Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

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Independent Regulatory Review Commission

IRRC Number:

(1) Agency
Department of Health

(2) Agency Number: 10

Identification Number: 221

(3) PA Code Cite: 28 Pa. Code §§ 201.1, 201.2, 201.3

(4) Short Title:

Long-term care nursing facilities: *Rulemaking 1 – General Applicability and Definitions*

Please note that this is the first of four final-form rulemaking packages, with respect to long-term care nursing facilities, to be promulgated by the Department.

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: Ann Chronister, Director, Bureau of Facility Licensure and Certification, 717-547-3131, RA-DHLTCRegs@pa.gov

(6) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- ☒ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

This is the first of four rulemaking packages that amend Subpart C (relating to long-term care facilities) of Part IV of Title 28 of the Pennsylvania Code. Subpart C consists of 6 different chapters: Chapters 201, 203, 205, 207, 209 and 211. This final-form rulemaking amends the general applicability provisions and the definitions section under Chapter 201.

The purpose of this final-form rulemaking is to create consistency between Federal and State requirements for long-term care nursing facilities by expanding the adoption of the Federal requirements to include the requirements set forth at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). This final-form rulemaking also updates existing definitions applicable to long-term care nursing facilities.

Although the proposed rulemaking proposed changes to the minimum hours of direct resident care under section 211.12 (relating to nursing services), for readability and clarity, those substantive amendments are addressed with similar nursing services amendments in Rulemaking 4 – *Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services.*

(8) State the statutory authority for the regulation. Include specific statutory citation.

Sections 601 and 803 of the Health Care Facilities Act (HCFA or act) (35 P.S. §§ 448.601 and 448.803) authorize the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the HCFA. Section 801.1 of the HCFA (35 P.S. § 448.801a) seeks to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities. The minimum standards are to assure safe, adequate and efficient facilities and services and to promote the health, safety and adequate care of patients or residents of those facilities. In section 102 of the HCFA, 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. 35 P.S. § 448.102. Finally, Section 201(12) of the HCFA (35 P.S. § 448.201(12)) provides the Department with explicit authority to enforce its rules and regulations promulgated under the HCFA.

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

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

The regulations are not mandated by any Federal or State statute, court order, or Federal regulation. With respect to State law, the Department is authorized under the HCFA to promulgate regulations that promote the health, safety and adequate care of patients and residents in health care facilities, which includes residents in long-term care nursing facilities. 35 P.S. §§ 448.604 and 448.803. In addition, the act states that the Department shall take into consideration Federal certification standards, as appropriate, when developing rules and regulations for licensure of health care facilities. 35 P.S. § 448.806(b).

The Department's expansion of its adoption of the Federal health and safety requirements for long-term care facilities at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) complies with this requirement. Under this final-form rulemaking, all facilities licensed by and seeking licensure by the Department will be required to comply with the Federal requirements in 42 CFR Part 483, Subpart B, with the exception of 42 CFR 483.1 (relating to basis and scope) and the data transmission and MDS reporting requirements. These exceptions will only apply to facilities participating in the Medicare or Medical Assistance (MA) Programs.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

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

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

Further, the COVID-19 pandemic highlighted the vulnerability of older adults, with a larger percentage of deaths occurring in individuals 65 years of age and older. Centers for Disease Control and Prevention (CDC). Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC. Retrieved from https://covid.cdc.gov/covid-data-tracker/#demographics. *See also*, CDC. COVID-19 Weekly Cases and Deaths per 100,000 Population by Age, Race/Ethnicity and Sex, United States, March 1, 2020—June 25, 2022. Retrieved from https://covid.cdc.gov/covid-data-tracker/#demographicsovertime. Further, it is estimated that at least a quarter of COVID-19 deaths occurred in long-term care nursing facilities. The COVID Tracking Project. (March 2021). Long-Term-Care COVID Tracker. Retrieved from https://covidtracking.com/nursing-homes-long-term-care-facilities. In this Commonwealth alone, there have been approximately 11,443 confirmed deaths of residents in long-term care nursing facilities since January 2020. AARP. (September 15, 2022). AARP Nursing Home COVID-19 Dashboard Fact Sheets. Retrieved from https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-states.html.

The Department's long-term care nursing facilities regulations have not been updated since 1999, with the last significant update occurring in 1997 after the 1996 amendment to the Health Care Facilities Act (the HCFA or act) (35 P.S. §§ 448.101—448.904b). Since that time, there have been substantial changes in the means of delivering care and providing a safe environment for residents in long-term care nursing facilities, with the pandemic further highlighting the need for change.

Approximately 72,000 individuals reside in the 682 long-term care nursing facilities currently licensed by the Department. These 72,000 individuals, and their family members, will benefit from this final-form regulation. Further, the current residents for the three private pay facilities will benefit with the updated standards from 1998. Since the Department's adoption of the 1998 regulations 23 years ago,

there have been expanded requirements for emergency preparedness; quality assurance and infection control; abuse, neglect and exploitation protections; and admission and discharge protections to ensure the health and safety of residents. These three facilities had a reported, combined census of 79 residents for the Department's 2020-2021 annual report. Department of Health. (2021). Nursing Home Reports. Retrieved from: https://www.health.pa.gov/topics/HealthStatistics/HealthFacilities/NursingHomeReports/Pages/nursing-home-reports.aspx.

Further, the regulated community will benefit from the efficiency of the consistent adoption and application of the Federal requirements for health and safety at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). The Commonwealth generally will also benefit from the efficiency of Department surveyors applying consistent health and safety standards.

(11) Are there provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

As provided above, this final-form rulemaking incorporates the Federal standards and certification requirements for long-term care facilities under 42 CFR Part 483, Subpart B. All facilities licensed by or seeking licensure by the Department will be required to comply with these Federal requirements, except for the following provisions: 42 CFR 483.1 (relating to basis and scope); and the data transmission and MDS reporting requirements. These exceptions, however, only apply to those facilities not participating in the Medicare or MA Programs.

Section 201.3 (relating to definitions) conforms with Federal definitions, except in instances where specified terms are defined elsewhere in state law.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

Pennsylvania's ability to compete with other states will not be impacted by the adoption of the Federal health and safety requirements and definitions. All long-term care nursing facilities that participate in the Federal Medicare or Medicaid programs are required to comply with the Federal standards and certification requirements for long-term care facilities, regardless of where the facilities are located.

The Department reviewed the regulations of other states to determine which states have expressly adopted the Federal requirements as State licensing requirements. Of the states surrounding Pennsylvania, Delaware has expressly adopted the Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). 16 Del. Admin. Code § 3201-1.21. New York has not expressly adopted the Federal requirements but has a general provision in its regulations requiring that long-term care facilities comply with all pertinent Federal regulations. N.Y. Comp. Codes R. & Regs. tit. 10 § 415.1(4). Ohio, New Jersey, West Virginia and Virginia have not expressly adopted the Federal requirements.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

This final-form rulemaking will not affect the regulations of any other state agency. As provided above, the Department is currently updating the various regulatory chapters relating to long-term care facilities. This final-form rulemaking is the first of four rulemaking packages that amend the 6 chapters of Subpart C (relating to long-term care facilities) of 28 Pa. Code Part IV.

This final-form rulemaking amends the general applicability provisions and the definitions section. The other three nursing facility regulatory packages are as follows:

Rulemaking 2 – *General Operation and Physical Requirements*

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

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

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

The Department's outreach has included various representatives from industry stakeholders and consumer advocacy groups, including small businesses and those groups representing them. As analyzed in further detail below, at least 91% of nursing facilities in the Commonwealth meet the definition of a small business due to $30 million or less in annual receipts.

The Department began the process of updating the current long-term care nursing facilities 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 members of the LTC Work Group met regularly during 2018 with the LTC Work Group's primary focus being the simplification and modernization of the existing long-term care regulations. After these discussions were complete, the Department reviewed the recommendations of the LTC Work Group and consulted with other potentially impacted agencies in 2019 and 2020. In 2020, 2021 and 2022, the Department continued its efforts to draft amendments to the long-term care nursing facility regulations

while also handling the day-to-day challenges of protecting the residents of those facilities, who were being hit the hardest by the COVID-19 pandemic.
In 2019 and 2020, the Department consulted with the Department of Aging, Department of Human Services (DHS) and Department of Military and Veterans Affairs (DMVA), who also participated in the above LTC Work Group discussions. The Department presented the proposed regulations to the Health Policy Board on October 29, 2020

In addition to considering comments on the four proposed regulatory packages during and outside of the four public comment periods, the Department also met with stakeholders on three occasions following the receipt of public and IRRC comments to discuss their concerns and to gain additional insight into comments that were received.

The first of these meetings occurred on December 15, 2021. Representatives from AARP, Alzheimer's Association – Delaware Valley and Greater Pennsylvania Chapters, Center for Advocacy for the Rights & Interests of the Elderly (CARIE), Community Legal Services, LeadingAge, Pennsylvania Health Care Association (PHCA), Pennsylvania Coalition of Affiliated Healthcare & Living Communities (PACAH), and SEIU Healthcare Pennsylvania attended that meeting.

The second meeting, for proposed Rulemaking 3, occurred on June 8, 2022. Representatives from AARP, Alzheimer's Association, CARIE, Community Legal Services, LeadingAge, PHCA, Pennsylvania Health Law Project (PHLP), and SEIU attended that meeting. The Department explicitly stressed to stakeholders during this June 8, 2022, meeting that it would be considering comments on all proposed rulemakings, and that it would welcome any additional comments or feedback that stakeholders might have after the meeting regarding proposed amendments to the regulations. The Department also indicated in a press release on June 3, 2022, that it would be considering comments on all four proposed rulemakings before submitting final-form regulations.

The Department held a third stakeholder meeting in August 2022 after the public and IRRC comment periods ended for proposed Rulemaking 4. The Department presented the final-form regulations to the Health Policy Board on August 10, 2022, and met with stakeholders one last time on August 17, 2022, to present the final-form regulations for final discussion and feedback. At this meeting, the Department presented stakeholders with an overview of the amendments that were made from proposed to final-form in response to their comments, on all four rulemakings, and provided them with an opportunity to comment and provide feedback on the final-form regulations. Present at that meeting were representatives from the Alzheimer's Association, CARIE, Community Legal Services, County Commissioners Association (CCAP), Disability Rights, LeadingAge, PHCA, PHFC, and SEIU.

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

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

Long-Term Care Nursing Facilities

The final-form rulemaking will affect the 682 long-term care nursing facilities licensed by the Department since these facilities will have to comply with the rulemaking. These facilities provide health services to approximately 72,000 residents. This total includes 19 county-owned and operated facilities, 6 veterans' homes that are operated by the Department of Military and Veterans Affairs, 654 privately-owned facilities that participate in the Medicare and/or MA Programs, and three private-pay facilities that do not participate in either Medicare or MA.

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

All 19 county-owned long-term care nursing facilities participate in the Medicare or MA program and thus, are already required to comply with the Federal health and safety standards. Similarly, the 654 privately-owned facilities that participate in the Medicare or MA Programs are already required to comply with the incorporated Federal health and safety standards.

The three private-pay facilities have a combined capacity of 102 licensed beds of the approximate 72,000 residents. Further, these facilities had a reported, combined census reported of 79 residents for the Department's 2020-2021 annual report. Department of Health. (2021). Nursing Home Reports. Retrieved from: https://www.health.pa.gov/topics/HealthStatistics/HealthFacilities/NursingHomeReports/Pages/nursing-home-reports.aspx. These facilities are presently required to comply with the Federal requirements, as they existed on October 1, 1998, except for specified provisions relating to resident rights, admission, transfer and discharge, resident assessment, nursing, physician and dental services, physical environment and administration.

The existing regulations of the Department already incorporate many of the Federal health and safety requirements. Further, the incorporation of additional requirements impacts only those long-term care nursing facilities that do not participate in Medicare or MA. There are currently 3 private-pay long-term care nursing facilities that do not participate in either Medicare or MA. Based on comments received, the Department is exempting these private-pay facilities from complying with 42 CFR 483.1 (relating to basis and scope) and the data transmission and Minimum Data Set (MDS) reporting requirements.

The regulated community will benefit from the efficiency of the consistent adoption and application of the Federal requirements for health and safety at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities).

Small Business Analysis

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

Department determined that a long-term care nursing facility is a small business if it has $30 million or less in annual receipts.

Based on the analysis of the latest long-term care nursing facility cost reports from the Centers for Medicare & Medicaid Services (CMS), the Department determined that 623 facilities that participate in Medicare and/or MA have $30 million or less in annual receipts. In making this determination, the Department applied current Federal Standards of Accounting to this data to determine each facility's annual receipts. The latest cost report data from CMS is 2018. Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data. Although the data from CMS is from 2018, the Department expects a consistent number of facilities to meet the definition of a small business.

The Department also asked stakeholders during the meetings held in 2021 and 2022 for assistance in determining the impact to small businesses. The stakeholders were not able to provide the Department with specific information regarding how the Department's proposed regulations would impact small businesses. However, during the stakeholder meeting for Rulemakings 1 and 2, a stakeholder suggested that the Department search GuideStar, which provides financial information regarding nonprofit entities, to determine whether the three private-pay facilities are small businesses. The Department searched the GuideStar website at https://www.guidestar.org/ for the three private-pay facilities that are licensed by the Department. Based on this data, one of the private-pay facilities, Friends Home in Kennett/Linden Hall, meets the definition of a small business under NAICS standards. Another private-pay facility, Foulkeways at Gwynedd does not meet the definition of a small business under NAICS standards because its gross receipts exceed $30 million. Data for the third private-pay facility, Dallastown Nursing Center, is not available on GuideStar, but for the purposes of this analysis, the Department assumes that Dallastown, similar to other nursing facilities, is a small business.

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

Residents of Long-Term Care Nursing Facilities

More than 72,000 residents in the 682 licensed long-term care nursing facilities will benefit from the adoption of the Federal requirements because the same standards will now be applied to all long-term care nursing facilities, regardless of whether those facilities participate in the Medicare or MA Programs.

Department

The Department licenses long-term care nursing facilities. 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 Department does not expect there to be an increase in costs associated with its responsibility to license and survey long-term care nursing facilities as a result of this rulemaking. It is anticipated that the adoption of the Federal requirements will create consistency in the licensing and survey process for long-term care nursing facilities because the same standards will now apply to all long-term care nursing facilities in the Commonwealth. This will result in a more streamlined licensing and inspection process for both the Department and long-term care nursing facilities operating in the Commonwealth.

Department of Human Services
Although the provisions of this final-form rulemaking, which relate to incorporation of federal health and safety standards and the updating of definitions, will not have a cost impact to the Department of Human Services, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023, was enacted under Act 2022-54 and appropriated under the General Appropriations Act of 2022 (Act 2022-1A).

Department of Military and Veterans Affairs
This final-form rulemaking will not have a cost impact to Department of Military and Veterans Affairs since its facilities already participate in the Medicare and MA Programs.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

All 682 licensed long-term care nursing facilities in the Commonwealth will be required to comply with the health and safety standards of this final-form rulemaking. At least 91% of nursing facilities meet the definition of a small business. These facilities provide care to approximately 72,000 residents.

As provided above, pursuant to section 3 of the Regulatory Review Act (71 P.S. § 745.3), the Department applied the NAICS standards to determine how many long-term care nursing facilities licensed by the Department are small businesses. Based on the latest cost report from CMS, the Department determined that 623 facilities that participate in the Medicare and/or MA Programs meet the definition of small business since they have $30 million or less in annual receipts. The latest cost report data from CMS is available at https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data.

Based on GuideStar, which provides financial information regarding nonprofit entities, one of the private-pay facilities, Friends Home in Kennett/Linden Hall meets the definition of a small business under NAICS standards. Another private-pay facility, Foulkeways at Gwynedd does not meet the definition of a small business under NAICS standards because its gross receipts exceed $30 million. Data for the third private-pay facility, Dallastown Nursing Center, is not available on GuideStar, but for the purposes of this analysis, the Department assumes that Dallastown, similar to other nursing facilities, is a small business. https://www.guidestar.org/

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

Long-Term Care Nursing Facilities

This final-form rulemaking applies to all 682 licensed long-term care nursing facilities in the Commonwealth. At least 91% of nursing facilities meet the definition of a small business. These facilities provide health services to approximately 72,000 residents. The existing regulations of the Department already incorporate many of the Federal requirements and the expansion to incorporate the remaining Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) will impact the 3 long-term care nursing facilities that do not participate in either the Medicare or MA Program. However, based on comments received, the Department is exempting facilities from complying with 42 CFR 483.1 (relating to basis and scope) and the data transmission and Minimum Data Set (MDS) reporting requirements, unless the facility participates in the Medicare or MA Programs.

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

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

Total $67,862

However, based on the Department's experience with facilities' compliance with existing regulatory requirements, these facilities already comply with various provisions, such as infection prevention and control measures, emergency preparedness and planning, food service safety, and homelike environment requirements. Therefore, it is unlikely that the facilities would reach the maximum estimated costs. Further, in response to comments related to the grievance officer, it is not expected that a facility hire a new individual to perform this function, but instead that a facility have a person to serve this function, consistent with the needs of the facility. In addition, it is likely that most facilities already have a process to address complaints.

In addition, a facility may apply for an exception to the requirements of Subpart C (relating to long-term care facilities) under §§ 51.31—51.34 (relating to exceptions). This includes the ability to apply for an exception to the incorporation of a specific Federal requirement. Specifically, all facilities, including private-pay facilities, may request an exception under the process identified in 28 Pa. Code §§ 51.31—51.34. To assist the Department in rendering decisions on requests for exceptions, a facility requesting such an exception is required to identify the specific Federal requirements to which it is seeking an exception, rather than broadly requesting an exception to all the Federal requirements.

Requiring all long-term care nursing facilities to comply with the minimum Federal health and safety standards for long-term care facilities will increase health and safety standards, improve the survey process, create consistency and eliminate any confusion in the application of standards to long-

term care nursing facilities, which will benefit all long-term care nursing facilities. Although there is anticipated to be a fiscal impact regarding incorporation of certain federal standards for the three facilities that do not participate in Medicare or MA Programs, the cost of these health and safety standards is outweighed by the health and safety benefits for nursing facility residents. The benefit of this final-form rulemaking is consistent standards for licensure to ensure the health, safety, and welfare of all residents of long-term care nursing facilities in this Commonwealth.

Department of Human Services

Although the provisions of this final-form rulemaking, which relate to incorporation of federal health and safety standards and the updating of definitions, will not have a cost impact to the Department of Human Services, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023, were enacted under Act 2022-54 and appropriated under the General Appropriations Act of 2022 (Act 2022-1A

Department of Military and Veterans Affairs

This final-form rulemaking will not have a cost impact to Department of Military and Veterans Affairs since its facilities already participate in the Medicare and MA Programs.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

Although there is anticipated to be a fiscal impact regarding incorporation of certain federal standards for the three facilities that do not participate in Medicare or MA Programs, the cost of these health and safety standards is outweighed by the health and safety benefits for nursing facility residents. The benefit of this final-form rulemaking is consistent standards for licensure to ensure the health, safety, and welfare of all residents of long-term care nursing facilities in this Commonwealth.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The existing regulations of the Department already incorporate many of the Federal health and safety requirements. Further, the incorporation of additional requirements impacts only those long-term care nursing facilities that do not participate in Medicare or MA. There are currently 3 private-pay long-term care nursing facilities that do not participate in either Medicare or MA. However, based on comments received, the Department is exempting these private-pay facilities from complying with 42 CFR 483.1 (relating to basis and scope) and the data transmission and Minimum Data Set (MDS) reporting requirements.

Assuming that the three private-pay facilities have not updated any of their practices and procedures since 1998, it is anticipated that the maximum cost to each facility to incorporate current federal health and safety standards would be approximately $68,349. This maximum estimate, adjusted for inflation, is based on the cost analysis from the Federal Department of Health and Human Services when it promulgated its comprehensive updates at 81 FR 68688 (October 4, 2016). A break-down of these potential costs, adjusted for inflation through the U.S. Bureau of Labor Statistics CPI Inflation Calculator, are as follows:

- Resident Rights, (42 CFR § 483.10) $13,020
- Admission, Discharge, and Transfer Rights (42 CFR § 483.15) $230
- Comprehensive Resident Centered Care Planning (42 CFR § 483.21) $6,760
- Nursing Services (42 CFR § 483.35) $304
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- Training (42 CFR § 483.95) $897

Total $67,862

However, based on the Department's experience with facilities' compliance with existing regulatory requirements, these facilities already comply with various provisions, such as infection prevention and control measures, emergency preparedness and planning, food service safety, and homelike environment requirements. Therefore, it is unlikely that the facilities would reach the maximum estimated costs. Further, in response to comments related to the grievance officer, it is not expected that a facility hire a new individual to perform this function, but instead that a facility have a person to serve this function, consistent with the needs of the facility. In addition, it is likely that most facilities already have a process to address complaints.

In addition, a facility may apply for an exception to the requirements of Subpart C (relating to long-term care facilities) under §§ 51.31—51.34 (relating to exceptions). This includes the ability to apply for an exception to the incorporation of a specific Federal requirement. Specifically, all facilities, including private-pay facilities, may request an exception under the process identified in 28 Pa. Code §§ 51.31—51.34. To assist the Department in rendering decisions on requests for exceptions, a facility requesting such an exception is required to identify the specific Federal requirements to which it is seeking an exception, rather than broadly requesting an exception to all the Federal requirements.

As provided above, the cost of these health and safety standards is outweighed by the health and safety benefits for nursing facility residents. The benefit of this final-form rulemaking is consistent standards for licensure to ensure the health, safety, and welfare of all residents of long-term care nursing facilities in this Commonwealth.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are currently 19 county-owned long-term care nursing facilities which account for approximately 7.5 percent (6,524 beds) of long-term care nursing beds across the Commonwealth. Allegheny County owns four of the nursing homes; the remaining homes are in the following 15 counties: Berks, Bradford, Bucks, Chester, Clinton, Crawford, Delaware, Erie, Indiana, Lehigh, Monroe, Northampton, Philadelphia, Warren, and Westmoreland.

All of the county-owned long-term care nursing facilities participate in either the Medicare or MA Programs and, thus, will not be impacted by the Department's incorporation of the Federal health and safety requirements.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

Department

The Department licenses long-term care nursing facilities. 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 Department does not expect there to be any increase in costs associated with its responsibility to license and survey long-term care nursing facilities under this final-form rulemaking. Rather, the amendments, in particular the adoption of the Federal requirements, will create consistency in the licensing and survey process for long-term care nursing facilities because the same standards will now apply to all long-term care nursing facilities in the Commonwealth. This will result in a more streamlined licensing and inspection process for both the Department and long-term care nursing facilities operating in the Commonwealth.

Department of Human Services

Although the provisions of this final-form rulemaking, which relate to incorporation of federal health and safety standards and the updating of definitions, will not have a cost impact to the Department of Human Services, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023, was enacted under Act 2022-54 and appropriated under the General Appropriations Act of 2022 (Act 2022-1A).

Department of Military and Veterans Affairs

This final-form rulemaking will not have a cost impact to Department of Military and Veterans Affairs since its facilities already participate in the Medicare and MA Programs.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

The incorporation of Federal health and safety requirements impact only those long-term care nursing facilities that do not participate in Medicare or MA. There are currently 3 private-pay long-term care nursing facilities that do not participate in either Medicare or MA. As such, the final-form rulemaking may require some additional paperwork for these facilities. However, there is no reasonable alternative to the increased paperwork.

Assuming that the three private-pay facilities have not updated any of their recordkeeping practices and procedures since 1998, it is anticipated the new paperwork requirements for the 3 private-pay facilities may include the following:

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

In addition, based on comments received, the Department is exempting facilities from complying with 42 CFR 483.1 (relating to basis and scope) and the data transmission and Minimum Data Set (MDS) reporting requirements, unless the facility participates in Medicare or MA.

(22a) Are forms required for implementation of the regulation?

There are no new forms required for implementation of this final-form rulemaking.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here.** If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

N/A

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY 2022-2023	FY +1 Year 2023-2024	FY +2 Year 2024-2025	FY +3 Year 2025-2026	FY +4 Year 2026-2027	FY +5 Year 2027-2028
SAVINGS:	$	$	$	$	$	$
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0

Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community – Facilities the participate in Medicare or MA	0	0	0	0	0	0
Regulated Community – 3 Private Pay Facilities	0	203,586	213,765	224,454	235,676	247,460
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs	0	203,586	213,765	224,454	235,676	247,460
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses	0	0	0	0	0	0

(23a) Provide the past three-year expenditure history for programs affected by the regulation.

Program	FY -3 2019-2020	FY -2 2020-2021	FY -1 2021-2022	Current FY 2022-2023
DOH Quality Assurance	22,513,000.	23,093,000.	24,393,000.	25,349,000.
MA – Long-Term Care	470,244,000	208,841,000	121,346,000	165,981,000
MA – Community Health Choices	2,328,939,000	3,165,550,000	4,251,550,000	5,061,602,000
DMVA (actual expenditures)	80,108,213	80,386,733	77,671,425	82,903,586

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.

This final-form rulemaking applies to all 682 licensed long-term care nursing facilities in the Commonwealth. At least 91% of nursing facilities meet the definition of a small business. These facilities provide health services to approximately 72,000 residents. This total includes 19 county-owned and operated facilities, 6 veterans' homes that are operated by DMVA, 654

privately-owned facilities that participate in Medicare and/or MA, and three private-pay facilities that do not participate in either Medicare or MA.

Under section 3 of the Regulatory Review Act, 71 P.S. § 745.3, a small business is "defined in accordance with the size standards described by the United States Small Business Administration's Small Business Size Regulations under 13 CFR Ch. 1 Part 121 (relating to Small Business Size Regulations) or its successor regulation." Under 13 CFR 121.101 (relating to what are SBA size standards), the Small Business Administration's (SBA) "size standards determine whether a business entity is small." Size standards are developed under the North America Industry Classification System (NAICS). The Department applied the NAICS standards to determine how many long-term care nursing facilities, licensed by the Department, are small businesses. Based on these federal standards, the Department determined that a long-term care nursing facility is a small business if it has $30 million or less in annual receipts.

Based on the analysis of the latest long-term care nursing facility cost reports from the Centers for Medicare & Medicaid Services (CMS), the Department determined that 623 facilities that participate in Medicare and/or MA have $30 million or less in annual receipts. In making this determination, the Department applied current Federal Standards of Accounting to this data to determine each facility's annual receipts. The latest cost report data from CMS is 2018. Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data. Although the data from CMS is from 2018, the Department expects a consistent number of facilities to meet the definition of a small business.

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

Based on this data, one of the private-pay facilities, Friends Home in Kennett/Linden Hall meets the definition of a small business under NAICS standards. Another private-pay facility, Foulkeways at Gwynedd does not meet the definition of a small business under NAICS standards because its gross receipts exceed $30 million. Data for the third private-pay facility, Dallastown Nursing Center, is not available on GuideStar, but for the purposes of this analysis, the Department assumes that Dallastown, similar to other nursing facilities, is a small business.

As provided above, at least 91% of nursing facilities meet the definition of a small business. Consistent with the HCFA and function of licensure, the purpose of these regulatory amendments is to ensure the health, safety, and welfare of all residents of long-term care nursing facilities in this Commonwealth by providing the minimum health and safety standards. Given that most facilities are a small business and the need for surveying for the health and safety of residents, the Department did not establish differing criteria for nursing facilities that are small business compared to the minority of facilities that are not small businesses. Further, in determining the minimum health and safety requirements, the department considered the myriad

of received comments, feedback from meetings and stakeholder groups and attempted to balance the interests between consumers and the stakeholder industry. The Department's responsibility to ensure that residents receive safe, quality care applies to all residents of long-term care nursing facilities in this Commonwealth, and it is critical that all residents of long-term care nursing facilities receive the same level of high-quality care, regardless of whether the facility they reside in is a small business under NAICS standards.

(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.

The incorporation of Federal health and safety requirements impact only those long-term care nursing facilities that do not participate in Medicare or MA. Assuming that the three private-pay facilities have not updated any of their recordkeeping practices and procedures since 1998, it is anticipated the new paperwork requirements for the 3 private-pay facilities include the following:

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

(c) A statement of probable effect on impacted small businesses.

See Question 15. Small businesses will be affected by these regulations in the same manner as other facilities that are not small businesses. Further, the Department anticipates that only two of the three private-pay facilities meets the definition of a small business, with gross receipts under $30 million.

(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

See answer to Question 26. The Department did not identify any less costly alternative that would be consistent with public health and safety. However, based on comments received, the Department is exempting private pay facilities from complying with 42 CFR 483.1 (relating to basis and scope) and the data transmission and Minimum Data Set (MDS) reporting requirements. In addition, in response to public comments, the effective date of this rulemaking is now July 1, 2023, which will allow the private pay facilities more time to prepare to comply with the new requirements.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

No special provisions have been developed as this final-form rulemaking applies to long-term care nursing facilities. Specifically, the regulations apply to all 682 long-term care nursing facilities in the Commonwealth, which serve approximately 72,000 nursing facility residents.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

Based on comments received, the Department is exempting private pay facilities from complying with 42 CFR 483.1 (relating to basis and scope) and the data transmission and Minimum Data Set (MDS) reporting requirements.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;
b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
c) The consolidation or simplification of compliance or reporting requirements for small businesses;
d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

(a) As provided above, the purpose of these amendments is to ensure the health, safety, and welfare of all residents of long-term care nursing facilities in this Commonwealth. Further, at least 91% of nursing facilities meet the definition of a small business with gross receipts under $30 million. Given the need for minimum health and safety requirements, coupled with the overwhelming majority of facilities meeting the definition of a small business, the Department did not establish less stringent compliance or reporting requirements. Further, with the exception of three facilities, the remainder of the facilities are presently required to comply with the Federal requirements. However, based on comments received, the Department is exempting facilities from complying with 42 CFR 483.1 (relating to basis and scope) and the data transmission and Minimum Data Set (MDS) reporting requirements, unless the facility participates in Medicare or MA.

(b) This final-form rulemaking does not have any less stringent or alternative schedules or deadlines for small businesses, which as defined, include at least 91% of nursing facilities.

(c) This final-form rulemaking does not have any consolidated or alternative reporting requirements for small business, which as defined, include at least 91% of nursing facilities. However, based on comments received, the Department is exempting the three private pay facilities from complying with the data transmission and Minimum Data Set (MDS) reporting requirements.

(d) This final-form rulemaking does not have alternative design or operational standards for small businesses, which as defined, include at least 91% of nursing facilities.

(e) This final-form rulemaking does not have specific exemptions for small businesses since, as defined, this includes as least 91% of nursing facilities.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

The Department relied on data obtained from the following sources:

Penn State Harrisburg, Pennsylvania State Data Center. (July 2018). *Population Characteristics and Change: 2010 to 2017 (Research Brief)*. https://pasdc.hbg.psu.edu/data/research-briefs/pa-population-estimates (report compiled based on US census data).

Penn State Harrisburg, Pennsylvania State Data Center. (June 2022). Population in Pennsylvania's Population by Age. (Research Brief). Retrieved from https://pasdc.hbg.psu.edu/sdc/pasdc_files/researchbriefs/June_2022.pdf.

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.

Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC. Retrieved from https://covid.cdc.gov/covid-data-tracker/#demographics.

The COVID Tracking Project. (March 2021). Long-Term-Care COVID Tracker. Retrieved from https://covidtracking.com/nursing-homes-long-term-care-facilities.

Kaiser Family Foundation. *Nursing Facilities, Staffing, Residents and Facility Deficiencies: 2009 through 2016*. (2018). https://www.kff.org/medicaid/report/nursing-faciliites-staffing-residents-and-facility-deficiencies-2009-through-2016 (last visited: November 25, 2020) (study of long-term care facilities conducted in 2018).

AARP Nursing Home COVID-19 Dashboard Fact Sheets. Retrieved from https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-states.html.

The Adverse Effects of the COVID-19 Pandemic on Nursing Home Resident Well-Being." *Journal of the American Medical Directors Association*, 22(5), 948-954.e2. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7980137/.

"Front-line Nursing Home Staff Experiences During the COVID-19 Pandemic." *Journal of the American Medical Directors Association*, 22(1), 199-203. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7685055/.

Department of Health. (2021). *Nursing Home Reports*. Retrieved from: https://www.health.pa.gov/topics/HealthStatistics/HealthFacilities/NursingHomeReports/Pages/nursing-home-reports.aspx.

State Policies Related to Nursing Facility Staffing. Retrieved from: https://www.macpac.gov/publication/state-policies-related-to-nursing-facility-staffing/

Gross Receipt Information -GuideStar Website - https://www.guidestar.org/

(29) Include a schedule for review of the regulation including:

A. The length of the public comment period:

30 days after notice or publication in the *Pennsylvania Bulletin*

B. The date or dates on which any public meetings or hearings will be held:

- The proposed regulations were presented to the Health Policy Board on October 29, 2020.
- On September 15, 2021, a public hearing was held before the Senate Aging & Youth Committee and the Senate Health & Human Services Committee, during which advocates provided feedback on proposed rulemaking 1.
- The Department held meetings on December 15, 2021, June 8, 2022, and August 3, 2022. The Department invited stakeholders and commentators to these meetings to discuss their comments on the proposed regulations.
- The final-form regulations were presented to the Health Policy Board on August 10, 2022.
- The Department held a meeting on August 17, 2022. At this meeting, the Department presented stakeholders with an overview of the amendments that were made from proposed to final-form in response to their comments, on all four rulemakings, and provided them with an additional opportunity to comment and provide feedback on the final-form regulations.

C. The expected date of delivery of the final-form regulation: September 2022

D. The expected effective date of the final-form regulation: July 1, 2023

E. The expected date by which compliance with the final-form regulation will be required:

July 1, 2023

F. The expected date by which required permits, licenses or other approvals must be obtained:

Long-term care nursing facilities are already required to be licensed in the Commonwealth. This final-form rulemaking will not alter that requirement and all statutory timeframes for licensure will remain in effect.

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Department regularly reviews the validity and efficacy of its regulations and will continue to do so in the future and as needs arise. In addition, the Department will be providing technical assistance and outreach to the regulated community to assist with implementation of this final-form regulation.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED

SEP 27 2022

Independent Regulatory
Review Commission

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General	Copy below is here by certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or Independent Agencies.
BY: _____ (DEPUTY ATTORNEY GENERAL)	Department of Health (AGENCY)	BY: _____
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO: 10-221	September 27, 2022 DATE OF APPROVAL
☐ Check if applicable Copy not approved. Objections attached.	DATE OF ADOPTION: _____ BY: Denise Johnson, M.D. _____ TITLE: Acting Secretary of Health (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	Deputy General Counsel (Chief Counsel, Independent Agency) (Strike inapplicable title) ☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING

DEPARTMENT OF HEALTH

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

SUBPART C. LONG-TERM CARE FACILITIES

28 PA. CODE §§ 201.1—201.3

RULEMAKING 1 — GENERAL APPLICABILITY AND DEFINITIONS

The Department of Health (Department), after consultation with the Health Policy Board, amends 28 Pa. Code §§ 201.1—201.3, to read as set forth in Annex A. This is the first of four final-form rulemaking packages for long-term care nursing facilities being promulgated by the Department.

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

Rulemaking 1 – General Applicability and Definitions

§ 201.1. Applicability.

§ 201.2. Requirements.

§ 201.3. Definitions.

Rulemaking 2 – General Operation and Physical Requirements

§ 201.23. Closure of facility.

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

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

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

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

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

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

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

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

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

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

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

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

§ 201.14. Responsibility of licensee.

§ 201.15. Restrictions on license.

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

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

§ 201.17. Location.

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

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

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

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

§ 211.1. Reportable diseases.

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

§ 201.18. Management.

§ 201.19. Personnel records.

§ 201.20. Staff development.

§ 201.21. Use of outside resources.

§ 201.24. Admission policy.

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

§ 201.26. Resident representative.

§ 201.29. Resident rights.

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

§ 201.31. Transfer agreement.

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

§ 209.3. Smoking.

§ 211.2. Medical director.

§ 211.3. Verbal and telephone orders.

§ 211.4. Procedure in event of death.

§ 211.5. Medical records.

§ 211.6. Dietary services.

§ 211.7. Physician assistants and certified registered nurse practitioners.

§ 211.8. Use of restraints.

§ 211.9. Pharmacy services.

§ 211.10. Resident care policies.

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

§ 211.12. Nursing services.

§ 211.15. Dental services.

§ 211.16. Social services.

§ 211.17. Pet therapy.

Comments on Multiple Packages; Stakeholder Engagement

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

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

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

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

Rulemaking 4 expressed the same concerns as in the previous proposed rulemakings, but additionally suggested that the Department consider issuing an Advance Notice of Final Rulemaking (ANFR) to assist in reaching consensus.

Response

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

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

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

In addition to considering comments on the four proposed packages during and outside of the four public comment periods, the Department met with stakeholders on four occasions

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

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

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

Background and Need for Amendments

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

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

much-care-will-you-need. Approximately 72,000 individuals reside in the 682 long-term care nursing facilities currently licensed by the Department.

The COVID-19 pandemic highlighted the vulnerability of older adults, with a larger percentage of deaths occurring in individuals 65 years of age and older. Centers for Disease Control and Prevention (CDC). Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC. Retrieved from https://covid.cdc.gov/covid-data-tracker/#demographics. *See also*, CDC. COVID-19 Weekly Cases and Deaths per 100,000 Population by Age, Race/Ethnicity and Sex, United States, March 1, 2020—June 25, 2022. Retrieved from https://covid.cdc.gov/covid-data-tracker/#demographicsovertime. Further, it is estimated that at least a quarter of COVID-19 deaths occurred in long-term care nursing facilities. The COVID Tracking Project. (March 2021). Long-Term-Care COVID Tracker. Retrieved from https://covidtracking.com/nursing-homes-long-term-care-facilities. In this Commonwealth alone, there have been approximately 11,443 confirmed deaths of residents in long-term care nursing facilities since January 2020. AARP. (September 15, 2022). AARP Nursing Home COVID-19 Dashboard Fact Sheets. Retrieved from https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-states.html.

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

The Department's long-term care nursing facilities regulations have not been updated since 1999, with the last significant update occurring in 1997 after the 1996 amendment to the Health Care Facilities Act (the HCFA or act) (35 P.S. §§ 448.101—448.904b). Since that time, there have been substantial changes in the means of delivering care and providing a safe environment for residents in long-term care nursing facilities, with the pandemic further highlighting the need for change. The Department has been attempting to complete this much needed reform since before the pandemic, in late 2017. At that time, the Department sought assistance and advice from members of a long-term care work group (LTC Work Group). The Department worked with the LTC Work Group regularly in 2018. The members of the LTC Work Group were drawn from a diverse background and included representatives from urban

and rural long-term care facilities and various stakeholder organizations and consumer groups that work in the area of resident care and delivery of services. The LTC Work Group members consisted of representatives from the following organizations: American Institute of Financial Gerontology; Baker Tilly Virchow Krause, LLP; Berks Heim and Rehabilitation; Fulton County Medical Center; Garden Spot Community; HCR ManorCare; Inglis House; Landis Communities; Leading Age; Legg Consulting Services; LIFE Pittsburgh; Luzerne County Community College; The Meadows at Blue Ridge; Mennonite Home, Lutheran Senior Life Passavant Community; PA Coalition of Affiliated Healthcare and Living Communities; Pennsylvania Home Care Association; University of Pittsburgh; and Valley View Nursing Home. The following State agencies participated: Department of Aging; the Department of Human Services (DHS); and the Department of Military and Veteran's Affairs (DMVA).

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

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

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

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

Unfortunately, while commentators agree for the most part that an update to the regulations is needed, they do not agree on the extent of the update needed. Some commentators strongly argued that the Department's proposed amendments do not go far enough in protecting

residents, while other commentators strongly argued that the Department's proposed amendments go too far and result in a fiscal impact. The Department has considered all comments it received both in favor of and against the proposed amendments and has responded to those comments. In considering those comments and balancing the competing interest of the parties in this regulatory review process, the Department has made revisions from the proposed rulemakings to the final-form rulemakings. The Department has also provided explanations to comments received in the preambles for each of the four final rulemakings, as explained more fully above.

Public Comments

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

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

Description of Amendments / Summary of Comments and Responses

§ 201.1. Applicability.

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

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

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

§ 201.2. Requirements.

Subsection (a)

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

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

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

General concerns regarding § 201.2

One commentator to proposed Rulemaking 1 suggested adding the phrase, "and thereby requires long-term care facilities to comply with" after the words "incorporates by reference" and before the citation to 42 CFR Part 483, Subpart B. As defined by *Black's Law Dictionary*, incorporation by reference is "a method of making a secondary document part of a primary document by including in the primary document a statement that the secondary document should be treated as if it were contained in the primary one." The addition of the language proposed by the commentator is redundant and unnecessary, and the Department declines to include it. The

same commentator questioned why the Department is referencing and incorporating the 1998 version of the Federal requirements. In response to this question, the Department notes it is not incorporating the 1998 version but is instead deleting the outdated reference to the 1998 version as indicated, on proposed, by brackets before and after the following language, "42 CFR 483.1—483.75 (relating to requirements for long-term care facilities) revised as of October 1, 1998."

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

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

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

the *Pennsylvania Code & Bulletin Style Manual* (*Style Manual*), as well, which the Department follows in drafting regulations.

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

Application of § 201.2 to private-pay facilities

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

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

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

Although not specifically expressed by commentators, upon further review, the Department believes this confusion may stem from the incorporation of 42 CFR 483.1 (relating to basis and scope), which sets forth the basis and scope for the Federal requirements and indicates that the Federal requirements pertain to facilities that participate in Medicare or MA.

To clarify this issue and eliminate this confusion, the Department has revised § 201.2, on final-form, to expressly exclude 42 CFR 483.1, from the requirements that facilities must comply with under State law. In addition, based on comments received regarding transmission of data and data set reporting to the Centers for Medicare & Medicaid Services (CMS), the Department is clarifying that the federal standards for reporting of Minimum Data Set (MDS) reporting and the transmission of data to CMS are not required, unless a facility is participating in the Medicare or MA program.

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

Impact of § 201.2 on private-pay facilities

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

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

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

Private-Pay Fiscal Impact - Grievance Officer

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

Moreover, any fiscal impact to these three facilities is vastly outweighed by the need for a properly managed process through which residents may assure their resident rights and voice

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

grievances. The grievance officer plays a vital role in the oversight of this process and is necessary to ensure that grievances are properly managed and promptly resolved.

Private-Pay Fiscal Impact – CMS Reporting Requirements

The existing regulations of the Department already incorporate many of the Federal requirements and the expansion to incorporate the remaining Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) will impact the three long-term care nursing facilities that do not participate in either the Medicare or MA Program. However, based on comments received, the Department is exempting facilities from complying with 42 CFR 483.1 (relating to basis and scope) and the data transmission and Minimum Data Set (MDS) reporting requirements, unless the facility participates in the Medicare or MA programs.

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

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

Total $67,862

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

In addition, a facility may apply for an exception to the requirements of Subpart C (relating to long-term care facilities) under §§ 51.31—51.34 (relating to exceptions). This includes the ability to apply for an exception to the incorporation of a specific Federal requirement. Specifically, all facilities, including private-pay facilities, may request an exception under the process identified in 28 Pa.Code §§ 51.31—51.34. To assist the Department in rendering decisions on requests for exceptions, a facility requesting such an exception is required to identify the specific Federal

requirements to which it is seeking an exception, rather than broadly requesting an exception to all the Federal requirements.

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

Private-Pay Other Reporting, Recordkeeping, and Paperwork requirements

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

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

In addition, based on comments received, the Department is exempting facilities from complying with 42 CFR 483.1 (relating to basis and scope) and the data transmission and Minimum Data Set (MDS) reporting requirements, unless the facility participates in Medicare or MA.

Subsection (b)

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

Subsection (c)

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

Subsection (d)

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

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

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

§ 201.3. Definitions

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

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

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

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

Definition of Abuse

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

Commentators also requested that if the Department defers to the Federal definition of abuse, that the Department retain more specific definitions of abuse, such as "physical abuse" and "verbal abuse" in regulation, because these terms are incorporated in the Federal definition

but not separately or specifically defined. The Department, in consideration and in response to these comments, retains these definitions as separately defined terms and moves the terms "verbal abuse," "sexual abuse," "physical abuse," "mental abuse," "involuntary seclusion" and "neglect" so that they appear in alphabetical order. Any amendments to these definitions are described more specifically below.

Definition of Act

The definition of "act" is unchanged from proposed to final-form. As explained on proposed, the citation to HCFA in the definition of "act" is amended to reflect the proper citation that encompasses all provisions of the act.

Definitions of Administration of Drugs, Drug Administration and Drug Dispensing

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

Definition of Administrator

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

Definition of Alteration

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

Definitions of Ambulatory Resident and Nonambulatory Resident

The definitions for "ambulatory resident" and "nonambulatory resident" were proposed to be deleted, and continue to be deleted on final-form, because the ordinary dictionary definition applies. The terms "ambulatory" and "nonambulatory" are understood to have their ordinary dictionary definitions when applied to describe a resident who can walk or not walk in a long-term care nursing facility. A commentator questioned the Department's decision to delete these

definitions, indicating that it may be necessary to retain them with respect to requirements related to a facility's ability to evacuate residents. The Department may not define terms in regulation where the dictionary meanings for those terms apply. *See* § 2.11 of the *Style Manual*. The Department therefore declines to retain or amend these terms in response to this comment.

Request for Definition of Applicant

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

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

Definition of Audiologist

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

Definition of Authorized Person to Administer Medications

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

Definition of Basement

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

Definition of CRNP

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

Definition of Charge Nurse

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

Definition of Clinical Laboratory

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

Definition of Clinical Records

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

Definition of Controlled Substance

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

Definition of Corridor

The definition of "corridor" is revised from proposed to final-form. The Department replaces the word "patient's" with "resident's" before the words "sleeping quarters" at the

request of a commentator. The Department agrees that the term "resident" more appropriately describes an individual who is admitted to a long-term care nursing facility.

Definition of Department

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

Definitions of Dietician, Dietetic Service Supervisor and Qualified Dietician

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

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

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

Definition of Director of Nursing Services

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

Definition of Discharge

On final-form the Department added the definition of "discharge" in response to comments received on proposed Rulemaking 4 in order to distinguish between a "transfer" and a "discharge". On final-form a "discharge" is defined as "[t]he movement of a resident from a bed

in one certified facility to a bed in another certified facility or other location in the community, when return to the original facility is not expected."

Definition of Drug or Medication; Medication

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

Definition of Elopement

The definition of "elopement" is revised, from proposed to final-form. The Department had proposed to delete the definition of "elopement" on proposed. In response to comments from commentators and IRRC regarding ease of finding terms that are defined in the State Operations Manual, the definition of "elopement" is retained, and amended, on final-form, to mirror the current definition in the State Operations Manual, that elopement occurs "when a resident leaves the premises or a safe area without authorization."

Definition of Existing Facility

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

Definition of Exit or Exitway

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

Definition of Exploitation

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

Definition of Facility

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

Definition of Full Compliance and Substantial Compliance

To further aid the regulated community in understanding the criteria for a license, the Department adds a definition for "full compliance" and a definition for "substantial compliance". A facility will be in "full" compliance if they are in "total" compliance. Further, as defined, a facility will be in "substantial" compliance if the requirements in paragraphs (1) and (2) of the

definition are met. Under paragraph (1), any cited deficiencies must be, individually and in combined effect, of a minor nature such that neither the deficiencies nor efforts toward their correction will interfere with or adversely affect normal facility operations or adversely affect any resident's health or safety. Under paragraph (2), the facility must have implemented a plan of correction approved by the Department. These definitions are based on the definitions for "full compliance" and "substantial compliance" that exists for hospitals in 28 Pa. Code § 101.92(b) (relating to regular license).

Definition of Full-Time

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

Definition of Health Care Practitioner

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

Definition of Interdisciplinary Team

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

Definition of Intimidation

In response to public comment, a new definition for "intimidation" is added from proposed to final-form. Per requests from commentators, the Department adopts the definition of "intimidation" in section 3 of OAPSA (35 P.S. § 10225.103), which defines "intimidation" as "an act or omission by any person or entity toward another person which is intended to, or with knowledge that the act or omission will, obstruct, impede, impair, prevent or interfere with the administration of [OAPSA] or any law intended to protect older adults from mistreatment."

Definition of Involuntary Seclusion

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

Definition of Licensed Practical Nurse

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

Definition of Licensee

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

Definition of Locked Restraint

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

Definition of Long-Term Care Ombudsman

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

Definition of Medical Record Practitioner

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

Definition of Mental Abuse

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

Definitions of Misappropriation of Resident Property and Mistreatment

In response to comments from commentators and IRRC requesting that Federal definitions be added to the regulation for clarity, definitions are also added on final-form for

"misappropriation of resident property" and "mistreatment," with cross-references to these definitions in 42 CFR 483.5.

Definition of Neglect

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

Definition of NFPA

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

Definition of Nonproprietary Drug

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

Definition of Nurse Aide

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

Definitions of Nursing Care and Nursing Service Personnel

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

Definitions of Occupational Therapist and Occupational Therapy Assistant

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

Definition of Person

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

Definitions of Pharmacist and Pharmacy

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

Definition of Physical Abuse

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

Definitions of Physical Therapist and Physical Therapy Assistant

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

Definition of Physician Assistant

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

Definition of Practice of Pharmacy

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

Definition of Proprietary Drug

The definition of "proprietary drug" remains deleted from proposed to final-form. As explained on proposed, the definition of "proprietary drug" is replaced with the definition of "non-prescription medication." The shift from the use of the term "proprietary drug" to "non-prescription medication" reflects a change in terminology used in the long-term care nursing environment. The definition is also amended to reflect common usage of this term to refer to an over-the-counter medication that is purchased without a prescription. One commentator questioned the Department's proposal to replace the term "proprietary drug" with the term "non-prescription medication" because a proprietary drug is defined as "a drug that has a trade name and is protected by a patent brand-name drug" at www.thefreeedictionary.com. However, the term "proprietary drug" as defined in the Department's existing regulation, is "a drug which does not contain a quantity of a controlled substance *which can be purchased without a prescription*

and may be purchased from sources other than a pharmacy and is usually sold under a patented or trade name" (emphasis added). The term "non-prescription medication" more closely aligns with this existing definition and with the definition amended to, "an over-the-counter medication legally purchased without a prescription" is reflective of current terminology and understanding in the long-term care environment. The Department declines to retain or amend the term "proprietary drug" in response to this comment.

Definition of Registered Nurse

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

Definition of Resident

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

Definition of Resident Activities Coordinator

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

Definitions of Resident Representative; Responsible Person

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

Definition of Residential Unit

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

Definition of Restraint

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

Definitions of Serious Bodily Injury and Serious Physical Injury

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

Definition of Sexual Abuse

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

Definition of Skilled or Intermediate Care

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

Definition of Social Worker

The definition of "social worker" continues to be deleted but is replaced on final-form with the definition for "qualified social worker." The Department had proposed to delete the definition of "social worker" based on the Federal requirements. Under the Federal requirements, a social worker is referred to as a "qualified social worker" and is defined at 42 CFR 483.70(p) (relating to administration). In response to comments from commentators and IRRC, on final-form, the Department is replacing the definition of "social worker" with a definition for "qualified social worker" and cross-referencing the definition for this term in 42 CFR 483.70(p). In response to concerns raised by commentators regarding the deletion of qualifications for certain individuals in regulation, the Department notes that the Federal definition for "qualified social worker" in 42 CFR 483.70(p) contains the qualifications for an

individual who serves in this capacity. It is therefore not necessary to repeat those qualifications in the text of § 201.3.

Definition of Speech/Language Pathologist

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

Definition of Transfer

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

Definition of Verbal Abuse

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

§ 211.12(i) Nursing services

Based on comments received, the Department is not amending this section in final-form Rulemaking 1– *General Applicability and Definitions.* Instead, for ease of readability and responding to comments related to nursing services requirements being proposed in more than one rulemaking, the Department is amending this section, as a whole, in final-form Rulemaking 4 – *Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services.* As such, the amendments on proposed are stricken in final-form Rulemaking 1.

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

As further provided in the preamble to final-form Rulemaking 4 – *Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services,* the Department increased the direct resident care hours from 2.7 to 2.87 hours of minimum direct resident care for each resident during a 24-hour period, beginning July 1, 2023. The following year, July 1, 2024, the number of hours of minimum direct resident care for each resident, when totaled for the entire facility, will be increased to 3.2 hours of direct resident care for each resident.

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

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

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

The Department carefully considered the varying comments in support of and in opposition to the increased direct resident care hours. In balancing the interests of consumers, advocates and industry stakeholders, in combination with the substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023 (Act 2022-54; Act 2022-1A), the Department amended this section in Rulemaking 4 – *Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services*, as provided previously, with a graduated implementation date. The rate of 3.2 hours of direct resident care for each resident is comparable to surrounding states and similarly situated states: Delaware 3.28 hours; Maryland 3.00 hours; New York 3.50 hours; New Jersey 2.50 hours; District of Columbia 3.50-4.10 hours; Ohio 2.50 hours; Florida 3.6 hours; Rhode Island 3.58 hours; and West Virginia 2.25 hours.
https://www.macpac.gov/publication/state-policies-related-to-nursing-facility-staffing/.

In addition, as further provided in Rulemaking 4 – *Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services,* the Department deletes the words "during each shift" in response to concerns raised by commentators that this language is confusing. Specifically, commentators were concerned that this language, as drafted, could be construed to require the same number of nursing personnel at night when residents are sleeping

as during the day when they are more active and need more care, and that facilities would be required to provide a total of 12.3 hours of direct care per day, rather than the proposed 4.1 hours of direct care. The Department agrees that the addition of "during each shift" is confusing. As such, the Department deletes the words "during each shift" on final-form Rulemaking 4 to alleviate this concern. In addition, during the public comment period for Rulemaking 4, the Department received further comments on this provision regarding the type of services included as "general nursing care". The Department has further addressed these comments in the preamble to Rulemaking 4 – *Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services.*

Other Comments

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

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

One commentator asked whether the proposed increase in direct care hours will impact pharmacy technicians. The increase in direct care hours will impact nursing service personnel as explained above in § 211.12(i) and in final-form Rulemaking 4 – *Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services* at § 211.12(f.1). Pharmacy technicians are not considered direct care providers for general nursing care and will not be impacted by this rulemaking under § 211.12(i).

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

agents under power of attorney. As defined, "resident representative" means any of the following:

> (1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;
> (2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;
> (3) Legal representative, as used in section 712 of the Older Americans Act; or.
> (4) The court-appointed guardian or conservator of a resident.
> (5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.
>
> 42 CFR 483.5 (relating to definitions).

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

One commentator requested that the regulations be amended to include the following requirements: (1) staff to wear name and position badges that are clearly visible to all; (2) staff to knock before entering a resident's room and introduce and announce themselves before entering the room; (3) that residents be able to place cameras in their rooms if their roommates agree; (4) facilities be open 24/7 to family and this be made clear when a resident is admitted; (5) facilities have a published process in place for residents and family members to submit care or treatment concerns and a timeframe in which to respond to them; (7) residents and family members be allowed to submit anonymous complaints to the local ombudsman for investigation and resolution. Another commentator requested that the regulations be amended to include the following requirements: (1) every doctor to be board certified in geriatrics; (2) residents have the freedom to be transported to their primary care physician if they want; (3) doctors on staff meet with every new resident and family for at least 30 minutes on admission or within 1-2 days to assess the resident, review medications, answer questions and make recommendations; (4) doctors do a follow-up assessment a week later with the resident and family to review care and to answer questions; (5) a list of medications be provided to family members; (6) medical records and charts be available upon request; (6) residents be allowed to transfer to a different facility if they are not happy; (7) improved requirements for facility inspections and investigation complaints that involve different employees conducting inspections versus complaints; and (7) evaluation and inspection reports for facilities be published in local papers and any violations or citations highlighted.

Although this final-form regulation does not specifically address facility requirements, physician requirements, medical records, transfer agreement, facility inspections and surveys, grievances and resident rights, final-form Rulemaking 2 – *General Operation and Physical Requirements*, Rulemaking 3 – *Applications for Ownership, Management and Changes of Ownership; Health and Safety* and Rulemaking 4 – *Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services* address these various requirements.

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

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

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

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

Comments on Effective Date

Some commentators, in proposed Rulemaking 1, urged the Department to make all four proposed rulemakings effective upon publication as final-form regulations, stating that these amendments are so long overdue that no phase-in period should be allowed. Other

commentators, however, felt that the changes being proposed are too significant, and that the regulated community needs time to budget, plan and hire staff, particularly for the proposed increase in direct care hours. Some commentators suggested that the Department allow for a year or more for implementation of the regulations, while other commentators suggested a ramp-up period before all the regulations become effective. IRRC asked, in comment to proposed Rulemaking 1, if the Department would consider a delayed implementation timetable for compliance. Commentators and IRRC also raised concerns in comments to proposed Rulemaking 3, regarding the Department's proposal to set the same effective date for all four final-form rulemakings. IRRC asked the Department to address these concerns and explain why this timeframe was reasonable.

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

Fiscal Impact and Paperwork Requirements

Fiscal Impact

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

In response to the comments and concerns raised during this legislative hearing, throughout the public comment process, and in other discussions, the Governor's Fiscal Year 22-23 budget proposal proposed a MA rate increase of $190 million; $91 million in state funding to be matched with $99 million in federal funds for the first 6 months of calendar year 2023 and a

proposed $250 million one-time investment of American Rescue Plan Act (ARPA) funds in long-term living programs, including direct one-time funding for all facilities to support their workforce and help them to hire more staff to meet the requirements of the forthcoming regulations. The funding was proposed to be provided to facilities in advance of the expected staffing increases to allow facilities to stabilize their existing workforce and recruit additional staff prior to the regulatory increases going into effect.

Following the Governor's budget proposal, industry stakeholders called for $294 million in MA funding in the Commonwealth's FY 22-23 budget. The FY 22-23 Appropriations Act signed by Governor Wolf included bipartisan support for a historic increase in one-time and ongoing funding for facilities. As enacted, $147 million in state funding was appropriated to support implementation of the Department's regulations. Specifically, this funding will be used to support a 17.5% Medicaid rate increase beginning January 1, 2023, which allows facilities time to ramp up staffing to meet the direct care staffing hours required on July 1, 2023. Assuming Federal approval, these state funds will be matched with an additional $159 million in federal funds, totaling $306 million in Medicaid funding for the first 6 months of calendar year 2023. All nursing facilities will also receive $131 million in one-time ARPA funding during FY 22-23. A detailed fiscal impact for the regulated community, the commonwealth and local government is as follows:

Regulated community

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

The existing regulations of the Department already incorporate many of the Federal requirements and the expansion to incorporate the remaining Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) will not impact the facilities that participate in the Medicare or MA programs. However, the 3 private-pay long-term care nursing facilities that do not participate in either the Medicare or MA Program will be impacted.

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

- Resident Rights (42 CFR § 483.10)..... $13,020
- Admission, Discharge, and Transfer Rights (42 CFR § 483.15).....$230

- Comprehensive Resident Centered Care Planning (42 CFR § 483.21) $6,760
- Nursing Services (42 CFR § 483.35) $304
- Food and Nutrition Services (42 CFR § 483.60) $145
- Quality Assurance and Performance Improvement (42 CFR § 483.75)..... $3,926
- Infection Control (42 CFR § 483.80) $23,318
- Compliance and Ethics Program (42 CFR § 483.85).....$19,262
- Training (42 CFR § 483.95) $897

Total $67,862

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

In addition, a facility may apply for an exception to the requirements of Subpart C (relating to long-term care facilities) under §§ 51.31—51.34 (relating to exceptions). This includes the ability to apply for an exception to the incorporation of a specific Federal requirement. Specifically, all facilities, including private-pay facilities, may request an exception under the process identified in 28 Pa.Code §§ 51.31—51.34. To assist the Department in rendering decisions on requests for exceptions, a facility requesting such an exception is required to identify the specific Federal requirements to which it is seeking an exception, rather than broadly requesting an exception to all the Federal requirements.

Further, based on comments received, the Department is exempting facilities from complying with 42 CFR 483.1 (relating to basis and scope) and the data transmission and Minimum Data Set (MDS) reporting requirements, unless the facility participates in the Medicare or MA programs

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

Commonwealth – Department

The amendments will not increase costs to the Department. The Department's surveyors perform the function of surveying and inspecting long-term care nursing facilities for compliance with both Federal and State regulations. The elimination of subsections that are outdated and duplicative of the Federal requirements will streamline the survey process for long-term care

nursing facilities and provide consistency and congruency to the stakeholder industry. This, in turn, will reduce confusion in the application of the standards that apply to long-term care nursing facilities.

Commonwealth – Department of Military and Veterans Affairs (DMVA)

Of the 682 long-term care nursing facilities licensed by the Department, six facilities are veterans' homes that are operated by DMVA. These facilities are already required to comply with the Federal requirements and thus, are already required to comply with existing Federal health and safety standards.

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

Commonwealth – Department of Human Services

Although the provisions of this final-form rulemaking, which relate to incorporation of federal health and safety standards and the updating of definitions, will not have a cost impact to the Department of Human Services, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023, was enacted under Act 2022-54 and appropriated under the General Appropriations Act of 2022 (Act 2022-1A).

Local Government

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

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

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

Residents of Long-Term Care Nursing Facilities

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

Paperwork Requirements

Assuming that the three private-pay facilities have not updated any of their recordkeeping practices and procedures since 1998, it is anticipated the new paperwork requirements for the 3 private-pay facilities may include the following:

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

In addition, based on comments received, the Department is exempting facilities from complying with 42 CFR 483.1 (relating to basis and scope) and the data transmission and Minimum Data Set (MDS) reporting requirements, unless the facility participates in the Medicare or MA program.

Small Business Analysis

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

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

The Department conducted a search on the NAICS website to find the NAICS code for long-term care nursing facilities. The NAICS code for nursing care facilities (skilled nursing facilities) is 623110. The Department looked this code up in the table located at 13 CFR 121.201 (relating to what size standards has SBA identified by NAICS codes) and determined that a long-term care nursing facility is a small business if it has $30 million or less in annual receipts. The Department then pulled the latest long-term care nursing facility cost report from CMS to determine the impact to facilities that participate in Medicare or MA. The latest cost report data

from CMS is 2018. Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data. The Department applied current Federal Standards of Accounting to this data to determine each facility's annual receipts. Based on this analysis, the Department determined that 623 facilities that participate in Medicare or MA have $30 million or less in annual receipts. Although the data from CMS is from 2018, the Department believes that currently, at least the same number of facilities, if not more, would meet the definition of a small business. This analysis aligns with the Department's previous assumption that most long-term nursing facilities licensed by the Department meet the definition of a small businesses.

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

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

Statutory Authority

Sections 601 and 803 of the HCFA (35 P.S. §§ 448.601 and 448.803) authorize the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the HCFA. Section 801.1 of the HCFA (35 P.S. § 448.801a) seeks to promote the public health and welfare through the establishment of

regulations setting minimum standards for the operation of health care facilities. The minimum standards are to assure safe, adequate and efficient facilities and services and to promote the health, safety and adequate care of patients or residents of those facilities. In section 102 of the HCFA (35 P.S. § 448.102), the General Assembly has found that a purpose of the HCFA is, among other things, to assure that citizens receive humane, courteous and dignified treatment. Finally, section 201(12) of the HCFA (35 P.S. § 448.201(12)) provides the Department with explicit authority to enforce its rules and regulations promulgated under the HCFA.

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

Effectiveness/Sunset Date

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

Regulatory Review

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

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

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

Contact Person

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

Findings

The Department finds that:

(1) Public notice of intention to adopt the regulations adopted by this order has been given under sections 201 and 202 of the Act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), and the regulations promulgated under those sections at 1 Pa. Code §§ 7.1 and 7.2.

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

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

(4) The adoption of the regulations is necessary and appropriate for the administration of the Health Care Facilities Act (35 P.S. §§ 448.101—448.904b).

Order

(1) The regulations of the Department at Title 28 of the Pennsylvania Code at §§ 201.1—201.3 are amended as set forth in Annex A.

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

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

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

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

LIST OF COMMENTATORS WHO REQUESTED MORE INFORMATION ON DEPARTMENT OF HEALTH LONG-TERM CARE NURSING FACILITY REGULATION #s 10-221, 10-222, 10-223, 10-224[1]

Commentator Name	Commentator Address
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Patricia Savage	998 Logan Boulevard Altoona, PA 16602
Jeffrey Long	685 Angela Drive Greensburg, PA 15601
John Cusick	Northampton County Government Center 669 Washington St. Easton, PA 18042
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[1] Due to the overlap in comments between regulatory packages, the Department has compiled the list of commentators who requested more information on the four final-form long-term care nursing facility regulations into one list and provided a copy of all four packages to these commentators.

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Annex A

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

Subpart C. LONG-TERM CARE FACILITIES

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

GENERAL PROVISIONS

§ 201.1. Applicability.

This subpart applies to **[profit and nonprofit]** long-term care nursing facilities **[which provide either skilled nursing care or intermediate nursing care, or both, within the facilities under the act]** as defined in section 802.1 of the act (35 P.S. § 448.802a).

§ 201.2. Requirements.

(a) The Department incorporates by reference 42 CFR Part 483, Subpart B of the Federal requirements for long-term care facilities, **[42 CFR 483.1—483.75 (relating to requirements for long-term care facilities) revised as of October 1, 1998]** (relating to requirements for long-term care facilities), as licensing regulations for long-term care nursing facilities **[with the exception of the following sections and subsections:**

(1) Section 483.1 (relating to basis and scope).

(2) Section 483.5 (relating to definitions).

(3) Section 483.10(b)(10), (c)(7) and (8) and (o) (relating to level A requirement: Resident rights).

(4) Section 483.12(a)(1), (b), (c)(1) and (d)(1) and (3) (relating to admission, transfer and discharge rights).

(5) Section 483.20(j) and (m) (relating to resident assessment).

(6) Section 483.30(b)—(d) (relating to nursing services).

(7) Section 483.40(e) and (f) (relating to physician services).

(8) Section 483.55 (relating to dental services).

(9) Section 483.70(d)(1)(v) and (3) (relating to physical environment).

(10) Section 483.75(e)(1), (h) and (p) (relating to administration)], WITH THE EXCEPTION OF 42 CFR 483.1 (RELATING TO BASIS AND SCOPE) AND THE REQUIREMENTS UNDER 42 CFR PART 483 SUBPART B FOR THE TRANSMISSION OF DATA AND MINIMUM DATA SET (MDS) REPORTING TO THE CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) UNLESS

THE FACILITY IS PARTICIPATING IN THE MEDICARE OR MEDICAL ASSISTANCE PROGRAM.

~~(b) The Department incorporates by reference the Centers for Medicare & Medicaid State Operations Manual, Chapter 7 and Appendix PP—Guidance to Surveyors for Long-Term Care Facilities.~~

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

~~(d) Failure to comply with the requirements specified in 42 CFR Part 483, Subpart B shall be considered a violation of this subpart, unless an exception has been granted under §§ 51.31—51.34.~~

§ 201.3. Definitions.

~~(a) The Department incorporates by reference all terms defined in 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) and in the Centers for Medicare & Medicaid State Operations Manual, Chapter 7 and Appendix PP—Guidance to Surveyors for Long-Term Care Facilities.~~

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

~~[~~*Abuse*—**[The infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental and psychosocial well-being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish. The term includes the following:**

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

(A) Threats of harm.

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

(ii) *Sexual abuse*—**Includes sexual harassment, sexual coercion or sexual assault.**

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

(iv) ***Mental abuse*—Includes humiliation, harassment, threats of punishment or deprivation.**

(v) ***Involuntary seclusion*—Separation of a resident from other residents or from his room or confinement to his (with/without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs.**

(vi) ***Neglect*—The deprivation by a caretaker of goods or services which are necessary to maintain physical or mental health.]** AS DEFINED IN 42 CFR 483.5 (RELATING TO DEFINITIONS).

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

Administration of **[*drugs*]** ***medication***—The giving of a dose of medication to a ~~patient~~ RESIDENT as a result of an order of a practitioner licensed by the Commonwealth to prescribe **[drugs]** **medications**.

~~[~~***Administrator*—[An individual who is charged with the general administration of a facility, whether or not the individual has an ownership interest in the facility and whether or not the individual's functions and duties are shared with one or more other individuals.]** AS DEFINED IN 42 CFR 483.70(d)(2) (RELATING TO ADMINISTRATION). **The administrator shall be currently licensed and registered by the Department of State under the Nursing Home Administrators License Act (63 P.S. §§ 1101—1114.2).~~]~~

~~*Alteration*—An addition, modification or modernization in the structure or usage of a building or section thereof or change in the services rendered.~~

[*Ambulatory resident*—An individual who is physically and mentally capable of getting in and out of bed and walking a normal path to safety in a reasonable period of time, including the ascent and descent of stairs without the aid of another person.

***Audiologist*—A person licensed as an audiologist by the Pennsylvania State Board of Examiners in Speech-Language and Hearing, or excluded from the requirement of licensure under the Speech-Language and Hearing Licensure Act (63 P.S. §§ 1701—1719).]**

Authorized person to administer ~~*drugs and*~~ *medications*—Persons qualified to administer ~~drugs and~~ medications in facilities are as follows:

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

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

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

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

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

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

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

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

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

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

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

(i) ~~**A registered nurse.**~~ AN RN.

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

~~(iii) A practical nurse who is a graduate of a Commonwealth recognized school of practical nursing or who has 2 years of appropriate experience following licensure by waiver as a practical nurse.~~

~~(iv) A practical nurse shall be designated by the facility as a charge nurse only on the night tour of duty in a facility with a census of 59 or less.]~~ (iii) AN LPN DESIGNATED BY THE FACILITY AS A CHARGE NURSE ON THE NIGHT TOUR OF DUTY IN A FACILITY WITH A CENSUS OF 59 OR LESS IN ACCORDANCE WITH SECTION 211.12.

Clinical laboratory—**[A place, establishment or institution, organized and operated primarily for the performance of bacteriological, biochemical, hematological, microscopical, serological or parasitological or other tests by the practical application of one or more of the fundamental sciences to material originating from the human body, by the use of specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health. The tests are conducted using specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health.]** AS DEFINED IN 42 U.S.C.A. § 263a(a).

~~*Clinical records*—Facility records, whether or not automated, pertaining to a resident, including medical records.~~

CONSTRUCTION, ALTERATION OR RENOVATION—THE ERECTION, BUILDING, REMODELING, MODERNIZATION, IMPROVEMENT, EXTENSION OR EXPANSION OF A FACILITY, OR THE CONVERSION OF A BUILDING OR PORTION THEREOF TO A FACILITY. THE TERM DOES NOT INCLUDE PART-FOR-PART REPLACEMENT OR REGULAR FACILITY MAINTENANCE.

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

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

Department—The Department of Health of the Commonwealth.

[*Dietetic service supervisor*—A person who meets one of the following requirements:

(i) Is a dietitian.

(ii) Is a graduate of a dietetic technician or dietetic assistant training program, correspondence course or classroom course approved by the American Dietetic Association.

(iii) Is a member of the American Dietetic Association or the Dietary Managers Association.

(iv) Is a graduate of a State approved course that provided 90 or more hours of classroom instruction in food service supervision and has experience as a supervisor in a health care institution with consultation from a dietitian.

(v) Has training and experience in food service supervision and management in a military service equivalent in content to the program in subparagraph (iv).

(vi) Has a baccalaureate degree from a State approved or accredited college or university and has at least 12 credit hours in food service, nutrition or diet therapy and at least 1 year of supervisory experience in the dietary department of a health care facility.

***Dietitian*—A person who is either:**

(i) Registered by the Commission on Dietetic Registration of the American Dietetic Association.

(ii) Eligible for registration and who has a minimum of a bachelor's degree from a United States regionally accredited college or university and has completed the American Dietetic Association (ADA) approved dietetic course requirements and the requisite number of hours of ADA approved supervised practice.]

***Director of nursing services*—[A registered nurse who is licensed and eligible to practice in this Commonwealth and has 1 year of experience or education in nursing service administration and supervision, as well as additional education or experience in areas such as rehabilitative or geriatric nursing, and participates annually in continuing nursing education. The director of nursing services is responsible for the organization, supervision and administration of the total nursing service program in the facility.]** AN RN DESIGNATED BY A FACILITY UNDER 42 CFR 483.35(b)(2) (RELATING TO NURSING SERVICES) AND HAS 1 YEAR OF EXPERIENCE OR EDUCATION IN NURSING SERVICE ADMINISTRATION AND SUPERVISION, AS WELL AS ADDITIONAL EDUCATION OR EXPERIENCE IN AREAS, SUCH AS REHABILITATIVE OR GERIATRIC NURSING, AND PARTICIPATES ANNUALLY IN CONTINUING NURSING EDUCATION.

DISCHARGE—THE MOVEMENT OF A RESIDENT FROM A BED IN ONE CERTIFIED FACILITY TO A BED IN ANOTHER CERTIFIED FACILITY OR OTHER LOCATION IN THE COMMUNITY, WHEN RETURN TO THE ORIGINAL FACILITY IS NOT EXPECTED.

[*Drug administration*—An act in which a single dose of a prescribed drug or biological is given to a resident by an authorized person in accordance with statutes and regulations governing the act. The complete act of administration entails removing an individual dose from a previously dispensed, properly labeled container, verifying it with the physician's

orders, giving the individual dose to the proper resident and promptly recording the time and dose given.

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

~~*Drug or medication*—A substance meeting one of the following qualifications:~~

~~—(i) Is recognized in the official United States Pharmacopeia, or official National Formulary or a supplement to either of them.~~

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

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

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

[*Elopement*—When a resident leaves the ~~facility without the facility staff being aware that the resident has done so~~ PREMISES OR A SAFE AREA WITHOUT AUTHORIZATION.

[*Existing facility*—A long-term care nursing facility or section thereof which was constructed and licensed as such on or before July 24, 1999.]

***Exit* or *exitway*—[A required means of direct egress in either a horizontal or vertical direction leading to the exterior grade level.]** A MEANS OF EGRESS WHICH IS LIGHTED AND HAS THREE COMPONENTS: AN EXIT ACCESS (CORRIDOR LEADING TO THE EXIT), AN EXIT (A DOOR) AND AN EXIT DISCHARGE (DOOR TO THE STREET OR PUBLIC WAY).

EXPLOITATION—AS DEFINED IN 42 CFR 483.5.

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

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

FULL COMPLIANCE – MEANS TOTAL COMPLIANCE.

HEALTH CARE PRACTITIONER—AS DEFINED IN SECTION 103 OF THE ACT (35 P.S. § 448.103).

Interdisciplinary team—**[A team including the resident's attending physician, a registered nurse with responsibility for the resident and other appropriate staff in disciplines as determined by the resident's needs, and the resident. If the resident is cognitively impaired and unable to fully participate, the team shall include to the extent practicable, the participation of the resident, and shall also include the resident's family, a responsible person or the resident's legal representative.]** AS DEFINED IN 42 CFR 483.21(b)(2)(ii) (RELATING TO COMPREHENSIVE PERSON-CENTERED CARE PLANNING).

~~***Health Care Practitioner*** **As defined in section 103 of the act (35 P.S. § 448.103). The term "practitioner" when used alone in this subpart is deemed to be synonymous with this definition.~~

INTIMIDATION—AS DEFINED IN SECTION 3 OF THE OLDER ADULTS PROTECTIVE SERVICES ACT (35 P.S. § 10225.103).

INVOLUNTARY SECLUSION—SEPARATION OF A RESIDENT FROM OTHER RESIDENTS OR FROM THE RESIDENT'S ROOM OR CONFINEMENT WITH OR WITHOUT ROOMMATES AGAINST THE RESIDENT'S WILL, OR THE WILL OF THE RESIDENT'S REPRESENTATIVE, EXCLUDING EMERGENCY OR SHORT TERM MONITORED SEPARATION FROM OTHER RESIDENTS FOR A LIMITED PERIOD OF TIME AS A THERAPEUTIC INTERVENTION TO REDUCE AGITATION UNTIL PROFESSIONAL STAFF CAN DEVELOP A PLAN OF CARE TO MEET THE RESIDENT'S NEEDS.

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

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

LONG-TERM CARE OMBUDSMAN—AN INDIVIDUAL AT THE STATE OR LOCAL LEVEL WHO IS RESPONSIBLE FOR CARRYING OUT THE DUTIES AND FUNCTIONS OF THE STATE LONG-TERM CARE OMBUDSMAN PROGRAM UNDER 42 U.S.C.A. § 3058g.

[*Locked restraints*—A mechanical apparatus or device employed to restrict voluntary movement of a person not removable by the person. The term includes shackles, straight jackets and cage-like enclosures and other similar devices.

***Medical record practitioner*—A person who is certified or eligible for certification as a registered records administrator (RRA) or a health information technologist/accredited record technician by the American Health Information Management Association (AHIMA) and who has the number of continuing education credits required for each designation by the AHIMA.]**

MEDICATION—A SUBSTANCE MEETING ONE OF THE FOLLOWING QUALIFICATIONS:

(I) IS RECOGNIZED IN THE OFFICIAL UNITED STATES PHARMACOPEIA, OR OFFICIAL NATIONAL FORMULARY OR A SUPPLEMENT TO EITHER OF THEM.

(II) IS INTENDED FOR USE IN THE DIAGNOSIS, CURE, MITIGATION, TREATMENT OR PREVENTION OF DISEASE IN MAN OR OTHER ANIMALS.

(III) IS OTHER THAN FOOD AND INTENDED TO AFFECT THE STRUCTURE OR A FUNCTION OF THE HUMAN BODY OR OTHER ANIMAL BODY.

(IV) IS INTENDED FOR USE AS A COMPONENT OF AN ARTICLE SPECIFIED IN SUBPARAGRAPH (I), (II) OR (III), BUT NOT INCLUDING DEVICES OR THEIR COMPONENTS, PARTS OR ACCESSORIES.

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

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

MENTAL ABUSE—INCLUDES HUMILIATION, HARASSMENT, THREATS OF PUNISHMENT OR DEPRIVATION.

MISAPPROPRIATION OF RESIDENT PROPERTY—AS DEFINED IN 42 CFR 483.5.

MISTREATMENT—AS DEFINED IN 42 CFR 483.5.

NEGLECT—AS DEFINED IN 42 CFR 483.5.

NFPA—National Fire Protection Association.

[*Nonambulatory resident*—A resident who is not physically or mentally capable of getting in and out of bed and walking a normal path to safety in a reasonable period of time, including the ascent and descent of stairs, without the aid of another person.

***Nonproprietary drug*—A drug containing a quantity of controlled substance or drug requiring a prescription, a drug containing biologicals or substances of glandular origin—**

except intestinal-enzymes and liver products—and drugs which are administered parenterally.]

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

[*Nurse aide*—An individual, AS DEFINED IN 42 CFR 483.5, **providing nursing or nursing-related services to residents in a facility who:**

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

(ii) Does not volunteer services for no pay.

(iii) Has met the requisite training and competency evaluation requirements as defined in 42 CFR 483.75 (relating to administration).

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

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

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

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

[*Occupational therapist*—A person licensed as an occupational therapist by the State Board of Occupational Therapy Education and Licensure.

***Occupational therapy assistant*—A person licensed as an occupational therapy assistant by the State Board of Occupational Therapy Education and Licensure.]**

PERSON— AS DEFINED IN SECTION 103 OF THE ACT (35 P.S. § 448.103).

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

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

PHYSICAL ABUSE—INCLUDES HITTING, SLAPPING, PINCHING AND KICKING. THE TERM ALSO INCLUDES CONTROLLING BEHAVIOR THROUGH CORPORAL PUNISHMENT.

[*Physical therapist*—A person licensed as a physical therapist by the State Board of Physical Therapy.

***Physical therapy assistant*—A person registered as a physical therapy assistant by the State Board of Physical Therapy.]**

Physician assistant—An individual certified as a physician assistant by the State Board of Medicine under the Medical Practice Act of 1985 (63 P.S. §§ 422.1—422.45), or by the State Board of Osteopathic Medical Examiners under the Osteopathic Medical Practice Act (63 P.S. §§ 271.1—271.18).

[*Practice of pharmacy*—The practice of the profession concerned with the art and science of the evaluation of prescription orders and the preparing, compounding and dispensing of drugs and devices, whether dispensed on the prescription of a medical practitioner or legally dispensed or provided to a consumer. The term includes the proper and safe storage and distribution of drugs, the maintenance of proper records, the participation in drug selection and drug utilization reviews and the responsibility of relating information as required concerning the drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease. The term does not include the operations of a manufacturer or distributor as defined in The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144).]

PRACTITIONER—A HEALTH CARE PRACTITIONER AS DEFINED IN SECTION 103 OF THE ACT (35 P.S. § 448.103).

Prescription—A written or verbal order for **[drugs]** **medications** issued by a **[licensed medical]** **health care** practitioner in the course of **[his]** professional practice.

[*Proprietary drug*—A drug which does not contain a quantity of a controlled substance which can be purchased without a prescription and may be purchased from sources other than a pharmacy, and is usually sold under a patented or trade name.]

QUALIFIED DIETICIAN—AS DEFINED IN 42 CFR 483.60(a)(1) (RELATING TO FOOD AND NUTRITION SERVICES).

QUALIFIED SOCIAL WORKER—AS DEFINED IN 42 CFR 483.70(p) (RELATING TO ADMINISTRATION).

QUALIFIED THERAPEUTIC RECREATION SPECIALIST—AS DEFINED IN 42 CFR 483.24(c) (RELATING TO QUALITY OF LIFE).

***RN*—*Registered nurse*—[A nurse]** **An individual** licensed to practice **[in this Commonwealth]** **professional nursing** under The Professional Nursing Law (63 P.S. §§ 211—225.5) **and the regulations of the State Board of Nursing at 49 Pa. Code Chapter 21, Subchapter A (relating to registered nurses)**.

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

[*Resident activities coordinator*—A person who meets one of the following requirements:

(i) Is a qualified therapeutic recreation specialist.

(ii) Has 2 years of experience in a social or recreational program, within the last 5 years, 1 year of which was full-time in a patient activities program in a health care setting.]

RESIDENT REPRESENTATIVE—AS DEFINED IN 42 CFR 483.5.

[*Residential unit*—A section or area where persons reside who do not require long-term nursing facility care.

***Responsible person*—A person who is not an employe of the facility and is responsible for making decisions on behalf of the resident. The person shall be so designated by the resident or the court and documentation shall be available on the resident's clinical record to this effect. An employe of the facility will be permitted to be a responsible person only if appointed the resident's legal guardian by the court.]**

***Restraint*—A restraint can be physical or chemical.**

(i) A physical restraint includes [any apparatus, appliance, device or garment applied to or adjacent to a resident's body, which restricts or diminishes the resident's level of independence or freedom.] ANY MANUAL METHOD, PHYSICAL OR MECHANICAL DEVICE, EQUIPMENT OR MATERIAL THAT IS ATTACHED OR ADJACENT TO THE RESIDENT'S BODY, CANNOT BE REMOVED EASILY BY THE RESIDENT, AND RESTRICTS THE RESIDENT'S FREEDOM OF MOVEMENT OR NORMAL ACCESS TO THE RESIDENT'S BODY.

(ii) A chemical restraint includes [psychopharmacologic drugs that are used for discipline or convenience and not required to treat medical symptoms.] ANY MEDICATION THAT IS USED FOR DISCIPLINE OR CONVENIENCE AND NOT REQURIED TO TREAT MEDICAL SYMPTOMS.

SERIOUS BODILY INJURY—AS DEFINED IN SECTION 3 OF THE OLDER ADULTS PROTECTIVE SERVICES ACT (35 P.S. § 10225.103).

SERIOUS PHYSICAL INJURY— AS DEFINED IN SECTION 3 OF THE OLDER ADULTS PROTECTIVE SERVICES ACT (35 P.S. § 10225.103).

SEXUAL ABUSE—NON-CONSENSUAL CONTACT OF ANY TYPE WITH A RESIDENT, INCLUDING SEXUAL HARRASSMENT, SEXUAL COERCION OR SEXUAL ASSAULT.

[*Skilled or intermediate nursing care*—Professionally supervised nursing care and related medical and other health services provided for a period exceeding 24 hours to an individual not in need of hospitalization, but whose needs are above the level of room and board and can only be met in a long-term care nursing facility on an inpatient basis because of age, illness, disease, injury, convalescence or physical or mental infirmity. The term includes the provision of inpatient services that are needed on a daily basis by the resident, ordered by and provided under the direction of a physician, and which require the skills of professional personnel, such as, registered nurses, licensed practical nurses, physical therapists, occupational therapists, speech pathologists or audiologists.

***Social worker*—An individual with the following qualifications:**

(i) A Bachelor's Degree in social work or a Bachelor's Degree in a human services field including sociology, special education, rehabilitation counseling and psychology.

(ii) One year of supervised social work experience in a health care setting working directly with individuals.

***Speech/language pathologist*—A person licensed as a speech/language pathologist by the State Board of Examiners in Speech-Language and Hearing, or excluded from the requirements of licensure under the Speech-Language and Hearing Licensure Act (63 P.S. §§ 1701—1719).]**

SUBSTANTIAL COMPLIANCE MEANS THAT:

(1) ANY CITED DEFICIENCIES ARE, INDIVIDUALLY AND IN COMBINED EFFECT, OF A MINOR NATURE SUCH THAT NEITHER THE DEFICIENCIES NOR EFFORTS TOWARD THEIR CORRECTION WILL INTERFERE WITH OR ADVERSELY AFFECT NORMAL FACILITY OPERATIONS OR ADVERSELY AFFECT ANY RESIDENT'S HEALTH OR SAFETY.

(2) THE FACILITY HAS IMPLEMENTED A PLAN OF CORRECTION APPROVED BY THE DEPARTMENT.

TRANSFER—THE MOVEMENT OF A RESIDENT FROM A BED IN ONE CERTIFIED FACILITY TO A BED IN ANTOTHER CERTIFIED FACILITY WHEN THE RESIDENT EXPECTS TO RETURN TO THE ORIGINAL FACILITY.

VERBAL ABUSE—ANY USE OF ORAL, WRITTEN OR GESTURED LANGUAGE THAT WILLFULLY INCLUDES DISPARAGING AND DEROGATORY TERMS TO RESIDENTS OR THEIR FAMILIES, OR WITHIN THEIR HEARING DISTANCE, REGARDLESS OF THEIR AGE, ABILITY TO COMPREHEND OR DISABILITY. EXAMPLES OF VERBAL ABUSE INCLUDE:

(A) THREATS OF HARM.

(B) SAYING THINGS TO FRIGHTEN A RESIDENT, SUCH AS TELLING A RESIDENT THAT THE RESIDENT WILL NEVER BE ABLE TO SEE THE RESIDENT'SFAMILY AGAIN.

CHAPTER 211. PROGRAM STANDARDS FOR LONG-TERM CARE NURSING FACILITIES

§ 211.12. Nursing services.

(a) The facility shall provide services by sufficient numbers of personnel on a 24-hour basis to provide nursing care to meet the needs of all residents.

* * * * *

(i) A minimum number of general nursing care hours shall be provided for each 24-hour period.

(1) The total number of hours of general nursing care provided ~~during each shift~~ in each 24-hour period shall, when totaled for the entire facility, be a minimum of ~~[~~2.7~~]~~ 4.1 hours of direct resident care for each resident.

~~(2) A facility shall have, during each shift in each 24-hour period, a sufficient number of nursing staff with the appropriate competencies and skill sets to provide nursing care and related services to:~~

~~(1) assure resident safety; and~~

~~(2) attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.~~

(j) Nursing personnel shall be provided on each resident floor.

* * * * *

COMMONWEALTH OF PENNSYLVANIA
OFFICE OF THE SECRETARY OF HEALTH

September 27, 2022

Mr. David Sumner
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, PA 17101

Re: Department of Health – Final Regulation No. 10-221
Long-Term Care Nursing Facility Regulations
28 Pa. Code §§ 201.1, 201.2, 201.3
Rulemaking 1 – General Applicability and Definitions

Dear Mr. Sumner:

Enclosed are final-form regulations for review by the Independent Regulatory Review Commission (IRRC) in accordance with the Regulatory Review Act (71 P.S. §§ 745.1—745.15). This is the first of four rulemaking packages that amend Subpart C (relating to long-term care facilities) of Part IV of Title 28 of the Pennsylvania Code. Subpart C consists of 6 different chapters: Chapters 201, 203, 205, 207, 209 and 211. The purpose of this final-form rulemaking is to create consistency between Federal and State requirements for long-term care nursing facilities by expanding the adoption of the Federal requirements to include the requirements set forth at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). This final-form rulemaking also updates existing definitions applicable to long-term care nursing facilities.

The Regulatory Review Act provides that upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to IRRC and the Standing Committees of the General Assembly a copy of the agency's response to the comments received, the names and addresses of the commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt. *See* 71 P.S. §§745.5a(a).

A list of the names and addresses of the commentators who requested a copy of the final-form regulations is enclosed. The Department previously forwarded these comments to the Commission.

The Act also provides that IRRC may have until its next scheduled meeting which occurs no less than 30 days after receipt of the final-form regulation to approve or disapprove the final-form regulation. 71 P.S § 745.5a(e).

The Department will provide IRRC with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact David Toth, Director of the Office of Legislative Affairs, at (717) 787-6436.

Sincerely,

Denise Johnson, MD
Acting Secretary of Health

Enclosures

From:	Bradbury, Joan
To:	Smith, Pamela (Health); Brooks, Senator Michele
Subject:	RE: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 1 (10-221)
Date:	Tuesday, September 27, 2022 9:49:14 AM

Received, thank you Pam.

Joan Bradbury
Executive Director
Senate Health & Human Services Committee
717-787-1475 (direct)

From: Smith, Pamela (Health) <pamesmith@pa.gov>
Sent: Tuesday, September 27, 2022 8:11 AM
To: Brooks, Senator Michele <mbrooks@pasen.gov>
Cc: Bradbury, Joan <jbradbury@pasen.gov>
Subject: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 1 (10-221)
Importance: High

Good morning,

Attached are final-form long-term care nursing facility regulations – rulemaking 1 (10-221) from the Department of Health. This is one of four long-term care nursing facility packages that are being delivered to you today.

Under the Regulatory Review Act, the Department is required to deliver a final-form regulatory package to the Standing Committees of the General Assembly and the Independent Regulatory Review Commission (IRRC) **on the same day**, with IRRC receiving the package last. Confirmation of receipt by the Standing Committees is required for delivery to IRRC.

Please respond as soon as possible to this email indicating that you have received the attached final-form regulatory package so that I can deliver the package to IRRC **today, September 27, 2022**.

Thanks,
Pam

Pamela G. Smith | Assistant Counsel
Pennsylvania Department of Health | Office of Legal Counsel
625 Forster Street | Harrisburg, PA 17120 - 0701
Phone: 717.783.2500 | Fax: 717.705.6042
www.health.state.pa.us

From:	Fricke, Erika L.
To:	Smith, Pamela (Health); Frankel, Dan
Subject:	RE: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 1 (10-221)
Date:	Tuesday, September 27, 2022 10:46:04 AM

Received

From: Smith, Pamela (Health) <pamesmith@pa.gov>
Sent: Tuesday, September 27, 2022 8:10 AM
To: Frankel, Dan <DFrankel@pahouse.net>
Cc: Fricke, Erika L. <EFricke@pahouse.net>
Subject: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 1 (10-221)
Importance: High

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Pennsylvania Department of Health | Office of Legal Counsel
625 Forster Street | Harrisburg, PA 17120 - 0701
Phone: 717.783.2500 | Fax: 717.705.6042
www.health.state.pa.us

From: Freeman, Clarissa
To: Smith, Pamela (Health)
Subject: Re: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 1 (10-221)
Date: Tuesday, September 27, 2022 9:26:21 AM

Received.
Thank you,
Clarissa

Get Outlook for iOS

From: Smith, Pamela (Health) <pamesmith@pa.gov>
Sent: Tuesday, September 27, 2022 8:12:21 AM
To: Haywood, Senator Art <art.haywood@pasenate.com>
Cc: Freeman, Clarissa <clarissa.freeman@pasenate.com>
Subject: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 1 (10-221)

■ EXTERNAL EMAIL ■

Good morning,

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Pennsylvania Department of Health | Office of Legal Counsel
625 Forster Street | Harrisburg, PA 17120 - 0701
Phone: 717.783.2500 | Fax: 717.705.6042
www.health.state.pa.us

From:	Michael Siget
To:	Smith, Pamela (Health); Kathy Rapp
Subject:	RE: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 1 (10-221)
Date:	Tuesday, September 27, 2022 8:36:25 AM

Received.

From: Smith, Pamela (Health) <pamesmith@pa.gov>
Sent: Tuesday, September 27, 2022 8:09 AM
To: Kathy Rapp <Klrapp@pahousegop.com>
Cc: Michael Siget <Msiget@pahousegop.com>
Subject: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 1 (10-221)
Importance: High

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