

PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

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

Long-Term Care Facilities

The Department of Health (Department), after consultation with the Health Policy Board, proposes to amend 28 Pa. Code §§ 201.12—201.17, 201.22, 209.1, 209.7, 209.8 and 211.1 and add §§ 201.12a and 201.13a to read as set forth in Annex A.

The Department initially decided to submit proposed amendments to Subpart C (relating to long-term care facilities) in five separate packages. The Department acknowledges the concerns regarding the opportunity to comment holistically on this group of proposed rulemakings. The Department has since decided, in response to concerns raised during the public comment period for the previous packages, to reduce the number of proposed packages from five to four by combining the fourth and fifth packages. Given the volume of the regulations, and only slight overlap between packages, presenting the proposed amendments in separate packages has allowed the public a greater opportunity to thoroughly examine, over a longer period of time, the proposed amendments. This has afforded the public the opportunity to provide detailed comments to the proposed amendments. It has also allowed the Department to focus more closely on comments, provide a more considered response to questions and comments, and tailor the remaining proposed packages based on public and stakeholder input.

The Department will begin drafting the corresponding four final-form rulemaking packages after the public has had the opportunity, through the separate public comment periods provided for in each package, to review and comment on all four proposed rulemaking packages. This will ensure that the public has had an opportunity to vet and comment on each package separately as well as in relation to the other packages. For example, if a commentator believes that an amendment in proposed rulemaking 4 does not align with amendments that were proposed in proposed rulemaking 1, the commentator may comment on this during the 30-day public comment period for proposed rulemaking 4.

To be clear, the Department recognizes that it is imperative that the public have the opportunity to review each proposed package separately so that no detail is missed. Each separate package will contain important provisions that deserve to be the focus of discussion. Attempting to combine all four packages into one package will serve to diffuse public comment. The result would not be in the public's interest.

The Department is planning to hold meetings with stakeholders after each public comment period has ended. The first of these meetings, to discuss proposed groups 1 and 2, took place on December 15, 2021. Additional meetings will be scheduled to discuss proposed groups 3 and 4 after the public comment period has ended for each of those groups. The Department also intends to submit all four final-form regulatory packages to the House Health Committee, Senate Health and Human Services Committee, and the Independent Regulatory Review Commission (IRRC) together on the same day, so that all four final-form regulatory packages can be reviewed together as a whole.

As outlined in its first and second proposed rulemakings, the Department tentatively proposes to submit the amendments to Subpart C in the following sequence. The Department is providing this proposed schedule of amendments to aid the public in its review of the proposed packages. This is the third set of amendments to be proposed. The contents of the remaining, proposed rulemaking package, that is, proposed rulemaking 4, may change as the Department reviews and considers that content in the context of feedback received on proposed packages that have already been released for public consideration.

Proposed Rulemaking 1

§ 201.1. Applicability.

§ 201.2. Requirements.

§ 201.3. Definitions.

§ 211.12(i). Nursing Services.

Proposed Rulemaking 2

§ 201.23. Closure of facility.

Chapter 203. Application of Life Safety Code for Long-Term Care Nursing Facilities.

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

Chapter 205. Physical Environment and Equipment Standards for Long-Term Care Nursing Facilities.

§ 207.4. Ice containers and storage.

Proposed Rulemaking 3

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

§ 201.12a. Evaluation of application for license of a new facility or change in ownership. (new)

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

§ 201.13a. License renewal. (new)

§ 201.14. Responsibility of licensee.

§ 201.15. Restrictions on license.

§ 201.17. Location.

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

§ 209.1. Fire department service.

§ 209.7. Disaster preparedness.

§ 209.8. Fire drills.

§ 211.1. Reportable diseases.

Proposed Rulemaking 4

§ 201.18. Management.

§ 201.19. Personnel records. (new proposed title)

§ 201.20. Staff development.

§ 201.21. Use of outside resources.

§ 201.24. Admission policy.

§ 201.25. Discharge policy.

§ 201.26. Power of attorney.

§ 201.27. Advertisement of special services.

- § 201.29. Resident's rights.
- § 201.30. Access requirements.
- § 201.31. Transfer agreement.
- § 207.2. Administrator's responsibility.
- § 209.3. Smoking.
- § 211.2. Physician services.
- § 211.3. Oral and telephone orders.
- § 211.4. Procedure in event of death.
- § 211.5. Clinical 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.
- § 211.12. Nursing services.
- § 211.15. Dental services.
- § 211.16. Social services.
- § 211.17. Pet therapy.

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%. 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>. 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 nursing care during the remainder of their lifetime. 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>. Currently, there are approximately 73,000 Pennsylvanians residing in 689 long-term care nursing facilities licensed by the Department.

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. This proposed rulemaking is necessary to improve the quality of care delivered to residents, increase resident safety and minimize procedural burdens on health care practitioners who provide care to residents in long-term care nursing facilities.

The Department began the process of updating the current long-term care regulations in late 2017. The Department sought review, assistance and advice from members of a long-term care work group (LTC Work Group) consisting of relevant stakeholders. 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 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. Upon completion of the LTC Work Group's discussions, the Department conducted an internal review of the recommended changes. While the Department accepted most of the language and substantive changes proposed by the LTC Work Group and attempted to incorporate them in this proposed rulemaking, the Department is proposing additional changes to language and additional substantive changes, as well.

During 2019 and 2020, the Department conferred with other agencies, that will be potentially affected by the proposed regulatory changes, to seek their input on provisions within their substantive expertise. These agencies included the Department of Aging, DHS and DMVA. The Department received recommendations from these agencies regarding the draft proposed regulations and made additional changes to the proposed regulations to enhance patient safety and quality of care.

The Department in its first and second proposed rulemakings addressed inconsistencies between Federal and State requirements for long-term care nursing facilities licensed in the Commonwealth. In the first proposed rulemaking, the Department proposed to expand the adoption of the Federal requirements to include all of the requirements set forth in 42 CFR Part 483, Subpart B (relating to requirements for long term care facilities). The purpose of that amendment was to create consistency in the application of Federal and State requirements to long-term care nursing facilities in the Commonwealth. In the second proposed rulemaking, the Department proposed to amend existing regulations pertaining to the closure of a long-term care nursing facility to eliminate duplication between existing Federal requirements and State requirements. The Department also proposed in that rulemaking to update requirements for alterations, renovations or construction of long-term care nursing facilities.

In this third proposed rulemaking, the Department is shifting its focus to the requirements that a long-term care nursing facility must meet for licensure, as well as safety requirements and requirements for infection pre-

vention and control. The amendments in this proposed rulemaking include: the continued elimination of provisions that are duplicative of the Federal requirements, and updating requirements for the application for licensure of new facilities and changes in ownership for existing facilities.

Description of Proposed Amendments

Proposed amendments to address application for licensure of new facilities and changes in ownership for existing facilities

Federal regulations for long-term care nursing facilities require that a long-term care nursing facility be licensed under State and local laws. 42 CFR 483.70(a) (relating to administration). The Commonwealth's HCFA is the State law that governs the licensing of long-term care nursing facilities in this Commonwealth. Section 807 of the HCFA (35 P.S. § 448.807) requires any person desiring to secure a license to maintain and operate a health care facility, which includes long-term care nursing facilities, to submit an application containing the information the Department considers necessary to determine that the facility meets the requirements for licensure. In section 103 of the HCFA (35 P.S. § 448.103) a person is defined as a natural person, corporation (including associations, joint stock companies and insurance companies), partnership, trust, estate, association, the Commonwealth, and any local governmental unit, authority and agency thereof. As used in § 201.3 (relating to definitions) the term "facility" means a licensed long-term care nursing facility as defined in Chapter 8 of the HCFA (35 P.S. §§ 448.801—448.821). The Department, under section 808 of the HCFA (35 P.S. § 448.808), shall issue a license when it is satisfied that certain standards specified within the HCFA have been met. These standards include a determination that the health care provider is a responsible person, that the place to be used as a facility is adequately constructed, equipped, maintained and operated to safely and efficiently render the services offered, that the facility provides safe and efficient services which are adequate for the care, treatment and comfort of the residents of the facility, and that there is substantial compliance with the rules and regulations adopted by the Department under the HCFA.

With respect to a change in ownership for a long-term care nursing facility, Federal regulations specify that a facility must provide written notice to the State agency responsible for licensing the facility. See 42 CFR 483.70(k). The facility must disclose the name and address of each person with an ownership or control interest of 5% or more, whether any of these persons are related to one another, and the name of any other disclosing entity in the past 3 years in which any of these persons has had an ownership or control interest or has held a position as a managing employee. See 42 CFR 483.70(k); 42 CFR 420.206 (relating to disclosure of persons having ownership, financial, or control interest); and 42 CFR 455.104 (relating to disclosure by Medicaid providers and fiscal agents: information on ownership and control). Section 809(a)(3) of the HCFA (35 P.S. § 448.809(a)(3)) states that a transfer of a health care facility may not occur without the Department's approval. The Department uses the change of ownership process as the mechanism for taking a license from one entity and giving it to another. To obtain approval from the Department, the new, proposed owner applies for licensure under § 201.12 (relating to application for license of a new facility or change in ownership). Thus, in practice, the Department has already been requiring the submission of an application under existing § 201.12 for new

long-term care nursing facilities and for changes in ownership for already existing long-term care nursing facilities. Existing § 201.12 contains similar disclosure requirements to the Federal regulations.

The Department, however, 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. The owner of Skyline Healthcare, Joseph Schwartz, began purchasing and operating long-term care nursing facilities from a small office above a pizza shop in New Jersey. Joseph Schwartz's wife co-owned most of the facilities, and their two sons were vice-presidents of the business. Joseph Schwartz started small with approximately half a dozen facilities, but rapidly began expanding the business. By 2017, it was estimated that Joseph Schwartz was operating more than 100 long-term care nursing facilities Nationwide. At least half of these facilities were leased from Golden Living Centers, whom Joseph Schwartz blamed for issues that arose in the operation of those facilities. Allegations of resident neglect, unpaid bills and bounced checks, and even a resident's death, led to investigations of Skyline in multiple states. 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>. Here, in this Commonwealth, the Department was forced to install temporary

management at nine facilities when it became clear that Skyline could no longer fiscally operate the facilities. 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 of what happened with Skyline. 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, therefore, in this proposed rulemaking, is proposing several changes and additions to the regulations to clarify the licensure process for new long-term care nursing facilities and renewal of licenses for existing facilities, and to address changes in ownership. These changes and additions go above and beyond the Federal requirements and are being proposed to ensure the health and safety of residents. These changes are detailed more fully as follows.

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

The Department is proposing to add "of a new facility or change in ownership" to the title of this section. The Department has always required the submission of an application under existing § 201.12 for changes in ownership for already existing facilities, in addition to new facilities. To eliminate confusion, the Department is proposing to add "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. The Department is also proposing several new requirements in this section, described as follows, to aid the Department in evaluating a person's ability to operate a long-term care nursing facility.

Subsection (a)

The Department is proposing to delete this subsection and to replace it with new subsections (a.1) and (a.2) described as follows.

Subsection (a.1)

The Department is proposing to move the first sentence from § 201.13(a) (relating to issuance of license for a new facility or change in ownership) into this subsection, with modifications. Specifically, the Department is proposing to replace the words "maintain or operate a facility" with the words "operate or assume ownership of a facility." The Department is proposing the deletion of the word "maintain" because renewals of licenses for existing facilities will be addressed separately in new proposed § 201.13a (relating to license renewal). Moving this language, with

this modification, to § 201.12 makes 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)

The Department is proposing to move the second sentence from existing subsection (a) into this subsection, with modifications. Specifically, the Department is proposing 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. The Department is proposing to delete the "Bureau of Quality Assurance" from the regulation because it is expected that this office will undergo a name change in the future.

Subsection (b)

Subsection (b) specifies information that shall be submitted with an application for licensure of a long-term care nursing facility. The Department is proposing to amend the phrase "the following shall be submitted with the application for licensure" with the phrase "in addition to the completed application and fee required under section 807 of the act, a person seeking to operate or assume ownership of a facility shall submit the following" to clarify that the requirements in this subsection are in addition to the form and fee required by section 807 of the act. Section 807(a) of the act requires a person seeking to operate a long-term care nursing facility to submit an application on a form prescribed by the Department, and section 807(b) of the act delineates the fee that is required to be submitted with an application for licensure. As provided for in proposed subsection (a.2), a person may obtain this application from the Division of Nursing Care Facilities in the Department.

Paragraph (1)

The Department is proposing to rephrase the requirements in paragraph (1). The Department is proposing to replace the phrase "names and addresses" with the phrase "names, addresses, e-mail addresses and phone numbers" throughout this paragraph. The Department is proposing to add the phrase, "or will have an ownership or control interest in the facility, whether the interest is in its profits or in the land or building occupied and used as the facility." This proposed language clarifies that this information is required not only for individuals who currently have an ownership interest in a facility but also those that will have an ownership or control interest, as is the case with a change in ownership. Expanding the requirement to include e-mail addresses and phone numbers will provide the Department with additional means of contacting individuals who have or will have an ownership interest in the facility. E-mail addresses and phone numbers also tend to be the most effective and efficient way to communicate with individuals.

The Department is additionally proposing to add the phrase "[f]or purposes of this section, a person who has ownership or control interest is a person with a . . ." before the existing phrase ". . . direct or indirect ownership interest of 5% or more in the facility" and to add the phrase "the organization that holds the license or the land or building occupied and used in the facility" to define the types of persons the Department considers as having an ownership or a control interest in the facility. The Department proposes to break these requirements into subparagraphs (i) and (ii), respectively, for clarity.

Paragraphs (2), (3) and (4)

The Department is proposing in paragraph (2) to add the requirement that a person seeking to operate or assume ownership of a facility provide e-mail addresses and phone numbers for owners who are nonprofit corporations of the officers and directors of the corporation. The Department is proposing in paragraph (3) to require partnerships to provide e-mail addresses and phone numbers of the partners. The Department is proposing in paragraph (4) to add the requirement that the e-mail address and phone number of the administrator be provided as well. Expanding the existing requirements in paragraphs (2), (3) and (4) to include e-mail addresses and phone numbers 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 also proposes to amend the word "owner" to "person" for consistency in the use of that term throughout this section and in the HCFA.

Paragraph (5)

This proposed paragraph is new. The Department is proposing, in this paragraph, to require the names, addresses, e-mail addresses and phone numbers of any persons that have or will have a direct or indirect interest in the management of the facility or the provision of services at the facility. Having this contact information provides the Department with a means of contacting the individuals who are responsible for the management of the facility or provision of services, in the event that there is an issue at the facility.

Paragraph (6)

This proposed paragraph is new. The Department is proposing to require that corporate history be submitted with the application. The corporate history of the person seeking to operate or assume ownership of a facility will demonstrate whether the person has a sound background in business management, and whether the person has been involved in businesses that have incurred financial distress or legal difficulties. A person with a corporate history of financial or legal difficulties may not be able to operate a long-term care nursing facility.

Paragraph (7)

This proposed paragraph is new. The Department is proposing to require a person seeking to operate or assume ownership of a facility to provide a list of every licensed facility in any state, the District of Columbia or territory in which the applicant has or had any percentage of interest in the ownership, management or real property of that facility. Having this list will allow the Department to investigate an applicant's experience with owning or managing other facilities. Prior and 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.

Paragraph (8)

This proposed paragraph is new. The Department is proposing to require a person seeking to operate or assume ownership of a facility to provide their licensing and regulatory history in all jurisdictions where they have or have had a direct or indirect ownership interest in a long-term care nursing facility. The licensing and regulatory history of a prospective owner's other long-term care nursing facilities demonstrates the prospective owner's ability to provide quality care to residents. A history of noncompliance or licensing issues, such as

revocation of a license, demonstrate that there may be issues regarding the applicant's ability to properly manage a facility or care for residents. Conversely, no history of compliance issues is an indicator that the facilities owned by the person are well managed and provide quality care to residents.

Paragraph (9)

This proposed paragraph is new. The Department is proposing to require a person seeking to operate or assume ownership of a facility to provide a detailed summary of current or settled civil actions or criminal actions filed against the person. Civil and criminal actions may not always be captured in a person's licensing and regulatory history. A wrongful death action, for example, may show that a person acted inappropriately in providing care to a resident, but may slip through the cracks from a regulatory perspective. Requiring a person to provide this type of information provides an additional mechanism for capturing potential performance issues during the application process.

Paragraph (10)

This proposed paragraph is new. The Department is proposing to require a person seeking to operate or assume ownership of a facility to 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 nursing facilities, the land it sits on or the building in which it is located. For a long-term care nursing facility to provide quality care, the 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 owner's financial health, the Department will be able evaluate the ability of the prospective owner to properly operate a long-term care nursing facility.

Paragraph (11)

This proposed paragraph is new. The Department is proposing to add, in this paragraph, a catch-all provision that will require a person seeking to operate or assume ownership of a facility to provide any additional information the Department may require. This catch-all provision will provide the Department with flexibility to require additional information as circumstances warrant. The Department recognizes, especially given the lessons learned during the novel coronavirus (COVID-19) pandemic, that there may be circumstances when more information is needed to support an application for licensure of a long-term care facility. Without this additional requirement, these issues could evade review during the initial application process.

Subsection (c)

This proposed subsection is new. The Department is proposing to include 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 proposed amendments to subsection (b) focus on requirements that will allow the Department to assess the financial health and stability of a person, as well as a person's history in operating long-term care nursing facilities. The proposed requirements in subsection (c), on the other hand, are intended to provide the Department with additional infor-

mation, detailed as follows, regarding the person's intentions with respect to the actual operation of the long-term care nursing facility, to ensure that the person will be able to provide safe and adequate care for long-term care nursing residents.

Paragraphs (1) through (5)

The Department is proposing in paragraph (1) to require a person seeking to operate or assume ownership of a facility to provide a proposed staffing and hiring plan, which shall include management and oversight staff and the participants of the governing body. The Department is proposing in paragraph (2) to require an applicant to provide a proposed training plan for staff. The Department is proposing in paragraph (3) to require an applicant to provide a proposed emergency preparedness plan that meets the requirements of 42 CFR 483.73(a) (relating to emergency preparedness). The Department is proposing in paragraph (4) to require a person seeking to operate or assume ownership of a facility to provide proposed standard admissions and discharge agreements. The Department is proposing in paragraph (5) to require an applicant to provide a detailed budget for 3 years of operations, prepared in accordance with generally accepted accounting principles and evidence of access to sufficient capital needed to operate the facility in accordance with the budget and facility assessment. Having this information will allow the Department to assess the reasonableness of a prospective owner's proposed plans and the prospective owner's level of preparedness to operate a long-term care nursing facility.

Subsection (d)

This proposed subsection is new. The Department recognizes that the application process being proposed is arduous and that mistakes can happen. In addition, the Department may need additional information or explanations regarding information submitted with the application. The Department is therefore proposing to add language to allow an applicant 30 days from the date of the denial of an application to cure defects in the application.

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

This proposed section is new. The Department is proposing, in this section, to outline the Department's 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 applicants as to what the Department will be considering in its evaluation of applicants.

Subsection (a)

Under proposed subsection (a), the Department will consider the application form and documents submitted under § 201.12.

Subsection (b)

Under this proposed subsection, the Department will approve or deny an application upon completion of the evaluation conducted under subsection (a).

Subsection (c)

In this proposed subsection, the Department has outlined what it will consider in determining whether it may 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 demon-

strated financial and organizational capacity and capability to successfully perform the requirements of operating a facility, and the applicant'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.

The Department will evaluate each application to determine whether the applicant can operate a long-term care facility.

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

The Department is proposing to add "for a new facility or change in ownership" to the title of this section to describe the contents of this section more accurately. The Department is proposing changes, detailed as follows, throughout this section to clarify that the contents of this section apply to new facilities or changes in ownership for existing facilities. License renewals for existing facilities will be addressed in new proposed § 201.13a.

Subsection (a)

The Department is proposing to delete this subsection. As noted previously, the Department is proposing to move the first sentence of this subsection into § 201.12(a.1) with changes. 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. The Department uses the change of ownership process as the mechanism for taking a license from one entity and giving it to another. To obtain approval from the Department, the new, proposed owner applies for licensure under existing § 201.12. To eliminate confusion, the Department is proposing to update § 201.12 and add new requirements under § 201.12a to clarify what exactly is required of both new applicants and those who desire to assume ownership of an already existing facility.

Subsection (b)

The Department is proposing to delete existing language in this subsection requiring an inspection. The Department conducts inspections or surveys, before the issuance of a license for a new facility. See 35 P.S. § 448.806d(a); 35 P.S. § 448.813(a); 35 P.S. §§ 448.806d(a) and 448.813(a)). However, depending on the circumstances, the Department may or may not conduct a survey when there is a change in ownership. For example, if the Department's surveyors were recently in the facility, there may be no need for a survey because the facility has already been inspected. Once the change in ownership has been approved, a survey may be conducted if there is a concern that the facility is not adhering to the Department's regulations. Notwithstanding this practice, the Department has the authority, under sections 806d(a) and 813(a) of the act, to conduct a survey under the act for both the issuance of license for a new facility and a change in ownership. The Department is preserving that right by retaining the language in subsection (e). It is not necessary to retain the requirement of a survey in this particular subsection because, as noted previously, it is already required in the act and in current § 201.13(e), which the Department is retaining, without amendment.

The Department is also proposing to delete references to an application form and licensure fee. Requirements for the application and licensure fee are addressed in the

act and in the proposed changes to § 201.12, as described previously. The Department is proposing to add cross-references to §§ 201.12 and 201.12a to clarify that a license will be issued after the Department receives a completed application, fee, and all of the additional information required to be submitted with an application under § 201.12, and after the Department has completed the evaluation process under § 201.12a.

Subsection (c)

The Department is proposing to delete 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. Section 807(b) of the act 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.

Subsection (d)

The Department is proposing to add “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 is proposing to delete “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 is proposing no changes to subsection (e).

Subsection (f)

The Department is proposing to delete subsection (f) to eliminate duplication and potential confusion between the regulations and the act. The circumstances under which the Department will issue a provisional license are covered in section 812 of the act (35 P.S. § 448.812).

Subsection (g)

The Department is proposing to move subsection (g) into § 201.14 (relating to responsibility of licensee), based on the Department’s decision to amend this section so that it applies only 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 will clarify that this responsibility applies to all facilities.

Subsection (h)

The Department is proposing to delete the language in existing subsection (h), pertaining to plans of correction, because it is duplicative of the requirements in the HCFA 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 shall 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.

Subsection (i)

The Department is proposing to delete subsection (i) to eliminate duplication and potential confusion between the

regulations and the requirements in the act. Section 809(b) of the act provides that a license shall at all times be posted in a conspicuous place on the premises.

§ 201.13a. License renewal

The Department is proposing the addition of this new section to separate the requirements for license renewals from the requirements for licenses of new facilities and changes in ownership for existing facilities.

Subsection (a)

This proposed subsection will require 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 or burden on facilities.

Subsection (b)

This proposed subsection specifies that the Department will renew a license after a survey is conducted which indicates that the facility is in substantial compliance with the act. This is already required of facilities seeking to renew their licenses, and thus, does not impose any new obligation or burden on facilities.

§ 201.14. Responsibility of licensee

Subsection (a)

The Department is proposing to add the word “Federal” in the first sentence to clarify that licensees are responsible for adhering to Federal as well as State and local minimum standards. The Department is also proposing to add the following sentence to this subsection, “This includes complying with all applicable Federal and State laws, and rules, regulations and orders issued by Federal, State or local agencies.” The purpose of this addition is to make it clear that all licensees are required to adhere to all applicable Federal and State laws, and rules, regulations and orders issued by 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)

The Department is proposing to remove the word “the” from this subsection for grammatical reasons. The Department is also proposing to replace the word “insuring” with “ensuring” for the correct usage and spelling of that term. The Department is proposing to replace 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 is proposing this change for uniformity with the requirement in subsection (a) and 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 issued by Federal, State and local entities is imperative to ensure the health and safety of residents.

Subsection (c)

The Department is proposing to add “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 is proposing to move this language from subsection (e) into subsection (c) and to delete subsection (e) to streamline this requirement and for ease of readability. The Department is also proposing to move the phrase “as set forth in § 51.3 (relating to notification)” into the first sentence, for grammatical reasons.

Subsection (d)

The Department is proposing to delete 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 requirements in § 51.3.

Subsection (e)

The Department is proposing to delete this subsection as explained in subsection (c).

Subsection (f)

The Department is proposing no changes to this subsection.

Subsection (g)

The Department is proposing no changes to this subsection.

Subsection (h)

The Department is proposing to delete “and” before “program” and add “and any other” before the word “information” in this subsection. The addition of “and any other” before “information” will provide 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 is proposing to add 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 is proposing to delete “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.

Subsection (i)

As explained previously, the Department is proposing to move the language from § 201.13(g) to this subsection. The Department proposes to add the word “Federal” to the requirement that a facility have on file the most recent inspection reports. Facilities that participate in Medicare or Medical Assistance are subject to surveys for compliance with the Federal requirements.

Subsection (j)

This proposed subsection is new. The Department is proposing to require long-term care nursing facilities 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 has determined 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 assess the needs of residents and ensure that residents are receiving the most appropriate care and services.

*§ 201.15. Restrictions on license**Subsections (a)*

The Department is proposing to delete subsection (a) as it is duplicative of sections 809(a)(3) and (4) of the act. Section 809(a)(3) 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 change of ownership process as the mechanism for taking a license from one entity and giving it to another. Changes in ownership are addressed in proposed §§ 201.12 and 201.13, as discussed previously.

Subsection (b)

The Department is proposing to keep the existing language, in this subsection, with minor changes for clarity and ease of readability. The Department is proposing to add 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. In paragraph (1), the Department is proposing to replace the phrase “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. In paragraph (3), the Department is proposing to delete “for the transfer of the license” to eliminate confusion in terminology because as discussed previously, the Department uses the change of ownership process as the mechanism for taking a license from one entity and giving it to another. Changes in ownership are addressed in proposed §§ 201.12 and 201.13. The Department is proposing no changes to paragraphs (2) and (4).

Subsection (c)

The Department is proposing no changes to subsection (c).

§ 201.17. Location

The Department proposes to delete the existing language in this section. The existing language in § 201.17 (relating to location) requires the operation of a facility to be distinct from other related services when the facility is located in the same building as other related services.

The Department proposes to replace the existing language 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.

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 Department proposes the previous language to accommodate 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.

Proposed amendments to address infection prevention and control

In its first proposed rulemaking, the Department proposed to expand its adoption of the Federal requirements to include all of the requirements set forth in 42 CFR Part 483, Subpart B. Under the Department's proposal, all long-term care nursing facilities, even those that do not participate in Medicare or Medicaid, will be required to comply with the Federal requirements. The Department carefully reviewed and considered recommendations from advocacy groups for proposed regulations for infection prevention and control and noted that for the most part, these recommendations align with what is already required by the Federal requirements. The Federal requirements for infection prevention and control, which are located at 42 CFR 483.80 (relating to infection control), are extensive and in the Department's view, thoroughly and adequately address the health and safety needs of residents in long-term care nursing facilities. For example, the Federal requirements have been continuously updated as information has become available regarding best practices for COVID-19 infection control, testing and immunizations. Because the Federal requirements are so robust, the Department is proposing to defer to the Federal requirements in this area and to not add any additional requirements above and beyond the Federal requirements.

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

Subsection (a)

The Department is proposing only one change to this subsection. The Department proposes to amend "employees" with "employees" to reflect the current usage and spelling of that term.

Subsection (b)

The Department is proposing to add "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 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 is proposing to add "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)

The Department is proposing to delete 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.

Proposed amendments to address fire protection and safety and emergency preparedness

In its first proposed rulemaking, the Department proposed to expand its adoption of the Federal requirements to include all of the requirements set forth in 42 CFR Part 483, Subpart B. Under the Department's proposal, all long-term care nursing facilities, even those that do not participate in Medicare or Medicaid, will be required to comply with the Federal requirements. The Department carefully reviewed and considered recommendations from advocacy groups for fire protection and safety and emergency preparedness and noted that for the most part, these recommendations align with what is already required by the Federal requirements. The Federal requirements for fire protection and safety and emergency preparedness, which are located at 42 CFR 483.90 (relating to physical environment) and 42 CFR 483.73, are robust and in the Department's view, thoroughly and adequately address the health and safety needs of residents in long-term care nursing facilities. Since the Federal requirements are so robust, the Department is proposing to defer to the Federal requirements in this area and to delete any requirements in the current regulations which conflict with or duplicate the Federal requirements.

§ 209.1. Fire department service

The Department is proposing to delete this section as it is outdated and covered by the Department's proposed adoption of the Federal requirements in the proposed amendments to § 201.2 (relating to requirements), which are addressed in the Department's first proposed rulemaking published at 51 Pa.B. 4074 (July 31, 2021). The Federal requirements include requirements for smoke alarms and sprinkler systems, and also incorporate by reference the National Fire Protection Association's Life Safety Code (NFPA 101). See 42 CFR 483.90. The NFPA 101 includes requirements for fire protection and the safety of residents, including fire department service.

§ 209.7. Disaster preparedness

The Department is proposing to delete this section as it is outdated and covered by the Department's proposed adoption of the Federal requirements in the proposed amendments to § 201.2, which are addressed in the Department's first proposed rulemaking published at 51 Pa.B. 4074. 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.

§ 209.8. Fire drills

The Department is proposing to delete this section as it is outdated and covered by the Department's proposed adoption of the Federal requirements in the proposed amendments to § 201.2, which are addressed in the Department's first proposed rulemaking published at

51 Pa.B. 4074. Requirements for fire drills are addressed in the NFPA 101, which is incorporated by reference in the Federal requirements. See 42 CFR 483.90.

§ 211.1. *Reportable diseases*

Based on the recommendations of the LTC Work Group, and due to a rise in bed bug infestations, the Department is proposing to add “bed bug infestations” to the reporting requirements of subsection (b). As discussed previously, the Department is not proposing to add any additional requirements for infection prevention and control based on its adoption of the Federal requirements as State licensure requirements for long-term care nursing facilities.

Fiscal Impact and Paperwork Requirements

Fiscal Impact

Commonwealth.

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 proposed elimination of sections, as described previously, that are duplicative of the Federal requirements will streamline the survey process for long-term care nursing facilities. This, in turn, will create consistency and eliminate confusion in the application of standards that apply to long-term care nursing facilities.

However, the proposed amendments to the application process outlined in §§ 201.12 and 201.13 will result in costs to the Department. The Department will be required to hire additional staff with sufficient expertise to review and evaluate the financial and other documents that will be required with the new proposed requirements in § 201.12. This review will need to be performed in a very timely manner to prevent any delay in the approval or disapproval of an application for licensure.

Through discussions with other States, the Department learned that the Florida Department of Health (Florida DOH) has a separate financial unit in place that is responsible for the financial analysis of all facility types licensed by the Florida DOH. The Florida DOH financial unit consists of four accounting specialists supervised by an accounting manager, who is a certified public accountant. The Department anticipates that a similar unit would be required to review and process applications, including review of the new information required by the proposed changes to § 201.12. The Department estimates that this will result in an approximate cost of \$600,000 during the unit’s first year of operation. This estimate includes an estimated \$590,312 for salaries and benefits and initial operating costs of \$9,250 for IT equipment and office space for the unit. The Department envisions that this unit will not only review the financial information submitted with an application for licensure, but will also review the other, new types of information that is being proposed under the amendments.

The Department also estimates that there will be a cost to update the actual license to add the information contained in proposed § 201.13 and to update the computer system for the creation of any reports that are internally required for review of the new information required in § 201.12. The Department is not able to estimate the exact cost of this update at this time. It is estimated that the Department will need to expend approximately \$55,000 to make these updates; this cost includes a vendor assessment.

DMVA

The Department’s proposal to require a facility to complete a facility assessment on at least a quarterly basis goes above and beyond what is required by the Federal requirements, and therefore, may impose some financial burden on facilities. The Department consulted with DMVA, who operates six long-term care nursing facilities in this Commonwealth and would be required to meet this requirement as these facilities currently only perform an annual facility assessment. DMVA indicated that the cost of conducting a facility assessment is insignificant, as it generally just involves compiling information. The facilities operated by DMVA employ quality assurance staff to perform his function. These staff members are compensated at approximately \$65.42 per hour, which includes salary and benefits. Approximately 10 hours per month is spent working on the facility assessment, for an approximate annual cost of \$7,850.95, to meet the current, annual requirement. DMVA does not anticipate an increase in costs or labor to meet the new proposed requirement. Updating the facility assessment on at least a quarterly basis will allow a facility to properly assess the needs of residents and ensure that residents are receiving the most appropriate care and services, thus outweighing any financial burden from performing the additional assessments.

Regulated community

The Department anticipates little to no financial impact on the 689 licensed long-term care nursing facilities as a result of the proposed elimination of sections that are duplicative of the Federal requirements. All but 3 of the 689 long-term care nursing facilities participate in either Medicare or Medicaid and thus, are required to comply with existing Federal requirements. The three long-term care nursing facilities that do not participate in Medicare or Medicaid may be impacted if they do not already meet the minimum standards within the Federal requirements. However, any financial impact to the three facilities that do not participate in Medicare or Medicaid is outweighed by the need for consistency in the application of standards to all long-term care nursing facilities, regardless of whether the facilities participate in Medicare or Medicaid.

The Department’s proposal to require a facility to complete a facility assessment on at least a quarterly basis goes above and beyond what is required by the Federal requirements, and therefore, may impose some financial burden on facilities. The Department does not have sufficient data to estimate with any certainty the cost impact of requiring additional assessments. The Department believes that many facilities may already be conducting a facility assessment more often than once a year. Those that are not conducting a facility assessment on a quarterly basis may incur some costs related to additional staff hours to conduct the assessment. The Department consulted with DMVA, who operates six long-term care nursing facilities in this Commonwealth and would be required to meet this requirement as these facilities currently only perform an annual facility assessment. DMVA indicated that the cost of conducting a facility assessment is insignificant, as it generally just involves compiling information. The facilities operated by DMVA employ quality assurance staff to perform his function. These staff members are compensated at approximately \$65.42 per hour, which includes salary and benefits. Approximately 10 hours per month is spent working on the facility assessment, for an approximate annual cost of \$7,850.95, to meet the current, annual requirement. DMVA does not anticipate an increase in

costs or labor to meet the new proposed requirement. Updating the facility assessment on at least a quarterly basis will allow a facility to properly assess the needs of residents and ensure that residents are receiving the most appropriate care and services, thus outweighing any financial burden from performing the additional assessments. In addition, a facility may be able to identify cost saving measures during the course of the assessment which would benefit both the facility and the residents and would offset any cost associated with conducting the assessment more often.

The proposed amendments to the application for licensure will only impact existing facilities when there is a proposed change in ownership. Prospective owners of new and existing facilities will be required to submit additional paperwork and will be subject to greater scrutiny under the proposed regulations. This could make it more difficult for existing facility owners to sell their facilities.

Local government

There are currently 20 county-owned long-term care nursing facilities which account for approximately 8% (8,706 beds) of long-term care nursing beds across this Commonwealth. Allegheny County owns four of the nursing homes; the remaining homes are in the following 16 counties: Berks, Bradford, Bucks, Chester, Clinton, Crawford, Cumberland, Delaware, Erie, Indiana, Lehigh, Monroe, Northampton, Philadelphia, Warren and Westmoreland. All of the county-owned long-term care nursing facilities participate in either Medicare or Medicaid. Because these facilities are already required to comply with Federal requirements, they will not incur a cost as a result of the Department's proposed elimination of sections that are duplicative of the Federal requirements.

The Department's proposal to require a facility to complete a facility assessment on at least a quarterly basis goes above and beyond what is required by the Federal requirements, and therefore, may impose some financial burden on county-owned facilities. The Department does not have sufficient data to estimate with any certainty the cost impact of requiring additional assessments. The Department believes that many facilities may already be conducting a facility assessment more often than once a year. Those that are not conducting a facility assessment on a quarterly basis may incur some costs related to additional staff hours to conduct the assessment. The Department consulted with DMVA, who operates six long-term care nursing facilities in this Commonwealth and would be required to meet this requirement as these facilities currently only perform an annual facility assessment. DMVA indicated that the cost of conducting a facility assessment is insignificant, as it generally just involves compiling information. The facilities operated by DMVA employ quality assurance staff to perform his function. These staff members are compensated at approximately \$65.42 per hour, which includes salary and benefits. Approximately 10 hours per month is spent working on the facility assessment, for an approximate annual cost of \$7,850.95, to meet the current, annual requirement. DMVA does not anticipate an increase in costs or labor to meet the new proposed requirement. Updating the facility assessment on at least a quarterly basis will allow a facility to properly assess the needs of residents and ensure that residents are receiving the most appropriate care and services, thus outweighing any financial burden from performing the additional assessments. In addition, a facility may be able to identify cost saving measures during the course of the

assessment which would benefit both the facility and the residents and would offset any cost associated with conducting the assessment more often.

The proposed amendments to the application for licensure will only impact existing facilities when there is a proposed change in ownership, and new facilities. Prospective owners of new and existing facilities will be required to submit additional paperwork and will be subject to greater scrutiny under the proposed regulations. This could make it more difficult if the counties listed previously decide to sell their facilities.

Prospective owners of long-term care nursing facilities

Prospective owners of long-term care nursing facilities will be impacted by the amendments to the application for licensure. These prospective owners will be required to submit additional paperwork and will be subject to greater scrutiny under the proposed regulations. The Department does not have the ability to determine what costs a prospective owner may incur from providing this additional paperwork. The Department, however, is not requiring that a prospective owner submit this paperwork in any type of specific format, which may ease some of the burden. Some of the paperwork that will be required, such as financial documentation, may already be in the prospective owner's possession. Other paperwork, such as a staffing plan and an emergency preparedness plan, may need to be developed for the application for licensure if the prospective owner has not already prepared these documents as part of their business and operation plans. A prospective owner may incur a cost if they choose to consult with someone, such as an accountant or attorney when compiling this paperwork.

General public

There is expected to be no cost to the general public. The proposed amendments to the application for licensure process will provide peace of mind to the general public, especially those who reside in long-term care nursing facilities and their families, by ensuring that prospective owners are properly vetted. In addition, the proposed changes to § 201.12(d) to include the name and address of the owner of the facility will allow residents, and their families, to identify more readily who to contact if a problem occurs at the facility. These changes will provide much needed transparency in the process and allow for residents, and their families, to make informed decisions regarding where to go for their care.

Paperwork Requirements

There will be no change to the actual application form for licensure. This form is already required under existing § 201.12, and already covers new licenses, changes in ownership and license renewals. The proposed amendments to § 201.12 will require those seeking to operate a new long-term care nursing facility or to assume ownership of an already existing facility to submit additional paperwork but will not change what is already on the current application form for licensure. The Department is not proposing a specific format for the submission of this paperwork.

Under proposed § 201.14(j), long-term care nursing facilities will be required to complete a facility assessment, as needed, but at least quarterly, that meets the requirements of 42 CFR 483.70(e). This may be a new paperwork requirement for the three facilities that do not participate in either Medicare or Medicaid. The remaining facilities that participate in either Medicare or Medicaid are already required to complete a facility assessment at least annually under the Federal requirements but will

need to adjust their process to account for the additional assessments that are proposed under § 201.14(j). The Department is only requiring that the contents of the facility assessment meet, at a minimum, the requirements of 42 CFR 483.70(e) and is not proposing to impose any particular form or format for this information.

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 proposed rulemaking will become effective upon publication in the *Pennsylvania Bulletin* as a final-form rulemaking. A sunset date will not be imposed. The Department will monitor the regulation 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 a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to IRRC and to the Chairpersons of the Senate Health and Human Services Committee and the House Health Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations, or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review prior to final publication of the rulemaking, by the Department, the General Assembly and the Governor.

Contact Person

Interested persons are invited to submit comments, suggestions or objections to the proposed regulations within 30 days after publication of this notice in the *Pennsylvania Bulletin*. The Department prefers that comments, suggestions or objections be submitted by e-mail to RA-DHLTCRegs@pa.gov. Persons without access to e-mail may submit comments, suggestions or objections to Lori Gutierrez, Director, Office of Policy, 625 Forster Street, Room 814, Health and Welfare Building, Harrisburg, PA

17120, (717) 317-5426. 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 Lori Gutierrez at the previously listed e-mail, address or telephone number so that necessary arrangements can be made. Comments should be identified as pertaining to proposed rulemaking 10-223 (Long-term care nursing facilities, Proposed Rulemaking 3).

KEARA KLINEPETER, MSHCPM,
Acting Secretary

Fiscal Note: 10-223. (1) General Fund; (2) Implementing Year 2021-22 is \$0; (3) 1st Succeeding Year 2022-23 is \$655,000; 2nd Succeeding Year 2023-24 is \$620,000; 3rd Succeeding Year 2024-25 is \$651,000; 4th Succeeding Year 2025-26 is \$683,000; 5th Succeeding Year 2026-27 is \$718,000; (4) 2020-21 Program—\$23,093,000; 2019-20 Program—\$22,513,000; 2018-19 Program—\$23,009,000; (7) Quality Assurance; (8) recommends adoption. The Quality Assurance appropriation is able to absorb 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) [**An application for a license to operate a facility shall be made under section 807 of the act (35 P.S. § 448.807). The application form shall be obtained from the Division of Nursing Care Facilities, Bureau of Quality Assurance, Department of Health.] (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 person seeking to operate or assume ownership of a facility shall obtain an application form from the Division of Nursing Care Facilities, Department of Health.

(b) [**The following shall be submitted with the application for licensure] In addition to the completed application and fee required under section 807 of the act (35 P.S. § 448.807), a person seeking to operate or assume ownership of a facility shall submit the following:**

(1) [**The names and addresses of a person who has direct or indirect ownership interest of 5% or more in the facility as well as a written list of the names and addresses of the facility's officers and members of the board of directors.] The names, addresses, e-mail addresses and phone numbers of any person who has or will have an ownership or control interest in the facility, whether the interest is in its profits or in the land or building occupied and used as the facility, as well as a written list of the names, addresses, e-mail addresses and phone**

numbers of the facility's officers and members of the board of directors. For purposes of this subsection, a person who has or will have ownership or control interest is:

(i) A person with a direct or indirect ownership interest of 5% or more in the facility.

(ii) The organization that holds the license or the land or building occupied and used as the facility.

(2) If the [owner] person is a nonprofit corporation, a complete list of the [names and addresses] 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 the [owner] person is a partnership, the [names and addresses] 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 that have or will have a direct or indirect interest in the management of the facility or the provision of services at the facility.

(6) The person's corporate history.

(7) A list of every licensed facility in any state, the District of Columbia or territory in which the person has or had any percentage of interest in the ownership, management or real property of that facility.

(8) The person's licensing and regulatory history in all jurisdictions where the person has or has had a direct or indirect ownership interest in a facility.

(9) A detailed summary of current or settled civil actions or criminal actions filed against the person.

(10) Financial failures involving 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 nursing facility, the land it sits on or the building in which it is located.

(11) Any additional information the Department may require.

(c) In addition to the information required under subsection (b), a person seeking to operate or assume ownership of a facility shall provide 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 and discharge agreements.

(5) A detailed budget for 3 years of operations, prepared in accordance with generally accepted accounting principles, and evidence of access to

sufficient capital needed to operate the facility in accordance with the budget and the facility assessment.

(d) A person 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.

§ 201.12a. 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).

(b) Upon completion of the evaluation conducted under subsection (a), the Department will approve or deny the application.

(c) The Department will consider the following in determining whether to approve or deny an application:

(1) The person's past performance related to owning or operating a facility in this Commonwealth or other jurisdictions.

(2) The person'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 person's demonstrated history and experience with regulatory compliance, including evidence of consistent performance in delivering quality care.

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

(a) [A person may not maintain or operate a facility without first obtaining a license issued by the Department. A license to operate a facility is not transferable without prior approval of the Department.] (Reserved).

(b) A license to operate a facility will be issued when the Department [receives the completed application form and the licensure fee and when, after inspection by an authorized representative of the Department, it has been] has determined that the necessary requirements for licensure have been met under § 201.12 (relating to application for license of a new facility or change in ownership) and § 201.12a (relating to evaluation of application for a new facility or change in ownership).

(c) [The required fee for a license is:

Regular Licenses (new or renewal)	\$250
Each inpatient bed in excess of 75 beds ..	\$2
Provisional I License	\$400
Each inpatient bed.....	\$4
Provisional II License	\$600
Each inpatient bed.....	\$6
Provisional III License.....	\$800
Each inpatient bed.....	\$8
Provisional IV License.....	\$1,000
Each inpatient bed.....	\$10]

(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 [and types] of beds authorized and the date of the valid license.

(e) A regular license will be issued when, in the judgment of the Department, there is substantial compliance with this subpart.

(f) [A provisional license is governed by the following:

(1) A provisional license will be issued if there are numerous deficiencies or a serious specific deficiency and if the facility is not in substantial compliance with this subpart and the Department finds that:

(i) The applicant is taking appropriate steps to correct the deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the Department.

(ii) There is no cyclical pattern of deficiencies over a period of 2 or more years.

(2) The provisional license will be issued for a specified period of time not more than 6 months. The provisional license may be renewed, at the discretion of the Department, no more than three times. Upon substantial compliance with this subpart, a regular license will be issued.] (Reserved).

(g) [The facility shall have on file the most recent inspection reports, relating to the health and safety of residents, indicating compliance with applicable State and local statutes and regulations. Upon request, the facility shall make the most recent report available to interested persons.] (Reserved).

(h) [If the Department's inspection report indicates deficiencies, the facility shall indicate in writing its plans to make corrections and specify dates by which the corrective measures will be completed. The plans are valid only upon approval by the Department.] (Reserved).

(i) [The current license shall be displayed in a public and conspicuous place in the facility.] (Reserved).

§ 201.13a. 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. § 807(b)).

(b) The Department will renew a license to operate a facility after a survey is conducted by the Department that indicates the facility is in substantial compliance with section 808(a) of the act (35 P.S. § 448.808(a)) and this subpart.

§ 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 Federal, State or local agencies.

(b) If [the] services are purchased for the administration or management of the facility, the licensee is respon-

sible for [insuring] ensuring compliance with [this subpart, and other relevant Commonwealth regulations] 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 within 24 hours to the appropriate Division of Nursing Care Facilities field office serious incidents involving residents. [. As] 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) [In addition to the notification requirements in § 51.3, the facility shall report in writing to the appropriate division of nursing care facilities field office:

(1) Transfers to hospitals as a result of injuries or accidents.

(2) Admissions to hospitals as a result of injuries or accidents.] (Reserved).

(e) [The administrator shall notify the appropriate division of nursing care facilities field office as soon as possible, or, at the latest, within 24 hours of the incidents listed in § 51.3 and subsection (d).] (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 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 [, on forms issued by the Department,] census, rate [and], program occupancy and any other information [as] the Department may request.

(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) [A license shall apply only to the licensure, the name of the facility and the premises designated therein. It may not be transferrable to another licensee or property without prior written approval of the Department.] (Reserved).

(b) A license becomes automatically void without notice if any of the following conditions exist:

(1) The [expiration date has been reached] license term expires.

(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 [**for the transfer of the license**].

(4) There is a change in the location of the facility and the Department has not given prior approval.

(c) A final order or determination by 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.

[The facility shall be operated as a unit reasonably distinct from the other related services, if located in a building which offers various levels of health-related services.] With the approval of the Department, a facility may be located in a building that 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.

§ 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**] 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) [**A baseline TB status shall be obtained on all residents and employees in the facility.**] (Reserved).

(d) [**The intradermal tuberculin skin test is to be used whenever skin testing is done. This consists of an intradermal injection of 0.1 ml of purified protein derivative (PPD) tuberculin containing 5 tuberculin units (TU) using a disposable tuberculin syringe.**] (Reserved).

(e) [**The 2-step intradermal tuberculin skin test shall be the method used for initial testing of residents and employees. If the first test is positive, the person tested shall be considered to be infected. If the first test is negative, a second test should be administered in 1–3 weeks. If the second test is positive, the person tested shall be considered to be previously infected. If the second test result is negative, the person is to be classified as uninfected.**] (Reserved).

(f) [**Persons with reactions of ≥ 10 mm or persons with symptoms suggestive of TB regardless of the size of the test reaction, shall be referred for further diagnostic studies in accordance with CDC recommendations.**] (Reserved).

(g) [**A written report of test results shall be maintained in the facility for each individual, irrespective of where the test is performed. Reactions**

shall be recorded in millimeters of induration, even those classified as negative. If no induration is found, “0 mm” is to be recorded.] (Reserved).

(h) [**Skin test “negative” employees having regular contact of 10 or more hours per week with residents shall have repeat tuberculin skin tests at intervals determined by the risk of transmission in the facility. The CDC protocol for conducting a TB risk assessment in a health care facility shall be used to establish the risk of transmission.**] (Reserved).

(i) [**Repeat skin tests shall be required for tuberculin-negative employees and residents after any suspected exposure to a documented case of active TB.**] (Reserved).

(j) [**New employees shall have the 2-step intradermal skin test before beginning employment unless there is documentation of a previous positive skin reaction. Test results shall be made available prior to assumption of job responsibilities. CDC guidelines shall be followed with regard to repeat periodic testing of all employees.**] (Reserved).

(k) [**The intradermal tuberculin skin test shall be administered to new residents upon admission, unless there is documentation of a previous positive test.**] (Reserved).

(l) [**New tuberculin positive reactors (converters) and persons with documentation of a previous positive reaction, shall be referred for further diagnostic testing and treatment in accordance with current standards of practice.**] (Reserved).

(m) [**If an employee’s chest X-ray is compatible with active TB, the individual shall be excluded from the workplace until a diagnosis of active TB is ruled out or a diagnosis of active TB is established and a determination made that the individual is considered to be noninfectious. A statement from a physician stating the individual is noninfectious shall be required.**] (Reserved).

(n) [**A resident with a diagnosis of TB may be admitted to the facility if:**

(1) Three consecutive daily sputum smears have been negative for acid-fast bacilli.

(2) The individual has received appropriate treatment for at least 2-3 weeks.

(3) Clinical response to therapy, as documented by a physician, has been favorable.] (Reserved).

CHAPTER 209. FIRE PROTECTION AND SAFETY PROGRAMS FOR LONG-TERM CARE NURSING FACILITIES.

FIRE PROTECTION AND SAFETY

§ 209.1. [**Fire department service**] (Reserved).

[**The telephone number of the emergency services serving the facility shall be posted by the telephones in each nursing station, office and appropriate place within the facility.**]

§ 209.7. [**Disaster preparedness**] (Reserved).

[(a) The facility shall have a comprehensive written disaster plan which shall be developed and

maintained with the assistance of qualified fire, safety and other appropriate experts. It shall include procedures for prompt transfer of casualties and records, instructions regarding the location and use of alarm systems and signals and fire fighting equipment, information regarding methods of containing fire, procedures for notification of appropriate persons and specifications of evacuation routes and procedures. The written plan shall be made available to and reviewed with personnel, and it shall be available at each nursing station and in each department. The plan shall be reviewed periodically to determine its effectiveness.

(b) A diagram of each floor showing corridors, line of travel, exit doors and location of the fire extinguishers and pull signals shall be posted on each floor in view of residents and personnel.

(c) All personnel shall be instructed in the operation of the various types of fire extinguishers used in the facility.]

§ 209.8. [Fire drills] (Reserved).

[(a) Fire drills shall be held monthly. Fire drills shall be held at least four times per year per shift at unspecified hours of the day and night.

(b) A written report shall be maintained of each fire drill which includes date, time required for

evacuation or relocation, number of residents evacuated or moved to another location and number of personnel participating in a fire drill.]

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 [and] 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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