriate staffing and resources to meet the needs of the residents, including provision of medications, services, supplies and treatment.

(iii) Ongoing accounting, maintenance and reporting of resident personal funds.

(iv) Labeling, safekeeping and appropriate transfer of each resident's personal belongings.

These requirements align with guidance in section F845 of Appendix PP, and will ensure that all facilities, including the three private-pay facilities, are held to the same standards for the contents of a closure plan.

Subsection (c.2)

Subsection (c.2) is added from the proposed rulemaking to this final-form rulemaking. After carefully reviewing and considering public comments, the Department agrees that a longer notice period to the Department is needed to review a facility's closure plan. However, since communication between facilities and the Department is now submitted through electronic means (instead of the lengthier process of regular mail), the Department adds a provision that requires notice to the Department 75 days prior to the proposed date of closure. This time period will allow the Department 15 days to review and approve a facility closure plan.

Specifically, under 42 CFR 483.70(l)(1), a facility is required to provide written notification to the Department, at least 60 days prior to the date of closure. However, under 42 CFR 483.70(l)(3), this written notice must include "the plan, *that has been approved by the State*, for the transfer and adequate relocation of the residents of the facility by a date that would be specified by the State prior to closure." (emphasis added). The plan for the transfer and relocation of residents is part of the closure plan, which will be required under new subsection (c.1)(4). The Department will need time to review and approve the closure plan before the facility provides notice to the other individuals listed in 42 CFR 483.70(l)(1). The Department is therefore, adding subsection (c.2), on this final-form rulemaking, to require that a facility submit its notice of closure and the closure plan, developed under subsection (c.1) at least 75 days prior to the proposed date of closure.

The Department selected 75 days based on several factors. Specifically, in practice, the Department does not need more than 15 days to review and approve a closure plan. Additionally, most facility closures that the Department has overseen recently are due to a lack of adequate cashflow. Requiring facilities to submit a closure plan and notice of closure 90 days in advance of its proposed closure date may serve only to exacerbate the facility's financial issues and ability to effectuate safe and timely relocation of residents while providing no additional benefit to either the Department, residents, interested parties or the facilities.

Subsection (c.3)

Subsection (c.3) is added from the proposed rulemaking to this final-form rulemaking. As noted previously, commentators requested that the Department not delete subsection (b) but retain it and add additional individuals to the list of individuals under 42 CFR 483.70(l)(1) to whom notice must be provided. Commentators also requested that the Department add language to require that notice be in writing, and that notice be given in a language and manner that the resident or resident representative can understand. Under 42 CFR 483.70(l)(1), an administrator of a facility is required to provide written notice of the closure of the facility to the State Survey Agency (the Department), the State Long-Term Care Ombudsman and residents of the facility and their legal representatives or other responsible parties.

After reviewing these various comments, the Department agrees with commentators, and in the interest of safeguarding residents' rights, adds a requirement that notice, as well as the transfer and relocation plan of residents, be provided to residents and their resident representatives in writing or in a language or manner they understand. The Department also adds to subsection (c.3) a requirement that the written notice of closure and

the closure plan be provided to employees of the facility, the Office of the State Long-Term Care Ombudsman, and DHS, which oversees the MA Managed Care Organizations. Adding these additional individuals and organizations to this requirement will ensure that all applicable agencies and personnel are advised of the closure, which will help ensure that resident relocation and transition occurs more seamlessly. The Department agrees with commentators that the notice of closure, which includes certain pertinent information set forth as follows, should be distributed to these additional interested parties to ensure a cogent and concurrent response to a facility closure. The Department maintains the 60-day notice requirement to align with the Federal requirements. In response to commentators' concerns that 60 days is not enough, the Department notes that, if needed, the Department may extend the time that a facility remains open under subsection (e) for an additional 30 days to ensure a safe and orderly transfer of residents. These provisions work together to protect the health, safety and welfare of residents.

Commentators requested that the Department also require that the notice of closure be provided to various other persons and entities, including designated family members of each resident, the facility's resident council, the facility's family council, labor organizations that represent the facility's workforce, county commissioners, the County or Municipal Health Department, if one exists, and a representative of the local officials of the city or town where the facility is located. After carefully considering these comments and balancing competing interests between consumer advocates and facility stakeholders, the Department declines to explicitly name these additional parties in this final-form rulemaking. As provided under this final-form rulemaking, notice would be provided to residents, their resident representatives (which includes a family member designated by the resident), employees of the facility, the Office of the State Long-term Care Ombudsman and DHS.

Further, designated family members would also be "other responsible parties" under 42 CFR 483.70(l)(1), which provides facility closure requirements. Additionally, because the resident council of a facility is comprised of residents, it will necessarily receive notice of closure when the residents receive notice. Family councils do not exist at every facility, but family members may receive the notice if they are named as a resident representative. Since the Department has added a requirement that a facility's employees receive notice of the closure, it would be incumbent upon the employees to inform their respective labor organizations of the facility closure should they choose to do so. The Department declines to include a requirement that notice be provided to county commissioners or representatives of the local officials of the city or town where the facility is located. These parties are not part of the closure or relocation process. Because county or municipal health departments do not possess regulatory oversight of facility closures, the Department likewise declines to require a facility to provide these entities with notice of closure.

Subsection (c.4)

Subsection (c.4) is added from the proposed rulemaking to this final-form rulemaking, based on public comment, to include additional basic elements for the notice of closure. Under subsection (c.4), the notice to the groups and individuals listed in 42 CFR 483.70(l)(1) and in subsection (c.2) must include the proposed date of closure, the contact information for the facility representative delegated by the facility to respond to questions about the closure, the contact information for the office of the State Long-Term Care Ombudsman, and the transfer and relocation plan. These items are added at the request of commentators and reflect the most salient and important information related to a facility closure.

Commentators also requested that the Department require that the notice of closure include other items, such as the reasons leading to closure, the provision of a public information session, the ability for interested parties to file comments with the Department and a catch-all provision for other information that may be specified by the Department. In balancing the competing interests related to closure plans, the Department declines to add these additional provisions to the notice of closure. The importance of the notice of closure is to advise residents and other interested parties that the facility will close on a date certain, provide a facility contact to answer closure-related questions, and advise residents and interested parties of the facility's plan to transfer and relocate residents. Additional information is extraneous, an additional requirement and detracts from the purpose of the notice of closure.

Subsection (d)

Subsection (d) is unchanged from the proposed rulemaking to this final-form rulemaking. Subsection (d) prohibits a long-term care nursing facility from requiring a resident to leave the facility less than 30 days after notice is given, unless the Department deems removal is necessary for the health and safety of residents. As explained, on the proposed rulemaking, the Department retains subsection (d), without amendment, because this requirement is not covered within the Federal requirements, and the Department determined it was necessary to keep this provision to ensure the health and safety of residents during the closure of a facility. IRRC asked, "What is the benefit of having a 60-day notice requirement to residents if the facility can require a resident to leave on day 31?" This subsection provides a protective window in which the resident may refuse a transfer facilitated by the facility and locate a facility on their own. After 30 days, the facility may initiate a transfer or discharge for residents who have not yet arranged to leave on their own. Further, the facility-initiated transfer or discharge would be subject to transfer and discharge requirements in 42 CFR 483.15(c)(4) and this subpart.

Subsection (e)

Subsection (e) is unchanged from the proposed rulemaking to this final-form rulemaking. Subsection (e) permits the Department to require that a facility remain open for an additional 30 days when an orderly transfer cannot be effectuated within 30 days. As explained on the proposed rulemaking, the Department retains subsection (e), without amendment, because this requirement is not covered within the Federal requirements, and the Department determined it was necessary to keep this provision to ensure the health and safety of residents during the closure of a facility.

Subsection (f)

Subsection (f) is unchanged from the proposed rulemaking to this final-form rulemaking. Subsection (f) permits the Department to monitor the transfer of residents. As explained in the proposed rulemaking, the Department retains subsection (f), without amendment, because this requirement is not covered within the Federal requirements, and the Department determined it was necessary to keep this provision to ensure the health and

safety of residents during the closure of a facility. Commentators requested that the Department add a provision requiring the Department to appoint a single person to oversee implementation of the facility's closure plan and be onsite at the facility daily. After careful consideration, the Department declines to add this provision. The Department adds subsection (c.1), that requires identification of those responsible for daily operations and management during the closure process. Further, the contact information for the facility owner, the administrator or any replacement or temporary manager during the closure process is also required. The purpose of this information is for the Department to maintain frequent communication with a facility that is closing, including status calls, the submission of daily reports and monitoring surveys. In addition, the Department notes that representatives from the Office of the Local and State Ombudsman are often involved in the closure process as well.

Subsection (g)

Subsection (g) is retained from the proposed rulemaking to this final-form rulemaking, with amendments, based on comments received in response to the Department's proposed deletion of this subsection. The Department had proposed to delete subsection (g) because it referred to an "outdated" requirement that a licensee file proof of financial responsibility with the Department. Commentators, however, requested that the Department not delete this subsection because simply submitting a plan for closure that provides for continued payment of salaries and expenses is not evidence of a facility's ability to pay for salaries and expenses. IRRC noted commentators' concerns that a closure plan is not proof of financial responsibility and their concerns that the deletion of subsection (g) would put residents and caregivers at risk. IRRC asked the Department to explain the need for eliminating this provision and to explain how requiring a "plan" versus "proof" is reasonable and protects the public health, safety and welfare of residents.

After further consideration, the Department agrees with commentators and these comments and on this final-form rulemaking, adds the requirement in subsection (g) back into the regulation. As discussed, in its closure plan, a facility must include a plan outlining the ability to pay salaries and expenses. The Department acknowledges that a plan is different than an affirmative showing of proof that a facility will be able to continue to meet its financial obligations while it is closing. As such, the Department retains the language in existing subsection (g), on this final-form rulemaking, with two amendments. The Department makes a grammatical amendment by replacing the word "insure" with the word "ensure." The Department also amends subsection (g) on this final-form rulemaking to align with the notice of closure timeline set forth in subsection (c.3), by requiring proof of financial responsibility to ensure that the facility continue to operate in a satisfactory manner until closure of the facility, instead of 30 days, following the notice of intent to close.

Other comments

A commentator provided the Department with a detailed mark-up of § 201.23, with additional requirements that would expand § 201.23 into 26 subsections. Several other commentators wrote in support of this detailed mark-up. The Department thoroughly reviewed the mark-up language, comparing it to the existing regulation and the Federal requirements, and discussed the reasonableness of adding each one of these proposed subsections into regulation. Following is a general summary of this discussion with the Department's decision points.

These commentators seek to have a facility, intending to close, hold a public information session in conjunction with the Department. This public information session would be held at least 60 days prior to the intended date of closure and would be subject to public notice requirements developed by the Department. In balancing the competing interest of advocates and industry stakeholders, the Department declines to include this additional requirement in this final-form rulemaking. Through the closure plan and notice of closure requirements added to this section on this final-form rulemaking, interested parties can obtain and review relevant information pertaining to the intended closure of the facility. Interested persons that are concerned with the closure or any perceived issues surrounding the closure may also contact the Department, the facility, the office of the State Long-term Care Ombudsman or submit a complaint. Information on how to submit a complaint to the Department can be found on the Department's web site at https://www.health.pa.gov/topics/facilities/nursing%20homes/Pages/Nursing%20Homes.aspx. Due to these public processes, there is limited benefit to requiring both the Department and the facility to jointly pursue an additional requirement for a public information session.

The commentators also request that the Department add a requirement to prevent a facility from transferring any residents unless and until the Department approves the facility's closure plan. To provide additional clarity and in response to comments, the Department adds subsection (c.2) to require a facility to submit its closure plan to the Department for approval. In practice, the Department not only reviews and approves closure plans, but maintains frequent communication with facilities, including status calls, the submission of daily reports to monitor the transfer or residents and monitoring surveys during a facility closure, to ensure that residents are transferred in a safe and efficient manner. As such, this provision is not needed. Additionally, the Department notes that adding this prohibition might prevent short-term residents from being transferred or discharged while the Department is reviewing the closure plan. The Department, therefore, declines to add this language.

The commentators request that the Department add a requirement to prevent a facility from accepting new residents after submission of a closure plan. The Department agrees with this recommendation and it is addressed under the new subsection (c.1)(3).

The commentators also suggest a procedure for the submission of closure plans to the Department, that would include a public comment period and a public information session prior to approval of the closure plan, and a procedure for the submission of an amended closure plan, in the event of disapproval. As explained previously, under the closure plan and notice of closure requirements added to this section on this final-form rulemaking, interested parties can obtain and review relevant information pertaining to the intended closure of the facility. Interested persons that are concerned with the closure or any perceived issues surrounding the closure may contact the Department, the facility, the office of the State Long-term Care Ombudsman or submit a complaint. Information on how to submit a complaint to the Department can be found on the Department's web site at https://www.health.pa.gov/topics/facilities/nursing%20homes/Pages/Nursing%20Homes.aspx. As provided previ-

ously, given the additional procedures added to this final-form rulemaking, there is limited benefit to requiring both the Department and the facility to jointly pursue a public information session. As a result, the Department declines to add any provision providing for public information sessions or public comment in relation to closure plans. The Department additionally reiterates that its concern in the event of a facility closure is that the residents are transferred safely and there is no decline in the quality of services provided to residents or decline in the health, safety and welfare of the residents during the closure process. In practice, the Department reviews closure plans and where needed, requests that amendments be made to the plans prior to issuing its approval. If a closure plan continues to be deficient, even after amendment, the Department may, under section 814 of the act (35 P.S. § 448.814), institute a temporary manager and take other corrective actions to ensure that the residents are safely cared for until a safe transfer can be effectuated. Additional corrective actions available to the Department include requiring the facility to rectify the deficiency, having the facility submit a plan of corrective action, banning new admissions from the facility or revoking a facility's license. Id.

The commentators also request that the Department add a provision to state that a closure plan is deemed approved if the Department fails to act within 20 working days. As stated previously, the Department typically requires no more than a few days to review and approve or seek amendment of a closure plan. The Department declines to add this limitation to this final-form rulemaking, as it needs to explicitly ensure that all closure plans meet necessary regulations and requirements. Allowing a process through which a closure plan would be automatically approved would place residents at risk if the closure plan was inadequate to ensure their health and safety during the closure process.

The commentators also request that the Department add a requirement that the facility post an initial notice and provide a second notice of closure after the Department approves the closure plan. After carefully considering this comment and balancing the interests for notice and also the resources during the closure process, the Department declines to include this requirement in regulation. Under subsection (c.2), the facility must provide a notice of closure and closure plan to the Department at least 75 days in advance of closure. Once the Department approves the closure plan and notice of closure, the notice may then be distributed to residents and other interested parties. Due to this process, there is not an additional benefit to providing another notice of closure separate from what is already provided for in subsections (c.2), (c.3) and (c.4).

The commentators request that the Department add a provision to require a facility to provide at least weekly updates to the Department on closure status in addition to other provisions. The Department declines to add this language. As mentioned previously, the Department maintains frequent communication with a facility that is closing, including status calls, the submission of daily reports to monitor the transfer of residents, and monitoring surveys during a facility closure. Further, section 813(a) of the act (35 P.S. § 448.813(a)) provides the Department with authority to enter and inspect facilities for the purpose of determining the adequacy of the care and treatment provided to residents. Section 802.1 of the act (35 P.S. § 448.802a) also defines "survey" as an announced or unannounced examination which may include an onsite visit, for the purpose of determining a facility's compliance with licensure requirements. Therefore, the Department may conduct an announced or unannounced survey of a facility that is closing should the Department receive any indication that the facility is not following the closure plan.

The commentators also request that the Department add a provision that gives the Secretary of the Department the authority to waive or modify all closure timeframes in the event of an involuntary facility closure. The Department declines to add this provision, as the sanctions process available to the Department under § 51.41 (relating to violations, penalties) would cover the process suggested by commentators. The Department also refers commentators to § 201.15a (relating to enforcement), in final-form Rulemaking 3, that outlines the enforcement actions that are available to the Department. That section applies to the entirety of this subpart, including § 201.23.

The commentators request that the Department include a provision that includes explicit penalties and sanctions for a facility's failure to comply with the provisions of § 201.23. The Department appreciates the concern regarding compliance; however, this addition is unnecessary. As such, the Department declines to add this provision, and notes that the existing sanction provisions in § 51.41 apply if a facility fails to comply with § 201.23. The Department also refers commentators to § 201.15a, in final-form Rulemaking 3, that outlines the enforcement actions that are available to the Department. That section applies to the entirety of this subpart, including § 201.23.

The commentators request that the Department add a requirement that a facility is explicitly liable to the Department for funds expended by the Department to provide care and relocation services for residents and for funds expended to use a temporary manager. Section 817(c) of the act (35 P.S. § 448.817(c)) provides that funds collected because of an assessment of a civil penalty, may be used to provide temporary management and to relocate residents, among other things, when all other sources of funding have been exhausted. The act, however, does not give the Department the authority to require a facility to reimburse it for the expenditure of these funds. The Department will not be adopting this recommendation.

The commentators request that the Department add language that a temporary manager may be appointed if a facility fails to comply with notice of closure provisions, fails to implement an appropriate relocation plan or transfers residents prior to the 60-day notice period. As provided previously, there are existing enforcement provisions for provider violations. Under section 814(b) of the act, the Department is authorized to appoint temporary management to ensure the health and safety of residents. This authority is also echoed in these final-form rulemakings, based on the review and consideration of additional public comments. The Department also refers commentators to § 201.15a, in final-form Rulemaking 3, that outlines the enforcement actions that are available to the Department. That section applies to the entirety of this subpart, including § 201.23. The Department declines to adopt this recommendation.

The commentators request that the Department add a provision to indicate that failure to ensure appropriate notice to and relocation of all residents may result in a finding of abuse or neglect as defined under the Older Adults Protective Services Act (OAPSA) (35 P.S. §§ 10225.101—10225.5102) or the Adult Protective Ser-

vices Act (35 P.S. §§ 10210.101—10210.704). The Department declines to add this provision to this final-form rulemaking, as it is unnecessary. Those acts and accompanying regulations provide for the identification and reporting of abuse. It is not necessary for the Department to expand on those provisions within this final-form rulemaking. The Department further notes that it investigates complaints of abuse and neglect in facilities and will continue to do so during the closure process.

Finally, commentators requested the Department add a forfeiture provision in the event that a facility fails to comply and abandons the facility and residents, resulting in an immediate and substantial threat to the health and safety of residents. After careful consideration, the Department declines to add this provision. Regardless of the reason for closure, any facility that closes would be required to apply for an application for subsequent licensure and would be subject to the comprehensive requirements related to prior ownership, adjudicated or settled civil actions, financial reporting, ownership structure and a public comment process as described in final-form Rulemaking 3 § 201.12 (relating to application for license of a new facility or change in ownership).

Chapter 203. Application of Life Safety Code for long-term care nursing facilities

Chapter 203 remains deleted from the proposed rulemaking to this final-form rulemaking. Commentators supported the deletion of this chapter. Section 203.1 (relating to application of the *Life Safety Code*) is the only section within this chapter. The Department proposed to delete § 203.1, and by extension, this chapter, as part of its process to streamline Federal and State requirements for long-term care nursing facilities for clarity and consistency. The National Fire Protection Association (NFPA) 101, *Life Safety Code*, 2012 Edition, is incorporated by reference in the Federal requirements for long-term care nursing facilities at 42 CFR 483.73(g)(1)(vii) (relating to emergency preparedness). Therefore, it is not necessary to have a separate provision within the State requirements regarding the applicability of the *Life Safety Code*. Deletion of this chapter assumes approval of final-form Rulemaking 1, which expands the adoption of the Federal requirements in § 201.2.

Chapter 204. Physical environment and equipment standards for construction, alteration or renovation of long-term care nursing facilities

The Department retains Chapter 204 from the proposed rulemaking to this final-form rulemaking, but with amendments, as explained more fully as follows. As explained in the proposed rulemaking, the Department has decided to separate regulatory provisions pertaining to construction, alteration or renovation of long-term care nursing facilities into two chapters to clarify what standards apply to new versus existing construction, alteration or renovation. The Department had proposed to make Chapter 204 applicable to plans for construction, alteration or renovation of long-term care nursing facilities approved on or after 6 months from the publication date of this final-form rulemaking. However, given the estimated timing of this final-form rulemaking, and to be consistent with the effective date established for other sections of the final-form rulemakings, the Department has decided to make Chapter 204 applicable to plans for construction, alteration or renovation approved on or after July 1, 2023. Existing Chapter 205 (relating to physical plant and equipment standards for long-term care nursing facilities), as amended, will continue to be the baseline standard for all construction, alteration or renovation of long-term care nursing facilities performed based on plans that were approved by the Department before July 1, 2023, the effective date of Chapter 204.

A commentator expressed concern that there is no definition or threshold as to what classifies as "construction," "alteration" or "renovation." IRRC requested that the Department define these terms to provide clarity for the regulated community. The term "construction, alteration or renovation" is already used in § 51.3(d) and is already understood by the regulated community. However, to be responsive to the concern raised by the commentator and IRRC, the Department deletes the existing definition for "alteration" in § 201.3 (relating to definitions) and adds a new definition for the term "construction, alteration or renovation" to § 201.3 in final-form Rulemaking 1. The Department chose to use the term "construction, alteration or renovation" to align with the use of this term in § 51.3(d). The term "construction, alteration or renovation" is defined as "the erection, building, remodeling, modernization, improvement, extension or expansion of a facility, or the conversion of a building or portion thereof to a facility." For the purposes of the requirements in Chapters 204 and 205, there is no distinction between the terms "construction," "alteration" or "renovation." A facility will need to submit plans for any work that falls within the scope of this definition. In response to concerns from commentators that facilities could be restricted from making small changes to improve the physical environment for residents, the Department notes that it does not intend for the definition of "construction, alteration or renovation" to encompass work that consists of part-for-part replacement or regular facility maintenance. For clarity, the Department adds language to the definition of "construction, alteration or renovation" to reflect this intention.

The Department, in this final-form rulemaking, amends the title of Chapter 204 to replace the words "alterations, renovations or construction" with the words "construction, alteration or renovation" to align with the use of this term and definition in § 201.3 in final-form Rulemaking 1, as explained previously. The Department has made amendments throughout Chapter 204, as well, for consistency in the use of this term, as indicated more specifically below.

Commentators and IRRC expressed concern regarding certain provisions of Chapter 205 that were not carried over into Chapter 204. The Department, in the proposed rulemaking, explained which sections and subsections of Chapter 205 were being carried over into Chapter 204 because they were not covered by the 2018 edition of the Facility Guidelines Institute's (FGI) *Guidelines for Design and Construction of Residential Health, Care, and Support Facilities (Guidelines)*. The Department explained that it was only copying provisions from Chapter 205 into Chapter 204 that go above and beyond the 2018 FGI *Guidelines*. IRRC asked the Department to clarify, in response to commentators' concerns, specifically which provisions are not copied from Chapter 205 into Chapter 204 because they are addressed in the 2018 *Guidelines*. In response to this comment, the Department has completed a crosswalk with citations to the specific sections in the 2018 FGI *Guidelines* for the provisions in Chapter 205 that are not being copied into the new Chapter 204. The Department has provided these citations in each section discussed as follows, as well as a summary at the end of the discussion of this chapter. While performing this crosswalk, the Department identified additional provisions that are added to Chapter 204. These amendments are described as follows, as well.

§ 204.1. Application of guidelines for design and construction of residential health, care and support facilities

Subsection (a)

Subsection (a) is amended from the proposed to this final-form rulemaking. The Department proposed in subsection (a) to adopt the 2018 FGI *Guidelines* as the minimum standard for construction, alteration or renovation for plans approved on or after the effective date of Chapter 204. The Department, in this final-form rulemaking, amends subsection (a) to indicate that this subsection applies to plans for construction, alteration or renovation approved on or after July 1, 2023, as explained previously. The Department also amends subsection (a) in this final-form rulemaking to replace the words "alterations, renovations and construction" with the words "construction, alteration or renovation" for consistency in the use of this terminology.

Commentators, citing to concerns over the length of time it takes to update regulations, requested that the Department amend subsection (a) to allow for adoption of future versions of the FGI *Guidelines* and not specifically reference the 2018 version. IRRC further requested that the Department explain how requiring facilities to comply with the 2018 FGI *Guidelines* is not an improper delegation of authority given that this document is not subject to regulatory review requirements.

In response to these comments, the Department notes that it is explicitly incorporating only the 2018 edition of the FGI *Guidelines*—a specific edition of the FGI *Guidelines* and is not allowing for the adoption of future editions in the regulations because doing so would constitute an improper delegation of authority. The Department may not delegate its authority to make rules and regulations by adopting a private organization's future recommendations. See, for example., *Protz v. Workers' Compensation Appeal Board (Derry Area Sch. Dist.)*, 161 A.3d 827 (Pa. 2017) (holding that a provision in the Workers' Compensation Act, requiring a physician to apply the methodology set forth in the most recent version of the American Medical Association *Guides to the Evaluation of Permanent Impairment*, was an unconstitutional delegation of legislative authority). This non-delegation doctrine does not, however, prohibit the adoption of a particular set of standards which are already in existence at the time of the adoption. Id.; *Pennsylvania AFL-CIO v. Commonwealth*, 219 A.3d 306 (Pa. Cmwlth. 2019).

The Department's adoption of the 2018 edition of the FGI *Guidelines* does not constitute an impermissible delegation of authority because it is a specific edition, and the Department carefully reviewed the necessity for application of these standards to long-term care nursing facilities. The 2018 edition of the FGI *Guidelines* is a specific edition, with new editions of the *Guidelines* being published every 4 years. The Department, on the proposed rulemaking, indicated that the 2018 edition of the FGI *Guidelines* would be incorporated in regulation and provided the public with the opportunity to review and offer comment through the regulatory review process. The adoption of the 2018 FGI *Guidelines* does not circumvent the regulatory review process. As indicated in the proposed rulemaking, the Department plans to review and update the regulations through the regulatory promulgation process, as necessary, to incorporate new editions of the FGI *Guidelines*. The FGI recently updated the *Guidelines* in May 2022. The Department has not had an opportunity yet to review and consider these updates, but will do so and then update the regulations, at a future date, if necessary to incorporate these newer construction requirements.

Subsection (b)

Subsection (b) is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, subsection (b) will require all facilities to comply with the standards set forth in Chapter 205 for construction, alteration or renovation approved prior to the effective date of Chapter 204. The Department, on this final-form rulemaking, amends subsection (b) to indicate that this subsection applies to plans for construction, alteration or renovation approved before July 1, 2023, which will be the effective date of Chapter 204, as explained previously. The Department also amends subsection (b) in this final-form rulemaking to replace the words "alterations, renovations and construction" with the words "construction, alteration or renovation" for consistency in the use of this terminology.

The Department recognizes that a broad, overall adoption of the FGI *Guidelines* to all long-term care nursing facilities, regardless of when plans were approved or when the construction, alteration or renovation occurred, will impose an undue burden on those facilities that are presently operating under the requirements set forth in Chapter 205. Subsection (b) allows these facilities to continue to operate under the requirements set forth in Chapter 205 until they wish to perform any new construction, alteration or renovation. Construction, alteration or renovation plans approved on or after July 1, 2023, will fall under subsection (a) of the Chapter 204. This is further clarified by subsection (c), described as follows.

Subsection (c)

Subsection (c) is amended from the proposed rulemaking to this final-form rulemaking. Commentators indicated they understood the intent of this subsection but were concerned that the wording would permit facilities to allow buildings to deteriorate and fall out of compliance where they had once met the FGI *Guidelines* but did not maintain those standards. IRRC asked for clarification as to the circumstances under which a facility would be deemed to be compliant. The Department believes that the confusion expressed from commentators is due to the first sentence of this subsection. In response to those comments, the Department, therefore, deletes this sentence from this final-form rulemaking. As explained in the proposed rulemaking, under subsection (c), a long-term care nursing facility must meet the requirements that were in effect at the time of approval of the plans for construction, alteration or renovation. The Department intends to hold facilities to the standards that were in effect at the time the plans for construction, alteration or renovation were approved. A facility must remain in compliance with those standards until the time that they perform new construction, alteration or renovation. At that time, the facility will need to comply with the standards that are in effect at the time that their plans for construction, alteration or renovation are approved by the Department. To be clear, a facility will not be allowed to fall into disrepair. A facility will be cited if it is not in compliance with the standards that were in effect at the time that its plans for construction, alteration or renovation were approved. The Department also amends subsection (c) in this final-form rulemaking to replace the words "alterations, renovations and construction" with the words "construction, alteration or renovation" for consistency in the use of this terminology.

§ 204.2. Building plans

The Department proposed to delete existing § 205.4 (relating to building plans) and copy several provisions from that section into this section. Section 205.4 is deleted because all plans for construction, alteration or renovation approved on or after July 1, 2023, the effective date of the regulation, will need to meet the requirements of § 204.2 (relating to building plans).

In response to commentators and IRRC, the Department provides the following explanation for why certain provisions of § 205.4 were not carried over into the new requirements in § 204.2. The Department did not copy the requirements of existing § 205.4(a) and (b) into § 204.2 because these requirements are duplicative of existing requirements in § 51.3(d) (relating to notification). Section 51.3(d) applies to all healthcare facilities licensed by the Department, including long-term care nursing facilities. Section 51.3(d) requires that a facility submit architectural plans and blueprints of proposed new construction, alteration or renovation to the Department for approval before beginning new construction, alteration or renovation. Section 205.4(c) is copied to § 204.2(b), as noted as follows. Section 205.4(d) is replaced with new language in § 204.2(c), which clarifies construction to begin within 2 years of the Department's approval of the plans submitted under § 51.3(d) and to be completed within 5 years.

The Department did not copy the requirements of existing § 205.4(e) into § 204.2 because these requirements do not accurately reflect modern practices concerning plan submissions. Under § 51.3(d), facilities are currently required to submit plans for construction or renovation that demonstrate compliance with the applicable regulations and codes for each individual project. The minimum elements that must be included in each plan will vary widely depending on what type of construction, alteration or renovation is being performed. It is the intent of the Department to not require facilities to include extraneous information when submitting construction plans for approval. Plans will differ based on a variety of factors such as, the portion of the facility undergoing construction (for example, resident rooms, corridors, workstations), the type of construction being performed (for example, upgrading electrical work, installing new plumbing, new buildings) and other ancillary factors that are all but impossible for the Department to account for in a rigid checklist of requirements for every plan. In practice, a universal set of standards applicable to each distinct plan that is submitted to the Department is unworkable, provides an additional requirement on regulated industry and does not achieve the Department's goal to assure compliance with applicable regulations and codes. Information regarding the submission of plans can be found on the Department's web site at https://www.health.pa.gov/topics/facilities/safety/Pages/Review.aspx.

However, § 204.2 is amended from the proposed rulemaking to this final-form rulemaking. The Department adds new language to the beginning of this section in subsection (a) to indicate that the Department will post instructions for the submission of plans for construction, alteration or renovation on its public web site. As a result of this addition, the remaining proposed subsections are renumbered accordingly and this is described more fully as follows.

Subsection (a)

Subsection (a) is amended from the proposed rulemaking to this final-form rulemaking. As noted previously, the Department has added language, in this final-form rulemaking, to indicate that the Department will post instructions for the submission of plans for construction, alteration or renovation on its public web site.

A commentator suggested that the Department add language to require a facility to provide written plans, architectural renderings, and a plain language description of alterations or renovations to the resident and family councils of the facility, as well as the Office of the Local Long-Term Care Ombudsman. After careful consideration, the Department declines to make this amendment. The primary goal of the Department's licensure regulations is to ensure that residents are safe, healthy and comfortable. The Department considers the sharing of construction, alteration or renovation plans to be a best practice, and declines to add a requirement for the sharing of items, such as architectural plans, which may be difficult for lay persons to understand. It is also the Department's experience that generally facilities that are conducting construction, alteration or renovation are proud of these upgrades to the facility and generally voluntarily promote and share plans with the resident council.

Subsection (b)

The language that was proposed in subsection (a) is moved to subsection (b), in this final-form rulemaking, without amendment. The Department maintained the language from existing § 205.4(c), with the addition of a cross-reference to § 51.3(d) to clarify that this subsection applies to plans approved under that section. Subsection (b) reflects the current practice that a licensee or prospective licensee be allowed to present and discuss plans with the Department. If differences occur and cannot be resolved, the licensee or prospective licensee may seek an administrative hearing.

A commentator sought clarification as to what the term "prospective licensee" means and suggested that the Department use the term "applicant" instead and add a corresponding definition for that term. The commentator proposed that the term "applicant" be defined as, "the entity applying for licensure, whether initial licensure for a new facility or transfer of ownership licensure for an existing facility that would, if approved by the Department, be transferred to the new owner." Although the Department appreciates this comment, the Department declines to add the term "applicant" to the regulation and instead retains the term "prospective licensee" since "licensee" is already a defined term. The Department also declines to add a definition for the additional term "prospective licensee." The term "licensee" is presently defined in § 201.3 as, "the individual, partnership, association or corporate entity including a public agency or religious or fraternal or philanthropic organization authorized to operate a licensed facility." The Department is not amending this definition in this final-form rulemaking. The term "prospective" is commonly understood and is defined as "relating to or effective in the future; likely to come about; likely to be or become" in Webster's dictionary. Merriam-Webster. "Prospective." Retrieved from https://www.merriam-webster.com/dictionary/prospective. As the term "prospective" is generally understood by its ordinary dictionary meaning, it is unnecessary to include a separate definition for the term "prospective licensee." See also 1 Pa.C.S. § 1903 (relating to words and phrases).

A commentator asked what is meant by the phrase "if differences occur." In response to this question, the Department first notes that this is existing language used in the Department's current regulations. As applied, it means that the Department works with licensees and

prospective licensees and attempts to resolve questions and disputes concerning plans for construction, alteration or renovation without the need for an administrative hearing. However, if the Department and the facility are at an impasse and further discussions will not resolve the perceived issue with the plans for construction, alteration or renovation, the facility may seek an administrative hearing in accordance with 1 Pa. Code Part II (relating to General Rules of Administrative Practice and Procedure).

A commentator also asked whether the Department provides licensees and prospective licensees with a written decision regarding plans for construction, alteration or renovation that includes a notice of appeal rights. Historically, the Department has never had a licensee or prospective licensee appeal a decision regarding plans for construction, alteration or renovation because the Department generally works with licensees and prospective licensees to resolve any issues that may arise with plans. If there is a disagreement between the Department and a licensee or prospective licensee regarding plans for construction, alteration or renovation, the licensee or prospective licensee may, as indicated in the language of this subsection, seek an administrative hearing in accordance with 1 Pa. Code Part II.

Subsection (c)

The language that was proposed in subsection (b) is moved to subsection (c), in this final-form rulemaking, but with one amendment. The words "alterations, renovations or construction" are replaced with the words "construction, alteration or renovation" for consistency in the use of that terminology. The Department proposed in this subsection to require construction, alteration or renovation to begin within 2 years of the Department's approval and to be completed within 5 years of the Department's approval. A commentator suggested adding the words "date of the" before "Department's approval." Although the Department appreciates this comment, the Department declines to make this amendment in this final-form rulemaking due to consistency with the 2-year limitation language and readability. Further, the suggested language does not add anything substantive to the regulation.

As explained in the proposed rulemaking, building and construction codes are typically updated every 3 years to 4 years. The Department has received and approved numerous plans that were never completed due to financial and other issues. The Department has also received and approved plans for renovation of an entire building that was never fully completed. Placing a 5-year time limit on the completion of construction, alteration or renovation will prevent a facility from having plans approved but then proceeding to build at a much later date when codes that were applicable at the time of the approval no longer apply. The 5-year time limit also reflects the Department's current practice of contacting facilities after 4 1/2 years to inform them that they have 6 months left to complete approved projects or resubmit plans under current codes.

Subsection (d)

The language that was proposed in subsection (c) is moved to subsection (d), in this final-form rulemaking, but with minor amendments. The words "alterations, renovations or construction" are replaced with the words "construction, alteration or renovation" for consistency in the use of that terminology. The Department also replaces the cross-reference to subsection (b) with a cross-reference to subsection (c) due to the language in subsection (b) being moved to subsection (c). The Department did not receive any comments on this subsection. As explained in the proposed rulemaking, the addition of subsection (d) contemplates circumstances in which a facility may need to request an extension of time for completion of a project, such as an extremely large project involving multiple stories above and below ground.

Subsection (e)

The language that was proposed in subsections (d) and (e) is deleted from this final-form rulemaking. The Department, in this final-form rulemaking, adds language to subsection (e) to require a facility to obtain approval from the Department before using an area of the facility for resident care when that area has not been occupied or used by residents for 1 year or more.

The Department had proposed in subsection (d) to add language stating that any part of a facility that has not been occupied or used for 1 year or more may not be used by the facility for any purpose except as provided for in this section. The Department had proposed in subsection (e) to require a facility to submit architectural plans and blueprints related to occupancy or use if a facility intends to occupy or use a space that has been unoccupied or unused for 1 year or more.

Commentators and IRRC asked what is meant by the terms "any part" and "occupied or used" in proposed subsection (d). Commentators also asked if using a space for storage would constitute "use" and whether subsection (d) would apply to a room that has been left unoccupied for a year. Some commentators expressed concern that the requirement in proposed subsection (e) would be an additional barrier for facilities to overcome to return to full operation and provide access to residents in need of services. Specifically, commentators stated that facilities have already needed to limit admissions and available beds due to staffing issues and there is concern that the cost to update those unoccupied beds to newer requirements will result in the facilities simply delicensing those beds, reducing available capacity. A commentator also suggested that the Department should have the ability to approve a new use in situations where no additional work, or minor work, is needed to utilize the portion of the facility for the desired purpose, without the need for the facility to comply with the requirements of this subsection. IRRC asked the Department to clarify the language of both proposed subsections (d) and (e), and to explain how the final-form regulation is reasonable and feasible, and how it protects the public health, safety and welfare.

After carefully considering the comments from public commentators and IRRC, the Department agrees and deletes the language that was proposed in subsections (d) and (e). The Department, however, adds language in subsection (e), in this final-form rulemaking, to balance resident health and safety by simply requiring a facility to obtain approval from the Department before using an area of the facility for resident care when that area has not been occupied or used by residents for 1 year or more. The intent of final-form subsection (e) is to prevent facilities from allowing portions of the facility to fall into disrepair if they are not used or occupied. As explained in the proposed rulemaking, the Department has encountered situations where facilities want to reopen a portion of the facility that has been closed for years. Building codes and construction codes change over time. Even if the facility intends to use that area for the same purpose, the area may no longer be suitable for that purpose if it has been unoccupied or unused for a year or more, or

even safe for residents as the area may have been allowed to deteriorate. The Department adds the words "for resident care" after the words "area of the facility" and "by residents" after "occupied or used" to clarify what is meant by an "area of the facility" and "occupied or used."

The Department deleted the language in proposed subsection (e) to automatically require architectural plans and blueprints any time a portion of the facility has gone unoccupied or unused for 1 year or more to address commentators' concerns regarding the need to update areas of a facility to comply with newer codes that may not need to be updated. The Department recognizes that there may be situations where an area has not been used or occupied but remains in good condition and safe for occupancy. The Department also notes, as it did at the beginning of this chapter, in response to concerns regarding completion of minor work, that it does not intend for the definition of "construction, alteration or renovation" to encompass work that consists of part-for-part replacement or regular facility maintenance. Requiring a facility to obtain approval from the Department before using an area for resident care that has not been occupied or used by residents for 1 year or more will allow the Department to inspect the area that the facility intends to use for resident care to ensure that it has not fallen into disrepair and still meets the appropriate standards for the health, safety and welfare of residents.

IRRC and commentators raised concerns to proposed subsection (d) as to how facilities would be able to respond rapidly in emergency situations such as the COVID-19 pandemic where it became necessary to isolate people and spread them out to the maximum extent possible. In the event of a broad-based emergency, such as the COVID-19 pandemic, CMS can issue waivers allowing for flexibility with regards to Federal requirements. CMS did so during the COVID-19 pandemic by utilizing 1135 waivers under section 1230b-5 of the Social Security Act (42 U.S.C.A. § 1320b-5). Further, to the extent there is a disaster emergency, under 35 Pa.C.S. § 7301 (relating to general authority of Governor), the Governor may also utilize emergency powers under the Emergency Management Services Code in coping with the disaster emergency, including the suspension of regulations and regulatory statutes, if needed. Additionally, by virtue of the expansion of the incorporation of the Federal requirements in § 201.2 in final-form Rulemaking 1, all facilities, including private-pay facilities, will be required to implement an emergency preparedness program under 42 CFR 483.73 that addresses various emergency scenarios and requires facilities to draft plans, enact policies and provide training to help facilities respond to various potential emergency situations as outlined by risk assessments. (This assumes approval of final-form Rulemaking 1). The Department additionally adds new § 204.20 (relating to airborne infection isolation room) to this final-form rulemaking, described as follows, which will require facilities to provide at least one airborne infection isolation room to isolate residents to prevent the spread of communicable diseases. Finally, in the event of an emergency, a facility may also submit a request for an exception under the existing exceptions process in § 51.33 (relating to requests for exceptions) for the Department's consideration.

Commentators also asked the Department to add language requiring water systems to undergo thorough flushing and disinfecting to prevent residents from being exposed to bacteria that could result in illness or death. Due to the existing Federal requirement, the Department declines to make this amendment. Under 42 CFR 483.80(a)(1) (relating to infection control), a facility must establish an infection prevention and control program that includes "a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases." This would include the prevention of waterborne illnesses, such as Legionnaires' disease. Facilities that participate in Medicare or Medical Assistance (MA) are currently required to comply with 42 CFR 483.80(a)(1). Although private-pay facilities are currently required to have an infection prevention and control program, the additional requirements may be a new requirement for the three private-pay facilities under the expanded adoption of the Federal requirements in § 201.2, in final-form Rulemaking 1. This assumes approval of final-form Rulemaking 1.

For proposed subsection (e), some commentators expressed concern that facilities might move residents around to avoid having a space go unoccupied or unused for a year. These commentators also asked that the Department add language requiring a facility to provide notice before moving a resident. After careful consideration, the Department declines to add this provision because a resident has the right to receive written notice, including the reason for the change, before the resident's room in the facility is changed under 42 CFR 483.10(e)(6) (relating to resident rights). Facilities, including the three private-pay facilities, are currently required to comply with this notice requirement under existing § 201.2, which adopts the Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long term care facilities), in part.

The Department also declines to add language requiring that notice be provided to a resident before moving the resident to another room due to existing Federal requirements. Under 42 CFR 483.10(e)(6), a facility is required to notify a resident in writing if the facility intends to change a resident's room and provide a reason for the move. The resident has the right to refuse the move to another room in the facility if the purpose of the move is solely for the convenience of staff under 42 CFR 483.10(e)(7). Facilities, including the three private-pay facilities are required currently to comply with these requirements, under existing § 201.2, which adopts the Federal requirements at 42 CFR Part 483, Subpart B, in part.

Other comments

One commentator requested that the Department add a new subsection to § 204.2 to allow a facility to request an exception to proposed subsections (d) and (e) for an area that has been unused or unoccupied for 1 year or more in the event of disease outbreak. The proposed exception request would be effective for no more than 30 days to allow the facility time to submit architectural plans and blueprints related to its occupancy or use to the Department as required under § 51.3(d) and receive approval from the Department to continue to operate. This amendment is unnecessary due to the Department's amendment to subsection (e), described previously, to eliminate the requirement for submission of additional plans and blueprints for unoccupied space.

§ 204.3. Buildings and grounds; general

The title of this section is amended from the proposed rulemaking to this final-form rulemaking to add "and grounds" after the word "buildings" at the request of a commentator. This amendment more accurately reflects the contents of this section. Several provisions of Chapter 205 are carried over into this section, as described more fully as follows.

Subsection (a)

Subsection (a) is amended from the proposed rulemaking to this final-form rulemaking. The Department had proposed to copy § 205.1 (relating to location or site) into subsection (a) without amendment because this requirement goes above and beyond the requirements in the 2018 FGI *Guidelines*. Commentators, however, expressed confusion over the use of the word "area" in this subsection, asking that the Department clarify whether this is a reference to the safety of the geographical area where the facility is located. A commentator also expressed confusion over the use of the words "conducive to health and safety." In response to these comments, the Department adds the qualifiers "that is geographically and environmentally" before the word "conducive" to clarify that a facility shall be located in an area that is both geographically and environmentally conducive to the health and safety of residents. The Department would not, for example, want a facility to be built on top of a subway station, or in an area where residents might be exposed to environmental hazards. The Department notes, as well, that facilities must adhere to the *Life Safety Code*, which is incorporated by reference in 42 CFR 483.73(g)(1), and other applicable construction and zoning ordinances for construction, alteration and renovation projects, which also ensures compliance with subsection (a).

Subsection (b)

Subsection (b) is amended from the proposed rulemaking to this final-form rulemaking at the request of IRRC to replace the word "before" with the word "if." The Department agrees and has added this language. As explained in the proposed rulemaking, the requirement in § 205.6(a) (relating to function of building) is copied into subsection (b), with one minor grammatical amendment, because this requirement goes above and beyond the requirements in the 2018 FGI *Guidelines*.

A commentator expressed similar concerns with this subsection as with subsection (a). Under subsection (b), no part of a building may be used for a purpose that interferes with or jeopardizes the health and safety of residents. The commentator indicated that it was not clear what purposes would be covered by this provision and expressed concern that this language could be interpreted to mean that no part of the building could be used for cooking as there are residents that could be harmed by knives or fire involved in cooking. The Department's number one priority is the health, safety and welfare of residents. The Department applies a common-sense interpretation and ordinary dictionary definition to the words "interferes with or jeopardizes" in the context of a resident's health and safety and would not cite a facility for having an area dedicated for cooking if that area meets the requirements of the act and this subpart. The Department notes that subsection (b) also requires special authorization if part of the building is to be used for a purpose other than health care. This language mirrors the language in existing § 205.6(a). Facilities have requested exceptions under that subsection, which have been granted by the Department. The Department would anticipate continuing to receive similar exception requests under this subsection.

Subsection (c)

Subsection (c) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the requirement in § 205.6(b) is copied into subsection (c) because this requirement goes above and beyond the requirements in the 2018 FGI *Guidelines*.

Commentators questioned whether the allowance in this subsection for administrators' family members to reside in a newly constructed facility remains appropriate. These commentators indicate that although this was the practice in the past, it appears to now be outdated. Although the Department is unaware of this provision being currently utilized, the Department is concerned that the removal of the ability of the administrator's family members to reside at the facility may make it difficult to obtain and retain administrators. Additionally, it may be important to allow administrators' family members to reside in a care-focused portion of a facility, and removal of this language might prevent family members needing that care from residing in the facility. The Department, therefore, declines to remove this language from the regulation.

Subsection (d)

Subsection (d) is amended from the proposed rulemaking to this final-form rulemaking. The Department had proposed to copy § 205.2(a) into this subsection without amendment because this requirement goes above and beyond the requirements in the 2018 FGI *Guidelines*.

A commentator asked what is meant by the term "service areas" in the first sentence of this subsection. The term "service areas" could include, for example, a loading dock, dumpster or other outdoor maintenance area that is separate from outdoor areas that would be used by residents. A commentator also asked, with respect to the second sentence in this subsection, why only a facility with site limitations can provide balcony areas. Upon further consideration, the Department agrees and does not intend for this sentence to be limiting. Therefore, the Department has removed "with site limitations" from the second sentence to make it clear that any facility may provide rooftop or balcony areas so long as adequate protective enclosures are provided.

Commentators also requested that the term "adequate protective enclosures" in the second sentence be defined or more fully described. Facilities are generally responsible for providing a safe environment for residents and are further responsible for assessing what is necessary to create a safe environment. Adequate protective enclosures could vary based on the acuity of the residents in the facility and could include, for example, railings or plexiglass or cinderblock walls. It is also not common in the Department's experience for facilities to have rooftop or balcony areas for residents. It is much more common for outdoor areas to be on the ground level, due to safety concerns. The Department, therefore, declines to add a definition for this term.

Subsection (e)

Subsection (e) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies § 205.2(b) into this subsection because this requirement goes above and beyond the requirements in the 2018 FGI *Guidelines*.

§ 204.4. Basement

Section 204.4 is amended from the proposed rulemaking to this final-form rulemaking. The Department had proposed to copy language from § 205.7 (relating to basement or cellar) with minor amendments, because that requirement goes above and beyond the requirements in the 2018 FGI *Guidelines*. In this final-form rulemaking,

the Department moves this language into subsection (a) and creates subsection (b). In subsection (b), the Department copies language from § 205.10(e) (relating to doors), which prohibits a door to a basement from being in a resident's room but removes the outdated term "cellar." When comparing the provisions of Chapter 205 to the FGI *Guidelines*, the Department discovered that this requirement is not covered by the 2018 FGI *Guidelines*. The Department does not believe that there would ever be a reason for a basement door to be in a resident's room, but is adding it in this final-form rulemaking, out of an abundance of caution, to ensure the health and safety of residents.

The remaining provisions of § 205.10 were not carried over to Chapter 204 and continue to not be carried over in this final-form rulemaking. In response to commentators and IRRC, the Department provides the following explanation for why the remaining provisions of § 205.10 were not carried over into the new requirements in Chapter 204. Section 205.10(a)—(d) are not carried over to Chapter 204 because requirements for door openings can be found in section 2.4-2.2.4.2 of the 2018 FGI *Guidelines*. Additional requirements for doors are in the *Life Safety Code* at sections 7.2.1—7.2.1.4.5.2, 18.2.2.2—18.2.2.2.10.2 and 19.2.2.2—19.2.2.2.10.2. Section 205.10(f) is not carried over because the requirement for screens is covered by section 2.4-2.2.4.3 of the 2018 FGI *Guidelines*.

One commentator expressed concern that under the regulations, residents might be moved into basements under certain situations. The commentator stated that under no circumstances is it acceptable to utilize a space below grade as a bedroom. The Department agrees and points this commentator to § 204.5(b) (relating to resident rooms), which states that the basement of a facility may not be used for resident rooms.

§ 204.5. Resident rooms

Subsection (a)

Subsection (a) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies § 205.20(a) (relating to resident bedrooms) into subsection (a) to align with terminology used by CMS. This requirement is necessary in Chapter 204 because it goes above and beyond the requirements in the 2018 FGI *Guidelines*.

Subsection (b)

Subsection (b) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, this new provision is added at the request of the LTC Work Group to prohibit a facility from using a basement for resident rooms.

Subsection (c)

Subsection (c) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies § 205.20(b) and (c) into subsection (c) with no substantive amendments, because these requirements go above and beyond the 2018 FGI *Guidelines*.

Subsection (d)

Subsection (d) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department adds subsection (d), at the request of the LTC Work Group, to clarify that a resident shall have a choice in the placement of the resident's bed in the room. The Department added "unless the placement presents a safety hazard" to the LTC Work Group's recommended language.

Commentators asked the Department to revise this subsection to be more specific as to what constitutes a safety hazard. These commentators were concerned that without a definition, facilities will have too much leeway to deny residents' choices and preferences. Commentators also asked that the Department add language to allow a resident, who has the capacity, a certain level of risk or informed decision making, as well as language that would prevent a facility from using arbitrary or ambiguous reasons as a basis for denying the resident's wishes. IRRC asked the Department to clarify this provision or explain the reasonableness of retaining this language in this final-form rulemaking. IRRC noted that this comment also applies to § 205.22 (relating to placement of beds).

In balancing the competing interests for resident autonomy and choice with also the need for health and safety requirements, the Department declines to amend this subsection. The addition of "unless the placement presents a safety hazard" is not only reasonable, but critical to ensure the safety of residents. As explained in the proposed rulemaking, the Department supports a resident's ability to choose where a bed is placed in the room but can envision circumstances where a resident's choice of bed placement could pose a health or safety hazard, such as placement near a radiator, heat source or blocking a doorway. In those circumstances, the health and safety of the resident needs to come first. Safety hazards must be determined through an evaluation of the resident's needs and an assessment of the physical environment. A safety hazard for one resident may not necessarily be a safety hazard for another resident, based on the resident's acuity, and a facility will need to determine this on a case-by-case basis. Additionally, if the Department receives a complaint regarding this subsection, the Department will ask the facility why the resident's preference was not considered and will attempt to resolve the complaint in a manner that addresses the resident's concerns and preferences while also ensuring safe placement of the bed.

Subsection (e)

Subsection (e) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies § 205.22 into subsection (e) with amendment. Specifically, the Department added on proposed, "unless the resident chooses to do so and the placement does not pose a safety hazard" to align with the language in subsection (d). The Department did not receive any comments specifically on this subsection but did receive comments regarding the addition of this language in subsection (d), addressed previously.

Subsection (f)

Subsection (f) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies § 205.72 (relating to furniture) into this subsection, without amendment. Commentators requested that the Department require education to residents about the right to have a locked drawer or cabinet. Commentators request that this occur during the resident's first care plan meeting, and that the resident be specifically informed of the right to have a locked drawer or cabinet, and the need to inform staff when the key is lost, the drawer is broken or when something is stolen. The Department, in proposed Rule-

making 4, proposed to add requirements for admission policies and procedures in § 201.24(e)(5) (relating to admission policy), which would include assisting the resident, if needed, in creating a homelike environment and settling personal possessions in the room to which the resident has been assigned. In response to commentators' concerns, on this final-form rulemaking, the Department amends § 201.24(e)(5), by removing the words "if needed" and adding the words "and securing" after the word "settling" to ensure that facilities have policies and procedures in place to assist residents in securing their personal possessions.

In response to commentators and IRRC, who asked the Department to clarify why certain provisions of Chapter 205 were not carried over to Chapter 204, § 205.20(d) and (f) are not carried over because 42 CFR 483.90(e)(1)(ii) (relating to physical environment) provides minimum square footage requirements for resident rooms and requires that rooms "measure at least 80 square feet per resident in multiple resident bedrooms, and at least 100 square feet in single resident rooms." Facilities, including the three private-pay facilities, are currently required to comply with this provision under existing § 201.2.

Additionally, § 205.20(e) and (g) are not carried over to Chapter 204 because these requirements apply to facilities that were licensed before 1975. Facilities that perform new construction, alteration or renovation will be required to comply with newer requirements set forth in Chapter 204.

Commentators requested that the Department add an additional subsection to § 204.5 to prohibit facilities from housing more than two residents in a room, although they feel strongly that all rooms should be single occupancy. The Department declines to add this requirement to regulation due to existing Federal requirements. Under 42 CFR 483.90(e)(1)(i), bedrooms must accommodate no more than two residents for facilities that receive approval of construction after November 28, 2016. Facilities that participate in Medicare or MA are already required to comply with this requirement. With the expansion of the incorporation of the Federal requirements in final-form Rulemaking 1, the requirement in 42 CFR 483.90(e)(1)(i) could potentially impact the three private-pay facilities, if they perform new construction, alteration or renovation under this Chapter. This assumes approval of final-form Rulemaking 1, which expands the adoption of the Federal requirements in § 201.2.

§ 204.6. Locks

Section 204.6 (relating to locks) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies language from existing § 205.14 (relating to locks) into this section, without amendment, because this requirement goes above and beyond the requirements in the 2018 FGI *Guidelines*. Commentators requested that the Department add a requirement that staff must knock prior to entering a resident's room and a requirement for a doorbell outside of each resident's room. These commentators noted that there is little dignity, respect or privacy in staff just walking into resident rooms unannounced. The Department declines to make this amendment. The Department considers knocking and requesting permission to enter to fall within a resident's preferences, subject to an emergency, which is covered by 42 CFR 483.10(e)(3), which provides that a resident has the right to reside and receive services in the facility with reasonable accommodation of resident needs and preferences except when to do so would endanger the health or safety of the resident or other residents. Facilities that participate in Medicare or MA are currently required to comply with 42 CFR 483.10(e)(3). This will be a new requirement for the three private-pay facilities under the expanded adoption of the Federal requirements in § 201.2, in final-form Rulemaking 1. This assumes approval of final-form Rulemaking 1. There is no fiscal impact associated with this provision.

§ 204.7. Laundry

Section 204.7 (relating to laundry) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies language from existing § 205.26(e) (relating to laundry) into this section, with no amendment because this provision goes above and beyond what is required in the 2018 FGI *Guidelines*.

In response to commentators and IRRC, who requested that the Department clarify which provisions of Chapter 205 are not being carried over into Chapter 204, the Department is not carrying over § 205.26(a)—(d) because these requirements are covered by the 2018 FGI *Guidelines* at sections 3.1-4.6, 3.1-4.2.7, and 2.3-4.2.7, as adopted by the Department in § 204.1(a). Additionally, under 42 CFR 483.10(i)(3), a resident has a right to a safe, clean, comfortable and homelike environment, which includes the provision of clean bed and bath linens. Facilities, including the three private-pay facilities are currently required to comply with 42 CFR 483.10(i)(3) under existing § 201.2.

§ 204.8. Utility room

Section 204.8 (relating to utility room) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies language from § 205.33(a) (relating to utility room) into this section, with two amendments. In the proposed rulemaking, the Department deleted the phrase "near the nurses' station" in the first sentence and deletes the last sentence regarding nursing stations in its entirety. The Department eliminates the requirement that utility rooms be located near nursing stations for two reasons: (1) the long-term care nursing industry has begun to shift away from the use of the term "nurses' station" in favor of terms such as "workstations" that focus more on person centered care; and (2) it is more appropriate to have utility rooms located near resident rooms or other locations where they are needed for easier access. The remaining language in § 205.33(a) is being copied into this section because it goes above and beyond what is required in the 2018 FGI *Guidelines*.

In response to commentators and IRRC, who requested the Department to clarify which provisions of Chapter 205 are not being carried over into Chapter 204, the Department is not carrying over § 205.33(b) and (c) because these requirements are covered by the 2018 FGI *Guidelines* at sections 2.3-4.2.5 and 2.3-4.2.6, as adopted by the Department in § 204.1.

§ 204.9. Bathing facilities

Subsection (a)

Subsection (a) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copied § 205.36(a) (relating to bathing facilities) into this subsection, with amendment. In the proposed rulemaking, the Department replaced the word "bedrooms" with the word "rooms" to align with terminology used by CMS. The Department

copied this requirement into this section because it goes above and beyond what is required in the 2018 FGI *Guidelines*.

Subsection (b)

Subsection (b) is unchanged from the proposed rulemaking to this final-form rulemaking. The requirement in § 205.36(c) is copied into this subsection, without amendment. The Department copied this requirement into this section because it goes above and beyond what is required in the 2018 FGI *Guidelines*.

Subsection (c)

Subsection (c) is unchanged from the proposed rulemaking to this final-form rulemaking. The requirement in § 205.36(e) is copied into this subsection, without amendment. The Department copied this requirement into this section because it goes above and beyond what is required in the 2018 FGI *Guidelines*.

Subsection (d)

Subsection (d) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copied the requirement in § 205.36(h) into this subsection but removed outdated language regarding accessibility and measurements required for the bath area. The Department copied this requirement into this section because it goes above and beyond what is required in the 2018 FGI *Guidelines*.

In response to commentators and IRRC, who requested the Department to clarify which provisions of Chapter 205 are not being carried over to Chapter 204, the Department is not carrying over § 205.36(b), (d), (f) and (g) because these requirements are covered by the 2018 FGI *Guidelines* at sections 3.1-4.2.3, 3.1-4.2.3.1, 2.5-2.3.3.2 and 3.1-4.2.3.2, as adopted by the Department in section 204.1. Additionally, the Department does not include subsection (b) from § 205.36 because although it is not difficult for a facility to provide 1 bathing fixture per 15 beds, in reality, multiple bathing fixtures are not utilized simultaneously, and the space designated as bathing fixtures could be better utilized by the facility. Additionally, for subsection (d), facilities typically performing new construction, alteration or renovation will include provisions for bathing in a bathroom attached to the resident's room. Where not provided or possible for certain renovation projects, the FGI *Guidelines* require a ratio of 1 bathing fixture per 20 residents. Subsection (f) is not carried forward to Chapter 204 because it conflicts with section 608.2 of the 2010 Americans with Disabilities Act Standards Standards for Accessible Design (ADA Standards), which requires transfer type shower compartments to be at least 36″ by 36″, standard roll-in type shower compartments to be at least 30″ by 60″ in size, and alternate roll-in type shower compartments to be 36″ by 60″. ADA.gov. 2010 ADA Standards for Accessible Design. Retrieved from https://www.ada.gov/regs2010/2010ADAStandards/2010ADAstandards.htm. Facilities, including the three private-pay facilities, are required to comply with ADA Standards. Subsection (g) is not carried forward because shower controls are covered under section 608.5 of the ADA Standards and section 2.5-2.3.3.2 of the FGI *Guidelines*.

§ 204.10. Toilet facilities

The Department adds this section in this final-form rulemaking. As noted previously, commentators and IRRC requested that the Department clarify which provisions of Chapter 205 are not being carried over to Chapter 204. While reviewing Chapter 204 and the FGI *Guidelines*, the Department determined that there was no provision for toilet facilities for visitors of long-term care nursing facilities as set forth in existing § 205.38(f) (relating to toilet facilities). On this final-form rulemaking the Department corrects this oversight by copying the requirement from § 205.38(f) into this section, to require facilities to provide toilets and lavatories for visitors that are independent of the toilet facilities utilized by residents, with one amendment. The Department removes the words "male and female" because the prevailing general trend is that public restroom facilities do not need to be gender-specific. Due to this amendment, §§ 204.10—204.18 are renumbered, as explained as follows.

In response to commentators and IRRC, who requested that Department clarify which provisions of Chapter 205 are not being carried over to Chapter 204, the Department is not carrying over § 205.38(a) and (e) because these requirements have been replaced by more up-to-date requirements at 42 CFR 483.90(f). With the expansion of the incorporation of the Federal requirements in final-form Rulemaking 1, this requirement could potentially impact the three private-pay facilities, if they perform new construction, alteration or renovation under this chapter. This assumes approval of final-form Rulemaking 1, which expands the adoption of the Federal requirements in § 201.2. The Department does not carry § 205.38(b) and (c) forward to Chapter 204 because these requirements are covered by the 2018 FGI *Guidelines* at section 3.1-2.2.2.6, as adopted by the Department in § 204.1. Section 205.38(d) is not carried forward to Chapter 204 because toilet training is part of a facility's rehab program in accordance with the 2018 FGI *Guidelines* at section 3.1-3.3.7.

§ 204.11. Equipment for bathrooms

This section is renumbered to § 204.11 (relating to equipment for bathrooms), in this final-form rulemaking, but otherwise, is not amended from the proposed rulemaking to this final-form rulemaking.

Subsection (a)

Subsection (a) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies § 205.37(a) (relating to equipment for bathrooms) into this subsection, but replaces the language referring to a specific weight limit for grab bars in tubs and showers with the phrase "to accommodate the residents' needs." The Department recognizes that there are a wide variety of reasons that a resident may be at risk for falling and has made this change in language to require long-term care nursing facilities to provide grab bars that will accommodate residents of any size and physical or mental condition. As noted, in the proposed rulemaking, the Department is retaining this requirement in Chapter 204 because it goes above and beyond what is required in the 2018 FGI *Guidelines*.

Subsection (b)

Subsection (b) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies § 205.37(b) into this subsection, but replaces the term "nursing station" with "workstation" because the long-term care nursing industry has begun to shift away from the use of the term "nurses' station" in favor of terms such as "workstations" that focus more on person-centered care. As noted in the proposed rulemaking, the Department is retaining this requirement in Chapter 204 because it goes above and beyond what is required in the 2018 FGI *Guidelines*.

Subsection (c)

Subsection (c) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies § 205.37(c) into this subsection, with only grammatical amendments because it goes above and beyond what is required in the 2018 FGI *Guidelines*.

Subsection (d)

Subsection (d) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies § 205.37(d) into this subsection, without amendment because it goes above and beyond what is required in the 2018 FGI *Guidelines*.

Subsection (e)

Subsection (e) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copies § 205.37(e) into this subsection, without amendment because it goes above and beyond what is required in the 2018 FGI *Guidelines*.

§ 204.12. Toilet room equipment

This section is renumbered to § 204.12 (relating to toilet room equipment), in this final-form rulemaking, but otherwise, is not amended from the proposed rulemaking to this final-form rulemaking. As noted in the proposed rulemaking, the Department copied language from § 205.39(b) (relating to toilet room equipment) into this section, with two amendments. First, the Department removed the phrase "and an emergency call bell within reaching distance." Under the 2018 FGI *Guidelines*, at section 3.1-6.5.2, an emergency call device shall be accessible from each toilet, bathtub and shower used by residents. Second, the Department replaced the language referring to a specific weight limit for handrails or assist bars with the phrase "of accommodating the residents' needs." The Department recognizes that there are a wide variety of reasons that a resident may be at risk for falling and has made this change in language to require long-term care nursing facilities to provide handrails or assist bars that will accommodate residents of any size and physical or mental condition. This provision goes above and beyond what is required in the 2018 FGI *Guidelines*.

Commentators expressed concern that the Department did not carry the requirement from § 205.23 (relating to location of bedrooms) into this section. Section 205.23 requires a resident bedroom to have adjoining toilet facilities and to be conveniently located near bathing facilities. Commentators were also concerned that the Department failed to include a ratio for number of toilets to residents. The Department declines to amend this section due to existing Federal requirements. Under 42 CFR 483.90(f), resident rooms are required to be equipped with or located near toilet and bathing facilities, and for facilities that receive approval of construction after November 28, 2016, each resident room must have its own bathroom equipped with at least a commode and sink. Facilities that participate in Medicare or MA are already required to comply with this requirement. With the expansion of the incorporation of the Federal requirements in final-form Rulemaking 1, this requirement could potentially impact the three private-pay facilities, if they perform new construction, alteration or renovation under this chapter. This assumes approval of final-form Rulemaking 1, which expands the adoption of the Federal requirements in § 201.2.

In response to commentators and IRRC, who requested the Department to clarify which provisions of Chapter 205 are not being carried over to Chapter 204, the Department is not carrying over § 205.39(a) because section 3.1-2.2.2.6 of the 2018 FGI *Guidelines* cover the requirements in § 205.39(a). Specifically, the 2018 FGI *Guidelines* provide that each resident shall have access to a toilet room without entering a general corridor. Additionally, toilet rooms must contain a toilet, a handwashing station, a mirror and individual storage for each resident.

§ 204.13. Linen

This section is renumbered to § 204.13 (relating to linen), in this final-form rulemaking, but otherwise, is not amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copied language from § 205.74 (relating to linen) into this section without amendment, because this requirement goes above and beyond what is required in the 2018 FGI *Guidelines*.

§ 204.14. Supplies

This section is renumbered to § 204.14 (relating to supplies), in this final-form rulemaking, but otherwise, is not amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department copied language from § 205.75 (relating to supplies) into this section without amendment because this requirement goes above and beyond what is required in the 2018 FGI *Guidelines*.

§ 204.15. Windows

This section is renumbered to § 204.15 (relating to windows), in this final-form rulemaking, but otherwise, is not amended from the proposed rulemaking to this final-form rulemaking. As noted, in the proposed rulemaking, the Department copies existing language from § 205.19 (relating to windows and windowsills) into this section, with minor amendment. In addition to minor grammatical amendments, the Department replaced the word "bedrooms" with "rooms" in this section to align with terminology used by CMS. The Department copies this provision into this section because it goes above and beyond what is required in the 2018 FGI *Guidelines*.

§ 204.16. Dining

This section is renumbered to § 204.16 (relating to dining), in this final-form rulemaking, but otherwise, is not amended from the proposed rulemaking to this final-form rulemaking. As noted, in the proposed rulemaking, the Department copied language from § 205.24(a) (relating to dining room) into this section, with one amendment. The Department deleted the last sentence indicating, "these areas shall be well lighted and well ventilated." This language is not necessary because lighting requirements are covered within the FGI *Guidelines* at section 2.5-7. The remaining language in this provision, regarding space for dining areas, is copied into this section because it goes above and beyond what is required in the 2018 FGI *Guidelines*.

In response to commentators and IRRC, who requested that the Department clarify which provisions of Chapter 205 are not being carried over to Chapter 204, the Department is not carrying over § 205.24(b) because these requirements are covered by the 2018 FGI *Guidelines* at section 2.3-2.3.3.2, as adopted by the Department in § 204.1 of this final-form rulemaking.

§ 204.17. Lounge and recreation

This section is renumbered to § 204.17 (relating to lounge and recreation), in this final-form rulemaking, but otherwise, is not amended from the proposed rulemaking to this final-form rulemaking. As noted, in the proposed rulemaking, the Department copies language from § 205.27 (relating to lounge and recreation rooms) into this section, without amendment because this provision goes above and beyond what is required in the 2018 FGI *Guidelines*.

§ 204.18. Storage

This section is renumbered to § 204.18 (relating to storage), in this final-form rulemaking, but otherwise, is not amended from the proposed rulemaking to this final-form rulemaking. As explained, in the proposed rulemaking, the Department copied language from § 205.31 (relating to storage) into this section, without amendment because this provision goes above and beyond what is required in the 2018 FGI *Guidelines*.

§ 204.19. Plumbing, heating ventilation and air conditioning (HVAC) and electrical

This section is renumbered to § 204.19 (relating to plumbing, heating, ventilation and air conditioning (HVAC) and electrical, in this final-form rulemaking, but otherwise, is not amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, this catch-all section is new and replaces the requirements for new construction in §§ 205.61—205.68 (relating to mechanical and electrical requirements). Under this section, all building systems, such as plumbing, HVAC and electrical systems, must comply with all State and local codes. This language is similar to existing language in § 205.61(a) (relating to heating requirements for existing and new construction), but expanded to include all building systems, such as plumbing, HVAC and electrical systems.

While this catch-all section is intended to replace the requirements for new construction in §§ 205.61—205.68, the Department is also not carrying forward these requirements because they are already covered by the Federal requirements, the *Life Safety Code* or the 2018 FGI *Guidelines*. Section 205.61(b) is not carried over to Chapter 204 because it is encompassed by the Federal requirements at 42 CFR 483.25(d) (relating to quality of care) which require a facility to ensure that residents are free from accident hazards and subject to adequate supervision to prevent accidents. Facilities, including the three private-pay facilities, are required to comply with 42 CFR 483.25(d) under existing § 201.2. The *Life Safety Code* contains additional provisions for HVAC in sections 9.2.1, 9.2.2, and Chapter 43. Section 205.62 (relating to special heating requirements for new construction) is not carried over to Chapter 204 because the requirements in that section are covered in the *Life Safety Code* in Chapter 43. Section 205.63 (relating to plumbing and piping systems required for existing and new construction) is not carried over to Chapter 204 because these requirements are covered by the 2018 FGI *Guidelines* at sections 2.5-2.2.3 and 2.5-1, as adopted by the Department in § 204.1.

Section 205.64 (relating to special plumbing and piping systems requirements for new construction) is not carried over to Chapter 204 because the requirements are covered by the 2018 FGI *Guidelines* at section 2.5-2, as adopted by the Department in § 204.1. These requirements are also covered by the Federal requirements at 42 CFR 483.90(b). Facilities that participate in Medicare or MA are currently required to comply with 42 CFR 483.90(b). The expansion of the adoption of the Federal requirements in § 201.2 in final-form Rulemaking 1 will make this a new requirement for the three private-pay facilities. This assumes approval of final-form Rulemaking 1. As with other building system requirements, the FGI *Guidelines* defers to local and State codes first but provides additional specific plumbing requirements for facilities. Section 205.66 (relating to special ventilation requirements for new construction) is not carried over to Chapter 204 because these requirements are covered by the 2018 FGI *Guidelines* at sections 2.5-3, 3.1-6.3 and 3.1-1, as adopted by the Department in § 204.1. These requirements are also covered by the Federal requirements at 42 CFR 483.90(i). Facilities, including the three private-pay facilities, are required to comply with 42 CFR 483.90(i) under existing § 201.2. The *Life Safety Code* contains additional requirements at sections 9.2.1 and 9.2.2.

Section 205.67 (relating to electric requirements for existing and new construction) is not carried over to Chapter 204 because these requirements are covered by the 2018 FGI *Guidelines* at sections 3.1-6.7 and 3.1-6.5-2, as adopted by the Department in § 204.1. The *Life Safety Code* contains additional requirements at sections 18 and 19.2.9. NFPA 99, *Standards for Health Care Facilities Code*, incorporated by reference in 42 CFR 483.90(j)(1)(i), contains additional requirements at section 6.3.2.2.6.2. Facilities that participate in Medicare or MA are currently required to comply with 42 CFR 483.90(j)(1)(i). The expansion of the adoption of the Federal requirements in § 201.2 in final-form Rulemaking 1 will make this a new requirement for the three private-pay facilities. This assumes approval of final-form Rulemaking 1. Finally, § 205.68 (relating to special electrical requirements for new construction) is not carried over to Chapter 204 because these requirements are covered by the 2018 FGI *Guidelines* at section 3.1-6.7, as adopted by the Department in § 204.1 of this rulemaking. Additionally, the requirements in § 205.68 are covered by the Federal requirements at 42 CFR 483.90(d). Facilities that participate in Medicare or MA are currently required to comply with 42 CFR 483.90(d). The expansion of the adoption of the Federal requirements in § 201.2 in final-form Rulemaking 1 will make this a new requirement for the three private-pay facilities. This assumes approval of final-form Rulemaking 1.

Commentators requested that the Department amend this section to require facilities to ensure safe ventilation practices and to regularly evaluate these practices. One commentator requested that the Department add COVID-19 ventilation requirements to this section. Other commentators requested that the Department add requirements in this section and in § 205.66(i) to require HEPA filtration systems be installed in facilities. The Department declines to amend this section to incorporate any specific ventilation requirements. HEPA filtration systems may not necessarily be appropriate in all settings. For example, a wall unit that pulls in air from the outside would not be HEPA-compliant. If a facility wants to provide fresh airflow to a room, installing an appropriate unit may also be at odds with HEPA air filtration requirements. The 2018 FGI *Guidelines* provide HVAC requirements at section 2.5-3, and State and local codes may provide additional requirements for facilities. The Department also does not believe it is prudent to require a specific type of air-filtration system to be installed in facilities when there is alternative technology that may be better suited for individual facilities.

§ 204.20. Airborne infection isolation room

This section is added in this final-form rulemaking. This section is based on the infection control provisions in § 205.21 (relating to special care room) but is updated to align with the Department's adoption of the 2018 FGI *Guidelines*. Under this section, a facility will be required to have at least one airborne infection isolation room for isolating residents as necessary to prevent the spread of infections in accordance with the 2018 edition of the FGI *Guidelines*. Based on a facility's assessment, a facility may have more than one airborne infection isolation room in accordance with the 2018 FGI *Guidelines*. The requirements for an airborne infection isolation room are at section 3.1-2.2.4.1 of the 2018 FGI *Guidelines*. The Department realized, while performing its crosswalk of Chapter 205 to the 2018 FGI *Guidelines*, that although the 2018 FGI *Guidelines* state what is required for an airborne isolation room, it does not actually require a facility to have one. Rather than copy that requirement from § 205.21 into this section, the Department adds the specific requirement to have at least one airborne infection isolation room to align with more current standards found in the 2018 FGI *Guidelines*.

Other comments

Commentators recommended that the Department add an additional section to permit a facility to repurpose rooms, permit cohorting or move residents as necessary to implement infection controls during an outbreak of infection. The Department declines to add this section. Facilities, including the three private-pay facilities, will be required to establish and maintain infection prevention and control programs under 42 CFR 483.80 and those programs should consider the best methods to minimize the spread of communicable disease. Facilities that participate in Medicare or MA are already required to comply with 42 CFR 483.80. The requirements under 42 CFR 483.80 will be new for the three private-pay facilities, if final-form Rulemaking 1 is approved. Additionally, all facilities, including the three private-pay facilities, will be required, based on the expansion of the incorporation of the Federal requirements in final-form Rulemaking 1 at § 201.2, to have disaster and emergency preparedness plans under 42 CFR 483.73, which address an all-hazards approach and encompass scenarios such as a pandemic or outbreak of communicable disease. This also assumes approval of final-form Rulemaking 1. The Department further notes that not all diseases are the same. Therefore, cohorting may not be a necessary part of an infection response in all cases. During the COVID-19 pandemic, the Department addressed the movement and cohorting of residents through its Pennsylvania Health Alert Network communications and expects to utilize this health alert, advisor and update tool in the future as well.

Commentators also requested that the Department add a section requiring that stations for hand cleaning and sanitizing be installed outside every resident room and at least every 20 feet in hallways and common areas. The Department declines to add this section. The Department chooses to promote hand hygiene generally and not only as a means of infection control and prevention. Additionally, the *Life Safety Code* addresses the installation and location of hand sanitizer stations at sections 18.3.2.6 and 19.3.2.6. The *Life Safety Code* provides spacing specifications in terms of where hand sanitizer stations may be installed and other considerations for resident safety to ensure residents have safe access and to prevent accidental consumption or other accidents. There are also requirements related to the amount of hand sanitizer that can be stored in one place and how it must be stored, as hand sanitizer is flammable. Additionally, the *Life Safety Code* contains comprehensive fire safety requirements related to hand sanitizer dispensers. Finally, there are infection prevention and control standards related to hand hygiene for staff in the Federal requirements, and this should be covered in the facilities' infection prevention and control program under 42 CFR 483.80(a)(2)(vi). Facilities that participate in Medicare or MA are currently required to comply with 42 CFR 483.80(a)(2)(vi). This requirement will extend to the three private-pay facilities by virtue of the expansion of the adoption of the Federal requirements in § 201.2 in final-form Rulemaking 1. This assumes approval of final-form Rulemaking 1.

Finally, the Department provides the following list, in response to commentators and IRRC, who requested the Department to clarify which provisions of Chapter 205 are not being carried over to Chapter 204. This list is in addition to the sections and subsections that were previously identified throughout the preamble for Chapter 204. The Department does not carry over § 205.8 (relating to ceiling heights) because these requirements are covered by the 2018 FGI *Guidelines* at section 2.4-2.2.3, as adopted by the Department in § 204.1 in this final-form rulemaking. The *Life Safety Code* also contains requirements at section 7.1.5. The Department does not carry § 205.9(a) (relating to corridors) because this subsection is covered by the Federal requirements at 42 CFR 483.90(i)(3). The Department also does not carry over § 205.9(b) because this requirement is covered by the *Life Safety Code*. Further, the Department does not carry over § 205.9(c) because this requirement is covered by the *Life Safety Code* at section 7.1.10. The Department does not carry over § 205.12 (relating to elevators) because this requirement is covered by the 2018 FGI *Guidelines* at section 3.1-6.9, as adopted by the Department in § 204.1 of this final-form rulemaking. The Department also does not carry over § 205.13 (relating to floors) because these requirements are covered by the 2018 FGI *Guidelines* at sections 2.4-2.3.2, 2.4-2.3.2.1, 2.4-2.3.2.5, 2.4-2.3.2.6, and 2.4-2.3.2.7, as adopted by the Department in § 204.1 of this final-form rulemaking.

The Department does not carry over § 205.16 (relating to stairs) because these requirements are covered by the 2018 FGI *Guidelines* at section 7.1.10, as adopted by the Department in § 204.1. The Department does not carry over § 205.17 (relating to stairways) because these requirements are outdated and inapplicable to the functioning of a facility. The Department does not carry over § 205.23 (relating to location of bedrooms) because these requirements are covered by the Federal requirements at 42 CFR 483.90(f). Under 42 CFR 483.90(f), each resident room must be equipped with or located near toilet and bathing facilities. For facilities that receive approval of construction after November 28, 2016, each resident room must have its own bathroom equipped with at least a commode and a sink. This will be a new requirement for the three private-pay facilities based on the expansion of the adoption of the Federal requirements in § 201.2 in final-form Rulemaking 1. This assumes approval of final-form Rulemaking 1. The Department does not carry over § 205.25 (relating to kitchen) because these requirements are covered by the 2018 FGI *Guidelines* at sections 2.3-4.5 and 3.1-4.5, as adopted by the Department in § 204.1.

The Department does not carry over § 205.28(a) and (c) (relating to nurses' station) because these requirements are covered by the 2018 FGI *Guidelines* at sections

2.3-4.2.2, 3.1-4.2.1.1, 3.1-4.1.2, 3.1-4.2.2 and 3.1-6.5.2, as adopted by the Department in § 204.1. The Department does not carry over § 205.28(b) because there has been a shift from requiring centralized nursing stations to create a more homelike environment for residents instead of a more rigid, traditional institutional facility.

The Department does not carry over § 205.32 (relating to janitor closet) because these requirements are covered by the 2018 FGI *Guidelines* at sections 2.3-4.9 and 2.3-4.5.3.10, as adopted by the Department in § 204.1. The Department does not carry over § 205.40 (relating to lavatory facilities) because these requirements are covered by the Federal requirements at 42 CFR 483.90(f). These requirements are also covered by the 2018 FGI *Guidelines* at section 3.1-2.2.2.6, as adopted by the Department in § 204.1. The Department does not carry over § 205.71 (relating to bed and furnishings) because these requirements are also covered by the Federal requirements at 42 CFR 483.90(e).

Chapter 205. Physical environment and equipment standards for long-term care nursing facilities construction, alteration or renovation approved before July 1, 2023.

The title of Chapter 205 is amended from the proposed rulemaking to this final-form rulemaking. The Department amends the title from the proposed rulemaking to this final-form rulemaking by adding July 1, 2023, as the date after which any construction, alteration or renovation approved by the Department must comply with the provisions of Chapter 204. As explained in the proposed rulemaking, the Department has decided to separate regulatory provisions pertaining to construction, alteration or renovation of long-term care nursing facilities into two chapters to clarify the specific standards that apply to new versus existing construction, alteration or renovation. The Department had proposed to make Chapter 204 applicable to plans for construction, alteration or renovation of long-term care nursing facilities approved on or after 6 months from the publication date of this final-form rulemaking. However, given the estimated timing of this final-form rulemaking, and to be consistent with the effective date established for other sections of the regulations, the Department has decided to make Chapter 204 applicable to plans for construction, alteration or renovation approved on or after July 1, 2023. Existing Chapter 205, as amended, will continue to be the baseline standard for all construction, alteration or renovation of long-term care nursing facilities performed based on plans that were approved by the Department before July 1, 2023, the effective date of Chapter 204.

Buildings and grounds

§ 205.4. Building plans

This section remains deleted from the proposed rulemaking to this final-form rulemaking. Section 205.4 is deleted because all plans for construction, alteration or renovation approved on or after July 1, 2023, will need to meet the requirements of § 204.2, as described previously.

§ 205.6. Function of building

This section is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department amends the term "employes" to "employees" in subsection (b) to reflect the current use and spelling of this term.

A commentator expressed concerns with subsection (a), which the Department did not propose to amend. Under subsection (a), no part of a building may be used for a purpose that interferes with or jeopardizes the health and safety of residents. The commentator indicated that it was not clear what purposes would be covered by this provision and expressed concern that this language could be interpreted to mean that no part of the building could be used for cooking as there are residents that could be harmed by knives or fire involved in cooking. As explained previously in § 204.3(b) (relating to building and grounds; general) to the same comment, the Department's number one priority is the health, safety and welfare of residents. The Department applies a common-sense interpretation and dictionary definition to the words "interferes with or jeopardizes" in the context of a resident's health and safety and would not cite a facility for having an area dedicated for cooking if that area meets the requirements of the act and this subpart. The Department notes that subsection (a) also requires special authorization if part of the building is to be used for a purpose other than health care. Facilities have requested exceptions under this subsection, which have been granted by the Department. The Department would anticipate continuing to receive similar exception requests under this subsection.

Commentators suggested that the Department add a grandfather clause to subsection (b) for non-resident family members currently residing in a facility, as it is only appropriate for residents to reside at a facility. The Department declines to add this language. As explained, in § 204.3(c) to similar comments, the Department fears that removal of the ability of the administrator's family members to reside at the facility may make it difficult to obtain and retain administrators. Additionally, it may be important to allow administrators' family members to reside in a care-focused portion of a facility, and removal of this language might prevent family members needing that care from residing in the facility. The Department, therefore, declines to remove this language from the regulation.

§ 205.7. Basement or cellar.

This section is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department removes the words "and the like" as grammatically unnecessary and because they are duplicative of the words "such as." The Department also replaces the word "areas" with the phrase "any part of the basement" for clarity.

Minimum Physical Environment Standards

This heading is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department replaces the word "plant" with the word "environment" in this heading to reflect current terminology used in the long-term care nursing environment.

§ 205.21. Special care room

This section is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes language in this section that pertains to new construction. Plans for construction, alteration or renovation approved on or after July 1, 2023, will be required to comply with the requirements in Chapter 204.

§ 205.22. Placement of beds

This section is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department replaces the phrase "adequate provisions are made for resident com-

fort and safety" with the phrase "the resident chooses to do so and such placement does not pose a safety hazard." The Department is making this amendment, at the request of the LTC Work Group, to clarify that a resident has a choice in the placement of the resident's bed in the room. However, the Department also adds language to clarify that the resident has this choice unless the placement of the bed presents a safety hazard.

Commentators asked the Department to revise this section to be more specific as to what constitutes a safety hazard. These commentators were concerned that without a definition, facilities will have too much leeway to deny residents' choices and preferences. Commentators also asked that the Department add language to allow a resident, who has the capacity, a certain level of risk or informed decision making, as well as language that would prevent a facility from using arbitrary or ambiguous reasons as a basis for denying the resident's wishes. IRRC also asked the Department to clarify this provision or explain the reasonableness of retaining this language in this final-form rulemaking.

As provided previously, in balancing the competing interests for resident autonomy and choice with also the need for health and safety requirements the Department declines to amend this section. As explained in response to the same comments to § 204.5(d), the addition of "unless the placement presents a safety hazard" is not only reasonable, but critical to ensure the safety of residents. As explained in the proposed rulemaking, the Department supports a resident's ability to choose where a bed is placed in the room but can envision circumstances where a resident's choice of bed placement could pose a health or safety hazard, such as placement near a radiator or heat source or blocking a doorway. In those circumstances, the health and safety of the resident needs to come first. Safety hazards must be determined through an evaluation of the resident's needs and an assessment of the physical environment. A safety hazard for one resident may not necessarily be a safety hazard for another resident, based on the resident's acuity, and a facility will need to determine this on a case-by-case basis. Additionally, if the Department receives a complaint regarding this subsection, the Department will ask the facility why the resident's preference was not considered and will attempt to resolve the complaint in a manner that addresses the resident's concerns and preferences while also ensuring safe placement of the bed.

Mechanical and electrical requirements

§ 205.61. Heating requirements for existing construction

This section is unchanged from the proposed rulemaking to this final-form rulemaking. As noted, in the proposed rulemaking, the Department removes the words "and new" from the title of this section. Plans for construction, alteration or renovation approved on or after July 1, 2023, will be required to comply with the requirements in the new Chapter 204.

§ 205.62. Special heating requirements for new construction

This section remains deleted from this final-form rulemaking. Plans for construction, alteration or renovation approved on or after July 1, 2023, will be required to comply with the requirements in the new Chapter 204.

§ 205.63. Plumbing and piping systems required for existing construction

This section is unchanged from the proposed rulemaking to this final-form rulemaking. As explained, in the proposed rulemaking, the Department removes the words "and new" from the title of this section. Plans for construction, alteration or renovation approved on or after July 1, 2023, will be required to comply with the requirements in the new Chapter 204.

§ 205.64. Special plumbing and piping systems requirements for new construction

This section remains deleted in this final-form rulemaking. Plans for construction, alteration or renovation approved on or after July 1, 2023, will be required to comply with the requirements in the new Chapter 204.

§ 205.66. Special ventilation requirements for new construction

This section remains deleted in this final-form rulemaking. Plans for construction, alteration or renovation approved on or after July 1, 2023, will be required to conform to the requirements in the new Chapter 204. Commentators requested that the Department not delete this section and instead add a requirement to subsection (i) for HEPA filtration systems. The Department has determined neither to retain nor amend this section to incorporate any specific ventilation requirements. HEPA filtration systems may not necessarily be appropriate in all settings. For example, a wall unit that pulls in air from the outside would not be HEPA-compliant. If a facility wants to provide fresh airflow to a room, installing an appropriate unit may also be at odds with HEPA air filtration requirements. The 2018 FGI *Guidelines* provide HVAC requirements at section 2.5-3, and State and local codes may provide additional requirements for facilities. The Department does not believe it is prudent to require a specific type of air-filtration system to be installed in facilities when there is alternative technology that may be better suited for individual facilities and maintaining compliance with all HVAC requirements required by the 2018 FGI *Guidelines*.

§ 205.67. Electric requirements for existing construction

This section is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department removes the words "and new" from the title of this section. Plans for construction, alteration or renovation approved on or after July 1, 2023, will be required to comply with the requirements in Chapter 204.

§ 205.68. Special electrical requirements for new construction

This section remains deleted in this final-form rulemaking. Plans for construction, alteration or renovation approved on or after July 1, 2023, will be required to comply with the requirements in the new Chapter 204.

§ 205.101. Scope

This section is amended from the proposed rulemaking to this final-form rulemaking. The Department replaces the words "alterations, renovations and construction" with the words "construction, alteration or renovation" for consistency in the use of these words elsewhere in the regulation. The Department also replaces the blank space and Editor's Note with "July 1, 2023" to indicate, as noted previously, that Chapter 205 applies to construction, alteration or renovation approved before July 1, 2023.

Other comments

Commentators requested that the Department add a section to ensure that residents have access to Wi-Fi, broadband or Internet technology, as well as devices to keep up with current events, engage in activities and

remain connected to the outside world. Commentators pointed out that the ability to send and receive e-mail and participate in Zoom calls were critical for families and residents to stay in touch during the COVID-19 pandemic. The Department declines to add this requirement, as this is already covered under the Federal requirements. Under 42 CFR 483.10(g)(7)(ii), the facility must provide reasonable access to the Internet, to the extent available to the facility and under 42 CFR 483.10(g)(9), the resident must have reasonable access to electronic communications such as e-mail and video communications and for Internet research, if access is available to the facility, or at the resident's expense if any additional expense is incurred by the facility to provide access to the resident. Facilities that participate in Medicare or MA are currently required to comply with these requirements. However, this will be a new requirement for private-pay facilities due to the expansion of the incorporation of the Federal requirements in § 201.2, in final-form Rulemaking 1. This assumes approval of final-form Rulemaking 1.

Chapter 207. Housekeeping and maintenance standards for long-term care nursing facilities

Housekeeping and maintenance

§ 207.4. Ice containers and storage

This section remains deleted in this final-form rulemaking. A commentator expressed concern that the Department referenced CMS' State Operations Manual, Appendix PP, as its rationale for deleting this section. IRRC asked the Department to retain this section or amend it to include the specific requirements from Appendix PP with which a facility must comply. Upon further review, however, the Department has determined that this section is not needed because of Federal requirements. Specifically, the Federal requirement at 42 CFR 483.60(i)(2) (relating to food and nutrition requirements) requires that a facility store, prepare, distribute and serve food in accordance with professional standards for food service safety. This existing requirement sufficiently covers the prior requirement in § 207.4 (relating to ice containers and storage) for ice containers and storage without the need to retain or amend this provision. The deletion of § 207.4 assumes approval of final-form Rulemaking 1, as the requirement that food be stored, prepared and distributed "in accordance with professional standards for food service safety" in 42 CFR 483.60(i)(2) will be a new requirement for private-pay facilities due to the expansion of the incorporation of the Federal requirements in § 201.2. Other facilities participate in Medicare or MA and thus are already required to comply with the Federal requirements.

Other comments

A commentator expressed concern that there is no provision in the regulations permitting access for ordained clergy regardless of emergency public health declarations or other states of emergency. During the COVID-19 pandemic, the Department did not bar access to the practice of religion. Instead, the Department followed CMS guidance regarding general limitation related to facility access based on disease exposure at https://www.cms.gov/files/document/qso-20-39-nh.pdf. That guidance provided that clergy members should continue to be allowed access to facilities if they were not subject to a work exclusion due to an exposure to COVID-19 or show signs or symptoms of COVID-19 after being screened. As emergency situations are not a one-size-fits-all proposition, the Department believes it would be detrimental to attempt to include, in regulation, an explicit list of persons authorized to have access to a facility during any state of emergency. The Department prefers instead to assess each state of emergency individually and will provide guidance to facilities, regarding facility access, in conjunction with CMS and other relevant authorities, such as the Centers for Disease Control and Prevention (CDC).

A commentator stated that they would like to see a requirement that anyone working in a long-term care nursing facility be vaccinated against flu, COVID-19 and any other contagious disease for which there is a vaccine. This requirement is already partially provided for in 42 CFR 483.80(i), which requires a facility to develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. Facilities that participate in Medicare or MA are required to comply with this requirement. The three private-pay facilities will be required to comply with 42 CFR 483.80(i), by virtue of the Department's expansion of the incorporation of the Federal requirements in § 201.2, in final-form Rulemaking 1. This assumes approval of final-form Rulemaking 1. With respect to influenza and other contagious diseases, the Department strongly encourages staff to obtain available vaccines but does not require vaccination and declines to add this requirement to regulation.

Commentators expressed generally that there needs to be comprehensive reform in the areas of direct care staffing, training, infection prevention and control requirements, emergency and pandemic preparedness planning requirements, application for licensure and change in ownership procedures, and resident rights. A commentator suggested that the Department revise the regulations to require more disclosure and public notice to prevent irresponsible owners from acquiring facilities in this Commonwealth. Another commentator stated that staff of facilities should be paid more so that they do not leave. Requirements for applications for licensure of new facilities and for changes in ownership are addressed in final-form Rulemaking 3 at § 201.12 (relating to application for license). Infection prevention and control, and emergency preparedness, are also addressed in final-form Rulemaking 3. Direct care staffing is addressed in both final-form Rulemaking 1 and Rulemaking 4 at § 211.12 (relating to nursing services). Training and resident rights are addressed in final-form Rulemaking 4 at §§ 201.20 and 201.29 (relating to staff development; and resident rights), respectively.

Fiscal Impact and Paperwork Requirements

Fiscal Impact

In response to the comments and concerns raised during the September 15, 2021 Senate Health and Human Services and Aging and Youth Committees joint legislative hearing, throughout the public comment process, and in other discussions, the Governor's Fiscal Year (FY) 2022-2023 budget proposal proposed an MA rate increase of $190 million; $91 million in State funding to be matched with $99 million in Federal funds for the first 6 months of calendar year 2023 and a proposed $250 million one-time investment of American Rescue Plan Act (ARPA) funds in long-term living programs, including direct one-time funding for all facilities to support their workforce and help them to hire more staff to meet the requirements of the forthcoming regulations. The funding was proposed to be provided to facilities in advance of the expected staffing increases to allow facilities to stabilize their existing workforce and recruit additional staff prior to the regulatory increases going into effect.

Following the Governor's budget proposal, industry stakeholders called for $294 million in MA funding in the Commonwealth's FY 2022-2023 budget. The FY 2022-2023 Appropriations Act signed by Governor Tom Wolf included bipartisan support for a historic increase in one-time and ongoing funding for facilities. As enacted, $147 million in State funding was appropriated to support implementation of the Department's regulations. Specifically, this funding will be used to support a 17.5% Medicaid rate increase beginning January 1, 2023, which allows facilities time to ramp up staffing to meet the direct care staffing hours required on July 1, 2023. Assuming Federal approval, these State funds will be matched with an additional $159 million in Federal funds, totaling $306 million in Medicaid funding for the first 6 months of calendar year 2023. Nursing facilities will also receive $131 million in one-time ARPA funding during FY 2022-2023. A detailed fiscal impact for the regulated community, the Commonwealth and local government is as follows:

Regulated community

The amendments will apply to all 682 long-term care nursing facilities licensed by the Department. These facilities provide health services to more than 72,000 residents. This total includes 19 county-owned and operated facilities, 6 veterans' homes that are operated by the Department of Miliary and Veterans Affairs (DMVA), 654 privately-owned facilities that participate in Medicare or MA and 3 private-pay facilities that do not participate in Medicare or MA.

There will be little to no financial impact to any of these facilities due to the deletion of subsections in § 201.23 (relating to closure of facility) that are duplicative of the Federal requirements. All but 3 of the 682 long-term care nursing facilities participate in Medicare or MA and thus, are already required to comply with existing Federal requirements in 42 CFR 483.70(l) and (m) (relating to administration) for the closure of a facility. Although the specific requirements under 42 CFR 483.70(l) and (m) are new for the three private-pay facilities, the general requirement to provide notice of a facility closure is not new. Prior to this final-form rulemaking, the Department's existing regulations required notification to the Department and to residents and a resident's responsible person when a facility was closing. The additional requirements regarding identification of responsible individuals during the closure is anticipated to be a nominal cost. Further, these three facilities will only incur a cost under 42 CFR 483.70(l), which requires the facility to provide notice of a closure if they close. Under 42 CFR 483.70(m), these three facilities will be required to have in place policies and procedures to ensure that the administrator's duties and responsibilities involve providing the appropriate notices in the event of a closure. This will be a new paperwork requirement for these three facilities.

The addition of subsections (c.1)—(c.4) to § 201.23 in this final-form rulemaking adds clarity to the regulation by incorporating the requirements for a closure plan to require that notice include additional information and be provided to additional individuals who have an interest in the closure of a facility. As noted previously, the 682 facilities licensed by the Department will only be impacted by these amendments if they close. Further, the fiscal impact regarding providing notice of the closure is anticipated to be minimal. Under this final-form rulemaking, facilities will have to provide written notice of a proposed closure to residents, resident representatives, employees, the Office of the State Long-Term Care Ombudsman and DHS.

The deletion of Chapter 203 will not result in an additional cost to the regulated community. Long-term care nursing facilities are required to comply with Chapter 203 and the *Life Safety Code* currently. The deletion of this Chapter merely aligns this requirement with the expansion of the incorporation by reference of the Federal requirements in § 201.2 in final-form Rulemaking 1. The *Life Safety Code* is incorporated by reference in the Federal requirements for long-term care nursing facilities at 42 CFR 483.73(g)(1). The deletion of Chapter 203 to align with the Federal requirements will benefit the regulated community by eliminating duplication between Federal and State regulations to ensure a smooth and streamlined survey process.

The Department's separation of new standards for construction, alteration or renovation from existing standards into two chapters, new Chapter 204 and existing Chapter 205, will add clarity to the survey process for long-term care nursing facilities by making it clear which standards apply to plans for new construction, alteration or renovation versus older, existing construction, alteration or renovation. The addition of Chapter 204 and the requirement that long-term care nursing facilities comply with the FGI *Guidelines* will result in a minimal additional cost to those long-term care nursing facilities that submit plans for construction, alteration or renovation after the effective date of Chapter 204.

Firstly, the FGI *Guidelines* will only apply to new construction, alteration or renovation. They will not apply to existing facilities that are not making any changes or facilities that are only performing regular facility maintenance, such as making cosmetic upgrades, for example paint, new flooring or changing light fixtures. Secondly, the costs associated with compliance with the FGI *Guidelines* relate to patient care items. That is, the major cost factor to new construction of long-term care facilities and renovations and alterations to existing facilities is square footage; specifically square footage requirements for rooms and spaces that have specific materials and equipment to support these rooms and spaces. The addition of the 2018 FGI *Guidelines* for long-term care facilities, however, does not specifically add square footage to any new construction, renovation or alteration. Further, the Department maintains the existing square footage requirements under this final-form rulemaking. Instead, the FGI *Guidelines* provide the design team with requirements that promote a physical environment that is safe for residents, promotes home-like environments and provides up-to-date and relevant requirements to today's challenges in facilities.

Specifically, facility ownership essentially determines the ultimate cost of any new construction, renovation or alteration project. Decisions to keep the facility "as-is" only incurs costs to maintain the facility; whereas business decisions to complete new construction, renovation or alteration projects will be decided by the scope approved by ownership. Further, facilities are required to comply with the requirements of the Uniform Construction Code (UCC), initially adopted by the Department of Labor and Industry in April 2004 and updated to the 2018 edition, effective February 14, 2022. Likewise, facilities are already required to comply with the requirements of the 2012 edition of the National Fire Protection Association's (NFPA) 101, *Life Safety Code* for State licensure and Federal certification purposes, effective July 5, 2016.

Existing requirements related to UCC and *Life Safety Code* compliance affect construction, renovation and alteration costs significantly, as these codes determine requirements such as, but not limited to:

1. Type of construction of the building;

2. Fire protection systems, such as sprinkler and fire alarm systems;

3. Hazardous area protection;

4. Heating, Ventilating and Air Conditioning (HVAC);

5. Normal and emergency electrical systems;

6. Means of egress requirements;

7. Smoke and fire compartments to support "defend in place" evacuation principles;

8. Medical gas requirements;

9. Plumbing requirements, and the like.

However, these same types of costs are not reflected under the 2018 FGI *Guidelines*. While the UCC and the *Life Safety Code* require the corridor width in a new health care occupancy to be 8 feet wide, the FGI *Guidelines* will add requirements that the flooring be non-slip and handrails provided for resident safety. Similarly, where sinks are required, the FGI *Guidelines* will provide requirements on the temperature of the water for proper handwashing hygiene and things such as the depth of the basin to limit the probability of splash and wet floors that may lead to falls. Where nurse call buttons are required, the FGI *Guidelines* will provide for considerations for residents that wish to move their bed within their room for resident preference. Further, where a dining room is already required, the FGI *Guidelines* will provide requirements on proper lighting, ensuring residents in wheelchairs are able to easily navigate the room, and requirements to promote smells from the food to permeate through the facility to encourage nutrition.

As stated previously, ownership business decisions will ultimately determine the overall cost of any new construction, renovation or alteration. Whether decisions are made to only renovate two rooms, renovate one or more wings, complete alterations to replace emergency generators or HVAC equipment (and to what extent), use interior finishes and fixtures that are either higher or lower priced, or build an entire replacement facility, that will be made by facility ownership.

New construction, renovations or alterations are already required to meet the UCC and *Life Safety Code* requirements. As important as it is to ensure a facility has code compliant electrical receptacles per the UCC and *Life Safety Code*, it is just as important to ensure the FGI requirements for proper placement of the receptacles so residents may have proper access. This is similar to where UCC will provide requirements to ensure the number of toilets in the facility will function; whereas the FGI *Guidelines* provide requirements on proper location and staff assistance to ensure residents have access and are provided a safe environment for fall protection. The examples are nearly endless, but the FGI *Guidelines* are paramount to supplementing existing codes that are written for all types of facilities (residential, commercial, industrial, and the like) to provide and promote safe environments for the unique and fragile population of the facilities.

In addition, compliance with the FGI *Guidelines* will benefit long-term care nursing facilities by ensuring that any construction, alteration or renovation are built to current, updated standards for maintained health and safety versus existing facilities that have not built to these standards. Further, the amendments to Chapter 205 will not increase costs to long-term care nursing facilities, as the Department is only deleting language pertaining to new construction, alteration or renovation.

The 682 licensed facilities will not incur any cost due to the deletion of § 207.4 to align with the Federal requirements. As noted, all but 3 of the 682 facilities participate in Medicare or MA and thus, already required to comply with the Federal requirements. The three private-pay facilities will not incur a cost due to the elimination of this requirement that is duplicative of the Federal requirements, as they are already required under existing § 207.4 to ensure that ice is properly stored and handled.

Commonwealth—Department

The amendments will not increase costs to the Department. The Department's surveyors perform the function of surveying and inspecting long-term care nursing facilities for compliance with both Federal and State regulations. The elimination of subsections that are outdated and duplicative of the Federal requirements will streamline the survey process for long-term care nursing facilities and provide consistency and congruency to the stakeholder industry. This, in turn, will reduce confusion in the application of the standards that apply to long-term care nursing facilities. The deletion of Chapter 203 will also benefit the Department's surveyors and long-term care nursing facilities by eliminating duplication between Federal and State regulations to ensure a smooth and streamlined process. Further, separating new standards for construction, alteration or renovation from existing standards in Chapter 205 to new standards under Chapter 204, will also add clarity to the survey process and industry stakeholders by making it clear which standards apply to plans for new construction, alteration or renovation versus older, existing construction, alteration or renovation.

Commonwealth—DMVA

Of the 682 long-term care nursing facilities licensed by the Department, six facilities are veterans' homes that are operated by the DMVA. These facilities are already required to comply with the Federal requirements and thus, are already required to comply with existing Federal requirements in 42 CFR 483.70(l) and (m) for the closure of a facility. The addition of subsections (c.1)—(c.4) to § 201.23 on this final-form rulemaking adds clarity to the regulation by incorporating the requirements for a closure plan and expanding upon the already existing notice requirement in 42 CFR 483.70(l) and (m) to require that notice include additional information and be provided to additional individuals who have an interest in the closure of a facility. Further, the DMVA-operated facilities licensed by the Department will only be impacted by providing this additional information under these amendments if they close. The Department anticipates the cost associated with providing this additional information to be nominal.

The deletion of Chapter 203 will not result in an additional cost to the DMVA-operated facilities. Long-term care nursing facilities are required to comply with Chapter 203 and the *Life Safety Code* currently. The deletion of this Chapter merely aligns this requirement with the expansion of the incorporation by reference of the Federal requirements in § 201.2 in final-form Rulemaking 1. The *Life Safety Code* is incorporated by reference in the Federal requirements for long-term care nursing facilities at 42 CFR 483.73(g)(1). The deletion of

Chapter 203 to align with the Federal requirements will benefit the regulated community by eliminating duplication between Federal and State regulations to ensure a smooth and streamlined survey process.

The Department's separation of new standards for construction, alteration or renovation from existing standards into two chapters, new Chapter 204 and Chapter 205, will add clarity to the survey process for long-term care nursing facilities by making it clear which standards apply to plans for new construction, alteration or renovation versus older, existing construction, alteration or renovation. The addition of Chapter 204 and the requirement that long-term care nursing facilities comply with the FGI *Guidelines* will result in a cost to those long-term care nursing facilities that submit plans for construction, alteration or renovation after the effective date of Chapter 204. As provided previously, the Department considers the cost for complying with the FGI *Guidelines* to be minimal. In addition, compliance with the FGI *Guidelines* will benefit long-term care nursing facilities and their residents. Further, the amendments to Chapter 205 will not increase costs to long-term care nursing facilities, as the Department is only deleting language pertaining to new construction, alteration or renovation.

The DMVA-operated licensed facilities will not incur any additional cost due to the deletion of § 207.4 to align with the Federal requirements. As noted, these facilities are already required to comply with the Federal requirements.

Commonwealth—DHS

Although the provisions of this final-form rulemaking, which relate to general operations and physical requirements, will not have a cost impact to DHS, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023, was enacted under Act 2022-54 and appropriated under the General Appropriations Act of 2022 (Act 2022-1A).

Local government

As mentioned previously, there are currently 19 county-owned long-term care nursing facilities, licensed by the Department. These facilities account for approximately 7.5% (6,524 beds) of licensed nursing facility beds across this Commonwealth. Allegheny County owns four of the nursing homes; the remaining homes are in the following 15 counties: Berks, Bradford, Bucks, Chester, Clinton, Crawford, Delaware, Erie, Indiana, Lehigh, Monroe, Northampton, Philadelphia, Warren and Westmoreland.

County-owned long-term care nursing facilities participate in Medicare or MA and thus, are already required to comply with the Federal requirements and thus, are already required to comply with existing Federal requirements in 42 CFR 483.70(l) and (m) for the closure of a facility. The addition of subsections (c.1)—(c.4) to § 201.23 in this final-form rulemaking adds clarity to the regulation by incorporating the requirements for a closure plan and expanding upon the already existing notice requirement in 42 CFR 483.70(l) and (m) to require that notice include additional information and be provided to additional individuals who have an interest in the closure of a facility. The county-owned facilities licensed by the Department will only be impacted by these amendments if they close. Further, the Department anticipates that the cost associated with providing this additional information to be nominal.

The deletion of Chapter 203 will not result in an additional cost to the county-owned facilities. Long-term care nursing facilities are required to comply with Chapter 203 and the *Life Safety Code* currently. The deletion of this chapter merely aligns this requirement with the expansion of the incorporation by reference of the Federal requirements in § 201.2 in final-form Rulemaking 1. The *Life Safety Code* is incorporated by reference in the Federal requirements for long-term care nursing facilities at 42 CFR 483.73(g)(1). The deletion of Chapter 203 to align with the Federal requirements will benefit the regulated community by eliminating duplication between Federal and State regulations to ensure a smooth and streamlined survey process.

The Department's separation of new standards for construction, alteration or renovation from existing standards into two chapters, new Chapter 204 and Chapter 205, will add clarity to the survey process for long-term care nursing facilities by making it clear which standards apply to plans for new construction, alteration or renovation versus older, existing construction, alteration or renovation. The addition of Chapter 204 and the requirement that long-term care nursing facilities comply with the FGI *Guidelines* will result in a cost to those long-term care nursing facilities that submit plans for construction, alteration or renovation after the effective date of Chapter 204. As detailed previously, the Department considers the cost for complying with the FGI *Guidelines* to be minimal. In addition, compliance with the FGI *Guidelines* will benefit long-term care nursing facilities and their residents. Further, the amendments to Chapter 205 will not increase costs to long-term care nursing facilities, as the Department is only deleting language pertaining to new construction, alteration or renovation.

The county-owned licensed facilities will not incur any additional cost due to the deletion of § 207.4, to align with the Federal requirements. As noted, these facilities participate in Medicare or MA and thus, are already required to comply with the Federal requirements.

Residents of long-term care nursing facilities

The more than 72,000 individuals that reside in the 682 long-term care nursing facilities licensed by the Department will be affected by the amendments. Residents will be positively affected by the closure plan requirements in the event of a facility closure in § 201.23(c.1). Residents will also be positively affected by the expansion of the Federal notice requirements in State regulation to include additional information and to include additional individuals. The addition of new Chapter 204 and the requirement that long-term care nursing facilities comply with the FGI *Guidelines* for construction, alteration or renovation plans approved on or after July 1, 2023, will also positively affect residents by ensuring that facilities that complete new construction, alteration or renovation are meeting current construction standards. Residents are also benefiting from the health and safety requirements of an airborne infection isolation room and the maintaining of facility requirements for the health and safety of residents.

Paperwork Requirements

The Department's adoption of 42 CFR 483.70(l) will result in a new paperwork requirement for the three private-pay facilities, by requiring that notice be provided to certain individuals in the event of a facility closure. The Department's expansion of this requirement in § 201.23(c.3) and (c.4) will impose additional paperwork requirements on all facilities, including those that already are required to comply with 42 CFR 483.70(l). However, this requirement will only affect facilities if they close.

Under these provisions, a closing facility will have to provide notice of the closure to the Department, residents, resident representatives, employees, the State long-term care ombudsman program and DHS.

The Department's adoption of 42 CFR 483.70(m) in § 201.23 will result in a new paperwork requirement for the three private-pay facilities that are licensed by the Department, by requiring these facilities to have in place policies and procedures to ensure that the administrator's duties and responsibilities involve providing the appropriate notices in the event of a closure.

Licensees and prospective licensees are already required, under § 51.3(d) to submit architectural and blueprint plans to the Department for approval before performing any construction, alteration or renovation. The amendment to § 204.2 simply directs licensees and prospective licensees to the Department's web site for instructions on how to submit plans for construction, alteration or renovation.

Small Business Analysis

A commentator asserted that the Department failed to give adequate attention to the financial and economic impact of the regulation on small businesses, and that simply stating that all minimum requirements apply to all facilities, regardless of whether they are a small business, is not an analysis. IRRC also asked if the Department has the ability, in conjunction with other State agencies, to access data to evaluate the potential impact on small businesses. IRRC asked that the Department calculate and address the impact of the final-form regulation on small businesses as required under the Regulatory Review Act (71 P.S. §§ 745.1—745.14).

Under section 3 of the Regulatory Review Act (71 P.S. § 745.3), a small business is "defined in accordance with the size standards described by the United States Small Business Administration's Small Business Size Regulations under 13 CFR Ch. 1 Part 121 (relating to Small Business Size Regulations) or its successor regulation." Under 13 CFR 121.101 (relating to what are SBA size standards?), the Small Business Administration's (SBA) "size standards determine whether a business entity is small." Size standards are developed under the North America Industry Classification System (NAICS). The Department applied the NAICS standards to determine how many long-term care nursing facilities, licensed by the Department, are small businesses.

The Department conducted a search on the NAICS web site to find the NAICS code for long-term care nursing facilities. The NAICS code for nursing care facilities (skilled nursing facilities) is 623110. The Department looked this code up in the table located at 13 CFR 121.201 (relating to what size standards has SBA identified by North American Industry Classification System codes?) and determined that a long-term care nursing facility is a small business if it has $30 million or less in annual receipts. The Department then pulled the latest long-term care nursing facility cost report from CMS to determine the impact to facilities that participate in Medicare or MA. The latest cost report data from CMS is 2018. Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data. The Department applied current Federal Standards of Accounting to this data to determine each facility's annual receipts. Based on this analysis, the Department determined that 623 facilities that participate in Medicare or MA have $30 million or less in annual receipts. Although the data from CMS is from 2018, the Department believes that currently, at least the same number of facilities, if not more, would meet the definition of a small business. This analysis aligns with the Department's previous assumption that most long-term nursing facilities licensed by the Department meet the definition of a small businesses.

The Department also asked stakeholders during the meetings held in 2021 and 2022 for assistance in determining the impact to small businesses. The stakeholders were not able to provide the Department with specific information regarding how the Department's proposed regulations would impact small businesses. However, during the stakeholder meeting for Rulemakings 1 and 2, a stakeholder suggested that the Department search GuideStar, which provides financial information regarding nonprofit entities, to determine whether the three private-pay facilities are small businesses. The Department searched the GuideStar web site at https://www.guidestar.org/ for the three private-pay facilities that are licensed by the Department. Based on this data, one of the private-pay facilities, Friends Home in Kennett/Linden Hall, meets the definition of a small business applying the NAICS standards. Another private-pay facility, Foulkeways at Gwynedd does not meet the definition of a small business based on its gross receipts. Data for the third private-pay facility, Dallastown Nursing Center, is not available on GuideStar, but for the purposes of this analysis, the Department assumes that Dallastown is a small business.

In sum, at least 91% of nursing facilities meet the definition of a small business. Consistent with the HCFA and function of licensure, the purpose of these regulatory amendments is to ensure the health, safety and welfare of all residents of long-term care nursing facilities in this Commonwealth by providing the minimum health and safety standards. Given that most facilities are a small business and the need for surveying for the health and safety of residents, the Department did not establish differing criteria for nursing facilities that are small business compared to the minority of facilities that are not small businesses. Further, in determining the minimum health and safety requirements, the department considered the myriad of received comments, feedback from meetings and stakeholder groups and attempted to balance the interests between consumers and the stakeholder industry. The Department's responsibility to ensure that residents receive safe, quality care applies to all residents of long-term care nursing facilities in this Commonwealth, and it is critical that all residents of long-term care nursing facilities receive the same level of high-quality care, regardless of whether the facility they reside in is a small business.

Statutory Authority

Sections 601 and 803 of the HCFA (35 P.S. §§ 448.601 and 448.803) authorize the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the HCFA. Section 801.1 of the HCFA (35 P.S. § 448.801a) seeks to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities. The minimum standards are to assure safe, adequate and efficient facilities and services and to promote the health, safety and adequate care of patients or residents of those facilities. In section 102 of the HCFA (35 P.S. § 448.102), the General Assembly has found that a purpose of the HCFA is, among other things, to assure

that citizens receive humane, courteous and dignified treatment. Finally, section 201(12) of the HCFA (35 P.S. § 448.201(12)) provides the Department with explicit authority to enforce its rules and regulations promulgated under the HCFA.

The Department also has the duty to protect the health of the people of this Commonwealth under section 2102(a) of The Administrative Code of 1929 (71 P.S. § 532(a)). The Department has general authority to promulgate regulations under section 2102(g) of The Administrative Code of 1929 (71 P.S. § 532(g)).

Effectiveness/Sunset Date

This final-form rulemaking will become effective on July 1, 2023. A sunset date will not be imposed. The Department will monitor the regulations and update them as necessary.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on September 27, 2021, the Department submitted notice of this proposed rulemaking, published at 51 Pa.B. 6401 (October 9, 2021), to IRRC and the Chairpersons of the Senate Health and Human Services Committee and the House Health Committee for review and comment.

Under section 5(c) of the Regulatory Review Act, 71 P.S. § 745.5(c), IRRC, the Senate Health and Human Services Committee and the House Health Committee were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the Senate Health and Human Services Committee, the House Health Committee, and the public.

Under section 5.1(j.2) of the Regulatory Review Act, 71 P.S. § 745.5a(j.2), on October 27, 2022, the final-form rulemaking was deemed approved by the Senate Health and Human Services Committee and the House Heath Committee. Under section 5.1(e) of the Regulatory Review Act, IRRC met on October 28, 2022, and approved the final-form rulemaking.

Contact Person

Additional information regarding this final-form rulemaking may be obtained by contacting Ann Chronister, Director, Bureau of Long-Term Care Programs, 625 Forster Street, Rm. 526, Health and Welfare Building, Harrisburg, PA 17120, (717) 547-3131, or RA-DHLTCRegs@pa.gov. Persons with a disability may submit questions in an alternative format such as audio tape, Braille or by using V/TT (717) 783-6514 or the Pennsylvania Hamilton Relay Service at (800) 654-5984 (TT). Persons who require an alternative format of this document may contact Ann Chronister at the previous address or telephone number so that necessary arrangements can be made.

Findings

The Department finds that:

(1) Public notice of intention to adopt the regulations adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) referred to as the Commonwealth Documents Law, and the regulations promulgated under those sections at 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law and all comments were considered in drafting this final-form rulemaking.

(3) The amendments made to the final-form rulemaking do not enlarge the original purpose of the proposed rulemaking as published under section 201 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. § 1201).

(4) The adoption of the regulations is necessary and appropriate for the administration of the act.

Order

(1) The regulations of the Department in 28 Pa. Code Chapters 201, 203, 204, 205 and 207 are amended by amending §§ 201.23, 205.6, 205.7, 205.21, 205.22, 205.61, 205.63, 205.67 and 205.101, adding §§ 204.1—204.20 and deleting §§ 203.1, 205.4, 205.62, 205.64, 205.66, 205.68 and 207.4.

(2) The Department shall submit this final-form rulemaking to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(3) The Department shall submit this final-form rulemaking to IRRC, the Senate Health and Human Services Committee and the House Health Committee as required by law.

(4) The Department shall certify this final-form rulemaking, as approved for legality and form, and shall deposit it with the Legislative Reference Bureau as required by law.

(5) This final-form rulemaking shall take effect on July 1, 2023.

DR. DENISE A. JOHNSON,
Acting Secretary

(*Editor's Note*: See 52 Pa.B. 7054 (November 12, 2022) for IRRC's approval order.)

Fiscal Note: 10-222. No fiscal impact; (8) recommends adoption.

Annex A

ITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

Subpart C. LONG-TERM CARE FACILITIES

CHAPTER 201. APPLICABILITY, DEFINITIONS, OWNERSHIP AND GENERAL OPERATION OF LONG-TERM CARE NURSING FACILITIES

OWNERSHIP AND MANAGEMENT

§ 201.23. Closure of facility.

In addition to the requirements set forth in 42 CFR 483.70(l) and (m) (relating to administration), the following conditions apply to the closure of a long-term care nursing facility:

(a) [Reserved].

(b) [Reserved].

(c) [Reserved].

(c.1) The facility shall develop a closure plan that includes all of the following:

(1) The identification of those who will be responsible for the daily operation and management of the facility during the closure process.

(2) The roles and responsibilities, and contact information, for the facility owner and the administrator or any replacement or temporary manager during the closure process.

(3) Assurance that no new residents will be admitted to the facility after the written notice of closure is provided under subsection (c.3).

(4) A plan for identifying and assessing available facilities to which residents can be transferred, taking into consideration each resident's individual best interests and resident's goals, preferences and needs regarding services, location and setting. This shall include all of the following:

(i) Interviewing each resident and resident representative, if applicable, to determine each resident's goals, preferences and needs.

(ii) Offering the opportunity, to each resident and resident representative, if applicable, to obtain information regarding options within the community.

(iii) Providing residents and resident representatives, if applicable, with information or access to information regarding providers and services.

(5) A plan for the communication and transfer of resident information, including of medical records.

(6) Provisions for the ongoing operations and management of the facility, its residents and staff during the closure process, that include all of the following:

(i) Payment of salaries and expenses.

(ii) Continuation of appropriate staffing and resources to meet the needs of the residents, including provision of medications, services, supplies and treatment.

(iii) Ongoing accounting, maintenance and reporting of resident personal funds.

(iv) Labeling, safekeeping and appropriate transfer of each resident's personal belongings.

(c.2) The facility shall provide the notice of closure and the closure plan developed under subsection (c.1) to the department for approval at least 75 days prior to the proposed date of closure.

(c.3) At least 60 days before the proposed date of closure, the facility shall provide written notice of the proposed closure to the following:

(1) Residents and their resident representatives, if applicable, in writing or in a language and manner they understand.

(2) Employees of the facility.

(3) The Office of the State Long-Term Care Ombudsman Program.

(4) The Department of Human Services.

(c.4) The written notice provided under subsections (c.2) and (c.3) shall contain all of the following:

(1) The date of the proposed closure.

(2) Contact information for the facility representative delegated to respond to questions about the closure.

(3) Contact information for the Office of the State Long-Term Care Ombudsman Program.

(4) The transfer and relocation plan of residents.

(d) No resident in a facility may be required to leave the facility prior to 30 days following receipt of a written notice from the licensee of the intent to close the facility, except when the Department determines that removal of the resident at an earlier time is necessary for health and safety.

(e) If an orderly transfer of the residents cannot be safely effected within 30 days, the Department may require the facility to remain open an additional 30 days.

(f) The Department is permitted to monitor the transfer of residents.

(g) The licensee of a facility shall file proof of financial responsibility with the Department to ensure that the facility continues to operate in a satisfactory manner until closure of the facility.

CHAPTER 203. [Reserved].

§ 203.1. [Reserved].

CHAPTER 204. PHYSICAL ENVIRONMENT AND EQUIPMENT STANDARDS FOR CONSTRUCTION, ALTERATION OR RENOVATION OF LONG-TERM CARE NURSING FACILITIES

§ 204.1. Application of *Guidelines for Design and Construction of Residential Health, Care and Support Facilities*.

(a) In addition to the requirements set forth in this chapter, facility construction, alteration or renovation approved on or after July 1, 2023, shall comply with the 2018 edition of the Facility Guidelines Institute *Guidelines for Design and Construction of Residential Health, Care, and Support Facilities*.

(b) Facility construction, alteration or renovation approved before July 1, 2023, shall comply with the standards set forth in Chapter 205 (relating to physical environment and equipment standards for existing long-term care nursing facilities).

(c) Construction, alteration or renovation shall meet the requirements in effect on the date that the facility's plans for construction, alteration or renovation are approved by the Department.

§ 204.2. Building plans.

(a) A licensee or prospective licensee shall submit its plans for construction, alteration or renovation to the department. The Department will post instructions for submissions on its public web site.

(b) A licensee or prospective licensee shall have the opportunity to present and discuss with the Department its purposes and plans concerning the requested changes indicated on architectural plans submitted under § 51.3(d) (relating to notification). If differences occur and cannot be resolved, an administrative hearing may be sought under 1 Pa. Code Part II (relating to General Rules of Administrative Practice and Procedure).

(c) Construction, alteration or renovation approved by the Department shall begin within 2 years of the Department's approval and shall be completed within 5 years of the Department's approval.

(d) A facility may seek an extension of the time periods under subsection (c) for beginning or completing an approved construction, alteration or renovation by written request to the Department. The Department may approve an extension for good cause shown.

(e) A facility shall obtain approval from the Department before using an area of the facility for resident care when that area has not been occupied or used by residents for 1 year or more.

§ 204.3. Buildings and grounds; general.

(a) A building to be used for and by residents shall be located in an area that is geographically and environmentally conducive to the health and safety of residents.

(b) No part of a building may be used for a purpose that interferes with or jeopardizes the health and safety of residents. Special authorization shall be given by the Department's Division of Nursing Care Facilities if a part of the building is to be used for a purpose other than health care.

(c) Only residents, employees, the licensee, the administrator or members of the administrator's immediate family may reside in the facility.

(d) Grounds shall be adequate to provide necessary service areas and outdoor areas for residents. A facility may provide rooftop or balcony areas if adequate protective enclosures are provided.

(e) A delivery area, service yard or parking area shall be located so that traffic does not cross an area commonly used by residents.

§ 204.4. Basement.

(a) A basement may be used for storage, laundry, kitchen, heat, electric and water equipment. Approval from the Department's Division of Nursing Care Facilities shall be secured before any part of the basement may be used for other purposes, such as physical therapy, central supply and occupational therapy.

(b) A door to a basement may not be located in a resident room.

§ 204.5. Resident rooms.

(a) A bed for a resident may be placed only in a room approved by the Department as a resident room.

(b) The basement of a facility may not be used for resident rooms.

(c) The maximum number of residents who may be accommodated in a facility shall be indicated on the facility license. The number of resident rooms and the number of beds in a room may not exceed the maximum number approved by the Department.

(d) A resident shall have a choice in the placement of the resident's bed in the room unless the placement presents a safety hazard.

(e) A bed may not be placed close to a radiator, heat vent, air conditioner, direct glare of natural light or draft unless the resident chooses to do so and the placement does not pose a safety hazard.

(f) A resident shall be provided with a drawer or cabinet in the resident's room that can be locked.

§ 204.6. Locks.

A door into a room used by a resident may not be locked from the outside when the resident is in the room.

§ 204.7. Laundry.

Equipment shall be made available and accessible for residents desiring to do their personal laundry.

§ 204.8. Utility room.

The facility shall make provisions in each nursing unit for utility rooms. The nursing unit shall have separate soiled and clean workrooms. The rooms may not be more than 120 feet from the most remote room served.

§ 204.9. Bathing facilities.

(a) A facility shall provide a general bathing area in each nursing unit to serve resident rooms that do not have adjoining bathrooms with a bathtub or shower.

(b) Unless bathing fixtures are located in a separate room, there shall be compartments to permit privacy. Cubicle curtains may provide this privacy.

(c) Each bathing room shall include a toilet and lavatory. If more than one tub or shower is in the bathing room, privacy shall be provided at each bathing facility and at the toilet.

(d) The facility shall have at least one bathtub in each centralized bath area on each floor.

§ 204.10. Toilet Facilities.

Toilets and lavatories, other than resident facilities, shall be provided for visitors in a facility.

§ 204.11. Equipment for bathrooms.

(a) Grab bars shall be installed as necessary at each tub and shower for safety and convenience. Grab bars, accessories and anchorage shall have sufficient strength to accommodate the residents' needs.

(b) The general bathroom or shower room used by residents shall have one emergency signal bell located in close proximity to the tub or shower and which registers at the workstation. An emergency signal bell shall also be located at each toilet unless a signal bell can be reached by the resident from both the toilet and tub or shower.

(c) The facility shall make provisions to get residents in and out of bathtubs in a safe way to prevent injury to residents and personnel. The facility shall provide appropriate supervision and assistance to ensure the safety of all residents being bathed.

(d) A dressing area shall be provided immediately adjacent to the shower stall and bathtub. In the dressing area, there shall be provisions for keeping clothes dry while bathing.

(e) The facility shall ensure that water for baths and showers is at a safe and comfortable temperature before the resident is bathed.

§ 204.12. Toilet room equipment.

Each toilet used by residents shall be provided with handrails or assist bars on each side capable of accommodating the residents' needs.

§ 204.13. Linen.

The facility shall have available at all times a quantity of linens essential for proper care and comfort of residents.

§ 204.14. Supplies.

Adequate supplies shall be available at all times to meet the residents' needs.

§ 204.15. Windows.

(a) Each window opening in the exterior walls that are used for ventilation shall be effectively covered by screening.

(b) A room with windows opening onto light or air shafts, or onto an exposure where the distance between the building or an obstruction higher than the windowsill is less than 20 feet, may not be used for resident rooms.

§ 204.16. Dining.

The dining area shall be a minimum of 15 square feet per bed for the first 100 beds and 13 1/2 square feet per bed for beds over 100. This space is required in addition to the space required for lounge and recreation rooms.

§ 204.17. Lounge and recreation rooms.

A recreation or lounge room shall be a minimum of 15 square feet of floor space per bed provided for the first 100 beds and 13 1/2 square feet for all beds over 100. A facility shall provide recreation or lounge rooms for residents on each floor.

§ 204.18. Storage.

General storage space shall be provided for storage of supplies, furniture, equipment, residents' possessions and the like. Space provided for this purpose shall be commensurate with the needs of the nursing facility but may not be less than 10 square feet per bed.

§ 204.19. Plumbing, heating, ventilation, air conditioning and electrical.

Building systems, such as plumbing, heating, ventilation, air conditioning and electrical must comply with all State and local codes.

§ 204.20 Airborne infection isolation room.

A facility shall have at least one airborne infection isolation room for isolating residents as necessary to prevent the spread of airborne infections. An airborne infection isolation room shall be in accordance with the 2018 edition of the Facility Guidelines Institute *Guidelines for Design and Construction of Residential Health, Care, and Support Facilities*.

CHAPTER 205. PHYSICAL ENVIRONMENT AND EQUIPMENT STANDARDS FOR LONG-TERM CARE NURSING FACILITIES CONSTRUCTION, ALTERATION OR RENOVATION APPROVED BEFORE JULY 1, 2023.

BUILDINGS AND GROUNDS

§ 205.4. [Reserved].

§ 205.6. Function of building.

(a) No part of a building may be used for a purpose which interferes with or jeopardizes the health and safety of residents. Special authorization shall be given by the Department's Division of Nursing Care Facilities if a part of the building is to be used for a purpose other than health care.

(b) The only persons who may reside in the facility shall be residents, employees, the licensee, the administrator or members of the administrator's immediate family.

MINIMUM PHYSICAL ENVIRONMENT STANDARDS

§ 205.7. Basement or cellar.

Basements or cellars may be used for storage, laundry, kitchen, heat, electric and water equipment. Approval from the Department's Division of Nursing Care Facilities shall be secured before any area of the basement may be used for other purposes, such as physical therapy, central supply and occupational therapy.

§ 205.21. Special care room.

(a) Provisions shall be made for isolating a resident as necessary in a single room which is ventilated to the outside.

(b) Provisions shall be available to identify this room with appropriate precautionary signs.

§ 205.22. Placement of beds.

A bed may not be placed in proximity to radiators, heat vents, air conditioners, direct glare of natural light or drafts unless the resident chooses to do so and the placement does not pose a safety hazard.

MECHANICAL AND ELECTRICAL REQUIREMENTS

§ 205.61. Heating requirements for existing construction.

(a) The heating system shall comply with local and State codes. If there is a conflict, the more stringent requirements shall apply.

(b) Exposed heating pipes, hot water pipes or radiators in rooms and areas used by residents or within reach of residents, shall be covered or protected to prevent injury or burns to residents. This includes hot water or steam piping above 125°F.

§ 205.62. [Reserved].

§ 205.63. Plumbing and piping systems required for existing construction.

(a) Potable ice may not be manufactured or stored in the soiled utility room.

(b) Water distribution systems shall be designed and arranged to provide potable hot and cold water at hot and cold water outlets at all times. The system pressure shall be sufficient to operate fixture and equipment during maximum demand periods.

(c) Hot water outlets accessible to residents shall be controlled so that the water temperature of the outlets does not exceed 110°F.

§ 205.64. [Reserved].

§ 205.66. [Reserved].

§ 205.67. Electric requirements for existing construction.

(a) Artificial lighting shall be restricted to electric lighting.

(b) Spaces occupied by people, machinery and equipment within buildings shall have electric lighting which is operational at all times.

(c) Electric lights satisfactory for residents' activities shall be available.

(d) Electric lights in rooms used by residents shall be placed or shaded to prevent direct glare to the eyes of residents.

(e) Night lights shall be provided in bedrooms, stairways, corridors, bathrooms and toilet rooms used by residents.

(f) Arrangements to transfer lighting from overhead fixtures to night light fixtures in stairways and corridors shall be designed so that switches can only select between two sets of fixtures and cannot extinguish both sets at the same time.

(g) In addition to night lights, residents' bedrooms shall have general lighting. The light emitting surfaces of the night light may not be in direct view of a resident in a normal in-bed position.

(h) A reading light shall be provided for each resident.

(i) In each resident room there shall be grounding type receptacles as follows: one duplex receptacle on each side of the head of each bed except for parallel adjacent beds. Only one duplex receptacle is required between beds plus sufficient duplex receptacles to supply portable lights, television and motorized beds, if used, and one duplex receptacle on another wall.

(j) A nurse's calling station—signal originating device—with cable with push button housing attached or other system approved by the Department shall be provided at each resident bed location so that it is accessible to the resident. Two cables and buttons serving adjacent beds may be served by one station. An emergency calling station within reach of the resident shall be provided at each bathing fixture and toilet unless a single bell can be reached by the resident from both the bathing fixture and the toilet. Cable and push button housing requirement will apply to those facilities constructed after July 1, 1987.

(k) Calls shall register by a signal receiving and indicating device at the nurses' station, and shall activate a visible signal in the corridor at the resident's door. In multicorridor nursing units, additional visible signal indicators shall be installed at corridor intersections.

§ 205.68. [Reserved].

MISCELLANEOUS PROVISIONS

§ 205.101. Scope.

This chapter applies to facility construction, alteration or renovation approved by the Department before July 1, 2023.

CHAPTER 207. HOUSEKEEPING AND MAINTENANCE STANDARDS FOR LONG-TERM CARE NURSING FACILITIES

HOUSEKEEPING AND MAINTENANCE

§ 207.4. [Reserved].

[Pa.B. Doc. No. 22-2017. Filed for public inspection December 23, 2022, 9:00 a.m.]

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CHS. 201, 207, 209 AND 211]

Long-Term Care Nursing Facilities

The Department of Health (Department), after consultation with the Health Policy Board, amends 28 Pa. Code §§ 201.18—201.21, 201.24, 201.26, 201.29, 201.31, 209.3, 211.2—211.10, 211.12, 211.15—211.17 and deletes §§ 201.25, 201.30, 207.2, and 211.11 to read as set forth in Annex A. This is the fourth of four final-form rulemaking packages for long-term care nursing facilities being promulgated by the Department.

The contents for the four final-form rulemaking packages are as follows:

Rulemaking 1—General Applicability and Definitions

§ 201.1. Applicability.

§ 201.2. Requirements.

§ 201.3. Definitions.

§ 211.12. Nursing services. (Withdrawn on final-form.)

Rulemaking 2—General Operation and Physical Requirements

§ 201.23. Closure of facility.

Chapter 203. Application of Life Safety Code for Long-Term Care Nursing Facilities. (Reserved on final-form.)

Chapter 204. Physical Environment and Equipment Standards for Construction, Alteration or Renovation of Long-Term Care Nursing Facilities after July 1, 2023.

Chapter 205. Physical Environment and Equipment Standards for Long-Term Care Nursing Facilities Construction, Alteration or Renovation Approved before July 1, 2023.

§ 207.4. Ice containers and storage. (Reserved on final-form.)

Rulemaking 3—Applications for Ownership, Management and Changes of Ownership; Health and Safety

§ 201.12. Application for license of a new facility or change in ownership.

§ 201.12a. Notice and opportunity to comment. (New section on final-form.)

§ 201.12b. Evaluation of application for license of a new facility or change in ownership. (Section renumbered on final-form.)

§ 201.13. Issuance of license for a new facility or change in ownership.

§ 201.13a. Regular license. (New section on final-form.)

§ 201.13b. Provisional license. (New section on final-form.)

§ 201.13c. License renewal. (Section renumbered on final-form.)

§ 201.14. Responsibility of licensee.

§ 201.15. Restrictions on license.

§ 201.15a. Enforcement. (New section on final-form.)

§ 201.15b. Appeals. (New section on final-form.)

§ 201.17. Location.

§ 201.22. Prevention, control and surveillance of tuberculosis (TB).

§ 209.1. Fire department service. (Reserved on final-form.)

§ 209.7. Disaster preparedness. (Reserved on final-form.)

§ 209.8. Fire drills. (Reserved on final-form.)

§ 211.1. Reportable diseases.

Rulemaking 4—Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services

§ 201.18. Management.

§ 201.19. Personnel records.

§ 201.20. Staff development.

§ 201.21. Use of outside resources.

§ 201.24. Admission policy.

§ 201.25. Discharge policy. (Reserved on final-form.)

§ 201.26. Resident representative.

§ 201.29. Resident rights.

§ 201.30. Access requirements. (Reserved on final-form.)

§ 201.31. Transfer agreement.

§ 207.2. Administrator's responsibility. (Reserved on final-form.)

§ 209.3. Smoking.

§ 211.2. Medical director.

§ 211.3. Verbal and telephone orders.

§ 211.4. Procedure in event of death.

§ 211.5. Medical records.

§ 211.6. Dietary services.

§ 211.7. Physician assistants and certified registered nurse practitioners.

§ 211.8. Use of restraints.

§ 211.9. Pharmacy services.

§ 211.10. Resident care policies.

§ 211.11. Resident care plan. (Reserved on final-form.)

§ 211.12. Nursing services. (Consolidated amendments on final-form.)

§ 211.15. Dental services.

§ 211.16. Social services.

§ 211.17. Pet therapy.

Comments on Multiple Packages; Stakeholder Engagement

The Department received comments during the public comment periods of all four proposed rulemaking packages expressing concern with the Department's decision to divide the long-term care nursing facility regulations into separate rulemakings. As provided previously, the Department divided the regulatory packages as follows: Rulemaking 1—General Applicability and Definitions; Rulemaking 2—General Operation and Physical Requirements; Rulemaking 3—Applications for Ownership, Management and Changes of Ownership; Health and Safety; and Rulemaking 4—Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services.

Although the Department intended to provide succinct areas for review and comment, commentators expressed some difficulty in reviewing sections of the regulations without the context of the remaining regulatory chapters and concern that multiple regulatory packages may lead to a lack of clarity and confusion for the regulated community and the public. Commentators also requested that the Department consider comments on all four proposed rulemaking packages outside of the 30-day comment period for each proposed package, or that the Department withdraw or resubmit all four proposed rulemaking packages as one package with an additional 30-day comment period. The Department also received comments regarding concern related to recent engagement with stakeholders, given that the Long-Term Care Work Group (LTC Work Group) last formally met in 2018 and was disbanded during the start of the novel coronavirus (COVID-19) COVID-19 pandemic.

In commenting on proposed Rulemaking 1, the Independent Regulatory Review Commission (IRRC) acknowledged the Department's authority to promulgate regulations as it deems appropriate. However, IRRC requested the Department to consider the regulated community's comments and the requests regarding the separate rulemakings. IRRC specifically asked the Department to explain why its approach in dividing the amendments into multiple packages was reasonable. IRRC also asked that the Department ensure that amendments be consistent across the packages, and that the interrelation and any impacts between the packages be clearly presented for the regulated community.

In commenting on proposed Rulemaking 2, IRRC again echoed concerns that separate rulemakings have the potential consequence of inconsistencies and errors across the four packages. IRRC inquired whether having multiple regulatory packages is in the public interest, whether it protects the public health, safety and welfare, and whether it is reasonable and lacks ambiguity. IRRC asked whether it was in the public interest or reasonable to expect the regulated community to hold multiple proposed regulations simultaneously in mind while reviewing a proposed regulation. IRRC also asked the Department to: (1) identify in this final-form preamble any provisions which assume approval of Rulemaking 1 as final-form; (2) cross-reference these provisions to the relevant provisions in Rulemaking 1; and (3) explain the impact if Rulemaking 1 is not approved before or at the same time as Rulemaking 2. IRRC recommended that the Department deliver each of the four individual packages as final-form rulemakings on the same day. In addition, IRRC, in its comment for proposed Rulemaking 3 and Rulemaking 4, expressed the same concerns as in the previous proposed rulemakings, but additionally suggested that the Department consider issuing an Advance Notice of Final Rulemaking to assist in reaching consensus.

Response

At the outset, the Department recognized that the changes to the long-term care nursing facility regulations would be numerous and complex, whether presented in one giant package or in multiple packages. A large single package would have been unwieldy and would likely have been presented around the date that the fourth regulatory package was completed and submitted (May 11, 2022). A later publication date would have resulted in less opportunity for comments, less time for the commentators to study the material and deliberate, and less time for necessary and valuable stakeholder engagement. Further, the regulated community's input throughout this process informed the administration and legislature's investment in this year's budget. As such, the decision was made to continue with the changes in smaller, separate more digestible packages. As provided previously, the Department initially decided to divide the proposed amendments to the six regulatory chapters under Subpart C (relating to long-term care facilities) into multiple packages to allow the public and interested parties a greater opportunity to thoroughly examine and digest the distinct proposed regulatory amendments over a longer period. In dividing these six chapters over four rulemakings, the public and interested parties would be permitted to provide more detailed comments and allow the Department to focus more closely on comments, provide a thoroughly considered response to questions and comments, and tailor the remaining proposed packages based on additional public and stakeholder input.

Further, in response to these public comments, the Department has considered all public comments and IRRC's comments across all four proposed rulemakings before drafting the four final-form rulemakings. In addition, based on comments received, the Department is submitting all four final-form rulemakings to IRRC, the legislative standing committees and the public commentators together on the same day. The drafting and submitting of all four final-form rulemakings together at the end of the last public comment period allows interested

parties and the public to vet and comment on each package separately, as well as in relation to the other packages. Throughout this process, the Department has continued to accept and review comments and be available to meet with stakeholders. If a commentator believed that a proposed amendment in Rulemaking 4 did not align with a proposed amendment in Rulemaking 1, the commentator could submit a comment to that effect for consideration by the Department during the public comment period for the proposed Rulemaking 4.

The Department did, in fact, take into consideration comments received on proposed Rulemakings 1 and 2, when drafting proposed Rulemakings 3 and 4. This is as evidenced by the proposal to expressly include text from the Centers for Medicare & Medicaid (CMS), State Operations Manual, Appendix PP into the text of the regulation. See for example, Proposed Rulemaking 4, Proposed § 201.29(o) (relating to resident's rights). This inclusion of specific text was based on comments received from commentators and IRRC in proposed Rulemaking 1. The Department also consolidated the total number of proposed packages from five to four packages in response to both public and IRRC comments received in proposed Rulemaking 1.

In addition to considering comments on the four proposed packages during and outside of the four public comment periods, the Department met with stakeholders on four occasions following the receipt of public comments to discuss their concerns and to gain additional insight into comments that were received. The first of these meetings, for proposed Rulemakings 1 and 2, occurred on December 15, 2021. Representatives from the American Association of Retired Persons (AARP), Alzheimer's Association—Delaware Valley and Greater Pennsylvania Chapters, Center for Advocacy for the Rights & Interests of the Elderly (CARIE), Community Legal Services, LeadingAge, Pennsylvania Health Care Association (PHCA), Pennsylvania Coalition of Affiliated Healthcare & Living Communities (PACAH), and SEIU Healthcare Pennsylvania (SEIU) attended that meeting. The second meeting, for proposed Rulemaking 3 occurred on June 8, 2022. Representatives from AARP, Alzheimer's Association, CARIE, Community Legal Services, LeadingAge, PHCA, Pennsylvania Health Law Project and SEIU again attended that stakeholder meeting. The Department explicitly stressed to stakeholders during this June 8, 2022, meeting that it would be considering comments on all proposed rulemakings, and that it would welcome any additional comments or feedback that stakeholders might have after the meeting regarding proposed amendments to the various regulatory chapters. The Department also indicated in a press release on proposed Rulemaking 4, issued on June 3, 2022, that it would be considering comments on all four proposed rulemakings before submitting final-form regulations. The third meeting with stakeholders, for proposed Rulemaking 4, occurred on August 3, 2022. Present at that meeting were representatives from AARP, Alzheimer's Association, CARIE, PHCA, Pennsylvania Health Funders Collaborative (PHFC) and SEIU. The Department held the fourth meeting on August 17, 2022. At this meeting, the Department presented stakeholders with an overview of the changes that were made from the proposed rulemakings to the final-form rulemakings in response to their comments, on all four rulemakings, and provided them with an opportunity to comment and provide feedback on the final-form regulations. Present at that meeting were representatives from the Alzheimer's Association, CARIE, Community Legal Services, County Commissioners Association, Disability Rights, LeadingAge, PHCA, PHFC and SEIU.

After consideration of all comments received on the four proposed packages, the Department firmly supports its decision in splitting the six long-term care nursing facility chapters into multiple packages. While the Department appreciates the comments and suggestion for one consolidated package, one is not needed at this stage due to the public, the regulated community, and advocates' full and continued opportunity to offer input on all of the long-term care nursing facilities' regulations throughout the four separate public comment periods, the first of which occurred over a year ago, as well as during the stakeholder meetings that occurred from 2021 through August 2022. In addition, as mentioned previously, at the meeting on August 17, 2022, the Department provided stakeholders an overview of the changes that were adopted on all four rulemakings, to ensure that stakeholders fully understood all amendments. At that meeting, the Department also permitted stakeholders the opportunity to further comment on the final-form amendments and incorporated this feedback into the final-form regulations. Finally, as previously noted, splitting the regulations into multiple, separate packages benefited the public, the regulated community, and advocates because it allowed the Department to incorporate their feedback as it moved forward with the drafting of subsequent packages, which promoted the public interest, health, safety, and welfare by improving the overall quality of the proposed regulations.

The Department has, in each of the four final-form preambles, discussed and responded to all comments received on the contents of the four proposed rulemakings, regardless of when the comment was received. The Department has added cross-references, as appropriate, where comments received on one package relate to another package to further aid in the review of the four packages together in their entirety. For example, in proposed Rulemaking 1, the Department received comments requesting that staff, other than nursing personnel, be considered when determining whether a facility has met the minimum number of direct resident care hours in § 211.12(a)(i) (relating to nursing services). In response to this comment, the types of individuals required for the minimum number of direct resident care hours was intentionally addressed in proposed Rulemaking 4 and generated additional comments during that proposed rulemaking's public comment period. The Department has, therefore, indicated in § 211.12(i) of the preamble for final-form Rulemaking 1, that it received comments on this topic and provided a cross-reference to the more in-depth discussion of this topic in this preamble. Further, to provide additional clarity and readability, the Department moved the proposed language relating to direct resident care hours from proposed Rulemaking 1 to this proposed rulemaking, as discussed in further detail as follows. Finally, the Department has noted where one rulemaking assumes approval of another rulemaking. Through this extended review and public comment process, the Department has been transparent in its proposals and has responded to these comments throughout each rulemaking.

Background and Need for Amendments

The percentage of adults 65 years of age or older in this Commonwealth is increasing. In 2010, approximately 15% of Pennsylvanians were 65 years of age or older. In 2017, this number increased to 17.8%. In 2020, just under 20%

of the population in this Commonwealth was 65 years of age or older. For every 10 individuals under 25 years of age lost in this Commonwealth since 2010, the State gained 21 persons aged 65 or older. This Commonwealth also has a higher percentage of older adults when compared to other states. In 2017, this Commonwealth ranked fifth in the Nation in the number (2.2 million) of older adults and seventh in percentage (17.8%). The increase in older residents of this Commonwealth is expected to continue. It has been estimated that by 2030, there will be 38 older Pennsylvanians (65 years of age or older) for every 100 working-age Pennsylvanians (15 years of age to 64 years of age). Penn State Harrisburg, Pennsylvania State Data Center. (July 2018). Population Characteristics and Change: 2010 to 2017 (Research Brief). Retrieved from https://pasdc.hbg.psu.edu/data/research-briefs/pa-population-estimates; Penn State Harrisburg, Pennsylvania State Data Center (July 2018). Trends in Pennsylvania's Population by Age. (Research Brief) (June 2022). Retrieved from https://pasdc.hbg.psu.edu/sdc/pasdc_files/researchbriefs/June_2022.pdf.

As the number of older Pennsylvanians increases, the number of those needing long-term care nursing will also increase. It has been estimated that an individual turning 65 years of age today has an almost 70% chance of needing some type of long-term services or support during the remainder of their lifetime; 20% will need long-term care support for longer than 5 years. More people use long-term care services at home and for longer; however, approximately 35% utilize nursing facilities for this type of care. Administration for Community Living. (February 2020). How Much Care Will You Need? Retrieved from https://acl.gov/ltc/basic-needs/how-much-care-will-you-need. Approximately 72,000 individuals reside in the 682 long-term care nursing facilities currently licensed by the Department.

The COVID-19 pandemic highlighted the vulnerability of older adults, with a larger percentage of deaths occurring in individuals 65 years of age and older. Centers for Disease Control and Prevention (CDC). Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC. Retrieved from https://stacks.cdc.gov/view/cdc/103602. See also, CDC. COVID-19 Weekly Cases and Deaths per 100,000 Population by Age, Race/Ethnicity and Sex, United States, March 1, 2020—June 25, 2022. Retrieved from https://covid.cdc.gov/covid-data-tracker/#demographicsovertime. Further, it is estimated that deaths of residents in long-term care facilities accounted for at least 34% of all COVID-19 deaths in the United States during the time that the CDC tracked this data. https://covidtracking.com/analysis-updates/what-we-know-about-the-impact-of-the-pandemic-on-our-most-vulnerable-community. In this Commonwealth alone, there have been approximately 11,443 confirmed deaths of residents in long-term care nursing facilities since January 2020. AARP. (September 15, 2022). AARP Nursing Home COVID-19 Dash board Fact Sheets. Retrieved from https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-states.html.

The repercussions of the pandemic have reached far beyond the direct, physical effects of contracting the COVID-19 virus. Lockdowns intended to protect vulnerable residents at the beginning of the pandemic led to social isolation and loneliness because residents were prevented from having in-person contact with their loved ones. This led to an increase in depression and anxiety, cognitive decline and in some cases, physical deterioration, among residents who were already fearful of contracting the virus. Levere, M., Rowan, P., & Wysocki, A. (2021). "The Adverse Effects of the COVID-19 Pandemic on Nursing Home Resident Well-Being." *Journal of the American Medical Directors Association*, 22(5), 948—954.e2. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7980137/. Nursing services personnel, who were already stressed before the pandemic, incurred additional stress from, among other things, shortages in personal protective equipment (PPE), limited access to COVID-19 testing supplies, fear of contracting COVID-19 while at work and spreading it to others, concern for residents under their care, lack of public support and recognition, and an increase in workloads due to the additional protective measures needed to prevent spread of COVID-19 and other nursing services personnel leaving the workforce. White, E.M., Wetle, T.F., Reddy, A. & Baier, R.R. (2021). "Front-line Nursing Home Staff Experiences During the COVID-19 Pandemic." *Journal of the American Medical Directors Association*, 22(1), 199-203. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7685055/.

The Department's long-term care nursing facilities regulations have not been updated since 1999, with the last significant update occurring in 1997 after the 1996 amendment to the Health Care Facilities Act (HCFA or act) (35 P.S. §§ 448.101—448.904b). Since that time, there have been substantial changes in the means of delivering care and providing a safe environment for residents in long-term care nursing facilities, with the pandemic further highlighting the need for change. The Department has been attempting to complete this much needed reform since before the pandemic, in late 2017. At that time, the Department sought assistance and advice from members of the LTC Work Group. The Department worked with the LTC Work Group regularly in 2018. The members of the LTC Work Group were drawn from a diverse background and included representatives from urban and rural long-term care facilities and various stakeholder organizations and consumer groups that work in the area of resident care and delivery of services. The LTC Work Group members consisted of representatives from the following organizations: American Institute of Financial Gerontology; Baker Tilly Virchow Krause, LLP; Berks Heim and Rehabilitation; Fulton County Medical Center; Garden Spot Community; HCR ManorCare; Inglis House; Landis Communities; Leading Age; Legg Consulting Services; LIFE Pittsburgh; Luzerne County Community College; The Meadows at Blue Ridge; Mennonite Home; Lutheran Senior Life Passavant Community; PA Coalition of Affiliated Healthcare and Living Communities; Pennsylvania Home Care Association; University of Pittsburgh; and Valley View Nursing Home. The following State agencies participated: Department of Aging; the Department of Human Services (DHS); and the Department of Military and Veterans' Affairs (DMVA).

The members of the LTC Work Group met regularly during 2018 with the LTC Work Group's primary focus being the simplification and modernization of the existing long-term care regulations. After these discussions were complete, the Department reviewed the recommendations of the LTC Work Group and consulted with other potentially impacted agencies, such as the Department of Aging and the DMVA, in 2019 and 2020. In 2020, 2021 and 2022, the Department continued its efforts to draft amendments to the long-term care nursing facility regulations while also handling the day-to-day challenges of protecting the residents of those facilities, who were being hit the hardest by the COVID-19 pandemic.

As discussed previously, in response to concerns raised by IRRC and commentators, the Department ramped up

its communications with stakeholders by holding the first of four stakeholder meetings, beginning in December 2021, to address comments received on proposed Rulemakings 1 and 2. The Department held a second meeting with stakeholders in June 2022 after the public comment and IRRC comment periods ended for proposed Rulemaking 3, and a third stakeholder meeting in August 2022 after the public and IRRC comment periods ended for proposed Rulemaking 4. The Department held a fourth stakeholder meeting on August 17, 2022, to provide an overview of changes from the proposed rulemakings to the final-form rulemakings and permitted stakeholders to provide additional feedback and comments on amendments during this meeting.

The discussions with stakeholders and the comments received on the four proposed rulemakings have made it abundantly clear that amendments to the current long-term care nursing facility regulations are desperately needed and must not be delayed any longer. Commentators expressed in comments to all four groups that they were pleased to see the Department updating these regulations. The comments in support of amending the regulations can generally be summarized as follows:

• Amendments are long overdue.

• Revisions to existing regulations are urgently needed.

• COVID-19 had a devastating impact on facilities and highlighted the need for revisions.

• Regulations need to be updated to provide additional protections to residents.

Unfortunately, while commentators agree for the most part that an update to the regulations is needed, they do not agree on the extent of the update needed. Some commentators strongly argued that the Department's proposed amendments do not go far enough in protecting residents, while other commentators strongly argued that the Department's proposed amendments go too far and result in a fiscal impact. The Department has considered all comments it received both in favor of and against the proposed amendments and has responded to those comments. In considering those comments and balancing the competing interest of the parties in this regulatory review process, the Department has made revisions from the proposed rulemakings to the final-form rulemakings. The Department has also provided explanations to comments received in the preambles for each of the four final-form rulemakings, as explained more fully in the preceding text.

Public Comments

In response to proposed Rulemaking 4, the Department received comments from 37 public commentators, two form letters, and comments from IRRC. These comments are discussed in further detail as follows IRRC requested that the Department address any provisions that currently expand upon the Federal requirements and which the Department deletes in this final-form rulemaking, as to why the change is reasonable, protects the public health, safety and welfare of residents, and is in the public interest. In addition, IRRC requested cross references to Federal regulations for provisions that are deleted. These provisions, including the applicable Federal cross references, are addressed in each section as follows.

Description of Amendments/Summary of Comments and Responses

§ 201.18. Management

Subsection (a)

Subsection (a) remains deleted in this final-form rulemaking. As explained on proposed, the Department deletes this subsection to eliminate duplication and avoid conflict with the Federal requirements for long-term care nursing facilities. Under 42 CFR 483.70(d)(1) (relating to administration), a facility is required to have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of a facility. All facilities, including the three private-pay facilities, are already required to comply with 42 CFR 483.70(d)(1) under existing § 201.2 (relating to requirements), and will continue to be required to comply with this requirement under amended § 201.2.

One commentator argued that the requirement for a governing body should not be deleted and should be retained in case the Federal requirements change. After careful consideration, the Department declines to retain this subsection in response to this comment. As noted in final-form Rulemaking 1, the Department has chosen to incorporate the Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long term care facilities) as the baseline standards for the minimum health and safety requirements for long-term care nursing facilities. The Department, where necessary, has retained and added requirements to State regulation that exceed the Federal health and safety requirements. However, the Department declines to retain or copy and paste the verbatim Federal requirements into State regulation as some commentators suggested. Under 45 Pa.C.S. § 727 (relating to matter not required to be published), the Department shall omit the text of the *Code of Federal Regulations* when incorporated by reference in documents that are published in the *Pennsylvania Code*. This is similarly prohibited under § 2.14(b) of the *Pennsylvania Code & Bulletin Style Manual (Style Manual)*, as well, which the Department follows in drafting regulations. The Department, therefore, declines, on final-form, to add the requirement in subsection (a) back into regulation. If a future update to the Federal requirements results in provisions being deleted that the Department determines is necessary to be codified in State regulation to ensure the health, safety and welfare of residents, the Department will update its regulations.

Other commentators requested that subsection (a) be retained and strengthened by expanding on and clarifying the duties of the governing body. These commentators seek to have the Department add several requirements to subsection (a). First, they seek to have the Department add a requirement that the facility maintain written documentation to evidence how the governing body was created and by whom and maintain a list of all current and past board members. After careful consideration, the Department declines to make this amendment. In Rulemaking 3, the Department is requiring a facility to submit the names and contact information of any persons who have or will have an interest in the management of the facility as part of the application for licensure under § 201.12(b)(5) (relating to application for license of a new facility or change in ownership). Management includes members of the governing body. In § 201.18(c) (relating to management), as described as follows, the facility will be required to report to the Department changes to this information within 30 days, so the Department will have

a record of current and previous members of the governing body. Also, in final-form Rulemaking 3, in § 201.12(e)(1), a prospective licensee is required to submit a proposed staffing and hiring plan, which shall include the structure of the facility's governing body and its participants. This assumes approval of Rulemaking 3.

The commentators also requested that the Department add a requirement that the governing body be legally responsible for establishing and implementing policies regarding the management and operation of the facility. After careful consideration, the Department declines to make this amendment because it is already required under the Federal requirements in 42 CFR 483.70(d)(1), which provide that the governing body is "legally responsible for establishing and implementing policies regarding the management and operation of the facility." As noted previously, all facilities, including the three private-pay facilities, are already required to comply with 42 CFR 483.70(d)(1) under existing § 201.2, and will continue to be required to comply with this requirement under amended § 201.2.

The commentators requested that the Department add a requirement that the governing body report monthly to the licensee on operational activities including, at a minimum, the items identified in § 201.18(b). After careful consideration, the Department declines to make this amendment because it would be overly prescriptive to instruct the governing body to communicate with the licensee at specific intervals. This is a business decision, and the licensee has an existing responsibility to be aware of issues related to the operation of the facility. It is, therefore, not necessary to mandate monthly reporting by the governing body to the licensee.

The commentators also requested that the Department add a requirement that the governing body appoint the administrator of the facility. After careful consideration, the Department declines to make this amendment because it is already required under the Federal requirements at 42 CFR 483.70(d)(2), which assign responsibility for appointing the administrator to the governing body. All facilities, including the three private-pay facilities, are already required to comply with 42 CFR 483.70(d)(2) under existing § 201.2, and will continue to be required to comply with this requirement under amended § 201.2.

The commentators requested that the Department add a requirement that the governing body actively engage in the establishment of all policies and procedures governing the facility and oversee the quality assurance and performance improvement (QAPI) process. After careful consideration, the Department declines to make this amendment because, as noted previously, the Federal requirements at 42 CFR 483.70(d)(1) already require that the governing body be legally responsible for policies regarding the management and operation of the facility. With regards to the governing body overseeing the QAPI program, that is also required by the Federal requirements at 42 CFR 483.70(d)(3) and 42 CFR 483.75(f) (relating to emergency preparedness). The commentator also recommended that the governing body be required to review the projects, provide oversight and analyze outcomes to ensure that the QAPI program is performing effectively. This is also generally covered by the Federal requirements at 42 CFR 483.75(f), which among other things, requires the governing body to be responsible and accountable for ensuring that the QAPI program identifies and prioritizes problems and opportunities based on performance indicator data and that corrective actions address gaps in systems and are evaluated for effectiveness. The Department notes that all facilities that participate in Medicare or Medical Assistance (MA) are required to comply with 42 CFR 483.70(d)(3) and 42 CFR 483.75(f), but this will be a new requirement for the three private-pay facilities. This response, therefore, assumes approval of final-form Rulemaking 1, in which the Department expands the incorporation of the Federal requirements in § 201.2.

In addition, the commentators requested that the Department add a requirement that the administrator present, at least quarterly, a detailed description of the QAPI projects being performed by facility staff and the results of QAPI projects completed. After careful consideration, the Department declines to make this amendment. The administrator is already required to maintain an ongoing relationship with the governing body under existing § 201.18(e)(3), which would necessarily involve communicating with the governing body. In addition, as described below, the Department adds language to § 201.18(e)(3) on final-form to require that the administrator maintain a relationship with the governing body through meetings and reports, which shall occur as often as necessary but at least monthly. Because the governing body is ultimately responsible for the QAPI program, the governing body could request that information about the QAPI program be included in some or all of those regular reports, depending on the current activities of the QAPI program. In addition, this amendment requires meetings and reports with medical and nursing staff and other professional and supervisory staff as often as necessary, but at least on a monthly basis.

Subsection (b)

Subsection (b) is amended from the proposed rulemaking to this final-form rulemaking. As explained on proposed, the Department adds language at the beginning of this subsection to clarify that the requirements in this subsection are in addition to the Federal requirements at 42 CFR 483.70(d). The Department also adds the words "of a facility" after "governing body" to make it clear that the governing body of a long-term care nursing facility shall perform the tasks delineated in paragraphs (1) through (3) of subsection (b). Some commentators recommended that the Department add a requirement to this subsection for the return of any resident property remaining at the facility within 10 business days after the resident's discharge or death. Another commentator simply suggested that the Department establish a deadline for the return of personal property. Commentators indicated that they were requesting this amendment because some facilities delay or do not return property at all. Under the Federal requirements at 42 CFR 483.10(f)(10)(v) (relating to resident rights), a facility is required to return resident funds within 30 days, but there is no requirement related to the return of personal property. The Department agrees that the addition of a requirement related to the return of personal property into regulation is appropriate, and therefore, in this final-form rulemaking, adds a requirement to the end of subsection (b)(2) for the return of personal property. The Department, however, aligns the timeframe with the Federal requirement related to resident funds, by requiring the return of personal property within 30 days after discharge or death.

Subsection (c)

Subsection (c) is amended from the proposed rulemaking to this final-form rulemaking. The Department proposed to replace the words "provide the information required in § 201.12 and prompt reports of changes

which would affect the accuracy of the information required" with the words "report to the Department within 30 days changes to the information that was submitted with the facility's application for licensure under § 202.12 (relating to application for licensure of a new facility or change in ownership)" to clarify the governing body's responsibility with respect to the information submitted under § 201.12. It is a prospective licensee's responsibility to submit the information required under § 201.12 with the application for licensure. Once an application for licensure is approved, the governing body becomes responsible for reporting to the Department any change to the information that was submitted with the application for licensure. The Department proposed to require that changes be reported within 30 days to align with § 51.4 (relating to change in ownership; change in management), which requires notification to the Department at least 30 days prior to a transfer involving 5% or more of stock or equity, a change in ownership or a change in management.

Commentators generally supported the Department's proposal to require that facilities report changes to the information included in a facility's application for licensure within 30 days of the change. One commentator requested that the Department clarify exactly what information must be reported to the Department to reduce the risk of accidental violations due to an oversight or misinterpretation of the regulation. The Department made various amendments on final-form to § 201.12 in Rulemaking 3. After finalizing these amendments, the Department reviewed the complete list of information that must be submitted with an application for licensure and determined that only changes to the information required under § 201.12(b)(1) through (6) must be reported to the Department within 30 days. The Department, in this final-form rulemaking, therefore, amends this subsection to require only changes to the information under these subsections be reported to the Department within 30 days. The information in § 201.12(b)(1) through (6) includes the names and contact information for the facility's owners, nonprofit officers and directors, partners, the administrator, those who have a management interest in the facility, and the facility's officers and board of directors, and represents the information that correlates most directly to the ownership and management of a facility. This assumes approval of Rulemaking 3.

Other items that must be submitted with the application, which do not have to be reported to the Department within 30 days of a change, are the requirements set forth in § 201.12(b)(7) through (13) and (e). The items listed in those subsections are required to be submitted with the application for licensure so the Department can determine whether a prospective licensee is a responsible person under the act to own and operate a long-term care nursing facility. Once the prospective licensee becomes licensed, the Department uses surveys to measure compliance with the regulations and does not need this background information to be updated. For example, the Department does not need for the licensee to continuously update their regulatory history in other jurisdictions, which is required in § 201.12(b)(10). The Department also decided not to require that the information in § 201.12(b)(8) be updated within 30 days because the Department decided in final-form Rulemaking 3 to make the financial report an annual requirement, which will be submitted with a facility's application for renewal in § 201.13c (relating to license renewal). This assumes approval of Rulemaking 3.

Another commentator urged the Department to establish a policy of conducting visits to facilities after each report of a change in the information included in the application for licensure to ensure that the new owners are providing residents with appropriate care. After careful consideration and balancing the frequency of existing surveys, the Department declines to add this amendment. For new facilities, the Department conducts an occupancy survey before a facility opens, a survey after the facility opens, and a survey for certification once the facility has a few residents. The Department also conducts surveys of all facilities on an annual basis. Further, the Department conducts a survey of a facility when a complaint is received, including subsequent unannounced examinations. Lastly, to the extent any deficiencies were previously identified by a prior owner of a facility, a new owner is required to correct these deficiencies to retain a facility license.

Subsection (d)

Subsection (d) is amended from the proposed rulemaking to this final-form rulemaking. The Department had proposed to delete the first sentence in subsection (d), which requires the governing body to adopt effective administrative and resident care policies and bylaws governing the operation of the facility, to eliminate duplication and avoid conflict with the Federal requirements. In the second sentence of subsection (d), the Department had proposed to add a cross-reference to 42 CFR 483.70(d)(1) for clarity. The Department also deletes the phrase "shall be made available to the members of the governing body, which shall ensure that they are operational," because it is unnecessary and redundant. Finally, the Department replaces the term "responsible persons" with the term "resident representatives" in the third sentence for consistency in the use of the term "resident representatives" throughout the final-form rulemakings.

Some commentators objected to the deletion of the first sentence, urging the Department to retain the requirement that the governing body adopt administrative and resident care policies and bylaws. In response to these comments, the Department further examined the requirement in 42 CFR 483.70(d)(1) and agrees that it does not rise to this level of specificity. The Department, therefore, in this final-form rulemaking, retains the first sentence of existing subsection (d) and deletes the cross-reference to 42 CFR 483.70(d)(1) in the second sentence.

A commentator also suggested that the policies and bylaws required in this subsection be reviewed on an annual basis. The Department agrees with this suggested amendment, and in this final-form rulemaking, amends the second sentence in this subsection to require that the policies and bylaws be reviewed and revised "as often as necessary but at least annually."

Subsection (d.1)

Subsection (d.1) is amended from the proposed rulemaking to this final-form rulemaking. As explained on proposed, the Department moves the requirement in existing subsection (e) into subsection (d.1) with minor amendments. The Department replaces language requiring the governing body to appoint an administrator with a cross-reference to that requirement in 42 CFR 483.70(d)(2) of the Federal requirements. The Department retains the requirement that the administrator be currently licensed and registered in this Commonwealth and that the administrator be full-time. The Department removes the requirement in existing subsection (e) that a facility, with 25 beds or less, seek an exception to share an administrator with another facility. The Department

adds language, in subsection (d.1), to permit a facility with 25 beds or less to share an administrator provided they meet certain conditions, set forth in paragraphs (1) through (5).

Some commentators expressed support for the addition of the requirements in this subsection that allow a facility with fewer than 25 beds to share an administrator. Commentators stated that the requirements are reasonable and eliminate the need for a facility to request an exception to the regulations to share an administrator, as was previously required in subsection (e). In this final-form rulemaking, the Department amends paragraph (3) to include the words "and resident representatives" after the word "resident." This amendment is in response to a comment recommending that there be a readily available method for resident representatives as well as residents to contact the administrator should they find it necessary.

One commentator and IRRC asked about the requirement in paragraph (4) that requires facilities that share an administrator to have a director of nursing with "adequate knowledge and experience to compensate for the time the administrator is not in the building." The commentator asked what is meant by "adequate knowledge and experience" and how that determination would be made. IRRC further asked what standards will determine "adequate knowledge and experience" and asked the Department to clarify this provision to establish enforceable standards that can be predicted by the regulated community. On final-form, the Department amends paragraph (4) by replacing the phrase "adequate knowledge and experience" with "at a minimum, knowledge and experience of the facility, its policies and procedures and resident needs" to clarify the type of knowledge and experience that the director of nursing needs to have in order to fulfill the role of the shared administrator when they are not in the building. Specifically, administrators are knowledgeable with the details of a facility, including its policies and procedures and needs of the residents. This type of knowledge needs to be available in an administrator's absence to ensure that there is always someone onsite who is equipped to respond to issues or emergencies that may arise, when that role is shared between two facilities with 25 beds or less.

Subsection (d.2)

This subsection is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department moves the requirement in the fourth sentence of subsection (e) into this subsection. The Department moves this requirement to its own subsection for clarity and ease of readability. One commentator requested that the Department amend this subsection to require that the administrator's "normal work schedule" be posted so that it does not have to be adjusted if the administrator needs to be absent without much notice. Other commentators requested that the Department add language requiring that the schedule include the days and times the administrator will be physically present in the building. IRRC also asked the Department to clarify the standards for implementation of this provision and what the expectations are for updating the accuracy of the schedule, and how often it is to be posted. IRRC specifically asked whether the schedule is to be posted daily or weekly, and whether the schedule can be a "normal" or "anticipated" schedule. IRRC also asked whether the schedule must be updated if the administrator gets sick. In response to these comments, in this final-form rulemaking, the words "anticipated biweekly work" are added before the word "schedule" to clarify the frequency and time when the administrator will be working. Further, the Department added the requirement that the administrator's "anticipated work schedule shall be updated within 24 hours of a change." This biweekly work schedule is required to be posted and kept up-to-date to, at a minimum, inform residents, resident representatives, staff and other visitors of the times the administrator is generally available and onsite.

Some commentators recommended that, in addition to the administrator's schedule being posted in the facility, it also be posted on a facility's public web site. After careful consideration, the Department declines to make this amendment due to potential personal security concerns, access by others unrelated to the facility and the unintended consequence of requiring facilities to maintain a public web site.

The same commentators suggested that the staffing numbers for all types of staff also be posted in the facility and on the facility's web site. The Department notes that, under 42 CFR 483.35(g) (relating to nursing services), a facility is already required to post, on a daily basis, the total number of hours worked by nursing personnel. That section also requires the information to be posted "in a prominent place readily accessible to visitors" as well as requiring that the facility "make nurse staffing data available to the public for review at a cost not to exceed the community standard." Facilities that participate in Medicare or MA are already required to comply with 42 CFR 483.35(g). This will be a new requirement for the three private-pay facilities under amended § 201.2 in final-form Rulemaking 1. This assumes approval of Rulemaking 1. The Department, however, declines to require staffing numbers for all staff types to be posted on a facility's web site due to the unintended consequence of requiring facilities to maintain a public web site.

Subsection (e)

The main body of subsection (e) is amended from the proposed rulemaking to this final-form rulemaking. A commentator suggested that the Department add a requirement for the administrator to engage in an analysis of all financial information relevant to the operation of the facility and participate in the development of the facility's budget in conjunction with the governing body and licensee. The Department, in response to this comment, adds a cross-reference to the beginning of this subsection, to 49 Pa. Code § 39.91 (relating to standards of professional practice and professional conduct for nursing home administrators). Under 49 Pa. Code § 39.91, an administrator of a facility is required to provide or recommend the development of a budget, among other items related to financial management.

As explained in the proposed rulemaking, the Department also deletes the requirement in the first sentence of this subsection and moves it to subsection (d.1), with amendments. The Department also deletes the next two sentences. The ability of a facility to share an administrator is contemplated through the addition of the language in subsection (d.1), which will permit facilities with 25 beds or less to have a part-time administrator if the requirements in subsection (d.1)(1)—(4) are met. As noted previously, the Department also deletes the requirement in the fourth sentence and moves it, with amended language discussed previously, into subsection (d.2). Amendments to paragraphs (1) through (7) are described more fully as follows.

Paragraph (1)

Paragraph (1) is unchanged from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to paragraph (1).

Paragraph (2)

Paragraph (2) is unchanged from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to paragraph (2).

Paragraph (2.1)

Paragraph (2.1) is amended from the proposed rulemaking to this final-form rulemaking. The Department had proposed to move into paragraph (2.1) existing language from § 207.2(a) (relating to administrator's responsibility), requiring an administrator to ensure satisfactory housekeeping and maintenance of the building and grounds. The Department proposed this amendment so that the administrator's responsibilities are all together in one place in the regulations. Although this was existing language and, therefore, already required by the regulated community, a commentator questioned the meaning of the word "satisfactory" before the word "housekeeping," commenting that this qualifier is vague and could be widely interpreted based on an individual's personal standards. IRRC also asked what standards will determine "satisfactory housekeeping" and asked the Department to clarify this provision to establish enforceable standards that can be predicted by the regulated community.

In response to these comments, the Department amends § 201.18(e)(2.1), in this final-form rulemaking, to add the words "that a sanitary, orderly and comfortable environment is provided for residents through" before the word "satisfactory." The addition of this language clarifies these standards and aligns with a resident's right to a safe, clean, comfortable and homelike environment in 42 CFR 483.10(i), and the requirement in 42 CFR 483.10(i)(2) that a facility must provide housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior. Although the Federal requirement does not express who within the facility is responsible for this task, existing § 207.2(a) assigned this responsibility to the administrator. The Department is maintaining this requirement in State regulation, but moving it to § 201.18(e)(2.1) with the previously noted amendment. All facilities, including the three private-pay facilities, are currently required to comply with 42 CFR 483.10(i) under existing § 201.2.

Paragraph (3)

Paragraph (3) is amended from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to paragraph (3). However, some commentators recommended that there be a requirement that the administrator report to the governing body at least monthly regarding the operation of the facility, including survey results, allegations of abuse or neglect, complaints or other information related to the safety of the facility's residents. They also suggested that the regulations require the governing body to respond in writing to the report within 30 days with a plan to address noncompliant conduct.

In response to these comments, the Department amends paragraph (3), in this final-form rulemaking, to require the administrator to report as often as necessary, but at least monthly to the governing body. In addition, this amendment requires meetings and reports with medical and nursing staff and other professional and supervisory staff as often as necessary, but at least on a monthly basis. Further, the word "periodic" is deleted before the word "reports." The Department, however, declines to add a requirement that the administrator prepare and submit a report that meets specific criteria and that the governing body respond to the report in writing within a certain period. Under this paragraph, the administrator is already required to maintain an "ongoing relationship with the governing body." Additionally, under 42 CFR 483.70(d)(2)(iii), the administrator reports to and is accountable to the governing body. If the governing body, which is responsible for implementation of the policies related to the management and operation of the facility, wishes to require additional or more specific reporting of certain information from the administrator, it may do so. Facilities that participate in Medicare or MA are already required to comply with 42 CFR 483.70(d)(2)(iii). This will be a new requirement for the private-pay facilities under the expansion of the Federal requirements in amended § 201.2, in final-form Rulemaking 1. This assumes approval of Rulemaking 1.

Some commentators suggested that the facility assessment process also include a detailed review of operations by the governing body. After careful consideration, the Department declines to make this amendment. As further discussed in final-form Rulemaking 3, under § 201.14 (relating to responsibility of licensee), facility assessments are focused on residents' needs and the resources needed to care for them, including staffing and training needs. To emphasize this focus and maintain congruency with Federal requirements under 42 CFR 483.70(e), the Department declines to make this change.

Paragraph (4)

Paragraph (4) is unchanged from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to paragraph (4).

Paragraph (5)

Paragraph (5) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department replaces the term "employe" with the term "employee" for correct usage and spelling of that term.

Paragraph (6)

Paragraph (6) is unchanged from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to paragraph (6).

Paragraph (7)

Paragraph (7) is unchanged from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to paragraph (7).

In addition to the previous comments received to paragraphs (1) through (7), some commentators recommended that the administrator also be responsible for clearly and openly communicating to residents and resident representatives any updates about the composition of or decisions made by the governing body. After careful consideration, the Department declines to make this amendment on final-form. It may not be necessary for residents to be informed of every decision made by the governing body. Decisions that impact residents, such as changes to policies, should be communicated by the facility to residents. This is required communication under various notice provisions of the Federal regulations. See for example, 42 CFR 483.10(c), (f)(4)(v) and (vi), (g)(1), (12), (16), (18) and (j)(4). With regards to communicating "clearly and openly," this is also addressed

under the Federal requirements. Under 42 CFR 483.10(g)(3), the facility is required to provide information to each resident in a form and manner the resident can access and understand. Facilities that participate in Medicare or MA are already required to comply with 42 CFR 483.10(g)(1) and (3). Further, the three private-pay facilities are already required to comply with 42 CFR 483.10(g)(1) under existing § 201.2. However, the requirement in 42 CFR 483.10(g)(3) regarding clear communications will technically be a new requirement for the three private-pay facilities under amended § 201.2 in final-form Rulemaking 1. This assumes approval of Rulemaking 1.

Subsection (f)

Subsection (f) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department replaces the term "responsible person" with the term "resident representative" for consistency in the use of that term throughout the regulations. The Department also deletes the words "and funds" and the phrase "and for expenditures and disbursements made on behalf of the resident" to eliminate duplication and avoid conflict with the Federal requirements at 42 CFR 483.10(f)(10) and (11), which address the facility's responsibility for resident funds.

Some commentators disagreed with the deletion of the language related to funds and expenditures and disbursements made on behalf of a resident, asserting it is important that a facility maintain a complete record regarding use of resident funds. Commentators asserted that the existing provision is more protective than the Federal requirements, with one commentator noting that the existing language requires the record of use of funds be always available, while the Federal requirements provide for financial records to be available to residents through quarterly statements. IRRC asked that the Department explain the need for and reasonableness of residents only receiving quarterly statements.

Contrary to these comments, a complete record is required under 42 CFR 483.10(f)(10)(iii)(A), which states that the facility must "establish and maintain a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf." In addition, under 42 CFR 483.10(f)(10)(iii)(C), an individual financial record must be available to the resident "through quarterly statements *and upon request*" (emphasis added). This means that a written record must be maintained and may be requested by a resident at any time. The Department, therefore, declines to amend subsection (f) in response to comments. Facilities that participate in Medicare or MA are already required to comply with 42 CFR 483.10(f)(10)(iii)(C). This will be a new requirement for the three private-pay facilities under the expansion of the Federal requirements in amended § 201.2, in final-form Rulemaking 1. This assumes approval of Rulemaking 1. IRRC also asked the Department to explain how the final regulation protects the public health, safety and welfare related to records of residents' personal possessions. The Department did not propose any changes in this subsection related to what the facility must do related to residents' personal possessions, and that standard remains the same in this final-form rulemaking. Under these provisions, a facility is required to maintain a written record on a current basis for each resident with written receipts for personal possessions received or deposited with the facility. This record is also available upon request. In addition, the Department has added in this final-form rulemaking, a requirement related to the return of personal property in § 201.18(b)(2) in response to comments, as explained further in that section.

Subsection (g)

Subsection (g) remains unchanged from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to this subsection.

Subsection (h)

Subsection (h) is amended from the proposed rulemaking to this final-form rulemaking. As explained on proposed, the Department replaces the term "resident's responsible person" with "resident representative" for consistency in the use of that term throughout the regulations. The Department also deletes the last sentence requiring a facility to provide the resident with access to their money, either cash or check, within 3 business days when requested by the resident. The Department updates this provision with a requirement that a facility provide the resident with cash, if requested, within 1 day of the request, or with a check, if requested, within 3 days of the request. The requirement that a facility provide a resident with cash, if requested within 1 day was new, on proposed. As explained by the Department, on proposed, based on the discussions with the LTC Work Group, facilities typically have enough cash on hand, or can obtain cash quickly, and therefore, should be able to provide a resident with cash, if requested, within 1 day. The Department is requiring that a check be provided, if requested, within 3 days because specific personnel are often needed to process a check and these personnel may not be onsite every day.

Some commentators opposed the amendments to this subsection, arguing that allowing a facility 3 days to provide a check to a resident is unnecessary, and that residents should have access to their funds almost immediately after a request is made. Some commentators suggested that all requests be processed within 1 day of the request, including requests for checks. Other commentators opposed the requirements in this section because of the challenges facilities could encounter fulfilling requests for funds. One commentator suggested that a facility only be required to provide cash within 1 day if the amount requested is $100 or less, while greater amounts be provided within 1 bank business day. Another commentator recommended that the section be amended to require the requests for cash and checks to be provided within 1 and 3 business days, respectively. This commentator asserted that most facilities do not have ATM cards for residents. In balancing the competing interest between consumer advocates and industry stakeholders, the Department will maintain the number of days required to respond to resident requests for funds by means of cash or check, as provided on proposed. IRRC noted that the Department in the proposed rulemaking removed the words "bank business" from the regulation and asked the Department to clarify how days are to be counted for implementation of this final-form rulemaking. In accordance with the Rules of Statutory Construction, the language "day" is interpreted as calendar days. 1 Pa.C.S. § 1991 (relating to definitions); 1 Pa. Code § 1.7 (relating to Statutory Construction Act of 1972 applicable). Given the increased accessibility of funds since the original promulgation of this provision and in balancing residents' access to their funds with a facility's business practices the Department is maintaining the time period as provided on proposed.

Some commentators pointed out that there is no recognition in this subsection of the possibility of electronic

transfer of funds. These commentators recommend that there be an acknowledgement of this option and a corresponding requirement that electronic transfer of funds be processed within 1 day. The Department agrees. In response to this comment, subsection (h) is amended in this final-form rulemaking to include a requirement that, if a facility utilizes electronic transfers, the facility shall initiate an electronic transfer of funds, if requested, within 1 day of the request.

§ 201.19. Personnel records

The title and main body of this section are unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department amends the name of this section from "personnel policies and procedures" to "personnel records," as this title more accurately describes the requirements of this section. The Department also replaces the term "employe" with the term "employee" to reflect the current usage and spelling of that term. The Department also adds the word "facility" before the word "employee" to clarify that this section applies to employees of the facility. The Department replaces the word "sufficient" with the words "the following" and deletes "to support placement in the position to which assigned" after the word "information." As explained on proposed, these amendments reflect the addition of several new requirements in paragraphs (1) through (9) of this section, as further explained as follows.

Paragraph (1)

Paragraph (1) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department is codifying that the personnel records for each facility employee contain the employee's job description, educational background and employment history. This requirement is currently part of the Department's interpretive guidelines for this section. The Department is codifying this requirement in this section for clarity. Department of Health Interpretive Guidelines. Retrieved from https://www.health.pa.gov/topics/facilities/nursing%20homes/Pages/Regulations.aspx.

Paragraph (2)

Paragraph (2) is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department is codifying the current requirement that the personnel records for each facility employee contain employee performance evaluations. The Department is codifying this requirement for clarity. Some commentators recommended that an employee's personnel record include documentation of any monitoring, performance or disciplinary action related to the employee. The Department agrees that information related to an employee's past performance is important to retain on file and is relevant to protecting the health, safety and welfare of residents. The Department, therefore, amends this paragraph in this final-form rulemaking to add "including documentation of any monitoring, performance or disciplinary action related to the employee" after the word "evaluations."

Paragraph (3)

Paragraph (3) is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department is codifying the current requirement that the personnel records for each facility employee contain documentation of current certification, registration or licensure, if applicable, for the position to which the employee is assigned. The Department is including this requirement in regulation to make it clear that facilities are expected to include this item in employee personnel records. Some commentators suggested that all the employee's credentials be included in the employee's personnel record. One commentator recommended that this paragraph be amended to include the words "all credentials including but not limited to" before the words "current certification." The Department agrees that a requirement for credentials is reasonable, as the employee could have other relevant credentials that are not contemplated by the Department's requirement for "current certification, registration or licensure." The Department, therefore, in this final-form rulemaking, adds the words "credentials, which shall include, at a minimum" before the words "current certification, registration or licensure."

Paragraph (4)

Paragraph (4) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department is codifying the current requirement that the personnel records for each facility employee contain a determination by a health care practitioner that the employee, as of the employee's start date, is free from the communicable diseases or conditions listed in § 27.155 (relating to restrictions on health care practitioners). The Department is codifying this requirement for clarity.

Paragraph (5)

Paragraph (5) is amended from the proposed rulemaking to this final-form rulemaking. In the proposed rulemaking, paragraph (5) mirrored an existing requirement for hospitals under § 103.36 (relating to personnel records). Although the Department did not receive any comments on this paragraph, based on comments to § 201.21(e) (relating to use of outside resources), the Department has removed the "physically able" language to clarify that it is not the intent of this provision to have any impact on an individual's disability, if any, or to impact a facility's reasonable accommodation under the Americans with Disabilities Act (42 U.S.C.A. §§ 12101—12213). In this final-form rulemaking, this paragraph is clarified to require that an employee personnel file contain records relating to a medical exam, if required by a facility, or attestation that the employee is able to perform the employee's job duties.

Paragraph (6)

Paragraph (6) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department is requiring that the personnel records for each facility employee contain documentation of the employee's orientation to the facility and the employee's assigned position prior to or within 1 week of the employee's start date. This requirement is currently part of the Department's interpretive guidelines for this section. The Department is including this requirement in regulation to make it clear that facilities are expected to include this item in employee personnel records.

Paragraph (7)

Paragraph (7) is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department is requiring that the personnel records for each facility employee contain documentation of the employee's completion of required trainings. This requirement is currently part of the Department's interpretive guidelines for this section. The Department is including this requirement in regulation to

make it clear that facilities are expected to include this item in employee personnel records. Some commentators suggested that an employee's personnel record include a record of all training the employee receives. One commentator recommended that this paragraph be amended to include the words "initial, annual, and ongoing" before the word "training." In response to this comment, the Department adds "under this chapter, including documentation of orientation and other trainings" to clarify that documentation of completed trainings must include all trainings required under this chapter.

Paragraph (8)

Paragraph (8) is amended from the proposed rulemaking to this final-form rulemaking. In the proposed rulemaking, this paragraph provided for the recordkeeping of an employee's criminal history record. In consideration of public comments and comments received from IRRC, the Department is clarifying the language in this final-form rulemaking that a copy of the final report from the Pennsylvania State Police and the Federal Bureau of Investigation be maintained in accordance with section 502 of the Older Adults Protective Services Act (OAPSA) (35 P.S. § 10225.502), the Adult Protective Services Act (35 P.S. §§ 10210.101—10210.704) and applicable regulations. Under these statutory and regulatory provisions, there is an existing requirement for the submission of a criminal history background check for individuals applying for employment in a long-term care nursing facility. Further, the Commonwealth Court's decision in *Peake v. Commonwealth*, 132 A.3d 506 (Pa. Cmwlth. 2015) (holding statutory lifetime employment bans to be facially unconstitutional with consideration of relevant factors) does not impact the statutory requirement to submit a criminal background check, as further detailed as follows.

One commentator recommended that the Department require comprehensive National background checks for all long-term care facility employees. The commentator asserted that background checks protect consumers. The Department appreciates this comment and agrees that criminal background checks are a consumer protection and must be obtained in accordance with law. As provided previously, applicants for employment are required to obtain a criminal background check in accordance with section 502 of OAPSA, the Adult Protective Services Act and the applicable agency's regulations. Further, the Department is supportive of legislative updates to the criminal background and employment provisions under OAPSA through the legislative process to provide further protections to consumers and address the employment ban provision decided in *Peake*. In addition, another commentator recommended this section be amended to require that other background checks be maintained as part of the personnel file. However, it is unclear what is intended with the suggested "other background checks" language. As provided previously, the Department is clarifying this language in this final-form rulemaking to specify that a personnel record include a copy of the final report from the Pennsylvania State Police and the Federal Bureau of Investigation in accordance with the Older Adult Protective Services Act, the Adult Protective Services Act, and the applicable regulations.

Paragraph (9)

Paragraph (9) is amended from the proposed rulemaking to this final-form rulemaking. In the proposed rulemaking, the Department added this paragraph to require, in the event that an employee has a conviction, that a facility include in the employee's personnel record a determination of the employee's suitability for employment in the position to which the employee is assigned. The Department recognizes that hiring decisions should be made on a case-by-case basis, and are dependent upon individual circumstances. For resident safety, this provision requires a facility document that the facility determine an applicant or employee's suitability for employment when the applicant or employee has been convicted of a criminal offense. This language is in response to the Commonwealth Court's decision in *Peake*, which determined statutory lifetime bans to be unconstitutional without the consideration of various factors. IRRC also inquired regarding the type of information to be included and the reasonableness of this requirement. Further, IRRC inquired whether this provision is consistent with the Commonwealth Court's decision in *Peake*. In addition, a commentator asserted there may be attorney-client privilege concerns related to suitability for employment determination in a personnel file.

After careful consideration of the comments received, the Department clarifies this language to provide that documentation of a determination of suitability for employment be maintained in a personnel file. The Department adds a definition of "suitability for employment" to further clarify this provision. As defined, "suitability for employment" includes a review of the offense; the length of time since the individual's conviction; the length of time since incarceration, if any; evidence of rehabilitation; work history; and the employee's job duties. These factors are consistent with the factors to be considered as articulated in *Peake*. Specifically, the Department is not requiring an employment ban, but instead is requiring documentation that a facility considered these enumerated factors as a consumer protection. In addition to this provision, the Department continues to support legislative amendments to the Older Adults Protective Services Act to update consumer protections and address the court's decision in *Peake* regarding statutory lifetime employment bans. In response to comments regarding attorney-client privilege, the Department is clarifying that it does not intend to have privileged documents between the facility and its counsel as part of an employee's personnel record. Instead, this requirement is to provide documentation that the facility considered the enumerated factors when hiring or maintaining an employee when that person is convicted of a criminal offense.

Paragraph (10)

This paragraph is added in this final-form rulemaking and is added at the request of commentators to require that the personnel records for each facility employee contain the employee's completed employment application. This requirement is reasonable and likely a common business practice. The Department, therefore, adds this requirement in this final-form rulemaking.

Other comments

A commentator stated generally that personnel records should not be limited to what is listed in this section of the regulations. The Department agrees that other information may be kept on file, in conformance with the law, to meet the needs of the facility. The requirements under Subpart C are minimum health and safety requirements for licensure in this Commonwealth. The Department notes there is nothing in this section that should be construed as limiting the contents of personnel record files. Rather, this section is intended only to set forth the minimum requirements for a facility. Facilities are encouraged to go beyond the minimum standards to set forth additional requirements to meet the needs of the facility and the residents.

Some commentators recommended that, in addition to the requirements in paragraphs (1) through (9), an employee's personnel record include a record of the employee's receipt of required vaccinations. The only vaccine that is currently required is the COVID-19 vaccine. Current Federal requirements related to COVID-19 vaccinations are found at 42 CFR 483.80(i) (relating to infection control), which requires a facility to develop and implement policies and procedures to ensure staff is vaccinated for COVID-19. All facilities that participate in Medicare or MA are required to comply with 42 CFR 483.80(i). This will be a new requirement for the private-pay facilities by virtue of the expansion of the incorporation of the Federal requirements in § 201.2 in Rulemaking 1. This assumes approval of Rulemaking 1. Currently, when demonstrating compliance with 42 CFR 483.80(i), facilities usually maintain this information in the aggregate and in one place, along with all necessary documentation related to the facility's compliance with vaccination-related policies and procedures. For example, under 42 CFR 483.80(i)(3)(iii), a facility is required to have a process for ensuring the implementation of additional precautions for staff who are not fully vaccinated, and under 42 CFR 483.80(i)(3)(vii), a facility is required to have a process for tracking exemptions. The most streamlined approach for ensuring compliance with vaccination requirements at this time is to permit a facility to use a centralized process, rather than requiring that they separately maintain information related to the employee's vaccination status in the personnel record for each employee. Therefore, the Department declines to add a requirement that vaccination status be maintained in each employee's personnel record.

One commentator disagreed with the Department's proposal to rename this section to "personnel records" and instead recommended that the Department rename this section to broaden its contents to cover all facility policies and procedures. In addition, the commentator recommended that the Department require, under this section, that a facility have written policies and procedures related to several specific topics, described as follows. The Department declines to make this amendment in this final-form rulemaking for the reasons identified as follows.

First, the commentator recommended language requiring facilities to have policies and procedures related to "hygiene, infection control and tracking resident interactions (for contract tracing)." This requirement is not added in this final-form rulemaking because this would be duplicative of Federal requirements at 42 CFR 483.80(a), which provide that the facility's infection prevention and control program must include written standards, policies and procedures for the program. The requirement for written standards, policies and procedures for infection control will technically be a new requirement for the three private-pay facilities under the expansion of the incorporation of the Federal requirements in § 201.2 in Rulemaking 1. This assumes approval of Rulemaking 1.

Next, the commentator recommended that the regulations include a requirement that facilities have written policies and procedures related to "hiring, staffing, staff sick time and sick pay and other family leave policies." While in practice a facility should have these policies, the Department declines to prescribe a facility's internal employment policies, such as policies related to the accrual of leave and other employment and human relations matters. The purpose of the Department's authority under the act is to provide minimum licensure standards to protect the health, safety and welfare of residents of long-term care nursing facilities. Further, employment and labor related policies and procedures are outside of the Department's grant of statutory authority. Therefore, the Department declines to make this amendment in this final-form rulemaking.

Next, the commentator recommended that the regulations include a requirement that facilities have written policies and procedures related to cultural nondiscrimination. The Department has included in § 201.29, as amended in this final-form rulemaking, protections from discrimination on the basis of race, color, familial status, religious creed, ancestry, age, sex, gender, sexual orientation, gender identity or expression, national origin, ability to pay, handicap or disability, use of guide or support animals because of the blindness, deafness or physical handicap of the resident or because the resident is a handler or trainer of support or guide animals. In addition, specific Federal requirements also address the protection of a resident's cultural preferences. For example, under 42 CFR 483.10(c)(3)(iii), in the development and implementation of a resident's person-centered plan of care, the planning process must incorporate a resident's personal and cultural preferences in developing goals of care. Similarly, when preparing foods and meals, a facility must take into consideration residents' religious, cultural and ethnic needs and preferences and the overall cultural and religious make-up of the facility's population. 42 CFR 483.10(f)(2); 483.60(c) (relating to food and nutrition services). All facilities will be required to comply with these regulatory requirements, by virtue of § 201.2, as amended in Rulemaking 1. This assumes approval of Rulemaking 1. The Department therefore declines to make this amendment.

Next, the commentator recommended that the regulations include a requirement that facilities have written policies and procedures related to "guaranteed access to the facility (for LTC Ombudsman, Protective Services, surveyors, etc.)." The right to receive visitors is set forth in the Federal requirements at 42 CFR 483.10(f)(4)(i), which require that the facility provide immediate access to any resident by any representative of the State, and any representative of the Office of the State Long-Term Care Ombudsman, among others. All facilities, including the three private-pay facilities, are required to comply with 42 CFR 483.10(f)(4)(i) under existing § 201.2, and will continue to be required to do so under amended § 201.2, in Rulemaking 1. In addition, section 813(a) of the act (35 P.S. § 448.813(a)) provides the Department with authority to enter and inspect facilities for the purpose of determining the adequacy of the care and treatment provided to residents. Section 802.1 of the act (35 P.S. § 448.802a) also defines "survey" as an announced or unannounced examination which may include an onsite visit, for the purpose of determining a facility's compliance with licensure requirements. Therefore, the Department may conduct an announced or unannounced survey of a facility regardless of whether a facility permits this through written policies and procedures. The Department, therefore, declines to make this amendment.

Next, the commentator recommended that the regulations include a requirement that facilities have written policies and procedures related to "conducting person-centered service planning and providing person-centered care." The Department appreciates this comment and supports person-centered care. Section 211.10 (relating to resident care policies), as amended in this final-form rulemaking, includes requirements related to resident care policies that address the total medical, nursing, and

mental and psychosocial needs of residents. Further, as explained in further detail under § 211.2 (relating to medical director), medical directors are required to support and promote person-directed care, including choice regarding medical care options. Under the minimum Federal health and safety requirements, comprehensive person-centered care planning is required. 42 CFR 483.21 (relating to comprehensive person-centered care planning). Specifically, a facility is required to develop and implement care plans that provide comprehensive, effective and person-centered care. Under the Federal definitions, person-centered care means to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives. 42 CFR 483.5 (relating to definitions).

The commentator also recommended that the regulations include a requirement that facilities have written policies and procedures related to "mandatory reporting of abuse, neglect, and exploitation and reporting of critical/adverse incidents or sentinel events." Under 42 CFR 483.12(b) (relating to freedom from abuse, neglect, and exploitation), a facility is required to develop and implement policies and procedures related to abuse, neglect and exploitation, which include: the prohibition and prevention of abuse, neglect and exploitation; investigation of any of these allegations; trainings; establishing coordination with the QAPI program; and reporting requirements. In addition, State law also addresses the requirement to report abuse, neglect and exploitation under the Older Adults Protective Service Act (35 P.S. §§ 10225.101—10225.5102) and the Adult Protective Services Act. In addition, under § 51.3 (relating to notification), a facility is required to notify the Department of events that seriously compromise quality assurance or resident safety. The Department, therefore, declines to make this amendment. The requirement for a facility to develop and implement policies and procedures related to abuse and neglect are not new for the private-pay facilities. However, the notification and written policy requirements under 42 CFR 483.12(b) will technically be new for the private-pay facilities under amended § 201.2 in final-form Rulemaking 1. This assumes approval of Rulemaking 1.

The same commentator also recommended that the regulations require that facilities submit all written policies to the Department and that facilities notify the Department, residents, resident representatives, and the Office of the Long-Term Care Ombudsman 30 days in advance of changes to any policies. The commentator also recommended requiring all policies and procedures always be available to the Department.

After careful consideration, the Department declines to make this amendment in this final-form rulemaking. While the Department appreciates this comment, it would be logistically impossible for the Department to manage and maintain a record of every policy and procedure for the 682 licensed long-term care nursing facilities on an ongoing basis. Under § 201.12(e), as amended in final-form Rulemaking 3, the Department is requiring prospective licensees to submit specific documentation when applying for licensure to demonstrate preparedness to operate a facility. That documentation includes a proposed staffing and hiring plan, a proposed training plan for staff, a proposed emergency preparedness plan, a proposed standard admissions agreement, and a 3-year budget. Once licensed, the facility is responsible for compliance with all regulatory requirements, including requirements for policies and procedures, such as those in § 201.18(d), which requires that the governing body adopt effective administrative and resident care policies.

In addition, it is important that facilities have the ability to update policies and procedures as needed in response to resident and business needs without prior approval. As to accessibility of written policies and procedures, section 813(a) of the act provides the Department with authority to enter and inspect facilities for the purpose of determining the adequacy of the care and treatment provided to residents and compliance with Departmental requirements. Specifically, the Department is granted the authority to review policies and procedures of the facility while conducting a survey. As defined in section 802.1 of the act, the term "survey" is "an announced or unannounced examination by the Department of Health or its representatives, which may include an onsite visit, interviews with employees, patients and other individuals and review of medical and facility records." As such, it is not necessary for the Department to add this suggested amendment.

The same commentator also recommended that policies and procedures be reviewed and updated at least annually in accordance with best practices in resident care and service delivery. The Department agrees with this recommendation. Under § 201.18(d), as further detailed previously, the Department has added a requirement that administrative and resident care policies be reviewed and revised by the governing body at least annually. Although the Department encourages facilities to consider best practices when establishing, reviewing and implementing policies and procedures, the Department does not require best practices in regulation since licensure of facilities is governed by the minimum health and safety standards for protection of the health, safety and welfare of residents. As such, the Department declines to make this amendment.

§ 201.20. Staff development

Subsection (a)

Subsection (a) is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department moves the requirement that a facility provide, at a minimum, annual in-service training from subsection (c) to this subsection, to add a cross-reference to the Federal training requirements in 42 CFR 483.95 (relating to training requirements), and to include from existing subsection (c) accident prevention, restorative nursing techniques, emergency preparedness and fire prevention and safety as additional training topics. The Department deletes from subsection (c) those requirements that are duplicative of the Federal requirements in 42 CFR 483.95 and moves from subsection (c) those topics that are not covered under 42 CFR 483.95. For additional clarity and ease of readability, the Department places these training topics into an enumerated list.

The topics deleted from subsection (c) include infection prevention and control, residents' confidential information, residents' psychosocial needs and resident rights, as these are required as part of the training requirements in 42 CFR 483.95. The Department retains and moves into subsection (a), accident prevention and restorative nursing techniques, as these two topics are not covered within the training requirements in 42 CFR 483.95. The Department retains these two training requirements to ensure the health and safety of residents. The Department also retains and moves into subsection (a), emergency preparedness and fire prevention and safety as training topics, as they are not covered within 42 CFR 483.95. These topics are covered elsewhere in the Federal requirements, but because they are not covered specifically

in 42 CFR 483.95, the Department retains them in this subsection with cross-references for clarity. Disaster preparedness is covered under 42 CFR 483.73(d) (relating to emergency preparedness), which requires facilities to develop and maintain an emergency preparedness training and testing program that is based on their emergency plan. Fire prevention and safety training is required by the National Fire Protection Association's *Life Safety Code (Life Safety Code)*, which has been adopted in the Federal requirements in 42 CFR 483.90(a) (relating to physical environment). Under sections 18.7.2.3.1 and 19.7.2.3.1 of the *Life Safety Code*, all facility personnel are to be instructed in their role in the use of and response to fire alarms.

Also, as explained in further detail as follows, the Department adds training requirements for resident rights, including nondiscrimination and cultural competency, and a general requirement for annual training based on needs identified through a facility assessment. The training requirements in 42 CFR 483.95, except for certain training requirements for nurse aides (NA) in 42 CFR 483.95(g)(2) and (3), will be new for the three private-pay facilities by virtue of § 201.2, as amended in Rulemaking 1. This assumes approval of Rulemaking 1.

Commentators requested the addition of various training requirements, including the following: disability competency; physical, intellectual, and mental health disabilities; assistive technology; physical accessibility; disability rights; available accommodations when voting; understanding dementia, Alzheimer's disease and effective communication skills; best care practices, including person-centered care, restraint-free care and social engagement, and communication with people with dementia; dementia training with a competency requirement; gerontology; nondiscrimination; racial equity and implicit bias; LGBTQ cultural competency; cultural sensitivity/competency trainings; person-centered care; assessment and care planning; activities of daily living; medical management information education; support; staffing; supportive and therapeutic environments; transitions and coordination of services; detection and the reporting of resident abuse, neglect and exploitation; best practices for infection prevention, detection and control; cleaning and disinfecting processes and procedures; fire prevention and resident safety; accident prevention; confidentiality of information; resident psychological needs; restorative nursing techniques; understanding brain injury; incident reporting; and donning and doffing of personal protective equipment. A commentator also requested specific training topics for administrative staff related to dementia care and treatment, person-centered care, assessment and care planning, activities of daily living, medical management information education and support, staffing, supportive and therapeutic environments, transitions and coordination of services. In addition, commentators also requested the Department require demonstration of competency through a combination of observation and competency testing. Commentators also suggested specifying the hours of each type of training, ranging from 4 to 16 hours of annual training, and providing for the portability of training.

The Department appreciates the myriad of suggested training topics. However, instead of enumerating a long list of training requirements, the Department, in this final-form rulemaking, adds a requirement for annual in-service training on resident rights, including nondiscrimination and cultural competency, and any other training needs identified through a facility assessment. The Department is enumerating annual resident rights training to emphasize the importance of these rights and resident health and safety. In addition, instead of listing a wide array of required annual training topics with minimum training hours, the Department adds the provision for training based on needs identified through a facility assessment. The purpose of a facility assessment is to evaluate resident acuity, ensure adequate and appropriately-trained staff, and assess the needs of a facility's specific resident population. Specifically, by identifying these specific resident needs, a facility can tailor its training of its staff to meet those needs, both in topics covered and duration. Similarly, training that results from facility-specific assessments is not necessarily portable. As such, the Department declines the recommendation of portability of training due to the preference that tailored training be provided annually at each facility. This reinforces training content and recognizes evolving standards, resident needs and best practices.

In addition, the Department declines to add annual training requirements on subjects that are already enumerated under Federal training requirements in 42 CFR 483.95. The Federally-required training includes, but is not limited to, resident abuse prevention and reporting, dementia management, infection control, resident rights and quality assurance and performance improvement.

Subsection (b)

Subsection (b) is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department replaces the term "employe" with the term "employee" for current usage and spelling of that term. On proposed, the Department deleted the second sentence of this subsection because training on the prevention of resident abuse and reporting of abuse is covered under the Federal training requirements. A commentator objected to deletion stating that although the Federal training requirements include this topic, the Federal requirements do not require the topic at orientation. IRRC also requested the Department to explain how the final regulation protects the public health, safety and welfare related to training on the prevention and reporting of abuse.

After careful consideration, the Department agrees with this recommendation. Based on the comments received, in this final-form rulemaking, the Department clarifies that orientation shall include training on the prevention, detection and reporting of resident abuse and dementia management and communication skills.

A commentator also suggested language be added to this subsection to clarify that training be provided in a manner that effectively conveys information and results in the learning of material. The commentator clarified that adding this language would alleviate concerns related to the potential for merely picking up literature and signing in that training was provided. The Department agrees that merely distributing literature is not training. Under the dictionary definition, "to train" means "to teach so as to make fit, qualified, or proficient." https://www.merriam-webster.com/dictionary/train. Although the Department agrees that mere distribution of literature is not training, the Department declines to add this language since training is an understood term. Further, Federal training requirements require that a facility develop, implement and maintain an effective training program. 42 CFR 483.95.

Other commentators suggested orientation be expanded to include infection prevention, detection and control procedures; emergency, pandemic, and disaster prepared-

ness planning and preparedness; fire prevention and resident safety procedures; incident reporting and accident prevention procedures; person-centered service planning and care; understanding dementia; and effective communication skills with people living with dementia and how to apply that to residents of the facility; transfer techniques; assistance with feeding; and management of aggressive behaviors. A commentator also suggested facility-specific and resident-specific orientation be added.

As provided previously, the Department adds dementia management and communication skills, in addition to resident abuse prevention, detection and reporting, as orientation topics to emphasize their importance and resident health and safety. The Department declines, however, to enumerate a vast array of required orientation subjects due to concerns related to length and breadth of orientation. As provided previously, certain training topics are required under Federal regulations or listed under subsection (a), such as accident prevention, emergency preparedness, and fire prevention and safety. Based on a facility's assessment, a facility shall tailor its orientation and training to meet its facility, staffing and resident needs. Specifically, a facility is required to develop, implement and maintain an effective training program based on the needs of residents and staff. 42 CFR 483.95. As previously noted, the training requirements in 42 CFR 483.95, except for certain training requirements for NAs in 42 CFR 483.95(g)(2) and (3), will be new for the three private-pay facilities by virtue of § 201.2, as amended in Rulemaking 1. This assumes approval of Rulemaking 1.

Subsection (c)

Subsection (c) remains deleted in this final-form rulemaking. As explained on proposed, the Department deletes this subsection in light of the proposed amendments to subsection (a), as described previously. A commentator requested this subsection remain in this final-form rulemaking and additional training topics be required. As explained previously, training requirements are not being removed and this subsection has been folded into subsection (a). Further, training topics have been expanded in this final-form rulemaking. However, the Department declines to add the myriad of topics requested by commentators. In addition to the training required under subsection (a), a facility shall tailor its orientation and training to meet its facility, staffing and resident needs based on its facility assessment.

Subsection (d)

Subsection (d) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes the word "the" between the words "at" and "staff development programs." A commentator requested adding a requirement for the method and format of the training records. The commentator also suggested a competency requirement be added. After careful consideration, the Department declines this recommendation since the existing regulation requires written records for training programs, including the content of the training and attendance. Further, based on a facility's assessment, training should be provided that is tailored to its employees and resident needs. This includes the method and format for meeting these training needs and requirements. In addition, as provided in further detail previously, the Department declines to add competency requirements.

Other Comments

A commentator stated that it is critical that training requirements be increased, including participating in quality improvement efforts. Two other commentators requested that training requirements be clarified to provide that training be provided by appropriately knowledgeable trainers. Another commentator restated its support of portability of training. A commentator also requested training on understanding dementia and effective communication skills.

To clarify, the Department is not reducing or eliminating any training requirements. As explained previously, the Department is cross-referencing the minimum training requirements in 42 CFR 483.95 and condensing existing subsections by adding accident prevention, restorative nursing techniques, emergency preparedness and fire prevention and safety under subsection (a). To not be duplicative, the Department is not restating the Federal requirements in 42 CFR 483.95. Based on comments received, however, the Department adds the following training and orientation requirements: resident rights, including nondiscrimination and cultural competency; training needs identified through a facility assessment; resident abuse prevention detection and reporting; dementia management and communication skills. Due to the requirement for training to be based on needs identified in a facility's assessment, the Department declines to add portability of training. The Department also agrees that training should be provided by appropriately knowledgeable trainers. However, the Department declines to add this language due to vagueness. Further, as previously provided, a facility is already required to develop, implement and maintain an effective training program based on the needs of residents and staff. 42 CFR 483.95. This includes the provision of training by trainers with appropriate knowledge and expertise.

§ 201.21. Use of outside resources

Subsection (a)

Subsection (a) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and to avoid conflict with the Federal requirements. Under 42 CFR 483.70(g)(2)(i), an arrangement or agreement for the use of outside resources must specify in writing that the facility assumes responsibility for obtaining services that meet professional standards and principles that apply to professionals providing services in the facility. A commentator suggested subsection (a) be retained since the Federal requirement at § 483.70(g)(2)(i) only applies to qualified professional persons and not all personnel. Specifically, the commentator asserted that subsection (a) is needed to require personnel meet all necessary licensure and certification requirements. IRRC also inquired how the deletion of this subsection protects the public health, safety and welfare.

The Department declines to make this amendment for the following reasons. When the Federal requirement under 42 CFR 483.70(g)(1) is read in pari materia with subsection 483.70(f), a qualified professional person includes "those professionals necessary to carry out the provisions [of services]." Further, subsection (f) applies not only to full-time and part-time professional employees, but also to consultation who provide professional services. Paragraph (2) of that provision specifically requires that professional staff "must be licensed, certified or registered in accordance with applicable State law." 42 CFR 483.70(f)(1) and (2). As such, no further amendments are needed.

Subsection (b)

Subsection (b) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the

Department deletes this subsection to eliminate duplication and to avoid conflict with the Federal requirements. Under 42 CFR 483.70(g)(1), a facility is required to have services furnished to residents by a person or agency outside the facility if the facility does not employ a qualified professional person to furnish that service.

A commentator suggested this requirement be retained since facilities must use contracted services if it cannot provide the needed services. To clarify, the Department is not deleting the requirement for services to be furnished by a person or agency outside the facility if the facility does not employ a person. This requirement is already required under 42 CFR 483.70(g) and incorporated under § 201.2. However, the requirement for contracted services will technically be new for the private-pay facilities under amended § 201.2 in final-form Rulemaking 1. This assumes approval of Rulemaking 1.

Subsection (c)

Subsection (c) is amended from the proposed rulemaking to this final-form rulemaking. On proposed, the Department deleted this subsection. However, based on comments received from commentators and IRRC to maintain this language and require written agreements between facilities and outside resources, the Department adds the following language: "In addition to the requirements under 42 CFR 483.70(g), the responsibilities, functions, objections and terms of agreements related to outside resources shall be delineated in writing and signed and dated by the parties."

Subsection (d)

Subsection (d) remains deleted in this final-form rulemaking. The Department deletes this subsection and replaces it with subsection (e), described as follows.

Subsection (e)

Subsection (e) is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, subsection (e) replaces the requirement in existing subsection (d) regarding outside resources that supply temporary employees to a facility. Under this new subsection, if a facility acquires employees from outside resources, the facility is required to obtain confirmation from the outside resource that the employees are free from the communicable diseases and conditions listed in § 27.155 and that the employees are able to perform their assigned job duties.

Based on comments received from a commentator and IRRC, the Department removes the word "physically" from "physically able." The Department removes this language to clarify that it is not intent of the provision to have any impact on an individual's disability, if any, or to impact a facility's reasonable accommodation under the Americans with Disabilities Act. The Department is not concerned with what specific conditions an employee may have but is only checking to see if the facility has obtained confirmation from an outside resource that the individual is able to work with residents and is free from communicable diseases and conditions. In addition, the Department adds the word "job" before "duties" to be consistent with language under § 201.19(5).

§ 201.24. Admission policy

Subsection (a)

This subsection is retained but amended in this final-form rulemaking. The Department had proposed to delete this subsection in its entirety to eliminate duplication with the Federal requirements at 42 CFR 483.10(b)(3), which address the ability of a resident representative to act on behalf of a resident.

Some commentators opposed the deletion of this subsection and argued that a facility should be prohibited from requiring a resident to designate a resident representative. They explained that designating a resident representative is a choice and the regulations should maintain that choice. One commentator indicated that many residents have full capacity to make all or many of their own decisions, and the regulations should reflect the fact that residents can remain free to maintain autonomy and independence if they can and wish to manage their own affairs. A commentator also pointed out that a prohibition on requiring a resident to designate a resident representative does not explicitly appear in the Federal requirements at 42 CFR 483.10(b). IRRC also asked the Department to explain the need for deleting this provision from regulation, and how the final regulation protects the public health, safety and welfare of residents capable of managing their own affairs.

After careful consideration, the Department agrees that the Federal requirements do not explicitly include language indicating that a resident is not required to name a resident representative. Therefore, the Department retains but amends this subsection in this final-form rulemaking, in response to these comments. In this final-form rulemaking, the Department deletes the first sentence of subsection (a) as the ability to appoint a resident representative is explicitly covered by the Federal requirements, but retains the second sentence with one amendment. The Department replaces the term "responsible person" with "resident representative" to reflect current terminology. The term "responsible person," as used in existing subsection (a), is an outdated term that is no longer used and has been replaced with the term "resident representative" to describe the types of individuals who may act on behalf of a resident. The term "resident representative" is defined in the Federal requirements at 42 CFR 483.5 and encompasses not only individuals who are authorized by law to act on behalf of a resident, but also other individuals who may be chosen by residents to act on their behalf.

Under 42 CFR 483.10(b)(3)(i), a resident representative has the right to exercise a resident's rights to the extent those rights are delegated to the resident representative, either by the resident or by law. Given the broad definition of "resident representative," this provision will technically be partially new for the three private-pay facilities under amended § 201.2, assuming approval of that section in final-form Rulemaking 1.

Some commentators also recommended that there be a prohibition on a facility requiring a resident representative or other third party to sign an admissions agreement or to otherwise financially bind the resident representative for a resident's care. Some commentators recommended language prohibiting a facility from requesting or requiring a resident representative or any other third party to sign an admissions contract unless the resident lacks decisional capacity and the resident representative or other third party has legal authority to act on the resident's behalf. The Federal requirements at 42 CFR 483.15(a)(3) (relating to admission, transfer and discharge rights) prohibit a facility from requesting or requiring a third-party guarantee of payment to the facility as a condition of admission or expedited admission or continued stay in the facility. However, a resident representative who is legally authorized to make a financial decision

and access a resident's income or resources may sign a contract and provide payment from the resident's income or resources. Therefore, the recommended language is duplicative of Federal requirements and unnecessary. As such, the Department declines to make this amendment.

A commentator also recommends language in this subsection prohibiting a facility employee from serving as a resident representative. As further detailed in § 201.26 (relating to resident representative) only a resident's family member who is employed in the facility may serve as resident representatives, so long as there is no conflict of interest. In addition, as further detailed as follows, the Department adds a paragraph (2) that clarifies a facility may be designated as a representative payee for Social Security as determined by the Social Security Administration in accordance with the Social Security Act and application regulations.

Subsection (b)

Subsection (b) is amended from the proposed rulemaking to this final-form rulemaking. In the proposed rulemaking, the Department deleted this subsection. However, based on comments received from commentators and IRRC, the Department retains this language in this final-form rulemaking. Some commentators objected to the deletion of this subsection in the proposed rulemaking because they believe it removes protections against a resident. They assert that the language in subsection (b) is needed because it prohibits a facility from forcing residents to release the facility from liability for failure to fulfill its duties, which is distinct from the Federal requirements at 42 CFR 483.15(a)(2)(iii). IRRC also asked whether facilities would be able to obtain a release from other types of liabilities and how removing this provision is reasonable and protects the public health, safety and welfare of residents related to liabilities other than liability for loss of personal property. The Department agrees with these concerns and is retaining this subsection.

Subsection (c)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to this subsection, which requires that a facility only admit residents whose nursing care and physical needs can be provided by the staff and facility. Some commentators commented that this subsection gives too much discretion to facilities to deny admission. Commentators assert that additional protections are necessary to ensure that facilities do not deny admission for arbitrary, discriminatory, payment or payor source reasons. Commentators recommended that the Department require facilities to have a written policy that outlines what nursing care and physical needs a facility can and cannot provide and that the policy be approved by the Department and be compliant with the Americans with Disabilities Act and all other non-discrimination laws and regulations. Further, commentators suggest that the policy be publicly posted in the facility, on the facility web site, and be uniformly applied. Commentators suggest that facilities should only be permitted to deny admission to a potential resident if the potential resident's care needs exceed the level of care a facility has stated it can provide, or if a facility is at capacity with available beds.

After careful consideration, the Department declines to adopt these recommendations. As an initial matter, a facility has to be compliant with all applicable Federal and State laws, including the American with Disabilities Act, and other non-discrimination laws. Further, as mentioned previously, the Department declines to manage, review and approve policies for the 682 licensed long-term care nursing facilities on an ongoing basis due to logistical concerns. Further, it would be impractical to require a facility to have a policy that states what care and physical needs the facility can and cannot provide when a facility's capacity to provide a certain level of care may fluctuate depending on the availability of staff with specific training and skillsets. Further, although a facility is not specifically required to have a policy that comprehensively states the services it can and will provide, a facility is required under 42 CFR 483.15(a)(6) to disclose and provide to a resident or potential resident, prior to the time of admission, notice of special characteristics or service limitations of the facility. Thus, a facility is required to inform a potential resident if the facility cannot serve the resident's needs. This will be a new requirement for the three private-pay facilities under amended § 201.2 in Rulemaking 1, assuming approval of that rulemaking.

Additionally, to the extent that the decision not to admit residents based on payment source has a disparate impact on a protected class of persons, there is case law that establishes precedent for complainants to seek injunctive relief to force facilities to remedy practices that have a discriminatory impact. *Linton v. Carney*, 779 F. Supp. 925 (M.D. Tenn. 1990).

In addition, there are protections to ensure that a resident is not subject to different treatment due to the source of payment for their care. For example, under 42 CFR 483.10(a)(2) a facility must provide equal access to quality care regardless of diagnosis, severity of condition, or payment source, and a facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the State plan for all residents regardless of payment source. The requirement in 42 CFR 483.10(a)(2) will be a new requirement for the three private-pay facilities under amended § 201.2 in final-form Rulemaking 1, assuming approval of that rulemaking.

Commentators also recommended that this subsection include language requiring a facility to provide the level of care residents require with a cross-reference to a new section that they propose requiring a facility to provide "all medical, social, nursing, pharmacy, dementia care, activities, protective supervision, cueing, and other services to meet the physical health, behavioral health, skilled nursing, nursing, psychosocial, emotional, cognitive, social, personal care, nutritional, rehabilitative, technological, equipment, transportation, [MA] eligibility, and other needs and preferences of each individual resident and as may be required of a person who meets the nursing facility level of care." They also suggest language requiring a facility to "assist residents with activities of daily living and instrumental activities of daily living and in preparing for transition out of the nursing facility." After careful consideration, the Department declines to add this language because these various health services topics are addressed in the entirety of 42 CFR Part 483, Subpart B. The purpose of these Federal health and safety standards is to provide the minimum standards relating to all aspects of a resident's care. As such, the suggested language would be duplicative of Federal requirements at 42 CFR 483.21, which requires that a resident's comprehensive care plan outline the care and services the resident needs and that the facility provide the services outlined in the care plan.

Subsection (d)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. The Department did not propose any changes to this section.

Subsection (e)

This subsection is amended from the proposed rulemaking to this final-form rulemaking. The Department adds this subsection, which exceeds the Federal requirements at 42 CFR 483.15(a) by requiring that the governing body of a facility establish written policies and procedures for the admissions process for residents, and through the administrator, develop and adhere to procedures implementing those policies. The Department requires that the facility's admissions policies and procedures include the requirements in paragraphs (1) through (5), which set forth requirements for orienting residents to the facility and introducing them to the basic information they need to reside in the facility.

Some commentators were supportive of the new requirements in this subsection and believed these requirements will help ensure that residents quickly become acclimated to the facility, its procedures and staff. A commentator stated that the timely review of immediate care orders and discussion of the resident's customary routines and preferences are important for a good start to the resident's stay, as are orientation to the facility and help settling into the resident's room.

Commentators to proposed Rulemaking 2 requested that the Department require education to residents about the right to have a locked drawer or cabinet. Commentators requested that this occur during the resident's first care plan meeting, and that the resident be specifically informed of the right to have a locked drawer or cabinet, and the need to inform staff when the key is lost, the drawer is broken or when something is stolen. The Department notes that there is not an existing right to have a locked drawer; however, the Federal requirements at 42 CFR 483.10(i)(1)(ii) establish that a facility must exercise reasonable care for the protection of the resident's property from loss or theft. To the extent that a facility provides a mechanism for residents to secure their possessions, the Department agrees that residents should be instructed on how to use that mechanism. Therefore, the Department amends paragraph (5) by removing the words "if needed" and adding the words "and securing" after the word "settling" and before the words "personal possessions," to ensure that facilities have policies and procedures in place to assist residents in securing their personal possessions.

Some commentators commented that, although requiring written admissions policies is a good start, the Department fell short in what must be included in those policies. These commentators recommended that facilities be required to include anti-discrimination provisions in their admissions policies. A commentator on proposed Rulemaking 1 and commentators in this rulemaking specifically recommended that the Department require facilities to include in their admissions policy prohibitions on discrimination against potential residents on the basis of sexual orientation, gender identity or gender expression. Some commentators also recommended that non-discrimination admission policies be submitted to and approved by the Department. Some commentators on this subsection also recommended that the Department require facilities' admissions policies to prohibit discrimination on the basis of payment source.

For the reasons described in further detail previously in response to similar comments in subsection (c), the Department declines to add these recommendations. As discussed previously, a facility has to be compliant with all applicable Federal and State laws, including the Americans with Disabilities Act and other non-discrimination laws.

Some commentators recommended that facilities be required to use a standard admissions agreement. One commentator recommended that the standard agreement be created by the Department for all facilities, because uniformity would benefit both the resident and the facility. Another commentator suggested that facilities submit their standard agreement to the Department for approval, and that facilities should be required to include in the agreement sections related to consent to treatment, resident rights, non-discrimination, financial arrangements, transfer and discharge, personal property and funds, photographs, confidentiality of medical information, and facility rules and grievance procedures. After careful consideration, the Department declines to adopt these recommendations. With regards to creating a standard admissions agreement, the Department declines to address and approve all contractual agreements between 682 nursing facilities and their approximate 72,000 residents on an ongoing basis due to feasibility and logistical concerns. In addition, it is important that facilities be able to update their admissions agreement in response to resident and business needs without having to wait for Department approval. Further, the Federal health and safety requirements and the Department's regulations address the myriad of topics suggested by commentators, including the provision of resident rights.

A commentator recommended that residents be advised that the admissions agreement can be reviewed by a legal representative or other advisor before signing. After careful consideration, the Department declines to make this amendment. Residents and resident representatives have the autonomy to seek legal or other counsel as the resident, or resident representative, deem appropriate.

Subsection (f)

This subsection is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, this subsection requires the coordination of introductions, orientation and discussions required under proposed subsection (e) be the responsibility of the facility's social worker or other delegee designated by the governing body. Social workers play a vital role in assisting residents with their psychosocial needs, and thus, are ideally suited for performing these types of tasks. Another individual, identified by the governing body, may be permitted to perform these tasks as the social worker may not always be available at the time of a resident's admission.

The Department proposed to require that the coordination of introductions, orientation and discussions occur within 2 hours of a resident's admission to further ensure that residents are not left on their own for too long after being admitted to a facility. A commentator, however, asserted that the 2-hour window of time proposed in § 201.24(f) (relating to admission policy) for the facility to coordinate introductions, orientation and discussions for a new resident is unrealistic, since most admissions occur during the afternoon and evening shifts and on weekends. The commentator further asserted that facilities need at least 72 hours to complete all the requirements in § 201.24(f) unless the information can be provided in writing. Other commentators also argued that facilities need more time to comply with the requirements in § 201.24(f). The commentators commented that it is

important not to overwhelm residents with too much information in a short amount of time, especially if they are arriving after a period of hospitalization or arriving late in the day. They asserted that transitioning to living in a facility can be a difficult time for a resident and the resident might prefer to receive information over a longer period after admission.

In contrast, another commentator recommended amending subsection (f) to require that within 2 hours of a resident's admission, the facility offer a basic welcome to the building and conduct a nursing assessment to determine the resident's care needs and preferences and begin the development of the resident's comprehensive care plan. The commentator pointed out that an assessment of the resident's needs and preferences should be the priority, and it can take up to 2 hours to complete. The commentator recommended that other provisions be completed within 24 hours of admission. Similarly, a commentator suggested that introduction to at least one member of the nursing staff can reasonably occur within 2 hours of admission but suggested that residents be allowed to conduct other portions of the orientation within 24 hours if that is the resident's preference. IRRC stated that they share commentators' concern with the need not to overwhelm a resident during this time of transition. IRRC asked if the 2-hour timeframe is reasonable considering that an individual might be coming directly from a hospital or have other serious health conditions. IRRC asked that the Department explain the reasonableness of the timeframe related to the coordination of introductions, orientation and discussion.

The Department amends subsection (f), in this final-form rulemaking, in response to these comments. Specifically, the Department amends this subsection to prioritize different activities. As amended, this subsection requires that the activities under subsection (e)(1) and (2) regarding orientation and introduction occur within 2 hours of a resident's admission. These activities include reviewing the orders of the physician or other health care practitioner for the resident's immediate care, introduction of the resident to at least one member of the professional nursing staff and to direct care staff assigned to care for the resident, and orientation of the resident to the facility and location of essential services and key personnel, including the dining room, nurses' workstations and offices for the facility's social worker and grievance or complaint officer. The activities included under subsection (e)(3) and (4) regarding routines and preferences shall occur within 24 hours of a resident's admission. These activities include providing a description of facility routines, including nursing shifts, mealtimes and posting of menus and discussion and documentation of the resident's customary routines and preferences, to be included in the resident's care plan. The activities included under subsection (e)(5) regarding adjustment to surroundings shall occur within 72 hours of a resident's admission. These include assisting the resident in creating a homelike environment and settling and securing personal possessions in the resident's room.

Other Comments

In addition to the comments on subsections (a) through (f), commentators recommended that a subsection be added to this section that requires facilities to retain a log of all referrals, verbal or written requests or applications for admission, and outcomes of any referrals, requests, or applications for admission. They also recommended that the log contain for each referral a patient identifier, and indicate the race, sex, color, national origin of the referral, the date of referral, the referring hospital or agency, and the date and the disposition of the referral by the facility. They recommended that the log be submitted to the Department annually with the Department's civil rights compliance questionnaire. After careful consideration, due to administrative burden concerns the Department declines to add an additional paperwork requirement relating to the creation and submission of an admission and referral log.

Some commentators also recommended a new subsection, requiring that in the event a facility denies admission to a potential resident, the facility provide that potential resident a written notice of denial stating the basis for denying admission, a statement of the potential resident's right to appeal and the process for appealing, contact information for local legal services to assist with the appeal, and contact information for the appropriate agency that can help the potential resident find alternative services. After careful consideration, the Department declines to incorporate this recommendation. The Department is not in the position or granted the authority to adjudicate resident appeals generally. Under the MA program, appeals are governed by the Department of Human Services. Otherwise, litigation surrounding denials have jurisdiction in the Court of Common Pleas.

§ 201.25. Discharge policy

This section remains deleted in this final-form rulemaking. However, the Department is not deleting the requirement for discharge plans. As explained in the proposed rulemaking, the Department deletes this section to eliminate duplication and avoid confusion with the Federal requirements. Under 42 CFR 483.21(c), a facility is required to develop and implement a discharge plan and a post-discharge plan of care. The Department notes that this is a new requirement for private-pay facilities under amended § 201.2 in final-form Rulemaking 1.

A commentator asserted that the Department should retain and amend § 201.25, arguing that the Federal requirements address the discharge planning process, but not the discharge plan itself. The commentator asserted that the Federal requirements do not clearly state that the discharge plan must ensure that the resident has a program of continuing care after discharge from the facility and that the plan must be in accordance with each resident's needs. Other commentators suggested that § 201.25 be retained and that the Department add language to stress that the program of continuing care be person-centered. The commentators also suggested adding language requiring that the setting the resident is discharged or transferred to have the capability of meeting the resident's needs and preferences. The commentators suggested adding language to require that the discharge plan include transfer of current person-centered service plans and any advance planning documents or orders related to the resident. IRRC asked whether the Federal requirements address a centralized coordinated discharge plan for each resident as required by existing § 201.25. IRRC asked the Department to explain how the final-form regulation protects the public health, safety and welfare of residents regarding discharge plans.

After careful consideration, the Department declines to retain or amend § 201.25. Although the Federal requirements do not specifically use the terminology "centralized coordinated discharge plan," robust and comprehensive discharge planning and plans are required. Under 42 CFR 483.21(b)(1)(iv)(C), a facility is required to include discharge plans in the comprehensive care plan that is developed for each resident. The Federal discharge plan

requirements are more robust and include specific elements that are not currently delineated in existing § 201.25, to ensure that the public health, safety and welfare of residents are protected when discharge from a facility takes place. Under 42 CFR 483.21(c), a facility must develop and implement an effective discharge planning process that focuses on the resident's discharge goals, the preparation of the resident to be an active partner in the planning process and to effectively transition them to post-discharge care, and the reduction of factors leading to preventable readmissions. The discharge planning process must be consistent with the discharge rights set forth in 42 CFR 483.15(c) and must ensure that the discharge needs of the resident are identified and result in the development of a discharge plan. The resident, resident representative and interdisciplinary team must be involved in the development of the discharge plan. The discharge plan must be updated, as needed, based on regular reevaluation of the resident. Under 42 CFR 483.21(c)(1)(iv), the discharge plan must take into consideration the availability of a caregiver or support person and the resident or caregiver's capacity and capability to perform the care identified in the resident's discharge needs. It must also address the resident's goals of care and treatment preferences and include documentation that a resident has been asked about their interest in receiving information regarding a return to the facility, as well as documentation of any referrals to local agencies or other appropriate entities. 42 CFR 483.21(c)(1)(vi) and (vii). The discharge plan must also contain all relevant information related to the resident to facilitate the plan's implementation and to avoid unnecessary delays in the resident's discharge and transfer. 42 CFR 483.21(c)(1)(ix). When discharge occurs, the facility must provide a discharge summary under 42 CFR 483.21(c)(2), which includes a recapitulation of the resident's stay, a final summary of the resident's status, reconciliation of all pre-discharge medications with post-discharge medications, and a post-discharge plan of care. A facility must also meet the requirements for transfer or discharge in 42 CFR 483.15(c)(2), which require documentation in the resident's medical record and communication of information to the receiving healthcare facility or provider. The Department additionally notes this communication of information includes advance directive information, all special instructions or precautions for ongoing care as appropriate, comprehensive care plan goals, and all other necessary information, including the discharge summary and any other documentation to ensure a safe and effective transition of care. 42 CFR 483.15(c)(2)(iii)(C) through (F).

Some commentators requested that the Department retain and amend § 201.25 to require a facility to follow a discharge policy that is approved by the Department. After careful consideration, the Department declines to make this amendment. As explained previously, the Federal requirements for a discharge policy are robust and serve as the minimum health and safety standards for facilities. In addition, as mentioned previously, it would be logistically impossible for the Department to approve every policy and procedure for the approximately 682 licensed long-term care nursing facilities on an ongoing basis.

A few commentators requested that the Department retain § 201.25 because residents lack adequate protections against unjust and unsafe discharges or transfers to other settings. After careful consideration, the Department declines to make this amendment. As further detailed previously, existing Federal health and safety requirements are robust regarding discharge of residents. Under 42 CFR 483.15(c), a facility must permit residents to remain in the facility and not transfer or discharge a resident unless: the transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility; the transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility; the safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident; the health of individuals in the facility would otherwise be endangered; the resident has failed after reasonable and appropriate notice to pay for a stay at the facility; or the facility ceases to operate. Under 42 CFR 483.15(c)(1)(ii), a facility may not transfer or discharge a resident when a resident exercises their right to appeal under 42 CFR 431.220(a)(2) (relating to when a hearing is required), unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility. Under 42 CFR 431.220(a)(2), the Department of Human Services must grant an opportunity for a hearing to any resident who requests it when the resident believes a facility has erroneously determined a transfer or discharge. This would be applicable only to those facilities that participate in MA, however, and not the three private-pay facilities. The Department does not have the authority to hear appeals from residents.

A few commentators requested that the Department retain and amend § 201.25 to require written notice to residents facing unwanted discharge with information on how to appeal the facility's decision before being unwillingly discharged or transferred from the facility. After careful consideration, the Department declines to make this amendment as this notice is already required under the Federal requirements. Under 42 CFR 483.15(c)(3), a facility must provide notice to the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they can understand. The facility must send a copy of this notice to the Office of the State Long-Term Care Ombudsman. Under 42 CFR 483.15(c)(4), the notice must be given at least 30 days before the resident is transferred or discharged, or as soon as practicable if the health and safety of individuals would be endangered, the resident's health improves sufficiently to allow a more immediate transfer or discharge, an immediate transfer or discharge is required by the resident's urgent medical needs, or the resident has not resided in the facility for 30 days. The notice must include, under 42 CFR 483.15(c)(5), the reason for the transfer or discharge, the effective date of the transfer or discharge, the location to which the resident is being transferred or discharged, a statement of the resident's appeal rights, contact information for the Office of the State Long-Term Care Ombudsman, and for residents with intellectual, developmental, mental or related disabilities, contact information to the agencies responsible for the protection and advocacy of these individuals. As noted previously, residents in facilities that participate in MA can appeal a facility's decision to transfer or discharge under 42 CFR 431.220(a)(2). The Department, however, does not have the authority to hear appeals from residents.

§ 201.26. Resident representative

This section is amended from the proposed rulemaking to this final-form rulemaking. As explained in the pro-

posed rulemaking, the Department replaces the words "power of attorney" in the title and body of this section with "resident representative." The term "resident representative" encompasses not only a power of attorney relationship, but also other types of individuals who are authorized to act on behalf of a resident. The Department deletes the slash mark and replaces the word "employe" with "employee" for stylistic and current usage reasons.

The Department adds to the end of the prohibition an exception for family members of residents who are employed in the facility. This section permits family members who are employed in the facility to serve as resident representatives, so long as there is no conflict of interest. In addition, as further provided as follows, the Department adds a paragraph (2) that clarifies a facility may be designated as a representative payee for Social Security payments under certain circumstances. Paragraph (2) clarifies that this designation must be in accordance with the Social Security Act and application regulations.

One commentator supported this provision stating that facility staff should not serve in the position of a substitute decision-maker. Another commentator requested the Department not delete the prohibition of a facility serving as a power of attorney for a resident. Commentators also suggested this section be expanded or clarified to prohibit staff from serving as guardian, healthcare proxy or another surrogate.

As currently drafted, a staff member may not be a resident representative, unless the staff member is also a resident's family member and there is no conflict of interest. Although the Department agrees with the commentators' concerns regarding employees serving in an agent or fiduciary role, the suggested amendments are unnecessary given the broad and inclusive definition of "resident representative." Specifically, a resident representative includes: legal representatives; court-appointed guardians or conservators of a resident; or a person authorized by Federal or State law (including, but not limited to, agents under power of attorney, representative payees, and other fiduciaries) or an individual chosen by the resident to act on behalf of the resident, to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications. 42 CFR 483.5. To further clarify the definition of "resident representative," the Department added this term and the cross-reference to 42 CFR 483.5 to Rulemaking 1. This assumes approval of Rulemaking 1.

A commentator also suggested that a facility could be a representative payee for Social Security payments with the permission of the resident or the resident's representative. The Department agrees with the exception for a facility to serve as a representative payee, as designated by the Social Security Administration. However, since the Social Security Administration administers the Social Security Act and determines whether a facility should be designated as a representative payee, the Department declines to include the additional suggested provisions regarding conditions for serving as a representative payee.

Another commentator also commented that facilities will only communicate with an agent of the resident and not with other family members when the agent and family members are fighting. As discussed previously, the definition of "resident representative" includes individuals chosen by a resident to act on the resident's behalf and also court-appointed representatives. Due to resident autonomy, the Department declines to add a designation for family members to access resident information when a family member is neither designated by the resident nor appointed by the courts.

§ 201.27. Advertisement of special services

The Department did not include this provision in the proposed rulemaking. Commentators, however, suggested that the Department add language in this final-form rulemaking to ensure that facilities comply with the requirements of the Unfair Trade Practices and Consumer Protection Law (UTPCPL) to prohibit facilities from advertising their services in a manner that misrepresents the facility's scope of services as being greater or lesser than their actual services, and to prohibit advertising that a facility provides services or specialties unless these services or specialties are defined specifically by the Commonwealth.

First, this comment is outside the scope of the proposed rulemaking. In addition, the Department declines to amend this section in this final-form rulemaking. Section 201.14(a) and (b) is amended in final-form Rulemaking 3 to add language that facilities must comply "with all applicable Federal and State laws, and rules, regulations and orders issued by the Department and other Federal, State or local agencies." This language provides additional awareness that facilities must adhere to any applicable Federal and State laws, which would include the UTPCPL.

Commentators further cite to the recent Pennsylvania Supreme Court case *Commonwealth by Shapiro v. Golden Gate National Senior Care, LLC*, 194 A.3d 1010, 1023 (Pa. 2018) to ensure compliance with the requirements of the UTPCPL. However, the decision in *Golden Gate* did not hold that the UTPCPL does not apply to nursing facilities; but instead, provided that the conduct in that matter was not actionable under the UTPCPL. To the extent that additional consumer protections are desired under the UTPCPL, a legislative amendment is needed.

§ 201.29. Resident rights

Commentators objected to the deletion of regulatory language in § 201.29 that is duplicative of residents' rights requirements in the Federal requirements at 42 CFR 483.10. Commentators indicated that it is necessary to specifically enumerate the Federal requirements in State regulation to provide a single point of reference for lay persons to understand a resident's rights. These commentators asserted that lay persons do not have the ability to understand the interplay between State and Federal requirements, and most people look to the State regulations to determine a resident's rights. Commentators requested that the Department either spell out all rights in § 201.29 or at a minimum, cross-reference the Federal requirements. IRRC further asked the Department to explain how the final-form regulation protects public health, safety and welfare in relation to making a resident's rights clear. In response to these comments, the Department has added an explicit cross-reference in § 201.29 to the Federal requirements for resident rights at 420 CFR 483.10 to make it clear that the requirements for resident rights include both the requirements in § 201.29 and 42 CFR 483.10. The resident rights under 42 CFR 483.10 are readily accessible in various locations, including, for example, https://www.law.cornell.edu/cfr/text/42/483.10; https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-483; https://www.govinfo.gov/content/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-sec483-10.pdf.

In addition, to further assist the regulated community, residents and others in understanding residents' rights,

the Department has also created a template of residents' rights, which sets forth a resident's rights in clear and easy to understand language. The creation of a template also addresses a comment that the Department received during the meeting with stakeholders on August 17, 2022, in which a stakeholder suggested that the Department create a comprehensive list of resident rights that can be shared with facilities. This template, which facilities may use as a tool to meet the posting and notice requirements in subsections (c.1) and (c.2) described as follows is attached as Exhibit A and will also be posted on the Department's web site.

Subsection (a)

Subsection (a) is amended from the proposed rulemaking to this final-form rulemaking in response to public comments. The Department did not propose any changes to the first sentence of this subsection. In this final-form rulemaking, the first sentence is broken into two sentences, and a phrase is added to the end of the new first sentence to clarify that the rights and responsibilities of residents referenced in this subsection include both the rights and responsibilities set forth in 42 CFR 483.10 and this section. This amendment is in response to some commentators' suggestion that this section should be amended to require that the governing body of a facility establish written policies consistent with Federal and State regulations regarding the rights and responsibilities of residents. IRRC also commented regarding the proposed deletion of subsection (m) because existing subsection (a) addresses the requirement that a facility have policies and procedures related to resident rights. IRRC noted, however, that, unlike subsection (m), subsection (a) does not require that a facility's policies and procedures reflect the residents' rights provided for in this section; only that policies regarding rights be developed and adhered to. The amendment in this final-form rulemaking in this first sentence addresses this comment by adding the requirement that the policies and procedures specifically reflect the rights set forth in this section and in 42 CFR 483.10.

The new second sentence in this subsection is amended for grammar and clarity. The word "and" is deleted at the beginning of the sentence, and the word "through" is capitalized because it is now the first word of the sentence. The words "the governing body" are added following the words "through the administrator," since a subject would otherwise be missing from this sentence.

The last sentence in this subsection is amended from the proposed rulemaking to this final-form rulemaking also in response to public comment. The Department proposed to add this sentence, which requires that the written policies established by the governing body include a mechanism for the inclusion of residents in the development, implementation and review of the policies and procedures regarding the rights and responsibilities of residents. The Department proposed this requirement as part of its efforts to promote more resident-centered environments in long-term care nursing facilities. Several commentators supported the proposal to require that residents be included in the development, implementation and review of policies related to resident rights. A commentator noted that facilities should have the option to include a resident representative on behalf of a resident if a resident is not able or willing to be included. This recommendation is adopted in this final-form rulemaking, and the words "or a resident representative" are added after the words "inclusion of residents."

Subsection (b)

Subsection (b) is unchanged from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to this subsection.

Subsection (c)

Subsection (c) is unchanged from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to this subsection.

Subsection (c.1)

Subsection (c.1) is added in this final-form rulemaking. The Department moves the requirement in existing subsection (n) that a facility post in a conspicuous place near the entrances and on each floor of the facility a notice which sets forth the list of resident's rights, into this subsection, with a cross-reference to subsection (c.3) and 42 CFR 483.10 to make it clear that the posting requirement includes both the Federal resident rights requirements and the resident rights requirements in subsection (c.3). The Department has moved the requirement in subsection (n) higher up in this section for organizational reasons to make the requirements clearer and easier to understand. As noted at the beginning of this section, the cross-reference to 42 CFR 483.10 is added in response to comments to make it clear that the requirements in § 201.29 include the Federal requirements at 42 CFR 483.10. As noted at the beginning of this section, the Department has created a template of resident's rights, which sets forth a resident's rights in clear and easy to understand language. This template, which facilities may use as a tool to meet the posting and notice requirements in this subsection and subsection (c.2) described as follows is attached as Exhibit A and will also be posted on the Department's web site.

Subsection (c.2)

Subsection (c.2) is added in this final-form rulemaking. This subsection requires a facility to provide personal notice of a resident's rights in accordance with 42 CFR 483.10(g)(16). The Department moves from existing subsection (n) the requirement that a certificate of the provision of personal notice be entered in the resident's medical record. The first sentence is added for clarity to cross-reference the requirement that personal notice of resident rights must be given to a resident, as this notice must be provided for it to be noted in the resident's medical record. For clarity, the Department has placed these requirements here in subsection (c.2) instead of adding or retaining them in subsection (n). Additionally, as noted at the beginning of this section, the Department has created a template of resident's rights, which sets forth a resident's rights in clear and easy to understand language. This template, which facilities may use as a tool to meet the posting and notice requirements in this subsection and subsection (c.1) described previously is attached as Exhibit A and will also be posted on the Department's web site.

Subsection (c.3)

This subsection is added in this final-form rulemaking in response to the previously discussed comments, which requested that all Federal and State regulatory requirements for resident rights be together or that a cross-reference be added into § 201.29 to the Federal requirements. The Department adds language in subsection (c.3) to clarify that the rights delineated in paragraphs (1) through (4), described as follows, are in addition to the rights set forth at 42 CFR 483.10.

Paragraph (1)

The Department moves into paragraph (1), current language from existing subsection (e), with amendments. Specifically, the Department moves all but the first sentence from subsection (e) into paragraph (1), with two grammatical amendments. As noted in the proposed rulemaking, the first sentence of subsection (e) is duplicative of the requirement in 42 CFR 483.10(g)(18) that a facility must inform each resident before or at the time of admission, and periodically during a resident's stay, of the availability of services and related charges. The Department deletes the word "the" before the word "charges" and replaces the word "money" with the word "deposit." The Department also replaces the term "responsible person" with "resident representative" for consistency in the use of that term in the regulations. The Department had proposed to delete subsection (e) to eliminate duplication and avoid conflict with the Federal requirements at 42 CFR 483.10(g)(18).

Commentators disagreed that the requirements in the second and third sentences of existing subsection (e) are duplicative of the Federal requirements and recommended that these sentences be retained. The Department had proposed to delete these two sentences because 42 CFR 483.10(g)(18)(i) and (ii) requires notice of changes in charges for items and services as soon as reasonably possible and changes for other items and services at least 60 days prior to implementation of the change. A commentator asserted that while 42 CFR 483.10(g)(18) requires facilities to inform a resident before changes are made to charges, the second sentence in existing subsection (e) requires the facility to inform the resident verbally and in writing of changes in charges. Commentators asserted that the words "verbally and in writing" offer greater protection than the Federal requirement and should be retained. Commentators also asserted that the deletion of the requirement for at least 30 days' advance notice regarding changes in charges from the second and third sentences is not appropriate, because the requirement in 42 CFR 483.10(g)(18)(ii) for 60 days' notice only applies to charges that are not covered by Medicare and MA, and therefore, the wholesale deletion of the requirement in subsection (e) for 30 days' notice is inappropriate. IRRC asked the Department to explain how the deletion of provisions related to notice for changes in charges are reasonable and protect the public health, safety and welfare of residents.

The Department agrees. In response to these comments, the Department retains the requirement for 30 days' notice, unless circumstances dictate otherwise, and moves it from subsection (e) to this paragraph for clarity. As noted, the Federal requirements provide for two separate notices related to charges under 42 CFR 483.10(g)(10). Under 42 CFR 483.10(g)(i), a facility is required to provide notice "as soon as is reasonably possible" when changes in coverage are made to items and services covered by Medicare or MA. Under 42 CFR 483.10(g)(ii), a facility is required to inform the resident at least 60 days prior to implementation of a change when changes are made to charges for other items and services that the facility offers. The 60-day notice period under 42 CFR 483.10(g)(ii), therefore only applies to charges for items and services not covered by Medicare or MA. After careful consideration, the Department agrees that the term "as soon as reasonably possible" is vague and moves both the second and third sentences of subsection (e) to this paragraph, with amendments, as described previously, to alleviate the concerns raised by commentators regarding the timelines provided in the Federal requirements. As amended, if a change in charges occurs during the resident's stay, a resident, or resident representative, shall be advised verbally and in writing reasonably in advance of the change. "Reasonably in advance of the change" is further defined as "30 days prior to the change unless circumstances dictate otherwise."

Commentators also objected to the deletion of the fourth and fifth sentences in subsection (e), which set forth requirements pertaining to security deposits, when required by a facility, and prohibit a facility from requiring a security deposit for an MA resident. A commentator asserted that these requirements, and the prohibition on security deposits for MA residents, should be retained because they are not explicitly covered by the Federal requirements. IRRC asked the Department to explain how the deletion of provisions related to security deposits are reasonable and protect the public health, safety and welfare of residents. The Department agrees. After careful consideration, the Department moves the fourth and fifth sentences of subsection (e) to this paragraph, with amendments, as described previously.

Paragraph (2)

The Department moves into paragraph (2), the second sentence from existing subsection (g), which the Department had proposed to retain with amendment. The Department carries over amendments that were proposed to replace the term "resident's responsible person" with "resident representative" and "MA" with "Medical Assistance Programs."

Paragraph (3)

The Department moves into paragraph (3), the language that was proposed in subsection (o), with amendments in this final-form rulemaking. The Department had proposed amendments to subsection (o) to align with Federal guidance. The Department adds "including the Department's Institutional Review Board" after "the approval of the Department" from the proposed rulemaking to this final-form rulemaking, in response to commentators who suggested that Department approval of experimental research or treatment should include approval by the Department's Institutional Review Board. The Department also makes minor adjustments to the proposed language in this final-form rulemaking, including breaking it down into subsections for clarity and ease of readability.

Some commentators commented that the language should more clearly state that it is a resident's choice to participate in experimental research or treatment, and that a resident is not required to participate in experimental research or treatment. After careful consideration, no amendments are made in response to this comment. Informed consent by the resident or resident representative is required under this paragraph prior to participation and initiation of the experimental research or treatment. Informed consent is a legal term of art that is defined by *Black's Law Dictionary* as, "a patient's *knowing choice* about a medical treatment or procedure, made after a physician or other healthcare provider discloses whatever information a reasonably prudent provider in the medical community would give to a patient regarding the risks involved in the proposed treatment or procedure" (emphasis added).

A commentator also commented that a resident representative should only be allowed to provide informed consent if the resident is unable to understand the situation and the risks and benefits of the proposed research. The commentator expressed that, if the resident

has capacity, only the resident should be able to provide consent for experimental research or treatment. After careful consideration, the Department declines to make this amendment, as there are protections in place in the Federal requirements, that address the relationship between a resident and resident representative. Specifically, under 42 CFR 483.10(b)(3), a resident who has not been adjudged incompetent by a State court has the right to choose a resident representative to act on the resident's behalf. The resident, however, retains the right to exercise any rights that are not delegated to a resident representative and also retains the right to revoke a delegation of rights, except as limited by State law. Therefore, if a resident has not been determined to be incompetent by a State court, they have the right, and autonomy, on whether to delegate, or not, decisions regarding experimental research and treatment to a resident representative.

The commentator also recommended the addition of language providing that facility staff have a responsibility, where a resident representative gives consent, to ensure that the consent is properly obtained and that essential measures are taken to protect the resident from harm or mistreatment. After careful consideration, the Department declines to make this amendment. The definition of "informed consent" extends to a resident representative under the plain language of this paragraph. In addition, there are other, existing protections in regulation to prevent residents from being harmed or mistreated, regardless of their participation in experimental research or treatment. For example, the Federal requirements at 42 CFR 483.12 specify that a resident has the right to be free from abuse, neglect, misappropriation of resident property and exploitation, including a prohibition on verbal, mental, sexual or physical abuse, corporal punishment or involuntary seclusion. 42 CFR 483.12(a)(1).

A commentator recommended that the definition of experimental research or treatment be expanded to add that experimental research and treatment could include nursing or social science exploration of new approaches to aiding with activities or daily living or addressing social isolation. After careful consideration, the Department declines to make this amendment because these items are encompassed under the definition of "experimental research" that has not yet been approved by the "medical community as effective" under paragraph (3)(iii).

Paragraph (4)

The Department moves into paragraph (4) the language that was proposed in subsection (p), without amendment. As explained in proposed subsection (p), the Department adds this language to make it clear that a resident has the right to care without discrimination based upon race, color, familial status, religious creed, ancestry, age, sex, gender, sexual orientation, gender identity or expression, national origin, ability to pay, handicap or disability, use of guide or support animals because of the blindness, deafness or physical handicap of the resident or because the resident is a handler or trainer of support or guide animals. As explained in the proposed rulemaking, this language mirrors existing protections under the Pennsylvania Human Relations Act (PHRA), as interpreted and applied by the Pennsylvania Human Relations Commission.

Some commentators in response to Rulemaking 2 stated that stronger protections are needed to address discrimination and ill treatment. Some commentators were supportive of the language that was proposed in subsection (p) and commented that this provision was past due and represented an important step forward to ensure that residents are free from discrimination. A commentator stated that these protections will help ensure that older LGBTQ adults receive the services they need. Another commentator expressed that they are hopeful that this protection will come with robust enforcement to ensure compliance. Another commentator stated that the addition of the proposed language in subsection (p) was unnecessary, since it is, with one exception, a duplication of the PHRA protections for all citizens in this Commonwealth, and Federally-required for clients of health care entities that receive Federal funding through section 1557 of the Patient Protection and Affordable Care Act (42 U.S.C.A. § 18116).

The inclusion of this anti-discrimination language, that was in the proposed rulemaking and carried over to this final-form rulemaking, is responsive to those comments. As stated on proposed, the Department's inclusion of the language in this paragraph is consistent with section 102 of the act (35 P.S. § 448.102) to ensure that "all citizens receive humane, courteous, and dignified treatment," and the Pennsylvania Human Relations Commission's application of the PHRA. Further, 42 CFR 483.10 provides that a resident has the right to be free from interference, coercion and discrimination in exercising the resident's rights.

Subsection (d)

This subsection remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection, which requires that staff of the facility be trained and involved in the implementation of residents rights policies and procedures, to eliminate duplication and to avoid conflict with the Federal requirements. Under 42 CFR 483.95(b), a facility must ensure that staff members are educated on the rights of residents and the responsibilities of the facility to properly care for residents, as further set forth in 42 CFR 483.10.

Some commentators objected to the deletion of this subsection, arguing that, while the Federal requirements require staff to be trained on residents' rights, they do not require staff to be involved in the implementation of policies related to residents' rights. IRRC asked the Department to clarify whether the existing regulation requires more involvement of staff in policies and procedures than the Federal requirements, and, if so, explain how the final-form regulation protects the public health, safety and welfare by lessening staff involvement. In response to these comments, the Department clarifies that existing subsection (d) does not require more involvement of staff in policies and procedures than the Federal requirements. "Implementation" refers to the process of putting a decision or plan into effect. Merriam-Webster. *Implementation*. Retrieved from https://www.merriam-webster.com/dictionary/implementation. Facility staff are necessarily involved in the implementation of all facility policies and procedures, including those pertaining to resident rights, because they are the ones who are required to put those policies and procedures into effect. For example, under 42 CFR 483.10(c), a resident has a right to be informed of, and participate in their treatment. The policies related to informing residents of and including them in their treatment are implemented by the staff who interact with residents during the development and implementation of their care plan. Further, surveys are conducted to ensure the implementation of both Federal and State requirements, including the implementation of resident rights requirements. The Department declines to make this amendment.

Some commentators also recommended requiring annual training by outside entities. They assert that the Federal requirements neither require annual trainings nor require training by outside organizations. A commentator specifically recommended that there be annual training provided by the Long-Term Care Ombudsman and by State or local "Older Adult Protective Services personnel." The Department declines to make these amendments. Requirements for annual training were in the proposed rulemaking, and are retained in this final-form rulemaking, in § 201.20 (relating to staff development), as further discussed previously. The Department also does not have the authority to require that the State Long-Term Care Ombudsman or personnel from other agencies perform trainings.

Subsection (e)

This subsection is deleted in this final-form rulemaking, as explained previously in subsection (c.3)(1).

Subsection (f)

This subsection remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and to avoid conflict with the Federal requirements. The requirements pertaining to the transfer and discharge of residents are in 42 CFR 483.15. The first sentence of existing subsection (f) is addressed in 42 CFR 483.15(c)(1). Under 42 CFR 483.15(c)(1), a facility must permit each resident to remain in the facility and not transfer or discharge the resident from the facility unless the transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility; the resident's health has improved sufficiently so that the resident no longer needs services provided by the facility; the health or safety of individuals is endangered; the resident has failed after reasonable and appropriate notice to pay for staying at the facility; or the facility ceases to operate. The notification requirements contained in the second, third and fourth sentences of existing subsection (f) are covered in 42 CFR 483.15(c)(3) and (4). Under 42 CFR 483.15(c)(3) and (4), a facility must notify a resident and the resident's representative of the transfer or discharge in writing and in a language and manner they understand, at least 30 days before the transfer or discharge, except where an immediate transfer or discharge is required, where the health and safety of individuals at the facility would be endangered, or when a resident has not resided in the facility for 30 days. Further, a facility's bed-hold policy is covered by 42 CFR 483.15(d), which requires written notice regarding the duration of its bed-hold policy to a resident, or the resident representative.

A commentator objected to the deletion of this subsection and recommended that the Department retain the existing language, with the addition of language and cross-references to conform with the Federal requirements at 42 CFR 483.15(c) cited previously. The commentator made the same assertions as those addressed at the beginning of this section, regarding the need for a single, comprehensive statement of resident rights with the inclusion of Federal resident rights and State resident rights in one section. After careful consideration, the Department declines to make this amendment in this final-form rulemaking. The Department first notes that the requirements at 42 CFR 483.15(c) represent the minimum standards necessary to ensure the health and safety of residents during a discharge or transfer from the facility. In addition, with respect to the comment regarding the availability of resident rights, the Department has also created a template of resident's rights, which sets forth a resident's rights in clear and easy to understand language. This template, which facilities may use as a tool to meet the posting and notice requirements in this subsection and subsection (c.1) described previously is attached as Exhibit A and will also be posted on the Department's web site.

Subsection (g)

This subsection is deleted in this final-form rulemaking. The last sentence of existing subsection (g) is moved to subsection (c.3)(2), as explained previously. Additional comments are discussed as follows.

Some commentators objected to the deletion, in the proposed rulemaking, of the first sentence of subsection (g), which requires a facility to assure that appropriate arrangements are made for a safe and orderly transfer and that the resident is transferred to an appropriate place that is capable of meeting the resident's needs, unless the discharge is initiated by the resident or resident's responsible person. The commentators assert that the Federal requirement at 42 CFR 483.15(c)(7), which requires a facility to "provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility" is not sufficient to prompt facilities to engage in comprehensive discharge planning, and that discussion of alternative settings, including returning to home and community settings, is frequently skipped. After careful consideration, the Department declines to amend this subsection. As discussed previously, Federal requirements require comprehensive discharge planning under 42 CFR 483.15(c) and 483.21(c), which include a requirement that the facility develop and implement an effective discharge planning process that focuses on the resident's discharge goals and the preparation of residents to be active partners and effectively transition them to post-discharge care. There are detailed requirements under 42 CFR 483.21(c)(1)(vii) related to ensuring that a resident has been asked about their interest in returning to the community and ensuring that the resident receives appropriate referrals if the resident does express a desire to return to the community. If a determination is made that discharge to the community is not feasible, the facility must document this as well, and include in the documentation why the determination was made.

Some commentators also objected to the deletion of the requirement in the first sentence that a resident be transferred to an appropriate place that can meet the resident's needs. These commentators assert that facilities regularly attempt to transfer residents to homeless shelters, hotel rooms, boarding homes and other settings where their needs cannot be met. They also assert that while the transfer and discharge requirements at 42 CFR 483.15(c) address transfer to another long-term care nursing facility, it does not address transfers to other settings. IRRC also asked how the final-form regulation will protect residents from transfers to settings where their needs cannot be met. IRRC further asked the Department to explain the reasonableness of removing this provision and how the final regulation protects the public health, safety and welfare related to transfers.

After careful consideration, the Department declines to amend this language, but has in response to comments added to final-form Rulemaking 1, definitions for "discharge" and "transfer" to provide this distinction. The Federal requirements define "transfer and discharge" together in 42 CFR 483.5, when in fact the two terms are separate and distinct concepts. This distinction is re-

flected in Appendix PP of the State Operations Manual, which defines the term "discharge" as "the movement of a resident from a bed in one certified facility to a bed in another certified facility or other location in the community, when return to the original facility is not expected" and the term "transfer" as "the movement of a resident from a bed in one certified facility to a bed in another certified facility when the resident expects to return to the original facility." The Department adds these definitions in § 201.3 in final-form Rulemaking 1 for clarity. The circumstances to which the commentators refer, for example, residents moving to homeless shelters, hotel rooms and other settings, are a discharge, not a transfer. Specifically, there are protections for residents who are being discharged from a facility, which include notice requirements at 42 CFR 483.15(c)(3) as well as a requirement at 42 CFR 483.15(c)(7) that the facility "provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility." There are also extensive discharge planning requirements as well at 42 CFR 483.21(c) that ensure that a resident is effectively transferred to post-discharge care and to reduce the chances of the resident having to be readmitted.

Subsection (h)

This subsection remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and to avoid conflict with the Federal requirements. The Federal requirements pertaining to the transfer of residents are in 42 CFR 483.15. Under 42 CFR 483.15(c), a facility is only permitted to transfer a resident under certain circumstances. These circumstances do not contemplate the ability to transfer a resident where the transfer would be harmful to the physical or mental health of the resident being transferred. Because the Department is proposing to adopt the Federal requirements, and a facility would be prohibited under 42 CFR 483.15(c) from transferring a resident where the transfer would be harmful to that resident, there is no need to include this requirement in State regulation.

Subsection (i)

This subsection remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and to avoid conflict with the Federal requirements. Under 42 CFR 483.10(b), a resident has the right to exercise their rights as a resident of the facility and as a citizen or resident of the United States. Under 42 CFR 483.10(g)(4) and (5), a resident has the right to receive notices orally and in writing in a format and a language that they understand. The notices required under 42 CFR 483.10(g)(4) include contact information for all pertinent State regulatory and informational agencies, advocacy groups, the State Long-Term Care Ombudsman and others. A facility is also required to provide information for filing grievances or complaints. Under 42 CFR 483.10(g)(5), a facility is required to post this information, in a form and manner that is accessible and understandable to residents and resident representatives. In addition, under 42 CFR 483.10(j), a resident has the right to voice grievances to the facility or to an agency or entity that hears grievances without discrimination or reprisal or fear of discrimination or reprisal. A facility is also required under 42 CFR 483.10(j)(4) to establish a grievance policy which meets certain minimum requirements, and under 42 CFR 483.10(j)(3), make available information on how to file a grievance or complaint.

Some commentators objected to the deletion of this subsection because they feel it is important to clearly include this requirement in State regulation, even though it is covered by the Federal requirements. The Department declines to make this amendment for the reasons stated at the beginning of this section. Commentators and IRRC commented that the requirement for a facility to "encourage and assist" residents in the exercise of their rights as a resident and a citizen is not present in the Federal requirements. However, the requirements at 42 CFR 483.10(b)(1) provide clear language that a facility must ensure that residents can exercise their rights. Commentators and IRRC also commented that the Department's hotline, which is included in this subsection is not included in the Federal requirements. The number of the hotline may be subject to change, so the broader requirement under 42 CFR 483.10(g)(4)(i)(C) that the phone number, names, addresses (mailing and e-mail) be provided will ensure that up-to-date information is provided to residents. In addition, the Department's web site provides contact information for a concern or a complaint. https://www.health.pa.gov/topics/facilities/nursing%20homes/Pages/Nursing%20Homes.aspx. As provided on the web site, if a resident, resident representative or family member has a concern or complaint, the Department may be contacted at (800) 254-5164; c-ncomplai@pa.gov; by the online complaint form http://apps.health.pa.gov/dohforms/FacilityComplaint.aspx; Fax (717) 772-2163, or by mail at Division of Nursing Care Facilities Director, Department of Health, Division of Nursing Care Facilities, 625 Forster Street, Room 526, Health and Welfare Building, Harrisburg, PA 17120-0701.

Commentators and IRRC also commented that the requirement that a facility include the telephone number of the local legal services program is not expressly listed in the Federal requirements. However, the Federal requirements at 42 CFR 483.10(g)(4)(i)(C) and 42 CFR 483.10(g)(4)(ii) do require that the facility provide contact information for State and local advocacy organizations, including, but not limited, to the State Long-Term Care Ombudsman program. If a resident is not provided with the information for legal advocacy organizations, the Ombudsman program would be able to provide an appropriate referral. Commentators and IRRC also commented that the Federal requirements do not include a requirement that the information be physically posted in a prominent location and in large print. However, under 42 CFR 483.10(g)(5), the facility must post the information in a form and manner accessible and understandable to residents and resident representatives.

Subsection (j)

This subsection remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and to avoid conflict with the Federal requirements. Under 42 CFR 483.10(a)(1), a facility is required to treat each resident with respect and dignity and to care for each resident in a manner and in an environment that promotes maintenance or enhancement of quality of life, while recognizing each resident's individuality. Under 42 CFR 483.10(h), a resident has a right to personal privacy and confidentiality of personal and medical records. Some commentators opposed the deletion of this subsection to keep a statement regarding treating each resident with respect and dignity in the regulations. Based on the Federal requirements that expressly require respectful and dignified treatment, the Department declines to make this requested change.

Subsection (k)

This subsection remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and to avoid conflict with the Federal requirements. Under 42 CFR 483.10(e)(2), a resident has the right to retain and use personal possessions, including clothing and furnishings, as space permits, unless to do so would infringe upon the rights or health and safety of other residents. Under 42 CFR 483.10(i), a facility must provide residents with a safe, clean, comfortable and homelike environment, and allow residents to use their personal belongings to the extent possible. This includes the provision of private closet space in each resident's room. Although commentators opposed the deletion of this subsection, they did not provide an explanation of why this provision should be retained. To maintain consistency and eliminate duplication, the Department declines to make this requested change.

Subsection (l)

Subsection (l) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and to avoid conflict with the Federal requirements. The ability of a resident representative to exercise the rights of a resident is addressed in 42 CFR 483.10(b). Under that subsection, a resident representative has the right to exercise a resident's rights to the extent those rights are delegated to the resident representative, either by the resident or by law. Some commentators objected to the deletion of subsection (l), with one commentator stating that the section should be retained and improved upon with an explicit statement that, regardless of any delegation of decision-making authority to third parties, facilities must ascertain the resident's wishes and preferences and allow the resident to participate in the care planning process. A commentator also recommended that the rights and authority of resident representatives be detailed in this subsection, and recommended language that mirrors the Federal requirements at 42 CFR 483.10(b)(7). The Department declines to make these requested changes because the rights and authority of a resident representative are clearly articulated in 42 CFR 483.10(b), including a statement that to the extent practicable, the resident must be provided with opportunities to participate in the care planning process, and a statement that resident representatives acting on behalf of a resident must consider the resident's wishes and preferences.

A commentator also recommended that language be added to this subsection codifying a resident's right to visitors and an essential caregiver. The commentator recommended language stating that a resident has a right to their choice of visitors, except where a court order restricts this right. The Department declines to make this requested change because visitation rights are already protected by the Federal requirements at 42 CFR 483.10(f)(4). When visitation is restricted by a court order, a facility is already required by law to comply with that order. The commentator also suggests that a statement be included that ensures that during periods when visitation is restricted, the resident retains the right to identify at least one essential caregiver to visit in-person, and that the facility may not prohibit entry of a caregiver who is following the facility's safety protocols. The Department declines to make this change because the allowance for an essential caregiver is set forth in and governed by statute under the Access to Congregate Care Facilities Act (35 P.S. §§ 10281—10289).

Subsection (m)

This subsection remains deleted in this final-form rulemaking. Comments received on this subsection are addressed previously in subsection (a).

Subsection (n)

This subsection is deleted in this final-form rulemaking. The first and last sentence of existing subsection (n) are moved to subsection (c.2), as explained previously. Additional comments are discussed as follows.

Commentators opposed the deletion of the second sentence in this subsection, which currently requires rights to be provided on admission and requires the facility to ensure that this policy is fully communicated to residents who cannot read, write or understand English. Commentators noted that this provision helps ensure that that limited English proficiency (LEP) residents and residents with disabilities understand their rights. IRRC noted these comments and asked the Department to explain how deleting this provision protects the public health, safety and welfare related to providing notice of resident rights to a resident, particularly to a resident who cannot understand English. After careful consideration, the Department declines to make this change and retain this provision as it is covered by the Federal requirements. As the Department explained in the proposed rulemaking, under 42 CFR 483.10(g)(16), a facility must provide a notice of rights and services to residents prior to or upon admission and during the residents' stay. Specifically, a facility must inform a resident of their rights and all rules and regulations governing resident conduct and responsibilities during their stay in the facility, both orally and in writing, in a language that the resident understands. 42 CFR 483.10(g)(16)(i). Additionally, the Federal requirements at 42 CFR 483.10(g)(3) require that a facility provide information to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand.

Subsection (o)

This subsection is deleted in this final-form rulemaking. Resident rights with respect to experimental treatment are moved to new subsection (c.3)(3), with amendments, as described previously.

Subsection (p)

This subsection is deleted in this final-form rulemaking. The language that was proposed in subsection (p) is moved to new subsection (c.3)(4), without amendment, as described previously.

Other Comments

A commentator stated that it is critical that the regulations include requirements that aid residents and their representatives in understanding their rights. The commentator also stated the importance of communicating what recourses are available to residents if their rights are violated.

As previously provided, clear communication of resident rights is already detailed at 42 CFR 483.10(g)(3), which requires that the facility provide information to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand. The Federal requirements establish that facilities must furnish to each resident a written description of legal rights, which includes the names and contact information of all pertinent State regulatory and informational agencies, resi-

dent advocacy groups, the State licensure office, the State Long-Term Care Ombudsman program, and adult protective services, among others. In addition, facilities must provide residents a statement that the resident may file a complaint with the State Survey Agency concerning any suspected violation of State or Federal long-term care nursing facility regulations. 42 CFR 483.10(g)(4)(i)(C)—(D). Since these comments are addressed by adoption of the Federal requirements, the Department declines to make these requested changes.

A commentator recommended that each place where a resident right is set forth begin with the words "residents have a right to. . ." The Department recognizes the importance of communicating information to residents in a manner that residents can understand, but declines to make this amendment in this final-form rulemaking. Under 42 CFR 483.10(g)(3), a facility is required to provide information to each resident in a form and manner the resident can access and understand. In addition, as noted at the beginning of this section, the Department has created a template of resident's rights, which sets forth a resident's rights in clear and easy to understand language, which facilities may utilize. This template is attached as Exhibit A and will also be posted on the Department's web site.

A commentator highlighted the need for residents to be respected and treated as responsible adults and not be treated as though they are living in prisons. The Department agrees that it is important that residents be treated with respect, and this right is provided for in the Federal requirements at 42 CFR 483.10(a)(1), which provides that a facility must treat each resident with respect and dignity and care for each resident in a manner and in an environment that promotes maintenance or enhancement of their quality of life. The commentator also stated that, when possible, a variety of enriching experiences outside of the facility and inside the facility should be made available to residents. Enriching experiences are also provided for in the Federal requirements at 42 CFR 483.24(c) (relating to quality of life), which requires that a facility provide an ongoing program to support residents in their choice of activities designed to meet the interests of residents and encouraging both independence and interaction in the community. Therefore, the Department declines to make this requested amendment.

A commentator, in comment to proposed Rulemaking 2, recommended that, when a facility plans to conduct construction, alteration or renovation, they first present the written plan, architectural renderings and a plain language description of their plans to the resident and family council and the Long-Term Care Ombudsman. The Department considered this comment in its review of comments on § 201.29, because the commentator's recommendation would afford residents a right to review the previously-mentioned documents. After careful consideration, the Department determined that, while it may be a best practice to share information regarding plans for construction, alteration or renovation with the resident council, it does not constitute a minimum health and safety requirement that must be included in the regulations to protect the health, safety and welfare of residents. Therefore, the Department declines to make this requested amendment.

Another commentator, in comment to proposed Rulemaking 2, suggested that a doorbell be installed outside of each resident room and that staff be required to knock prior to entering a resident's room. The Department declines to include a requirement that a doorbell be installed outside each room. The Department considers knocking and requesting permission to enter to fall within a resident's preferences, subject to an emergency, which is covered by 42 CFR 483.10(e)(3), which provides that a resident has the right to reside and receive services in the facility with reasonable accommodation of resident needs and preferences except when to do so would endanger the health or safety of the resident or other residents. If a resident prefers that staff knock before entering the resident's room, then the resident has the right to that accommodation, as long as it does not endanger their health or safety or the health or safety of others. Therefore, the Department declines to make the requested amendment.

A commentator recommended adding language that establishes a resident's right to visitors and essential caregivers. The Department declines to make this requested amendment because the Federal requirements at 42 CFR 483.10(f)(4) provide that a resident has the right to receive visitors of the resident's choosing. In addition, the Department declines to make this change because the allowance for an essential caregiver is set forth in and governed by statute under the Access to Congregate Care Facilities Act (35 P.S. § 10281—10289) as discussed previously.

A commentator also requested the Department to add protections for residents related to a resident's ability to appeal an "involuntary discharge" from the facility due to concerns related to Medical Assistance (MA) appeals regarding the discharge of residents who are MA beneficiaries. The commentator specifically asserts concerns regarding burden of proof and the ability for a resident to prepare an effective case. The Department notes that a notice of discharge is required and Federal requirements at 42 CFR 483.15(c)(3) require the notice to include the reasons for the discharge. The reason must also be noted in the medical record, which the resident has a right to access under 42 CFR 483.10(g)(2). Furthermore, this comment, which relates to the hearing and appeals process under 55 Pa. Code Chapter 1181 (relating to nursing facility care) for providers participating in the MA program is outside the scope of this rulemaking and the Department's authority. The Department declines to make this suggested amendment.

A commentator suggested that the Department add a requirement that residents have the right to receive care in accordance with the resident's care plan. The Department declines to make this suggested amendment because it would be duplicative of 42 CFR 483.10(c)(2), which provides that a resident has the right to participate in the development and implementation of their person-centered plan of care, including the right to receive the services or items included in the plan of care.

A commentator also recommended that the Department add a requirement that residents have the right to recognition of their families of choice and domestic partnerships the same as traditional family units and marriages. The Department declines to make this additional amendment to this section because under amended subsection (c.3)(4), described previously, a resident has the right to care without discrimination on the basis of sexual orientation. Residents also have the right to dignity, self-determination, and communication with and access to persons inside and outside the facility under 42 CFR 483.10(a). Also, in the case of visitation, under 42 CFR 483.10(f)(4)(vi), residents have a right to receive visitors designated by the resident, including a spouse, a domestic partner, another family member or a friend. The right to

visitation shall not be restricted on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation or disability.

Next, the commentator recommended that the Department add a requirement that residents have the right to go to their hospital of choice even if the facility has a transfer agreement with other hospitals and to also require that facilities inform residents of the facility's transfer agreements upon admission. The Department declines to add this requirement because there are protections in place to ensure that a resident's preferences regarding medical care are honored. For example, the Federal requirements at 42 CFR 483.10(f) provide that a resident has the right to, and the facility must promote and facilitate resident self-determination through support of resident choice. Under 42 CFR 483.10(c), residents have the right to be informed of, and to participate in, their treatment, which includes the right to be fully informed in language that they can understand of their total health status, including but not limited to, their medical condition. Residents also have the right to participate in the development and implementation of their person-centered plan of care, which includes but is not limited to, the right to participate in the planning process and in establishing goals and the right to be informed in advance of changes to the plan of care. In addition, the facility is required to inform residents of the right to participate in their treatment and is required to support residents in this right. Residents also have the right to be informed, in advance, of the care to be furnished and the type of caregiver or professional that will furnish care. Residents have the right to be informed in advance of risks and benefits of proposed care, of treatment and treatment alternatives or treatment options and to choose the alternative or option they prefer. Finally, residents also have the right to request, refuse or discontinue treatment. 42 CFR 483.10(c). The Department expects facilities to comply with these rights, which would extend to a resident's right to make choices regarding their care including the ability to choose a hospital, in a non-emergency situation. However, the Department also notes that while a facility should strive to honor a resident's choice in hospitals, it may not always be feasible to transfer residents to their hospital of choice in an emergent situation, due to the location of the preferred hospital or the type or level of care needed.

The commentator also recommended that the Department add a requirement that residents be provided with annual resident rights training by the Long-Term Care Ombudsman. As provided previously, the Department declines to make this amendment since the Department does not have the authority to require that the State Long-Term Care Ombudsman or personnel from other agencies conduct trainings.

Next, the commentator recommended that the Department add a statement that residents have the right to bring a private right of action and establish a prohibition on facilities asking residents to waive that right. Generally, residents have a right, under 42 CFR 483.10(b), to exercise their rights as a resident of the facility and as a citizen or resident of the United States. Where a private right of action is available by law, that right applies to residents in a facility. Further, based on comments received, the Department is maintaining the provision that a facility may not obtain from or on behalf of residents a release of liabilities or duties imposed by law or Subpart C in § 201.24(b).

Next, the commentator recommended that there be a requirement that residents be provided with a written notice of resident rights and responsibilities and payment policies, including filial responsibility and estate recovery rules that may apply as well as information about the right to choose whether to have the facility serve as the resident's representative payee for Social Security. After careful consideration, the Department declines to make this amendment. Under 42 CFR 483.10(g)(16), a facility must inform the resident both orally and in writing of their rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. In addition, under amended § 201.29(b), policies and procedures regarding rights and responsibilities of residents must be available to residents. Further, under amended § 201.29(c.1), a facility must post a notice in the facility which sets forth the list of resident rights. A facility must also provide residents with personal notice of resident rights. See § 201.29(c.2).

Regarding payment policies, the Federal requirements under 42 CFR 483.10(g)(18) provide that the facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services. Further, the designation of the facility as a representative payee by the Social Security Administration is governed by the Social Security Act and accompanying regulations. Similarly, the Medical Assistance Estate Recovery program is only applicable to MA beneficiaries and governed by the Department of Human Services regulations under 55 Pa. Code Chapter 258 (relating to Medical Assistance estate recovery). In addition, filial support is governed by the statutory provisions under 23 Pa.C.S. Chapter 46 (relating to support of the indigent). The Department declines to make this amendment to require nursing facilities to provide notice regarding these other Federal and State programs as they are outside of the Department's purview.

Next, the commentator recommended that the Department add a requirement that residents be informed about bed hold policies prior to a transfer to a hospital and provide information on how the facility tracks the period in which the resident is absent from the facility. After careful consideration, the Department declines to add this requirement. Under the Federal requirements at 42 CFR 483.15(d), when a resident is transferred, the facility must provide written information about the facility's policies regarding bed-hold periods, as well as written notice that specifies the duration of the bed-hold policy. For MA beneficiaries, beds may be held for a maximum of 15 days per hospitalization. 55 Pa. Code 1187.104 (relating to limitations on payment for reserved beds).

Next, the commentator recommended that language be added establishing that a resident has a right to privacy, and that LGBT residents have the right to decide who knows about their sexual orientation and gender identity, and if, when or how they choose to come out. They suggest that outing a resident or disclosing their gender history, sexual orientation or HIV status without their consent should be prohibited. After careful consideration, the Department declines to make this suggested amendment. Residents have a right, under 42 CFR 483.10(a)(1), to respect and dignity and care in a manner that promotes maintenance or enhancement of their quality of life, recognizing each resident's individuality. Additionally, under 42 CFR 483.10(e)(3), a resident has a right to be treated with respect and dignity, including reasonable accommodation of resident needs and preferences. In some cases, sharing of information such as gender history or HIV status could constitute sharing of medical information, which is prohibited under 42 CFR 483.10(h),

which states that a resident has a right to personal privacy and confidentiality of their personal and medical records. Finally, under § 201.29(c.3)(4), a resident has the right to care without discrimination based upon sexual orientation or gender identity or expression.

Lastly, the commentator suggested that language be added stating that residents have the right to be free from restraints except where medically ordered and where restraints provide the least restrictive alternative, as outlined in the resident's care plan. After careful consideration, the Department declines to make this amendment. Restraints are addressed in § 211.8 (relating to use of restraints), described as follows, and a medical order is required for restraints in accordance with § 211.8(d). In addition, the Federal requirements at 42 CFR 483.12(a)(2) establish that when the use of restraints is indicated, a facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints. This is reiterated in § 211.8(c.1), which provides that when utilized, a facility must use the least restrictive method for the least amount of time to safely and adequately respond to individual resident needs in accordance with the resident's comprehensive assessment and comprehensive care plan.

§ 201.30. Access requirements

This section remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this section to eliminate duplication and avoid conflict with the Federal requirements at 42 CFR 483.10(f). Under 42 CFR 483.10(f)(4), a resident has a right to receive visitors of their choosing at the time of their choosing. A facility must provide immediate access to certain individuals, subject to the resident's right to deny visitation. The Federal requirements further require that a facility must provide reasonable access to any entity or individual that provides health, social, legal or other services to the resident, subject to the resident's right to deny visitation. A facility must also have written policies and procedures regarding visitation rights, including any clinically necessary or reasonable restriction or limitation or safety restriction or limitation the facility may need to place on these rights. These policies and procedures must include the reasons for this restriction or limitation. 42 CFR 483.10(f)(4).

Subsection (a)

Commentators requested that the Department retain the language in subsection (a) with amendments. Specifically, commentators requested that the Department add language that facilities may not limit forms of access (telephonic, videographic and electronic) to residents, except in accordance with State and Federal public health mandates or court orders. After careful consideration, the Department declines to retain this subsection or add any additional language in this final-form rulemaking. The Federal requirements at 42 CFR 483.10(g)(7) provide that a facility must protect and facilitate a resident's right to communicate with individuals and entities within and external to the facility, including reasonable access to telephone, internet, stationery, postage, writing implements and the ability to send mail. Under 42 CFR 483.10(g)(8), a resident has the right to send and receive mail, and to receive letters, packages and other materials delivered to the facility for the resident through a means other than a postal service.

A commentator also requested that the Department retain the language in subsection (a) prohibiting a facility from questioning an attorney, ombudsman staff or agency representatives about the reason for their visit to a resident, as similar language is not included in the Federal requirements. After careful consideration, the Department declines to retain this language. The intent behind the language in subsection (a) that the Department deleted was to prevent a facility from retaliating against a resident who has complained about the facility by dissuading the resident from meeting with the Ombudsman or an attorney. However, the Federal requirements at 42 CFR 483.10(b)(1) provide that a facility must ensure that a resident can exercise their rights without interference, coercion, discrimination or reprisal from the facility. Further, 42 CFR 483.10(b)(2) states: "The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising their rights and to be supported by the facility in the exercise of their rights as required under this subpart." Therefore, the language noted by the commentator in subsection (a) is covered under the Federal requirements and the Department declines to make this change.

Subsection (b)

A commentator requested that the Department retain language in subsection (b) that requires that a person not enter the living area of a resident without identifying themselves to the resident and receiving permission to enter as this provision is not included in the Federal requirements. After careful consideration, the Department declines to retain this language. As stated previously, 42 CFR 483.10(f)(4) provides that "[t]he resident has a right to receive visitors of their choosing at the time of their choosing, subject to the resident's right to deny visitation when applicable, and in a manner that does not impose on the rights of another resident." This covers the language that the Department deleted in subsection (b). Specifically, 42 CFR 483.10(f)(4) provides that the resident has the ability and right to receive visitors of their choosing. As applied, this regulation requires that the resident would need to be aware of the identity of the visitor and the time for visitation prior to consenting to visitation. To the extent that the potential visitor does not identify themselves to the resident, the resident has the right to deny visitation.

Other Comments

IRRC previously noted in several comments and requested the Department explain the reasonableness of not providing in the final regulation for the protection of a resident's right to visitors and control over who enters the living area, and how the final regulation protects the public health, safety and welfare related to a resident's right to visitors and control over who enters the living area. As explained previously, the Department is not removing the protections related to the rights of visitors and control of who enters the living area. The Federal regulations at 42 CFR 483.10(b)(2), (f)(4) and (g)(7) and (8) address the Federal health and safety requirements related to consenting to and denying visitation, communication, and freedom from interference and coercion. As previously stated, the Department declines to make the suggested change.

A commentator suggested that the Department add a subsection prohibiting facilities from limiting access to the facility by State and local officials, including the Department, the Department of Human Services, the Long-Term Care Ombudsman Program, Protective Services, Protection and Advocacy, Law Enforcement, and others with legal authority to enter. Another commentator requested that the Department make facilities' obligations

to allow visitors and representatives from government agencies and other entities, such as those similar to and including the ones listed previously, more explicit. After careful consideration, the Department declines to add this language. Under 42 CFR 483.10(f)(4)(i), representatives of the State and representatives of the Office of the State Long-Term Care Ombudsman are to be provided immediate access to any resident of the facility. Furthermore, other parties with the legal authority to enter the facility would already be granted this authority by operation of law, and the Department need not include duplicative language in this subsection. Finally, the Federal requirements at 42 CFR 483.10(f)(4) provide explicit requirements for facilities to follow in allowing residents to have visitors. The Federal requirements at 42 CFR 483.10(f)(4)(iv) specifically state that "[t]he facility must provide reasonable access to a resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time."

§ 201.31. Transfer agreement

The Department retains this section in this final-form rulemaking. The Department had proposed to delete this section to eliminate duplication and avoid conflict with the Federal requirements at 42 CFR 483.70(j), which requires a facility to have in effect a written transfer agreement with one or more hospitals that are approved for participation under Medicare or MA. Commentators opposed the deletion of this section, asserting that the Federal requirements are less stringent and that it is unacceptable for a facility to lack an agreement for the transfer of residents, even if the facility has tried in good faith to obtain one but has failed. IRRC asked, if the provisions in this section were removed in this final-form rulemaking, that the Department address how the regulation would protect the public health, safety and welfare in the event of a need to transfer a resident to a hospital if no transfer agreement is in effect. Upon further review of the Federal requirements at 42 CFR 483.70(j) and in consideration of public comments, the Department has decided to retain the existing language in § 201.31 (relating to transfer agreement) which requires a facility to have a transfer agreement with one or more hospitals, without exception.

Some commentators requested that the Department add language to this section to allow for a resident to have a choice of hospitals in non-emergency situations. One commentator also indicated that a facility should be required to counsel residents on the implications of receiving care at different local hospitals, which would include providing residents with information on whether the hospital participates in their health insurance plan. Other commentators echoed that the Department should add language requiring a facility to assist residents in determining which providers are considered in-network providers for insurance coverage.

After carefully considering these comments, the Department declines to make these amendments, as these considerations are contemplated and discussed under Resident Rights. As discussed previously, under 42 CFR 483.10(f), a resident has the right to, and the facility must promote and facilitate resident self-determination through support of resident choice. Under 42 CFR 483.10(c), residents have the right to be informed of, and to participate in, their treatment, which includes the right to be fully informed in language that they can understand of their total health status, including but not limited to, their medical condition. Residents also have the right to participate in the development and implementation of their person-centered plan of care, which includes but is not limited to, the right to participate in the planning process and in establishing goals and the right to be informed in advance of changes to the plan of care. In addition, the facility is required to inform residents of the right to participate in their treatment and is required to support residents in this right. Residents also have the right to be informed, in advance, of the care to be furnished and the type of caregiver or professional that will furnish care. Residents have the right to be informed in advance of risks and benefits of proposed care, of treatment and treatment alternatives or treatment options and to choose the alternative or option they prefer. Finally, residents also have the right to request, refuse or discontinue treatment. The Department expects facilities to comply with these rights, which would extend to a resident's right to make choices regarding their care including the ability to choose a hospital, in a non-emergency situation. However, the Department also notes that while a facility should strive to honor a resident's choice in hospitals, it may not always be feasible to transfer residents to their hospital of choice in an emergent situation, due to the location of the preferred hospital or the type or level of care needed.

One commentator also requested that the Department add a subsection to require a facility to consider resident Medicare and MA health plan network limitations prior to proposing a transfer to a hospital. After careful consideration, the Department declines to make this amendment as part of the licensure requirements for a nursing facility. Payment provisions and participation requirements are governed by the Medicare and MA Programs.

§ 207.2. Administrator's responsibility

Subsection (a)

This subsection remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the requirement in existing subsection (a), pertaining to the administrator's responsibility for housekeeping and maintenance, is moved to § 201.18(e)(2.a). Thus, there is no need to retain this requirement here.

Subsection (b)

This subsection remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes subsection (b) as this provision is outdated. In recent years, there has been a shift in the long-term care nursing environment to providing residents with a more homelike environment; therefore, services are sometimes provided by a limited set of nursing staff, who, as in a household, are responsible for a variety of tasks, including housekeeping duties. As provided as follows, facilities are still expected to comply with the requirement under 42 CFR 483.35(a)(1) that the facility must provide services by sufficient numbers of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans. In addition, facilities still must meet the requirement in § 211.12(i)(1) that only direct resident care provided by nursing service personnel may be counted towards the total minimum number of hours of general nursing care required under § 211.12(i).

A commentator thanked the Department for broadening the scope of tasks allowed to be completed by nursing personnel. Other commentators expressed concern that the deletion of this provision will result in facilities requiring nursing personnel to perform housekeeping duties, which will reduce the time nursing personnel

spend on direct nursing care to residents. These commentators believe there is a risk that, without the language in subsection (b), nursing staff will be expected to complete an ever-increasing list of tasks, and facilities will use nursing staff to address staff shortages in other areas of the facility. IRRC agreed with commentators and questioned the reasonableness of expanding the duties of nursing personnel to include housekeeping duties given the numerous comments received on the existing nurse staffing shortage. IRRC asked the Department to explain how adding housekeeping duties to nursing personnel in the final regulation is reasonable and protects the public health, safety and welfare.

In response to these comments, the Department clarifies that the deletion of this subsection is intended to promote the use of household model facilities where nursing personnel attend to a small number of residents, for example ten residents, in which the residents and staff contribute to the maintenance of the household. These models are resident-centered and directed and include the empowerment of staff and residents to work as a team to provide care. PHI. (2018) The Household Model: Creating a 'Home' in Nursing Homes. Retrieved from https://www.phinational.org/household-model-creates-real-home-people-living-nursing-homes/. As provided above, despite the deletion of subsection (b), facilities would still be expected to comply with the requirement under 42 CFR 483.35(a)(1) that the facility must provide services by sufficient numbers of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans, as well as the requirement in § 211.12(i)(1) that only nursing service personnel may be counted towards the total number of minimum hours of general nursing care required under § 211.12(i).

A commentator also recommended adding a subsection requiring that housekeeping and maintenance staff be properly trained in infection control and that they operate at all times in accordance with the infection control instructions of the facility's infection preventionist. The Department declines to add this requirement because the training of all staff related to infection control is already required by the Federal requirements. Under 42 CFR 483.95(e), a facility must include as part of its infection prevention and control program mandatory training that includes the written standards, policies and procedures for the program as described at § 483.80(a)(2) (relating to infection control). Facility staff are expected to follow the written standards, policies and procedures of the infection prevention and control program.

§ 209.3. Smoking

The Department amends this section in this final-form rulemaking. As explained on proposed, the Department deletes this section in its entirety to eliminate duplication and avoid conflict with the Federal requirements. Under 42 CFR 483.90(i)(5), a facility is required to establish policies, in accordance with applicable Federal, State and local laws and regulations, regarding smoking, smoking areas and smoking safety that also take into account non-smoking residents. The *Life Safety Code*, which has been adopted in the Federal requirements at 42 CFR 483.90(a), also addresses requirements for smoking policies at 18.7.4 and 19.7.4.

Commentators commented that there are several aspects of this section that are not included in the Federal requirements, which should be retained, including the requirement that smoking policies be posted in a conspicuous place and in legible format, and the requirement that adequate supervision be provided for residents who smoke. Commentators indicated that they assume that requirements in this section are included in the *Life Safety Code*, but if they are not, they should be retained. Commentators also expressed concern for the rights of residents who smoke, indicating that it is extremely difficult for residents to give up smoking. Commentators recommended that the Department add a requirement that changes in smoking policies may only be implemented prospectively, with residents who were admitted under an earlier smoking policy being grandfathered into that policy. Commentators argued that at a minimum, smoking policies should be communicated with residents before admission so they can decide whether the facility will meet their needs.

IRRC noted the comments regarding the posting of smoking policies and adequate supervision of residents while smoking and asked the Department to explain how the regulation protects the public health, safety and welfare by not providing requirements related to the posting of smoking policies and a requirement for adequate supervision for residents while smoking.

After careful consideration, the Department amends § 209.3 in response to these comments to retain subsections (a), (c) and (d), to retain provisions related to the posting of smoking policies, adequate supervision for residents who require it, and to prohibit smoking in bed. The Department deletes the word "the" and adds the words "smoking and" before the word "nonsmoking" to make it clear that a facility's policies shall include provisions for the protection of the rights of both smoking and nonsmoking residents. In response to questions the Department received regarding whether subsections (b), (e), (f) and (g) are covered by the *Life Safety Code*, the Department notes that the *Life Safety Code* at sections 18.7.4 and 19.7.4. states the following with regards to smoking, which supplant these deleted subsections:

1) Smoking regulations shall be adopted and shall include not less than the following provisions: Smoking shall be prohibited in any room, ward, or individual enclosed space where flammable liquids, combustible gases, or oxygen is used or stored and in any other hazardous location, and these areas shall be posted with signs that read NO SMOKING or shall be posted with the international symbol for no smoking.

2) In health care occupancies where smoking is prohibited and signs are prominently placed at all major entrances, secondary signs with language that prohibits smoking shall not be required.

3) Smoking by patients classified as not responsible shall be prohibited.

4) The requirement of 18.7.4(3) shall not apply where the patient is under direct supervision.

5) Ashtrays of noncombustible material and safe design shall be provided in all areas where smoking is permitted.

6) Metal containers with self-closing cover devices into which ashtrays can be emptied shall be readily available to all areas where smoking is permitted.

§ 211.2. Medical director

The title of this section is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department amends the title of this section to "medical director" to more accurately reflect the substance of this section, as amended.

Subsection (a)

Subsection (a) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and avoid conflict with the Federal requirements for facilities. Under 42 CFR 483.30 (relating to physician services), a physician is required to approve in writing an individual's admission to a facility, and each resident in a facility must remain under the care of a physician. Under 42 CFR 483.21(b), a facility is required to develop and implement a comprehensive person-centered care plan for each resident. This care plan is prepared by an interdisciplinary care team that includes the attending physician, the resident and resident representative, and others who are involved in the resident's care.

A commentator suggested that the Department retain subsection (a), arguing that the Federal requirements do not provide the specificity required to ensure that the medical care delivered to residents is compliant on a consistent basis. The requirements under 42 CFR 483.30 require that the medical care of each resident is supervised by a physician, who must review the resident's total program of care, including medications and treatments, at each visit. Further, the resident must be seen by a physician at least once every 30 days for the first 90 days after admission and at least once every 60 days thereafter. Under 42 CFR 483.70(h), a facility must designate a physician to serve as medical director, who is responsible for the coordination of medical care in the facility. Facilities are required to comply with these requirements to ensure that residents are receiving quality medical care. The Department declines to make this suggested amendment.

Subsection (b)

Subsection (b) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and avoid conflict with the Federal requirements. Under 42 CFR 483.20(a) (relating to resident assessment), a facility is required to have, at the time of admission, a physician's orders for the resident's immediate care. Further, under 42 CFR 483.21(a), a facility is required to develop and implement, within 48 hours of admission, a baseline care plan for each resident. The baseline care plan must include the minimum healthcare information necessary to properly care for a resident, including physician orders. A facility is also required, under 42 CFR 483.20(b), to conduct a comprehensive assessment of a resident's needs, strengths, goals, life history and preferences, using a resident assessment instrument. Under 42 CFR 483.20(b)(2)(i), this assessment must be conducted within 14 days after admission.

A commentator recommended retaining subsection (b) but amending it to require that the initial medical assessment be conducted no later than 3 calendar days after admission, instead of the current requirement for no later than 14 days after admission. As noted, a facility must initially conduct a comprehensive resident assessment under 42 CFR 483.20(b)(2)(i), which must occur within 14 days after admission. However, prior to this comprehensive resident assessment, a facility must develop and implement a baseline care plan, under 42 CFR 483.21(a) within 48 hours of admission, which provides for initial goals based on admission orders, physician orders, dietary orders, therapy services, social services and a PASARR recommendation, if applicable. The facility may develop a comprehensive care plan in place of the baseline care plan if the comprehensive care plan is developed within 48 hours. The baseline care plan serves the same purpose as the "initial medical assessment" suggested by the commentator and is required to be completed in an even shorter timeframe than the one suggested by the commentator. The Department, therefore, declines to make this amendment.

Subsection (c)

Subsection (c) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department amends the first sentence of subsection (c), to delete language that is duplicative of the Federal requirements for the provision of a medical director and to include a cross-reference to the Federal requirements for a medical director at 42 CFR 483.70(h). Under 42 CFR 483.70(h), a facility is required to designate a physician to serve as medical director. The medical director is responsible for implementation of resident care policies and the coordination of medical care in the facility. The Department, however, retains the requirement that the medical director be licensed as a physician in this Commonwealth, as that is not specifically indicated in the Federal requirements for a medical director.

The Department also adds, at the request of stakeholders, a requirement that the medical director complete at least 4 hours annually of continuing medical education (CME) pertinent to the field of medical direction or post-acute and long-term care medicine. The Department has determined that this addition, which is not included in the Federal requirements, is necessary to ensure that the medical director of a facility remains current in the field. Having a knowledgeable medical director is critical to the provision of quality care. Additionally, requiring 4 hours of CME pertinent to the field of medical direction or post-acute and long-term care medicine will not present a burden for medical directors as these hours would count towards the 100 minimum CME hours required annually for physicians to maintain their licensure in this Commonwealth. In the second sentence, the Department removes the ability of a facility to have a medical director serve on a full or part-time basis. Under 42 CFR 483.70(f), a facility is required to have professional staff on a full-time, part-time or consultant basis as needed. This would extend to the medical director.

Several commentators were supportive of the amendments to this section in the proposed rulemaking. A commentator requested that the Department explain how it would oversee and track the medical director CME requirement. The commentator suggests that the Department consider changing its proposed 4-hour CME requirement to 1 hour of in-service training by the long-term care nursing facility within its QAPI program. Finally, the commentator seeks clarification on whether there will be an approved training site for medical directors. IRRC also asked how this provision would be implemented; "[f]or example, who will monitor whether the training is completed?"

In response to these comments and questions, the Department notes that CME requirements would simply be noted in the medical director's personnel file with the facility, as required by § 201.19(7) (relating to personnel records). The Department will check for compliance with § 201.19(7) when it surveys a facility. Also, while the Department appreciates the suggestion that the CME requirement be replaced with in-service training in the QAPI program, training in the QAPI program is required separately under 42 CFR 483.95(d), which requires mandatory training that outlines and informs staff of the

elements and goals of the facility's QAPI program. Also, requiring 4 hours of relevant CME training will not be overly burdensome to medical directors, as they are already required to complete 100 hours of CME training annually to maintain their physician's license. These 4 hours of CME pertinent to the field of medical direction or post-acute and long-term care medicine would count towards (and would not be in addition to) the 100 minimum CME hours. With respect to the question as to whether there will be an approved training site for medical directors, the Department is not able to address CME training locations as the Department is not vested with the authority to vet and oversee CME training.

Commentators objected to the deletion of language permitting a medical director to serve on a full-time or part-time basis depending on the needs of the residents and facility. Commentators expressed concern that the deletion of the full-time or part-time language would permit a facility to hire a consultant to serve as the medical director. A commentator also expressed concern with the deletion of "depending on the needs of the residents and facility," asserting that this is not covered in the Federal requirements. The commentator believes that deferring to the Federal requirements in 42 CFR 483.70(f) will lower the standard for medical director coverage in this Commonwealth. The commentator asserts that as the acuity of residents' needs has increased, professional oversight in facilities is crucial to ensuring quality care and is needed now more than ever. IRRC asked the Department to explain how permitting a medical director to serve on a consultant basis protects the public health, safety and welfare, particularly without the qualifying provision that the needs of the residents and facility serve as the basis for the amount of time that a medical director is present.

After careful consideration, the Department declines to make the suggested amendments. Regardless of employment status as either an employee of the facility or a contractor, a medical director is held to the same Federal and State requirements related to resident health and safety. Specifically, the responsibility for the coordination of medical care in the facility remains the same. Additionally, the requirement for the presence of the Medical Director must not be conflated with the employment status of the director. Resident and facility needs, including the medical director's responsibilities under subsection (d), will dictate the level of medical director presence, as both medical directors and residents are involved in the development of residential care policies pursuant to 42 CFR 483.70(h).

Subsection (d)

Subsection (d) is amended from the proposed rulemaking to this final-form rulemaking. In the proposed rulemaking, the Department deleted this subsection in its entirety to eliminate duplication and avoid conflict with the Federal requirements. Paragraph (1) is covered by 42 CFR 483.75(g)(1), which requires a facility to maintain a quality assessment and assurance committee. The medical director or the medical director's designee serves on this committee. Paragraph (2) is covered under 42 CFR 483.70(h)(2). Under 42 CFR 483.70(h)(2), the medical director is responsible for the implementation of resident care policies and the coordination of medical care in the facility. This includes oversight of the responsibilities of attending physicians.

Commentators asked that the Department retain this subsection and add several requirements addressing the responsibility, role and duties of the medical director in a facility. Commentators assert that the Federal regulations do not provide the specificity to ensure that medical care delivered to residents is compliant on a consistent basis. The Department has carefully considered the suggestions of the commentators. The Department declines to retain paragraphs (1) and (2) as these are covered by the Federal requirements, as explained previously. However, the Department has decided to retain the introductory portion of subsection (d) and to add new requirements in paragraphs (3) through (10) to align with the Federal guidance. As amended in this final-form rulemaking, the medical director's responsibilities shall include at least the following:

Under paragraph (3), ensuring the appropriateness and quality of medical care and medically related care.

Under paragraph (4), assisting in the development of educational programs for facility staff and other professionals.

Under paragraph (5), working with the facility's clinical team to provide surveillance and develop policies to prevent the potential infection of residents in accordance with the infection control requirement under 42 CFR 483.80.

Under paragraph (6), cooperating with facility staff to establish policies for assuring that the rights of individuals are respected.

Under paragraph (7), supporting and promoting person-directed care such as the formation of advance directives, end-of-life care, and provisions that enhance resident decision making, including choice regarding medical care options.

Under paragraph (8), identifying performance expectations and facilitating feedback to physicians and other health care practitioners regarding their performance and practices.

Under paragraph (9), discussing and intervening, as appropriate, with a health care practitioner regarding medical care that is inconsistent with current standards of care.

Under paragraph (10), assisting in developing systems to monitor the performance of the health care practitioners including mechanisms for communicating and resolving issues related to medical care and ensuring that other licensed practitioners who may perform physician-delegated tasks act within their scope of practice.

The Department adds this language from guidance into regulation to provide additional clarity to the regulated community, advocacy organizations, and residents and resident representatives regarding the functions and roles of a medical director in a facility.

Other Comments

Commentators suggested adding a new subsection to require that medical director communication and interactions with residents and resident representatives be person-centered and conducted in a manner easily understood by each resident and provided in the form, format, and language of the resident's need or preference. After careful consideration, the Department declines to make this suggested amendment. Under 42 CFR 483.10(c)(1), a resident has the right to be fully informed in language that they can understand of their total health status, including but not limited to, their medical condition. Section 483.10(c)(2) further states that residents have the right to participate in the development and implementation of their person-centered plan of care. These rights would extend to communications with the medical director.

§ 211.3. Verbal and telephone orders

The title of this section is unchanged from the proposed rulemaking to this final-form rulemaking. As set forth in the proposed rulemaking, the Department replaces the word "oral" with the word "verbal" in the title of this section, as the word "verbal" is more commonly used now in the long-term care nursing environment to describe nonwritten communications.

Subsection (a)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department replaces "a physician's oral" with the word "verbal" at the beginning of this subsection. The amendment from "oral" to "verbal" is made for consistency in the use of terminology. The Department deletes the word "physician" because physicians are not the only individuals permitted to issue orders under scope of practice standards. Under 42 CFR 483.30(e), a physician may delegate tasks to a physician assistant, nurse practitioner or clinical nurse specialist acting within the scope of their practice as defined by State law. The scope of practice for physician assistants, including supervision by a physician, is set forth under section 13 of the Medical Practice Act of 1985 (63 P.S. § 422.13) and in regulation at 49 Pa. Code Chapter 18, Subchapter D (relating to physician assistants). The scope of practice for certified registered nurse practitioners is set forth under section 8.2 of the Professional Nursing Law (63 P.S. § 218.2), and in regulation at 49 Pa. Code Chapter 21, Subchapter C (relating to certified registered nurse practitioners). The scope of practice for clinical nurse specialists is set forth under section 8.6 of the Professional Nursing Law (63 P.S. § 218.6), and in regulation at 49 Pa. Code Chapter 21, Subchapter H (relating to clinical nurse specialists). The Department deletes the last sentence allowing written orders to be faxed, as this is duplicative of existing language in subsection (d), which is retained with amendments, as described as follows.

Subsection (b)

This subsection is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department replaces "a physician's oral" with the word "verbal" in the first sentence for consistency with the proposed amendments to subsection (a). The Department replaces "and treatments" with "treatment or medication" to clarify that this subsection applies to medication orders as well as orders for care or treatment. The Department adds "or physician's delegee authorized under 42 CFR 483.30(e) (relating to physician services)" after the word "physician" to clarify which individuals are permitted to issue verbal orders. The Department deletes the second sentence to align with a physician's ability to delegate tasks under 42 CFR 483.30(e). In this final-form rulemaking, the Department replaces the words "treatment or medication" with "and treatment" and retains subsection (c), which the Department had proposed to delete, with amendment.

The Department had proposed to merge the requirement that verbal and telephone orders for care and treatment be dated and countersigned with the original signature of the physician or physician's delegee within 7 days, with the requirement, currently in existing subsection (c), that verbal and telephone orders for medications be dated and countersigned within 48 hours. The Department's rationale for shortening the length of time from 7 days to 48 hours was that it is imperative that orders be signed within 48 hours to ensure that the orders are correct, especially in cases where the medical issue that is being addressed is urgent.

Commentators, however, commented that the amendment from 7 days to 48 hours, in this subsection, is unreasonable and will be challenging for many facilities. One commentator suggested that 72 hours is a more reasonable timeframe. IRRC agreed regarding the importance of accuracy in orders but asked the Department to further explain the need for a seemingly significant change. IRRC asked if the Department has data to support the need for this amendment and to explain the reasonableness for reducing the timeframe from 7 days to 48 hours. In this final-form rulemaking, the Department has decided to retain the existing requirement in subsection (c) that verbal and telephone medication orders be dated and countersigned within 48 hours, and amended the requirement that verbal and telephone orders for care and treatment be within 72 hours, in response to these comments. The timeframe for verbal and telephone orders for care and treatment is amended from 48 hours to 72 hours, in this final-form rulemaking, to provide an additional 24 hours for orders to be signed and countersigned. With the prevalence of electronic transmittal methods to help expedite the signing of orders, 72 hours is a practical and achievable timeframe.

Subsection (c)

This subsection is retained in this final-form rulemaking. The Department had proposed to move the 48-hour requirement from the first sentence of this subsection into subsection (b). The Department has decided to retain the existing 48-hour requirement for verbal and telephone medication orders to separate this requirement from orders for care and treatment. This timeframe is necessary to ensure prompt review and approval of resident medications and orders. As noted in subsection (b), the Department has amended the timeframe for verbal and telephone orders for care and treatment to 72 hours based on comments received from commentators and IRRC. In this final-form rulemaking, the second sentence of this subsection, pertaining to Schedule II medications, remains deleted because dispensation of controlled substances is covered under Federal law. See 21 CFR 1306.11 (relating to requirement of prescription).

Subsection (d)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department replaces the word "oral" with the word "verbal" for consistency in terminology. The Department replaces "medication or treatment" with "care, treatment or medication" for consistency with the proposed amendments to subsection (b), as described previously. The Department replaces the term "responsible practitioner" with "physician, or physician's delegee authorized under 42 CFR 483.30(e)" as well for consistency with the proposed amendments in subsection (b). The Department replaces the word "received" with the word "sent" for grammatical reasons. The Department also adds "or secure electronic transmission" after the word "fax" to account for the use of electronic health record systems, as well as other electronic mechanisms, such as e-mail or text, that are used to enter orders.

Subsection (e)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department, throughout this

subsection, replaces the words "an oral" with the words "a verbal" for consistency in terminology. In paragraph (2), the Department replaces "practitioner" with "physician, or physician's delegee authorized under 42 CFR 483.30(e)" for consistency in terminology. In paragraph (4), the Department adds the words "or secure electronic" between the word "fax" and the word "transmissions" for consistency with the use of this term as proposed in subsection (d).

§ 211.4. Procedure in event of death

Subsection (a)

Subsection (a) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department replaces the words "at each nursing station" with the words "to all personnel." The long-term care nursing industry has begun to shift away from terms such as "nurses' station" and "nursing station" towards terms that focus more on resident-centered care. The term "all personnel" is more specific and more accurately reflects who should have access to written postmortem procedures.

A commentator suggested that the Department add the word "readily" before the word "available" as well as a requirement that procedures be "kept onsite in a location accessible and familiar to" all personnel "at all times." Adding the word "readily" before the word "available" adds no additional value and would make this provision unnecessarily vague. Adding that the procedures be kept onsite would not allow a facility to make its procedures available electronically to personnel. The Department declines to make these suggested amendments.

Subsection (b)

Subsection (b) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department makes only one amendment to this subsection. The Department replaces the term "responsible party" with the term "resident representative" for consistency in the use of that term throughout the regulations.

§ 211.5. Medical records

The Department amends the title of this section from "clinical records" to "medical records" to align with the use of "medical records" in the Federal requirements throughout 42 CFR Part 483, Subpart B. Instead of "medical records," a commentator suggested the title be renamed "resident records." The Department appreciates this comment. However, the Department is maintaining the terminology "medical records" to be consistent with Federal requirements. See for example, 42 CFR 483.70(i).

Subsection (a)

Subsection (a) remains deleted in this final-form rulemaking. The Department deletes subsection (a) to eliminate duplication and to avoid conflict with the Federal requirements at 42 CFR 483.10(h)(3)(ii). Under 42 CFR 483.10(h)(3)(ii), a facility must allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social and administrative records in accordance with State law.

In this final-form rulemaking, a commentator requested the language be retained and expanded to require records be comprehensive and include all assessments, treatments, items, services and case notes. Further, the commentator suggested the records be provided to Older Adult and Adult Protective Services and the State Protection and Advocacy entity. The Department, however, declines to make these amendments. Existing Federal requirements already require for medical records to contain the following: sufficient information to identify the resident; a record of the resident's assessments; the comprehensive plan of care and services provided; the results of any preadmission screening and resident review evaluations and determinations; the physician's, nurse's and other licensed professional's progress notes; and laboratory, radiology and other diagnostic services reports. 42 CFR 483.70(i). In addition, the access to records and whether a resident wants to receive protective services under the Older Adults Protective Services Act or the Adult Protective Services Act is determined by the resident in accordance with these respective acts. 35 P.S. §§ 10210.304(b) and 10225.304. The Department declines to make these requested amendments.

Subsection (b)

Subsection (b) is amended from the proposed rulemaking to this final-form rulemaking. In the proposed rulemaking, the Department deleted this subsection. Commentators opposed this deletion, asserting the need to maintain written consent. Based on comments received, the Department is retaining this language, as amended. In this final-form rulemaking, subsection (b) provides that information contained in the resident's record shall be privileged and confidential. Written consent of the resident or the resident representative is required for release of information, except as follows: written consent is not necessary for authorized representatives of the Federal and State government during the conduct of their official duties; and written consent is not necessary for the release of medical records for treatment purposes in accordance with Federal and State law.

Subsection (c)

Subsection (c) remains deleted in this final-form rulemaking. The Department deletes this subsection to eliminate conflict with the Federal requirements at 42 CFR 483.70(i)(4), which requires medical records to be retained for the period of time required by State law or for 5 years from the date of discharge when there is no State law requirement, or in the case of a minor, for 3 years after the resident reaches legal age under State law. Commentators suggested this language be retained. The Department declines to make this requested amendment as the record retention policy provided under 42 CFR 483.70(i)(4) meets the Department's licensure needs during annual surveys.

Subsection (d)

Subsection (d) remains unchanged from the proposed rulemaking to this final-form rulemaking. The word "medical" replaces the word "clinical" for consistency in terminology.

Subsection (e)

Subsection (e) remains unchanged from the proposed rulemaking to this final-form rulemaking. The Department replaces the word "clinical" with the word "medical" before the word "records" for consistency in the use of the term "medical records." In the second sentence, the Department adds the word "resident" before "medical records" for clarity. The Department also replaces the phrase, "notify the Department of how the records may be obtained" with "provide to the Department, within 30 days of providing notice of closure under § 201.23 (relating to closure of facility), a plan for the storage and retrieval of medical records." When a facility closes, it is often difficult to determine where medical records have been stored as there is no longer a point of contact for the

facility. Requiring a facility to have a plan for storage and retrieval and to provide the Department with that plan ensures that residents will be able to access their medical records after the facility closes.

A commentator suggested that the closing facility retain a copy of each resident's record in addition to the receiving facility. After careful consideration, the Department declines to make this suggested amendment. If the records are transferred to the facility the resident is residing in, it is unnecessary for the closing facility to also maintain those records.

Subsection (f)

Subsection (f) remains unchanged from the proposed rulemaking to this final-form rulemaking. The Department replaces the word "clinical" with the word "medical" for consistency in the use of the term "medical record." The Department deletes the words "at a minimum, the" at the beginning of this subsection and add a cross-reference to 42 CFR 483.70(i)(5) to clarify that the items listed in this subsection are required in addition to the items in the Federal requirements. For clarity, the Department enumerates the items that are presently in subsection (f).

A commentator suggested this subsection be amended to include the following additional information in a resident's medical record: identification and demographic information, the comprehensive person-centered assessment, the person-centered service planning document and services notes. Another commentator requested all plans of care and reports, investigations and action taken concerning injuries be contained within the medical record. 42 CFR 483.70(i)(5), however, already requires a medical record to contain the following: sufficient information to identify the resident; a record of the resident's assessments; the comprehensive plan of care and services provided; the results of any preadmission screening and resident review evaluations and determinations; physician's, nurse', and other licensed professional's progress notes; and laboratory, radiology and other diagnostic services reports. Further, subsection (f) requires observations, notes, medical reports and treatments be contained. This includes reports related to injuries. To the extent there is a concern regarding potential abuse or neglect, employees, contractors and administrators are required to report suspected abuse for investigation under the Older Adults Protective Services Act (35 P.S. §§ 10225.101—10225.5102) and the Adult Protective Services Act (35 P.S. §§ 10210.101—10210.704). Therefore, the Department declines to makes this suggested amendment.

Subsection (g)

Subsection (g) remains deleted in this final-form rulemaking. The Department deletes this subsection to eliminate duplication and avoid conflict with the Federal requirements. A commentator opposes this deletion. The Department, however, is retaining the deletion of recording symptoms and other indications of illness or injury as duplicative. Under 42 CFR 483.70(i)(1), a facility must maintain medical records in accordance with accepted professional standards and practices. As provided previously, medical records must contain sufficient information to identify the resident, a record of the resident's assessments, a comprehensive plan of care and services provided, the results of any preadmission screening and resident review evaluations and determinations, progress notes from physicians, nurses and other licensed professionals, and laboratory, radiology and other diagnostic services reports.

Subsection (h)

Subsection (h) remains deleted in this final-form rulemaking. The Department deletes this subsection to eliminate duplication and avoid conflict with the Federal requirements. A commentator suggested this language be retained and amended to include that each staff person, contracted provider or professional enter the appropriate historical, service and progress notes. The Department declines to make this change. Under 42 CFR 483.70(i)(5)(v), a resident's medical record must contain progress notes from physicians, nurses and other licensed professionals.

Subsection (i)

Subsection (i) remains unchanged from the proposed rulemaking to this final-form rulemaking. The Department replaces the word "clinical" with the word "medical" for consistency in the use of the term "medical record."

§ 211.6. Dietary services

Subsection (a)

Subsection (a) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department adds language to require that menus not only be planned but also posted in the facility or distributed to residents at least 2 weeks in advance. The Department adds this requirement as part of its efforts to promote more resident-centered environments in long-term care nursing facilities.

Subsection (b)

Subsection (b) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and avoid conflict with the Federal requirements. Under 42 CFR 483.60, a facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the resident's daily nutritional and special dietary needs, taking into consideration the resident's preferences. Further, facilities should utilize the emergency plan developed under 42 CFR 483.73 to determine how much food is needed in the event of an emergency. Specifically, a facility's emergency plan is required to be based on and include a documented, facility-based and community-based risk assessment, with the emergency preparedness policy and procedure addressing food, water, medical and pharmaceutical supplies. 42 CFR 483.73(a) and (b)(1)(i). Each facility's needs will be different in terms of facility size and the amount of time they need to shelter in place. Requiring a facility to have food on hand for a specific number of days could result in a cost and waste to some facilities; and be insufficient for others. Instead, facilities should utilize the emergency plan developed under 42 CFR 483.73 to determine how much food is needed for the subsistence needs of staff and residents in the event of an emergency.

Some commentators opposed the deletion of this subsection and the removal of the requirement that facilities must have enough food onsite to last at least 3 days. Commentators underscored the importance of ensuring resident safety in the event of a natural disaster or storm, as well as human-caused emergencies, such as the sudden bankruptcy of a facility operator. A commentator indicated that facilities could interpret the requirements at 42 CFR 483.73 as not requiring them to have sufficient food on hand and asked how compliance would be determined. In addition, IRRC asked, "what are the minimum number of days' supply of food available in the facility provided for in an emergency plan?" IRRC requested that

the Department explain the need for and reasonableness of the proposed deletion of this subsection in the final-form regulation. IRRC also asked the Department to explain how the final-form regulation protects the public health, safety and welfare related to always having a sufficient food supply available in the facility.

After careful consideration, the Department declines to add the requirement that facilities always have at least 3 days' supply of food in the facility to this final-form rulemaking, as the current requirement imposed a uniform standard on facilities that do not have uniform needs. The Department also notes that while the current regulation requires a facility to have a specific amount of food onsite, there is not a corresponding standard for other supplies and provisions, such as medicine, medical supplies, water and clean linens.

Further, the Department is not removing the requirement for a sufficient food supply. Instead, a facility's emergency plan, which is based on and includes a documented, facility-based and community-based risk assessment, addresses the food, water, medical and pharmaceutical supplies needs of the facility. 42 CFR 483.73(a) and (b)(1)(i). The Department will monitor and enforce this provision during its survey process. During a facility's survey, the Department will review the facility's emergency plan to see how much food the facility-specific plan requires the facility to have onsite, and then check for compliance with the requirements of the emergency plan. The deletion of this specific requirement will create consistency in enforcement related to emergency preparedness.

Another commentator recommended that meals served should be tasty, interesting, of good variety, and nutritious, as needed and requested by each resident. The Department declines to make this amendment in this final-form rulemaking. Under 42 CFR 483.60, a facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the resident's nutritional and dietary needs, taking into consideration the resident's preferences. All facilities, including the three private-pay facilities are required to comply with the portion of 42 CFR 483.60 that requires the provision of a nourishing, palatable and well-balanced diet that meets the resident's daily nutritional and dietary needs, under existing § 201.2. The portion of 42 CFR 483.60 requiring that a facility take into consideration the preferences of each resident will be new under the expansion of the incorporation of the Federal requirements in § 201.2, as amended in final-form Rulemaking 1. This assumes approval of Rulemaking 1.

Subsection (c)

Subsection (c) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and avoid conflict with the Federal requirements. Under 42 CFR 483.60(a), a facility is required to employ sufficient staff with the appropriate competencies and skills necessary to carry out the functions of the food and nutrition service, taking into account resident assessments, individual plans of care, and the number, acuity and diagnoses of the resident population in accordance with the facility assessment. In addition, under 42 CFR 483.60(a)(1), a facility must employ a qualified dietitian or other clinically qualified nutrition professional on either a full-time, part-time or on a consultant basis. This individual must meet the requirements of 42 CFR 483.60(a)(1)(i) through (iv). If a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a director of food and nutrition services, who meets the requirements set forth in 42 CFR 483.60(a)(2)(i) through (iii). Facilities that participate in Medicare or MA are required to comply with these requirements. The requirement for sufficient staff to carry out the functions of the food and nutrition service is not a new requirement for the three private-pay facilities under existing § 201.2. However, the remaining requirements identified previously will be new for the three private-pay facilities by virtue of the expansion of the incorporation of the Federal requirements in § 201.2, as amended in Rulemaking 1. This assumes approval of Rulemaking 1.

A commentator opposed the deletion of this subsection but did not explain why they were opposed to the deletion. Therefore, the Department has not made any amendments in response to this comment, in this final-form rulemaking.

Subsection (d)

Subsection (d) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and avoid conflict with the Federal requirements. A facility must employ sufficient dietary staff that meet the requirements in 42 CFR 483.60(a) to carry out the functions of the food and nutrition service, as described in 42 CFR 483.60. All facilities, including the three private-pay facilities, are currently required to comply with this requirement.

A commentator opposed the deletion of subsection (d). The commentator and IRRC noted that resident counseling is not included in the Federal requirements. IRRC asked whether the Department is reducing the standard of care for residents by eliminating this provision and asked that the Department explain how the final regulation protects the public health, safety and welfare related to resident counseling by a dietary consultant. The Department is not reducing the standard of care for residents, and this final-form rulemaking protects the public health, safety and welfare related to resident counseling by a dietary consultant because in addition to the requirements in 42 CFR 483.60, a resident's comprehensive care plan must be prepared by an interdisciplinary team that includes a member of food and nutrition services staff. 42 CFR 483.21(b)(2)(ii). In addition, under 42 CFR 483.10(c)(2), residents have a right to participate in the development of their person-centered care plan and, therefore, can discuss their dietary needs and preferences with a member of food and nutrition services staff.

Subsection (e)

Subsection (e) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and avoid conflict with the Federal requirements. Under 42 CFR 483.60(b), a member of the food and nutrition services staff must participate on the interdisciplinary team as required by 42 CFR 483.21(b)(2)(ii). The Federal requirements are also quite extensive regarding the requirements for menus and food and nutrition for residents. Menu requirements are addressed in 42 CFR 483.60(c), food and drink requirements are addressed in 42 CFR 483.60(d), therapeutic diets are addressed in 42 CFR 483.60(e), meal frequency requirements are addressed in 42 CFR 483.60(f), and equipment and utensils are addressed in 42 CFR 483.60(g).

A commentator opposed the deletion of this section but did not provide a reason. Therefore, the Department has

not made any amendments in response to this comment, in this final-form rulemaking. The interdisciplinary team planning and some of the menu requirements identified previously will be new for the three private-pay facilities by virtue of the expansion of the incorporation of the Federal requirements in § 201.2, as amended in Rulemaking. This assumes approval of Rulemaking 1.

Subsection (f)

Subsection (f) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department replaces the words "an employe" with "employees" and "employes" with "employees." The Department makes these two amendments for grammatical reasons and for consistency in the usage and spelling of the term "employees."

A commentator suggested that subsection (f) be revised to say that dietary personnel shall follow facility infection control protocols. This requirement is not needed, however, because all facility staff are subject to the infection prevention and control program. Per 42 CFR 483.80(a)(1), a facility's infection prevention and control program must include a "system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to § 483.70(e) and following accepted national standards." Further, 42 CFR 483.80(a)(2)(v) requires that there be written standards, policies and procedures that include the circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesion from direct contact with residents or their food. Therefore, the Department declines to make these suggested amendments.

§ 211.7. Physician assistants and certified registered nurse practitioners

This section is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes subsections (a), (b)(1), (c), (d) and (e) to eliminate duplication and avoid conflict with the Federal requirements and State scope of practice standards. Under 42 CFR 483.30, each resident must remain under the care of a physician. The circumstances under which a physician may delegate tasks to a physician assistant, nurse practitioner or clinical nurse specialist are delineated in 42 CFR 483.30(e) and (f), and includes the requirement that the physician assistant, nurse practitioner or clinical nurse specialist be acting within the scope of their practice as defined by State law. The scope of practice for physician assistants, including supervision by a physician, is set forth under section 13 of the Medical Practice Act of 1985 (63 P.S. § 422.13) and in regulation at 49 Pa. Code Chapter 18, Subchapter D (relating to physician assistants). The scope of practice for certified registered nurse practitioners is set forth under section 8.2 of the Professional Nursing Law (63 P.S. § 218.2), and in regulation at 49 Pa. Code Chapter 21, Subchapter C (relating to certified registered nurse practitioners). The scope of practice for clinical nurse specialists is set forth under section 8.6 of the Professional Nursing Law (63 P.S. § 218.6), and in regulation at 49 Pa. Code Chapter 21, Subchapter H (relating to clinical nurse specialists).

The Department retains the requirements in subsection (b)(2) through (4) as the Federal requirements do not cover posting and notification requirements for supervising physicians. The Department makes one minor amendment to subsection (b)(2). As noted in the proposed rulemaking, the Department replaces the term "nursing station" with the term "workstation." As noted in the Department's other long-term care nursing regulatory packages, the long-term care nursing industry has begun to shift away from the use of the term "nurses' station" in favor of terms such as "workstations" that focus more on person-centered care. When the proposed rulemaking was published at 52 Pa.B. 3070 (May 28, 2022), an error occurred in which the word "workstation" was inadvertently missed being underscored and placed in bold faced text. In this final-form rulemaking, the word "workstation" is added in place of "nursing station."

§ 211.8. Use of restraints

Subsection (a)

Subsection (a) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection to eliminate duplication and avoid conflict with the Federal requirements at 42 CFR 483.10(e)(1) and 42 CFR 483.12(a)(2), which prohibit the use of physical or chemical restraints imposed for the purpose of discipline or convenience, and require that, when the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.

Commentators recommended that the Department retain subsection (a) and add language to also prohibit the use of restraints for discipline or due to lack of staffing. A commentator also suggested that language be added to require the least restrictive means necessary be applied if restraints are necessary. The Department declines to make these suggested amendments because it is duplicative of the Federal requirements. As provided previously, 42 CFR 483.10(e)(1) and 483.12(a)(2) prohibit any physical or chemical restraint imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms, consistent with 42 CFR 483.12(a)(2) which further provides that when the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time.

A commentator also recommended that the prohibition on locked restraints that the Department proposed to delete be retained and that it be expanded to prohibit "any mechanical apparatus or device, such as shackles, straightjackets, cage-like enclosures or other similar devices. . .that is not removable by that person." The Department declines to make this amendment because the definition of locked restraints has been removed from § 201.3 (relating to definitions) in final-form Rulemaking 1 in favor of the Federal definition of "physical restraints" from the State Operations Manual, as explained further in Rulemaking 1. As defined, a "physical restraint" is "any manual method, physical or mechanical device, equipment or material that is attached or adjacent to the resident's body, cannot be removed easily by the resident, and restricts the resident's freedom of movement or normal access to the resident's body."

Subsection (b)

Subsection (b) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection, which requires that restraints may not be used or applied in a manner which causes injury to the resident. Some commentators requested that the Department retain this requirement. The Department declines to do so, because any restraint to a resident that results in injury to the resident would be considered abuse as defined in the Federal require-

ments at 42 CFR 483.5 and prohibited by 42 CFR 483.12(a)(1). The definition of "abuse" under 42 CFR 483.5 includes the "the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish."

Subsection (c)

Subsection (c) remains deleted in this final-form rulemaking. The Department had proposed to delete this subsection and replace it with new language in proposed subsection (c.1) because it was concerned that setting forth a requirement in regulation for the removal of restraints for a specified period of time could result in a facility only complying with the minimum standard for removal, rather than considering the health and safety of the particular individual that is being restrained. Commentators opposed the deletion of this subsection and recommended that it be added back into the regulations, in addition to the requirements in subsection (c.1). After careful consideration, the Department amends subsection (c.1) in this final-form rulemaking to address these comments, as described as follows.

Subsection (c.1)

Subsection (c.1) is amended from the proposed rulemaking to this final-form rulemaking. The Department had proposed to add this new subsection in place of current subsection (c) to clarify that when a resident is restrained, the facility must determine what interventions are appropriate for each resident to protect their health and safety. A commentator and IRRC commented that the former subsection (c) provided finite time limits; whereas the new subsection (c.1) provided ambiguous and nonregulatory language. IRRC requested the Department to ensure that the final regulation sets standards of compliance related to the use of restraints that are clear, enforceable, lack ambiguity and protect the public health, safety and welfare. A commentator also recommended subsection (c) be retained and expanded. The commentator suggested this subsection address additional appropriate interventions to be utilized in addition to subsection (c).

Based on the comments received, the Department amends subsection (c.1), in this final-form rulemaking, to provide that if restraints are used, a facility shall use the least restrictive method for the least amount of time to safely and adequately respond to individual resident needs in accordance with the resident's comprehensive assessment and comprehensive care plan. Further, when a recurring restraint is ordered, the facility shall document the need for the restraint and the personnel responsible for performing the intervention on each shift. In addition, a facility is required to document the type of restraint used and each time a restraint is used or removed. The Department also specifies that the following minimums apply when determining the least restrictive method for the least amount of time: (i) physical restraints shall be removed at least 10 minutes out of every 2 hours during normal waking hours to allow the resident an opportunity to move and exercise, and (2) during normal working hours, the resident's position shall be changed at least every 2 hours.

Subsection (d)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes the words "a signed, dated, written" because orders for restraints may be either written or verbal. The Department also replaces the word "physician" with the phrase "from a physician, or physician's delegee authorized under 42 CFR 483.30(e) (relating to physician services)" for consistency in the use of terminology. The Department deletes the last two sentences of this subsection because the requirement for an order for restraint applies to all types of restraints.

A commentator recommended subsection (d) be retained in its entirety and also be expanded to require that an order for restraints include the period for which the restraint is authorized and the circumstances under which the restraint may be used. The Department declines to make this requested amendment. As provided in amended subsection (c.1), a facility is required to document the need for the restraint, the type of restraint and each time a restraint is used or removed. However, since orders may be either written or verbal, the Department is deleting the signed and dated language from the subsection.

Subsection (e)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department adds "or physician's delegee authorized under 42 CFR 483.30(e)" after the word "physician" for consistency in the use of terminology.

Subsection (f)

Subsection (f) is amended from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to this subsection, which maintains the current requirement that every 30 days, or sooner, if necessary, the interdisciplinary team review and reevaluate the use of all restraints ordered. In this final-form rulemaking, the Department replaces the term "physicians" with "a physician or physician's delegee authorized under 42 CFR 483.30(e)" for consistency with the use of this terminology in subsections (d) and (e).

Some commentators suggested that the results of these reviews be documented in the resident's chart or care plan. The requirement in subsection (f) satisfies this recommendation because the review would have to be recorded in the resident's medical record for the Department to survey for compliance with this subsection. Additionally, 42 CFR 483.21(b)(2)(iii) requires that the comprehensive care plan be reviewed and revised by the interdisciplinary team after each assessment. The requirement that the comprehensive care plan be reviewed and revised will not be new for the private-pay facilities; however, the requirement that the plan be reviewed and revised by the interdisciplinary team will be new for these facilities under amended § 201.2 in final-form Rulemaking 1. This assumes approval of Rulemaking 1.

In addition to the comments on subsections (a) through (f) summarized previously, commentators recommended adding language to this section. A commentator recommended adding language in this section stating that residents have the right to be free of physical, mechanical and chemical restraints. The commentator also recommended that restraints be prohibited unless:

(i) Authorized in accordance with Federal and State law;

(ii) Ordered by a physician as appropriate to treat the individual's medical condition;

(iii) Consented to by the resident or resident's representative; and

(iv) Approved by the resident's person-centered service planning interdisciplinary team as part of the resident's

written person-centered service plan and must include a written demonstration that less restrictive alternative means of controlling movement or behavior do not work. The person-centered service plan must outline how and when restraints are approved.

The Department declines to make this suggested amendment. Regarding the commentator's proposed language in immediately preceding (i), facilities are already required to follow all applicable Federal and State laws. The proposed language in immediately preceding (ii) is already provided for in subsection (d), which requires a physician's order for a restraint. The language proposed in immediately preceding (iii) is not needed because a resident already has the right, under 42 CFR 483.10(c)(6), to request, refuse or discontinue treatment. For (iv), although person-centered planning is not specifically addressed, Federal regulations already require a facility to use the least restrictive alternative for the least amount of time and to document the ongoing reevaluation of the need for restraints. 42 CFR 483.12(a). The Department declines to make this amendment.

Commentators also recommended that a provision be added to require that the use of chemical restraints be monitored for any adverse reaction. The Department declines to make this amendment in this final-form rulemaking, as the Federal requirements already prohibit the use of "unnecessary drugs." This includes the use of any drug without adequate monitoring or a drug used in the presence of adverse consequences which indicate the dose should be reduced or discontinued. 42 CFR 483.45(d) (relating to pharmacy services). All residents who receive medication in a facility must, therefore, be monitored for adverse consequences related to the medications.

§ 211.9. Pharmacy services

Subsection (a)

Subsection (a) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department retains the requirement in paragraph (1) with minor stylistic amendments. The Department deletes paragraph (2) because in practice, medications are dispensed by pharmacies to facilities, not directly to the residents. Medications are administered to residents by authorized persons to administer drugs and medication, as defined in § 201.3.

Subsection (b)

Subsection (b) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department amends subsection (b) by replacing "medications shall be" with "facility policies shall ensure that medications are" before "administered by authorized persons." This amendment is made to clarify that a facility is required to have policies in place to ensure that medications are administered by authorized persons to administer drugs and medications.

Subsection (c)

Subsection (c) is unchanged from the proposed rulemaking to this final-form rulemaking. The Department retains the language in this subsection, without amendment.

Subsection (d)

Subsection (d) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department adds the words "both prescription and non-prescription" after the word "medications" to clarify that a written order is required for both prescription and non-prescription medications. An order is necessary for both prescription and non-prescription medications so as to maintain a resident's continuity of care. Requiring an order for both prescription and non-prescription medications enables a facility to monitor and track all medications that a resident receives, to ensure that there are no contraindications or interactions between medications, and to help prevent accidental overdoses from residents self-administering non-prescription medications. The Department deletes the word "written" before the word "orders" because orders may be written or verbal. The Department also adds "or the physician's delegee authorized under 42 CFR 483.30(e)" for consistency in the use of this term throughout the regulation, and because these individuals may also provide medication orders.

A commentator suggested adding a sentence to this subsection to require a facility to timely refill prescriptions for residents and to ensure that residents are not administered expired prescription or non-prescription medications. The commentator indicated that they were aware of instances in which facilities have not timely refilled prescriptions as well as times in which facilities have not taken care to ensure that medications are not expired. After careful consideration, the Department declines to make this suggested amendment. The Department takes very seriously the administration of medications and considers late administration to be a medication error. Under 42 CFR 483.45(f), a facility must ensure that medication error rates are not 5% or greater and that residents are free of any significant medication errors. Facilities are required to comply with 42 CFR 483.45(f) under existing § 201.2.

Subsection (e)

Subsection (e) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, it is not necessary to retain this requirement given the amendment to subsection (d), to require an order for both prescription and non-prescription medications. A commentator opposed the deletion of this subsection, explaining that there needs to be a paper trail to resolve any concerns or discrepancies regarding medications. The Department believes that subsection (d), imposing the requirement for orders, is duplicative of subsection (e).

Subsection (f)

Subsection (f) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department makes only one amendment to this subsection. In paragraph (1), the Department replaces the term "resident's responsible person" with the term "resident representative" for consistency in the use of that term throughout the regulations.

Subsections (g) and (h)

Subsections (g) and (h) remain deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes subsections (g) and (h) to eliminate duplication and avoid conflict with the Federal requirements. Pharmacy services requirements for facilities are located at 42 CFR 483.45. Under 42 CFR 483.45(a), a facility is required to provide pharmaceutical services, including procedures that assure accurate acquiring, receiving, dispensing and administering of all medications, to meet the needs of each resident. The Federal requirements further require that a facility employ a pharmacist and outline the responsibilities of the pharmacist, which include providing consultation on all aspects of the provision of pharmacy services. The phar-

macist is to conduct a review of the medication regiment for each resident at least once a month and must report any irregularities to the attending physician, the medical director and the director of nursing. Other requirements in 42 CFR 483.45 address unnecessary medications, psychotropic medications, labeling and storage.

Subsections (i) and (j)

Subsections (i) and (j) remain deleted in this final-form rulemaking. As explained in the proposed rulemaking the Department deletes subsections (i) and (j) and adds subsection (j.1), pertaining to the disposition of medications, described as follows.

Subsection (j.1)

Subsection (j.1) is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Federal requirements for pharmacy services do not directly address the disposition of medications. The Department, therefore, adds subsection (j.1) to require a long-term care nursing facility to have written policies and procedures for the disposition of medications. The Department also requires that a facility's policies and procedures address: (1) timely identification and removal of medications for disposition; (2) identification of storage methods for medications awaiting final disposition; (3) control and accountability of medications awaiting final disposition consistent with standards of practice; (4) documentation of actual disposition of medications to include the name of the individual disposing of the medication, the name of the resident, the name of the medication, the strength of the medication, the prescription number if applicable, the quantity of medication and the date of disposition; and (5) a method of disposition to prevent diversion or accidental exposure consistent with applicable Federal and State requirements, local ordinances and standards of practice. Proper procedures for the disposition of medications are vital for the health and safety of residents. In this final-form rulemaking, the Department makes one minor amendment by adding the words "and safe" after the word "timely" in paragraph (1), at the request of a commentator.

A commentator requested that the Department require that a facility submit its written policies and procedures for the disposition of medications to the Department for approval. After careful consideration, the Department declines to make this suggested amendment. As explained previously, it would be logistically impossible for the Department to manage and maintain a record of every policy and procedure for the approximately 682 licensed long-term care nursing facilities on an ongoing basis. In addition, it is important that facilities have the discretion to update policies and procedures as needed in response to resident and business needs without waiting for Departmental approval.

Subsection (k)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. The Department retains this subsection without amendment.

Subsection (l)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department moves the requirement that an emergency medication kit be "readily available to staff" from paragraph (4) to the first sentence in this subsection. Moving this requirement to the beginning of the subsection adds clarity to the requirement that a facility have at least one medication kit.

In paragraph (1), the Department adds the words "security" and "inventory tracking" to the policies and procedures that a facility is required to have for the emergency medication kit. The Department adds this language to prevent diversion and to protect the integrity of the contents of the emergency medication kit to ensure that the medications within it are available in the event of an emergency.

In paragraph (2), the Department deletes the phrase "kept to a minimum and shall be" because this language is unclear and unnecessary. It is more important that the medications within the emergency kit meet the needs of the residents than to be kept at a minimum. The Department also adds, in paragraph (2), a requirement that the criteria for the contents of the emergency medication kit be reviewed not less than annually. This requirement will ensure that the emergency medication kits are tailored to the needs of the facility's current resident population.

In paragraph (3), the Department makes a grammatical amendment from the word "pre-scribe" to "prescribe." The Department also corrects the citation to the Pharmacy Act from (63 P.S. §§ 390.1—390.13) to (63 P.S. §§ 390-1—390-13).

The Department deletes paragraph (4). As noted, the Department moves the phrase "readily available to staff" to the first sentence of this subsection. The Department deletes the requirement that an emergency medical kit have a breakaway lock that is replaced after each use because this requirement is outdated. When the regulations were promulgated, facilities used tackle boxes with locks for emergency medication kits. A breakaway lock was required to ensure quick access in an emergency. Due to technological advances, many emergency medication kits now can be locked electronically, with the use of a code. Thus, the requirement for a breakaway lock is no longer necessary. Instead, the Department requires, in paragraph (1), that the facility has policies and procedures that address the security of the emergency medication kits. In this way, the facility will have discretion to determine the best way to secure the medication.

§ 211.10. Resident care policies

Subsection (a)

This subsection is amended from the proposed rulemaking to this final-form rulemaking.

As explained in the proposed rulemaking, the Department deletes the last sentence in this subsection to eliminate duplication and to avoid conflict with the Federal requirements. A facility is required to establish and implement an admissions policy under 42 CFR 483.15(a). Transfers and discharges are covered in 42 CFR 483.15(c). Admission, transfer and discharge planning are also part of the resident's comprehensive care plan and are covered in 42 CFR 483.21(b) and (c). The Department retains the first sentence in subsection (a) because even though the Federal requirements address what is required for resident care planning, the requirements do not require a facility to have resident care policies, and the Department considers resident care policies to be an integral part of resident care planning.

A commentator asked the Department to add the word "cognitive" to the phrase, "meeting the total medical and psychosocial needs of residents," explaining that they feel that cognitive needs should be expressly stated in resident care policies. Under 42 CFR 483.21(b), the comprehensive person-centered care plan for each resident must include "measurable objectives and timeframes to meet a

resident's *medical, nursing, and mental and psychosocial needs* that are identified in the comprehensive assessment" (emphasis added). The Department replaces "medical and psychosocial" with "medical, nursing, and mental and psychosocial" for consistency in the use of this terminology in the Federal requirements.

Subsections (b) through (d)

These subsections are unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department retains these subsections without amendment.

§ 211.11. Resident care plan

This section remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this section to eliminate duplication and to avoid conflict with the Federal requirements. Under 42 CFR 483.21(b), a facility is required to develop and implement a comprehensive person-centered care plan for each resident. This care plan is prepared by an interdisciplinary care team that includes the attending physician, an RN and an NA with responsibility for the resident, a member of the food and nutrition services staff, the resident and resident representative and others who are involved in the resident's care. Nursing services personnel are responsible, under 42 CFR 483.35(a)(4), for assessing, evaluating, planning and implementing resident care plans.

Commentators requested that the Department retain this section, amend the title to "resident person-centered service plan" and make amendments throughout this section to reflect this language, and amend the substance of the section to include more detail around the "person-centered service planning process," frequency of meetings, involvement of managed long-term care MA plans through the Community HealthChoices program, training staff to understand person-centered service delivery and reading and following person-centered service plans. After careful consideration, the Department declines to make these suggested amendments, as described more fully as follows.

Commentators recommended that the Department add language in subsection (b) requiring that the interdisciplinary team include individuals selected by the resident or resident representative and requiring the team to meet at least every 3 months, at the request of the resident or resident representative, or upon a change of condition to revise, if necessary, the resident service plan. Another commentator suggested that the Department add language requiring that the plan be reviewed and updated at least once every 6 months and as needed for a significant change in the resident's condition, and that this review include various individuals to include the resident, staff, providers, and the resident's family or legal representative. Commentators also requested that the Department include language requiring the facility to encourage residents to include their insurer's service coordinator, if applicable, in the interdisciplinary team.

The Department declines to make these amendments as these are already covered by the Federal requirements. Specifically, under 42 CFR 483.21(b)(2)(ii), the interdisciplinary team includes, but is not limited to, the attending physician, an RN with responsibility for the resident, an NA with responsibility for the resident, a member of the food and nutrition services staff, the resident and the resident representative to the extent practicable, and other appropriate staff or professionals in disciplines as determined by the resident's needs or as requested by the resident. Therefore, under 42 CFR 483.21(b)(2)(ii), the resident could choose to have other staff or professionals be a part of the interdisciplinary team, including their insurer's service coordinator. In addition, a facility is required to complete a comprehensive assessment within 14 calendar days after admission and within 14 calendar days after the facility determines or should have determined that there was a significant change in the resident's physical or mental condition under 42 CFR 483.20(b)(2)(i) and (ii). A facility is also required to assess a resident on a quarterly basis using the quarterly review instrument specified by the State and approved by CMS under 42 CFR 483.20(c). Under 42 CFR 483.21(b)(2)(i) and (iii), the comprehensive person-centered care plan must be developed within 7 days after the completion of the comprehensive assessment and must be reviewed and revised by the interdisciplinary team after each assessment of the resident, including both the comprehensive and quarterly review assessments. The resident can also request revisions to the person-centered care plan under 42 CFR 483.10(c)(2)(i).

Commentators recommended that the Department add a new subsection between existing (b) and (c) requiring a facility to ensure an educational strategy so that staff have the knowledge and skills to understand and implement person-centered planning and care. After careful consideration, the Department declines to make this suggested amendment. Under 42 CFR 483.95, a facility is required to develop, maintain, and implement an effective training program for staff, individuals providing services under a contractual agreement and volunteers, consistent with their expected roles. A facility must determine the amount and types of training necessary based on their facility assessment. It is expected that a facility will train those who are required to develop and implement a resident's care plan in that function.

In subsection (d), commentators recommended adding language to require staff to acquaint themselves with and to refer to the person-centered care plans for all residents to ensure that needs and preferences are being met. After careful consideration, the Department declines to make this suggested amendment because, under 42 CFR 483.21(b)(1), the care plan must not only be developed, but implemented, which would require a facility to ensure that the plan is being followed. Commentators also recommended adding language to require, under a facility's policy, that person-centered care be provided to residents and that person-centered care plans be honored even during a pandemic or other disaster. After careful consideration, the Department declines to make this suggested amendment, because it may not be possible for a facility to follow all aspects of a resident's care plan in the event of an emergency, pandemic or other disaster. For example, in cases of a weather emergency, a facility may not be able to provide a community quality of life activity under 42 CFR 483.25 (relating to quality of care).

In subsection (e), commentators requested that the Department add language to indicate that when desired by the resident, family and the resident representative shall participate in the development and review of the person-centered care plan. Commentators requested that the Department add language that the resident and the resident representative are the center of the interdisciplinary team, and the care planning process should maximize decision making and participation of residents at all cognitive functioning. Commentators also requested that the Department add language indicating that residents who have a legal guardian must have the opportunity to address any concerns. The Department declines to

make these amendments as these concepts are covered by the Federal requirements. Specifically, under 42 CFR 483.5, the term person-centered care "means to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives." The term "resident representative" as defined in 42 CFR 483.5 includes an individual chosen by the resident to act on their behalf to support in decision-making, a person authorized under Federal or State law to act on behalf of the resident, a legal representative, and a court-appointed guardian or conservator. This could include family members. Also, as mentioned previously, the resident and resident representative are part of the interdisciplinary team under 42 CFR 483.21(b)(2)(ii).

Commentators requested that the Department add a new subsection requiring a facility to provide information regarding the person-centered planning process in plain language and in a manner that is accessible to individuals with disabilities and persons who do not speak English. The Department declines to make this amendment because under 42 CFR 483.10(c), a resident has the right to be informed of and participate in their treatment. This includes the right to be fully informed in a language that the resident can understand of their total health status, including but not limited to, their medical condition. 42 CFR 483.10(c)(1).

Commentators requested that the Department add a new subsection requiring that the person-centered care plan include preferences around social interactions, with specific planning focused on supporting the resident during periods of prolonged isolation; ensure human dignity; reflect the individuality, values, and cultural considerations of the resident; identify any unmet needs while including clear language as to how staff can provide proper support to meet these needs; and identify and support ongoing opportunities for meaningful engagement, support interests and preferences, and allow for choice. Another commentator requested that the Department add a new subsection requiring that the care plan include the following: (1) a description of identified needs and date identified based upon the admission, physical examination, resident interview, fall risk, assessment of psychological, behavioral, and emotional functioning, and other sources; (2) a written description of what services will be provided to address identified needs, and if applicable, other services, and who will provide them; (3) preferences around social interaction, with specific planning focused on supporting the resident during periods of prolonged isolation; (4) considerations that reflect the individuality, values and cultural preferences of the resident; and (5) opportunities for meaningful engagement, support interests and preferences, and allow for choice.

After careful consideration, the Department declines to make these suggested amendments because these concepts are covered under the Federal requirements. First, as noted previously, under 42 CFR 483.21(b)(1), a facility is required to develop and implement a comprehensive person-centered care plan for each resident, consistent with the resident's rights under 42 CFR 483.10(c)(2) and (3), that includes measurable objectives and timeframes to meet a resident's medical, nursing and mental and psychosocial needs that are identified in the comprehensive assessment. The comprehensive care plan must describe the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under 42 CFR 483.24, 483.25 and 483.40 (relating to behavioral health services). The requirements under 42 CFR 483.24 address activities of daily living; the requirements under 42 CFR 483.25 address physical care; and the requirements under 42 CFR 483.40 address behavioral health. A facility is also required to complete, initially and periodically, a resident assessment on each resident under 42 CFR 483.20, which takes into consideration the resident's needs, strengths, goals and life history and preferences.

A commentator recommended that the Department require that the comprehensive care plan be completed using a template approved by the Department within 30 days after admission. As mentioned previously, a facility is required to complete a comprehensive assessment within 14 calendar days after admission and within 14 calendar days after the facility determines or should have determined that there was a significant change in the resident's physical or mental condition under 42 CFR 483.20(b)(2)(i) and (ii). A facility is also required to assess a resident on a quarterly basis using the quarterly review instrument specified by the State and approved by CMS under 42 CFR 483.20(c). Under 42 CFR 483.21(b)(2)(i) and (iii), the comprehensive person-centered care plan must be developed within 7 days after the completion of the comprehensive assessment and must be reviewed and revised by the interdisciplinary team after each assessment of the resident, including both the comprehensive and quarterly review assessments. The Department declines to extend this timeline as doing so could be detrimental to residents.

A commentator requested that the Department add a subsection requiring that the care plan be signed and dated by the licensee, administrator or designee, and the resident or resident representative. The commentator requested that the Department also require the plan to indicate any other individuals who contributed to the development of the plan, with a notation as to the date of the contribution and the title or relationship to the resident of each person involved in the care plan. The commentator recommended that these requirements also apply to reviews and updates of the care plan. After careful consideration, the Department declines to make these suggested amendments. There is no explicit requirement in the Federal requirements that the care plan indicate who participated or that the plan be signed and dated by these individuals. Nonetheless, the Federal requirements at 42 CFR 483.21(b)(2)(ii) do require that certain individuals, as noted previously, be involved in the development of the care plan. To demonstrate compliance with that provision, the facility would need to have some record of their involvement, through notes or other documentation in the care plan. Also, it would not be appropriate for the licensee or the administrator to sign the care plan as these individuals are not involved in the care planning process.

A commentator requested that the Department add language to indicate that there may be a deviation from the care plan when mutually agreed upon between the facility and the resident and resident representative at the time the care or services are scheduled or when there is an emergency that prevents the care or services from being provided. The commentator also suggested adding language that would require this deviation to be documented, include a description of the circumstances warranting deviation and the date the deviation will occur, certify that notice of this deviation was provided to the resident and resident representative, be included in the resident's file, and be signed by an authorized representative of the facility and the resident or resident representative. After careful consideration, the Department declines to make this suggested amendment. The

comprehensive care plan is a living document, which as discussed previously, is required to be reviewed and updated under 42 CFR 483.21(b)(2)(iii).

§ 211.12. Nursing services

Subsection (a)

Subsection (a) remains deleted in this final-form rulemaking. As explained on proposed, the Department deletes this subsection to eliminate duplication and to avoid conflict with the Federal requirements. Under 42 CFR 483.35(a)(1), a facility is required to provide services by a sufficient number of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans.

Subsection (b)

Subsection (b) is retained and not deleted in this final-form rulemaking. Existing subsection (b) requires a facility to have a full-time director of nursing services who shall be a qualified licensed RN. The Department had proposed to delete this subsection to eliminate duplication and to avoid conflict with the Federal requirements under 42 CFR 483.35(b)(2), which provide that a facility is required to designate an RN to serve as the director of nursing on a full-time basis, except when waived.

A commentator objected to the deletion of this subsection because the requirement that a facility designate an RN to serve as the director of nursing on a full-time basis could be waived under the Federal requirement. IRRC asked what the impact would be if this provision were waived. The requirement that an RN serve as the full-time director of nursing may be waived under 42 CFR 483.35(f)(1), under certain circumstances. Existing subsection (b), however, does not permit for the waiver of this requirement. The Department does not know of any instances in which a facility has obtained a waiver of this requirement but agrees with the commentator that this requirement should be mandatory. The Department therefore retains subsection (b) in this final-form rulemaking without amendment.

Subsection (c)

Subsection (c) remains unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department replaces the word "staff" with the word "personnel" for consistency in the use of the term "nursing services personnel" throughout the regulations.

Subsection (d)

Subsection (d) remains unchanged from the proposed rulemaking to this final-form rulemaking. In the proposed rulemaking, the Department proposed to add the word "services" between the words "nursing" and "personnel" for consistency in the use of the term "nursing services personnel" throughout the regulations. When the proposed rulemaking was published at 52 Pa.B. 3070, an error occurred in which the word "services" was inadvertently missed being underscored and placed in bold faced text. On this final-form rulemaking, the word "services" is added before the word "personnel."

Subsection (e)

Subsection (e) is retained, with amendment, and not deleted in this final-form rulemaking. Existing subsection (e) requires a facility to designate an RN who is responsible for overseeing total nursing activities within the facility on each tour of duty each day of the week. The Department had proposed to delete this subsection to eliminate duplication and to avoid conflict with the Federal requirements at 42 CFR 483.35(a)(2), which provide that a facility is required to designate a licensed nurse to serve as a charge nurse on each tour of duty, unless waived.

A commentator objected to the deletion of this subsection because the requirement under 42 CFR 483.35(a)(2) may be waived under 42 CFR 483.35(e). The commentator also indicated that 42 CFR 483.35(a)(2) requires only a licensed nurse, while existing subsection (e) requires that an RN serve in this capacity. IRRC asked what the impact would be if this provision was waived under the Federal requirements. IRRC also asked what the impact would be of having an RN versus a licensed nurse designated with the responsibility of overseeing total nursing activities within a facility. IRRC asked the Department to explain how the deletion of a provision designating an RN to be responsible for overseeing total nursing activities within a facility protects the public health, safety and welfare of residents. The Department does not know of any instances in which a facility has obtained a waiver of this requirement but agrees with the commentator that this requirement should be mandatory. The Department also agrees that an RN should be the one serving in this capacity. The Department therefore retains subsection (e) in this final-form rulemaking. However, the Department replaces the term "a registered nurse" with the term "charge nurse" as this term more accurately describes the person who is responsible for overseeing total nursing activities within the facility, on each tour of duty. The term "charge nurse" is defined in § 201.3.

Subsection (f)

Subsection (f) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes paragraph (1) and replaces it with new minimum staffing requirements in subsection (f.1). The requirement in paragraph (2) is retained and moved to subsection (f.2)(3)(i) in this final-form rulemaking, as explained as follows.

Subsection (f.1)

Paragraph (1)

Paragraph (1) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department moves the requirement in existing subsection (j) to this paragraph for clarity and ease of readability.

Paragraphs (2) and (3)

The language that was proposed in paragraphs (2) and (3) is deleted in this final-form rulemaking. The Department had proposed to move the language in subsection (h), which required a facility to have a minimum of two nursing services personnel on duty, at all times, to paragraph (2), and to move the language in subsection (g), which required a facility to have a minimum of one nursing services personnel on duty, per 20 residents, to paragraph (3). A commentator indicated that they were confused by the language in proposed paragraph (3) because it was inconsistent with proposed requirements for NAs. Upon review, the Department deletes the language that was proposed in paragraphs (2) and (3) because it conflicts with the new minimum requirements for each type of nursing services personnel in this final-form rulemaking, described as follows.

Due to the previous deletions, the language that the Department proposed in paragraph (4) is moved to paragraph (2) on final-form. This language is amended to

indicate that effective July 1, 2023, a facility is required to have a minimum of 1 NA per 12 residents during the day, 1 NA per 12 residents during the evening, and 1 NA per 20 residents overnight. New language is also added to paragraph (3) in this final-form rulemaking to indicate that effective July 1, 2024, a facility is required to have a minimum of 1 nurse aide per 10 residents during the day, 1 NA per 11 residents during the evening, and 1 NA per 15 residents overnight.

Paragraph (4)

Paragraph (4) is amended from the proposed rulemaking to this final-form rulemaking. As noted previously, the language that was proposed in paragraph (4) is moved to paragraph (2) with amendment. New language is added to paragraph (4) to indicate that effective July 1, 2023, a facility is required to have a minimum of 1 LPN per 25 residents during the day, 1 LPN per 30 residents during the evening, and 1 LPN per 40 residents overnight.

Paragraph (5)

Paragraph (5) is amended from the proposed rulemaking to this final-form rulemaking. The language that was proposed in paragraph (5) is deleted. New language is added to paragraph (5) in this final-form rulemaking to indicate that effective July 1, 2023, a minimum of 1 RN is required per 250 residents during all shifts.

The Department received numerous comments to proposed Rulemaking 1 and proposed Rulemaking 4 both in support of and in opposition to the proposed increase in the staffing ratio. These comments are detailed further in subsection (i). Some commentators, in comment to proposed Rulemaking 4, proposed a ramp-up period as a solution to balance the need for higher staffing with available resources and MA funding. These commentators recommended that the Department require, effective July 1, 2023, 1 NA per 12 residents on the day shift, 1 NA per 12 residents on the evening shift, 1 nurse aide per 20 residents on the overnight shift, 1 LPN per 25 residents on the day shift, 1 LPN per 30 residents on the evening shift, and 1 LPN per 40 residents on the overnight shift. For Year 2, effective July 1, 2024, they recommended 1 NA per 10 residents on the day shift, 1 NA per 11 residents on the evening shift, and 1 NA per 15 residents on the overnight shift.

The Department adopts this recommendation in paragraphs (2) through (4). Paragraph (5) reflects, in sentence form, the existing requirement for RNs in subsection (f)(1), except for language permitting an LPN to serve on the overnight shift in a facility with a census of 59 or under, which has been moved to subsection (f.2)(3)(i).

The Department after careful consideration and weighing the need to ensure the health, safety and welfare of residents with the concerns raised by the regulated community agrees with commentators to adopt a graduated approach to the increase in types of nursing personnel. This graduated approach aligns with the graduated approach in the number of direct care hours that the Department has adopted in subsection (i), described as follows.

Subsection (f.2)

Subsection (f.2) is amended from the proposed rulemaking to this final-form rulemaking. The Department had proposed to add language to this subsection that would prohibit a facility from substituting a NA for an LPN or RN, but permitting the substitution of an RN for a NA or an LPN to meet the minimum nursing staff ratio. Commentators were supportive of this language. In this final-form rulemaking, the Department breaks the proposed language down into paragraphs for ease of readability, and in paragraph (3) adds the language from existing subsection (f.1)(3), which permits a facility with a census of 59 or under to substitute an LPN for an RN on the overnight shift only if an RN is on call and located within a 30-minute drive of the facility. The Department adds this language back into regulation based on comments received in proposed Rulemaking 1, expressing concern that smaller facilities, particularly smaller rural facilities, may have difficulty meeting a more stringent requirement for an RN on the overnight shift.

Subsections (g) and (h)

Subsections (g) and (h) remain deleted in this final-form rulemaking. The Department had proposed to move the language in subsection (h), which required a facility to have a minimum of 2 nursing services personnel on duty, at all times, to subsection (f.1)(2), and to move the language in subsection (g), which required a facility to have a minimum of 1 nursing services personnel on duty, per 20 residents, to paragraph (3). A commentator indicated that they were confused by the language in proposed paragraph (3) because it was inconsistent with proposed requirements for NAs. As indicated previously, in this final-form rulemaking, the Department deletes the language that was proposed in paragraphs (2) and (3) because it conflicts with the new minimum requirements for each type of nursing services personnel in this final-form rulemaking, described as follows.

Subsection (i)

Subsection (i) is amended from the proposed rulemaking to this final-form rulemaking. The Department had proposed in Rulemaking 1 to amend subsection (i) to add the phrase "for each shift" and to increase the minimum number of direct resident care hours from 2.7 to 4.1. The Department had also proposed to add language to align with 42 CFR 483.35 to require a facility to have a sufficient number of staff with the appropriate competencies and skill sets to provide nursing care and related services to assure resident safety and to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.

The Department amended § 211.12 in both proposed Rulemaking 1 and this rulemaking. In both rulemakings, the Department received comments regarding the difficulty of review and also specific comments regarding the minimum hours of direct resident care under subsection (i). To ease the concerns with clarity, readability and interrelatedness of this subsection, the Department is combining the amendments to this section in one rulemaking. In addition, in response to IRRC's comments, the Department is submitting all four final-form rulemakings to IRRC and the legislative standing committees of the General Assembly at the same time.

As discussed in final-form Rulemaking 1, commentators to proposed Rulemaking 1 indicated that the use of the words "for each shift" were confusing and suggested this language could be construed to require the same number of nursing personnel at night when residents are sleeping as during the day when residents are more active and need more care. Commentators also stated that this language could be construed to require a facility to provide a total of 12.3 hours of direct care per day, rather than the proposed 4.1 hours of direct care. IRRC asked

that the Department clarify whether the increase in direct care hours is intended to be per shift or per day. The Department agrees that the addition of "during each shift" is confusing. The Department deletes the words "during each shift" in this final-form rulemaking to alleviate this concern. The number of direct care hours per resident required by subsection (i) is calculated based a 24-hour period.

A large portion of the comments received by the Department on proposed Rulemaking 1 were related to the proposal to increase the number of hours of direct resident care from 2.7 to 4.1. The Department received comments in proposed Rulemaking 4 on this proposed amendment as well. Many commentators strongly supported the increase, citing to research that shows that 4.1 is essential to ensure that residents receive quality care and indicating that an increase is long overdue. These commentators cited to many of the benefits that the Department noted on proposed, including health benefits to residents, fewer reports of abuse, and higher job satisfaction for nursing services personnel. Some commentators also suggested that 4.1 is too low.

Commentators opposed to the increase asserted that a proposed increase to 4.1 is not realistic because the regulated community has experienced, and continues to experience, a dire workforce shortage that has only been exacerbated by the COVID-19 pandemic. Facility owners, operators and administrators described in detail the difficulties they have experienced recruiting and maintaining nursing services personnel at the existing minimum of 2.7 direct care hours per day. These commentators also described in detail the various incentives they have tried to recruit and maintain staff. Commentators also indicated that facilities have had to resort to the use of agency staff, who are not as familiar with the needs of residents that are specific to the facility they are assigned to, and thus, are not able to provide the same high-quality care as nursing services personnel who work with the residents on a day-to-day basis. Commentators cited to the high cost of utilizing agency staff as well and noted that it is often difficult to even find agency staff who are available. Commentators also felt that rural communities may be more greatly impacted due to their smaller populations and that the increase may impact the poor and minorities who already have limited access to care. Other commentators pointed out that the regulated community is still reeling from the impacts of COVID-19 and indicated that they feel now is not the time to be making changes to nursing services personnel requirements. Commentators indicated that nursing services personnel are burned out, are paid a very little amount for the type of work that they perform and can easily find other employment for more money and less stress.

Commentators felt that due to the fiscal impact of the increase to 4.1, facilities may need to close, sell to large out-of-state providers, or reduce admissions, pointing out that some facilities have already had to do this. Commentators felt that facilities may have to sacrifice other staff such as therapists, dietary staff, activity staff, housekeeping staff and office staff, who are just as crucial to residents' well-being, to hire more nursing services personnel. Some commentators felt that the cost of hiring additional nursing services personnel might result in costs needing to be passed on to residents, which would require residents to spend down faster to receive MA, which will impact the MA program. Many commentators also pointed out that the MA program has been underfunded for years, while costs to facilities have increased. Commentators argued that without a significant increase in MA funds, facilities will not have the resources to cover the cost of additional nursing services personnel. Commentators indicated that there is already a shortfall in MA reimbursement to facilities, which the facilities or their residents must cover.

Commentators also argued that quantity does not necessarily equal quality, and a one size fits all approach will not work. Commentators argued that the Department should base the level of care on the needs of the facility, considering resident care plans, resident acuity, facility characteristics, and training, competency, and tenure of staff. Commentators argued, for example, that a facility with a ventilator unit may require a significantly higher staffing level, while a primary care facility with no specialty units may require lower staffing.[1] Some commentators stressed as well that 4.1 should be a floor, not a ceiling, and facilities should be required to staff higher if required by resident acuity. The Department notes, in response to this comment, that the requirement in subsection (i) is indeed a minimum, and under subsection (i)(3), a facility is required to have a sufficient number of nursing services personnel to provide nursing care and related services to assure resident safety and to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident. Other commentators argued that the Department's proposal to increase direct care hours would stifle innovation as facilities scramble to pay for increased staffing levels. Others argued that the Department should follow CMS' lead on this issue by not requiring a minimum staffing level at all.

Commentators suggested that the Department and the State develop strategies to address staffing shortages, such as assistance with education and training for nursing services personnel. Commentators suggested that the State provide incentives to those who choose to work in the profession, such as tax cuts, tuition reimbursement, loan forgiveness, and free training and certification. The Department is supportive of these efforts, and notes that many of the facilities that submitted comments indicate they are already providing these incentives as a mechanism to recruit and retain nursing services personnel. Some commentators indicated that the temporary nurse aide (TNA) waiver program was a great help and urged the State to make this program permanent. The TNA waiver program was a pathway for individuals to become a TNA, with extended deadlines to meet training requirements to become a certified NA. The TNA waiver was one of several temporary Federal emergency declaration blanket waivers enacted by CMS to provide for extra flexibility needed to respond to the COVID-19 pandemic. Although CMS ended the waiver on June 6, 2022, CMS will accept waiver requests to extend the TNA certification testing deadline of October 6, 2022. Department of Education. Temporary Nurse Aide. Retrieved from https://www.education.pa.gov/K-12/Career%20and%20Technical%20Education/Nurse%20Aide%20Training%20Program/TempNurseAide/Pages/default.aspx. As such, the Commonwealth submitted a Statewide waiver request to CMS to further extend this deadline to continue testing and retaining TNAs.

IRRC, in proposed Rulemaking 1, noted that commentators both supported and opposed the proposed increase

[1] One commentator suggested that staffing hours should be based on facility needs and resident acuity as determined by the completion of a monthly facility assessment under 42 CFR 483.40(e). Under 42 CFR 483.70(e), a facility must complete a facility assessment, as often as necessary, but at least annually. The Department has amended § 201.14(j) to require a facility assessment as often as necessary, but at least quarterly. This amendment is discussed more fully in the preamble for Rulemaking 3 in § 201.14(j).

to 4.1 direct care hours and provided specific examples related to the previously listed comments. IRRC asked that the Department explain how the final-form regulation protects residents, while also addressing the impact of the minimum number of direct care hours on facilities, regardless of whether the Department retains or amends § 211.12(i). IRRC also asked if the Department sees any potential negative impact for residents if positions remain unfilled when the regulation goes into effect.

As stated above, the Department received similar comments to subsection (i) in proposed Rulemaking 4. Some commentators proposed a ramp-up period as a solution to balance the need for higher staffing with available resources and MA funding. These commentators suggested staffing ratios that would equate to an increase to 2.87 direct care hours per resident per day in the first year, with the first year beginning on July 1, 2023, and 3.2 direct care hours per resident per day in the second year, with the second year beginning on July 1, 2024. IRRC asked the Department to explain the need for and reasonableness of staffing ratios that are more stringent than the Federal requirements.

In this final-form rulemaking, the Department amends subsection (i) in accordance with the graduated period suggested by commentators. First, the Department rephrases the existing language in subsection (i) for ease of readability and adds two paragraphs to align with the graduated implementation period proposed by commentators. Under paragraph (1), effective July 1, 2023, the total number of hours of general nursing care provided in each 24-hour period shall, when totaled for the entire facility, be a minimum of 2.87 hours of direct resident care for each resident. Under paragraph (2), effective July 1, 2024, the total number of hours of general nursing care provided in each 24-hour period shall, when totaled for the entire facility, be a minimum of 3.2 hours of direct resident care for each resident. The language the Department had previously proposed in paragraph (2), in proposed Rulemaking 1, is deleted on final-form because this language is duplicative of 42 CFR 483.35 and is not needed due to the expansion of the incorporation of the Federal requirements in § 201.2.

The Department carefully considered the varying comments in support of and in opposition to the increased direct resident care hours. In balancing the interests of consumers, advocates and industry stakeholders, in combination with the substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023 (Act 2022-54), the Department amended this section, as provided previously, with a graduated implementation date. The final rate of 3.2 hours of direct resident care for each resident, effective July 1, 2024, is comparable to surrounding states and similarly situated states: Delaware 3.28 hours; Maryland 3.00 hours; New York 3.50 hours; New Jersey 2.50 hours; District of Columbia 3.50—4.10 hours; Ohio 2.50 hours; Florida 3.6 hours; Rhode Island 3.58 hours; and West Virginia 2.25 hours. https://www.macpac.gov/publication/state-policies-related-to-nursing-facility-staffing/.

The increase in direct care hours from the current minimum of 2.7 to 2.87 represents a small increase, which should be achievable for facilities. In fact, 622 facilities are already meeting or exceeding this requirement. The increase from 2.87 to 3.2 in year 2 represents a small increase as well. Currently, 523 nursing facilities (or 77%) already meet a 3.0 standard, with 374 nursing facilities (or 55%) meeting or exceeding the 3.2 requirement. The delayed implementation date until July 1, 2023 for year 1, with a graduated implementation beginning year 2, coupled with a reduced rate in combination with increased funding for nursing facilities generally and increased MA payments provides ample time and funding to fill positions. If positions are not filled, residents are impacted because they will not benefit from the quality of care that a higher staffing ratio would provide.

In response to IRRC's question regarding the need for staffing ratios, CMS is revisiting the need to set minimum staffing ratios in long-term care nursing facilities. The White House announced, earlier this year, that CMS intends to propose minimum standards for staffing and is conducting a new research study to determine the level and type of staffing needed to ensure safe and quality care. The White House. *Fact Sheet: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes*. Retrieved from https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/. As noted by the White House, "establishing a minimum staffing level ensures that all nursing home residents are provided safe, quality care, and that workers have the support they need to provide high-quality care." As pointed out by commentators, as well, numerous studies have found a direct correlation between the quality of resident care, quality of resident life, and the number of direct care hours that the resident receives. The benefits of higher staffing ratios include improved activity levels, lower mortality rates, fewer infections, less antibiotic use, fewer pressure ulcers and fewer catheterized residents, improved eating patterns and pain levels, and improved mental health. Juh Hyun Shin, PhD, RN & Sung-Heui Bae, PhD, MPH, RN. *Nurse Staffing, Quality of Care, and Quality of Life in U.S. Nursing Homes*, 1996-2011, 38 Journal of Gerontological Nursing 46 (2012).

Subsection (i.1)

This subsection remains unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, under subsection (i.1), only direct resident care provided by nursing services personnel may be counted towards the total number of hours of general nursing care required under subsection (i). Under this requirement, only direct care provided to residents by RNs, LPNs and NAs count toward the number of direct care hours in subsection (i). As explained on proposed, RNs, LPNs and NAs are better positioned to provide this type of resident care based on their training and experience, than other types of professionals, such as physical therapists, who are primarily focused on providing residents with specialized care.

Commentators to proposed Rulemaking 1 commented that the Department should permit facilities to include staff, other than nursing services personnel, in the calculation of direct care hours. These commentators argued that staff, such as physical, occupational and rehabilitative therapists, activities staff, dieticians, housekeeping staff, maintenance staff, dining staff and social workers often assist residents with activities of daily living. Some commentators argued that CMS recognizes these individuals in its definition of "direct care." Some commentators, on the other hand, commented that direct care should only be provided by nursing services personnel. IRRC, in comment to proposed Rulemaking 1, questioned whether the health, safety and welfare of residents would be protected by expanding the definition of direct care staff to align with the Federal definition.

The Department received similar comments to proposed Rulemaking 4. Commentators additionally argued that ancillary staff, who meet the licensure requirements to be nursing services personnel, also should not be included in the calculation for who provides direct care under subsection (i). In response to this comment, in practice, the Department only counts the staff if they are working in their capacity as licensed nursing services personnel, outside of the scope of their other role in the facility. For example, a facility that is required to have a full-time administrator cannot count the work of a licensed RN who is working as the administrator towards the direct care hours, if that work subtracts from the number of hours they are required to work as an administrator. IRRC, in comment to proposed Rulemaking 4, asked the Department to explain why the Federal requirements are not sufficient related to who provides direct care, given the Department's deference to Federal requirements throughout the regulations.

Direct care typically involves assisting residents with tasks such as grooming and dressing themselves, exercise, eating, changing soiled clothing, repositioning and providing toileting assistance. As explained on proposed, RNs, LPNs and NAs are in the best position to provide this type of resident care based on their training and experience compared to other types of professionals. While physical therapists and others may assist with these tasks on an ad hoc basis, residents benefit from having this care provided on a consistent basis from nursing personnel who are more familiar with the overall needs of the residents in their care, as opposed to other types of professionals such as physical therapists, who are primarily focused on providing residents with specialized care. John F. Schnelle PhD, L. Dale Schroyer MMS, Avantika A. Saraf MPH, Sandra F. Simmons PhD, *Determining Nurse Aide Staffing Requirements to Provide Care Based on Resident Workload: A Discrete Event Simulation Model*, JAMDA 17 (2016) 970-977; Charlene Harrington, Susan Chapman, Elizabeth Halifax, Mary Ellen Dellefield, and Anne Montgomery, *Time to Ensure Sufficient Nursing Home Staffing and Eliminate Inequities in Care*, HSOA Journal of Gerontology and Geriatric Medicine, Geriatr Med 2021, 7:099.

Subsection (j)

This subsection remains deleted in this final-form rulemaking. As explained previously, and in the proposed rulemaking, the Department moves this requirement into subsection (f.1)(1) for clarity.

Subsection (k)

This subsection remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deleted this subsection to eliminate duplication and to avoid conflict with the Federal requirements. Under 42 CFR 483.35(g), a facility is required to post on a daily basis and at the beginning of each shift, the total number and actual hours worked by RNs, LPNs and NAs.

A commentator requested that the Department require facilities to post this information online as well as inside and outside of the front door of the facility for residents and visitors to see. After careful consideration, the Department declines to make this suggested amendment. Under 42 CFR 483.35(g)(2)(ii)(B), a facility is required to post the nursing staff data specified in 42 CFR 483.35(g)(1) "in a prominent place readily accessible to residents and visitors." The facility must also, under 42 CFR 483.35(g)(3), "upon oral or written request make nurse staffing data available to the public for review at a cost not to exceed the community standard."

Subsection (l)

This subsection remains deleted in this final-form rulemaking. Commentators requested that the Department not delete subsection (l) and that the Department add language to specifically indicate that the nursing staff ratios are minimum levels, and that actual staffing levels, which shall meet or exceed these levels, must be determined specifically for each facility based on the actual needs of each resident as outlined in their comprehensive assessments and person-centered care plans, as well as in accordance with the quarterly facility assessment. In contrast, some commentators in both proposed Rulemakings 1 and 4 suggested that the Department should not have minimum staffing requirements at all and should instead require facilities to staff based on resident care needs, as determined by the facility assessment. After careful consideration of these comments, the Department declines to make these suggested amendments. As explained in subsections (f.1) and (i), the Department has determined that minimum nursing staff levels are needed to ensure the health, safety and welfare of residents. The Department also declines to add the language requested by other commentators, regarding minimum standards. Under 42 CFR 483.35, a facility "must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at" 42 CFR 483.70(e). In addition, under 42 CFR 483.35(a)(1), a facility must provide a sufficient number of licensed nurses and other nursing personnel "on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans." The Department considers the staffing levels in subsection (f.1) to be the minimum. If a facility's assessment or resident care plans show that a higher staffing level is required, then the facility must staff to that level under 42 CFR 483.35. This is not a new requirement for facilities.

§ 211.15. Dental services

Subsection (a)

This subsection remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection because it is duplicative of 42 CFR 483.55 (relating to dental services), which requires a facility to provide or obtain from an outside resource routine and emergency dental services. In response to a commentator who requested that the Department add a provision requiring that a facility provide necessary assistance to ensure the resident can access their provider of choice, the Department notes that a facility is required under 42 CFR 483.55 to assist residents in making dental appointments and arranging transportation to and from dental services locations. The three private-pay facilities are currently exempted from the requirements in 42 CFR 483.55 under existing § 201.2, but will be required to comply with this section under § 201.2, as amended in Rulemaking 1. This assumes approval of Rulemaking 1.

Subsection (b)

Subsection (b) is amended from the proposed rulemaking to this final-form rulemaking. The Department had proposed to delete this subsection because under 42

CFR 483.55, a facility is also required to have a policy to identify the circumstances in which the loss or damage of dentures is the facility's responsibility and to provide a referral for dental services for residents with lost or damaged dentures, within 3 days. A commentator, and IRRC, noted that the requirement in subsection (b), which ensures that resident dentures are retained by residents and marked for each resident, does not appear to be directly covered by the Federal requirements. IRRC asked if the deletion of this provision would reduce existing protections for residents of facilities. IRRC asked the Department to explain how the removal of this provision protects the public health, safety and welfare of residents.

Upon further review, the Department has decided to retain, not delete, the requirement in this subsection in this final-form rulemaking, but to rephrase it for ease of readability. Although facilities are required under 42 CFR 483.55 to have policies in place regarding loss or damage of dentures, there is no explicit requirement for a facility to assure that resident dentures are retained by residents and marked for each resident. The Department has also added a cross-reference to 42 CFR 483.55 to make it clear to facilities that this requirement is in addition to the requirements in that section.

§ 211.16. Social services

Subsection (a)

This subsection is amended from the proposed rulemaking to this final-form rulemaking. The Department had proposed to require that all facilities have a full-time qualified social worker, regardless of size. The Federal requirements at 42 CFR 483.70(p) only require a full-time qualified social worker for facilities with more than 120 beds.

One commentator indicated that smaller facilities may have someone working as a social worker who has not been professionally trained as a social worker, or a social worker who is serving in another capacity, such as the activities director. This commentator stated that requiring a full-time qualified social worker would result in a turnover of staff that do not meet the technical definition of a qualified social worker. In response to this comment, the Department notes that under existing § 211.16 (relating to social services), a facility with more than 120 residents is required to have a qualified social worker on a full-time basis, and a facility with 120 beds or less that does not have a full-time qualified social worker is required to provide social work consultation by a qualified social worker. Therefore, all facilities, under the current standards, are already required to utilize a qualified social worker, just not on a full-time basis.

Other commentators felt that small facilities, who are also more likely to be small businesses, would be disproportionately harmed by the requirement to have a full-time qualified social worker, particularly with the Department's proposal to increase nursing staff ratios. One commentator suggested that the Department amend this subsection to require a full-time qualified social worker for facilities with 60 or more beds, allow facilities with 26 to 59 beds to have a part-time social worker based off the facility assessment and needs of the residents, and allow facilities with 25 beds or less to share a qualified social worker, like the provision in § 201.18, related to the sharing of administrators. However, some commentators did express support for the Department's proposal to require that all facilities have a full-time qualified social worker.

IRRC asked what alternatives the Department considered to assist rural and small facilities with implementation of this requirement. IRRC also asked that the Department explain the reasonableness and feasibility of requiring a full-time qualified social worker for all facilities regardless of size.

As explained in the proposed rulemaking, the Department asserts that all facilities need to have a full-time social worker on staff regardless of the size of the facility. Social workers have specialized education and training and are well-suited to assist residents and their families with all aspects of their stay in a long-term care nursing facility, including the social, emotional, financial, and psychological aspects, and preparing residents and their families for life post-discharge. In addition, over time, the condition of residents seeking care in the long-term care nursing environment has changed, and there has been an increase in the number of residents presenting with a wide range of psychosocial or behavioral issues. For example, facilities may have younger residents with mental health conditions, veterans with post-traumatic stress disorder or older residents with dementia. These residents require engaged qualified social workers to assist with their care planning and to provide psychosocial support.

However, recognizing that requiring a full-time qualified social worker could be unduly burdensome to rural and small facilities, the Department amends this subsection. In accordance with the suggestion put forth by a commentator, this section is amended to permit a facility with 26 to 59 beds to employ a part-time qualified social worker if the facility assessment indicates that a full-time qualified social worker is not needed, and to permit facilities with 25 beds or less to either employ a part-time qualified social worker or share the services of a qualified social worker with another facility. All other facilities will be required to employ a full-time qualified social worker.

Subsection (b)

Subsection (b) remains deleted in this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection due to the amendments to subsection (a) as described previously.

Other Comments

Commentators requested that the Department expand § 211.16 to require the social worker or a designee to meet with each resident and to document in the resident's person-centered care plan the resident's wants and needs as they relate to social services. Commentators also requested that the Department add language requiring that the person-centered care plan address how the resident might be supported during any prolonged periods of isolation caused by pandemic, infection or other contagious disease, and to require the facility to consider best practices in minimizing isolation as it plans its social services and resident supports. The Department declines to make these suggested amendments, for the following stated reasons.

Existing Federal requirements at 42 CFR 483.21(a) and (b) require that a facility must develop and implement both a baseline care plan and a comprehensive care plan for each resident and include objectives and timeframes to meet a resident's social and psychosocial needs. Further, the comprehensive care plan must be developed and implemented by the facility with the input of the resident. Additionally, 42 CFR 483.21(b)(2)(ii) provides that the interdisciplinary care team that prepares the comprehensive care plan must include—but is not limited to—an enumerated team of individuals with an interest in the well-being of the resident. Subsection 483.21(b)(2)(ii)(F)

specifies that an interdisciplinary care team may include "other appropriate staff or professionals in disciplines as determined by the resident's needs or as requested by the resident." This language provides for a social worker to be part of the interdisciplinary team based either on the resident's needs or at the request of the resident.

With regards to planning for prolonged periods of isolation, 42 CFR 483.10(f)(4) provides that a resident has a right to receive visitors of their choosing and a facility needs to provide immediate access to any resident by an enumerated group of persons including government officials, professionals and most importantly to address the concerns of commentators in this subsection, immediate family and other visitors. Additionally, the facility must provide reasonable access to a resident "by any entity or individual that provides health, social, legal, or other services to the resident" under § 483.10(f)(4)(iv). Residents and their representatives, if applicable, must be provided notice of written visitation policies pursuant to § 483.10(f)(4)(v) and (vi).

In response to the COVID-19 pandemic, the Commonwealth also enacted legislation that helps address isolation for residents during declarations of emergency. The act of July 1, 2021, (P.L. 355, No. 67) established the Access to Congregate Care Facilities Act (35 P.S. §§ 10281—10289) which provides for residents to name an essential caregiver to help provide physical or emotional support to the resident during a declaration of disaster emergency.

Commentators requested that the Department expand § 211.16 to also require the social worker or a designee to support residents in acquiring technology-based skills so that they can better connect with friends and family outside of the facility. The Department declines to make this suggested amendment. While the Department understands the need for residents to be supported in acquiring technology-based skills to ensure contact with persons outside the facility, 42 CFR 483.10(g)(7) requires facilities to ensure resident access to phones, internet and stationary, postage and mail services. A resident has the right to private use of electronic communication at the resident's expense. The Department will not require a social worker to teach residents technological skills, as it is outside the scope of the social worker's role.

§ 211.17. Pet therapy

This section is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department rephrases this section to require a facility to have written policies and procedures that incorporate the requirements that already exist in this section, with amendments, if pet therapy is utilized. The Department has made grammatical changes to paragraphs (2)—(4) and (6) for ease of readability. In paragraphs (4) and (6), the Department replaces the word "pets" with "animals" for consistency in the use of terms throughout this section. The Department deletes paragraph (5) and replaces it with paragraph (5.1) to address the health of animals and the health and safety of residents by requiring that a facility have policies and procedures in place to ensure that animals are up-to-date on vaccinations, are in good health and do not pose a risk to the health and safety of residents. In paragraph (6), the Department adds the words "or visit" to clarify that a facility shall have policies and procedures in place to ensure that animals and places where they visit, as well as where they reside, are kept clean and sanitary. Paragraph (7) is added to require a facility to have in place policies and procedures to ensure that infection prevention and control measures, such as hand hygiene, are followed by residents and personnel when handling animals, to reduce the risk of illness or infection that can sometimes occur when handling animals.

A commentator asked that the Department not unnecessarily regulate pet therapy requirements. The commentator stated that these visits are very appreciated and sometimes are the highlight of the residents' day. The commentator added that this is the least infectious thing that facilities do. The Department declines to further amend this section, on final-form, in response to this comment. The Department recognizes the benefit of permitting pets and animals to visit with residents. The Department, however, must balance this benefit with its goal of protecting the health, safety and welfare of residents. The Department believes that amending § 211.17 (relating to pet therapy) to add requirements such as hand washing, are minimal health and safety standards and necessary to ensure the health, safety and welfare of residents. The Department notes as well that these amendments align with CDC guidelines for pet therapy and visitation in healthcare facilities. See CDC. Guidelines for Environmental Infection Control in Health-Care Facilities. (2003). Retrieved from https://www.cdc.gov/infectioncontrol/guidelines/environmental/background/animals.html.

Fiscal Impact and Paperwork Requirements

Fiscal Impact

The Department participated in the Senate Health and Human Services and Aging and Youth Committees joint legislative hearing regarding proposed Rulemaking 1 on September 15, 2021. Various stakeholders participated, including the Pennsylvania Health Care Association (PHCA), AARP Pennsylvania, LeadingAge Pennsylvania, the Pennsylvania Coalition of Affiliated Healthcare & Living Communities (PACAH), SEIU Healthcare Pennsylvania, and the Center for Advocacy for the Rights & Interests of the Elderly (CARIE). During this hearing, there was much discussion about the proposed staffing increase from 2.7 to 4.1 hours of direct resident care and the related cost and staff concerns. Specifically, concerns were raised regarding stagnate MA rates since MA pays for 70% of all nursing home care. There were also comments regarding increased costs related to the increased staffing generally. During this hearing, stakeholder testimony provided that many facilities struggle to reach 3.3 hours of direct resident care. Resident advocates also expressed concerns with staff turnover and the need for greater transparency to understand how facilities are spending public funds. There was further testimony regarding staff burnout due to high demands of resident care, workers leaving the field, and the need to address systemic underfunding of these services in this Commonwealth.

In response to the comments and concerns raised during this legislative hearing, throughout the public comment process, and in other discussions, the Governor's Fiscal Year (FY) 2022-2023 budget proposal proposed an MA rate increase of $190 million; $91 million in State funding to be matched with $99 million in Federal funds for the first 6 months of calendar year 2023 and a proposed $250 million one-time investment of American Rescue Plan Act (ARPA) funds in long-term living programs, including direct one-time funding for all facilities to support their workforce and help them to hire more staff to meet the requirements of the forthcoming regulations. The funding was proposed to be provided to facilities in advance of the expected staffing increases to

allow facilities to stabilize their existing workforce and recruit additional staff prior to the regulatory increases going into effect.

Following the Governor's budget proposal, industry stakeholders called for $294 million in MA funding in the Commonwealth's FY 2022-2023 budget. The FY 2022-2023 Appropriations Act signed by Governor Tom Wolf included bipartisan support for a historic increase in one-time and ongoing funding for facilities. As enacted, $147 million in State funding was appropriated to support implementation of the Department's regulations. Specifically, this funding will be used to support a 17.5% Medicaid rate increase beginning January 1, 2023, which allows facilities time to ramp up staffing to meet the direct care staffing hours required on July 1, 2023. Assuming Federal approval, these State funds will be matched with an additional $159 million in Federal funds, totaling $306 million in Medicaid funding for the first 6 months of calendar year 2023. All nursing facilities will also receive $131 million in one-time ARPA funding during FY 2022-2023. A detailed fiscal impact for the regulated community, the Commonwealth and local government is as follows:

Regulated community

The amendments will apply to all 682 long-term care nursing facilities licensed by the Department. These facilities provide health services to approximately 72,000 residents. This total includes 19 county-owned and operated facilities, 6 veterans' homes that are operated by the Department of Military and Veterans' Affairs, 654 privately-owned facilities that participate in the Medicare or MA Programs, and 3 private-pay facilities that do not participate in Medicare or MA.

Cost to add qualified social worker

Some long-term care nursing facilities will be financially impacted by the requirements in § 211.16, which require facilities to employ a full-time or part-time social worker or permit sharing of the services of a social worker, depending on the size of the facility.

To estimate the number of facilities that will be impacted by the increased requirements in § 211.16, the Department pulled data from the most recent, available annual report, for FY 2020-2021. This report is available on the Department's web site. Department of Health. (2021). Nursing Home Reports. Retrieved from https://www.health.pa.gov/topics/HealthStatistics/HealthFacilities/NursingHomeReports/Pages/nursing-home-reports.aspx. Data within the report is obtained through an annual survey of facilities. The data, therefore, is dependent on self-reporting from the facilities who complete the survey.

According to this Commonwealth's Center for Workforce Information & Analysis, the median annual wage for a healthcare social worker is $55,890. Center for Workforce Information & Analysis (2021). Occupational Wages. Retrieved from https://www.workstats.dli.pa.gov/Products/Occupational%20Wages/Pages/default.aspx. This does not include the cost of benefits. According to the United States Bureau of Labor Statistics, benefits make up approximately 31% of an employer's cost for compensation in the private sector. United States Bureau of Labor Statistics (2021). Economic News Release: Employer Costs for Employee Compensation Summary. Retrieved from https://www.bls.gov/news.release/ecec.nr0.htm. The Department therefore estimates the cost to hire a full-time social worker to be $73,216, which includes wages + benefits. The Department estimates the cost to hire a part-time social worker to be approximately half that amount, or $36,608. This assumes that a part-time social worker is working approximately 20 hours per week.

Under existing § 211.16, facilities with 120 beds or more are already required to have a full-time social worker. The amendment to § 211.16(a) will require facilities with 60 beds to 119 beds to have a full-time social worker. Based on data pulled from the annual report, the Department estimates that 9 facilities will need to staff up from a part-time social worker to a full-time social worker, at an approximate cost of $329,472 ($36,608 × 9). These facilities are all privately-owned facilities that participate in the MA program. According to data obtained from DHS, approximately 75.82%, or $249,806 of the total costs to MA facilities will be covered by the MA program. Applying the Federal share of approximately 52% to the total costs to the MA program results in an estimated Federal match of $129,899 and a State general fund investment of $119,907. There are 83 facilities that do not currently have a social worker that will need to hire a full-time social worker, at an approximate cost of $6,076,928 ($73,216 × 83). Out of these 83 facilities, 3 are Medicare-only facilities ($219,648) and 80 are privately-owned MA facilities ($5,857,280). According to data obtained from DHS, approximately 75.82%, or $4,440,990 of the total costs to MA facilities will be covered by the MA program. Applying the Federal share of approximately 52% to the total costs covered by the MA program results in an estimated Federal match of $2,309,315 and a State general fund investment of $2,131,675. These estimates are for fiscal year 1.

The amendment to § 211.16(a)(1) will require facilities with 26 to 59 beds to employ at least a part-time social worker if their facility assessment indicates that a full-time social worker is not needed. There are 22 facilities that currently do not employ a social worker, that will need to hire a part-time social worker under this requirement, for an estimated cost of $805,376 ($36,608 × 22). Out of these 22 facilities, 3 are Medicare-only ($109,824) and 19 are privately-owned MA facilities ($695,552). According to data obtained from DHS, approximately 75.82%, or approximately $527,368 of the costs to MA facilities will be covered by the MA program. Applying the Federal share of approximately 52% to the total costs results in an estimated Federal match of $274,231 and a State general fund investment of $253,136. These estimates are for fiscal year 1.

The amendment to § 211.16(a)(2) will require facilities with 25 beds or less to employ either a part-time social worker or share the services of a social worker with another facility. Based on the annual report, all facilities that have 25 beds or less are currently meeting this requirement. Thus, there will be no fiscal impact on these facilities by the addition of § 211.16(a)(2).[2]

The cost to facilities to employ a full-time or part-time social worker is outweighed by the need to have a social worker on staff. As stated previously, social workers have specialized education and training and are well-suited to assist residents and their families with all aspects of their stay in a long-term care nursing facility, including the social, emotional, financial, and psychological aspects, and preparing residents and their families for life post-discharge. In addition, over time, the condition of resi-

[2] DMVA indicated to the Department that the six veterans' homes that it operates will not be affected by the Department's amendment to § 211.16. In addition, out of the 19 county-owned facilities, 18 have more than 120 beds and thus, are already required to have a full-time social worker. The one county-owned facility with 120 or less beds reported having a full-time social worker in the 2020-2021 annual report. If this continues to be the case, there will be no impact to this facility.

dents seeking care in the long-term care nursing environment has changed, and there has been an increase in the number of residents presenting with a wide range of psychosocial or behavioral issues. These residents require engaged social workers to assist with their care planning and to provide psychosocial support.

Cost to meet proposed nursing staff ratio.

Privately-owned and MA Program; 2023-2024

The increase in LPNs set forth in § 211.12(f.1)(4), is projected to require the 589 privately-owned facilities that participate in MA[3] to employ an additional 522 full-time equivalent (FTE) LPNs in the aggregate. In FY 2023-2024, the cost for an LPN is projected to be $85,276, which is an increase of 13% from the average LPN wage across all industries in 2021, according to data from the United States Bureau of Labor Statistics. This estimate for the increased cost includes wages and benefits and is based on the 75th percentile of Bureau of Labor Statistics (BLS) wage data reported for these professions across all industries in this Commonwealth. The wages were increased to reflect the most recent benefit cost percentage (28%) and trended for inflation to 2023 (5%).[4] The 75th percentile wage was used as a proxy for expected wages in 2023 due to trends in the labor market for LPNs and NAs and unchecked pressures on staffing agency use and pricing. The total cost to the privately-owned facilities that participate in MA to add 522 FTE LPNs is estimated to be $44,514,072 in the aggregate. The affected privately-owned facilities will also need to hire an estimated 249 FTE NAs to meet the requirements in § 211.12(f.1)(2), which are effective from July 1, 2023, through June 30, 2024. The NA salary during that period, FY 2023-2024, is projected at $54,542, which is a 14% increase from the average nurse aide wage across all industries in 2021, according to data from the United States Bureau of Labor Statistics. The total estimated cost during FY 2023-2024 to add 249 FTE NAs is $13,580,958 in the aggregate. There will be no additional cost to meet the total general nursing care hours per resident per day because facilities that meet or exceed the minimum RN, LPN and NA requirements will meet or exceed the minimum requirements for direct care hours set forth in § 211.12(i).

In fiscal year 2023-2024, the total increased cost for privately-owned MA facilities to meet the requirements of § 211.12(f.1)(2) and (4) will be approximately $58,095,030 in the aggregate. According to data obtained from DHS, approximately 75.82%, or about $44,047,652, of this cost will be covered by the MA program. Applying the Federal share of approximately 52% to the total costs results in an estimated Federal match of $22,904,779 and a State general fund investment of $21,142,873.

Privately-owned and MA Program; 2024-2025

In the following year, the requirements for NAs in § 211.12(f.1)(4) that go into effect on July 1, 2024, will require the privately-owned facilities that participate in MA to hire an additional 1,389 NAs, for a total of 1,638 FTE NAs in FY 2024-2025. The NA salary during that period, FY 2024-2025, is projected at $57,958, which is a 21.5% increase from the average NA wage across all industries in 2021, according to data from the United States Bureau of Labor Statistics. Therefore, the total estimated cost during FY 2024-2025 for 1,638 FTE NAs is $94,935,204 in the aggregate. The annual LPN salary for that period is projected to increase to $90,281, which is a 20% increase from the average LPN wage across all industries in 2021, according to data from the United States Bureau of Labor Statistics. The cost to employ the 522 FTE LPNs in FN 2024-2025 will, therefore, be approximately $47,126,682 in the aggregate.

In FY 2024-2025, the total increased cost for privately-owned MA facilities to meet the requirements of § 211.12(f.1)(3) and (4) will be, in the aggregate, approximately $142,061,886. According to data obtained from DHS, approximately 75.82%, or about $107,711,322, of this cost will be covered by the MA program. Applying the Federal share of approximately 52% to the total costs results in an estimated Federal match of approximately $56,009,887 and a State general fund investment of approximately $51,701,435.

Medicare-only Facilities; 2023-2024

There are 59 facilities that participate only in Medicare. The increase in LPNs, set forth in § 211.12(f.1)(4), will require these 59 facilities to employ an additional 119 FTE LPNs. This estimate is based on data obtained from the Department's 2020-2021 annual report. In FY 2023-2024, the cost for an LPN is projected to be $85,276. This estimate includes wages and benefits. The total cost to add 119 FTE LPNs in FY 2023-2024, based on the same cost assumptions provided by DHS, will be approximately $10,147,844. In FY 2023-2024, the affected Medicare facilities will also need to hire approximately 550 FTE NAs to meet the requirements in § 211.12(f.1)(2), which are effective from July 1, 2023, through June 30, 2024. The NA salary during that period is projected at $54,542. The total estimated cost during FY 2023-2024 to add 550 FTE NAs is $29,998,100. There will be no additional cost to meet the total general nursing care hours per resident per day because facilities that meet or exceed the minimum RN, LPN and NA requirements will meet or exceed the minimum requirements for direct care hours set forth in § 211.12(i).

In FY 2023-2024, the total increased cost for Medicare facilities to meet the requirements of § 211.12(f.1)(2) and (4) will be approximately $40,145,944. The Department is not able to assess to what extent these costs will be offset by Medicare as Medicare is a Federally managed healthcare program and the Department does not have access to data regarding payment of Medicare to facilities.

Medicare-only Facilities; 2024-2025

In the following year, the requirements for NAs in § 211.12(f.1)(3) that go into effect on July 1, 2024, will require the facilities that participate only in Medicare to hire an additional 90 NAs, for a total of 640 FTE NAs in FY 2024-2025. The NA salary during that period, FY 2024-2025, is projected at $57,958. Therefore, the total estimated cost during FY 2024-2025 to employ 640 FTE NAs is $37,093,120. The annual LPN salary for that period is projected to increase to $90,281. The cost to employ the 119 FTE LPNs in FY 2024-2025 will therefore be approximately $10,743,439. There will be no additional cost to meet the total general nursing care hours per resident per day because facilities that meet or exceed the minimum RN, LPN and NA requirements will meet or exceed the minimum requirements for direct care hours set forth in § 211.12(i).

In FY 2024-2025, the total increased cost for Medicare facilities to meet the requirements of § 211.12(f.1)(3) and (4) will be approximately $47,836,559. The Department is

[3] This number includes facilities that participate only in MA and those that participate in both Medicare and MA.

[4] The Department is using a 5% inflation projection in 2023, even though the Federal outlook indicates a 2.5—2.9% inflation projection. Congressional Budget Office Outlook: 2022 to 2032; Figure 2-4. Inflation and Interest Rates. Retrieved from https://www.cbo.gov/publication/58147#_idTextAnchor075. The Department, however, erred on the side of a 5% projection due to the historic inflation rates and the desire to account for a potential higher rate if the 2023 projections are missed.

not able to assess to what extent these costs will be offset by Medicare as Medicare is a Federally managed healthcare program and the Department does not have access to data regarding payment of Medicare to facilities.

Private-pay facilities; 2023-2024

There are three private-pay facilities that do not participate in either Medicare or MA. The increase in LPNs, set forth in § 211.12(f.1)(4), will require these three facilities to employ an additional four FTE LPNs. This estimate is based on data obtained from the Department's 2020-2021 annual report. In FY 2023-2024, the cost for an LPN is projected to be $85,276. This estimate includes wages and benefits. The total cost to add four FTE LPNs in FY 2023-2024, based on the same cost assumptions provided by DHS, will be approximately $341,104. In FY 2023-2024, the affected private-pay facilities will also need to hire approximately six FTE NAs to meet the requirements in § 211.12(f.1)(2), which are effective from July 1, 2023, through June 30, 2024. The NA salary during that period is projected at $54,542. The total estimated cost during FY 2023-2024 to add six FTE NAs is $327,252. There will be no additional cost to meet the total general nursing care hours per resident per day because facilities that meet or exceed the minimum RN, LPN and NA requirements will meet or exceed the minimum requirements for direct care hours set forth in § 211.12(i). In FY 2023-2024, the total increased cost for private-pay facilities to meet the requirements of § 211.12(f.1)(2) and (4) will be approximately $668,356.

Private-pay facilities; 2024-2025

In the following year, the requirements for NAs in § 211.12(f.1)(3) that go into effect on July 1, 2024, will require the private-pay facilities to hire an additional four NAs, for a total of ten FTE NAs in FY 2024-2025. The NA salary during that period, FY 2024-2025, is projected at $57,958. Therefore, the total estimated cost during FY 2024-2025 to employ ten FTE NAs is $579,580. The annual LPN salary for that period is projected to increase to $90,281. The cost to employ the four FTE LPNs in FY 2024-2025 will therefore be approximately $361,124. There will be no additional cost to meet the total general nursing care hours per resident per day because facilities that meet or exceed the minimum RN, LPN and NA requirements will meet or exceed the minimum requirements for direct care hours set forth in § 211.12(i). In FY 2024-2025, the total increased cost for private-pay facilities to meet the requirements of § 211.12(f.1)(3) and (4) will be approximately $940,704.

County-owned facilities; 2023-2024

The increase in LPNs set forth in § 211.12(f.1)(4), is projected to require the 19 county-owned facilities that participate in MA to employ an additional 69 FTE LPNs in the aggregate. In FY 2023-2024, the cost for an LPN is projected to be $85,276, as described previously. The total cost to facilities to add 69 FTE LPNs is estimated to be $5,884,044 in the aggregate. The affected county-owned facilities will also need to hire an estimated 2 FTE NAs to meet the requirements in § 211.12(f.1)(2), which are effective from July 1, 2023, through June 30, 2024. The NA salary during that period, FY 2023-2024, is projected at $54,542, as described previously. The total cost to facilities to add two FTE NAs is estimated to be $109,084 in the aggregate. There will be no additional cost to meet the total general nursing care hours per resident per day because facilities that meet or exceed the minimum RN, LPN and NA requirements will meet or exceed the minimum requirements for direct care hours set forth in § 211.12(i).

In FY 2023-2024, the total increased cost for county-owned MA facilities to meet the requirements of § 211.12(f.1)(2) and (4) will be approximately $5,993,128 in the aggregate. According to data obtained from DHS, approximately 75.82%, or about $4,543,990, of this cost will be covered by the MA program. Applying the Federal share of approximately 52% to the total costs results in an estimated Federal match of $2,362,875 and a State general fund investment of $2,181,115.

County-owned facilities; 2024-2025

In the following year, the requirements for NAs in § 211.12(f.1)(4) that go into effect on July 1, 2024, will require the county-owned facilities to hire an additional 96 NAs, for a total of 98 FTE NAs in FY 2024-2025. The NA salary during that period, FY 2024-2025, is projected at $57,958, as described previously. Therefore, the total estimated cost during FY 2024-2025 for 98 FTE NAs is $5,697,884 in the aggregate. The annual LPN salary for that period is projected to increase to $90,281, as described previously. The cost to employ the 69 FTE LPNs in FY 2024-2025 will, therefore, be approximately $6,229,389 in the aggregate.

In FY 2024-2025, the total increased cost for county-owned MA facilities to meet the requirements of § 211.12(f.1)(3) and (4) will be, in the aggregate, approximately $11,909,273. According to data obtained from DHS, approximately 75.82%, or about $9,029,611, of this cost will be covered by the MA program. Applying the Federal share of approximately 52% to the total costs results in an estimated Federal match of approximately $4,695,398 and a State general fund investment of approximately $4,334,213.

DMVA-operated facilities

The Department consulted with the DMVA to determine the impact of the increase to the nursing personnel staffing requirements in § 211.12. The DMVA operates 6 veterans' homes across the State with the bed capacity to serve 1,526 total residents and employs more than 2,000 clinical and professional staff. Due to increased funding under the Commonwealth's enacted budget, the increase in LPNs in § 211.12(f.1)(4) and the increase in NAs in § 211.12(f.1)(2) and (3) will not impact DMVA staffing requirements. DMVA will also not be impacted by the increase in general nursing care hours per resident per day in § 211.12(i). DMVA staff levels are established by the resident acuity level which generally requires staffing between 3.6 and 3.8 hours of direct nursing care per resident per day.

Training requirements

Under § 201.20 of this final-form rulemaking, facilities will be required to have annual in-service training on accident prevention, restorative nursing techniques, resident rights, including nondiscrimination and cultural competency, and training needs identified through a facility assessment. Also, under § 201.20, orientation shall also include dementia management and communication skills, which is in addition to the current requirement of resident abuse prevention, detection and reporting training. These trainings are in addition to the training requirements under 42 CFR Part 483 (relating to requirements for States and Long Term Care Facilities). Given that facilities have already incorporated various portions of these required trainings into their annual training curriculum, the Department anticipates an estimated 2 hours of additional training per year under this final-form rulemaking. The training costs are estimated as follows:

• The average hourly rate for physicians is $110/hour = $220 training costs per person. A 5% wage increase is applied in year 2 and thereafter.

• The average hourly rate for orderlies, aides and attendants is $16/hour = $32 training costs per person. A 5% wage increase is applied in year 2 and thereafter.

• The average hourly rate for other professionals, including therapists, technicians and nursing, is $32/hour = $64 training costs per person. A 5% wage increase is applied in year 2 and thereafter.

Statewide, the estimated total additional training costs, in the aggregate, is:

- FY 2023-2024—$4,827,048 (or $67 per resident)
- FY 2024-2025—$5,118,229 (or $71 per resident)

These aggregate costs are based on the following estimations:

Physicians:

- FY 2023-2024—1,990 × $220 = $437,800
- FY 2024-2025—1,990 × $231 = $459,690

Orderlies, aides and attendants:

- FY 2023-2024—61,310 × $32 = $1,961,920
- FY 2024-2025—62,793 × $33.60 = $2,109,845

Other professionals:

- FY 2023-2024—37,927 × $64 = $2,427,328
- FY 2024-2025—37,927 × $67.20 = $2,548,694

The totals for FY 2023-2024 include the additional social workers that will be needed to comply with § 201.16, as well as the LPNs and NAs that will be needed to comply with § 211.12(f.1)(2) and (4). The totals for FY 2024-2025 include both a 5% wage increase as well as the additional NAs that will be needed to comply with § 211.12(f.1)(3).

In addition, although the requirement for 4 hours annually of continuing medical education is not an additional cost since physicians are required to obtain 100 hours, the Department estimates the 4 hours of time would cost approximately $552 per physician.

Department

The amendments will not increase costs to the Department. The Department's surveyors perform the function of surveying and inspecting long-term care nursing facilities for compliance with both Federal and State regulations. For those facilities that participate in MA, there will be a fiscal impact as identified previously.

DMVA

The Department consulted with DMVA to determine the impact of the increase to the nursing personnel staffing requirements in § 211.12. DMVA operates 6 veterans' homes across the State with the bed capacity to serve 1,526 total residents and employs more than 2,000 clinical and professional staff. As provided previously, due to increased funding under the Commonwealth's enacted budget, the increase in LPNs in § 211.12(f.1)(4) and the increase in NAs in § 211.12(f.1)(2) and (3) will not impact DMVA staffing requirements. DMVA will also not be impacted by the increase in general nursing care hours per resident per day in § 211.12(i). DMVA staff levels are established by the resident acuity level which generally requires staffing between 3.6 and 3.8 hours of direct nursing care per resident per day.

To address the increased staffing and related costs, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023, was enacted under the act of July 11, 2022 (P.L. 540, No. 54) (Act 2022-54) and appropriated under the act of July 8, 2022 (No. 1a), known as the General Appropriation Act of 2022.

The training requirements set forth in § 201.20 will cost the DMVA facilities approximately $83,912 in FY 2023-2024 and $88,108 in FY 2024-2025, using the same cost estimations described previously in question 19. These costs are based on the following estimations:

Physicians:

- FY 2023-2024—14 × $220 = $3,080
- FY 2024-2025—14 × $231 = $3,234

Orderlies, aides and attendants:

- FY 2023-2024—1,396 × $32 = $44,672
- FY 2024-2025—1,396 × $33.60 = $46,906

Other professionals:

- FY 2023-2024—565 × $64 = $36,160
- FY 2024-2025—565 × $67.20 = $37,968

The totals for FY 2023-2024 include the additional social workers that will be needed to comply with § 201.16, as well as the LPNs and NAs that will be needed to comply with § 211.12(f.1)(2) and (4). The totals for FY 2024-2025 include both a 5% wage increase as well as the additional NAs that will be needed to comply with § 211.12(f.1)(3).

DHS

There will be costs to the MA program as previously noted. To address the increased staffing and related costs, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023, was enacted under the act of July 11, 2022 (P.L. 540, No. 54) and appropriated under the act of July 8, 2022, (No. 1A), known as General Appropriations Act of 2022.

Local Government

As mentioned previously, there are currently 19 county-owned long-term care nursing facilities, licensed by the Department. These facilities account for approximately 7.5% (6,524 beds) of licensed nursing facility beds across the Commonwealth. Allegheny County owns four of the nursing homes; the remaining homes are in the following 15 counties: Berks, Bradford, Bucks, Chester, Clinton, Crawford, Delaware, Erie, Indiana, Lehigh, Monroe, Northampton, Philadelphia, Warren and Westmoreland. As previously noted, the county-owned facilities should not incur a cost related to § 211.16. However, the county-owned facilities will incur a cost related to the increase in LPNs and NAs in § 211.12(f.1) through (f.4).

The training requirements set forth in § 201.20 will also cost the county-owned facilities approximately $276,824 in FY 2023-2024 and $290,665 in FY 2024-2025, using the same cost estimations described in previously listed question 19. These costs are based on the following estimations:

Physicians:

- FY 2023-2024—98 × $220 = $21,560
- FY 2024-2025—98 × $231 = $22,638

Orderlies, aides and attendants:

○ FY 2023-2024—3,885 × $32 = $124,320

○ FY 2024-2025—3,885 × $33.60 = $130,536

Other professionals:

○ FY 2023-2024—2,046 × $64 = $130,944

○ FY 2024-2025—2,046 × $67.20 = $137,491

The totals for FY 2023-2024 include the additional social workers that will be needed to comply with § 201.16, as well as the LPNs and NAs that will be needed to comply with § 211.12(f.1)(2) and (4). The totals for FY 2024-2025 include both a 5% wage increase as well as the additional NAs that will be needed to comply with § 211.12(f.1)(3).

Residents of Long-Term Care Nursing Facilities

Approximately 72,000 individuals that reside in the 682 long-term care nursing facilities licensed by the Department will benefit from the increased minimum staffing requirements. Numerous studies have found a direct correlation between the quality of resident care, quality of resident life, and the number of direct care hours that the resident receives. The benefits of higher staffing ratios include improved activity levels, lower mortality rates, fewer infections, less antibiotic use, fewer pressure ulcers and fewer catheterized residents, improved eating patterns and pain levels, and improved mental health. Residents will also benefit from the expanded adoption of the Federal requirements because the same standards will now be applied to all long-term care nursing facilities, regardless of whether those facilities participate in the Medicare or MA programs.

Paperwork Requirements

This final-form rulemaking will result in new paperwork requirements as follows:

■ Increased personnel record requirements, including documentation of suitability for employment under § 201.19

■ Written policies and procedures for admission under § 201.24

■ Closure plan development, including plan for storage and retrieval of medical records under § 211.5 (relating to medical records)

■ Posting of resident rights under § 201.29

■ Written policies and procedures for disposition of medications under § 211.9 (relating to pharmacy services)

■ Posting of meal plans under § 211.6 (relating to dietary services)

In addition, the three private-pay facilities will have the following new paperwork requirements under this final-form rulemaking:

■ Quality assurance and performance improvement documentation under 42 CFR 483.75

■ Posting of nursing staff data under 42 CFR 483.35(g)

■ Information provided to resident in a form and manner the resident can access and understand under 42 CFR 483.10(g)(3)

■ Written standards for infection control under 42 CFR 483.80(a)

■ Written policies and notifications related to abuse, neglect and exploitation under 42 CFR 483.12(b)

■ Discharge plan and post-discharge plan of care under 42 CFR 483.21

Small Business Analysis

A commentator expressed concern that the Department did not identify and estimate the number of small businesses that will be subject to the regulation. This commentator indicated that many facilities are small businesses under the definition of "small business" in the Regulatory Review Act. IRRC commented that the Department did not provide an estimate of the number of small businesses that will be impacted by the regulation. IRRC asked if the Department, in conjunction with other agencies, can evaluate potential impacts on small businesses. IRRC also asked that the Department work with the regulated community to calculate and address the economic impact of additional quarterly assessments on facilities, particularly those that are small businesses.

Under section 3 of the Regulatory Review Act (71 P.S. § 745.3), a small business is "defined in accordance with the size standards described by the United States Small Business Administration's Small Business Size Regulations under 13 CFR Ch. 1 Part 121 (relating to Small Business Size Regulations) or its successor regulation." Under 13 CFR 121.101 (relating to what are SBA size standards?), the Small Business Administration's (SBA) "size standards determine whether a business entity is small." Size standards are developed under the North America Industry Classification System (NAICS). The Department applied the NAICS standards to determine how many long-term care nursing facilities, licensed by the Department, are small businesses.

The Department conducted a search on the NAICS web site to find the NAICS code for long-term care nursing facilities. The NAICS code for nursing care facilities (skilled nursing facilities) is 623110. The Department looked this code up in the table located at 13 CFR 121.201 (relating to what size standards has SBA identified by North American Industry Classification System codes?) and determined that a long-term care nursing facility is a small business if it has $30 million or less in annual receipts. The Department then pulled the latest long-term care nursing facility cost report from CMS to determine the impact to facilities that participate in Medicare or MA. The latest cost report data from CMS is 2018. Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data. The Department applied current Federal Standards of Accounting to this data to determine each facility's annual receipts. Based on this analysis, the Department determined that 623 facilities that participate in Medicare or MA have $30 million or less in annual receipts. Although the data from CMS is from 2018, the Department believes that currently, at least the same number of facilities, if not more, would meet the definition of a small business. This analysis aligns with the Department's previous assumption that most long-term care nursing facilities licensed by the Department meet the definition of a small business.

The Department also asked stakeholders during the meetings held in 2021 and 2022 for assistance in determining the impact to small businesses. The stakeholders were not able to provide the Department with specific information regarding how the Department's proposed regulations would impact small businesses. However, during the stakeholder meeting for Rulemakings 1 and 2, a stakeholder suggested that the Department search GuideStar, which provides financial information regard-

ing nonprofit entities, to determine whether the three private-pay facilities are small businesses. The Department searched the GuideStar web site at https://www.guidestar.org/ for the three private-pay facilities that are licensed by the Department. Based on this data, one of the private-pay facilities, Friends Home in Kennett/Linden Hall, meets the definition of a small business applying the NAICS standards. Another private-pay facility, Foulkeways at Gwynedd, does not meet the definition of a small business based on its gross receipts. Data for the third private-pay facility, Dallastown Nursing Center, is not available on GuideStar, but for the purposes of this analysis, the Department assumes that Dallastown is a small business.

In sum, at least 91% of nursing facilities meet the definition of a small business. Consistent with the HCFA and function of licensure, the purpose of these regulatory amendments is to ensure the health, safety and welfare of all residents of long-term care nursing facilities in this Commonwealth by providing the minimum health and safety standards. Given that most facilities are small businesses and the need for surveying for the health and safety of residents, the Department did not establish differing criteria for nursing facilities that are small businesses compared to the minority of facilities that are not small businesses. Further, in determining the minimum health and safety requirements, the Department considered the myriad of received comments, feedback from meetings and stakeholder groups and attempted to balance the interests between consumers and the stakeholder industry. The Department's responsibility to ensure that residents receive safe, quality care applies to all residents of long-term care nursing facilities in this Commonwealth, and it is critical that all residents of long-term care nursing facilities receive the same level of high-quality care, regardless of whether the facility they reside in is a small business.

Statutory Authority

Sections 601 and 803 of the HCFA (35 P.S. §§ 448.601 and 448.803) authorize the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the HCFA. Section 801.1 of the HCFA (35 P.S. § 448.801a) seeks to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities that includes long-term care nursing facilities. The minimum standards are to assure safe, adequate, and efficient facilities and services and to promote the health, safety and adequate care of patients or residents of those facilities. In section 102 of the HCFA (35 P.S. § 448.102), the General Assembly has found that a purpose of the HCFA is, among other things, to assure that citizens receive humane, courteous and dignified treatment. Finally, section 201(12) of the HCFA (35 P.S. § 448.201(12)) provides the Department with explicit authority to enforce its rules and regulations promulgated under the HCFA.

The Department also has the duty to protect the health of the people of this Commonwealth under section 2102(a) of the Administrative Code of 1929 (71 P.S. § 532(a)). The Department has general authority to promulgate regulations under section 2102(g) of the Administrative Code of 1929.

Effectiveness/Sunset Date

This final-form rulemaking will become effective on July 1, 2023, except for § 211.12(f.1)(3) and (i)(2), which shall take effect on July 1, 2024. A sunset date will not be imposed. The Department will monitor the regulations and update them as necessary.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on May 11, 2022, the Department submitted notice of this proposed rulemaking, published at 52 Pa.B. 3070, to IRRC and the Chairpersons of the Senate Health and Human Services Committee and the House Health Committee for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the Senate Health and Human Services Committee and the House Health Committee were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the Senate Health and Human Services Committee, the House Health Committee and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on October 27, 2022, the final-form rulemaking was deemed approved by the Senate Health and Human Services Committee and the House Health Committee. Under section 5.1(e) of the Regulatory Review Act, IRRC met on October 28, 2022 and approved the final-form rulemaking.

Contact Person

Additional information regarding this final-form rulemaking may be obtained by contacting Ann Chronister, Director, Bureau of Long-Term Care Programs, 625 Forster Street, Room 526, Health and Welfare Building, Harrisburg, PA 17120, (717) 547-3131, RA-DHLTCRegs@pa.gov. Persons with a disability may submit questions in alternative format such as by audio tape, Braille or by using V/TT (717) 783-6514 or the Pennsylvania Hamilton Relay Service at (800) 654-5984 (TT). Persons who require an alternative format of this document may contact Ann Chronister at the previous address or telephone number so that necessary arrangements can be made.

Findings

The Department finds that:

(1) Public notice of intention to adopt the regulations adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) referred to as the Commonwealth Documents Law, and the regulations promulgated under, 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law and all comments were considered in drafting this final-form rulemaking.

(3) The amendments made to this final-form rulemaking do not enlarge the original purpose of the proposed rulemaking as published under section 201 of the Commonwealth Documents Law.

(4) The adoption of the regulations is necessary and appropriate for the administration of the Health Care Facilities Act.

Order

(1) The regulations of the Department at 28 Pa. Code Chapters 201, 207, 209 and 211 are amended by amending §§ 201.18—201.21, 201.24, 201.26, 201.29, 201.31, 209.3, 211.2—211.10, 211.12, 211.15—211.17 and deleting

§§ 201.25, 201.30, 207.2, and 211.11 as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(2) The Department shall submit this final-form rulemaking to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(3) The Department shall submit this final-form rulemaking to IRRC, the Senate Health and Human Services Committee and the House Health Committee as required by law.

(4) The Department shall certify this final-form rulemaking, as approved for legality and form, and shall deposit it with the Legislative Reference Bureau as required by law.

(5) This final-form rulemaking shall take effect on July 1, 2023, except for § 211.12(f.1)(3) and (i)(2), which shall take effect on July 1, 2024.

DR. DENISE A. JOHNSON,
Acting Secretary

(*Editor's Note*: See 52 Pa.B. 7054 (November 12, 2022) for IRRC's approval order.)

Fiscal Note: 10-224. (1) General Fund;

(7) DHS—MA—Community HealthChoices; (2) Implementing Year 2022-23 is $0; (3) 1st Succeeding Year 2023-24 is $23,504,000; 2nd Succeeding Year 2024-25 is $53,386,000; 3rd Succeeding Year 2025-26 is $56,055,000; 4th Succeeding Year 2026-27 is $58,858,000; 5th Succeeding Year 2027-28 is $61,801,000; (4) 2021-22 Program—$4,252,000,000; 2020-21 Program—$3,166,000,000; 2019-20 Program—$2,329,000,000;

(7) DHS—MA—Long-Term Living; (2) Implementing Year 2022-23 is $0; (3) 1st Succeeding Year 2023-24 is $2,325,000; 2nd Succeeding Year 2024-25 is $5,280,000; 3rd Succeeding Year 2025-26 is $5,544,000; 4th Succeeding Year 2026-27 is $5,821,000; 5th Succeeding Year 2027-28 is $6,112,000; (4) 2021-22 Program—$121,346,000; 2020-21 Program—$208,841,000; 2019-20 Program—$470,244,000;

(7) DMVA—MA—Veterans Homes; (2) Implementing Year 2022-23 is $0; (3) 1st Succeeding Year 2023-24 is $84,000; 2nd Succeeding Year 2024-25 is $88,000; 3rd Succeeding Year 2025-26 is $93,000; 4th Succeeding Year 2026-27 is $97,000; 5th Succeeding Year 2027-28 is $102,000; (4) 2021-22 Program—$77,671,000; 2020-21 Program—$80,387,000; 2019-20 Program—$80,108,000;

(8) recommends adoption. Funds have been included in the budget to cover this increase.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

Subpart C. LONG-TERM CARE FACILITIES

CHAPTER 201. APPLICABILITY, DEFINITIONS, OWNERSHIP AND GENERAL OPERATION OF LONG-TERM CARE NURSING FACILITIES.

OWNERSHIP AND MANAGEMENT

§ 201.18. Management.

(a) [Reserved].

(b) In addition to the requirements under 42 CFR 483.70(d) (relating to administration), the governing body of a facility shall adopt and enforce rules relative to:

(1) The health care and safety of the residents.

(2) Protection of personal and property rights of the residents, while in the facility, and upon discharge or after death, including the return of any personal property remaining at the facility within 30 days after discharge or death.

(3) The general operation of the facility.

(c) The governing body shall report to the Department within 30 days changes to the information that was submitted with the facility's application for licensure under § 201.12(b)(1)—(6) (relating to application for license of a new facility or change in ownership).

(d) The governing body shall adopt effective administrative and resident care policies and bylaws governing the operation of the facility in accordance with legal requirements. The administrative and resident care policies and bylaws shall be in writing; shall be dated; and shall be reviewed and revised, in writing, as often as necessary but at least annually. The policies and bylaws shall be available upon request, to residents, resident representatives and for review by members of the public.

(d.1) The administrator appointed by the governing body under 42 CFR 483.70(d)(2) shall be currently licensed and registered in this Commonwealth and shall be employed full-time in facilities that have more than 25 beds. Facilities with 25 beds or less may share an administrator provided that all of the following apply:

(1) The Department is informed of this arrangement.

(2) There is a plan in the event of an emergency when the administrator is not working.

(3) There is a readily available method for residents and resident representatives to contact the administrator should they find it necessary.

(4) The director of nursing services has at a minimum, knowledge and experience of the facility, its policies and procedures and resident needs to compensate for the time the administrator is not in the building.

(5) The sharing of an administrator shall be limited to two facilities.

(d.2) The administrator's anticipated biweekly work schedule shall be publicly posted in the facility. The anticipated work schedule shall be updated within 24 hours of a change.

(e) In addition to the requirements under 49 Pa. Code § 39.91 (relating to the standards of professional practice and professional conduct for nursing home administrators), the administrator's responsibilities shall include the following:

(1) Enforcing the regulations relative to the level of health care and safety of residents and to the protection of their personal and property rights.

(2) Planning, organizing and directing responsibilities obligated to the administrator by the governing body.

(2.1) Ensuring that a sanitary, orderly and comfortable environment is provided for residents through satisfactory housekeeping in the facility and maintenance of the building and grounds.

(3) Maintaining an ongoing relationship with the governing body, medical and nursing staff and other professional and supervisory staff through meetings and reports, occurring as often as necessary, but at least on a monthly basis.

(4) Studying and acting upon recommendations made by committees.

(5) Appointing, in writing and in concurrence with the governing body, a responsible employee to act on the administrator's behalf during temporary absences.

(6) Assuring that appropriate and adequate relief personnel are utilized for those necessary positions vacated either on a temporary or permanent basis.

(7) Developing a written plan to assure the continuity of resident care and services in the event of a strike in a unionized facility.

(f) A written record shall be maintained on a current basis for each resident with written receipts for personal possessions received or deposited with the facility. The record shall be available for review by the resident or resident representative upon request.

(g) The governing body shall disclose, upon request, to be made available to the public, the licensee's current daily reimbursement under Medical Assistance and Medicare as well as the average daily charge to other insured and noninsured private pay residents.

(h) When the facility accepts the responsibility for the resident's financial affairs, the resident or resident representative shall designate, in writing, the transfer of the responsibility. The facility shall provide cash, if requested, within 1 day of the request or a check, if requested, within 3 days of the request. If a facility utilizes electronic transfers, the facility shall initiate an electronic transfer of funds, if requested, within one day of the request.

§ 201.19. Personnel records.

Personnel records shall be kept current and available for each facility employee and contain all of the following information:

(1) The employee's job description, educational background and employment history.

(2) Employee performance evaluations, including documentation of any monitoring, performance, or disciplinary action related to the employee.

(3) Documentation of credentials, which shall include, at a minimum, current certification, registration or licensure, if applicable, for the position to which the employee is assigned.

(4) A determination by a health care practitioner that the employee, as of the employee's start date, is free from the communicable diseases or conditions listed in § 27.155 (relating to restrictions on health care practitioners).

(5) Records relating to a medical exam, if required by a facility, or attestation that the employee is able to perform the employee's job duties.

(6) Documentation of the employee's orientation to the facility and the employee's assigned position prior to or within 1 week of the employee's start date.

(7) Documentation of the employee's completion of required trainings under this chapter, including documentation of orientation and other trainings.

(8) A copy of the final report received from the Pennsylvania State Police and the Federal Bureau of Investigation, as applicable, in accordance with the Older Adults Protective Services Act (35 P.S. §§ 10225.101—10225.5102), the Adult Protective Services Act (35 P.S. §§ 10210.101—10210.704), and applicable regulations.

(9) In the event of a conviction prior to or following employment, documentation that the facility determined the employee's suitability for initial or continued employment in the position to which the employee is assigned. "Suitability for employment" shall include a review of the offense; the length of time since the individual's conviction; the length of time since incarceration, if any; evidence of rehabilitation; work history; and the employee's job duties.

(10) The employee's completed employment application.

§ 201.20. Staff development.

(a) There shall be an ongoing coordinated educational program which is planned and conducted for the development and improvement of skills of the facility's personnel, including, at a minimum, annual in-service training on the topics outlined in 42 CFR 483.95 (relating to training requirements) in addition to the following topics:

(1) Accident prevention.

(2) Restorative nursing techniques.

(3) Emergency preparedness in accordance with 42 CFR 483.73(d) (relating to emergency preparedness).

(4) Fire prevention and safety in accordance with 42 CFR 483.90 (relating to physical environment).

(5) Resident rights, including nondiscrimination and cultural competency.

(6) Training needs identified through a facility assessment.

(b) An employee shall receive appropriate orientation to the facility, its policies and to the position and duties. The orientation shall include training on the prevention, detection and reporting of resident abuse and dementia management and communication skills.

(c) [Reserved].

(d) Written records shall be maintained which indicate the content of and attendance at staff development programs.

§ 201.21. Use of outside resources.

(a) [Reserved].

(b) [Reserved].

(c) In addition to the requirements under 42 CFR 483.70(g) (relating to administration), the responsibilities, functions, objectives and terms of agreements related to outside resources shall be delineated in writing and signed and dated by the parties.

(d) [Reserved].

(e) If a facility acquires employees from outside resources, the facility shall obtain confirmation from the outside resource that the employees are free from the communicable diseases and conditions listed in § 27.155 (relating to restrictions on health care practitioners) and are able to perform their assigned job duties.

§ 201.24. Admission policy.

(a) The resident is not required to name a resident representative if the resident is capable of managing the resident's own affairs.

(b) A facility may not obtain from or on behalf of residents a release from liabilities or duties imposed by law or this subpart except as part of formal settlement in litigation.

(c) A facility shall admit only residents whose nursing care and physical needs can be provided by the staff and facility.

(d) A resident with a disease in the communicable stage may not be admitted to the facility unless it is deemed advisable by the attending physician—medical director, if applicable—and administrator and unless the facility has the capability to care for the needs of the resident.

(e) The governing body of a facility shall establish written policies for the admissions process for residents, and through the administrator, shall be responsible for the development of and adherence to procedures implementing the policies. The policies and procedures shall include all of the following:

(1) Introduction of residents to at least one member of the professional nursing staff for the unit where the resident will be living and to direct care staff who have been assigned to care for the resident. Prior to introductions, the professional nursing and direct care staff shall review the orders of the physician or other health care practitioner for the resident's immediate care.

(2) Orientation of the resident to the facility and location of essential services and key personnel, including the dining room, nurses' workstations and offices for the facility's social worker and grievance or complaint officer.

(3) A description of facility routines, including nursing shifts, mealtimes and posting of menus.

(4) Discussion and documentation of the resident's customary routines and preferences, to be included in the care plan developed for the resident under 42 CFR 483.21 (relating to comprehensive person-centered care planning).

(5) Assistance to the resident in creating a homelike environment and settling and securing personal possessions in the room to which the resident has been assigned.

(f) The coordination of introductions, orientation and discussions, under subsection (e), shall be the responsibility of the facility's social worker, or a delegee designated by the governing body. The activities included under subsection (e)(1) and (2) shall occur within 2 hours of a resident's admission. The activities included under subsection (e)(3) and (4) shall occur within 24 hours of a resident's admission. the activities included under subsection (e)(5) shall occur within 72 hours of a resident's admission.

§ 201.25. [Reserved].

§ 201.26. Resident representative.

A resident representative may not be a licensee, owner, operator, members of the governing body, an employee or anyone with a financial interest in the facility unless ordered by a court of competent jurisdiction, except that:

(1) A resident's family member who is employed in the facility may serve as a resident representative so long as there is no conflict of interest.

(2) A facility may be designated as a representative payee in accordance with Title II or XVI of the Social Security Act (42 U.S.C.A. §§ 401—434 and 1381—1385) and applicable regulations.

§ 201.29. Resident rights.

(a) The governing body of the facility shall establish written policies regarding the rights and responsibilities of residents as provided for in 42 CFR 483.10 (relating to resident rights) and this section. Through the administrator, the governing body shall be responsible for development of and adherence to procedures implementing the policies. The written policies shall include a mechanism for the inclusion of residents, or a resident representative, in the development, implementation and review of the policies and procedures regarding the rights and responsibilities of residents.

(b) Policies and procedures regarding rights and responsibilities of residents shall be available to residents and members of the public.

(c) Policies of the facility shall be available to staff, residents, consumer groups and the interested public, including a written outline of the facility's objectives and a statement of the rights of its residents. The policies shall set forth the rights of the resident and prohibit mistreatment and abuse of the resident.

(c.1) The facility shall post in a conspicuous place near the entrances and on each floor of the facility a notice which sets forth the list of resident rights. The posting of resident rights shall include the rights under subsection (c.3) and 42 CFR 483.10.

(c.2) A facility shall provide personal notice of a resident's rights in accordance with 42 CFR 483.10(g)(16). A certificate of the provision of personal notice shall be entered in the resident's medical record.

(c.3) In addition to the resident rights set forth in 42 CFR 483.10, residents have a right to the following:

(1) If changes in charges occur during the resident's stay, the resident, or resident representative, shall be advised verbally and in writing reasonably in advance of the change. "Reasonably in advance" shall be interpreted to be 30 days prior to the change unless circumstances dictate otherwise. If a facility requires a security deposit, the written procedure or contract that is given to the resident, or resident representative, shall indicate how the deposit will be used and the terms for the return of the deposit. A curity deposit is not permitted for a resident receiving medical assistance.

(2) Prior to transfer, the facility shall inform the resident, or the resident representative, as to whether the facility where the resident is being transferred is certified to participate in the Medicare and the Medical Assistance Programs.

(3) Experimental research or treatment in a facility may not be carried out without the approval of the Department, including the Department's Institutional Review Board, and without the written approval and informed consent of the resident, or resident representative, obtained prior to participation and initiation of the experimental research or treatment. The following apply:

(i) The resident, or resident representative, shall be fully informed of the nature of the experimental research or treatment and the possible consequences, if any, of participation.

(ii) The resident, or resident representative, shall be given the opportunity to refuse to participate both before and during the experimental research or treatment.

(iii) For the purposes of this subsection, "experimental research" means the development, testing and use of a clinical treatment, such as an investigational drug or therapy that has not yet been approved by the United States Food and Drug Administration or medical community as effective and conforming to medical practice.

(4) A resident has the right to care without discrimination based upon race, color, familial status, religious creed, ancestry, age, sex, gender, sexual orientation, gender identity or expression, national origin, ability to pay,

handicap or disability, use of guide or support animals because of the blindness, deafness or physical handicap of the resident or because the resident is a handler or trainer of support or guide animals.

(d) [Reserved].

(e) [Reserved].

(f) [Reserved].

(g) [Reserved].

(h) [Reserved].

(i) [Reserved].

(j) [Reserved].

(k) [Reserved].

(l) [Reserved].

(m) [Reserved].

(n) [Reserved].

(o) [Reserved].

§ 201.30. [Reserved].

§ 201.31. Transfer agreement.

(a) The facility shall have in effect a transfer agreement with one or more hospitals, located reasonably close by, which provides the basis for effective working arrangements between the two health care facilities. Under the agreement, inpatient hospital care or other hospital services shall be promptly available to the facility's residents when needed.

(b) A transfer agreement between a hospital and a facility shall be in writing and specifically provide for the exchange of medical and other information necessary to the appropriate care and treatment of the residents to be transferred. The agreement shall further provide for the transfer of residents' personal effects, particularly money and valuables, as well as the transfer of information related to these items when necessary.

CHAPTER 207. HOUSEKEEPING AND MAINTENANCE STANDARDS FOR LONG-TERM CARE NURSING FACILITIES

HOUSEKEEPING AND MAINTENANCE

§ 207.2. [Reserved].

CHAPTER 209. FIRE PROTECTION AND SAFETY PROGRAMS FOR LONG-TERM CARE NURSING FACILITIES

FIRE PROTECTION AND SAFETY

§ 209.3. Smoking.

(a) Policies regarding smoking shall be adopted. The policies shall include provisions for the protection of the rights of smoking and nonsmoking residents. The smoking policies shall be posted in a conspicuous place and in a legible format so that they may be easily read by residents, visitors and staff.

(b) [Reserved].

(c) Adequate supervision while smoking shall be provided for those residents who require it.

(d) Smoking by residents in bed is prohibited unless the resident is under direct observation.

(e) [Reserved].

(f) [Reserved].

(g) [Reserved].

CHAPTER 211. PROGRAM STANDARDS FOR LONG-TERM CARE NURSING FACILITIES

§ 211.2. Medical director.

(a) [Reserved].

(b) [Reserved].

(c) In addition to the requirements of 42 CFR 483.70(h) (relating to administration), the medical director of a facility shall be licensed as a physician in this Commonwealth and shall complete at least four hours annually of continuing medical education (CME) pertinent to the field of medical direction or post-acute and long-term care medicine. The medical director may be designated for single or multiple facilities. There shall be a written agreement between the physician and the facility.

(d) The medical director's responsibilities shall include at least the following:

(1) [Reserved].

(2) [Reserved].

(3) Ensuring the appropriateness and quality of medical care and medically related care.

(4) Assisting in the development of educational programs for facility staff and other professionals.

(5) Working with the facility's clinical team to provide surveillance and develop policies to prevent the potential infection of residents in accordance with the infection control requirements under 42 CFR 483.80 (relating to infection control).

(6) Cooperating with facility staff to establish policies for assuring that the rights of individuals are respected.

(7) Supporting and promoting person-directed care such as the formation of advance directives, end-of-life care, and provisions that enhance resident decision making, including choice regarding medical care options.

(8) Identifying performance expectations and facilitating feedback to physicians and other health care practitioners regarding their performance and practices.

(9) Discussing and intervening, as appropriate, with a health care practitioner regarding medical care that is inconsistent with current standards of care.

(10) Assisting in developing systems to monitor the performance of health care practitioners, including mechanisms for communicating and resolving issues related to medical care and ensuring that other licensed practitioners who may perform physician-delegated tasks act within their scope of practice.

§ 211.3. Verbal and telephone orders.

(a) Verbal and telephone orders shall be given to a registered nurse, physician or other individual authorized by appropriate statutes and the State Boards in the Bureau of Professional and Occupational Affairs and shall immediately be recorded on the resident's clinical record by the person receiving the order. The entry shall be signed and dated by the person receiving the order.

(b) Verbal and telephone orders for care, and treatment shall be dated and countersigned with the original signature of the physician, or physician's delegee authorized under 42 CFR 483.30(e) (relating to physician services), within 72 hours of receipt of the order.

(c) Verbal and telephone orders for medications shall be dated and countersigned by the prescribing physician, or physician's delegee authorized under 42 CFR 483.80(e), within 48 hours.

(d) Verbal orders for care, treatment or medication shall be accepted only under circumstances where it is impractical for the orders to be given in a written manner by the physician, or physician's delegee authorized under 42 CFR 483.30(e). An initial written order as well as a countersignature may be sent by a fax or secure electronic transmission which includes the practitioner's signature.

(e) The facility shall establish policies identifying the types of situations for which verbal orders may be accepted and the appropriate protocols for the taking and transcribing of verbal orders in these situations, which shall include:

(1) Identification of all treatments or medications which may not be prescribed or dispensed by way of verbal order, but which instead require written orders.

(2) A requirement that all verbal orders be stated clearly, repeated by the issuing physician, or physician's delegee authorized under 42 CFR 483.30(e), and be read back in their entirety by personnel authorized to take the verbal order.

(3) Identification of all personnel authorized to take and transcribe verbal orders.

(4) The policy on fax or secure electronic transmissions.

§ 211.4. Procedure in event of death.

(a) Written postmortem procedures shall be available to all personnel.

(b) Documentation shall be on the resident's clinical record that the next of kin, guardian or resident representative has been notified of the resident's death. The name of the notified party shall be written on the resident's clinical record.

§ 211.5. Medical records.

(a) [Reserved].

(b) Information contained in a resident's record shall be privileged and confidential. Written consent of the resident or the resident representative is required for release of information, except as follows:

(1) Written consent is not necessary for authorized representatives of the Federal and State government during the conduct of their official duties.

(2) Written consent is not necessary for the release of medical records for treatment purposes in accordance with Federal and State law.

(c) [Reserved].

(d) Records of discharged residents shall be completed within 30 days of discharge. Medical information pertaining to a resident's stay shall be centralized in the resident's record.

(e) When a facility closes, resident medical records may be transferred with the resident if the resident is transferred to another health care facility. Otherwise, the owners of the facility shall make provisions for the safekeeping and confidentiality of resident medical records and shall provide to the Department, within 30 days of providing notice of closure under § 201.23 (relating to closure of facility), a plan for the storage and retrieval of medical records.

(f) In addition to the items required under 42 CFR 483.70(i)(5) (relating to administration), a resident's medical record shall include at a minimum:

(i) Physicians' orders.

(ii) Observation and progress notes.

(iii) Nurses' notes.

(iv) Medical and nursing history and physical examination reports.

(v) Admission data.

(vi) Hospital diagnoses authentication.

(vii) Report from attending physician or transfer form.

(viii) Diagnostic and therapeutic orders.

(ix) Reports of treatments.

(x) Clinical findings.

(xi) Medication records.

(xii) Discharge summary, including final diagnosis and prognosis or cause of death.

(g) [Reserved].

(h) [Reserved].

(i) The facility shall assign overall supervisory responsibility for the medical record service to a medical records practitioner. Consultative services may be utilized; however, the facility shall employ sufficient personnel competent to carry out the functions of the medical record service.

§ 211.6. Dietary services.

(a) Menus shall be planned and posted in the facility or distributed to residents at least 2 weeks in advance. Records of menus of foods actually served shall be retained for 30 days. When changes in the menu are necessary, substitutions shall provide equal nutritive value.

(b) [Reserved].

(c) [Reserved].

(d) [Reserved].

(e) [Reserved].

(f) Dietary personnel shall practice hygienic food handling techniques. Employees shall wear clean outer garments, maintain a high degree of personal cleanliness and conform to hygienic practices while on duty. Employees shall wash their hands thoroughly with soap and water before starting work, after visiting the toilet room and as often as necessary to remove soil and contamination.

§ 211.7. Physician assistants and certified registered nurse practitioners.

(a) [Reserved].

(b) If the facility utilizes the services of physician assistants or certified registered nurse practitioners, the following apply:

(1) [Reserved].

(2) There shall be a list posted at each workstation of the names of the supervising physician and the persons, and titles, whom they supervise.

(3) A copy of the supervising physician's registration from the State Board of Medicine or State Board of Osteopathic Medicine and the physician assistant's or certified registered nurse practitioner's certificate shall be available in the facility.

(4) A notice plainly visible to residents shall be posted in prominent places in the institution explaining the meaning of the terms "physician assistant" and "certified registered nurse practitioner."

(c) [Reserved].

(d) [Reserved].

(e) [Reserved].

§ 211.8. Use of restraints.

(a) [Reserved].

(b) [Reserved].

(c) [Reserved].

(c.1) If restraints are used, a facility shall use the least restrictive method for the least amount of time to safely and adequately respond to individual resident needs in accordance with the resident's comprehensive assessment and comprehensive care plan. The following shall apply:

(1) When a recurring restraint is ordered, the facility shall document the need for the restraint and the personnel responsible for performing the intervention on each shift.

(2) A facility shall document the type of restraint and each time a restraint is used or removed.

(3) In determining the least restrictive method for the least amount of time, the following minimums apply:

(i) Physical restraints shall be removed at least 10 minutes out of every 2 hours during normal waking hours to allow the resident an opportunity to move and exercise.

(ii) During normal waking hours, the resident's position shall be changed at least every 2 hours.

(d) An order from a physician, or physician's delegee authorized under 42 CFR 483.30(e) (relating to physician services), shall be required for a restraint.

(e) The physician, or physician's delegee authorized under 42 CFR 483.30(e), shall document the reason for the initial restraint order and shall review the continued need for the use of the restraint order by evaluating the resident. If the order is to be continued, the order shall be renewed by the physician, or physician's delegee authorized under 42 CFR 483.30(e), in accordance with the resident's total program of care.

(f) Every 30 days, or sooner if necessary, the interdisciplinary team shall review and reevaluate the use of all restraints ordered by a physician or physician's delegee authorized under 42 CFR 483.30(e).

§ 211.9. Pharmacy services.

(a) Facility policies shall ensure that:

(1) Facility staff involved in the administration of resident care shall be knowledgeable of the policies and procedures regarding pharmacy services including medication administration.

(2) [Reserved].

(b) Facility policies shall ensure that medications are administered by authorized persons as indicated in § 201.3 (relating to definitions).

(c) Medications and biologicals shall be administered by the same licensed person who prepared the dose for administration and shall be given as soon as possible after the dose is prepared.

(d) Medications, both prescription and non-prescription, shall be administered under the orders of the attending physician, or the physician's delegee authorized under 42 CFR 483.30(e) (relating to physician services).

(e) [Reserved].

(f) Residents shall be permitted to purchase prescribed medications from the pharmacy of their choice. If the resident does not use the pharmacy that usually services the facility, the resident is responsible for securing the medications and for assuring that applicable pharmacy regulations and facility policies are met. The facility:

(1) Shall notify the resident or the resident representative, at admission and as necessary throughout the resident's stay in the facility, of the right to purchase medications from a pharmacy of the resident's choice as well as the resident's and pharmacy's responsibility to comply with the facility's policies and Federal and State laws regarding packaging and labeling requirements.

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(g) [Reserved].

(h) [Reserved].

(i) [Reserved].

(j) [Reserved].

(j.1) The facility shall have written policies and procedures for the disposition of medications that address all of the following:

(1) Timely and safe identification and removal of medications for disposition.

(2) Identification of storage methods for medications awaiting final disposition.

(3) Control and accountability of medications awaiting final disposition consistent with standards of practice.

(4) Documentation of actual disposition of medications to include the name of the individual disposing of the medication, the name of the resident, the name of the medication, the strength of the medication, the prescription number if applicable, the quantity of medication and the date of disposition.

(5) A method of disposition to prevent diversion or accidental exposure consistent with applicable Federal and State requirements, local ordinances and standards of practice.

(k) The oversight of pharmaceutical services shall be the responsibility of the quality assurance committee. Arrangements shall be made for the pharmacist responsible for the adequacy and accuracy of the services to have committee input. The quality assurance committee, with input from the pharmacist, shall develop written policies and procedures for drug therapy, distribution, administration, control, accountability and use.

(l) A facility shall have at least one emergency medication kit that is readily available to staff. The kit used in the facility shall be governed by the following:

(1) The facility shall have written policies and procedures pertaining to the use, content, storage, security, refill of and inventory tracking for the kits.

(2) The quantity and categories of medications and equipment in the kits shall be based on the immediate needs of the facility and criteria for the contents of the emergency medication kits shall be reviewed not less than annually.

(3) The emergency medication kits shall be under the control of a practitioner authorized to dispense or prescribe medications under the Pharmacy Act (63 P.S. §§ 390-1—390-13).

(4) [Reserved].

§ 211.10. Resident care policies.

(a) Resident care policies shall be available to admitting physicians, sponsoring agencies, residents and the public and shall reflect an awareness of, and provision for, meeting the total medical, nursing, mental and psychosocial needs of residents.

(b) The policies shall be reviewed at least annually and updated as necessary.

(c) The policies shall be designed and implemented to ensure that each resident receives treatments, medications, diets and rehabilitative nursing care as prescribed.

(d) The policies shall be designed and implemented to ensure that the resident receives proper care to prevent pressure sores and deformities; that the resident is kept comfortable, clean and well-groomed; that the resident is protected from accident, injury and infection; and that the resident is encouraged, assisted and trained in self-care and group activities.

§ 211.11. [Reserved].

§ 211.12. Nursing services.

(a) [Reserved].

(b) There shall be a full-time director of nursing services who shall be a qualified licensed registered nurse.

(c) The director of nursing services shall have, in writing, administrative authority, responsibility and accountability for the functions and activities of the nursing services personnel and shall serve only one facility in this capacity.

(d) The director of nursing services shall be responsible for:

(1) Standards of accepted nursing practice.

(2) Nursing policy and procedure manuals.

(3) Methods for coordination of nursing services with other resident services.

(4) Recommendations for the number and levels of nursing services personnel to be employed.

(5) General supervision, guidance and assistance for a resident in implementing the resident's personal health program to assure that preventive measures, treatments, medications, diet and other health services prescribed are properly carried out and recorded.

(e) The facility shall designate a charge nurse who is responsible for overseeing total nursing activities within the facility on each tour of duty each day of the week.

(f) [Reserved].

(f.1) In addition to the director of nursing services, a facility shall provide all of the following:

(1) Nursing services personnel on each resident floor.

(2) Effective July 1, 2023, a minimum of 1 nurse aide per 12 residents during the day, 1 nurse aide per 12 residents during the evening, and 1 nurse aide per 20 residents overnight.

(3) Effective July 1, 2024, a minimum of 1 nurse aide per 10 residents during the day, 1 nurse aide per 11 residents during the evening, and 1 nurse aide per 15 residents overnight.

(4) Effective July 1, 2023, a minimum of 1 LPN per 25 residents during the day, 1 LPN per 30 residents during the evening, and 1 LPN per 40 residents overnight.

(5) Effective July 1, 2023, a minimum of 1 RN per 250 residents during all shifts.

(f.2) To meet the requirements of subsections (f.1)(2) through (5):

(1) A facility may substitute an LPN or RN for a nurse aide but may not substitute a nurse aide for an LPN or RN.

(2) A facility may substitute an RN for an LPN.

(3)(i) A facility may not substitute an LPN for an RN except as provided under subparagraph (ii).

(ii) A facility with a census of 59 or under may substitute an LPN for an RN on the overnight shift only if an RN is on call and located within a 30-minute drive of the facility.

(g) [Reserved].

(h) [Reserved].

(i) A minimum number of general nursing care hours shall be provided for each 24-hour period as follows:

(1) Effective July 1, 2023, the total number of hours of general nursing care provided in each 24-hour period shall, when totaled for the entire facility, be a minimum of 2.87 hours of direct resident care for each resident.

(2) Effective July 1, 2024, the total number of hours of general nursing care provided in each 24-hour period shall, when totaled for the entire facility, be a minimum of 3.2 hours of direct resident care for each resident.

(i.1) Only direct resident care provided by nursing services personnel may be counted towards the total number of hours of general nursing care required under subsection (i).

(j) [Reserved].

(k) [Reserved].

(l) [Reserved].

§ 211.15. Dental services.

In addition to the requirements in 42 CFR 483.55 (relating to dental services), a facility shall make provisions to assure that resident dentures are retained by the resident. Dentures shall be marked for each resident.

§ 211.16. Social services.

(a) A facility shall employ a qualified social worker on a full-time basis except:

(1) A facility with 26 to 59 beds may employ a part-time qualified social worker if the facility assessment indicates that a full-time qualified social worker is not needed.

(2) A facility with 25 beds or less may either employ a part-time qualified social worker or share the services of a qualified social worker with another facility.

(b) [Reserved].

§ 211.17. Pet therapy.

If pet therapy is utilized, a facility shall have written policies and procedures to ensure all of the following:

(1) Animals are not permitted in the kitchen or other food service areas, dining rooms when meals are being served, utility rooms and rooms of residents who do not want animals in their rooms.

(2) Careful selection of types of animals is made so the animals are not harmful or annoying to residents.

(3) The number and types of pets are restricted according to the layout of the building, type of residents, staff and animals.

(4) Animals are carefully selected to meet the needs of the residents involved in the pet therapy program.

(5) [Reserved].

(5.1) Animals are up to date on vaccinations, are in good health and do not pose a risk to the health and safety of residents.

(6) Animals and places where they reside or visit are kept clean and sanitary.

(7) Infection prevention and control measures, such as hand hygiene, are followed by residents and personnel when handling animals.

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Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CHS. 201, 209 AND 211]

Long-Term Care Nursing Facilities

The Department of Health (Department), after consultation with the Health Policy Board, amends §§ 201.12—201.17, 201.22, 209.1, 209.7, 209.8 and 211.1 and adds §§ 201.12a, 201.12b, 201.13a, 201.13b, 201.13c, 201.15a and 201.15b to read as set forth in Annex A. This is the third of four final-form rulemaking packages for long-term care nursing facilities being promulgated by the Department.

The contents for the four final-form rulemaking packages are as follows:

Rulemaking 1—General Applicability and Definitions

§ 201.1. Applicability.

§ 201.2. Requirements.

§ 201.3. Definitions.

§ 211.12. Nursing services. (Withdrawn on final-form.)

Rulemaking 2—General Operation and Physical Requirements

§ 201.23. Closure of facility.

Chapter 203. Application of Life Safety Code for Long-Term Care Nursing Facilities. (Reserved on final-form.)

Chapter 204. Physical Environment and Equipment Standards for Construction, Alteration or Renovation of Long-Term Care Nursing Facilities after July 1, 2023.

Chapter 205. Physical Environment and Equipment Standards for Long-Term Care Nursing Facilities Construction, Alteration or Renovation Approved before July 1, 2023.

§ 207.4. Ice containers and storage. (Reserved on final-form.)

Rulemaking 3—Applications for Ownership, Management and Changes of Ownership; Health and Safety

§ 201.12. Application for license of a new facility or change in ownership.

§ 201.12a. Notice and opportunity to comment. (New section on final-form.)

§ 201.12b. Evaluation of application for license of a new facility or change in ownership. (Section renumbered on final-form.)

§ 201.13. Issuance of license for a new facility or change in ownership.

§ 201.13a. Regular license. (New section on final-form.)

§ 201.13b. Provisional license. (New section on final-form.)

§ 201.13c. License renewal. (Section renumbered on final-form.)

§ 201.14. Responsibility of licensee.

§ 201.15. Restrictions on license.

§ 201.15a. Enforcement. (New section on final-form.)

§ 201.15b. Appeals. (New section on final-form.)

§ 201.17. Location.

§ 201.22. Prevention, control and surveillance of tuberculosis (TB).

§ 209.1. Fire department service. (Reserved on final-form.)

§ 209.7. Disaster preparedness. (Reserved on final-form.)

§ 209.8. Fire drills. (Reserved on final-form.)

§ 211.1. Reportable diseases.

Rulemaking 4—Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services

§ 201.18. Management.

§ 201.19. Personnel records.

§ 201.20. Staff development.

§ 201.21. Use of outside resources.

§ 201.24. Admission policy.

§ 201.25. Discharge policy. (Reserved on final-form.)

§ 201.26. Resident representative.

§ 201.29. Resident rights.

§ 201.30. Access requirements. (Reserved on final-form.)

§ 201.31. Transfer agreement.

§ 207.2. Administrator's responsibility. (Reserved on final-form.)

§ 209.3. Smoking.

§ 211.2. Medical director.

§ 211.3. Verbal and telephone orders.

§ 211.4. Procedure in event of death.

§ 211.5. Medical records.

§ 211.6. Dietary services.

§ 211.7. Physician assistants and certified registered nurse practitioners.

§ 211.8. Use of restraints.

§ 211.9. Pharmacy services.

§ 211.10. Resident care policies.

§ 211.11. Resident care plan. (Reserved on final-form.)

§ 211.12. Nursing services. (Consolidated amendments on final-form.)

§ 211.15. Dental services.

§ 211.16. Social services.

§ 211.17. Pet therapy.

Comments on Multiple Packages; Stakeholder Engagement

The Department received comments during the public comment periods of all four proposed rulemaking packages expressing concern with the Department's decision to divide the long-term care nursing facility regulations into separate rulemakings. As provided previously, the Department divided the regulatory packages as follows: Rulemaking 1—General Applicability and Definitions; Rulemaking 2—General Operation and Physical Requirements; Rulemaking 3—Applications for Ownership, Management and Changes of Ownership; Health and Safety; and Rulemaking 4—Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services.

Although the Department intended to provide succinct areas for review and comment, commentators expressed some difficulty in reviewing sections of the regulations without the context of the remaining regulatory chapters and concern that multiple regulatory packages may lead to a lack of clarity and confusion for the regulated community and the public. Commentators also requested that the Department consider comments on all four proposed rulemaking packages outside of the 30-day comment period for each proposed package, or that the Department withdraw or resubmit all four proposed rulemaking packages as one package with an additional 30-day comment period. The Department also received comments regarding concern related to recent engagement with stakeholders, given that the Long-Term Care Work Group (LTC Work Group) last formally met in 2018 and was disbanded during the start of the novel coronavirus (COVID-19) pandemic.

In commenting on proposed Rulemaking 1, the Independent Regulatory Review Commission (IRRC) acknowledged the Department's authority to promulgate regulations as it deems appropriate. However, IRRC requested that the Department consider the regulated community's comments and the requests regarding the separate rulemakings. IRRC specifically asked the Department to explain why its approach in dividing the amendments into multiple packages was reasonable. IRRC also asked that the Department ensure that amendments be consistent across the packages, and that the interrelation and any impacts between the packages be clearly presented for the regulated community.

In commenting on proposed Rulemaking 2, IRRC again echoed concerns that separate rulemakings have the potential consequence of inconsistencies and errors across the four packages. IRRC inquired whether having multiple regulatory packages is in the public interest, whether it protects the public health, safety and welfare, and whether it is reasonable and lacks ambiguity. IRRC asked whether it was in the public interest or reasonable to expect the regulated community to hold multiple proposed regulations simultaneously in mind while reviewing a proposed regulation. IRRC also asked the Department to: (1) identify in the final-form preamble any provisions which assume approval of Rulemaking 1 as final-form; (2) cross-reference these provisions to the relevant provisions in Rulemaking 1; and (3) explain the impact if Rulemaking 1 is not approved before or at the same time as Rulemaking 2. IRRC recommended that the Department deliver each of the four individual packages as final-form regulations on the same day. In addition, IRRC, in its comment for proposed Rulemaking 3 and proposed Rulemaking 4 expressed the same concerns as in the previous proposed rulemakings, but additionally suggested that the Department consider issuing an Advance Notice of Final Rulemaking to assist in reaching consensus.

Response

At the outset, the Department recognized that the changes to the long-term care nursing facility regulations would be numerous and complex, whether presented in one giant package or in multiple packages. A large single package would have been unwieldy and would likely have been presented around the date that the fourth regulatory package was completed and submitted (May 11, 2022). A later publication date would have resulted in less opportunity for comments, less time for the commentators to study the material and deliberate, and less time for necessary and valuable stakeholder engagement. Further, the regulated community's input throughout this process informed the administration and legislature's investment in this year's budget. As such, the decision was made to continue with the changes broken into smaller, separate more digestible packages. As provided previously, the Department initially decided to divide the proposed amendments to the six regulatory chapters under Subpart C (relating to long-term care facilities) into multiple packages to allow the public and interested parties a greater opportunity to thoroughly examine and digest the distinct proposed regulatory amendments over a longer period. In dividing these six chapters over four rulemakings, the public and interested parties would be permitted to provide more detailed comments and allow the Department to focus more closely on comments, provide a thoroughly considered response to questions and comments, and tailor the remaining proposed packages based on additional public and stakeholder input.

Further, in response to these public comments, the Department has considered all public comments and IRRC's comments across all four proposed rulemakings before drafting these four final-form rulemakings. In addition, based on comments received, the Department is submitting all four final-form rulemakings to IRRC, the legislative standing committees and the public commentator together on the same day. The drafting and submitting of all four final-form rulemakings together at the end of the last public comment period allows interested parties and the public to vet and comment on each package separately, as well as in relation to the other packages. Throughout this process, the Department has continued to accept and review comments and be available to meet with stakeholders. If a commentator believed that a proposed amendment in Rulemaking 4 did not align with a proposed amendment in Rulemaking 1, the commentator could submit a comment to that effect for consideration by the Department during the public comment period for proposed Rulemaking 4.

The Department did, in fact, take into consideration comments received on proposed Rulemakings 1 and 2, when drafting proposed Rulemakings 3 and 4. This is as evidenced by the proposal to expressly include text from the Centers for Medicare & Medicaid (CMS), State Operations Manual, Appendix PP into the text of the regulation. See for example, proposed Rulemaking 4, proposed § 201.29(o) (relating to resident's rights). This inclusion of specific text was based on comments received from commentators and IRRC in proposed Rulemaking 1. The Department also consolidated the total number of proposed packages from five to four packages in response to both public and IRRC comments received in proposed Rulemaking 1.

In addition to considering comments on the four proposed packages during and outside of the four public comment periods, the Department met with stakeholders on four occasions following the receipt of public comments to discuss their concerns and to gain additional insight into comments that were received. The first of these meetings, for proposed Rulemakings 1 and 2, occurred on December 15, 2021. Representatives from the American Association of Retired Persons (AARP), Alzheimer's Association—Delaware Valley and Greater Pennsylvania Chapters, Center for Advocacy for the Rights & Interests of the Elderly (CARIE), Community Legal Services, LeadingAge, Pennsylvania Health Care Association (PHCA), Pennsylvania Coalition of Affiliated Healthcare & Living Communities (PACAH), and SEIU Healthcare Pennsylvania attended that meeting. The second meeting, for proposed Rulemaking 3 occurred on June 8, 2022. Representatives from AARP, Alzheimer's Association, CARIE, Community Legal Services, LeadingAge, PHCA, Pennsylvania Health Law Project (PHLP) and SEIU again attended that stakeholder meeting. The Department explicitly stressed to stakeholders during this June 8, 2022, meeting that it would be considering comments on all proposed rulemakings, and that it would welcome any additional comments or feedback that stakeholders might have after the meeting regarding proposed amendments to the various regulatory chapters. The Department also indicated in a press release on proposed Rulemaking 4, issued on June 3, 2022, that it would be considering comments on all four proposed rulemakings before submitting final-form rulemakings. The third meeting with stakeholders, for proposed Rulemaking 4, occurred on August 3, 2022. Present at that meeting were representatives from AARP, Alzheimer's Association, CARIE, PHCA, Pennsylvania Health Funders Collaborative (PHFC), and SEIU. The Department held the fourth meeting on August 17, 2022. At this meeting, the Department presented stakeholders with an overview of the changes that were made from the proposed rulemaking to the final-form rulemaking in response to their comments, on all four rulemakings, and provided them with an opportunity to comment and provide feedback on the final-form rulemakings. Present at that meeting were representatives from the Alzheimer's Association, CARIE, Community Legal Services, County Commissioners Association of Pennsylvania (CCAP), Disability Rights, LeadingAge, PHCA, PHFC and SEIU.

After consideration of all comments received on the four proposed rulemaking packages, the Department firmly supports its decision in splitting the six long-term care nursing facility chapters into multiple packages. While the Department appreciates the comments and suggestion for one consolidated package, one is not needed at this stage due to the public, the regulated community and advocates' full and continued opportunity to offer input on all the long-term care nursing facilities' regulations, throughout the four separate public comment periods, the first of which occurred over a year ago, as well as during the stakeholder meetings that occurred from 2021 through August 2022. In addition, as mentioned previously, at the meeting on August 17, 2022, the Department provided stakeholders an overview of the changes that were adopted on all four rulemakings, to ensure that stakeholders fully understand all amendments. At that meeting, the Department also permitted stakeholders the opportunity to further comment on the final-form amendments and incorporated this feedback into these final-form rulemakings. Finally, as previously noted, splitting the regulations into multiple, separate packages benefited the public, regulated community, and advocates because it allowed the Department to incorporate their feedback as it moved forward with the drafting of subsequent packages, which promoted the public interest, health, safety and welfare by improving the overall quality of the proposed rulemakings.

The Department has, in each of the four final-form rulemaking preambles, discussed and responded to all comments received on the contents of the four proposed rulemakings, regardless of when the comment was received. The Department has added cross-references, as appropriate, where comments received on one package relate to another package to further aid in the review of the four packages together in their entirety. For example, in proposed Rulemaking 1, the Department received comments requesting that staff, other than nursing personnel, be considered when determining whether a facility has met the minimum number of direct resident care hours in § 211.12(a)(i) (relating to nursing services). In response to this comment, the types of individuals required for the minimum number of direct resident care hours was intentionally addressed in proposed Rulemaking 4 and generated additional comments during that proposed rulemaking's public comment period. The Department has, therefore, indicated in § 211.12(i) of the preamble for final-form Rulemaking 1, that it received comments on this topic and provided a cross-reference to the more in-depth discussion of this topic in the preamble for final-form Rulemaking 4. Further, to provide additional clarity and readability, the Department moved the proposed language relating to direct resident care hours from proposed Rulemaking 1 to final-form Rulemaking 4. Finally, the Department has noted where one rulemaking assumes the approval of another rulemaking. Through this extended review and public comment process, the Department has been transparent in its proposals and has responded to these comments through each final-form rulemaking.

Background and Need for Amendments

The percentage of adults 65 years of age or older in this Commonwealth is increasing. In 2010, approximately 15% of Pennsylvanians were 65 years of age or older. In 2017, this number increased to 17.8%. In 2020, just under 20% of the population in this Commonwealth was 65 years of age or older. For every 10 individuals under 25 years of age lost in this Commonwealth since 2010, the State gained 21 persons 65 years of age or older. This Commonwealth also has a higher percentage of older adults when compared to other states. In 2017, this Commonwealth ranked fifth in the Nation in the number (2.2 million) of older adults and seventh in percentage (17.8%). The increase in older Pennsylvanians is expected to continue. It has been estimated that by 2030, there will be 38 older Pennsylvanians (65 years of age or older) for every 100 working-age Pennsylvanians (15 years of age to 64 years of age). Penn State Harrisburg, Pennsylvania State Data Center (July 2018). Population Characteristics and Change: 2010 to 2017 (Research Brief). Retrieved from https://pasdc.hbg.psu.edu/data/research-briefs/pa-population-estimates; Penn State Harrisburg, Pennsylvania State Data Center (July 2018). Trends in Pennsylvania's Population by Age (June 2022). (Research Brief). Retrieved from https://pasdc.hbg.psu.edu/sdc/pasdc_files/researchbriefs/June_2022.pdf.

As the number of older Pennsylvanians increases, the number of those needing long-term care nursing will also increase. It has been estimated that an individual turning 65 years of age today has an almost 70% chance of needing some type of long-term services or support during

the remainder of their lifetime; 20% will need long-term care support for longer than 5 years. More people use long-term care services at home and for longer; however, approximately 35% utilize nursing facilities for this type of care. Administration for Community Living. (February 2020). How Much Care Will You Need? Retrieved from https://acl.gov/ltc/basic-needs/how-much-care-will-you-need. Approximately 72,000 individuals reside in the 682 long-term care nursing facilities currently licensed by the Department.

The COVID-19 pandemic highlighted the vulnerability of older adults, with a larger percentage of deaths occurring in individuals 65 years of age and older. Centers for Disease Control and Prevention (CDC). Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC. Retrieved from https://covid.cdc.gov/covid-data-tracker/#demographics. See also, CDC. COVID-19 Weekly Cases and Deaths per 100,000 Population by Age, Race/Ethnicity and Sex, United States, March 1, 2020—June 25, 2022. Retrieved from https://covid.cdc.gov/covid-data-tracker/#demographicsovertime. Further, it is estimated that deaths of residents in long-term care facilities accounted for at least 34% of all COVID-19 deaths in the United States during the time that the CDC tracked this data. https://covidtracking.com/analysis-updates/what-we-know-about-the-impact-of-the-pandemic-on-our-most-vulnerable-community. In this Commonwealth alone, there have been approximately 11,443 confirmed deaths of residents in long-term care nursing facilities since January 2020. AARP. (September 15, 2022). AARP Nursing Home COVID-19 Dashboard Fact Sheets. Retrieved from https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-states.html.

The repercussions of the COVID-19 pandemic have reached far beyond the direct, physical effects of contracting the COVID-19 virus. Lockdowns intended to protect vulnerable residents at the beginning of the COVID-19 pandemic led to social isolation and loneliness because residents were prevented from having in-person contact with their loved ones. This led to an increase in depression and anxiety, cognitive decline and in some cases, physical deterioration, among residents who were already fearful of contracting the virus. Levere, M., Rowan, P., & Wysocki, A. (2021). "The Adverse Effects of the COVID-19 Pandemic on Nursing Home Resident Well-Being." *Journal of the American Medical Directors Association*, 22(5), 948-954.e2. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7980137/. Nursing service personnel, who were already stressed before the COVID-19 pandemic, incurred additional stress from, among other things, shortages in personal protective equipment (PPE), limited access to COVID-19 testing supplies, fear of contracting COVID-19 while at work and spreading it to others, concern for residents under their care, lack of public support and recognition, and an increase in workloads due to the additional protective measures needed to prevent spread of COVID-19 and other nursing service personnel leaving the workforce. White, E.M., Wetle, T.F., Reddy, A. & Baier, R.R. (2021). "Front-line Nursing Home Staff Experiences During the COVID-19 Pandemic." *Journal of the American Medical Directors Association*, 22(1), 199-203. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7685055/.

The Department's long-term care nursing facilities regulations have not been updated since 1999, with the last significant update occurring in 1997 after the 1996 amendment to the Health Care Facilities Act (the HCFA or act) (35 P.S. §§ 448.101—448.904b). Since that time, there have been substantial changes in the means of delivering care and providing a safe environment for residents in long-term care nursing facilities, with the COVID-19 pandemic further highlighting the need for change. The Department has been attempting to complete this much needed reform since before the COVID-19 pandemic, in late 2017. At that time, the Department sought assistance and advice from members of the LTC Work Group. The Department worked with the LTC Work Group regularly in 2018. The members of the LTC Work Group were drawn from a diverse background and included representatives from urban and rural long-term care facilities and various stakeholder organizations and consumer groups that work in the area of resident care and delivery of services. The LTC Work Group members consisted of representatives from the following organizations: American Institute of Financial Gerontology; Baker Tilly Virchow Krause, LLP; Berks Heim and Rehabilitation; Fulton County Medical Center; Garden Spot Community; HCR ManorCare; Inglis House; Landis Communities; Leading Age; Legg Consulting Services; LIFE Pittsburgh; Luzerne County Community College; The Meadows at Blue Ridge; Mennonite Home; Lutheran Senior Life Passavant Community; PACAH; Pennsylvania Home Care Association; University of Pittsburgh; and Valley View Nursing Home. The following State agencies participated: Department of Aging; the Department of Human Services (DHS); and the Department of Military and Veterans Affairs (DMVA).

The members of the LTC Work Group met regularly during 2018 with the LTC Work Group's primary focus being the simplification and modernization of the existing long-term care regulations. After these discussions were complete, the Department reviewed the recommendations of the LTC Work Group and consulted with other potentially impacted agencies in 2019 and 2020. In 2020, 2021 and 2022, the Department continued its efforts to draft amendments to the long-term care nursing facility regulations while also handling the day-to-day challenges of protecting the residents of those facilities, who were being hit the hardest by the COVID-19 pandemic.

As discussed previously, in response to concerns raised by IRRC and commentators, the Department ramped up its communications with stakeholders by holding the first of four stakeholder meetings, beginning in December 2021, to address comments received on proposed rulemakings 1 and 2. The Department held a second meeting with stakeholders in June 2022 after the public comment and IRRC comment periods ended for proposed Rulemaking 3, and a third stakeholder meeting in August 2022 after the public and IRRC comment periods ended for proposed Rulemaking 4. The Department held a fourth stakeholder meeting on August 17, 2022, to provide an overview of changes from the proposed rulemakings to these final-form rulemakings and permitted stakeholders to provide additional feedback and comments on amendments during this meeting.

The discussions with stakeholders and the comments received on the four proposed rulemakings have made it abundantly clear that amendments to the current long-term care nursing facility regulations are desperately needed and must not be delayed any longer. Commentators expressed in comments to all four groups that they were pleased to see the Department updating these regulations. The comments in support of amending the regulations can generally be summarized as follows:

- Amendments are long overdue.
- Revisions to existing regulations are urgently needed.

• COVID-19 had a devastating impact on facilities and highlighted the need for revisions.

• Regulations need to be updated to provide additional protections to residents.

Unfortunately, while commentators agree for the most part that an update to the regulations is needed, they do not agree on the extent of the update needed. Some commentators strongly argued that the Department's proposed amendments do not go far enough in protecting residents, while other commentators strongly argued that the Department's proposed amendments go too far and result in a fiscal impact. The Department has considered all comments it received both in favor of and against the proposed amendments and has responded to those comments. In considering those comments and balancing the competing interest of the parties in this regulatory review process, the Department has made revisions from the proposed rulemakings to these final-form rulemakings. The Department has also provided explanations to comments received in the preambles for each of the four final-form rulemakings, as explained previously more fully.

Public Comments

In response to proposed Rulemaking 3, the Department received comments from 12 public commentators, 7 form letters, 1 legislative letter from Senator Collett, the Co-Chair of the Senate Aging and Youth Committee, and comments from IRRC. These comments are discussed in further detail as follows.

Description of amendments/summary of comments and responses

Amendments related to applications for licensure for new facilities and changes in ownership for existing facilities

As noted on the proposed rulemaking, the Department has seen a shift in ownership of long-term care nursing facilities, making it difficult to vet prospective owners of these types of facilities under the existing requirements. Specifically, over the past 20 years, the Department has seen a shift in ownership from non-profit entities to for-profit entities. It has been estimated that nationwide, approximately 70% of long-term care nursing facilities are owned by for-profit entities. Gupta, A., et al. "Does Private Equity Investment in Healthcare Benefit Patients? Evidence from Nursing Homes." (February 2021). Retrieved from https://bfi.uchicago.edu/wp-content/uploads/2021/02/BFI_WP_2021-20.pdf (hereinafter Gupta study).

The ownership structure of for-profit entities has also become increasingly complex as owners have sought to protect themselves from liability. Complex ownership structures make it difficult to determine exactly who owns the facility, who owns the real property that the facility occupies, and most importantly, who exactly is responsible for the care of residents in the facility. This makes it difficult for residents, their families and even regulators to hold owners accountable for the health and safety of residents. Private equity firms, in particular, have recently become interested in owning long-term care nursing facilities. Private equity firms are known for conducting leveraged buyouts, in which an entity is purchased by borrowing the cash needed to make the purchase. In the case of long-term care nursing facilities, private equity owners will often sell the facility's real estate assets shortly after the buyout to generate cash for their investors. This results in the need to pay rent. These rental payments, in addition to the debt incurred during the buyout, reduces the amount of cash available to provide for the care of residents. See Gupta study. This lack of cash can have dire consequences for residents in long-term care nursing facilities, as the facility is forced to cut costs, often by reducing staff. In some cases, the facility may end up closing due to its failure to meet its debt obligations, leaving residents scrambling to find care elsewhere. The Commonwealth and the Department experienced firsthand, with the well-publicized Skyline Healthcare collapse, the detrimental impact a business failure can have on residents of a long-term care nursing facility. Strickler, L., et al. (July 2019). "A nursing home grows too fast and collapses, and elderly and disabled residents pay the price." Retrieved from https://www.nbcnews.com/health/aging/nursing-home-chain-grows-too-fast-collapses-elderly-disabled-residents-n1025381 Marselas, K. (May 2018). "Skyline's implosion continues with Pennsylvania takeover." Retrieved from https://www.mcknights.com/news/skylines-implosion-continues-with-pennsylvania-takeover/.

The Department has spent the past several years investigating the best way to evaluate prospective owners of long-term care nursing facilities to protect the health and safety of residents and to prevent a recurrence. The Department has determined that the best way to accomplish this is through the application for licensure process. The application process provides the Department with the opportunity to gather information into the background of a prospective owner. Having as much information as possible regarding the background of a prospective owner will aid the Department in vetting prospective owners to determine whether they are a responsible person under the HCFA. For example, information pertaining to financial stability, corporate history, regulatory history in other jurisdictions and prospective plans for the management of the facility all provide insight into a person's ability to operate a long-term care nursing facility. This insight is vital in determining whether a person can provide the care necessary for residents in a long-term care nursing facility.

The Department amended several provisions to update and clarify the licensure process for new facilities and to address changes in ownership of existing facilities. The response from commentators to the proposed amendments was overall positive, although some commentators suggested additional amendments. These comments are addressed in each section as follows.

§ 201.12. Application for license of a new facility or change in ownership

The title of this section is unchanged from the proposed rulemaking to this final-form rulemaking. The Department proposed to add "of a new facility or change in ownership" to the title of this section. As explained on the proposed rulemaking, the Department has always required the submission of an application under existing § 201.12 (relating to application for license of a new facility or change in ownership) for changes in ownership for already existing facilities, in addition to new facilities. To eliminate confusion, the Department adds "a new facility or change in ownership" to the title of this section to clarify that the same application process applies to both new long-term care nursing facilities and changes in ownership for already existing facilities.

Commentators requested that the Department clarify what is meant by the term "person" and to include a definition for the term "person" in § 201.3 (relating to definitions) with a cross-reference to the definition of this term in the act. To assist readers, the Department adds a definition for the term "person" to § 201.3 in final-form

Rulemaking 1, with a specific cross-reference to the definition of that term in the HCFA. The use of the term "person" in this section refers to this definition. For clarity, the Department also uses the term "prospective licensee" in this section to describe a person who seeks to own or operate a facility. The Department has made this amendment throughout § 201.12, as noted as follows.

Commentators also suggested that the Department impose a timeline on the application for licensure process. One commentator recommended that a final determination on an application for licensure occur within 30 days from the date the application is submitted. Another commentator suggested the following timeline for changes in ownership: an initial review of the selling facility for stability and resident well-being within 5 days of receiving an application for licensure; a temporary determination issued to the selling facility within 10 business days; full document submission by the purchasing facility within 10 days of the application; 15 business days for the Department to request additional documentation; and a final determination within 30 days from the date the application is submitted. IRRC also inquired whether there will be set timelines for review of the application and documents submitted under § 201.12 and for a decision to be made on the application.

First, in response to the commentator who requested that the Department place deadlines on a selling facility, the Department notes that the purchasing facility (prospective licensee), not the selling facility, is responsible for obtaining a license by following the application process under § 201.12. Under § 201.12(a.2), the prospective licensee must submit to the Department, at the same time, the application form and fee and the other items delineated in subsections (b) and (e). Under § 51.4 (relating to change in ownership; change in management), a facility must notify the Department at least 30 days prior to a change in ownership. Therefore, the prospective licensee must submit the application form, fee and other items required under § 201.12 at least 30 days prior to the change in ownership. The Department will conduct its review of all items submitted under § 201.12, as well as comments received during the 10-day public comment period, concurrently. The Department, however, sees no advantage or benefit in breaking its review up with a temporary determination, as suggested by the commentator, and believes that doing so could confuse prospective licensees and others, who may mistakenly believe that a temporary determination is final.

In response to commentators who requested the Department implement a timeline for the application of licensure process generally, and in response to IRRC's question as to whether there will be set timelines for review of the application, the Department notes that it strives to review applications for licensure quickly and in a timely fashion, to ensure the health, safety and welfare of residents. However, based on departmental experience, the Department can foresee circumstances in which review of applications may be stalled due to delays in receiving completed applications and additional requested information from applicants. The Department therefore declines to place, in regulation, a time limit on its review of applications. Due to the need to ensure the health, safety and welfare of residents in reviewing and approving applications, the Department declines to make this change. The Department makes every effort to work with applicants when there is a delay in the review process, to ensure that the delay is resolved quickly and efficiently.

Subsection (a)

This subsection remains deleted on this final-form rulemaking. As explained on the proposed rulemaking, the Department deletes this subsection and replaces it with new subsections (a.1) and (a.2) described as follows.

Subsection (a.1)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department moves the first sentence from § 201.13(a) (relating to issuance of license for a new facility or change in ownership) into this subsection, with amendments. Specifically, the Department replaces the words "maintain or operate a facility" with the words "operate or assume ownership of a facility." The Department deletes the word "maintain" because renewals of licenses for existing facilities will be addressed separately in § 201.13c (relating to license renewal). The Department is moving this language to § 201.12 to make it clear that all persons who wish to operate or assume ownership of a long-term care nursing facility must first obtain a license from the Department.

Subsection (a.2)

Subsection (a.2) is amended from the proposed rulemaking to this final-form rulemaking. The Department proposed to move the second sentence from existing subsection (a) into this subsection, with amendments. Specifically, the Department proposed to reword this language to make it clear that a person seeking to operate or assume ownership of a long-term care nursing facility shall obtain an application form from the Division of Nursing Care Facilities in the Department. In this final-form rulemaking, the Department replaces the words "person seeking to operate or assume ownership" with the term "prospective licensee" for consistency in the use of this term to describe a person who seeks to own or operate a facility.

Subsection (b)

Subsection (b) is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, subsection (b) specifies information that must be submitted with the fee and completed application for licensure of a long-term care nursing facility. In this final-form rulemaking, the Department replaces the words "person seeking to operate or assume ownership" with the term "prospective licensee" for consistency in the use of this term to describe a person who seeks to own or operate a facility.

Paragraph (1)

Paragraph (1) is amended from the proposed rulemaking to this final-form rulemaking. The Department proposed several changes to existing paragraph (1), which included an expanded description of the types of persons that the Department considers as having an ownership or control interest in a facility. Commentators asked the Department to clarify what is meant by the term "person" and to clarify whether the definition of a "person" in subparagraphs (i) and (ii) should apply to other paragraphs in subsection (b). In response to these comments, the Department has simplified paragraph (1) in this final-form rulemaking by first, moving the requirement for the names, addresses, e-mail addresses and phone numbers of the facility's officers and members of the board of directors, so that this requirement is listed separately in paragraph (6). The Department has made other grammatical edits to paragraph (1) so that para-

graph (1) simply reads as, "the names, addresses, e-mail addresses and phone numbers of any person who has" followed by subparagraphs (i) through (iii).

The Department has also made grammatical edits to subparagraphs (i) and (ii) to include any person who has or will have a direct or indirect ownership interest of 5% or more and any person who holds or will hold the license or ownership interest in the land on which the facility is located or the building in which the facility is located. Further, in response to comments received from commentators, the Department adds subparagraph (iii), with language that includes any person who "owns or will own a whole or part interest in any mortgage, deed, trust, note or other long-term liability secured in whole or in part by the equipment used in the facility, the land on which the facility is located or the building in which the facility is located." Commentators explained at the stakeholder meeting with the Department on June 8, 2022, that this additional information is necessary because ownership structures can be quite complicated, and leases and land fees could be used to extract money from long-term care nursing facilities that should otherwise be spent on resident care. The Department agrees with this suggestion and, therefore, adds this provision in this final-form rulemaking.

Commentators requested that the Department clarify that the definition of a "person" in paragraph (1) applies to other paragraphs in subsection (b). The Department has done so by adding the qualifier "identified in paragraph (1)" after the term "person" where relevant in other paragraphs in subsection (b), described as follows.

Paragraphs (2) and (3)

Paragraphs (2) and (3) are amended from the proposed rulemaking to this final-form rulemaking. The Department proposed to add a requirement for e-mail addresses and phone numbers to the already existing requirement for names and addresses in these two paragraphs. As explained in the proposed rulemaking, expanding the existing requirements in paragraphs (2) and (3) to include an e-mail address and phone number will provide the Department with additional means of contacting these individuals. E-mail addresses and phone numbers also tend to be the most effective and efficient way to communicate with individuals. The Department retains these amendments in this final-form rulemaking and replaces the word "the" with the word "a" before the word "person" for grammatical reasons. The Department also adds the words "identified in paragraph (1)" after the word "person" to identify more clearly what is meant by the term "person" in these paragraphs.

Paragraph (4)

Paragraph (4) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department adds a requirement that the e-mail address and phone number of the administrator be provided in addition to the administrator's name, address and license number. As explained in the proposed rulemaking, expanding the existing requirement in paragraph (4) to include an e-mail address and phone number will provide the Department with additional means of contacting these individuals. E-mail addresses and phone numbers also tend to be the most effective and efficient way to communicate with individuals.

Paragraph (5)

Paragraph (5) is amended from the proposed rulemaking to this final-form rulemaking. The Department proposed to require that prospective licensees provide the names, addresses, e-mail addresses and phone numbers of any persons who have or will have a direct or indirect interest in the management of the facility or the provision of services at the facility. The Department explained that having this information provides the Department with a means of contacting these individuals if there is an issue at the facility. The Department retains this amendment in this final-form rulemaking but with grammatical edits, in response to IRRC's comment regarding inconsistent tenses. The Department also deletes "or the provision of services at the facility" in response to comment, as explained as follows.

A commentator asked what the intent is of including "the provision of services" in this paragraph, and what specifically is being asked of prospective licensees. IRRC also asked the Department to clarify what is meant by "provision of services." In response to these comments, the Department, in this final-form rulemaking, deletes the words, "or the provision of services at the facility." The definition of "related party", as used in paragraph (7), described as follows, more accurately reflects the Department's intent to capture information regarding parties who provide a service, facility or supply to the facility.

Paragraph (6)

The language in proposed paragraph (6) is deleted from this final-form rulemaking. The Department had proposed, in paragraph (6), to require that corporate history be submitted with the application. A commentator, and IRRC, requested that the Department clarify what is meant by the term "corporate history." The Department, in response to this comment, deletes the requirement for a "person's corporate history." The additions of paragraphs (7) and (8) in this final-form rulemaking, described as follows, more accurately reflects the Department's intent to capture information related to the financial reporting, ownership structure, gross revenues and identification of related parties of a prospective licensee, with "related party" being defined under subsection (c).

As mentioned previously, the Department, in this final-form rulemaking, moves the requirement that had been proposed in paragraph (1) for the names, addresses, e-mail addresses and phone numbers of the facility's officers and members of the board of directors, into paragraph (6). This amendment has been made in this final-form rulemaking for clarity and ease of readability.

Paragraph (7)

Paragraphs (7) through (11) are renumbered due to additional requirements being added in paragraphs (7) and (8) in this final-form rulemaking.

Paragraph (7), as amended in this final-form rulemaking, requires a prospective licensee to submit the names, addresses, e-mail addresses and phone numbers of a parent company, a shareholder and any related party of the persons identified in paragraphs (1) through (6). This requirement is added at the request of public commentators, a legislative comment and IRRC. Specifically, the Honorable Senator Maria Collett commented that she was "pleased to see that the Department included language which requires contact information for a person who has or will have ownership or control interests of 'the license or the land or building occupied and used as the facility.'" The Honorable Senator Maria Collett further requested that the Department consider expanding the contact information requirement to include any related business of the owner or operator of the facility which conducts

business with any level of the corporate structure of the facility, its parent or related businesses, the building, or the land on which the facility operates.

The Department defines a "related party" under subsection (c) as a person that provides a service, facility or supply to the facility or that is under common ownership or control, as defined under 42 CFR 413.17(b) (relating to cost to related organizations). The term includes: a home office; a management organization; an owner of real estate; an entity that provides staffing, therapy, pharmaceutical, marketing, administrative management, consulting, insurance or similar services; a provider of supplies or equipment; a financial advisor or consultant; a banking or financial entity; a parent company, holding company or sister organization.

Paragraph (8)

Public commentators and a legislative comment requested that the Department add a requirement for the submission of annual consolidated financial reports, and to include a parent organization or related entity providing goods or services in this requirement. Specifically, the Honorable Senator Maria Collett requested improved financial reporting since taxpayer funds make up more than 60% of the operating revenue of skilled nursing facilities across this Commonwealth. Commentators requested that the Department require that the report be reviewed or audited by a certified public accountant and contain a certification of accuracy. Commentators also requested that the report include a balance sheet showing assets, liabilities and net worth at the end of the fiscal year; a statement of income, expenses and operating surplus or deficit for the annual fiscal period; a statement of ancillary utilization and resident census; a statement detailing resident revenue by payer including but not limited to Medicare, Medical Assistance (MA) and other payers; a statement of cashflows, including but not limited to ongoing and new capital expenditures and depreciation; and a combined financial statement that includes all entities reported in the consolidated financial report, unless the organization is prohibited from including a combined financial statement in a consolidated report under Federal or State law or regulation or a National accounting standard. Commentators requested that prospective licensees indicate which State or Federal law, regulation or national accounting standard prohibits them from providing a combined financial statement. IRRC requested that the Department amend this final-form rulemaking to include submission of annual consolidated financial reports, or to explain how the public health, safety and welfare of residents is protected without this requirement.

A commentator also raised concerns about interlocking private equity fiscal arrangements. This commentator indicated it is critical that the Department have financial information to understand the underlying cash flows and ownership and to assure that adequate funds remain for residents' services and supports. IRRC requested that the Department amend this final-form rulemaking to require submission of information related to interlocking private equity fiscal arrangements, or to explain how this final-form rulemaking protects the public health, safety and welfare of residents.

In response to commentators and IRRC, the Department amends paragraph (8), on this final-form rulemaking, to require a prospective licensee to submit an annual financial report that includes the requirements in subparagraphs (i) through (iii). The Department is making this an annual requirement, at the request of commentators and IRRC, by adding language to § 201.13c to require that a facility submit, in addition to the application form and renewal fee, an updated annual financial report that meets the requirements in § 201.12(b)(8). This annual reporting will provide financial transparency of the facility to assess financial viability which could affect patient care and reasonableness of expenses. The Department, however, chose not to use the term "consolidated financial report," as requested by commentators and IRRC to prevent confusion with the use of the term "consolidated financial statement" which is a term of art used in accounting. Instead, the Department uses the term "financial report" without the term "consolidated" and outlines in paragraph (8) what exactly is required for the financial report that is to be submitted by prospective licensees.

In paragraph (8)(i), the Department requires submission of audited financial statements prepared in accordance with Generally Accepted Accounting Principles (GAAP), which is the commonly accepted standard for recording and reporting accounting information by accountants. If GAAP requires consolidated financial statements, then consolidated financial statements must be provided. In response to commentators, the Department has decided not to place into regulation, specific requirements for a balance sheet, a statement of income, expenses and operating surplus or deficit or a statement of cashflows as these items are already required for financial statements prepared in accordance with GAAP.

In paragraph (8)(ii), the Department requires a visual representation of the ownership structure, which must include parent companies, shareholders and any related parties of the persons identified in paragraphs (1) through (6). This requirement is added on this final-form rulemaking, at the request of commentators and IRRC. A visual representation of the ownership structure will assist the Department in determining the relationship between a prospective licensee and related businesses, shareholders and any related parties.

In paragraph (8)(iii), the Department requires a supplemental schedule of annual gross revenues, prepared in accordance with GAAP, broken out by payor type. This is added in response to public comments because a financial statement or consolidated financial statement prepared in accordance with GAAP generally would not provide information regarding payor type.

Paragraph (9)

The requirement proposed by the Department in paragraph (7) is moved to paragraph (9) in this final-form rulemaking. The Department makes two grammatical amendments, in response to comment from IRRC regarding inconsistent tenses. The Department adds the word "has" before "had" and deletes the words "of that facility" at the end of the sentence. The Department also replaces the words "any percentage of interest" with the words "a direct or indirect interest of 5% or more" in response to comment from IRRC and a commentator who requested this clarification. The Department adds "long-term care nursing" before the word "facility" in response to a commentator who asked for clarity regarding the standalone term "facility." The Department also replaces the word "person" with the term "prospective licensee" for consistency in the use of this term to describe a person who seeks to own or operate a facility.

As explained in the proposed rulemaking, the Department adds this requirement because prior as well as existing experience owning or managing other facilities is

a good indicator of a person's ability or inability to own a long-term care nursing facility. Having this information will allow the Department to investigate a prospective licensee's experience with owning or managing other facilities.

Paragraph (10)

The requirement proposed in paragraph (8) is moved to paragraph (10), in this final-form rulemaking, with amendment. In this final-form rulemaking, the Department replaces the word "person" with the words "prospective licensee" for consistency in the use of this term to describe a person who seeks to own or operate a facility. The Department adds "of 5% or more" after the word "interest" at the request of a commentator, and in response to IRRC's concern regarding the inconsistent use of the words "direct" and "indirect" interest.

As explained in the proposed rulemaking, the Department adds this requirement because the licensing and regulatory history of a prospective licensee's other long-term care nursing facilities demonstrates their ability to provide quality care to residents. A history of noncompliance or licensing issues, such as revocation of a license, demonstrates that there may be issues regarding the prospective licensee's ability to properly manage a facility or care for residents. Conversely, no history of compliance issues is an indicator that the facilities owned or operated by the prospective licensee are well managed and provide quality care to residents.

Paragraph (11)

The requirement proposed in paragraph (9) is moved to paragraph (11), in this final-form rulemaking, with amendment. The Department proposed to require that the prospective licensee provide a detailed summary of current or settled civil actions or criminal actions filed against the person.

One commentator expressed concern that the word "current" is ambiguous and suggested adding a timeframe to this requirement while another commentator suggested adding the word "adjudicated." The Department agrees that the word "current" is unclear and removes it. The Department adds the word "adjudicated" because the Department is only concerned about adjudicated and settled civil or criminal actions. The Department declines to put a timeframe on this requirement but will take the date of the legal action into consideration when conducting its analysis under § 201.12b (relating to evaluation of application for license of a new facility or change in ownership).

As explained in the proposed rulemaking, the Department adds this requirement because civil and criminal actions may not always be captured in a prospective licensee's licensing and regulatory history. A wrongful death action, for example, may show that a prospective licensee acted inappropriately in providing care to a resident, but may not present itself from a regulatory perspective. Requiring a prospective licensee to provide this type of information provides an additional mechanism for capturing potential performance issues during the application process.

Paragraph (12)

The requirement proposed in paragraph (10) is moved to paragraph (12), in this final-form rulemaking, with amendment. The Department proposed that a prospective licensee provide information regarding any financial failures involving any persons identified in the application that resulted in a bankruptcy, receivership, assignment, debt consolidation or restructuring, mortgage foreclosure, corporate integrity agreement, or sale or closure of a long-term care nursing facility, the land it sits on or the building in which it is located.

A commentator asked for clarification regarding the term "financial failures." The commentator pointed out that these types of actions may be taken by entities to remain viable and requested that consideration be given to the circumstances that necessitated the action and the way that an entity emerged from the action. In response to this comment, the Department replaces "financial failures involving persons identified in the application" with "a list of any persons, identified in paragraph (1), who have experienced financial distress" that resulted in a bankruptcy, receivership, assignment, debt consolidation or restructuring, mortgage foreclosure, corporate integrity agreement, or sale or closure of a long-term care nursing facility, the land it sits on or the building in which it is located. The Department will take into consideration the date and circumstances surrounding these types of actions when conducting its analysis under § 201.12b.

As explained in the proposed rulemaking, the Department adds this requirement because, to provide quality care, a facility must have the financial stability to properly operate. Staff must be paid, and residents must be provided the appropriate therapies, medications and accommodations for a facility to properly operate and provide quality care to residents. By obtaining information regarding a prospective licensee's financial health, the Department will be able to evaluate the ability of the prospective owner to properly operate a long-term care nursing facility.

Paragraph (13)

Based on comments received from public commentators, the Department adds a new paragraph to provide further transparency of a facility's organizational structure and relationships. Under paragraph (13), a prospective licensee is required to identify whether an immediate family relationship exists between a prospective licensee, a person identified under paragraph (1), regarding ownership and ownership interest, and a person under paragraph (7), regarding parent companies, stakeholders and related parties.

Paragraph (14)

The requirement proposed in paragraph (11) is moved to paragraph (14), in this final-form rulemaking, without amendment. One commentator asked that the Department amend this paragraph to require that the information sought be reasonably related to the finance and operation of facilities or other human service endeavors. Another commentator expressed concern that this paragraph is too vague and has the potential to delay approval of an application for a change in ownership. This commentator asked for examples of the types of information the Department may request. Another commentator requested that the Department amend this paragraph to include information responsive to inquiries from public comment on the application for license of a new facility or change in ownership.

After careful consideration, the Department declines to make these amendments. As explained in the proposed rulemaking, the purpose of this catch-all provision is to provide the Department with flexibility to require additional application information as circumstances warrant. The Department simply cannot predict every circumstance in which additional information is needed, or what

information may be needed based on its review of the information submitted under subsection (b). However, this additional information is limited to the same type of class of information under paragraphs (1) through (12) under 1 Pa. Code § 1.7 (relating to Statutory Construction Act of 1972 applicable), the Rules of Statutory Construction.

Subsection (c)

In response to comments received from commentators and IRRC, the Department adds language in subsection (c) in this final-form rulemaking, to define the term "related party" used in subsection (b). This definition is added to provide clarity regarding the use of this term in subsection (b)(7) and (8)(ii). Under this definition, a "related party" is a person that provides a service, facility or supply to a long-term care nursing facility or that is under common ownership or control, as defined in 42 CFR 413.17(b), and includes home offices; management organizations; owners of real estate; entities that provide staffing, therapy, pharmaceutical, marketing, administrative management, consulting, insurance or similar services; providers of supplies and equipment; financial advisors and consultants; banking and financial entities; any and all parent companies, holding companies and sister organizations. The Department researched statutes and regulations from other states and considered the definition of "related party" from the Financial Accounting Standards Board (FASB), but ultimately decided on this definition because the definition is tailored to services, facilities or supplies to the nursing facility and is less technical than the FASB definition, resulting in it being easier for the regulated community, residents and others to understand.

Due to this addition, the language that was proposed in subsection (c) is moved to subsection (e), as described as follows.

Subsection (d)

The Department adds language in subsection (d), in this final-form rulemaking, to define the term "immediate family member" which is used under paragraph (13), as previously discussed. This definition is added to provide clarity regarding the use of this term. The Department adopts the definition of "immediate family member" proposed by commentators. An "immediate family member" includes a spouse, biological parent, biological child, sibling, adopted child, adoptive parent, stepparent, stepchild, stepsibling, father-in-law, mother-in-law, sister-in-law, brother-in-law, son-in-law, daughter-in-law, grandparent or grandchild.

Due to this addition, the language that was proposed in subsection (d) is moved to subsection (f), as described as follows.

Subsection (e)

As mentioned previously, the language in proposed subsection (c) is moved to subsection (e) in this final-form rulemaking, with amendments. The Department replaces the words "person seeking to operate or assume ownership" with the term "prospective licensee" for consistency in the use of this term to describe a person who seeks to own or operate a facility. As explained in the proposed rulemaking, the Department is including in this subsection additional requirements to be included with the application to aid the Department in its evaluation of a person's ability to operate a long-term care nursing facility. The amendments to subsection (b) focus on requirements that will allow the Department to assess the financial health and stability of a prospective licensee, as well as a prospective licensee's history in operating long-term care nursing facilities. The proposed requirements in subsection (e), on the other hand, are intended to provide the Department with additional information, detailed as follows, regarding the prospective licensee's intentions with respect to the actual operation of the long-term care nursing facility, to ensure that the prospective licensee will be able to provide safe and adequate care for long-term care nursing residents.

Paragraphs (1) through (5)

Paragraphs (1) and (2) are unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department, in paragraph (1), requires that a prospective licensee provide a proposed staffing and hiring plan, which shall include management and oversight staff and the participants of the governing body. The Department in paragraph (2) requires that a prospective licensee provide a proposed training plan for staff.

Paragraph (3) is also unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department requires, under paragraph (3), that a prospective licensee provide a proposed emergency preparedness plan that meets the requirements of 42 CFR 483.73(a) (relating to emergency preparedness). A commentator requested that the Department amend paragraph (3) to require a "proposed emergency, pandemic and disaster preparedness plan" to align with the suggestion of commentators that the Department add requirements for pandemic and disaster preparedness plans. As explained later in this preamble, the Department has, after careful consideration, decided not to add requirements specifically for pandemic and disaster preparedness plans. Therefore, amending paragraph (3) to require submission of these plans would not be appropriate.

Paragraph (4) is amended from the proposed rulemaking to this final-form rulemaking. The Department proposed, in paragraph (4), to require that a prospective licensee provide the Department with proposed standard admissions and discharge agreements. A commentator asked the Department to clarify what is meant by a "discharge" agreement and whether this should instead be "transfer" agreement. IRRC also requested that the Department clarify what is meant by "discharge agreements." The Department agrees that "discharge agreements" is incorrect and, in response to these comments, deletes the words "and discharge" before the word "agreement." This provision as amended applies to proposed standard admissions agreements.

Paragraph (5) is amended from the proposed rulemaking to this final-form rulemaking. The Department proposed, in paragraph (5), to require that a prospective licensee provide a detailed budget for 3 years of operations, prepared in accordance with GAAP and to provide evidence of access to sufficient capital needed to operate the facility in accordance with the budget and facility assessment. As explained in the proposed rulemaking, having this information will allow the Department to assess the reasonableness of a prospective licensee's proposed plans and the prospective licensee's level of preparedness to operate a long-term care nursing facility. The Department, in this final-form rulemaking, replaces the words "generally accepted accounting principles" with the acronym "GAAP" to align with the use of this acronym in subsection (b). The Department also adds, at the request of a commentator, a cross-reference to the Federal requirements for a facility assessment under 42 CFR 483.70(e) (relating to administration).

A commentator asked that the Department be more specific about what information should be included in the plans and budget required in paragraphs (1) through (5). This commentator stated that prospective licensees should be required to make clear how they will, for example, train and recruit staff, and they should be held accountable if they end up failing to carry out their Department-approved plans. As explained in the proposed rulemaking, the Department's intent in requiring this staffing, hiring and training plan information is to assess the reasonableness of a prospective licensee's plans and to assess the prospective licensee's level of preparedness to operate a long-term care nursing facility. The Department, however, declines to add an additional requirement to this subsection holding a prospective licensee accountable if they fail to follow through with the initial plans that are submitted to the Department. The plans required under subsection (c) can and should evolve over time as the needs of the facility and residents change. In addition, the Department surveys for compliance with the requirements of the act and this subpart. Once an application for a license is approved by the Department, the licensee is expected and required to continue to meet the training and preparedness requirements of the act and this subpart. Facilities will be held accountable if they fail to do so.

Subsection (f)

The language in proposed subsection (d) is moved to subsection (f) in this final-form rulemaking with amendments. As explained in the proposed rulemaking, the Department recognizes that the application process that will now be required under this section is more comprehensive and detailed, with the potential for applicants to miss something while adjusting to these new requirements. In addition, the Department may need additional information or explanations regarding information submitted with the application. The Department adds subsection (f) to provide a prospective licensee 30 days from the date of the denial of an application to cure defects in an application.

A commentator requested that the Department amend this subsection to permit a prospective licensee only one opportunity to cure a defective application. The Department agrees and makes this amendment in this final-form rulemaking. The Department, however, will work with prospective licensees to identify information that is missing before issuing a denial. As pointed out by the commentator, a need for repeated, continual submissions suggests that a prospective licensee may not have the ability to successfully operate a facility. Limiting a prospective licensee's ability to cure the application to one time will also ensure that prospective licensees take the application for licensure process seriously. The Department, in this final-form rulemaking, also replaces the word "person" with the term "prospective licensee" for consistency in the use of this term to describe a person who seeks to own or operate a facility.

Other comments

A commentator recommended that the Department add a new section outlining a prospective licensee's ability to appeal if an application for license of a new facility or change in ownership is denied. IRRC asked if there is a process for appeal of a denial of an application for license of a new facility or change in ownership. Existing § 201.15(c) (relating to restrictions on license) provides for an appeal of a final order or determination by the Department to the Health Policy Board. For additional clarity, in this final-form rulemaking, the Department moves this subsection into its own section, § 201.15b (relating to appeals), for ease of readability.

A commentator recommended that the Department add a new section to address disclosure and confidentiality of information and records, to indicate that an application for licensure is subject to disclosure under the Right-to-Know Law (65 P.S. §§ 67.101—67.3104), except for certain information, which would be considered confidential. After careful consideration, the Department declines to add this language due to the intent to be transparent regarding identification of ownership structure and staffing, hiring, training and emergency preparedness planning. The Department will address any need for redactions or confidentiality concerns through programmatic guidance.

§ 201.12a. Notice and opportunity to comment

The language that was proposed in § 201.12a (relating to notice and opportunity to comment) is moved to § 201.12b in this final-form rulemaking.

Commentators strongly recommended that the Department include a notice and public comment period for applications for new licenses and changes in ownership. Commentators stressed the need for transparency and accountability and public comment and feedback. Commentators recommended that prospective licensees be required to provide notice to the Office of the State Long-Term Care Ombudsman and the Office of the Local Long-Term Care Ombudsman. Commentators recommended that in the case of a change in ownership, prospective licensees also provide notice to residents and employees of the facility. Commentators suggested that this notice be provided directly to these individuals and published in a local newspaper, the *Pennsylvania Bulletin* or on the Department's web site. Commentators strongly supported having a public comment period following the notice, as well, although one commentator stressed that it is important that the inclusion of a public comment period not further delay the review process for applications for licensure.

IRRC asked what the process is for receiving public feedback and input on an application for licensure, and whether the Department should require that notification of a sale or change in ownership be provided to residents, their families, employees of the facility, and the public, as well as when should notice be provided. IRRC asked the Department to explain how the public health, safety and welfare of residents will be protected without a public notice and comment period. IRRC asked the Department to explain the reasonableness of not soliciting feedback from persons who may have direct knowledge of a prospective licensee's history of administration of a long-term care nursing facility.

In response to commentators and IRRC, new language is added to § 201.12a, in this final-form rulemaking, to provide for a notice and comment period, as described as follows.

Subsection (a)

Under subsection (a), a prospective licensee of a new facility is required to provide, in addition to the requirements in § 201.12, concurrent written notice to the Office of the State Long-Term Care Ombudsman. The Department has included only that entity, under subsection (a), because in the case of a brand-new facility, there will not be any residents or employees yet to notify of the application for licensure.

Subsection (b)

Under subsection (b), a prospective licensee for a change in ownership is required to provide, in addition to the requirements in § 201.12, concurrent written notice to the residents of the facility being purchased or acquired and their resident representatives, employees of the facility being purchased or acquired and the Office of the State Long-Term Care Ombudsman. The Department agrees with commentators that it is important for residents, resident representatives, and employees of the facility to be notified of a change in ownership.

To provide additional transparency and timely notice as requested by commentators, the Department adds in subsection (d) a provision that the Department will post notice of the receipt of the applications for licensure and copies of completed application forms on the Department's web site.

Subsection (c)

Subsection (c) sets forth the requirements for the contents of the notice. The notice shall contain the name and address of the facility, the name and address of the prospective licensee, the contact information for the State Long-Term Care Ombudsman and a statement that an application for licensure has been submitted to the Department and that more information regarding the application, including the ability to comment, may be found on the Department's web site. The Department adds the requirement that the notice contain contact information for the State Long-Term Care Ombudsman, at the request of that office. The Department adds the requirement for the notice to contain a statement that more information regarding the application for licensure, including the ability to comment, may be found on the Department's web site so that those directly impacted by the application for new licensure or change in ownership are notified of their ability to comment.

Subsection (d)

The Department will, in accordance with subsection (d), post notice of the receipt of an application for license of a new facility or change in ownership, and a copy of the completed application form submitted under § 201.12 on the Department's web site and provide a 10-day public comment period. A stakeholder expressed concern, at the meeting on August 17, 2022, that 10 days is not enough time for the public to determine whether prospective licensees are bad actors and provide the Department with input. The Department chose a 10-day public comment period to align with the Department's current practice of providing a 10-day public comment period for requests for exceptions that are filed with the Department. Further, as mentioned previously, in balancing competing interests, the Department strives to complete its review of applications for new license or change in ownership in a timely manner, and does not want to delay the process by extending the timeline for review any further, out of concern for the health, safety and welfare of residents, who particularly in the case of a change in ownership, need a timely and smooth transition whenever a facility is sold.

During the stakeholder meeting on August 17, 2022, a stakeholder also asked for clarification regarding the timeline, and asked specifically how long in advance of a sale of a facility does notice need to be provided to those individuals identified in subsections (a) and (b). As noted previously, under § 51.4, a facility must notify the Department at least 30 days prior to a change in ownership. Therefore, in the case of a change in ownership, the prospective licensee must submit the application form, fee and other items required under § 201.12 at least 30 days prior to the change. Under § 201.12a(b), the prospective licensee will be required to provide concurrent notice to residents, resident representatives, employees of the facility and the Office of the State Long-Term Care Ombudsman at the same time the application for new license or change in ownership is submitted to the Department. Under § 201.12a(d), the Department will post the application form on its web site upon receipt and will provide a 10-day public comment period. The Department will conduct its review of all items submitted under § 201.12, as well as comments received during the 10-day public comment period, concurrently. As noted previously, the Department strives to conduct its review of applications for licensure efficiently and in a timely fashion, to ensure the health, safety and welfare of residents.

§ 201.12b. Evaluation of application for license of a new facility or change in ownership

The language that was proposed in § 201.12a is moved to § 201.12b in this final-form rulemaking, with amendments, described as follows. As explained in the proposed rulemaking, the Department outlines in this section its process for the evaluation of an application for licensure of a new facility or change in ownership. The purpose of delineating, in regulation, the Department's role in the application process is to provide transparency and guidance to prospective licensees as to what the Department will be considering in its evaluation of applications.

Subsection (a)

Subsection (a) is amended from the proposed rulemaking to this final-form rulemaking to indicate that the Department will consider comments submitted under § 201.12a(d) in addition to the application form and documents submitted under § 201.12. This amendment is made in this final-form rulemaking, based on feedback from commentators and IRRC, which is described more fully in § 201.12a, previously.

Subsection (b)

Subsection (b) is amended from the proposed rulemaking to this final-form rulemaking. The Department proposed to add language in subsection (b) indicating that it will approve or deny an application upon completion of the evaluation conducted under subsection (a). The Honorable Senator Maria Collett supports the addition of language requiring review of past performance related to owning or operating a facility in this Commonwealth or other jurisdictions. She further suggested that the Department consider putting together a publicly available report outlining the Department's approval or rejection of applications, including any underlying concerns and additional oversight requirements as a condition for licensure, if warranted. IRRC asked if the Department would produce a report. In response to these comments, and in balancing the need for timely information, the Department adds in this final-form rulemaking, that it will post notice of the approval or denial of the application on its web site. Posting this information on the Department's web site will promote transparency by allowing the public to see whether an application for licensure has been approved or denied. Although the Department appreciates the comment regarding a departmental report in conjunction with an approval or denial of an application, the Department is not moving forward with this suggestion at this time due to concerns regarding delay in issuance of an approval or denial as a result of concurrently producing a detailed report.

Subsection (c)

Subsection (c) is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department outlines in this subsection what it will consider in determining whether to approve or deny an application. Specifically, the Department will consider the prospective licensee's past performance related to owning or operating a facility in this Commonwealth or other jurisdictions, the prospective licensee's demonstrated financial and organizational capacity and capability to successfully perform the requirements of operating a facility, and the prospective licensee's demonstrated history and experience with regulatory compliance, as evaluated in part by evidence of consistent performance in delivering quality care. Past performance and financial issues and a history of regulatory citations are all indications that an applicant may not be able to operate a long-term care nursing facility. In this final-form rulemaking, the Department replaces the word "person" with "prospective licensee" to align with the use of that term throughout the regulation to describe a person who seeks to own or operate a facility. The Department also adds in this final-form rulemaking, that it will consider comments submitted under § 201.12a(d), in response to feedback from commentators and IRRC, which is described more fully in § 201.12a, previously.

Other comments

Several commentators requested that the Department add criteria that will result in the automatic denial of an application. IRRC asked if the Department has criteria that could be placed in the regulation. In response, the Department does not have criteria and declines to establish criteria in regulation. The regulations provide that the Department will consider certain factors in determining whether to approve or deny an application. The Department will not base its decision on any one factor alone, but instead will consider all the factors delineated in § 201.12b(c). Further, it would be problematic to include a specific approach of weighing these factors. Each application and the information submitted with it is different, and the Department cannot envision every type of scenario that may present itself during the application review process. The Department supports that a case-by-case approach is best.

A commentator and IRRC also asked what happens if an application for license of a new facility or change in ownership is in process on the effective date of the regulation. As noted elsewhere in this preamble, the effective date for § 201.12 will be October 31, 2023. Applications for licensure received prior to the effective date of the regulation, October 31, 2023, will be processed under the old requirements. Applications for licensure received on or after October 31, 2023, will be processed under the new requirements.

A commentator expressed support for the need to vet applications for licensure more diligently, particularly for a change in ownership, but asked that the Department also focus on steps to limit the number of facilities changing ownership by establishing reasonable and attainable regulatory requirements and addressing the chronic underfunding of facilities that rely on MA reimbursement. Although it is unclear from this comment what the commentator means by establishing reasonable and attainable regulatory requirements, the Department adds robust requirements for applications for new facilities and changes in ownership. As part of this regulatory framework, the Department has provided in regulation the minimum standards required to ensure the health, safety and welfare of residents. Additionally, the Department does not have the statutory oversight or authority with respect to MA funding. However, as provided in further detail in final-form Rulemaking 1—and Rulemaking 4—, there was a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023 (Act 2022-54; Act 2022-1A).

A commentator recommended that the process the Department plans to use to review applications be made publicly available to providers. As provided previously, § 201.12b publicly contains the factors that the Department will consider in determining whether to approve or deny an application. Specifically, the Department will consider the applicant's past performance related to owning or operating a facility in this Commonwealth or other jurisdictions, the applicant's demonstrated financial and organizational capacity and capability to successfully perform the requirements of operating a facility, the applicant's demonstrated history and experience with regulatory compliance, and the review of public comments the Department receives. After the review of an application and the consideration of these factors, the Department will either approve or deny an application. The Department's review will be on a case-by-case basis. The Department will then post notice of the approval or denial of the application on the Department's web site. In addition, as stated previously, a prospective licensee will be permitted one opportunity under § 201.12(f) in which to cure an application, if needed.

A commentator indicated that it is imperative that the Department's new financial unit be fully staffed and trained, and that processes for the unit be in place prior to the effective date of the regulation to ensure timely review of applications, and to not force a facility undergoing a change in ownership to close due to a delay. The Department agrees that additional resources may be needed to review the new comprehensive and robust requirements for applications of new facilities and changes in ownership under this final-form rulemaking. As such, the Department will be pursuing additional funding for a financial unit to implement these new provisions. Further, the effective date for §§ 201.12, 201.12a(c)(4) and (d), 201.12b, 201.13c(b) and (c) will be October 31, 2023 to ensure the Department can hire and train the new financial unit. This change also addresses comments and concerns received from commentators and IRRC about the proposed immediate effective date.

§ 201.13. Issuance of license for a new facility or change in ownership

As noted in the proposed rulemaking, the Department adds "for a new facility or change in ownership" to the title of this section to describe the contents of this section more accurately.

A commentator sought clarification as to whether the license issued under subsection (b) would be a regular license. A commentator suggested adding language that "admissions may begin under a new or changed ownership license" after a "regular license has been issued." This commentator also suggested adding that a regular license has a 1-year term and must be renewed annually. Commentators also requested that the Department retain subsection (f), pertaining to provisional licenses. Commentators requested that the Department add language to indicate that a provisional license will be granted to a licensee of a new facility or change in ownership as a first or initial license. Another commentator indicated that

prospective licensees for a change in ownership should be issued a provisional license if there are noncompliance issues that existed prior to the change in ownership.

IRRC asked if the license issued will be a regular license without conditions or if the license could be a provisional license. IRRC asked that, if the license can be a provisional license, that the Department clarify this and include a reference to section 812 of the act (35 P.S. § 448.812). IRRC also noted that the length of time that a license can be valid is not addressed and asked the Department to clarify this by including a timeframe in the regulation or a reference to section 809(a) of the act (35 P.S. § 448.809(a)).

In response to these comments, the Department notes that the license that is issued upon approval for a new facility or change in ownership could be either a regular license or a provisional license. Based on the comments received, the Department, in this final-form rulemaking, adds two new sections, § 201.13a and § 201.13b (relating to regular license; and provisional license) to clarify the distinctions of when a regular license will be issued versus a provisional license. The Department also includes requirements and timelines for the renewal of a license in new § 201.13c (relating to license renewal). These new sections are described in more detail as follows.

Subsection (a)

Subsection (a) remains deleted from this final-form rulemaking. As noted previously, the Department moved the first sentence of this subsection into § 201.12(a.1) with amendments. The second sentence of this subsection, regarding the non-transferability of a license, is duplicative of section 809(a)(3) of the act, which provides that no license shall be transferable except upon written approval of the Department. As explained in the proposed rulemaking, the Department uses the change of ownership process as the mechanism for taking a license from one entity and providing the opportunity for another entity to be issued a license, assuming approval. To obtain approval from the Department, the new, prospective licensee is required, under existing regulation, to apply for a license. To eliminate confusion, the Department updates § 201.12 and adds new requirements under § 201.12a to clarify the specific requirements for prospective licensees of new facilities and those who desire to assume ownership of an already existing facility.

Subsection (b)

Subsection (b) is amended from the proposed rulemaking to this final-form rulemaking. The Department, in this final-form rulemaking, amends the citation to §§ 201.12 and 201.12a to "this part" to account for the inclusion of new requirements for notice and comment, and the renumbering of § 201.12a to § 201.12b to accommodate these requirements. The remainder of this subsection remains unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes language in this subsection referring to the application form and the licensure fee as requirements for the application form and fee are addressed in the act and in § 201.12. The Department also deletes language requiring an inspection. As explained in the proposed rulemaking, the Department conducts inspections of new facilities, but may or may not conduct a survey when there is a change in ownership. A commentator suggested adding "and that issuance of a license is appropriate" before the word "met" and "under" §§ 201.12—201.12b. After carefully considering this comment, the Department declines to make this change as the purpose of this part is to codify the regulatory requirements for licensure and adding "appropriateness" language does not add substantively to the regulation.

Commentators expressed concern over the Department's deletion of language requiring an inspection under this subsection. Commentators requested that the Department add language to the regulation to indicate that licensees of both new facilities and changes in ownership are subject to a survey within the first 3—6 months of operation. Commentators argued that new licensees need to be subject to higher scrutiny, and surveys are necessary to confirm substantial compliance with requirements that could not be measured before the licensee was operating the facility. IRRC suggested that the Department consider including a survey into regulation. IRRC stated, "If such an inspection is not implemented in the final-form regulation, we ask the Department to explain how it will ensure protection of the public health, safety and welfare without heightened oversight in the initial months of operation."

After careful consideration and balancing the frequency of existing surveys, the Department declines to add this amendment. Existing surveys and unannounced examinations ensure protection of the public health, safety and welfare. For new facilities, the Department conducts an occupancy survey before a facility opens, a survey after the facility opens, and a survey for certification once the facility has a few residents. The Department also conducts surveys of all facilities on an annual basis. Further, the Department conducts a survey of a facility when a complaint is received, including subsequent unannounced examinations. Lastly, to the extent any deficiencies were previously identified by a prior owner of a facility, a new owner is required to correct these deficiencies to retain a facility license.

Subsection (c)

Subsection (c) remains deleted from this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes the existing language in subsection (c), which delineates the fees to be submitted with an application for licensure of a long-term care nursing facility because section 807(b) of the act (35 P.S. § 448.807(b)) sets forth the fees that are to accompany an application for a license or renewal of a license. Because these fees are set by statute, the Department is not able to change them, and it is not necessary to specify the fees in regulation.

Commentators indicated they do not object to the deletion of this subsection. However, they feel that applicants need clear information on what is required in the application process and feel it is not readily apparent that fee information is available elsewhere. After careful consideration, the Department declines to retain subsection (c) in response to these comments. Section 201.12(b) explicitly provides that a prospective licensee is to submit a completed application and the fee required under section 807 of the act. The Department has appropriately cross-referenced these requirements in subsection (b) and does not see a need to repeat them. Further, the same commentators commented on the need for the General Assembly to increase the fees set forth in the act. The Department agrees and would support an amendment to the act. Providing a cross-reference to the act, rather than delineating the fees, ensures that there will be no conflict between the regulations and the act when these required fees are updated by legislation.

Subsection (d)

Subsection (d) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department adds "the name and address of the owner of the facility" to the license that will be issued to the owner of a facility. Including this information on a facility's license will increase transparency for residents and their families, by allowing them to quickly determine who the owner of the facility is and how to contact them. The Department deletes "and types" of beds from the license as well because this requirement is obsolete. The Department no longer classifies bed types, and thus, this information is not needed on the license.

Subsection (e)

The Department deletes subsection (e) in this final-form rulemaking and as mentioned previously, adds § 201.13a to delineate the requirements for the issuance of a regular license, in response to public comment.

Subsection (f)

Subsection (f) remains deleted from this final-form rulemaking. The Department had proposed to delete subsection (f) to eliminate duplication and potential confusion between the regulations and section 812 of the act. As mentioned previously, the Department adds § 201.13b, in this final-form rulemaking, to delineate the requirements for the issuance of a provisional license in response to public comment.

Subsection (g)

Subsection (g) remains deleted from this final-form rulemaking. As explained in the proposed rulemaking, the Department moves subsection (g) into § 201.14 (relating to responsibility of licensee) so that this language clearly applies to licenses for new facilities or changes in ownership. Long-term care nursing facilities are required to have on file the most recent inspection reports. Moving this language to § 201.14 clarifies that this responsibility applies to all facilities.

Subsection (h)

Subsection (h) remains deleted from this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes the language in existing subsection (h), pertaining to plans of correction, because it is duplicative of the requirements in the act and not necessary to have in the regulations. Under section 814(a) of the act (35 P.S. § 448.814(a)), the Department shall provide notice when, upon inspection, investigation, or complaint, it finds a violation of its regulations or the act. This notice must require the facility to act or submit a plan of correction. The Department currently uses an electronic system for the submission of the plan of correction and provides facilities with instructions on how to submit a plan of correction through this system when one is required.

Commentators requested that the Department add language outlining the enforcement steps available to the Department. Commentators indicated that while enforcement actions are covered in multiple sections of the act, it would be beneficial to spell them out in regulation for the regulated community, residents, and others. Commentators also argued that spelling the enforcement actions out in regulation sends a message that the Department takes compliance with the act and its regulations seriously. In response to these comments and after careful consideration, the Department adds § 201.15a (relating to enforcement), in this final-form rulemaking to consolidate the information, as described as follows.

Subsection (i)

Subsection (i) remains deleted from this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes subsection (i) to eliminate duplication and potential confusion and conflict between the regulations and the requirements in the act. Section 809(b) of the act provides that a license shall be posted in a conspicuous place on the premises, at all times.

§ 201.13a. Regular license

In this final-form rulemaking, the language in proposed § 201.13a is moved to § 201.13c to accommodate the addition of this new section, which delineates the requirements for a regular license. As explained previously, this section is added in this final-form rulemaking, in response to feedback from commentators and IRRC, who requested that the Department clarify the circumstances under which a regular license will be issued, as well as the length of time for which a license is valid.

Under this section, the Department will issue a regular 1-year license when the facility is in full compliance with section 808 of the act (35 P.S. § 448.808) and is in full or substantial compliance with the provisions of this subpart. This language aligns with the requirements of the act in sections 808 and 809 of the act. In addition, to provide further clarity, the Department adds definitions for "full compliance" and "substantial compliance" in § 201.3 in final-form Rulemaking 1—General Applicability and Definitions.

§ 201.13b. Provisional license

As explained previously, this section is added in this final-form rulemaking, in response to feedback from commentators and IRRC, who asked that the Department not delete § 201.13(f) (relating to issuance of license for a new facility or change in ownership) and that the Department clarify the circumstances under which a provisional license will be issued, as well as the length of time for which a license is valid.

Subsection (a)

Subsection (a) provides the circumstances in which the Department will issue a provisional license. The Department will issue a provisional license when there are numerous deficiencies or a serious specific deficiency, the facility is not in substantial compliance with this subpart and the Department finds that: (1) the facility is taking appropriate steps to correct the deficiencies in accordance with a timetable submitted by the facility and agreed upon by the Department; and (2) there is no cyclical pattern of deficiencies over a period of 2 or more years. This language is copied directly from existing § 201.13(f)(1).

Subsection (b)

Subsection (b) provides that a provisional license will be issued for a specified time period of no more than 6 months. This is copied from the first sentence of existing § 201.13(f)(2).

Subsection (c)

Subsection (c) provides that a regular license will be issued, upon substantial compliance, including the payment of any fines and fees. This is copied from the last sentence of existing § 201.13(f)(2). The Department adds "including the payment of any fines and fees" to align with sections 807 and 812 of the act.

§ 201.13c. License renewal

As mentioned previously, the language from proposed § 201.13a is moved into this section in this final-form rulemaking, with amendments, as explained as follows.

Subsection (a)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, this subsection requires long-term care nursing facilities to apply for renewal of their licenses on a form prescribed by the Department with the fee required by the act. This is already required of facilities seeking to renew their licenses, and thus, does not impose any new obligation on facilities.

Subsection (b)

The language in subsection (b) is new in this final-form rulemaking. The Department adds to subsection (b), a requirement for facilities to submit an updated annual financial report that meets the requirements set forth in § 201.12(b)(8). After careful consideration for the need for additional transparency, this language is added in response to commentators who requested that facilities submit an annual financial report, as explained in § 201.12(b)(8) previously. Adding this submission requirement for a financial report at the same time as the license renewal process will make it easier and efficient for the regulated community to know when to submit this information. It will also be efficient and pertinent for the Department to review this information at the same time as it reviews the application for license renewal.

Subsection (c)

Subsection (c) is added in this final-form rulemaking. Under subsection (c), a facility is required to file the application to renew its license, and the updated financial report, at least 21 days before the expiration of the current license, unless the Department directs otherwise. This subsection is added in response to commentators and IRRC requesting that the Department spell out in regulation the timeline for renewal of a license. The Department generally sends out the application for renewal approximately 90 days before the license is due to expire. Requiring the application and updated financial report to be submitted at least 21 days in advance provides the Department with the time needed to review the application and the updated financial report. However, because the Department can envision circumstances in which additional time is needed, the Department adds "unless otherwise directed by the Department" to permit a facility additional time when circumstances warrant. This addition also aligns with the addition of language to § 201.15(b)(1) (relating to restrictions on license), at the request of commentators, to prevent the expiration of a license where the term expires due to a Departmental delay, a National emergency or State disaster emergency.

Subsection (d)

Subsection (d) is added in this final-form rulemaking. Subsection (d) provides that the Department will renew a regular 1-year license under this section if the facility is in full compliance with section 808 of the act and is in full or substantial compliance with the provisions of this subpart. This language is added, in response to public comments and IRRC's comments, to further clarify the circumstances under which a regular license will be renewed, as well as the length of time for which a license is valid.

Subsection (e)

Subsection (e) provides that a provisional license may be renewed no more than three times at the discretion of the Department. This is copied from the second sentence of existing § 201.13(f)(2). The Department further adds a cross-reference to section 812 of the act and § 201.13b for additional clarity.

§ 201.14. Responsibility of licensee

Subsection (a)

Subsection (a) is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department adds the word "Federal" in the first sentence and adds the following sentence, "This includes complying with all applicable Federal and State laws, and rules, regulations and orders issued by Federal, State or local agencies." In this final-form rulemaking, the Department adds "the Department and other" before the word "Federal" to align with subsection (b), as follows. The purpose of this addition is to make it clear that licensees are required to adhere to all applicable Federal and State laws and rules, regulations and orders issued by the Department and Federal, State and local agencies. This clarification is important because there may be instances, such as during the COVID-19 pandemic, where information is rapidly changing, and it is imperative that facilities are adhering to rules, regulations and orders that are being issued to ensure the health and safety of residents.

Subsection (b)

Subsection (b) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department removes the word "the" from this subsection for grammatical reasons. The Department replaces the word "insuring" with "ensuring" for the correct usage and spelling of that word. The Department replaces the phrase, "this subpart, and other relevant Commonwealth regulations" with the phrase, "all applicable Federal and State laws, and rules, regulations and orders issued by the Department and other Federal, State and local agencies." The Department makes this amendment to clarify that a licensee is responsible for ensuring that all services for the administration or management of the facility are compliant with all applicable Federal and State laws, and rules, regulations and orders issued by the Department and other Federal, State and local agencies. As mentioned previously, this clarification is important in situations, such as a pandemic, where information is rapidly changing and adherence to rules, regulations and orders is imperative to ensure the health and safety of residents.

Subsection (c)

Subsection (c) is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department adds "within 24 hours" from subsection (e) to this subsection to require a licensee, through the administrator, to report to the appropriate Division of Nursing Care Facilities field office within 24 hours serious incidents, involving residents, that are outlined in § 51.3 (relating to notification). The Department moves this language from subsection (e) into subsection (c) and deletes subsection (e) to streamline this requirement and for ease of readability. The Department also moves the phrase "as set forth in § 51.3 (relating to notification)" into the first sentence, for grammatical reasons. In this final-form rulemaking, the Department

adds "as soon as possible, or, at the latest" before the words "within 24 hours" to align more closely with the current language in subsection (e) that is deleted.

A commentator requested that the Department amend this subsection to require a licensee to timely comply with all reporting requirements related to hospitalizations or critical incidents as required by MA and other payor sources, including section 1150B of the Social Security Act (42 U.S.C.A. § 1320b-25), and to comply with all applicable reporting requirements outlined in the Older Adults Protective Services Act (OAPSA) (35 P.S. §§ 10225.101—10225.5102), the Adult Protective Services Act (35 P.S. §§ 10210.101—10210.704) and 23 Pa.C.S. Chapter 63 (relating to Child Protective Services Law). After careful consideration, the Department declines to make this amendment to limit compliance to only these specific citations. Under § 201.14(a), a facility is required to comply with all applicable Federal and State laws, and rules, regulations and orders issued by the Department and other Federal, State or local agencies.

Subsection (d)

Subsection (d) remains deleted from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection because it is duplicative of requirements that are already outlined in § 51.3. Health care facilities, including long-term care nursing facilities, are required to comply with the existing requirements in § 51.3.

In contrast, commentators requested that the Department re-enumerate State reporting requirements in this subsection to include requiring facilities to report events that cause or result in a resident's death or present an immediate danger of death or serious harm; events that cause or result in serious injury or significant change in a resident's condition; when staffing levels in the facility are below State minimum requirements; and deaths or serious injuries due to neglect, as defined in 42 CFR 483.5 (relating to definitions). Although the Department agrees with the reporting of these events, the Department declines to add this amendment since they are already required under existing Department regulations. Under § 51.3(e), which applies to all healthcare facilities, a facility is required to report noncompliance with any of the Department's regulations, where noncompliance seriously compromises quality assurance or patient safety. Further, under § 51.3(f), a facility is also required to report situations or occurrences of events at the facility which could seriously compromise quality assurance or patient safety. Section 51.3(g) provides a list of types of events that seriously compromise quality assurance or patient safety, which includes, but is not limited to, death or serious injury. This list is not all-inclusive. As provided under this existing regulation, any event that seriously compromises quality assurance or patient safety requires notification as a reportable event. This includes the reduction in staffing levels below the minimum requirements because a reduction in minimum staffing health and safety requirements seriously compromises quality assurance and resident safety.

Subsection (e)

This subsection remains deleted from this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this subsection due to the amendments to subsection (c), described previously.

Subsection (f)

This subsection is amended from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to this subsection. A commentator, however, recommended adding the Office of the Local Long-Term Care Ombudsman and the Office of the State Long-Term Care Ombudsman to the requirement that a facility notify the Department upon receipt of a strike notice. After careful consideration of this comment and discussion with the Office of the State Long-Term Care Ombudsman, the Department agrees with notification to the State Long-Term Care Ombudsman upon receipt of a strike notice and adds this requirement in this final-form rulemaking.

Subsection (g)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. The Department did not propose any amendments to this subsection.

Subsection (h)

This subsection is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes "and" before "program" and adds "and any other" before the word "information" in this subsection. The Department deletes the word "as" between the words "information" and "the" for grammatical reasons. The addition of "and any other" before "information" provides the Department with flexibility to require licensees to provide other information that may be important to ensure the health and safety of residents. The Department adds this language due to lessons learned during the COVID-19 pandemic. Throughout the COVID-19 pandemic, there have been times when the Department needed information such as the number of COVID cases within facilities, vaccination status and patient per day calculations. Adding this language into the regulation will make it easier to obtain this information from facilities. The Department deletes ", on forms issued by the Department," to allow for flexibility in how this information is obtained by the Department. Having this flexibility has proven to be vital during the COVID-19 pandemic.

A commentator expressed concern that the addition of "and any other" information is very vague and open-ended. The commentator recommended that, at a minimum, the Department add language to ensure that facilities are provided advance notice of any additional reporting requirements. IRRC asked that the Department amend the final-form regulation to ensure that facilities are provided advance notice of any additional reporting requirements. After careful consideration, the Department agrees with this suggestion. The Department will provide advance notice for new reporting requirements unless there is an emergency. For example, as the Department experienced with the COVID-19 pandemic, there may be ad-hoc needs for specific data or emergent needs that the Department and facilities may need to address immediately. Based on the comments received, the subsection is amended to require facilities to report to the Department census, rate, program occupancy and any other information. The Department will provide advance notice of new reporting requirements, except in instances of an emergency.

Subsection (i)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. As explained previously, the Department moves the language from § 201.13(g) to this subsection. The Department adds the word "Federal" to the requirement that a facility have on file the most recent inspection reports. As explained in the proposed rulemaking, the Department adds the word

"Federal" because facilities that participate in Medicare or MA are subject to surveys for compliance with the Federal requirements. A commentator expressed support for requiring facilities to keep inspection reports on file and providing them to parties who request to see them. The commentator noted that this increases transparency and helps consumers and their families to make better informed decisions when looking for a facility, especially those who may not have internet access to review information on CMS' web site.

Subsection (j)

This subsection is unchanged from the proposed rulemaking to this final-form rulemaking. Under this subsection, long-term care nursing facilities are required to conduct facility assessments that meet the requirements of 42 CFR 483.70(e), as necessary, but at least quarterly. Currently, under the Federal requirements, a facility must conduct and document a facility-wide assessment to determine the resources necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update the assessment, as necessary, and at least annually.

The Department explained, in the proposed rulemaking, that quarterly assessments provide a more accurate mechanism through which a facility can determine the resources, particularly staffing levels, needed to properly care for residents. Throughout the year, a facility may experience changes in resident population, resident conditions and staff levels and competencies. Updating the facility assessment on at least a quarterly basis will allow a facility to properly and accurately assess the needs of residents and ensure that residents are receiving the most appropriate care and services.

Some commentators expressed support for the Department's proposal to require quarterly facility assessments, with one commentator in proposed Rulemaking 1 suggesting that the Department increase facility assessments to a monthly basis. These commentators pointed out that the facility assessment is a valuable tool for evaluating resident acuity, ensuring adequate staffing and meeting the needs of the facility's specific resident population. These commentators pointed out that resident populations, and their needs, change with some frequency so the value of performing a quarterly assessment is enormous. Commentators pointed out, as well, that performing a meaningful facility assessment on a quarterly basis will improve internal quality assurance and will identify areas of noncompliance. These commentators further stated that the assertion that this is simply a burdensome paperwork requirement misses the importance of this requirement.

Other commentators, however, disagreed with the Department's proposal, indicating that they feel that the requirement for quarterly assessments is excessive, will create an undue burden on facilities that are already desperate to hire additional staff, and will burden staff and facilities with additional documentation and review, which will not contribute to an increase in quality of care. IRRC asked that the Department explain the need for this provision and how the benefits of this new requirement for quarterly facility-wide assessments outweigh the economic impacts.

After careful consideration and examination of the competing interests between consumer advocates and industry stakeholders, the Department declines to reduce the proposed requirement and will still require that a facility conduct facility-wide assessments at least quarterly to ensure resident health and safety. Requiring facilities to conduct a quarterly assessment provides timely indication of any systemic problems at the facility and identifies key areas for improvement. Currently, long-term care nursing facilities are required to conduct and document a facility-wide assessment at least annually to determine what resources are necessary to care for its residents during both day-to-day operations and emergencies. Analyzing the resident population every quarter provides a snapshot as to the overall conditions of the residents at that time, including the most common diseases, conditions, and diagnoses during that time period, and if the facility has the appropriate staff and/or equipment to take care of those residents, particularly if a trend, such as prevalence of pressure ulcers, is found among those residents. Further, staffing levels and job description openings also change on an ongoing basis. Quarterly facility assessments identify and document those changes, while providing a quality assurance function to assure that resident needs are being met by staff and financed.

§ 201.15. Restrictions on license

Subsection (a)

This subsection remains deleted from this final-form rulemaking. A commentator recommended keeping subsection (a) with the addition of the words "in whole or in part" after the word "transferrable." The commentator did not provide an explanation for this recommendation, and the Department declines to make this amendment. As explained in the proposed rulemaking, the Department deletes subsection (a) as it is duplicative of sections 809(a)(3) and (4) of the act. Section 809(a)(3) of the act provides that a license shall not be transferable except upon prior written approval of the Department. Section 809(a)(4) of the act, provides that a license shall be issued only for the health care facility or facilities named in the application. The Department uses the current change of ownership process as the mechanism for taking a license from one entity and providing the opportunity for another entity to be issued a license, assuming approval. Changes in ownership are addressed in §§ 201.12 and 201.13, as discussed previously.

Subsection (b)

This subsection is amended from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department adds the word "automatically" before the word "void" to reflect the understanding, in practice, that a long-term care nursing facility's license becomes automatically void, without notice, if any of the conditions in paragraphs (1) through (4) occur.

Paragraph (1) of subsection (b) is amended from proposed to final-form to add, at the request of a commentator, "unless the term expires due to a departmental delay, a national or state emergency or natural or human-caused disaster." The Department agrees that the addition of this language would be beneficial to the regulated community because there was a lot of confusion surrounding expired licenses during the COVID-19 pandemic. As explained in the proposed rulemaking, in paragraph (1), the Department also replaces the phrases "expiration date has been reached" with the phrase "license term expires" to eliminate possible confusion by clarifying that a license becomes automatically void when the license term expires.

Also, as explained in the proposed rulemaking, in paragraph (3), the Department deletes "for the transfer of

the license" to eliminate confusion in terminology because the Department uses the change of ownership process as the mechanism for taking a license from one entity and giving it to another. There are no amendments made to paragraphs (2) and (4).

Subsection (c)

This subsection is deleted from this final-form rulemaking. A commentator recommended that the Department add a new section outlining a prospective licensee's ability to appeal if an application for license of a new facility or change in ownership is denied. IRRC asked if there is a process for appeal of a denial of an application for license of a new facility or change in ownership. Existing § 201.15(c) provides for an appeal of a final order or determination by the Department to the Health Policy Board. In this final-form rulemaking, the Department moves this subsection into its own section, at § 201.15b, for clarity and ease of readability.

§ 201.15a. Enforcement

This section is added in this final-form rulemaking, in response to public comment, and delineates the types of actions the Department may take to enforce compliance with the act and this subpart. Specifically, actions the Department may take to enforce include, but are not limited to, requiring a plan of correction, issuing a provisional license, revoking a license, appointing a temporary manager, limiting or suspending admissions to a facility and assessing fines or civil monetary penalties. Commentators requested that the Department add this language, which outlines the enforcement steps available to the Department. Commentators indicated that while enforcement actions are covered in multiple sections of the act, it would be beneficial to spell them out in regulation for the regulated community, residents and others. Commentators also argued that spelling the enforcement actions out in regulation sends a message that the Department takes compliance with the act and its regulations seriously. The Department agrees that including enforcement actions in the regulation will be helpful for the regulated community, residents, employees and others.

A commentator requested that the Department also add language indicating that facilities will be cited for violations of both Federal and State requirements. The Department declines to make this amendment, as this could result in confusion for facilities that do not participate in Medicare or MA. Facilities that do not participate in Medicare or MA are not required, under Federal law, to comply with the Federal requirements, and thus, can only be cited for failure to comply with those requirements under State law by virtue of the amendment to § 201.2 (relating to requirements) in final-form Rulemaking 1.

§ 201.15b. Appeals

As noted previously, this section is added in this final-form rulemaking in response to public comments. The language in existing § 201.15(c) is copied into this section, without amendment, to make it easier for the regulated community and others to find.

§ 201.17. Location

This section is amended from the proposed rulemaking to this final-form rulemaking. The Department proposed to delete the existing language in this section and replace it with the following:

With the approval of the Department, a facility may be located in a building that also offers other health-related services, such as personal care, home health, or hospice services, and may share services such as laundry, pharmacy and meal preparations. The facility shall be operated as a unit distinct from other health-related services.

Commentators asked that this language be clarified because it is not clear whether the co-located health-related services would be offered as separate services under the facility's license or whether there would be separately licensed providers providing other health-related services co-located at the same physical location as the facility. A commentator suggested adding "within which there are separately licensed providers that operate and provide" between the words "building" and "other health-related." The Department agrees that this suggested language makes this provision clearer and adds it in this final-form rulemaking. As revised in this final-form rulemaking, the provision provides: "With the approval of the Department, a facility may be located in a building with other providers and share services as follows: (1) The provider is licensed, as applicable; (2) The provider operates or provides other health related services, such as personal care, home health or hospice services; (3) The shared services may include services such as laundry, pharmacy and meal preparations; (4) The facility shall be operated as a unit distinct from other health-related services."

As explained in the proposed rulemaking, the Department has had to grant a large number of exceptions to permit long-term care nursing facilities to be located in a building that offers other health-related services, such as personal care. The Department recognizes that it is beneficial for long-term care nursing facilities and their residents to have these types of services within the same building. The Department also recognizes that it is beneficial for these entities to share centralized services, such as laundry and meal preparations, to reduce costs. The amendment to § 201.17 (relating to location) accommodates these circumstances. The Department will, however, continue to consider the facility as a distinct unit and prohibit the facility from mixing approved beds, residents and staff between the related health care services.

§ 201.22. Prevention, control and surveillance of tuberculosis (TB)

Subsection (a)

Subsection (a) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department is only making one amendment to this subsection. The Department replaces the word "employes" with "employees" to reflect the current usage and spelling of that term.

Subsection (b)

Subsection (b) is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, the Department adds "screening, testing and surveillance for TB" to clarify that this section applies to the screening, testing and surveillance of TB as well as the treatment and management of TB. The Federal requirements for long-term care nursing facilities in 42 CFR Part 483, Subpart B (relating to requirements for long term care facilities) do not specifically address TB. The Department determined that it is important to keep this subsection to clarify that facilities must follow the Centers for Disease Control and Prevention (CDC) guidelines related to TB screening, testing and surveillance. See TB Screening and Testing of Health Care Personnel (2021). Retrieved from https://www.cdc.gov/tb/topic/testing/healthcareworkers.htm. The CDC provides

the most current and updated guidance regarding TB. The Department adds "and Prevention" after the words "Centers for Disease Control" as the appropriate name for the CDC is the Centers for Disease Control and Prevention.

Subsections (c) through (n)

Subsection (c) through (n) remain deleted from this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes subsections (c) through (n) as they are outdated requirements. As noted previously, the CDC provides the most updated guidance for facilities to follow regarding TB.

§ 209.1. Fire department service

This section remains deleted from this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this section as it is outdated and covered by the Department's adoption of the Federal requirements in § 201.2, in final-form Rulemaking 1—. The Federal requirements in 42 CFR 483.90 (relating to physical environment) include requirements for smoke alarms and sprinkler systems, and also incorporate by reference the National Fire Protection Association's *Life Safety Code* (NFPA 101). The *Life Safety Code* includes requirements for fire protection and the safety of residents, including fire department service. Facilities are already required to comply with the *Life Safety Code* under existing § 203.1 (relating to application of the *Life Safety Code*) and will continue to be required to comply with the *Life Safety Code* by virtue of the Department's expanded incorporation of the Federal requirements in § 201.2 in final-form Rulemaking 1. This assumes approval of final-form Rulemaking 1.

§ 209.7. Disaster preparedness

This section remains deleted from this final-form rulemaking. As explained in the proposed rulemaking, the Department deletes this section as it is outdated and covered by the Department's adoption of the Federal requirements in § 201.2, which are addressed in final-form Rulemaking 1. Emergency preparedness, which encompasses disaster preparedness, is thoroughly covered in 42 CFR 483.73. Facilities are required to have an emergency plan, which must include strategies to assess risks identified in an all-hazards, community-based risk assessment. All-hazards include emerging infectious diseases, as well as natural or man-made emergencies, which may include care-related emergencies, equipment and power failures, interruptions in communications (including cyberattacks), loss of all or a portion of a facility and interruptions in the normal supply of essentials such as food and water.

Commentators requested that the Department retain and expand this section to include emergencies, disasters and pandemics. Commentators requested that the Department require that facilities have a written plan to address each of these types of occurrences that is submitted with the application for licensure and annually thereafter for approval by the Department. Commentators also requested that the Department require that the plan include various items, such as the plan for communication with residents and families, the plan for communication with State and local public health and emergency management agencies, and how the facility will ensure sufficient supplies and staff, in addition to other requirements. After careful consideration, the Department declines to make this amendment. As mentioned previously, the requirements for an emergency plan are in 42 CFR 483.73 and encompass the items that the commentators would have the Department add to regulation. The Federal requirements are broad in that the emergency plan is based on facility-based and community-based risk assessments. Emergency plans therefore will differ from facility-to-facility. For example, a facility along the Susquehanna River would likely need to include emergency plans for flooding, but another facility that is built in a higher elevated, remote location that is not at risk of flooding would not need to include these plans. Instead, that facility may need to include a plan for loss of power and emergency fuel due to their remote location.

Facilities that participate in Medicare or MA are already required to meet 42 CFR 483.73. Although private-pay facilities are currently required to have disaster plans, the additional requirements for emergency planning will be a new requirement for the private-pay facilities. This requirement also assumes approval of final-form Rulemaking 1, which incorporates this requirement by reference in § 201.2.

In response to commentators who requested that the Department require that the emergency plan be submitted with the application for licensure and annually thereafter for approval by the Department, the Department notes that under § 201.12(e)(3), prospective licensees will be required to submit a proposed emergency preparedness plan as part of the application for licensure. In addition, the Department conducts annual surveys for compliance with the requirements of the act and its regulations. By virtue of the expanded incorporation of the Federal requirements in § 201.2, the Department will be surveying for compliance with this requirement under State law. This assumes approval of final-form Rulemaking 1—General Applicability and Definitions.

§ 209.8. Fire drills

This section remains deleted from this final-form rulemaking. The Department deletes this section as it is outdated and covered by the Federal requirements at 42 CFR 483.90. Requirements for fire drills are addressed in the *Life Safety Code*, which is incorporated by reference in the Federal requirements. Facilities are already required to comply with the *Life Safety Code* under existing § 203.1 and will continue to be required to comply with the *Life Safety Code* by virtue of the Department's expanded incorporation of the Federal requirements in § 201.2 in final-form Rulemaking 1. This assumes approval of final-form Rulemaking 1.

Commentators requested that the Department keep and expand this section to include all types of safety drills, including drills for emergencies, disasters, pandemics and active shooters, and to rename the section to reflect this change. After careful consideration, the Department declines to make this amendment. Under 42 CFR 483.73(a)(1) and (4), facilities are required to develop and maintain emergency preparedness programs, training and testing. These plans are required to be based on facility-based, community-based risk assessment, utilizing an all-hazards approach, that include a process for cooperation and collaboration with local, Federal and State emergency preparedness officials to maintain an integrated response during a disaster or emergency. Further, under 42 CFR 483.73(b)(3), (4) and (c), these plans require policies and procedures that address safe evacuation and a means to shelter in place for residents, staff and volunteers, in addition to communication plans. Initial and annual training is required for emergency preparedness under 42 CFR 483.73(d)(1). Further, drills are covered under 42 CFR 483.73(d)(2), which requires

facilities to "conduct exercises to test the emergency plan at least twice per year, including unannounced staff drills."

Facilities that participate in Medicare or MA are already required to meet 42 CFR 483.73. Although private-pay facilities are currently required to have both disaster plans and fire drill requirements, the additional requirements for emergency planning will be a new requirement for the private-pay facilities. This requirement also assumes approval of final-form Rulemaking 1, which incorporates this requirement by reference in § 201.2.

§ 211.1. Reportable diseases

This section is unchanged from the proposed rulemaking to this final-form rulemaking. As explained in the proposed rulemaking, based on the recommendations of the LTC Work Group, and due to a rise in bed bug infestations, the Department adds "bed bug infestations" to the reporting requirements of subsection (b). A commentator expressed support for this addition.

Commentators requested that the Department add a new subsection to clarify that facilities must report pandemic-prone infectious diseases, such as COVID-19, and other State or Federally declared pandemics or infectious disease outbreaks, to the Department and other relevant agencies, in the manner, frequency and format required by the Department. Commentators also recommended that the Department create a new section to address any future pandemic-related illnesses or outbreaks, where the facility would be required to follow all currently applicable Federal and State regulations, guidance, and protocols. Commentators recommended the Department add language for requirements of an infection control plan that would specifically address pandemics. After careful consideration, the Department declines to make this amendment. As provided previously, under § 201.14 (as revised in this final-form rulemaking), a facility is required to comply with all applicable Federal and State laws, rules, regulations and orders. This would include any laws, rules, regulations and orders related to pandemic-related illnesses or outbreaks. Further, existing § 27.3 (relating to reporting outbreaks and unusual diseases, infections and conditions) authorizes the Department to designate any unusual or group expression of illness as a public health emergency, which includes pandemic-related illnesses and outbreaks. Similarly, § 27.4 (relating to reporting cases) and Subchapter B (relating to reporting of diseases, infections and conditions) of Chapter 27 (relating to communicable and noncommunicable diseases) address the frequency and format of reportable diseases.

Comments on Effective Date

Commentators and IRRC commented regarding the Department's proposal to set the same effective date, upon publication, for all four final-form rulemakings. IRRC asked the Department to address these concerns and explain why this timeframe was reasonable.

In response to commentators and IRRC, these final-form regulations for all four regulatory packages will take effect on July 1, 2023, with the following exceptions. In this final-form rulemaking, § 201.12a(a), (b) and (c)(1) through (3), which require prospective licensees to provide written notice to certain individuals, will take effect on February 1, 2023. Sections 201.12, 201.12b, 201.13c(b) and (c) and 201.12a(c)(4) and (d) will take effect on October 31, 2023. In final-form Rulemaking 4, § 211.12(f.1)(3) and (i)(2) will take effect on July 1, 2024. This will allow the regulated community a reasonable amount of time to adequately plan and initiate the staffing and budget changes necessary to achieve compliance.

Fiscal Impact and Paperwork Requirements

Fiscal Impact

In response to the comments and concerns raised during the September 15, 2021 Senate Health and Human Services and Aging and Youth Committees joint legislative hearing, throughout the public comment process, and in other discussions, the Governor's Fiscal Year (FY) 2022-2023 budget proposal proposed an MA rate increase of $190 million; $91 million in State funding to be matched with $99 million in Federal funds for the first 6 months of calendar year 2023 and a proposed $250 million one-time investment of American Rescue Plan Act (ARPA) funds in long-term living programs, including direct one-time funding for all facilities to support their workforce and help them to hire more staff to meet the requirements of the forthcoming regulations. The funding was proposed to be provided to facilities in advance of the expected staffing increases to allow facilities to stabilize their existing workforce and recruit additional staff prior to the regulatory increases going into effect.

Following Governor Tom Wolf's budget proposal, industry stakeholders called for $294 million in MA funding in the Commonwealth's FY 2022-2023 budget. The FY 2022-2023 Appropriations Act signed by Governor Tom Wolf included bipartisan support for a historic increase in one-time and ongoing funding for facilities. As enacted, $147 million in State funding was appropriated to support implementation of the Department's regulations. Specifically, this funding will be used to support a 17.5% Medicaid rate increase beginning January 1, 2023, which allows facilities time to ramp up staffing to meet the direct care staffing hours required on July 1, 2023. Assuming Federal approval, these State funds will be matched with an additional $159 million in Federal funds, totaling $306 million in Medicaid funding for the first 6 months of calendar year 2023. Nursing facilities will also receive $131 million in one-time ARPA funding during FY 2022-2023. A detailed fiscal impact for the regulated community, the Commonwealth and local government is as follows:

Regulated community

The amendments will apply to all 682 long-term care nursing facilities licensed by the Department. These facilities provide health services to more than 72,000 residents. This total includes 19 county-owned and operated facilities, 6 veterans' homes that are operated by DMVA, 654 privately-owned facilities that participate in Medicare or MA and 3 private-pay facilities that do not participate in Medicare or MA. The requirement for facility assessments to be performed, at least, on a quarterly basis is a new requirement. Currently, facilities are required to complete facility assessments at least annually; however, practice varies regarding frequency. Since facilities are already required to care for their residents, determine and plan for staffing, resources and operate their facilities, the conducting and documenting of a facility assessment is a standard business practice with a nominal fiscal impact due to the increase in required frequency. As provided previously, quarterly assessments are used to determine what resources are needed to care for residents during both day-to-day operations and emergencies. Further, these assessments provide a timely indication of any systemic problems at a facility and assist with identifying areas for improvement.

There is also a nominal fiscal impact anticipated with the submission of financial reports and the additional submission of contact information for related parties, parent companies and shareholders. Facilities will incur a nominal cost related to the submission of the annual financial report with the renewal of the application for licensure under § 201.13c (relating to license renewal). This will initially be a new requirement for all facilities effective October 31, 2023, followed by an annual update. Facilities should already have, in their possession, the documents required for the submission of the annual financial report, as these items are already produced in the regular course of business. However, facilities may incur a nominal cost for copying these documents for submission to the Department.

Prospective licensees

Prospective licensees will incur nominal costs related to the submission of additional documents with the application for licensure in § 201.12 (relating to application for license of a new facility or change in ownership). Prospective licensees should already have, in their possession, the financial documents and other information listed in § 201.12, as many of these documents are already produced in the regular course of business. However, prospective licensees may incur nominal costs for copying these documents for submission to the Department. Prospective licensees will need to spend time compiling this information for submission to the Department, as well. The Department anticipates that a prospective licensee will need to spend approximately an hour compiling this information for submission. Prospective licensees will need to expend time developing other items required under § 201.12, such as a staffing plan and an emergency preparedness plan. The Department anticipates that a prospective licensee may need to spend approximately 2 hours to 4 hours developing these items. Prospective licensees will also incur nominal costs, such as postage and the cost of paper and supplies, associated with providing the notice under § 201.12a to the Office of the State Long-Term Care Ombudsman and residents, resident representatives, and employees, if applicable. The Department anticipates that a prospective licensee many need to expend anywhere from a few minutes to an hour, depending on the number of notices required under this section. Prospective licensees may incur additional costs if they choose to consult with an accountant or an attorney when completing these paperwork requirements.

Commonwealth—Department

The Department's surveyors perform the function of surveying and inspecting long-term care nursing facilities for compliance with both Federal and State regulations. The elimination of subsections that are outdated and duplicative of the Federal requirements will streamline the survey process for long-term care nursing facilities and provide consistency and congruency to the stakeholder industry. This, in turn, will reduce confusion in the application of the standards that apply to long-term care nursing facilities. These streamlining provisions will not increase costs to the Department. However, the Department is anticipating an approximate cost of $600,000 to hire accountants to establish a financial unit to review and manage the new financial submissions from facilities. This estimate includes an estimated annual cost of $590,312 for salaries and benefits and initial operating costs of $9,250 for equipment and office space.

The Department also estimates that there will be a cost to update licenses to add the additional information under § 201.13 and to update the computer system for the creation of internal reporting for review of new information. It is estimated that the Department will need to expend approximately $55,000 for these updates, which includes the cost for a vendor assessment.

Commonwealth—DMVA

Of the 682 long-term care nursing facilities licensed by the Department, 6 facilities are veterans' homes that are operated by the DMVA. These facilities are already required to comply with the Federal requirements.

The DMVA-operated licensed facilities will not incur any additional cost due to aligning with the Federal requirements. As noted, these facilities are already required to comply with the Federal requirements. Although there are additional paperwork requirements associated with quarterly facility assessments, the Department considers this to be a standard business practice with a nominal fiscal impact due to the increase in required frequency.

Commonwealth—DHS

Although the provisions of this final-form rulemaking, which relate to ownership, management and health and safety, will not have a cost impact to DHS, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023, was enacted under Act 2022-54 and appropriated under the General Appropriations Act of 2022 (Act 2022-1A).

Local government

As mentioned previously, there are currently 19 county-owned long-term care nursing facilities, licensed by the Department. These facilities account for approximately 7.5% (6,524 beds) of licensed nursing facility beds across this Commonwealth. Allegheny County owns four of the nursing homes; the remaining homes are in the following 15 counties: Berks, Bradford, Bucks, Chester, Clinton, Crawford, Delaware, Erie, Indiana, Lehigh, Monroe, Northampton, Philadelphia, Warren and Westmoreland.

County-owned long-term care nursing facilities participate in Medicare or MA and thus, are already required to comply with the Federal requirements.

The county-owned licensed facilities will not incur any additional cost due to align with the Federal requirements. As noted, these facilities participate in Medicare or MA and thus, already required to comply with the Federal requirements. Similar to other facilities, these facilities already have to conduct facility assessments. Although there are additional paperwork requirements associated with quarterly facility assessments, the Department considers this to be a standard business practice with a nominal fiscal impact due to the increase in required frequency.

Residents of long-term care nursing facilities

Approximately 72,000 individuals that reside in the 682 long-term care nursing facilities licensed by the Department will be affected by these amendments. Residents will be positively impacted by the increased frequency in facility assessments. As provided previously, quarterly assessments are used to determine what resources are needed to care for residents during both day-to-day operations and emergencies. Further, these assessments provide a timely indication of any systemic problems at a facility and assist with identifying areas for improvement. Specifically, analyzing the resident population every quar-

ter provides a snapshot as to the overall conditions of the residents at that time, including the most common diseases, conditions, and diagnoses during that time period, and if the facility has the appropriate staff and/or equipment to take care of those residents, particularly if a trend is found among those residents.

Paperwork Requirements

The Department's adoption of quarterly facility assessments will result in additional paperwork requirements for facilities. There are also additional paperwork requirements related to the submission of financial reports and the submission of contact information for related parties, parent companies and shareholders. These submissions are required upon application and annually.

Small Business Analysis

IRRC commented that the Department did not identify and provide an estimate of the number of small businesses that will be impacted by the regulation. IRRC asked if the Department, in conjunction with other agencies, can evaluate potential impacts on small businesses.

Under section 3 of the Regulatory Review Act (71 P.S. § 745.3), a small business is "defined in accordance with the size standards described by the United States Small Business Administration's Small Business Size Regulations under 13 CFR Ch. 1 Part 121 (relating to Small Business Size Regulations) or its successor regulation." Under 13 CFR 121.101 (relating to what are SBA size standards?), the Small Business Administration's (SBA) "size standards determine whether a business entity is small." Size standards are developed under the North America Industry Classification System (NAICS). The Department applied the NAICS standards to determine how many long-term care nursing facilities, licensed by the Department, are small businesses.

The Department conducted a search on the NAICS web site to find the NAICS code for long-term care nursing facilities. The NAICS code for nursing care facilities (skilled nursing facilities) is 623110. The Department looked this code up in the table located at 13 CFR 121.201 (relating to what size standards has SBA identified by North American Industry Classification System codes?) and determined that a long-term care nursing facility is a small business if it has $30 million or less in annual receipts. The Department then pulled the latest long-term care nursing facility cost report from CMS to determine the impact to facilities that participate in Medicare or MA. The latest cost report data from CMS is 2018. Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data. The Department applied current Federal Standards of Accounting to this data to determine each facility's annual receipts. Based on this analysis, the Department determined that 623 facilities that participate in Medicare or MA have $30 million or less in annual receipts. Although the data from CMS is from 2018, the Department believes that currently, at least the same number of facilities, if not more, would meet the definition of a small business. This analysis aligns with the Department's previous assumption that most long-term nursing facilities licensed by the Department meet the definition of a small businesses.

The Department also asked stakeholders during the meetings held in 2021 and 2022 for assistance in determining the impact to small businesses. The stakeholders were not able to provide the Department with specific information regarding how the Department's proposed regulations would impact small businesses. However, during the stakeholder meeting for Rulemakings 1 and 2, a stakeholder suggested that the Department search GuideStar, which provides financial information regarding nonprofit entities, to determine whether the three private-pay facilities are small businesses. The Department searched the GuideStar web site at https://www.guidestar.org/ for the three private-pay facilities that are licensed by the Department. Based on this data, one of the private-pay facilities, Friends Home in Kennett/Linden Hall, meets the definition of a small business applying the NAICS standards. Another private-pay facility, Foulkeways at Gwynedd, does not meet the definition of a small business based on its gross receipts. Data for the third private-pay facility, Dallastown Nursing Center, is not available on GuideStar, but for the purposes of this analysis, the Department assumes that Dallastown is a small business.

In sum, at least 91% of nursing facilities meet the definition of a small business. Consistent with the HCFA and function of licensure, the purpose of these regulatory amendments is to ensure the health, safety and welfare of all residents of long-term care nursing facilities in this Commonwealth by providing the minimum health and safety standards. Given that most facilities are a small business and the need for surveying for the health and safety of residents, the Department did not establish differing criteria for nursing facilities that are small businesses compared to the minority of facilities that are not small businesses. Further, in determining the minimum health and safety requirements, the Department considered the myriad of received comments, feedback from meetings and stakeholder groups and attempted to balance the interests between consumers and the stakeholder industry. The Department's responsibility to ensure that residents receive safe, quality care applies to all residents of long-term care nursing facilities in this Commonwealth, and it is critical that all residents of long-term care nursing facilities receive the same level of high-quality care, regardless of whether the facility they reside in is a small business.

IRRC also asked that the Department work with the regulated community to calculate and address the economic impact of additional quarterly assessments on facilities, particularly those that are small businesses. Although the Department inquired regarding the economic impact during a June stakeholder meeting, no comments or responses were provided. As additional background, when facility assessments were first required through the Federal Department of Health and Human Services (DHHS), due to existing requirements for sufficient staffing for acuity needs, no fiscal impact or burden was anticipated. Specifically, DHHS provided:

"We are finalizing our requirement for facilities to conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. LTC facilities must already determine and plan for what staffing they will need, as well as the other resources that will be required to care for their residents and operate their facilities. Thus, we believe that conducting and documenting a facility assessment is a standard business practice and do not include a burden for this requirement in the impact analysis."

81 FR 68688, 68844 (October 4, 2016)

In working with the DMVA, which operates six long-term care facilities, it indicated that the cost of conduct-

ing a facility assessment is insignificant, as it just involves compiling information. The DMVA does not anticipate an increase in costs or labor to meet the increased frequency of a currently utilized assessment. The DMVA currently has quality assurance staff to perform this function.

Statutory Authority

Sections 601 and 803 of the HCFA (35 P.S. §§ 448.601 and 448.803) authorize the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the HCFA. Section 801.1 of the HCFA (35 P.S. § 448.801a) seeks to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities that includes long-term care nursing facilities. The minimum standards are to assure safe, adequate, and efficient facilities and services and to promote the health, safety and adequate care of patients or residents of those facilities. In section 102 of the HCFA (35 P.S. § 448.102), the General Assembly has found that a purpose of the HCFA is, among other things, to assure that citizens receive humane, courteous and dignified treatment. Finally, section 201(12) of the HCFA (35 P.S. § 448.201(12)) provides the Department with explicit authority to enforce its rules and regulations promulgated under the HCFA.

The Department also has the duty to protect the health of the people of this Commonwealth under section 2102(a) of the Administrative Code of 1929 (71 P.S. § 532(a)). The Department has general authority to promulgate regulations under section 2102(g) of The Administrative Code of 1929.

Effectiveness/Sunset Date

This final-form rulemaking will become effective on July 1, 2023, except as follows. The effective date for § 201.12a(a), (b) and (c)(1)—(3) will be February 1, 2023. The effective date for §§ 201.12, 201.12a(c)(4) and (d), 201.12b, 201.13c(b) and (c) will be October 31, 2023. A sunset date will not be imposed. The Department will monitor the regulations and update them as necessary.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on March 2, 2022, the Department submitted notice of this proposed rulemaking, published at 52 Pa.B. 1626 (March 19, 2022), to IRRC and the Chairpersons of the Senate Health and Human Services Committee and the House Health Committee for review and comment.

Under section 5(c) of the Regulatory Review Act (71 P.S. § 745.5(c)), IRRC, the Senate Health and Human Services Committee and the House Health Committee were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the Senate Health and Human Services Committee, the House Health Committee, and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on October 27, 2022, the final-form rulemaking was deemed approved by the Senate Health and Human Services Committee and the House Heath Committee. Under section 5.1(e) of the Regulatory Review Act, IRRC met on October 28, 2022, and approved the final-form rulemaking.

Contact Person

Additional information regarding this final-form rulemaking may be obtained by contacting Ann Chronister, Director, Bureau of Long-Term Care Programs, 625 Forster Street, Rm. 526, Health and Welfare Building, Harrisburg, PA 17120, (717) 547-3131, RA-DHLTCRegs@pa.gov. Persons with a disability may submit questions in alternative format such as by audio tape, Braille, or by using V/TT (717) 783-6514 or the Pennsylvania Hamilton Relay Service at (800) 654-5984 (TT). Persons who require an alternative format of this document may contact Ann Chronister at the previous address or telephone number so that necessary arrangements can be made.

Findings

The Department finds that:

(1) Public notice of intention to adopt the regulations adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), referred to as the Commonwealth Documents Law and the regulations promulgated under those sections at 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law and all comments were considered in drafting this final-form rulemaking.

(3) The amendments made to this final-form rulemaking do not enlarge the original purpose of the proposed rulemaking as published under section 201 of the act of July 31, 1968.

(4) The adoption of the regulations is necessary and appropriate for the administration of the Health Care Facilities Act (35 P.S. §§ 448.101—448.904b).

Order

(1) The regulations of the Department at 28 Pa. Code Chapters 201, 209 and 211 are amended by amending §§ 201.12—201.15, 201.17, 201.22 and 211.1, deleting §§ 209.1 and 209.7 and adding §§ 201.12a, 201.12b, 201.13a, 201.13b, 201.13c, 201.15a and 201.15b as set forth in Annex A.

(2) The Department shall submit this final-form rulemaking to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(3) The Department shall submit this final-form rulemaking to IRRC, the Senate Health and Human Services Committee and the House Health Committee as required by law.

(4) The Department shall certify this final-form rulemaking, as approved for legality and form, and shall deposit it with the Legislative Reference Bureau as required by law.

(5) This final-form rulemaking shall take effect on July 1, 2023, except as follows:

(i) Section 201.12a(a), (b) and (c)(1)—(3) shall take effect February 1, 2023.

(ii) Sections 201.12, 201.12a(c)(4) and (d), 201.12b, 201.13c(b) and (c) shall take effect October 31, 2023.

DR. DENISE A. JOHNSON,
Acting Secretary

(*Editor's Note*: See 52 Pa.B. 7054 (November 12, 2022) for IRRC's approval order.)

Fiscal Note: 10-223. (1) General Fund; (2) Implementing Year 2022-23 is $0; (3) 1st Succeeding Year 2023-24 is

$655,000; 2nd Succeeding Year 2024-25 is $620,000; 3rd Succeeding Year 2025-26 is $651,000; 4th Succeeding Year 2026-27 is $683,000; 5th Succeeding Year 2027-28 is $718,000; (4) 2021-22 Program—$24,043,000; 2020-21 Program—$23,093,000; 2019-20 Program—$22,513,000; (7) Quality Assurance; (8) recommends adoption. Funds have been included in the budget to cover this increase.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

Subpart C. LONG-TERM CARE FACILITIES

CHAPTER 201. APPLICABILITY, DEFINITIONS, OWNERSHIP AND GENERAL OPERATION OF LONG-TERM CARE NURSING FACILITIES.

OWNERSHIP AND MANAGEMENT

§ 201.12. Application for license of a new facility or change in ownership.

(a) [Reserved].

(a.1) A person may not operate or assume ownership of a facility without first obtaining a license from the Department.

(a.2) A prospective licensee of a facility shall obtain an application form from the Division of Nursing Care Facilities, Department of Health.

(b) In addition to the completed application and fee required under section 807 of the act (35 P.S. § 448.807), a prospective licensee of a facility shall submit the following:

(1) The names, addresses, e-mail addresses and phone numbers of any person who meets any of the following:

(i) Has or will have a direct or indirect ownership interest of 5% or more in the facility.

(ii) Holds or will hold the license or ownership interest in the land on which the facility is located or the building in which the facility is located.

(iii) Owns or will own a whole or part interest in any mortgage, deed, trust, note or other long-term liability secured in whole or in part by the equipment used in the facility, the land on which the facility is located or the building in which the facility is located.

(2) If a person identified in paragraph (1) is a nonprofit corporation, a complete list of the names, addresses, e-mail addresses and phone numbers of the officers and directors of the corporation and an exact copy of its charter and articles of incorporation which are on file with the Department of State as well as amendments or changes.

(3) If a person identified in paragraph (1) is a partnership, the names, addresses, e-mail addresses and phone numbers of partners.

(4) The name, address, e-mail address, phone number and license number of the administrator.

(5) The names, addresses, e-mail addresses and phone numbers of any persons who have or will have an interest in the management of the facility.

(6) The names, addresses, e-mail addresses and phone numbers of the facility's officers and members of the board of directors.

(7) The names, addresses, e-mail addresses and phone numbers of the following:

(i) A parent company.

(ii) A shareholder.

(iii) A related party of the persons identified in paragraphs (1) through (6).

(8) An annual financial report which shall include the following:

(i) Audited financial statements prepared in accordance with generally accepted accounting principles (GAAP). If GAAP requires consolidated financial statements, then consolidated statements shall be provided.

(ii) A visual representation of the current ownership structure, which must include parent companies, shareholders and any related parties of the persons identified in paragraphs (1) through (6).

(iii) A supplemental schedule of annual gross revenues, prepared in accordance with GAAP. The supplemental schedule shall be broken out by payor type.

(9) A list of every licensed long-term care nursing facility in any state, the District of Columbia or territory in which the prospective licensee has or has had a direct or indirect interest of 5% or more in the ownership, management or real property.

(10) The prospective licensee's licensing and regulatory history in all jurisdictions where the prospective licensee has or has had a direct or indirect ownership interest of 5% or more in a facility.

(11) A detailed summary of adjudicated or settled civil actions or criminal actions filed against the prospective licensee.

(12) A list of any persons, identified in paragraph (1), who have experienced financial distress that resulted in a bankruptcy, receivership, assignment, debt consolidation or restructuring, mortgage foreclosure, corporate integrity agreement, or sale or closure of a long-term care nursing facility, the land it sits on or the building in which it is located.

(13) Identification of whether an immediate family member relationship exists between a prospective licensee, a person under paragraph (1) and a person under paragraph (7).

(14) Additional information the Department may require.

(c) For the purposes of subsection (B), a "related party" is a person that provides a service, facility or supply to a long-term care nursing facility or that is under common ownership or control, as defined in 42 CFR 413.17(b) (relating to cost to related organizations). The term includes the following:

(1) A home office.

(2) A management organization.

(3) An owner of real estate.

(4) An entity that provides staffing, therapy, pharmaceutical, marketing, administrative management, consulting, insurance or similar services.

(5) A provider of supplies and equipment.

(6) A financial advisor or consultant.

(7) A banking or financial entity.

(8) A parent company, holding company or sister organization.

(d) For the purposes of subsection (b), an "immediate family member" includes a spouse, biological parent, biological child, sibling, adopted child, adoptive parent,

stepparent, stepchild, stepsibling, father-in-law, mother-in-law, sister-in-law, brother-in-law, son-in-law, daughter-in-law, grandparent or grandchild.

(e) In addition to the information required under subsection (b), a prospective licensee of a facility shall provide all of the following:

(1) A proposed staffing and hiring plan, which shall include the management and oversight staff, the structure of the facility's governing body and its participants.

(2) A proposed training plan for staff.

(3) A proposed emergency preparedness plan that meets the requirements of 42 CFR 483.73(a) (relating to emergency preparedness).

(4) Proposed standard admissions agreements.

(5) A detailed budget for 3 years of operations, prepared in accordance with GAAP, and evidence of access to sufficient capital needed to operate the facility in accordance with the budget and the facility assessment conducted under 42 CFR 483.70(e) (relating to administration).

(f) A prospective licensee who fails, under this section, to demonstrate capacity to operate a facility, will be given 30 days from the date of the denial of an application to cure the application. A prospective licensee will be permitted one opportunity, under this subsection, in which to cure the application.

§ 201.12a. Notice and opportunity to comment.

(a) In addition to the requirements in § 201.12 (relating to application for license of a new facility or change in ownership), a prospective licensee of a new facility shall concurrently provide written notice to the Office of the State Long-Term Care Ombudsman when the prospective licensee submits its application.

(b) In addition to the requirements in § 201.12, a prospective licensee for a change in ownership of a facility shall concurrently provide written notice to all of the following:

(1) Residents of the facility being purchased or acquired, and their resident representatives.

(2) Employees of the facility being purchased or acquired.

(3) The Office of the State Long-Term Care Ombudsman.

(c) The written notice shall provide all of the following information:

(1) The name and address of the facility.

(2) The name and address of the prospective licensee.

(3) The contact information for the State Long-Term Care Ombudsman.

(4) A statement that an application for licensure has been submitted to the Department and more information regarding the application, including the ability to comment, may be found on the Department's web site.

(d) The Department will post notice of the receipt of an application for license of a new facility or change in ownership and a copy of the completed application form submitted under § 201.12 on the department's web site and provide a 10-day public comment period.

§ 201.12b. Evaluation of application for license of a new facility or change in ownership.

(a) The Department will conduct an evaluation of the application, which will include consideration of the application form and documents submitted under § 201.12 (relating to application for license of a new facility or change in ownership) and comments submitted under § 201.12a(d) (relating to notice and opportunity to comment).

(b) Upon completion of the evaluation conducted under subsection (a), the Department will approve or deny the application and post notice of the approval or denial of the application on the Department's web site.

(c) The Department will consider the following in determining whether to approve or deny an application:

(1) The prospective licensee's past performance related to owning or operating a facility in this Commonwealth or other jurisdictions.

(2) The prospective licensee's demonstrated financial and organizational capacity and capability to successfully perform the requirements of operating a facility based on the information provided under § 201.12.

(3) The prospective licensee's demonstrated history and experience with regulatory compliance, including evidence of consistent performance in delivering quality care.

(4) Comments submitted under § 201.12a(d).

§ 201.13. Issuance of license for a new facility or change in ownership.

(a) [Reserved].

(b) A license to operate a facility will be issued when the Department has determined that the necessary requirements for licensure have been met under this part.

(c) [Reserved].

(d) The license will be issued to the owner of a facility and will indicate the name and address of the facility, the name and address of the owner of the facility, the number of beds authorized and the date of the valid license.

(e) [Reserved].

(f) [Reserved].

(g) [Reserved].

(h) [Reserved].

(i) [Reserved].

§ 201.13a. Regular license.

The Department will issue a regular 1-year license when the facility is in full compliance with section 808 of the act (35 P.S. § 448.808) and is in full or substantial compliance with the provisions of this subpart.

§ 201.13b. Provisional license.

(a) Under section 812 of the act (35 P.S. § 448.812), the Department may issue a provisional license if there are numerous deficiencies or a serious specific deficiency and the facility is not in substantial compliance with this subpart and the Department finds that:

(1) The facility is taking appropriate steps to correct the deficiencies in accordance with a timetable submitted by the facility and agreed upon by the Department.

(2) There is no cyclical pattern of deficiencies over a period of 2 or more years.

(b) A provisional license will be issued for a specified time period of no more than 6 months.

(c) Upon a determination of substantial compliance, including the payment of any fines and fees, a regular license will be issued.

§ 201.13c. License Renewal.

(a) A facility shall apply to renew its license on a form prescribed by the Department with the fee required under section 807(b) of the act (35 P.S. § 448.807(b)).

(b) In addition to the application form and fee under subsection (a), a facility shall submit an updated annual financial report that meets the requirements set forth in § 201.12(b)(8) (relating to application for license of a new facility or change in ownership).

(c) A facility shall file an application to renew its license and the updated financial report at least 21 days before the expiration of the current license, unless otherwise directed by the Department.

(d) The Department will renew a regular 1-year license under this section if the facility is in full compliance with section 808 of the act (35 P.S. § 448.808) and is in full or substantial compliance with the provisions of this subpart.

(e) A provisional license issued in accordance with section 812 of the act (35 P.S. § 448.812) and § 201.13b (relating to provisional license) may be renewed, no more than three times at the discretion of the Department.

§ 201.14. Responsibility of licensee.

(a) The licensee is responsible for meeting the minimum standards for the operation of a facility as set forth by the Department and by other Federal, State and local agencies responsible for the health and welfare of residents. This includes complying with all applicable Federal and State laws, and rules, regulations and orders issued by the Department and other Federal, State or local agencies.

(b) If services are purchased for the administration or management of the facility, the licensee is responsible for ensuring compliance with all applicable Federal and State laws, and rules, regulations and orders issued by the Department and other Federal, State and local agencies.

(c) The licensee through the administrator shall report as soon as possible, or, at the latest, within 24 hours to the appropriate Division of Nursing Care Facilities field office serious incidents involving residents as set forth in § 51.3 (relating to notification). For purposes of this subpart, references to patients in § 51.3 include references to residents.

(d) [Reserved].

(e) [Reserved].

(f) Upon receipt of a strike notice, the licensee or administrator shall promptly notify the appropriate Division of Nursing Care Facilities field office, and the Office of the State Long-Term Care Ombudsman, and keep the Department apprised of the strike status and the measures being taken to provide resident care during the strike.

(g) A facility owner shall pay in a timely manner bills incurred in the operation of a facility that are not in dispute and that are for services without which the resident's health and safety are jeopardized.

(h) The facility shall report to the Department census, rate, program occupancy and any other information the Department may request. The Department will provide advance notice of new reporting requirements, except in instances of an emergency.

(i) The facility shall have on file the most recent inspection reports, relating to the health and safety of residents, indicating compliance with applicable Federal, State and local statutes and regulations. Upon request, the facility shall make the most recent report available to interested persons.

(j) The facility shall conduct a facility-wide assessment that meets the requirements of 42 CFR 483.70(e) (relating to administration), as necessary, but at least quarterly.

§ 201.15. Restrictions on license.

(a) [Reserved].

(b) A license becomes automatically void without notice if any of the following conditions exist:

(1) The license term expires unless the term expires due to a departmental delay, a Federal emergency or State disaster emergency.

(2) There is a change in ownership and the Department has not given prior approval.

(3) There is a change in the name of the facility, and the Department has not given prior approval.

(4) There is a change in the location of the facility and the Department has not given prior approval.

(c) [Reserved].

§ 201.15a. Enforcement.

Actions the Department may take to enforce compliance with the act and this subpart include but are not limited to the following:

(a) Requiring a plan of correction.

(b) Issuance of a provisional license.

(c) License revocation.

(d) Appointment of a temporary manager.

(e) Limitation or suspension of admissions to the facility.

(f) Assessment of fines or civil monetary penalties.

§ 201.15b. Appeals.

A final order or determination of the Department relating to licensure may be appealed by the provider of services to the Health Policy Board under section 2102(n) of The Administrative Code of 1929 (71 P.S. § 532(n)).

§ 201.17. Location.

With the approval of the Department, a facility may be located in a building with other providers and share services as follows:

(1) The provider is licensed, as applicable.

(2) The provider operates or provides other health-related services, such as personal care, home health or hospice services.

(3) The shared services may include services such as laundry, pharmacy and meal preparations.

(4) The facility shall be operated as a unit distinct from other health-related services.

§ 201.22. Prevention, control and surveillance of tuberculosis (TB).

(a) The facility shall have a written TB infection control plan with established protocols which address risk assessment and management, screening and surveillance methods, identification, evaluation, and treatment of residents and employees who have a possible TB infection or active TB.

(b) Recommendations of the Centers for Disease Control and Prevention (CDC), United States Department of Health and Human Services (HHS) shall be followed in screening, testing and surveillance for TB and in treating and managing persons with confirmed or suspected TB.

(c) [Reserved].

(d) [Reserved].

(e) [Reserved].

(f) [Reserved].

(g) [Reserved].

(h) [Reserved].

(i) [Reserved].

(j) [Reserved].

(k) [Reserved].

(l) [Reserved].

(m) [Reserved].

(n) [Reserved].

CHAPTER 209. FIRE PROTECTION AND SAFETY PROGRAMS FOR LONG-TERM CARE NURSING FACILITIES.

FIRE PROTECTION AND SAFETY

§ 209.1. [Reserved].

§ 209.7. [Reserved].

§ 209.8. [Reserved].

CHAPTER 211. PROGRAM STANDARDS FOR LONG-TERM CARE NURSING FACILITIES.

§ 211.1. Reportable diseases.

(a) When a resident develops a reportable disease, the administrator shall report the information to the appropriate health agencies and appropriate Division of Nursing Care Facilities field office. Reportable diseases, infections and conditions are listed in § 27.21a (relating to reporting of cases by health care practitioners and health care facilities).

(b) Cases of scabies or lice or bed bug infestations shall be reported to the appropriate Division of Nursing Care Facilities field office.

(c) Significant nosocomial outbreaks, as determined by the facility's medical director, Methicillin Resistant Staphylococcus Aureus (MRSA), Vancomycin-Resistant Staphylococcus Aureus (VRSA), Vancomycin-Resistant Enterococci (VRE) and Vancomycin-Resistant Staphylococcus Epidermidis (VRSE) shall be reported to the appropriate Division of Nursing Care Facilities field office.

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