RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 27]

Complete Reporting of CD4 T-Lymphocyte, Viral Load and Genotyping Test Results Relating to HIV

The Department of Health (Department), with the approval of the Advisory Health Board (Board), amends 28 Pa. Code §§ 27.1, 27.4, 27.21a, 27.22, 27.23 and 27.32a—27.32e to read as set forth in Annex A.

(*Editor's Note*: Exhibits A through C and Exhibit E referenced in this preamble are attached to the Department's Regulatory Analysis Form (RAF) relating to this final-form rulemaking. The RAF may be obtained through the contact information listed as follows, or by searching the regulation number, 10-209, on the Independent Regulatory Review Commission's (IRRC) web site at www.irrc.state.pa.us.)

I. *Purpose and Background*

This final-form rulemaking amends the Department's requirements for the reporting of HIV infection. Those requirements, which had included the reporting of CD4 T-lymphocyte test results with a count of equal to or less than 200 cells/µL or a CD4 T-lymphocyte percentage of less than 14% of total lymphocytes, will now require the reporting of all CD4 T-lymphocyte cell counts and percentages relating to HIV infection, as well as the reporting of all viral load test results, including detectable and undetectable viral loads, and genotyping results related to HIV.

The Department added the reporting of cases of HIV infection and CD4 T-lymphocyte test results to its communicable and noncommunicable disease reporting regulations in 2002. At the time, it limited the required reporting of CD4 T-lymphocyte test results to those results at or below a certain count or percentage and did not require viral load or genotyping test result reporting at all. Since that time, the manner and ability to detect and treat persons with HIV and to suppress the virus in persons with the infection has changed and improved, and the need for complete reporting, and complete reporting of viral loads and genotyping as well as CD4 counts, has become apparent. The Centers for Disease Control and Prevention (CDC) of the Federal Department of Health and Human Services has made it clear that reporting of all CD4 T-lymphocyte cell counts, viral loads and genotyping test results related to HIV is essential to early and appropriate treatment. To stop the spread of HIV, prevent the emergence of new cases and keep those living with HIV healthy, the National HIV/AIDS Strategy for the United States, updated for 2020, (National HIV/AIDS Strategy) has, as its critical foci, widespread testing and linkage to care, broad support for people living with HIV to remain engaged in comprehensive care, universal viral suppression among persons living with HIV, and full access to Pre-Exposure Prophylaxis services to prevent the spread of disease. See National HIV/AIDS Strategy (July 2015), at Executive Summary 3, at https://files.hiv.gov/s3fs-public/nhas-update.pdf. Accessed February 23, 2018.

To achieve these goals, the CDC recommends, among other things, the reporting of all CD4 test results (counts and percentages) and all viral load results (undetectable and detectable specific values). See Letter from Kenneth G. Castro, MD, Assistant United States Surgeon General, United States Public Health Service and Amy Lansky, PhD, MPH, Deputy Director for Surveillance, Epidemiology and Laboratory Sciences, Division of HIV Prevention, CDC, a copy of which is attached hereto as Exhibit A. A letter directly to the former Secretary of Health, Karen Murphy, from the Director of the Office for State, Tribal, Local and Territorial Support and Deputy Director of the CDC, reiterated this position to the Commonwealth, as one of only six[1] states that did not collect all CD4 test results. See Letter from Jose T. Montero, MD, MHCDS, Director, Office for State, Tribal, Local and Territorial Support and Deputy Director, Centers for Disease, Control and Prevention, and Jonathan A. Mermin, MD, MPH, RADM and Assistant Surgeon General, United States Public Health Services, and Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention to Secretary Karen Murphy, dated February 8, 2017 (Letter to Secretary Murphy), a copy of which is attached hereto as Exhibit B. The letter stated the following:

> The updated National HIV/AIDS Strategy for the United States identifies primary goals to guide our collective national fight against HIV. The success in advancing several of these goals, ensuring sustained viral suppression for person living with HIV and measuring progress towards HIV care, relies on *laboratory reporting of HIV-related tests, including all CD4+ T-lymphocyte (CD4) and viral load test results, to local and national HIV surveillance systems*. Complete laboratory data are critical to identifying cases, measuring care and treatment outcomes, and measuring the effectiveness of public health interventions. Specifically, these data are often used to monitor disease progression, determine the stage of HIV infection, monitor receipt of HIV care and treatment, and make decisions about public health interventions. Both viral load and CD4 data are used to assess whether patients are responding to treatment: when treatment is successful, CD4 counts rise and viral loads fall. Current HIV clinical management guidelines call for CD4 and viral load testing at the time of diagnosis and regularly thereafter. When CD4 and viral load results are reported, public health agencies can determine access to care and treatment outcomes. For these reasons, CDC recommends complete state reporting of all HIV test results.

Letter to Secretary Karen Murphy, supra (emphasis added).

At the present time, Pennsylvania is one of only four states that do not collect all CD4 T-lymphocyte test results. See e-mail from Richard Selik (CDC/OID/NCHSTP) to Godwin Obiri, Epidemiology Supervisor, Bureau of Epidemiology, Department of Health, attached hereto as part of Exhibit C. In addition, of the 50 states, only Pennsylvania and Idaho fail to require the reporting of all viral load test results. See e-mail from Richard Selik (CDC/OID/NCHSTP) to Godwin Obiri, Epidemiology Supervisor, Bureau of Epidemiology, Pennsylvania Department of Health, attached hereto as part of Exhibit C. To appropriately protect the public's health by suppress-

[1] At the time the letter was sent, the Commonwealth was one of six states that did not collect all CD4 test results. That number has since fallen to four. See e-mail from Richard Selik (CDC/OID/NCHSTP) to Godwin Obiri, Epidemiology Supervisor, Bureau of Epidemiology, Pennsylvania Department of Health (9/11/2018 10:56 AM), attached hereto as part of Exhibit C.

ing the spread of HIV and provide better, more effective treatment for persons living with HIV, the Department is amending its regulations to require complete reporting.

The Department is also taking this step to ensure that, if, in the future, public funding is tied to disease burden, as has been suggested could occur, the Commonwealth will not be disadvantaged. Goal 1 of the National HIV/AIDS Strategy, which calls for reducing new HIV infections, see National HIV/AIDS Strategy at 1, sets forth as a recommended action the allocation of public funding consistent with the geographic distribution of the epidemic. Id. at 19. The National HIV/AIDS Strategy recommends a similar action with regard to Goal 4, achieving a more coordinated national response to the HIV epidemic. Id. at 43; see also 45 (''The Federal government should review the methods used to distribute Federal HIV funds and take steps to ensure that resources go to the States and localities with the greatest burden of disease.'') If, in the future, Federal funding is tied to disease burden, the Commonwealth would be at a disadvantage among other states with more complete verifiable data. See Exhibit B.

II. *Summary and Overview of General Comments*

The Department received four letters of comment on its proposed rulemaking in addition to comments from IRRC, one opposed and three in support.

Comments supporting the rulemaking

Three commentators supported the Department's proposed rulemaking. Thomas A. Farley, the Health Commissioner of the City of Philadelphia, stated that the Office of the Health Commissioner of the City of Philadelphia was in ''full support'' of the Department's proposed regulations. Thomas A. Farley stated that the spread of HIV was a serious issue, pointed out that the Commonwealth was one of only four states not mandating reporting of all CD4 percentages and counts and one of only two not requiring all viral load test results. Thomas A. Farley also referenced the National HIV AIDS Strategy and stated that the ability to meet the goals set out in that document depended upon comprehensive reports of all HIV-related tests. Thomas A. Farley noted that the City of Philadelphia already requires reporting of all CD4 and viral load test results. Thomas A. Farley stated that this allows the City to better track the epidemic, focus resources based on the needs of the impacted communities and improve the health of the City's residents. Thomas A. Farley stated that the Department's regulation would help to ensure persons living with HIV (PLWH) have access to care and are engaged in care and virally suppressed, facilitate the monitoring of the HIV epidemic in the Commonwealth and bring HIV reporting in the Commonwealth in line with National standards.

The Community Co-Chair of the Pennsylvania HIV Planning Group provided a letter of support stating that they hoped that the Department's proposed rulemaking would be adopted, because the regulation would allow the pinpointing and accurate reporting of the epidemic in the Commonwealth and would allow the analysis of trends that would help to target treatment and prevention efforts. The Co-Chair stated that ''[this] information is the primary base for all planned activities [aimed at ending the epidemic in Pennsylvania].''

Finally, ViiV Healthcare, a pharmaceutical manufacturer of HIV medicines, commented in support of the proposed rulemaking. The Director of Government Relations (Director) of that company stated that it was devoted exclusively to supporting the needs of persons living with or affected by HIV, and that its singular focus was to improve their health and quality of life. The Director also stated that advances in the treatment of the disease has transformed HIV from a terminal illness to a manageable chronic condition, that effective treatment could help persons living with HIV (PLWH) live longer, healthier lives, and that effective HIV treatment could prevention transmission of disease. The Director cited a recent study in the British Journal, *The Lancet*, which found that when trading the HIV-positive partner in a serodiscordant couple with antiretroviral therapy, there were no linked infections observed with the infected partners HIV viral load was below the limit of detection. See Rodger A.J., et al., ''Risk of HIV Transmission through Condomless Sex in Serodifferent Gay Couples with the HIV-Positive Partner Taking Suppressive Antiretroviral Therapy (PARTNER): Final Results of a MultiCentre Prospective, Observational Study,'' *The Lancet*, (Published online May 2, 2019 at http://dx.doi.org/10.1016/S0140-6736(19)30418-0). The Director went on to comment that an important component of public health initiatives, including U=U (Undetectable = Untransmittable), is that policy makers have access to performance related data indicating the quality of health care to promote and achieve viral suppression goals and to assist the Department to better identify and target funding programs. The Director noted that if Federal funding decisions become based on states that can demonstrate the greatest disease burden, the Commonwealth will lose a significant portion of valuable Federal dollars, because it will only be reporting a portion of the total HIV population. The Director encouraged the adoption of the proposed amendments because the Commonwealth would then be brought into alignment with the reporting requirements of the majority of other states, and would be better able to track new cases, monitor clinical results and make program decisions that would have the greatest impact on the lives of PLWH in the Commonwealth.

The Department appreciates the support of the City of Philadelphia, which has the highest HIV disease burden in this Commonwealth. The Department also thanks the HPG Committee for its support, particularly given its experience, and its knowledge of the funding decisions and issues facing this Commonwealth and the need for accurate data to inform those decisions to ensure the funding received targets the epidemic appropriately and effectively. Finally, the Department agrees with and echoes the comments of ViiV, particularly in regard to the need for accurate and complete data to ensure that PLWH are referred to treatment early, so that they may receive the most effective treatment, HIV transmission may be checked, and the spread of new infections blocked.

In addition, the Department is in agreement with the concerns expressed by ViiV regarding the risk of losing Federal dollars if Federal funding were to be targeted at states that can demonstrate the greatest burden of disease, and the Commonwealth were to lack the requirement for complete reporting that is created by this final-form rulemaking. Such an action is not beyond the realm of possibility; it would be in line with changes made to the Comprehensive AIDS Resources Emergency (CARE) Act (42 U.S.C.A. §§ 300ff-21—300ff-38) at the time the Department made HIV reportable by name in the Commonwealth, almost the last state in the country to take that action. At that time, the Federal agency that provides funding for HIV/AIDS services, the Health Services Resource Administration (HRSA), changed its rules to condition the apportionment of state funding upon the number of live HIV cases within a jurisdiction, rather than live AIDS cases, based on changes to the CARE Act.

See The Ryan White CARE Act: A Side-by Side Comparison of Prior Law to the Newly Reauthorized CARE Act, The Henry J. KAISER FAMILY Foundation, December 2006, at 3 (https://www.kff.org/wp-content/uploads/2013/01/7531-03.pdf), accessed October 28, 2019. Although the enforcement of this formula was delayed some years, HRSA eventually required all states to institute name-based HIV reporting to meet the level of accuracy for the data demanded to support a fiscal claim by the state. Id., see also HIV Prevalence Estimates—United States, 2006, MMWR 57(39); 1073—1076 October 3, 2008), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5739a2.htm, accessed October 28, 2019. A similar circumstance could arise here, and states with more reliable data could receive the bulk, potentially all, of available Federal funding.

Comments opposed to the rulemaking

One commentator raised concerns that the Department's requirement to include hospitals among the reporters of all CD4 T-lymphocyte counts, viral loads and genotype testing was duplicative, and costly in time and money for a hospital, particularly when reference laboratories are providing these reports. IRRC echoed this comment and requested that the Department explain how the regulated community is to use the electronic reporting system, and that the Department work with the community to ensure they understand how the system will work, and the reporting options open to them.

The Department has not changed the requirements of the regulations that multiple persons report these, as well as all reportable diseases, infections and conditions listed in Chapter 27 (relating to communicable and noncommunicable diseases). The Department has received similar comments before when it has attempted to revise and update its reporting regulations. The Department considered and responded to the question of duplicative reporting when it last updated its regulations relating to communicable and noncommunicable diseases in 2002 published at 32 Pa.B. 491 (January 26, 2002) accessed October 28, 2019, and when it added the requirement that HIV test results, certain CD4 T-lymphocyte test results, and perinatal test results should be reported to the Department by name later that same year. See Reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts and Perinatal Exposure of Newborns to HIV published at 32 Pa.B. 3597, 3602 (July 20, 2002), accessed October 28, 2019. The Department's response then remains relevant today:

> With respect to issues involving the requirement of multiple reporters, the Department requires reporting from all different types of reporters, including practitioners, facilities, laboratories, other providers and the public for several reasons. The Department does not want possible reporters to self-censor, based on their assumption that another person will make the report. That could lead to under-reporting, and jeopardize the ability of the public health system to positively impact the health of infected individuals and their contacts. If the Department and local health departments are unaware of cases, they will be unable to offer or provide follow-up, including counseling and referral information, and perform case investigation.
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> The Department also receives different information from different reporters. For example, a report by a laboratory is a confirmatory report of a disease or condition diagnosed by a health care practitioner. From heads of institutions the Department will receive information that is neither a diagnosis nor a confirmed report, but a suspicion that may help to identify a disease outbreak. The monitoring of the disease in the patient is dependent on receiving information from a practitioner as well as a laboratory, as is the monitoring of the disease in the population as a whole. Information relating to opportunistic infections, referrals, mode of transmission and treatment are not shared by a practitioner with the laboratory, and, therefore, the Department would not be able to obtain this type of specific information from laboratories if laboratories alone were to report. A provider would not release this type of information to a laboratory because of its confidential nature. A laboratory does not need to be aware of the mode of transmission of a disease or types of referrals made for the individual to perform its licensed function—conducting laboratory tests of specimens.
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> The more specific the information received by the Department from all reporters, the more likely it is that the Department will be able to match information obtained from other sources, sometimes incomplete, and obtain complete information on each reported case. The more complete the demographic picture of the individual whose results are being reported, the easier it is for the Department to track the disease in this Commonwealth for purposes of implementing prevention measures, including targeting funding to affected populations. Further, the more complete the information on a specific individual the Department obtains, the easier it becomes for the Department and local health departments to provide follow-up services to that individual. For example, with a case of infectious tuberculosis, the Department will provide treatment, including directly observed therapy, to ensure that the case is cured, and will also locate and test and treat contacts as necessary. In the case of sexually transmitted diseases, the Department and local departments locate and offer counseling and testing services to partners of individuals who test positive.

Reporting of Communicable and Noncommunicable Diseases, 32 Pa.B. 491, 492-493. At that time, and for those reasons, the Department declined to change the proposed regulations, which were ultimately approved as final without change, and implemented. They have been in effect for at least 17 years. Therefore, all existing hospitals, laboratories, other health care providers and practitioners should be supplied with the appropriate credentials to report the listed reportable diseases electronically and should be reporting regularly as required by law. The Department is simply asking providers and laboratories to report all rather than some of the CD4 counts and percentages already being reported and has added reporting of viral loads and genotype testing relating to HIV to the existing list.

In addition, the National HIV/AIDS Strategy acknowledges the need for duplicate reporting, stating: "Surveillance necessitates a complex system of reporting from providers, laboratories, and State and local health departments to coordinate accurate, complete, and timely reporting." See National HIV/AIDS Strategy, at 46. The Department again declines to limit the types and number of entities required to report, in the interest of ensuring the most complete reporting that can be achieved. Forty-six states mandate reporting of all CD4 and viral load tests, and many of those states ask for reporting by both laboratories and providers. This requirement, therefore, is within the bounds of accepted public health practices.

IRRC asked that the Department explain to the regulated community how the system is to work. Reports are sent to the Department's electronic disease surveillance system through either manual key entry, or in the case of some laboratories, through electronic batch reporting to the Department's electronic laboratory reporting system. In considering the issue of manual reporting, the Department reviewed data relating to reporting of CD4 and viral load test results from 2016—2019. Of the 175,965 HIV-related reports submitted by hospitals and laboratories to the Department, only 9,277, or roughly 5%, were reported manually. The data shows that hospitals and laboratories that report a relatively small volume of cases are the entities that are reporting by manual entry. Hospital laboratories and commercial laboratories with larger volumes are more likely to report through batch reporting to the electronic laboratory reporting system. Once the parameters for sending data are updated, adding more reports to electronic feeds does not pose an ongoing burden to the laboratory. The Department is continuing to work with laboratories that are interesting in sending data through the electronic laboratory reporting system; however, some laboratories prefer manual reporting because they feel that the resources needed to report manually are less than those needed to establish electronic batch reporting.

With respect that request that the Department explain the system to reporters, the Department would also note that most reportable diseases, infections and conditions have been reportable electronically since 2002, and that HIV was made reportable electronically by notice as provided for in the HIV reporting regulations in 2006. At the time electronic reporting was first implemented, some 17 years ago, the Department reached out to reporters, and conducted trainings and provided access to its electronic disease surveillance system. The regulated community has been using the existing electronic disease surveillance system and reporting diseases, including those CD4 T lymphocyte cell counts equal to or less than 200 cells/μL, or less than 14% of total lymphocytes for 13 of those 17 years. To the extent any member of the regulated community has questions regarding the Department's current electronic disease surveillance system and its use, the Department provides a number and a contact person to whom questions may be addressed, and help sought, when new reporters are credentialed to use the system.

The Department is sensitive to cost concerns of its reporters. The Department, however, must view the resources, time and costs needed for reporting in the context of the need to monitor and promote the health of the citizens of this Commonwealth. With respect to HIV, there is an urgent public health need to monitor the proportion of cases under care and the proportion of cases adequately treated. Adequate treatment improves the health of persons with HIV and reduces their need for more expensive medical interventions. Furthermore, at least four clinical trials published since 2016 have demonstrated that adequate treatment of cases (indicated by low or non-existent viral loads and normal CD4 counts) dramatically reduces transmission of HIV. See Rodger A.J., Cambiano V., Bruun T., et al., "Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy," JAMA. 2016;316(2):171—181, DOI:10.1001/jama.2016.5148 (July 12, 2016) (https://jamanetwork.com/journals/jama/fullarticle/2533066), accessed October 28, 2019; Cohen M.S., Chen Y.Q., McCauley M., et al., "Antiretroviral Therapy for the Prevention of HIV-1 Transmission," NEW ENG. J. MED. 2016; 375:830—839. DOI:10.1056/NEJMoa1600693 (September 1, 2016) (https://www.nejm.org/doi/full/10.1056/NEJMoa1600693), accessed October 28, 2019; Bavinton B.R., Pinto A.N., Phanuphak N., et al., "Viral Suppression and HIV Transmission in Serodiscordant Male Couples: an International, Prospective, Observational, Cohort Study," *The Lancet HIV 2018*; 5(8): e438—e447 (July 16, 2018) (https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(18)30132-2/fulltext), accessed October 28, 2018; Rodger A.J., Cambiano V., Bruun T., et al., "Risk of HIV Transmission through Condomless Sex in Serodifferent Gay Couples with the HIV-Positive Partner Taking Suppressive Antiretroviral Therapy (PARTNER): Final Results of a Multicentre, Prospective, Observational Study," *The Lancet 2019*; 393(10189): P2428—2438 (June 15, 2019) (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30418-0/fulltext), accessed October 28, 2019.

Identifying populations or areas with substandard levels of treatment could lead to interventions, such as improving linkage to care in underserved populations, that could eventually significantly reduce the Commonwealth's burden of HIV. In 2010 dollars, the lifetime treatment cost of one HIV case is approximately $379,668. See https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html. Prevention of new cases, by among other things continuing existing cases in treatment and suppressing viral load is an obvious cost savings to the Commonwealth. The cost savings of a case of HIV averted has been estimated at between $20,000 to $100,000 per case. See Woodak and Cooney, "Do Needle Syringe Program Reduce HIV Infection Among Injecting Drug Users: A Comprehensive Review of the International Evidence," Substance Use & Misuse, Vol. 41, 2006 (Issue 6-7) at 20—22; see also "Effectiveness of Sterile Needle and Syringe Programming in Reducing HIV/AIDS Among Injecting Drug Users," (Evidence for Action Technical Papers) World Health Organization (2004) ("WHO White Paper"), at 15-16. This Commonwealth saw 991 new cases of HIV in 2016. Pennsylvania Department of Health, Annual HIV Surveillance Summary (2016) http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/E-H/HIV%20And%20AIDS%20Epidemiology/Documents/Pennsylvania%202016%20Annual%20HIV%20Surveillance%20Report.pdf, accessed July 2, 2018. Using these figures, the cost to the Commonwealth of those 991 cases could be as high as $376,250,998. Preventing them from occurring could be a savings of as much as $99,100,000. Although determining the actual cost that the final-form rulemaking will impose on providers and laboratories is not possible, it is extremely unlikely that this cost would outweigh the benefits of eventually improving the health of persons infected with HIV and decreasing the number of new cases of HIV.

Comments relating to specific sections

§ 27.4. Reporting of cases

IRRC raised several issues with sections of the Department's regulations relating to communicable and noncommunicable diseases that the Department had not originally included in the proposed rulemaking. Section 27.4 (relating to reporting cases), is one of those sections. IRRC specifically referenced subsections (a) and (e), and points out that the references to a forthcoming implementation of an electronic system in subsection (b) are outdated. In fact, those references did refer to the implementation of PA-NEDSS which occurred sometime after those regulations were promulgated in 2002. In addition,

IRRC pointed out that subsection (e) included references to multiple methods of reporting, which could cause confusion and raise issues of clarity. IRRC asked that the Department explain to the regulated community what reporting options are available and suggested that the final-form rulemaking be amended to reference other options for reporting, if paper reporting is acceptable.

In reviewing IRRC's comments, and the language in § 27.4, the Department determines that clarification of electronic versus paper reports is appropriate, and revisions to that section eliminating language that is outdated to specifically capture current reporting requirements is within the scope of this final-form rulemaking. The Department amends that section to clarify how reports are required.

By way of background, under current law and regulations, and not altered by this final-form rulemaking, reporters have a duty to report to the Department, and to report in the format required by the Department under section 4 of the Disease Prevention and Control Law of 1955 (act) (35 P.S. § 521.4). The Department first required electronic reporting of reportable diseases, infections and conditions in the final-form rulemaking published at 32 Pa.B. 491. To provide enough time for reporters other than laboratories to prepare for electronic reporting, (laboratories were required to report electronically immediately upon that rulemaking's publication), the Department, in § 27.4, set the implementation date of the electronic reporting requirement for most diseases, infections and conditions for 6 months after notice was published in the *Pennsylvania Bulletin*. See subsection (b). Because that language is no longer applicable, and electronic reporting has long been in place in this Commonwealth, the Department deletes this language from subsection (b).

The Department, however, exempted HIV, AIDS, CD4-T-lymphocyte test results for counts less than 200 cells/μL of less than 14% of total lymphocytes and perinatal exposure of a newborn, from electronic reporting under that notice. The Department did not make those diseases, infections and conditions reportable until 6 months after publication of a second notice at 35 Pa.B. 6192 (November 5, 2005). The Department waited several years after the institution of confidential HIV name-based reporting in 2002 to require electronic reporting of those specific items to ensure that certain data security requirements of the CDC were successfully met. By that date, the Department required that reports of all reportable diseases, infections and conditions were to be made electronically. That requirement remains in place. Paper reporting is slow and inefficient and requires resources for processing and key entry that the Department does not have. Amendments to § 27.4 included in this final-form rulemaking emphasize the Department's position.

The Department replaces concepts relevant to reporting in 2002 with language relevant to current electronic reporting requirements. References made to local morbidity reporting offices—the Department's district offices and the county/municipal health departments that partner with it in its disease control functions—which were necessary to manage work when reporting was on paper, but meaningless in the context of electronic reporting, are deleted. Subsection (c) removes references to hard copies and to the appropriate office being able to provide the form, since the form is now electronic in nature, all reports are made into the electronic system, and access is obtained from the Department upon request.

The Department notes, however, that a preliminary case report by telephone is still acceptable, an early warning to the Department in effect, but formal reports with all the appropriate information that make disease surveillance and control possible must still be made through the appropriate electronic surveillance system. See subsection (b).

The Department's interest is to obtain reports in a timely manner. Depending on the circumstances, a reporter may judge that some type of telephonic report is most appropriate. However, if a phone report is made, the reporter must still submit a formal case report to the appropriate surveillance system. As recommended, the Department eliminates the language from subsection (b) referencing the expectation that the electronic surveillance system will shortly be in place, and that reporters will be notified that electronic reporting has started. Subsection (e) is redesignated as subsection (c), and now refers to the content of the report as opposed to the method of reporting. The subsection makes it clear that assistance with reporting may be obtained by contacting the Department.

§ 27.22. Reporting of cases by clinical laboratories

IRRC commented that § 27.22(d) (relating to reporting of cases by clinical laboratories) includes a reference to electronic mechanisms, which could potentially create confusion with other references to electronic disease surveillance systems. The Department notes that while the Department proposed to amend subsection (b) of § 27.22, it did not propose revising subsection (d), although it should have done so. Section 27.22(d) did include a reference to CD4 T-lymphocyte counts and percentages and to HIV. That reference is deleted so that subsection (d) will comport with the rest of this final-form rulemaking.

At the time the regulatory amendment adding HIV and CD4 T-lymphocyte counts and percentages to subsection (d) was promulgated in 2002, the Department had not yet made HIV cases reportable electronically. The CDC had heightened security requirements relating to electronic reporting and storage of HIV information, and it was not until the Department received approval from the CDC to allow electronic reporting of HIV in 2006 that laboratories and providers began to report electronically. The Department revises subsection (d) in this final-form rulemaking to delete the references to HIV and to CD4 counts and percentages, as well as the reference to the specific section governing HIV reporting, which was a necessary reference in 2002, but is no longer required under the existing reporting requirements. The remainder of the diseases and conditions listed in subsection (d) are still reported through mechanisms delineated in the specific sections referenced in that subsection. The Department replaces the term "secure electronic mechanisms," with "electronic disease surveillance systems," to reflect the actual operations of the Department, and for the sake of consistency in the language of the regulation.

§ 27.32a. Reporting AIDS, HIV, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable viral load results and genotype test results, and perinatal exposure of newborns to HIV

IRRC had several comments on this section. IRRC suggested that, because the Department refers to the electronic reporting system as PA-NEDSS in the preamble and in the Regulatory Analysis Form, the Department defines "electronic disease surveillance system" in

the regulations, and if appropriate, reference PA-NEDSS in that definition. The Department agrees that a definition of "electronic disease surveillance system" should be added and has added the term to § 27.1 (relating to definitions). After considering whether to continue to reference PA-NEDSS, and whether to add the term to the definition section, the Department decided that including the term would not be useful. While PA-NEDSS was the Department's first electronic disease surveillance system, the Department has different electronic data collection systems for different program areas as well as an electronic system for submission of batch laboratory data. In addition, the Department may, sometime in the future, change or rename its electronic disease surveillance system. Therefore, while the Department provided a definition of "electronic disease surveillance system" that is broad enough to encompass all the systems that are used or will be used by the Department, including PA-NEDSS, the Department has chosen not to reference PA-NEDSS in this final-form rulemaking. The definition also includes, for purposes of this final-form rulemaking, electronic laboratory reporting systems. The Department provides a definition for "electronic laboratory reporting system" to help with the understanding of that term.

IRRC questioned the Department's use of the word, "shall," in this section, which makes reporting electronically mandatory, because the Department has stated that it will also accept paper reports. IRRC specifically referenced the regulation in § 27.4, which was not originally intended to be a part of this final-form rulemaking. IRRC suggested that the final regulation be amended to reference other options for reporting, if paper reporting is acceptable. Although § 27.4 was not originally included in the proposed rulemaking, the Department considered IRRC's comments, and agrees, for the sake of clarity and to update the regulations to reflect current practices, it has made revisions to that section. For a fuller explanation, see Preamble, supra, at pp. 15—18.

§ 27.32c. Partner services relating to HIV and AIDS

IRRC commented that it understood the Department's reasoning in deleting a reference to the Confidentiality of HIV-Related Information Act (35 P.S. §§ 7601—7612) (Act 148), from this section, and agreed with the Department's analysis that it was unnecessary. IRRC requested, however, that the Department keep the language in the regulations as a clear notice to the regulated community. The Department agrees with the comment and adds the reference back into the section, but as new subsection (c).

Subsections (a) and (b) explain that a person providing testing services and giving diagnoses to an individual may ask the Department for help with counseling services. The regulation also makes it clear that the person providing those services must also tell the individual that the Department or a local health department representative may contact the person for a voluntary and confidential interview to discuss the services available to them. This is so the individual is kept informed and is not surprised by the potential contact from the Department. The reference to Act 148, pointing out the need to comply with the law relating to HIV confidentiality, fit more naturally following these subsections than at the beginning of the section. The Department therefore adds the reference in new subsection (c).

Finally, the Department changes the word "patient," to "individual" and the phrase "who provides," to "providing" to make the construction of the subsections parallel.

III. *Cost and Paperwork Estimate*

1. *Cost*

The amendments would have no measurable fiscal impact on the Commonwealth, local government, the private sector or the general public because the disease reporting system already exists in this Commonwealth. The financial and economic impact of this final-form rulemaking outside of healthcare settings is very minimal. Healthcare practitioners, health care facilities and clinical laboratories currently are required to have systems in place to report some CD4 T-lymphocyte and HIV viral load test results into PA-NEDSS, so although the new regulation would result in reporting of all CD4 T-lymphocyte and HIV viral load results, they will not need to develop new systems. Currently, healthcare practitioners and clinical laboratories must separate out the CD4 T-lymphocyte and viral load test results required to be reported from those not required to be reported, and this process takes time and adds cost. The amended change will allow reporters to report all the test results received and remove the need to separate the results into those reported and those not reported.

Healthcare practitioners and laboratories without the ability to send data electronically directly to the electronic disease surveillance system will be required to key enter these additional test results into that system. However, as noted earlier, most CD4 and HIV viral load information is received from hospital and commercial laboratories with Information Technology (IT) systems allowing batch electronic reporting. For these facilities, once their IT system is modified to capture the additional test results, the data would automatically be extracted and submitted to the Department's system. There would therefore be no ongoing cost associated with the additional reporting requirements, and the cost of the additional reports required as a result of the proposed changes to the regulation would be negligible.

The costs to both the Commonwealth and to local governments would not increase because of these amendments. The Commonwealth, through the Department, and local health departments, already have infrastructure in place to accept reporting of diseases and conditions, and to carry out, as required by law, disease prevention and control activities relating to HIV and AIDS, among other things. The additional work and cost relating to the reporting of more cases would be minimal and is outweighed by the benefit accruing from better understanding of the epidemic that allows for more targeted intervention and prevention strategies. As noted above, in 2010, the cost per one HIV case in the Commonwealth over a lifetime was approximately $379,668. See https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html. The cost savings of a case of HIV averted has been estimated at between $20,000 to $100,000 per case. See Woodak and Cooney, at 20—22; see also WHO White Paper, at 15-16. The Commonwealth saw 991 new cases of HIV in 2016. Pennsylvania Department of Health, Annual HIV Surveillance Summary (2016) http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/E-H/HIV%20And%20AIDS%20Epidemiology/Documents/Pennsylvania%202016%20Annual%20HIV%20Surveillance%20Report.pdf, accessed July 2, 2018. Using these figures, the cost to the Commonwealth of those 991 cases could be as high as $376,250,998. Preventing them from occurring could be a savings of as much as $99,100,000.

2. *Paperwork*

Because the electronic disease surveillance system that receives and stores reports of diseases and conditions is already in place in this Commonwealth, expanding the list to include mandatory reports of all test results for an existing disease or condition and additional testing relating to that disease or condition would create no measurable increase in paperwork. Healthcare practitioners, health care facilities and clinical laboratories currently are required to have systems in place to report some CD4 T-lymphocyte and HIV viral load test results into PA-NEDSS, so although the amendments to the regulation would result in reporting of all CD4 T-lymphocyte and HIV viral load results, existing reporters should not need to develop new systems.

The ongoing savings each year from more effective HIV disease control, prevention and timely treatment of individuals infected with HIV which would be expected to occur from this expanded reporting are immeasurable. All persons of this Commonwealth would benefit from these amendments as they will allow the Department to monitor the proportion of persons with HIV who are under care and the proportion adequately treated. Identifying populations or areas with substandard levels of treatment could lead to interventions such as assisting patients with linkage to care and treatment before those patients develop significant and expensive medical complications. Furthermore, when people living with HIV are in continuous medical care and have a suppressed viral load, the chances of those persons transmitting HIV to other people is tremendously reduced. These final-form amendments will help to protect citizens in this Commonwealth from exposure to HIV and subsequent hardship, disability or death. In addition, it would enable the Commonwealth to comply with the CDC's recommendations for effective HIV disease surveillance, control and patient management.

IV. *Statutory Authority*

The Department obtains its authority to promulgate regulations relating to reporting of communicable and noncommunicable diseases from several sources. Section 16(a) of the act (35 P.S. § 521.16(a)) gives the Board the authority to issue rules and regulations on a variety of matters relating to communicable and non-communicable diseases, including the following: the diseases that are to be reported; the methods of reporting diseases; the contents of reports; the health authorities to whom diseases are to be reported; the control measures that are to be taken with respect to different diseases; the enforcement of control measures; the immunization and vaccination of persons and animals; the prevention and control of disease in public and private schools; the treatment of sexually transmitted diseases, including patient counseling; and any other matters the Board may deem advisable to address for the prevention and control of disease and for carrying out the provisions and purposes of the act. Section 16(b) of the act gives the Secretary of Health (Secretary) the authority to review existing regulations and make recommendations to the Board for changes the Secretary considers to be desirable.

The Department also finds general authority for the promulgation of its regulations in the Administrative Code of 1929 (code) (71 P.S. §§ 51—732) Section 2102(g) of the code (71 P.S. § 532(g)) gives the Department this general authority. Section 2111(b) of the code (71 P.S. § 541(b)) provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of this Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department. Section 2106(a) of the code (71 P.S. § 536(a)) provides the Department with additional authority to declare diseases to be communicable, and to establish regulations for the prevention and control of disease.

Section 2111(b) of the code provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of this Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department.

In addition, section 803 of the Health Care Facilities Act (35 P.S. § 448.803) provides the Department with the authority to promulgate regulations relating to the licensure of health care facilities, and allows the Department to require certain actions relating to disease control and prevention to occur within health care facilities.

V. *Effectiveness/Sunset Dates*

The amendments will be effective upon publication in the *Pennsylvania Bulletin*. The Department will continually review and monitor the effectiveness of these regulations.

VI. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.4(a)), on May 15, 2019, the Department submitted a copy of the notice of proposed rulemaking, published at 49 Pa.B. 2605 (May 25, 2019), to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Health Committee and the Senate Health and Human Services Committee for review and comment.

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

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on August 12, 2020, the final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on September 17, 2020, and approved the final-form rulemaking.

VII. *Contact Person*

Questions regarding these regulations may be submitted to Sharon Watkins, Director, Bureau of Epidemiology, Department of Health, 625 Forster Street., Harrisburg, PA 17108, Room 933, Health and Welfare Building, Harrisburg, PA 17120, (717) 787-3350, within 30 days after publication of this notice in the *Pennsylvania Bulletin*. Persons with a disability who wish to submit comments, suggestions or objections regarding the proposed regulation may do so by using the previous number or address. Speech and/or hearing-impaired persons may use V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800) 654-5984(TT). Persons who require an alternative format of this document may contact Sharon Watkins so that necessary arrangements may be made.

VIII. *Findings*

The Department finds that:

(1) Public notice of intention to adopt the regulations adopted by this order has been given under sections

201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) known as the Commonwealth Documents Law, and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law and all comments were considered.

(3) The adoption of regulations in the manner provided by this order is necessary and appropriate for the administration of the authorizing statute.

IX. *Order*

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

(1) The regulations of the Department at 28 Pa. Code Chapter 27 are amended by amending §§ 27.1, 27.4, 27.21a, 27.22, 27.23 and 27.32a—27.32e as set forth in Annex A.

(*Editor's Note*: Amended §§ 27.1 and 27.4 were not included in the proposed rulemaking published at 49 Pa.B. 2605 (May 25, 2019).)

(2) The Secretary of Health shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(3) The Secretary of Health shall submit this Order, Annex A and a Regulatory Analysis Form to IRRC, the House Health Committee and the Senate Health and Human Services Committee for their review and action as required by law.

(4) The Secretary of Health shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(5) This order shall take effect upon its publication in the *Pennsylvania Bulletin*.

RACHEL L. LEVINE, MD,
Secretary

(*Editor's Note*: See 50 Pa.B. 5597 (October 3, 2020) for IRRC's approval order.)

Fiscal Note: 10-209. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART III. PREVENTION OF DISEASES

CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASES

Subchapter A. GENERAL PROVISIONS

§ 27.1. Definitions.

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

* * * * *

District office—One of the district headquarters of the Department located within this Commonwealth.

Electronic Disease Surveillance System—Any of the electronic, web-based platforms that the Department uses to collect and manage information reportable under § 27.2 (relating to specific identified reportable diseases, infections and conditions). For purposes of this chapter, the term includes an electronic laboratory reporting system.

Electronic Laboratory Reporting System—The electronic platform that the Department uses to receive and process information electronically generated by clinical laboratories to fulfill their reporting responsibilities under § 27.22 (relating to reporting of cases by clinical laboratories). Information submitted to the electronic laboratory reporting system will be routed to the Department's electronic disease surveillance system when appropriate.

FDA—Food and Drug Administration.

* * * * *

§ 27.4. Reporting cases.

(a) Except where otherwise noted in this chapter, a case shall be reported to the Department through the appropriate electronic disease surveillance system.

(b) A reporter may make a preliminary report of a case by telephone. The preliminary report must be followed by a formal report made through the appropriate electronic disease surveillance system.

(c) A case shall be reported using the appropriate case report format. The requested information shall be provided by the reporter, irrespective of the manner in which the report is submitted. Access to the appropriate electronic disease surveillance system may be obtained from the Department upon request.

Subchapter B. REPORTING OF DISEASES, INFECTIONS AND CONDITIONS

GENERAL

§ 27.21a. Reporting of cases by health care practitioners and health care facilities.

(a) Except as set forth in this section or as otherwise set forth in this chapter, a health care practitioner or health care facility is required to report a case of a disease, infection or condition in subsection (b) as specified in § 27.4 (relating to reporting cases), if the health care practitioner or health care facility treats or examines a person who is suffering from, or who the health care practitioner or health care facility suspects, because of symptoms or the appearance of the individual, of having a reportable disease, infection or condition:

(1) A health care practitioner or health care facility is not required to report a case if that health care practitioner or health care facility has reported the case previously.

* * * * *

(b) The following diseases, infections and conditions in humans are reportable by health care practitioners and health care facilities within the specified time periods and as otherwise required by this chapter:

* * * * *

(2) The following diseases, infections and conditions are reportable within 5 work days after being identified by symptoms, appearance or diagnosis:

AIDS.

Amebiasis.

Brucellosis.

CD4 T-lymphocyte counts and percentages.

Campylobacteriosis.

Cancer.

Chancroid.

Chickenpox (varicella) (effective January 26, 2005).

Chlamydia trachomatis infections.

Congential adrenal hyperplasia (CAH) in children under 5 years of age.

Creutzfeldt-Jakob Disease.

Cryptosporidiosis.

Encephalitis.

Galactosemia in children under 5 years of age.

Giardiasis.

Gonococcal infections.

Granuloma inguinale.

Guillain-Barre syndrome.

HIV (Human Immunodeficiency Virus).

HIV viral load test results, including detectable and undetectable viral load results, and all HIV genotyping results.

Hepatitis, viral, acute and chronic cases.

Histoplasmosis.

Influenza.

Leprosy (Hansen's disease).

Leptospirosis.

Listeriosis.

Lyme disease.

Lymphogranuloma venereum.

Malaria.

Maple syrup urine disease (MSUD) in children under 5 years of age.

Meningitis (All types not caused by invasive Haemophilus influenza or Neisseria meningitis).

Mumps.

Perinatal exposure of a newborn to HIV (effective October 18, 2002).

Pertussis (whooping cough).

Phenylketonuria (PKU) in children under 5 years of age.

Primary congenital hypothyroidism in children under 5 years of age.

Psittacosis (ornithosis).

Rickettsial diseases.

Rubella (German measles) and congenital rubella syndrome.

Salmonellosis.

Shigellosis.

Sickle cell disease in children under 5 years of age.

Staphylococcus aureus, Vancomycin-resistant (or intermediate) invasive disease.

Streptococcal invasive disease (group A).

Streptococcus pneumoniae, drug-resistant invasive disease.

Syphilis (all stages).

Tetanus.

Toxic shock syndrome.

Toxoplasmosis.

Trichinosis.

Tuberculosis, suspected or confirmed active disease (all sites).

Tularemia.

* * * * *

§ 27.22. Reporting of cases by clinical laboratories.

(a) A person who is in charge of a clinical laboratory in which a laboratory test of a specimen derived from a human body yields microscopical, cultural, immunological, serological, chemical, virologic, nucleic acid (DNA or RNA) or other evidence significant from a public health standpoint of the presence of a disease, infection or condition listed in subsection (b) shall promptly report the findings, no later than the next work day after the close of business on the day on which the test was completed, except as otherwise noted in this chapter.

(b) The diseases, infections and conditions to be reported include the following:

Amebiasis.

Anthrax.

An unusual cluster of isolates.

Arboviruses.

Botulism—all forms.

Brucellosis.

CD4 T-lymphocyte counts and percentages.

Campylobacteriosis.

Cancer.

Chancroid.

Chickenpox (varicella).

Chlamydia trachomatis infections.

Cholera.

Congential adrenal hyperplasia (CAH) in children under 5 years of age.

Creutzfeldt-Jakob disease.

Cryptosporidiosis.

Diphtheria infections.

Enterohemorrhagic E. coli 0157 infections, or infections caused by other subtypes producing shiga-like toxin.

Galactosemia in children under 5 years of age.

Giardiasis.

Gonococcal infections.

Granuloma inguinale.

HIV (Human Immunodeficiency Virus).

HIV viral load results, including detectable and undetectable viral load results, and HIV genotype test results.

Haemophilus influenzae infections—invasive from sterile sites.

Hantavirus.

Hepatitis, viral, acute and chronic cases.

Histoplasmosis.

Influenza.

Lead poisoning.

Legionellosis.

Leprosy (Hansen's disease).

Leptospirosis.

Listeriosis.

Lyme disease.

Lymphogranuloma venereum.

Malaria.

Maple syrup urine disease (MSUD) in children under 5 years of age.

Measles (rubeola).

Meningococcal infections—invasive from sterile sites.

Mumps.

Pertussis.

Phenylketonuria (PKU) in children under 5 years of age.

Primary congenital hypothyroidism in children under 5 years of age.

Plague.

Poliomyelitis.

Psittacosis (ornithosis).

Rabies.

Respiratory syncytial virus.

Rickettsial infections.

Rubella.

Salmonella.

Shigella.

Sickle cell disease in children under 5 years of age.

Staphylococcus aureus Vancomycin-resistant (or intermediate) invasive disease.

Streptococcus pneumoniae, drug-resistant invasive disease.

Syphilis.

Tetanus.

Toxoplasmosis.

Trichinosis.

Tuberculosis, confirmation of positive smears or cultures, including results of drug susceptibility testing.

Tularemia.

Typhoid.

* * * * *

(d) Laboratory test results shall be reported by the person in charge of a laboratory through the appropriate electronic disease surveillance system. Reports of CAH, galactosemia maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism, sickle cell disease and cancer, shall be made in the manner specifically designated in this subchapter. See §§ 27.30 and 27.31 (relating to reporting cases of certain diseases in the newborn; and reporting cases of cancer).

* * * * *

§ 27.23. Reporting of cases by persons other than health care practitioners, health care facilities, veterinarians or laboratories.

Except with respect to reporting cancer, AIDS, CD4 T-lymphocyte counts and percentages, HIV test results or perinatal exposure of a newborn to HIV, HIV viral load results, including detectable and undetectable viral load results, and HIV genotype test results, individuals in charge of the following types of group facilities identifying a disease, infection or condition listed in § 27.21a (relating to reporting of cases by health care practitioners and health care facilities) by symptom, appearance or diagnosis shall make a report within the timeframes required in § 27.21a:

(1) Institutions maintaining dormitories and living rooms.

(2) Orphanages.

(3) Child care group settings.

DISEASES AND CONDITIONS REQUIRING SPECIAL REPORTING

§ 27.32a. Reporting AIDS, HIV, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable viral load results and HIV genotype test results, and perinatal exposure of newborns to HIV.

(a) *Reporting by clinical laboratories.*

(1) A person in charge of a clinical laboratory shall report CD4 T-lymphocyte counts and percentages electronically to the Department through the appropriate electronic disease surveillance system within 5 work days of obtaining the test results.

(2) A person in charge of a clinical laboratory shall report positive test results of any test approved by the FDA to establish the presence of HIV, including a serologic, virologic, nucleic acid (DNA or RNA) or any other type of test the FDA approves to establish the presence of HIV. The report shall be made to the appropriate electronic disease surveillance system within 5 work days of obtaining the test results.

(3) A person in charge of a clinical laboratory shall report HIV viral load test results, including detectable and undetectable viral load results, and HIV genotyping results, to the Department through the appropriate electronic disease surveillance system, within 5 work days of obtaining the test results.

(4) The report shall include the following information:

(i) The individual's name and the address, city, county and zip code of the individual's residence.

(ii) The patient identifying number assigned to the individual by the physician or at the facility requesting the laboratory test.

(iii) The individual's date of birth (month, day, year).

(iv) The individual's sex.

(v) The individual's race/ethnicity.

(vi) The date of each test performed.

(vii) The type of tests performed.

(viii) The results of the tests.

(ix) The name of the person or entity submitting the specimen for testing.

(x) The address of the person or entity submitting the specimen for testing, including the zip code, physical address and telephone number of the submitter.

(5) To enable the laboratory to complete the report it is required to file with the Department, a person or entity that requests a laboratory test for HIV, a CD4 T-lymphocyte count or percentage, or HIV viral load test results, including detectable or undetectable test results, and HIV genotype test results shall provide to the laboratory the information in subsection (a)(4), with the

exception of subparagraphs (vi)—(ix). In addition to the information included in subsection (a)(4), a person or entity that requests a laboratory test for HIV, a CD4 T-lymphocyte count or percentage, an HIV viral load test result, including detectable or undetectable test results, and HIV genotype test results shall provide to the laboratory the date each test was requested and the type of test or tests requested.

(b) *Reporting by health care practitioners, hospitals, and other persons or entities, who diagnose AIDS or who receive or provide HIV test results, CD4 T-lymphocyte counts and percentages, or HIV viral load test results, including detectable and undetectable results, and HIV genotype test results.*

(1) A health care practitioner, hospital, person providing HIV services or person in charge of an entity providing HIV services, who makes a diagnosis of AIDS or who receives HIV test results, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable results, or HIV genotype test results, or who provides an AIDS diagnosis, HIV test results, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable test results, and HIV genotype test results to patients, shall report the following to the Department through the appropriate electronic disease surveillance system within 5 work days of the diagnosis of AIDS or the receipt of the results of the test:

(i) A diagnosis of AIDS.

(ii) A positive result of any test approved by the FDA to establish the presence of HIV, including a serologic, virologic, nucleic acid (DNA or RNA) or any other type of test the FDA approves to establish the presence of HIV.

(iii) CD4 T-lymphocyte counts and percentages.

(iv) A perinatal exposure of a newborn to HIV.

(v) HIV viral load results, including detectable and undetectable viral load results, and HIV genotype test results.

(2) A report of an HIV test result, CD4 T-lymphocyte count and percentage, HIV viral load test result, including detectable and undetectable test results, and HIV genotype test result, AIDS case based on the CDC case definition, or perinatal exposure of a newborn to HIV shall include the following information:

* * * * *

(xi) The name, address and telephone number of the health care practitioner, hospital, or other person or entity that secured a specimen from the individual and submitted it for laboratory testing.

(xii) The name, address and telephone number of the entity in which the AIDS diagnosis was made or that received the HIV test result, CD4 T-lymphocyte count and percentage, HIV viral load test results, including detectable and undetectable test results, or HIV genotype test results.

(3) In addition to reporting the AIDS diagnosis or the receipt of test results, the reporter shall maintain the data required in paragraph (2) in the patient file on the Department's HIV/AIDS report form.

(4) A local health department receiving reports of diagnoses of AIDS, positive HIV test results, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable test results, and HIV genotype test results, and perinatal exposures to HIV shall forward completed case reports containing the information included in paragraph (2) to the Department through the Department's electronic disease surveillance system.

§ 27.32b. Confidential and anonymous testing.

* * * * *

(b) Anonymous test results shall be reported in accordance with § 27.32a(b)(2) (relating to reporting AIDS, HIV, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable test results, and HIV genotype test results and perinatal exposure of newborns to HIV). In lieu of the information required in § 27.32a(b)(2)(i), the report of an anonymous test shall include an assigned number preprinted on the HIV counseling and testing report form. The report shall also include the individual's county of residence.

* * * * *

§ 27.32c. Partner services relating to HIV and AIDS.

(a) A person providing an AIDS diagnosis, HIV test results, CD4 T-lymphocyte counts and percentages, HIV viral load test results including detectable and undetectable viral load test results, or HIV genotype test results to an individual may ask for the Department's assistance with counseling if the person chooses to do so.

(b) A person providing an AIDS diagnosis, HIV test results, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable viral load test results, or HIV genotype test results to an individual shall inform the individual that the Department or a local health department may contact the individual for a voluntary confidential interview to discuss partner services, including counseling, testing, referral and partner notification.

(c) Counseling, testing referral and partner notification services shall be performed in accordance with the Confidentiality of HIV-Related Information Act (35 P.S. §§ 7601—7612).

§ 27.32d. Department authority to require complete reporting.

The Department will have access to and may review the patient records of health care practitioners, hospitals, persons providing HIV services and persons in charge of entities providing HIV services, who make diagnoses of AIDS, or who receive or provide HIV test results, CD4 T-lymphocyte counts or percentages, HIV viral load test results including detectable and undetectable test results, or HIV genotype test results. Access and review will enable the Department to conduct case investigations, to determine whether under-reporting is occurring, to investigate reporting delays and to investigate other reporting problems.

§ 27.32e. Record audits.

(a) The Department may conduct record audits of the records of health care practitioners, hospitals, persons providing HIV services and persons in charge of entities providing HIV services, who make diagnoses of AIDS or who receive or provide HIV test results, CD4 T-lymphocyte counts and percentages, HIV viral load test results including detectable and undetectable test results, or HIV genotype test results for the purpose of obtaining information allowing the Department to complete HIV, CD4 T-lymphocyte case reports, and viral load and HIV genotyping case reports to aid it in tracking trends in disease and obtaining additional funding for prevention and treatment programs. The Department may audit records going back to January 1, 2000, for this purpose.

(b) The Department may require special reports of persons or entities required to report under this chapter to ensure compliance with this chapter.

[Pa.B. Doc. No. 20-1487. Filed for public inspection October 30, 2020, 9:00 a.m.]

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF CERTIFIED REAL ESTATE APPRAISERS

[49 PA. CODE CH. 36]

Appraisal Management Companies; Federally Mandated Revisions

The State Board of Certified Real Estate Appraisers (Board) hereby amends § 36.401 (relating to definitions) to read as set forth in Annex A.

Effective Date

This final-omitted rulemaking will be effective upon publication in the *Pennsylvania Bulletin*.

Statutory Authority

Section 4(a) of the Appraisal Management Company Registration Act (act) (63 P.S. § 457.24(a)) authorizes the Board to implement, administer and enforce the act, including the power to adopt rules and regulations consistent with the act.

Omission of Proposed Rulemaking

Under section 204(3) of the Commonwealth Documents Law (CDL) (45 P.S. § 1204(3)), the Board is authorized to omit the procedures for proposed rulemaking in section 201 and 202 of the CDL (45 P.S. §§ 1201 and 1202) if the Board finds that the specified procedures are impracticable, unnecessary or contrary to the public interest. The Board has determined that publication of proposed rulemaking is unnecessary under the circumstances because this final-omitted rulemaking is merely amending definitions to comply with applicable Federal law.

Background and Need for the Amendments

Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA) (Pub.L. No. 101-73, 103 Stat. 183) (12 U.S.C.A. §§ 3331—3356) requires the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the National Credit Union Administration Board, the Bureau of Consumer Financial Protection and Federal Housing Finance Agency (hereinafter collectively referred to as "Federal agencies") to establish minimum requirements to be applied by states in the registration and supervision of appraisal management companies (AMC) at 12 U.S.C.A. § 3353 regarding appraisal management company minimum requirements. Under this authority, these Federal agencies jointly adopted regulations establishing the minimum requirements for appraisal management companies at 12 CFR 34.210—34.216, 12 CFR 225.190—225.196, 12 CFR 323.8—323.14 and 12 CFR 1222.20—1222.26. The Federal agencies defined "appraiser panel" to include "a network, list or roster of **licensed or certified appraisers** approved by an AMC to perform appraisals as independent contractors for the AMC." See, 12 CFR 225.191(f), 12 CFR 323.9(e), 12 CFR 1222.21(e) and 12 CFR 34.211(e) (emphasis added).

When the Board originally promulgated its regulations implementing the act, the intent was to promulgate a definition of appraiser panel that comported with the Federal requirements. Upon further review, however, the Board has determined that it erroneously did not include "licensed" appraisers in the definition of appraiser panel. While the Real Estate Appraisers Certification Act (63 P.S. §§ 457.1—457.19) does not authorize a licensure category of "licensed appraisers" in this Commonwealth, the Board must include licensed appraisers in determining the composition of appraisal panels to comply with the Federal laws and regulations. For that reason, the Board is amending the definition of "appraiser panel" to include both licensed and certified real estate appraisers.

Federal law also sets forth registration limitations for owners of AMCs. Under FIRREA at 12 U.S.C.A. § 3353(d) regarding registration limitations, "[a]n appraisal management company shall not be registered by a State or included on the national registry if such company, in whole or in part, directly or indirectly, is owned by any person who has had an appraiser license or certificate refused, denied, cancelled, surrendered in lieu of revocation, or revoked in any State. Additionally, each person that owns more than 10 percent of an appraisal management company shall be of good moral character, as determined by the State appraiser certifying and licensing agency, and shall submit to a background investigation carried out by the State appraiser certifying and licensing agency." While the act incorporates the Federal limitations regarding good moral character and appraiser discipline for owners, it did not provide a definition of owner within the act.

Therefore, the Board included a definition of the term "owner" in its regulations at § 36.401 as "[a] person that owns 10% or more of an appraisal management company." In defining the term "owner," the Board relied upon guidance available at the time from the Appraisal Subcommittee of the Federal Financial Institutions Examination Council (ASC), the Federal agency responsible for the oversight of the Board. Since the Board promulgated its regulations, the ASC has advised the Board that the definition in the Board's existing regulations is inconsistent with Federal law because the 10% threshold is not applicable to the ownership limitation prohibiting an owner from having specific types of discipline against an appraiser license. Thus, the Board must amend the definition of owner because, except under certain limited circumstances, Federal law prohibits an AMC from being registered if any owner, and not just owners who own 10% or more of an AMC, has had an appraiser license or certificate refused, denied, canceled, surrendered instead of revocation or revoked in any state.

Description of the Amendments

The Board amends the definitions of "appraiser panel" and "owner" in § 36.401. The Board includes licensed appraisers in the definition of "appraiser panel." The Board modifies the definition of "owner" to accurately reflect the Federal limitations for owners by removing the 10% threshold and amends the definition as follows: "A person that owns, in whole or in part directly or indirectly, an appraisal management company." The ASC reviewed the Board's regulations and Annex A and supports the Board's amendments.

Fiscal Impact and Paperwork Requirements

This final-omitted rulemaking has a minimal fiscal impact on the regulated community. AMCs will incur

minimal costs relating to registration, paperwork, recordkeeping and reporting. All owners, even owners who own less than 10%, must be identified in applications and must submit to a criminal history information report as required by the Board's regulations in § 36.404(a)(6) (relating to content of application). The cost of the criminal history information report is minimal ($22 in Pennsylvania). The Board estimates that it receives approximately seven AMC initial applications and five change of ownership applications each year. For initial applications, even if the Board assumes that three of the seven AMCs have owners who own less than 10%, the economic impact is only $66 per year. For change of owner applications, if the Board assumes two of the five applications have owners who own less than 10%, the economic impact is $44 per year. Thus, the total annual economic impact is estimated at approximately $110 per year.

The costs to the Board include those associated with processing applications of AMCs with owners who own less than 10%. However, since the Board modified its applications in the fall of 2018 to include all owners, the Board has not experienced an increase in the number of criminal history information report reviews. To the extent that additional costs are incurred, it will be borne by the applicants through payment of the criminal history information report. Costs of enforcing the regulations are borne by the licensees/registrants through payment of biennial renewal fees and application fees, so there is no adverse fiscal impact to the Board.

This final-omitted rulemaking will not have a fiscal impact and will not create additional paperwork to the general public or the Commonwealth's political subdivisions.

Sunset Date

The Board continuously monitors the effectiveness of the regulations. Therefore, no sunset date has been assigned.

Regulatory Review

Under section 5.1(c) of the Regulatory Review Act (71 P.S. § 745.5a(c)), on September 3, 2020, the Board submitted a copy of the final-omitted rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee (SPC/PLC) and the House Professional Licensure Committee (HPLC). On the same date, the Board submitted a copy of the regulation to the Office of Attorney General under the Commonwealth Attorneys Act (71 P.S. §§ 732-101—732-506).

Under section 5.1(j.2) of the Regulatory Review Act, on October 14, 2020, the final-omitted rulemaking was deemed approved by the SPC/PLC and the HPLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on October 15, 2020, and approved the final-omitted rulemaking.

Additional Information

Further information may be obtained by contacting Heidy Weirich, Board Administrator, State Board of Certified Real Estate Appraisers, 2601 North Third Street, P.O. Box 2649, Harrisburg, PA 17105-2649. Reference regulation No. 16A-7023 (Appraisal Management Companies), when requesting information.

Findings

The Board finds that:

(1) Public notice of the Board's intention to amend the Board's regulations under the procedures in sections 201 and 202 of the CDL has been omitted under section 204 of the CDL because publication of proposed rulemaking and public comment is unnecessary in that the rulemaking merely amends definitions to comply with Federal law and regulations.

(2) The amendment of the Board's regulations in the manner provided in this order is necessary and appropriate for the administration of the Appraisal Management Company Registration Act (63 P.S. §§ 451.21—457.31).

Order

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board at 49 Pa. Code Chapter 36 are amended by amending § 36.401 to read as set forth in Annex A.

(b) The Board shall submit this final-omitted regulation to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(c) The Board shall submit this final-omitted regulation to the Independent Regulatory Review Commission, the SPC/PLC and the HPLC as required by law.

(d) The Board shall certify this final-omitted regulation and deposit it with the Legislative Reference Bureau as required by law.

(e) This final-omitted rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

JOSEPH D. PASQUARELLA,
Chairperson

(*Editor's Note*: See 50 Pa.B. 6096 (October 31, 2020) for IRRC's approval order.)

Fiscal Note: 16A-7023. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 36. STATE BOARD OF CERTIFIED REAL ESTATE APPRAISERS

Subchapter E. APPRAISAL MANAGEMENT COMPANIES

GENERAL PROVISIONS

§ 36.401. Definitions.

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

* * * * *

Appraiser panel—A network or panel of certified or licensed appraisers who are independent contractors to an appraisal management company. Appraisers on an appraisal management company appraisal panel include all of the following:

(i) Appraisers engaged by the appraisal management company.

(ii) Appraisers accepted by the appraisal management company for consideration in future appraisal assignments.

* * * * *

Owner—A person that owns, in whole or in part, directly or indirectly, an appraisal management company.

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[Pa.B. Doc. No. 20-1488. Filed for public inspection October 30, 2020, 9:00 a.m.]