

<h1>Regulatory Analysis Form</h1> <p>(Completed by Promulgating Agency)</p> <p><i>(All Comments submitted on this regulation will appear on IRRC's website)</i></p>		<p><b>INDEPENDENT REGULATORY RECEIVED</b></p> <p>JUL 21 2021</p> <p>Independent Regulatory Review Commission</p>
<p>(1) Agency Department of Health</p>		
<p>(2) Agency Number: 10 Identification Number: 221</p>		<p>IRRC Number: 3312</p>
<p>(3) PA Code Cite: 28 Pa. Code §§ 201.1, 201.2, 201.3 and 211.12(i).</p>		
<p>(4) Short Title: Long-term care nursing facilities</p> <p>Please note that this is the first of five proposed rulemaking packages, with respect to long-term care nursing facilities, to be promulgated by the Department.</p>		
<p>(5) Agency Contacts (List Telephone Number and Email Address):</p> <p>Primary Contact: Lori Gutierrez, Deputy Director, Office of Policy, 717-547-3311, <a href="mailto:RA-DHLTCReqs@pa.gov">RA-DHLTCReqs@pa.gov</a></p> <p>Secondary Contact: Ann Chronister, Director, Bureau of Facility Licensure and Certification, 717-547-3131, <a href="mailto:RA-DHLTCReqs@pa.gov">RA-DHLTCReqs@pa.gov</a></p>		
<p>(6) Type of Rulemaking (check applicable box):</p> <p><input checked="" type="checkbox"/> Proposed Regulation</p> <p><input type="checkbox"/> Final Regulation</p> <p><input type="checkbox"/> Final Omitted Regulation</p>		<p><input type="checkbox"/> Emergency Certification Regulation;</p> <p><input type="checkbox"/> Certification by the Governor</p> <p><input type="checkbox"/> Certification by the Attorney General</p>
<p>(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)</p> <p>This proposed regulation is the first of five rulemaking packages, with respect to long-term care nursing facilities, that the Department intends to promulgate.</p> <p>The purpose of this proposed 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 all the requirements set forth at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). This proposed rulemaking also updates existing definitions applicable to long-term care nursing facilities by adding, updating and deleting definitions. Finally, this proposed rulemaking increases the number of direct care hours that long-term care nursing facilities are required to provide to residents, per shift, while also clarifying that nursing staff providing such care must possess the appropriate competencies and skills necessary to do so.</p>		

(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 proposed regulations are not mandated by any Federal or State law or court order, or Federal regulation. With respect to State law, the Department is authorized under the act 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 proposed expansion of its adoption of the Federal 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.

(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%. Pennsylvania also has a higher percentage of older adults when compared to other states. In 2017, Pennsylvania 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 (aged 65 or older) for every 100-working age Pennsylvanians (15 to 64 years of age). Penn State Harrisburg, Pennsylvania State Data Center. *Population Characteristics and Change: 2010 to 2017 (Research Brief)*. <https://pasdc.hbg.psu.edu/data/research-briefs/pa-population-estimates> (last visited: November 30, 2020). As the number of older Pennsylvanians increases, the number of those needing long-term nursing care will also increase. It has been estimated that an individual turning

65 today has an almost 70% chance of needing some type of long-term nursing care during the remainder of their lifetime. U.S. Department of Health and Human Services. *How Much Care Will You Need?* <https://longtermcare.acl.gov/the-basics/how-much-care-will-you-need.html> (last visited: December 4, 2020).

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 act. Since that time, there have been substantial changes in the means of delivering care and providing a safe environment for residents in long-term care nursing facilities. This proposed rulemaking is necessary to improve the quality of care delivered to residents, increase resident safety and minimize procedural burdens on health care practitioners who provide care to residents in long-term care nursing facilities.

The Department's surveyors, as well as the long-term care nursing facilities licensed by the Department, will benefit from the consistency and efficiency created by the expanded adoption of the Federal requirements for long-term care nursing facilities at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). More than 72,000 residents in the 689 long-term care nursing facilities licensed by the Department will also 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 Medicare or Medicaid. In addition, it is expected that the proposed increase in direct care hours provided to residents will improve the quality of life and care of approximately 67,500 of the residents in the 603 long-term care nursing facilities that do not meet the proposed direct care staffing ratio of 4.1 direct care hours. It is expected that family members of long-term care residents will also reap emotional benefits from their loved ones receiving better quality of care.

(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.

The changes proposed by the Department to section 201.1 (relating to applicability) address the scope of the regulations which is consistent with the act and is not more stringent than Federal standards.

The changes proposed to sections 201.2 (relating to requirements) and 201.3 (relating to definitions) bring the Department's regulations in line with the Federal requirements for long-term care nursing facilities, and thus, are not more stringent than Federal standards.

With respect to the increase in direct care resident hours in subsection (i) of § 211.12 (relating to nursing services), the Federal requirements do not specify the minimum number of direct care hours to be provided to residents. Instead, the Federal regulations require long-term care nursing facilities "to have sufficient staff with the appropriate competencies and skills sets" to provide care to residents. The Centers for Medicare & Medicaid Services (CMS) has acknowledged a correlation between level of care and a higher number of direct care hours. In a 2001 study, CMS suggested that a minimum of 4.1 hours of direct care daily would improve the quality of care provided to a resident and acknowledged that anything below that level could "result in harm and jeopardy to residents." *Medicare and Medicaid Programs; Reform of Requirements for Long-Term care Facilities*, 80 Fed. Reg. 42168, 42202 (July 16, 2015). However, when updating the Federal regulations in 2016, CMS declined to impose a standard, citing insufficient information and a concern that a mandated ratio could result in unintended consequences, such as staffing to a minimum, input substitution, task diversion or stifling innovation.

*Id.*; *Medicare and Medicaid Programs; Reform of Requirements for Long-Term care Facilities*, 81 Fed. Reg. 68688, 68753-68759 (October 4, 2016). The lack of a Federal requirement leaves it up to states to determine and set a minimum amount of direct care hours.

The Department has a duty to protect the health of all Pennsylvanians, including those who are 65 and older. Given that a significant number of the population in Pennsylvania consists of individuals aged 65 and older, with an expected increase in that population in the next several years, it is even more important that the Department act to ensure the health and safety of this vulnerable population. The Department strongly believes that increasing the number of direct care staffing hours from 2.7 to 4.1 will have a positive impact on the quality of life and quality of care for every resident in a long-term care nursing facility. Numerous studies have found a direct correlation between the quality of resident care, quality of resident life, and the number of direct care hours that the resident receives. Benefits of higher staffing ratios include improved activity levels, lower mortality rates, fewer infections, less antibiotic use, fewer pressure ulcers and fewer catheterized residents, improved eating patterns and pain levels, and improved mental health. Juh Hyun Shin, PhD, RN & Sung-Heui Bae, PhD, MPH, RN. *Nurse Staffing, Quality of Care, and Quality of Life in U.S. Nursing Homes, 1996-2011*, 38 *Journal of Gerontological Nursing* 46 (2012). (Attachment 1). While there will be an impact on long-term care nursing facilities as a result of this increase, the Department feels strongly that the benefits to older Pennsylvanians now and in the future outweighs those costs.

(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 requirements. All long-term care nursing facilities that participate in Medicare or Medicaid are required to comply with the Federal requirements regardless of where they are located. The Department is not aware of the number of long-term care nursing facilities in other states that do or do not participate in Medicare or Medicaid. The Department reviewed the regulations of other states to determine which states have 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 adopted the Federal requirements.

Increasing the minimum number of direct care hours from 2.7 to 4.1 places Pennsylvania above the surrounding states. While some states have set minimum direct care hours for residents of long-term care nursing facilities, these minimums are typically lower than expert recommendations. A review of the states surrounding Pennsylvania shows established minimum requirements between 2.25 and 3.67. New York does not have a minimum level, but instead merely provides in regulation that sufficient staffing is required. N.Y. Comp. Codes R. & Regs. tit. 10 § 415.13(a). West Virginia has a minimum requirement of 2.25 hours. W. Va. Code R. § 64-13-8. Ohio and New Jersey require a minimum of 2.5 hours, Maryland requires a minimum of 3.0 hours, and Delaware has the highest requirement at 3.67

hours of care. Ohio Admin. Code 3701-17-08; N.J. Admin. Code § 8:85-2.2; Md. Code Regs. 10.07.02.19; 16 Del. Admin. Code § 3201-5.0.<sup>1</sup>

Momentum is gaining for states to act regarding nursing staff ratios in long-term care nursing facilities as the COVID-19 pandemic has heightened awareness of this issue. Legislation was recently introduced in New York that, if passed and enacted, will establish a minimum requirement of 4.85 direct care nursing hours. Safe Staffing for Quality Care Act, Assembly Bill 108, 244<sup>th</sup> State Assembly Reg. Sess. (N.Y. 2021). Legislation has also been introduced in Connecticut that, if passed and enacted, will establish a minimum requirement of 4.1 direct care nursing hours. Raised S.B. 1030, General Assembly Reg. Session (Conn. 2021). The Rhode Island Senate also recently passed a bill, which, if enacted, will require all nursing facilities to provide a minimum daily average of 4.1 hours of direct nursing care per resident, per day. Nursing Home Staffing and Quality Care Act, S.B. 0002, General Assembly Reg. Session (R.I. 2021).

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

The proposed regulations will not affect the regulations of any other state agency. The Department is currently revising other parts of the regulations relating to long-term care facilities (28 Pa. Code Ch. 28, Subpart C). These proposed regulations will complement those revisions.

(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 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.

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.

<sup>1</sup> See also, Harrington, Charlene, Ph.D. *Nursing Home Staffing Standards in State Statutes and Regulations*. (2010). <https://theconsumervoice.org/uploads/files/issues/Harrington-state-staffing-table-2010.pdf> (last visited: March 19, 2021) (state-by-state summary of statutes and regulations pertaining to nursing home staffing requirements).

The Department presented the proposed regulations to the Health Policy Board on October 29, 2020.

(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 proposed regulations will apply to all 689 licensed long-term care nursing facilities in the Commonwealth. These facilities provide health services to more than 72,000 residents. The existing regulations of the Department already incorporate many of the Federal requirements and any burden by the expansion to incorporate the remaining Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) will only impact those long-term care nursing facilities that do not participate in Medicare or Medicaid. There are currently only three long-term care nursing facilities that do not participate in either Medicare or Medicaid. Requiring all long-term care nursing facilities to comply with all of the Federal requirements across the board, without exceptions, will make the survey process more efficient and will create consistency and eliminate confusion in the application of standards to long-term care nursing facilities, which will benefit all long-term care nursing facilities. Any negative impact on the three facilities that do not participate in Medicare or Medicaid will be minimum as they are already required by existing section 201.2 to comply with the majority of the requirements in 42 CFR Part 483, Subpart B. Any negative impact is also vastly outweighed by the need for consistency in the application of standards for all long-term care nursing facilities in the Commonwealth.

The increase in direct nursing care hours from 2.7 to 4.1 hours, per shift, will directly impact 603 of the total 689 licensed long-term care nursing facilities licensed by the Department. The 603 impacted facilities provide care to approximately 67,500 residents. To determine this number, the Department utilized data extracted in January 2020. It was determined by the Department that this data would be more accurate than data from 2020 as there was concern that 2020 data may be skewed because of the COVID-19 pandemic and its impact on long-term care nursing facility staffing. The Department of Human Services (DHS) determined the cost impact on facilities that participate in Medicaid, also known as Medical Assistance (MA). The median hourly rate for a nursing staff assistant was determined to be \$22.19. The total additional nursing assistant staff hours needed to bring each MA facility up from 2.7 to 4.1 direct care hours is 15,986,835. To provide the most accurate estimate of the cost impact on MA facilities, DHS considered actual nursing staff assistant costs for each facility, rather than the median hourly rate. The additional nursing staff hours needed for each MA long-term care nursing facility multiplied by the hourly rate results in \$385.7 million in additional costs across all MA long-term care nursing facilities (\$355.7 million for the 595 private facilities and \$30.0 million for county facilities). The Federal MA match in Federal fiscal year 2022 is 52.68% of this \$385.7 million, or \$203.2 million, which results in a net cost to DHS of approximately \$182.5 million. DHS does not have sufficient data to determine who will bear the burden of the remaining costs not covered by MA but believes that at least some of this amount will have to be borne by the regulated community.

Of the long-term care nursing facilities that do not participate in MA, the Department identified 65 long-term care nursing facilities that accept only Medicare as payment and three facilities that are “private pay only.” Medicare is an insurance program managed by the Federal government. According to Medicare.gov, direct care services, *i.e.*, assistance with activities of daily living in long-term care nursing facilities, are generally not covered. Medicare Part A may cover care in a certified skilled

nursing facility if it is deemed medically necessary. The Department does not have sufficient data to determine whether any of the direct care services being provided to long-term care nursing residents is medically necessary, and thus, covered under Medicare. Of the 65 Medicare-only facilities, in January 2020, 40 were above the proposed staffing ratio of 4.1, five did not have any residents, and 20 were operating below the proposed 4.1 staffing ratio. In an attempt to determine the most accurate estimate, the Department excluded the five facilities that did not have residents in January 2020 and estimated costs based on the 20 facilities that were operating below the proposed 4.1 ratio. Assuming that the direct care services provided by nursing staff in the Medicare-only facilities are not covered by Medicare, the Department estimates that the cost to the 20 impacted facilities will be \$183,450 annually. Of the three private pay facilities, two already exceed the proposed 4.1 ratio; one does not exceed the proposed ratio. The annual cost to the single private pay facility is estimated to be \$10,205. The Department believes that the increase in quality of life and safety for the approximately 67,500 residents in these long-term care nursing facilities outweighs any additional cost to the regulated community.

The Department applied the North America Industry Classification System (NAICS) standards to the long-term care nursing facilities identified above. Under the NAICS, a long-term care facility is a small business if it has \$35.5 million or less in total income annually. The Commonwealth's Department of Labor and Industry (L&I) defines a small business by the number of employees rather than total annual income. The Department does not maintain data on long-term care nursing facility annual income, or the number of individuals employed by long-term care nursing facilities. Therefore, the Department is not able to determine the number of long-term care nursing facilities that fall into the small business category.

If any of the Commonwealth's 689 licensed long-term care nursing facilities are considered to be a small business, they will still be required to meet the requirements of the Department's long-term care nursing facilities regulations, as will any long-term care nursing facility that is not considered a small business. The Department's responsibility to the quality of care to residents in long-term care nursing facilities applies to all of those residents and is not altered by the fact that a long-term care nursing facility may be considered a small business.

#### **Residents of Long-Term Care Nursing Facilities**

More than 72,000 residents in the 689 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 Medicare or Medicaid. It is expected that the proposed increase in direct care hours provided to residents will improve the quality of life and care of approximately 67,500 of the residents in the long-term care nursing facilities that currently do not meet the new proposed minimum requirement. It is expected that family members of long-term care residents will also reap emotional benefits from their loved ones receiving better quality of care.

#### **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. Rather, the proposed amendments, in particular the adoption of the Federal requirements without exceptions, 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.

The Department is also the State agency charged with administering and overseeing the Nurse Aide Registry for the Commonwealth. Pursuant to Federal law, any individual who works in a long-term care nursing facility as a nurse aide must meet the statutory requirements to be included on the State's Nurse Aide Registry. 42 U.S.C. § 1396r(b)(5)(c). The Department is required to handle the administrative hearings related to the annotation process for nurse aides accused of abuse. There is currently a total of 335,792 nurse aides on the registry. The Department is not able to quantify the impact that the proposed regulations will have on its management of the Nurse Aide Registry. The Department's proposal to increase the number of direct care hours will most likely result in the hiring of additional nurse aids, which may increase the number of nurse aide annotations. However, it is the Department's position that an increase in the number of nurse aides hired at a long-term care nursing facility would actually increase the level of care provided to residents and thus should decrease the number of abuse allegations.

### **DHS**

The proposed amendment to the number of direct care hours will increase costs to the MA program in DHS. DHS determined the cost impact of the Department's proposed increase in direct care hours. Although the Department currently licenses a total of 689 long-term care nursing facilities, for its analysis, DHS excluded the six long-term care nursing facilities that are operated by DMVA. Of the 683 remaining long-term care nursing facilities, a total of 615 receive MA payments. Of these 615 long-term care nursing facilities, 595 are private facilities and 20 are county facilities. The median hourly rate for a nursing staff assistant was determined to be \$22.91. The total additional nursing assistant staff hours needed to bring each MA facility up from 2.7 to 4.1 direct care hours is 15,986,835. To provide the most accurate estimate, DHS considered actual nursing staff assistant costs for each MA facility rather than the median hourly rate. The additional nursing assistant staff hours needed for each MA long-term care nursing facility multiplied by the facility-specific hourly rate results in \$385.7 million in additional costs across all MA long-term care nursing facilities (\$355.7 million for the 595 private facilities and \$30.0 million for county facilities). The Federal MA Program match in Federal fiscal year 2022 is 52.68% of this \$385.7 million, or \$203.2 million, which results in a net cost to DHS of approximately \$182.5 million. DHS does not have sufficient data to determine who will bear the burden of the remaining costs not covered by MA, for the MA facilities, but believes that at least some of this amount will have to be borne by the regulated community. Nonetheless, the Department feels strongly that the increase in quality of life and safety for the approximately 67,500 residents in the impacted long-term care nursing facilities outweighs any additional costs to either the Medical Assistance program in DHS or the regulated community.

### **DMVA**

DMVA operates six veterans' homes across the state with more than 1,300 residents and employs more than 2,000 clinical and professional staff. An increase in direct care nursing hours to 4.1 requires the Bureau of Veterans Homes to add staff to the direct care complement resulting in an additional 235 employees. The average cost to DMVA for one direct care provider is \$105,207.42. This cost includes salary and benefits. The total overall estimated cost to DMVA for the increase will be \$24,723,743.70. This will also be a cost-to-carry for subsequent fiscal years. The Federal MA Program rate will apply to these direct care workers. This increase in staff (\$12.9 million) could be implemented over a 3-year period, and with an estimated Federal MA Program rate of 52%, would be an increase of approximately \$4.3M in state funding per year.

(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 689 licensed long-term care nursing facilities in the Commonwealth will be required to comply with this proposed rulemaking. These facilities provide care to more than 72,000 residents. The Department does not maintain data on long-term care nursing facility annual income, or the number of individuals employed by long-term care nursing facilities. Therefore, the Department is unable to identify which long-term care nursing facilities may be small businesses. The proposed regulations will apply to all long-term care nursing facilities irrespective of whether they are considered a small business. The Department's responsibility to the health and welfare of all residents in long-term care nursing facilities is not altered by the fact that a long-term care nursing facility may be a small business.

(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.

### **Financial and Economic Impact and Benefits**

#### *Long-Term Care Nursing Facilities*

The proposed regulations will apply to all 689 licensed long-term care nursing facilities in the Commonwealth. These facilities provide health services to more than 72,000 residents. The existing regulations of the Department already incorporate many of the Federal requirements and any burden by the expansion to incorporate the remaining Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) will only impact those long-term care nursing facilities that do not participate in Medicare or Medicaid. There are currently only three long-term care nursing facilities that do not participate in either Medicare or Medicaid. Requiring all long-term care nursing facilities to comply with all of the Federal requirements across the board, without exceptions, will make the survey process more efficient and will create consistency and eliminate confusion in the application of standards to long-term care nursing facilities, which will benefit all long-term care nursing facilities. Any negative impact on the three facilities that do not participate in Medicare or Medicaid will be minimum and is vastly outweighed by the need for consistency in the application of standards for all long-term care nursing facilities in the Commonwealth.

The increase in direct nursing care hours from 2.7 to 4.1 hours, per shift, will directly impact 603 of the total 689 licensed long-term care nursing facilities licensed by the Department. The 603 impacted facilities provide care to approximately 67,500 residents. To determine this number, the Department utilized data extracted in January 2020. It was determined by the Department that this data would be more accurate than data from 2020 as there was concern that 2020 data may be skewed because of the COVID-19 pandemic and its impact on long-term care nursing facility staffing. The Department of Human Services (DHS) determined the cost impact on facilities that participate in Medicaid, also known as Medical Assistance (MA). The median hourly rate for a nursing staff assistant was determined to be \$22.19. The total additional nursing assistant staff hours needed to bring each MA facility up from 2.7 to 4.1 direct care hours is 15,986,835. To provide the most accurate estimate of the cost impact on MA facilities, DHS considered actual nursing staff assistant costs for each facility, rather than the median hourly rate. The additional nursing staff hours needed for each MA long-term care nursing facility multiplied by the hourly rate results in \$385.7 million in additional costs across all MA long-term care nursing facilities (\$355.7 million for the 595 private facilities and \$30.0 million for county facilities). The Federal MA match in Federal fiscal year 2022 is 52.68% of this \$385.7 million, or \$203.2 million,

which results in a net cost to DHS of approximately \$182.5 million. DHS does not have sufficient data to determine who will bear the burden of the remaining costs not covered by MA but believes that at least some of this amount will have to be borne by the regulated community.

Of the long-term care nursing facilities that do not participate in MA, the Department identified 65 long-term care nursing facilities that accept only Medicare as payment and three facilities that are “private pay only.” Medicare is an insurance program managed by the Federal government. According to Medicare.gov, direct care services, *i.e.*, assistance with activities of daily living in long-term care nursing facilities, are generally not covered. Medicare Part A may cover care in a certified skilled nursing facility if it is deemed medically necessary. The Department does not have sufficient data to determine whether any of the direct care services being provided to long-term care nursing residents is medically necessary, and thus, covered under Medicare. Of the 65 Medicare-only facilities, in January 2020, 40 were above the proposed staffing ratio of 4.1, five did not have any residents, and 20 were operating below the proposed 4.1 staffing ratio. In an attempt to determine the most accurate estimate, the Department excluded the five facilities that did not have residents in January 2020 and estimated costs based on the 20 facilities that were operating below the proposed 4.1 ratio. Assuming that the direct care services provided by nursing staff in the Medicare-only facilities are not covered by Medicare, the Department estimates that the cost to the 20 impacted facilities will be \$183,450 annually. Of the three private pay facilities, two already exceed the proposed 4.1 ratio; one does not exceed the proposed ratio. The annual cost to the single private pay facility is estimated to be \$10,205. The Department believes that the increase in quality of life and safety for the approximately 67,500 residents in these long-term care nursing facilities outweighs any additional cost to the regulated community.

#### *Small businesses*

The Department applied the North America Industry Classification System (NAICS) standards to the long-term care nursing facilities identified above. Under the NAICS, a long-term care facility is a small business if it has \$35.5 million or less in total income annually. The Commonwealth’s Department of Labor and Industry (L&I) defines a small business by the number of employees rather than total annual income. The Department does not maintain data on long-term care nursing facility annual income, or the number of individuals employed by long-term care nursing facilities. Therefore, the Department is not able to determine the number of long-term care nursing facilities that fall into the small business category.

If any of the Commonwealth’s 689 licensed long-term care nursing facilities are considered to be a small business, they will still be required to meet the requirements of the Department’s long-term care nursing facilities regulations, as will any long-term care nursing facility that is not considered a small business. The Department’s responsibility to the quality of care to residents in long-term care nursing facilities applies to all of those residents and is not altered by the fact that a long-term care nursing facility may be considered a small business.

#### *Labor Communities*

Long-term care nursing facilities with unionized medical staff will benefit from the increase in the staffing ratio as they will be better staffed to handle the needs of the residents. With increased staffing, there should be better medical staff morale and less medical staff turnover leading to better resident care and outcomes. Medical staff injuries should decrease as more staff will be available to assist in resident needs. Less staff turnover and a decrease in injuries and worker compensation claims will also benefit long-term-care nursing facilities.

### *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. Rather, the proposed amendments, in particular the adoption of the Federal requirements without exceptions, 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.

The Department is also the State agency charged with administering and overseeing the Nurse Aide Registry for the Commonwealth. Pursuant to Federal law, any individual who works in a long-term care nursing facility as a nurse aide must meet the statutory requirements to be included on the State's Nurse Aide Registry. 42 U.S.C. § 1396r(b)(5)(c). The Department is required to handle the administrative hearings related to the annotation process for nurse aides accused of abuse. There is currently a total of 335,792 nurse aides on the registry. The Department is not able to quantify the impact that the proposed regulations will have on its management of the Nurse Aide Registry. The Department's proposal to increase the number of direct care hours will most likely result in the hiring of additional nurse aids, which may increase the number of nurse aide annotations. However, it is the Department's position that an increase in the number of nurse aides hired at a long-term care nursing facility would actually increase the level of care provided to residents and thus should decrease the number of abuse allegations.

### *DHS*

The proposed amendment to the number of direct care hours will increase costs to the MA program in DHS. DHS determined the cost impact of the Department's proposed increase in direct care hours. Although the Department currently licenses a total of 689 long-term care nursing facilities, for its analysis, DHS excluded the six long-term care nursing facilities that are operated by DMVA. Of the 683 remaining long-term care nursing facilities, a total of 615 receive MA payments. Of these 615 long-term care nursing facilities, 595 are private facilities and 20 are county facilities. The median hourly rate for a nursing staff assistant was determined to be \$22.91. The total additional nursing assistant staff hours needed to bring each MA facility up from 2.7 to 4.1 direct care hours is 15,986,835. To provide the most accurate estimate, DHS considered actual nursing staff assistant costs for each MA facility rather than the median hourly rate. The additional nursing assistant staff hours needed for each MA long-term care nursing facility multiplied by the facility-specific hourly rate results in \$385.7 million in additional costs across all MA long-term care nursing facilities (\$355.7 million for the 595 private facilities and \$30.0 million for county facilities). The Federal MA Program match in Federal fiscal year 2022 is 52.68% of this \$385.7 million, or \$203.2 million, which results in a net cost to DHS of approximately \$182.5 million. DHS does not have sufficient data to determine who will bear the burden of the remaining costs not covered by MA, for the MA facilities, but believes that at least some of this amount will have to be borne by the regulated community. Nonetheless, the Department feels strongly that the increase in quality of life and safety for the approximately 67,500 residents in the impacted long-term care nursing facilities outweighs any additional costs to either the Medical Assistance program in DHS or the regulated community.

### *DMVA*

DMVA operates six veterans' homes across the state with more than 1,300 residents and employs more than 2,000 clinical and professional staff. An increase in direct care nursing hours to 4.1 requires the

Bureau of Veterans Homes to add staff to the direct care complement resulting in an additional 235 employees. The average cost to DMVA for one direct care provider is \$105,207.42. This cost includes salary and benefits. The total overall estimated cost to DMVA for the increase will be \$24,723,743.70. This will also be a cost-to-carry for subsequent fiscal years. The Federal MA Program rate will apply to these direct care workers. This increase in staff (\$12.9 million) could be implemented over a 3-year period, and with an estimated Federal MA Program rate of 52%, would be an increase of approximately \$4.3M in state funding per year.

*Public*

The Department anticipates no financial or economic impact on the public as a result of the proposed regulations.

**Social Impact and Benefits**

*Public*

More than 72,000 residents in the 689 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 Medicare or Medicaid. It is expected that the proposed increase in direct care hours provided to residents will improve the quality of life and care of approximately 67,500 of the residents in the long-term care nursing facilities that currently do not meet the new proposed minimum requirement for direct care nursing hours. It is expected that family members of long-term care residents will also reap emotional benefits from their loved ones receiving better quality of care.

The Department anticipates little to no social impact on the other entities identified in this question.

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

*Long-Term Care Nursing Facilities*

The proposed regulations will apply to all 689 licensed long-term care nursing facilities in the Commonwealth. These facilities provide health services to more than 72,000 residents. The existing regulations of the Department already incorporate many of the Federal requirements and any burden by the expansion to incorporate the remaining Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) will only impact those long-term care nursing facilities that do not participate in Medicare or Medicaid. There are currently only three long-term care nursing facilities that do not participate in either Medicare or Medicaid. Requiring all long-term care nursing facilities to comply with all of the Federal requirements across the board, without exceptions, will make the survey process more efficient and will create consistency and eliminate confusion in the application of standards to long-term care nursing facilities, which will benefit all long-term care nursing facilities. Any negative impact on the three facilities that do not participate in Medicare or Medicaid will be minimum and is vastly outweighed by the need for consistency in the application of standards for all long-term care nursing facilities in the Commonwealth.

The increase in direct nursing care hours from 2.7 to 4.1 hours, per shift, will directly impact 603 of the total 689 licensed long-term care nursing facilities licensed by the Department. The 603 impacted facilities provide care to approximately 67,500 residents. To determine this number, the Department utilized data extracted in January 2020. It was determined by the Department that this data would be more accurate than data from 2020 as there was concern that 2020 data may be skewed because of the COVID-19 pandemic and its impact on long-term care nursing facility staffing. The Department of

Human Services (DHS) determined the cost impact on facilities that participate in Medicaid, also known as Medical Assistance (MA). The median hourly rate for a nursing staff assistant was determined to be \$22.19. The total additional nursing assistant staff hours needed to bring each MA facility up from 2.7 to 4.1 direct care hours is 15,986,835. To provide the most accurate estimate of the cost impact on MA facilities, DHS considered actual nursing staff assistant costs for each facility, rather than the median hourly rate. The additional nursing staff hours needed for each MA long-term care nursing facility multiplied by the hourly rate results in \$385.7 million in additional costs across all MA long-term care nursing facilities (\$355.7 million for the 595 private facilities and \$30.0 million for county facilities). The Federal MA match in Federal fiscal year 2022 is 52.68% of this \$385.7 million, or \$203.2 million, which results in a net cost to DHS of approximately \$182.5 million. DHS does not have sufficient data to determine who will bear the burden of the remaining costs not covered by MA but believes that at least some of this amount will have to be borne by the regulated community.

Of the long-term care nursing facilities that do not participate in MA, the Department identified 65 long-term care nursing facilities that accept only Medicare as payment and three facilities that are “private pay only.” Medicare is an insurance program managed by the Federal government. According to Medicare.gov, direct care services, *i.e.*, assistance with activities of daily living in long-term care nursing facilities, are generally not covered. Medicare Part A may cover care in a certified skilled nursing facility if it is deemed medically necessary. The Department does not have sufficient data to determine whether any of the direct care services being provided to long-term care nursing residents is medically necessary, and thus, covered under Medicare. Of the 65 Medicare-only facilities, in January 2020, 40 were above the proposed staffing ratio of 4.1, five did not have any residents, and 20 were operating below the proposed 4.1 staffing ratio. In an attempt to determine the most accurate estimate, the Department excluded the five facilities that did not have residents in January 2020 and estimated costs based on the 20 facilities that were operating below the proposed 4.1 ratio. Assuming that the direct care services provided by nursing staff in the Medicare-only facilities are not covered by Medicare, the Department estimates that the cost to the 20 impacted facilities will be \$183,450 annually. Of the three private pay facilities, two already exceed the proposed 4.1 ratio; one does not exceed the proposed ratio. The annual cost to the single private pay facility is estimated to be \$10,205. The Department believes that the increase in quality of life and safety for the approximately 40,00067,500 residents in these long-term care nursing facilities outweighs any additional cost to the regulated community.

#### *Small businesses*

The Department applied the North America Industry Classification System (NAICS) standards to the long-term care nursing facilities identified above. Under the NAICS, a long-term care facility is a small business if it has \$35.5 million or less in total income annually. The Commonwealth’s Department of Labor and Industry (L&I) defines a small business by the number of employees rather than total annual income. The Department does not maintain data on long-term care nursing facility annual income, or the number of individuals employed by long-term care nursing facilities. Therefore, the Department is not able to determine the number of long-term care nursing facilities that fall into the small business category.

If any of the Commonwealth’s 689 licensed long-term care nursing facilities are considered to be a small business, they will still be required to meet the requirements of the Department’s long-term care nursing facilities regulations, as will any long-term care nursing facility that is not considered a small business. The Department’s responsibility to the quality of care to residents in long-term care nursing facilities applies to all of those residents and is not altered by the fact that a long-term care nursing facility may be considered a small business.

### *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. Rather, the proposed amendments, in particular the adoption of the Federal requirements without exceptions, 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.

The Department is also the State agency charged with administering and overseeing the Nurse Aide Registry for the Commonwealth. Pursuant to Federal law, any individual who works in a long-term care nursing facility as a nurse aide must meet the statutory requirements to be included on the State's Nurse Aide Registry. 42 U.S.C. § 1396r(b)(5)(c). The Department is required to handle the administrative hearings related to the annotation process for nurse aides accused of abuse. There is currently a total of 335,792 nurse aides on the registry. The Department is not able to quantify the impact that the proposed regulations will have on its management of the Nurse Aide Registry. The Department's proposal to increase the number of direct care hours will most likely result in the hiring of additional nurse aids, which may increase the number of nurse aide annotations. However, it is the Department's position that an increase in the number of nurse aides hired at a long-term care nursing facility would actually increase the level of care provided to residents and thus should decrease the number of abuse allegations.

### *DHS*

The proposed amendment to the number of direct care hours will increase costs to the MA program in DHS. DHS determined the cost impact of the Department's proposed increase in direct care hours. Although the Department currently licenses a total of 689 long-term care nursing facilities, for its analysis, DHS excluded the six long-term care nursing facilities that are operated by DMVA. Of the 683 remaining long-term care nursing facilities, a total of 615 receive MA payments. Of these 615 long-term care nursing facilities, 595 are private facilities and 20 are county facilities. The median hourly rate for a nursing staff assistant was determined to be \$22.91. The total additional nursing assistant staff hours needed to bring each MA facility up from 2.7 to 4.1 direct care hours is 15,986,835. To provide the most accurate estimate, DHS considered actual nursing staff assistant costs for each MA facility rather than the median hourly rate. The additional nursing assistant staff hours needed for each MA long-term care nursing facility multiplied by the facility-specific hourly rate results in \$385.7 million in additional costs across all MA long-term care nursing facilities (\$355.7 million for the 595 private facilities and \$30.0 million for county facilities). The Federal MA Program match in Federal fiscal year 2022 is 52.68% of this \$385.7 million, or \$203.2 million, which results in a net cost to DHS of approximately \$182.5 million. DHS does not have sufficient data to determine who will bear the burden of the remaining costs not covered by MA, for the MA facilities, but believes that at least some of this amount will have to be borne by the regulated community. Nonetheless, the Department feels strongly that the increase in quality of life and safety for the approximately 67,500 residents in the impacted long-term care nursing facilities outweighs any additional costs to either the Medical Assistance program in DHS or the regulated community.

### *DMVA*

DMVA operates six veterans' homes across the state with more than 1,300 residents and employs more

than 2,000 clinical and professional staff. An increase in direct care nursing hours to 4.1 requires the Bureau of Veterans Homes to add staff to the direct care complement resulting in an additional 235 employees. The average cost to DMVA for one direct care provider is \$105,207.42. This cost includes salary and benefits. The total overall estimated cost to DMVA for the increase will be \$24,723,743.70. This will also be a cost-to-carry for subsequent fiscal years. The Federal MA Program rate will apply to these direct care workers. This increase in staff (\$12.9 million) could be implemented over a 3-year period, and with an estimated Federal MA Program rate of 52%, would be an increase of approximately \$4.3M in state funding per year.

*Public*

The Department anticipates no financial or economic impact on the public as a result of the proposed regulations. However, more than 72,000 residents in the 689 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 Medicare or Medicaid. It is expected that the proposed increase in direct care hours provided to residents will improve the quality of life and care of approximately 67,500 of the residents in the long-term care nursing facilities that currently do not meet the new proposed minimum requirement for direct care nursing hours. It is expected that family members of long-term care residents will also reap emotional benefits from their loved ones receiving better quality of care.

(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 proposed regulations will apply to all 689 licensed long-term care nursing facilities in the Commonwealth. These facilities provide health services to more than 72,000 residents. The existing regulations of the Department already incorporate many of the Federal requirements and any burden by the expansion to incorporate the remaining Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) will only impact those long-term care nursing facilities that do not participate in Medicare or Medicaid. There are currently only three long-term care nursing facilities that do not participate in either Medicare or Medicaid. Requiring all long-term care nursing facilities to comply with all of the Federal requirements across the board, without exceptions, will make the survey process more efficient and will create consistency and eliminate confusion in the application of standards to long-term care nursing facilities, which will benefit all long-term care nursing facilities. Any negative impact on the three facilities that do not participate in Medicare or Medicaid will be minimum and is vastly outweighed by the need for consistency in the application of standards for all long-term care nursing facilities in the Commonwealth.

The increase in direct nursing care hours from 2.7 to 4.1 hours, per shift, will directly impact 603 of the total 689 licensed long-term care nursing facilities licensed by the Department. The 340 impacted facilities provide care to approximately 40,000 residents. To determine this number, the Department utilized data extracted in January 2020. It was determined by the Department that this data would be more accurate than data from 2020 as there was concern that 2020 data may be skewed because of the COVID-19 pandemic and its impact on long-term care nursing facility staffing. The Department of Human Services (DHS) determined the cost impact on facilities that participate in Medicaid, also known as Medical Assistance (MA). The median hourly rate for a nursing staff assistant was determined to be

\$22.19. The total additional nursing assistant staff hours needed to bring each MA facility up from 2.7 to 4.1 direct care hours is 15,986,835. To provide the most accurate estimate of the cost impact on MA facilities, DHS considered actual nursing staff assistant costs for each facility, rather than the median hourly rate. The additional nursing staff hours needed for each MA long-term care nursing facility multiplied by the hourly rate results in \$385.7 million in additional costs across all MA long-term care nursing facilities (\$355.7 million for the 595 private facilities and \$30.0 million for county facilities). The Federal MA match in Federal fiscal year 2022 is 52.68% of this \$385.7 million, or \$203.2 million, which results in a net cost to DHS of approximately \$182.5 million. DHS does not have sufficient data to determine who will bear the burden of the remaining costs not covered by MA but believes that at least some of this amount will have to be borne by the regulated community.

Of the long-term care nursing facilities that do not participate in MA, the Department identified 65 long-term care nursing facilities that accept only Medicare as payment and three facilities that are “private pay only.” Medicare is an insurance program managed by the Federal government. According to Medicare.gov, direct care services, *i.e.*, assistance with activities of daily living in long-term care nursing facilities, are generally not covered. Medicare Part A may cover care in a certified skilled nursing facility if it is deemed medically necessary. The Department does not have sufficient data to determine whether any of the direct care services being provided to long-term care nursing residents is medically necessary, and thus, covered under Medicare. Of the 65 Medicare-only facilities, in January 2020, 40 were above the proposed staffing ratio of 4.1, five did not have any residents, and 20 were operating below the proposed 4.1 staffing ratio. In an attempt to determine the most accurate estimate, the Department excluded the five facilities that did not have residents in January 2020 and estimated costs based on the 20 facilities that were operating below the proposed 4.1 ratio. Assuming that the direct care services provided by nursing staff in the Medicare-only facilities are not covered by Medicare, the Department estimates that the cost to the 20 impacted facilities will be \$183,450 annually. Of the three private pay facilities, two already exceed the proposed 4.1 ratio; one does not exceed the proposed ratio. The annual cost to the single private pay facility is estimated to be \$10,205. The Department believes that the increase in quality of life and safety for the approximately 67,500 residents in these long-term care nursing facilities outweighs any additional cost to the regulated community.

(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 20 county-owned long-term care nursing facilities which account for approximately 8 percent (8,706 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 Medicare or Medicaid, and thus, will not be impacted by the Department’s incorporation of all of the Federal requirements in section 201.2 (relating to requirements).

None of the county-owned long-term care nursing facilities meet or exceed the proposed increase in direct care nursing hours. All sixteen counties will likely see a cost impact to meet the staffing requirements. The Department does not have the necessary data to calculate what the exact cost to these

counties will be. However, based on the analysis performed by DHS, some of this cost (\$30.0 million) will be covered by MA.

(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. Rather, the proposed amendments, in particular the adoption of the Federal requirements without exceptions, 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.

The Department is also the State agency charged with administering and overseeing the Nurse Aide Registry for the Commonwealth. Pursuant to Federal law, any individual who works in a long-term care nursing facility as a nurse aide must meet the statutory requirements to be included on the State's Nurse Aide Registry. 42 U.S.C. § 1396r(b)(5)(c). The Department is required to handle the administrative hearings related to the annotation process for nurse aides accused of abuse. There is currently a total of 335,792 nurse aides on the registry. The Department is not able to quantify the impact that the proposed regulations will have on its management of the Nurse Aide Registry. The Department's proposal to increase the number of direct care hours will most likely result in the hiring of additional nurse aids, which may increase the number of nurse aide annotations. However, it is the Department's position that an increase in the number of nurse aides hired at a long-term care nursing facility would actually increase the level of care provided to residents and thus should decrease the number of abuse allegations.

*DHS*

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that the increase in quality of life and safety for the approximately 67,500 residents in the impacted long-term care nursing facilities outweighs any additional costs to either the Medical Assistance program in DHS or the regulated community.

*DMVA*

DMVA operates six veterans' homes across the state with more than 1,300 residents and employs more than 2,000 clinical and professional staff. An increase in direct care nursing hours to 4.1 requires the Bureau of Veterans Homes to add staff to the direct care complement resulting in an additional 235 employees. The average cost to DMVA for one direct care provider is \$105,207.42. This cost includes salary and benefits. The total overall estimated cost to DMVA for the increase will be \$24,723,743.70. This will also be a cost-to-carry for subsequent fiscal years. The Federal MA Program rate will apply to these direct care workers. This increase in staff (\$12.9 million) could be implemented over a 3-year period, and with an estimated Federal MA Program rate of 52%, would be an increase of approximately \$4.3M in state funding per year.

*Department of State (DOS)*

DOS has jurisdiction to investigate complaints related to health care practitioners. The proposed amendments will not have any identifiable fiscal impact on DOS. Requiring all long-term care nursing facilities to comply with the Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) will provide consistency and will assist DOS' investigators and prosecutors in enforcing standards for nursing home administrators. Additionally, because the increase in direct care nursing hours is expected to improve the quality of life and care of residents in long-term care nursing facilities, DOS may see a decrease in the number of complaints.

(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 Department does not expect there to be any additional legal, accounting or consulting related costs or any additional reporting, recordkeeping or other paperwork associated with this rulemaking.

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

There are no forms required for implementation of this proposed 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	FY +1	FY +2	FY +3	FY +4	FY +5
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	Year	Year	Year	Year	Year	Year
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
<b>COSTS:</b>						
Regulated Community <sup>2</sup>	0	193,655	193,655	193,655	193,655	193,655
Local Government	0	0	0	0	0	0
State Government <sup>3</sup>	0	195,400,000	195,400,000	195,400,000	195,400,000	195,400,000
Total Costs	0	195,593,655	195,593,655	195,593,655	195,593,655	195,593,655
<b>REVENUE LOSSES:</b>						
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 2017-2018	FY -2 2018-2019	FY -1 2019-2020	Current FY 2020-2021
DOH Quality Assurance	22,440,000	23,009,000	22,513,000	23,093,000
MA – Long-Term Care	4,282,127,000	2,795,990,000	2,093,439,000	409,041,000
MA – Community Health Choices	0	3,253,837,000	7,910,041,000	10,214,150,000
DMVA (Includes actual expenditures.	80,724,546.52	82,862,758.74	80,914,282.95	83,125,710.43

<sup>2</sup> See the Department's answer to Question 19.

<sup>3</sup> See the Department's answer to Question 21.

Does not include Federal MA Program funding)				

(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.

*See answers to Questions 15, 16 and 17. The Department is unable to identify which long-term care nursing facilities may be small businesses. The proposed regulations will apply to all long-term care nursing facilities irrespective of whether they are considered a small business. The Department's responsibility to the health and welfare of all residents in long-term care nursing facilities is not altered by the fact that a long-term care nursing facility may be a small business.*

- (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 Department does not expect there to be any additional reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation.

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

*See answers to Questions 15, 16 and 17. The Department is unable to identify which long-term care nursing facilities may be small businesses. The proposed regulations will apply to all long-term care nursing facilities irrespective of whether they are considered a small business. The Department's responsibility to the health and welfare of all residents in long-term care nursing facilities is not altered by the fact that a long-term care nursing facility may be a small business.*

- (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.*

(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 to meet the particular needs of any groups or persons. The

proposed regulations will apply to all long-term care nursing facilities in the Commonwealth.

(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.

No alternatives were considered for the amendments to § 201.1 (relating to applicability), § 201.2 (relating to requirements) and § 201.3 (relating to definitions).

With respect to § 211.12(i), the Department considered other increases in the number of direct care resident hours, but ultimately decided that the increase to 4.1 hours represents the least burdensome acceptable alternative when weighed against the health and safety of residents in long-term care nursing facilities.

(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) Less stringent compliance or reporting requirements were not considered.
- b) Less stringent schedules or deadlines for compliance or reporting were not considered.
- c) Consolidation or simplification of compliance or reporting requirements were not considered.
- d) The establishment of performance standards for small businesses were not considered.
- e) The exemption of small business from all or any part of the proposed regulations were not considered.

The proposed regulations would apply to all long-term care nursing facilities regardless of whether those facilities are considered a small business. The Department's responsibility to the health and welfare of all long-term care nursing residents is not altered by the fact that a long-term care nursing facility may be a small business.

(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. *Population Characteristics and Change: 2010 to 2017 (Research Brief)*. <https://pasdc.hbg.psu.edu/data/research-briefs/pa-population-estimates> (last visited: November 25, 2020) (report compiled based on US census data).

*Medicare and Medicaid Programs; Reform of Requirements for Long-Term care Facilities*, 80 Fed. Reg. 42168, 42202 (July 16, 2015). <https://www.govinfo.gov/content/pkg/FR-2015-07-16/pdf/2015-17207.pdf#page=2> (last visited: November 25, 2020) (proposed rulemaking from CMS).

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Juh Hyun Shin, PhD, RN & Sung-Heui Bae, PhD, MPH, RN. *Nurse Staffing, Quality of Care, and Quality of Life in U.S. Nursing Homes, 1996-2011*, 38 *Journal of Gerontological Nursing* 46 (2012). (Attachment 1).

Fiscal impact information was obtained from DHS, DMVA and DOS to determine the impact to those agencies as discussed in Question 21.

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

A. The length of the public comment period:

30 days after 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. Notice of that meeting was published in the *Pennsylvania Bulletin* on December 21, 2019.

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

D. The expected effective date of the final-form regulation:

Upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*. The Department intends to set the same effective date for all five rulemaking packages.

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

Upon publication of the final rulemaking in the *Pennsylvania Bulletin*.

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. These proposed amendments would not alter that requirement and all statutory timeframes for licensure would 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.

# **ATTACHMENT "1"**

See discussions, stats, and author profiles for this publication at: <https://www.researchgate.net/publication/235393731>

# Nurse Staffing, Quality of Care, and Quality of Life in U. S. Nursing Homes, 1996–2011 An Integrative Review

Article in *Journal of Gerontological Nursing* · December 2012

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# Nurse Staffing, Quality of Care, and Quality of Life in U.S. Nursing Homes, 1996-2011

## An Integrative Review



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### ABSTRACT

The purpose of this study was to complete an integrated literature review of the relationship between staffing and quality outcomes in nursing homes. The majority of the reviewed studies showed better outcomes with higher nursing staff but depended heavily on cross-sectional observational studies and failed to differentiate RNs from other nursing staff. A total of 28 articles relating nurse staffing and quality outcomes were systematically reviewed and

synthesized. However, each study examined different aspects of staffing and different resident or organizational outcomes, making determination of appropriate staffing levels difficult. The reviewed studies have not clearly defined the relationship between differing levels of nurse-staffing skill mix and specific structure, process, outcome, and composite indicators of quality. The inconsistent findings suggest that further research is needed in this area.

Juh Hyun Shin, PhD, RN; and Sung-Heui Bae, PhD, MPH, RN

**N**ursing staff make up approximately 60% of total nursing home (NH) staff, making nursing staff the major human resource in NHs (Harrington, Carrillo, et al., 2000). As more people need to live in NHs, the number of qualified staff should also increase to elicit better resident outcomes of quality of care (QOC) and quality of life (QOL) (Geiger-Brown, Muntaner, Lipscomb, & Trinkoff, 2004). It is projected that the U.S. population 65 and older in 2030 will be 72 million, and those using long-term care services in 2050 is projected to be 27 million (American Health Care Association, 2010). However, quality of NHs has not reached acceptable levels since the Nursing Home Reform Act was passed in 1987 (Harrington, 2001). There continue to be concerns about the quality of NH care in public and private sectors, especially about the QOL of residents. The limited number of studies demonstrated that nurse staffing is a significant organizational variable related to resident outcomes, and appropriate staffing levels are an essential step in improving residents' QOC (Castle & Fogel, 1998; Harrington, Carrillo, et al., 2000; Harrington, Zimmerman, et al., 2000; Johnson-Pawilson & Infeld, 1996; Porell, Caro, Silva, & Monane, 1998; Unruh & Wan, 2004; Wunderlich, Sloan, & Davis, 1996). However, each study examined different aspects of staffing and different resident and organizational outcomes, making determination of appropriate staffing levels difficult (Maas & Specht, 1999). Therefore, it is important to review and articulate nurse staffing variables, as well as both QOC and QOL variables, to discern implications of nurse staffing to improve outcomes in NHs.

## PURPOSE

The purpose of this study was to review recent studies in which researchers systematically focused on nurse staffing and resident outcomes, including both QOC and QOL, in NHs in the United States from 1996 to 2011.

## METHOD

### Search Strategy

The search strategy for this review was guided by a preliminary literature review that identified relevant research terms, including *nurse/nursing staffing and long-term care (settings), nursing homes, quality of care, and quality of life*. An online search was conducted of the electronic bibliographic databases MEDLINE, CINAHL, OVID, and PubMed.

### Inclusion/Exclusion Criteria

Journal articles and theses published from 1996 to 2011 that met the following inclusion criteria were selected and reviewed: study population consisted of nurses working in long-term care settings, studies reported primary research, and studies examined the association between nurse staffing and resident outcomes including QOC or QOL. A total of 550 titles from the search of electronic bibliographic databases were retrieved and screened solely for the study on nurse staffing and its association with QOC and QOL in long-term care settings. After a review of abstracts and one of full texts, a total of 28 articles relating nurse staffing and QOC, including articles that investigated QOL, were systematically reviewed and synthesized.

## RESULTS

### Research Methods

Of the final 28 studies, more than half ( $n = 17$ ) used a cross-sectional or longitudinal design with observa-

tional study (Akinci & Krolkowski, 2005; Anderson, Hsieh, & Su, 1998; Bates-Jensen, Schnelle, Alessi, Al-Samarrai, & Levi-Storms, 2004; Berlowitz et al., 1999; Bostick, 2004; Bowers, Esmond, & Jacobson, 2000; Castle & Anderson, 2011; Castle & Myers, 2006; Christensen & Beaver, 1996; Crogan & Shultz, 2000; Harrington, Zimmerman, et al., 2000; Hickey et al., 2005; Horn, Buerhaus, Bergstrom, & Smout, 2005; Johnson-Pawilson & Infeld, 1996; Kang, 2008; Moseley & Jones, 2003; Weech-Maldonado, Meret-Hanke, Neff, & Mor, 2004). These observational studies used either resident interviews or a large database as a secondary analysis.

Only four studies used an experimental or quasi-experimental study design (Kayser-Jones, Schell, Porter, Barbaccia, & Shaw, 1999; Krichbaum, Pearson, Savik, & Mueller, 2005; Simmons, Osterweil, & Schnelle, 2001; Wan, 2003). The sample size varied by study, ranging from 4 residents to 15,970 NHs. The number of studies using primary data collection by interviewing residents was small, whereas the sample size of those studies using secondary data was larger, and these studies examined the causal relationship between nurse staffing and residents' outcomes using a longitudinal and quasi-experimental study design. Interestingly, Bates-Jensen et al. (2004), Crogan and Shultz (2000), Anderson et al. (1998), and Krichbaum et al. (2005) used a variety of tools to collect data directly from NH residents.

### Nurse-Staffing Variables

For nurse staffing, only 7 of 28 studies differentiated RNs from other nursing staff, such as licensed practical nurses (LPNs) and certified nursing assistants (CNAs) (Ak-

inci & Krolikowski, 2005; Castle & Anderson, 2011; Castle & Myers, 2006; Horn et al., 2005; Kayser-Jones & Schell, 1997; Schnelle, 2004; Wan, 2003). The remainder used nursing-care hours of either RNs only or LPNs only, and some studies used the total nursing staff or licensed nursing staff hours differentiated from unlicensed nursing-care hours without any distinction between RNs and other nursing staff.

To measure RN staffing specifically, researchers commonly used hours per resident day (HPRD) and staff skill mix. Interestingly, Castle and Engberg (2007) used a comprehensive measure of nurse staffing, including not only full-time equivalent (FTE) and staff skill mix, but also stability, agency staffing, and turnover. They specified the nursing staff composition by using staff stability, agency staff, turnover, and staff skill mix, in addition to staffing levels. Additionally, only one study examined nurse staffing at the advance practice level and the effect of organizational-level interventions by gerontological advanced practice nurses (GAPNs) on residents' health status (Krichbaum et al., 2005).

### Resident Outcome Variables

Both QOC (11 studies) and QOL (7 studies) outcome variables were found in our review. We excluded administrative deficiencies and regulatory violations because these outcomes are not directly related to resident outcomes. More detailed findings are presented below.

*Quality of Care.* Among a total of 11 categories of resident outcomes, the most studied outcomes were nutrition (10 studies) and infection (10 studies). Nutrition issues with weight loss are a major concern for NH residents because many studies and government reports have addressed undernutrition and weight loss as serious problems. Of greater interest in this review are concerns such as NH residents' nutrition. In

the infection category, pressure ulcers were examined in 9 of the 28 studies, and 3 studies focused on urinary tract infections.

In addition, Rantz et al. (2004), Weech-Maldonado et al. (2004), and Wan (2003) investigated medication overuse, use of psychoactive medications, and medication errors as outcome variables in relation to staffing. Contractures, bladder or bowel incontinence, and fecal impaction were examined in 5 studies. Rantz et al. (2004) and Wan (2003) included use of catheters as outcome variables. Anderson et al. (1998) and Rantz et al. (2004) examined falls and fractures. Regarding psychological status, Rantz et al. (2004), Weech-Maldonado, Neff, and Mor (2003), and Wan (2003) studied depression therapy, cognitive impairment, mood change, and retardation. Regarding behavior problems, verbal/physical aggression, behavior change, and restraint use were examined in 7 studies. Johnson-Pawlson and Infeld (1996) measured resident outcomes using deficiencies, including resident rights, behavior, resident assessment, and QOL. In addition, Akinci and Krolikowski (2005) studied deficiency rates and their relationship with total nursing staff hours.

*Quality of Life.* A total of 8 studies aimed to investigate the effect of staffing on QOL. The QOL studies included dignity, respect, rights, and general QOL. Harrington, Zimmerman, et al. (2000) used several aspects of deficiencies including QOC, QOL, and administrative deficiencies using a large body of data retrieved from the Online Survey, Certification and Reporting network. This investigation was different in that it broadened the scope of outcomes beyond previous research that focused only on QOC deficiencies. In addition, Wan's (2003) study is also significant because dignity and respect are considered to be outcomes, and these are important contributors to high QOL.

### Relationships Between Nurse Staffing and Resident Outcomes

Of the 28 studies, 18 studies showed that increased numbers of nursing staff and stable nurse staffing with less frequent turnover contributed positively to a variety of resident outcomes in NHs (Table A, available as supplemental material in the PDF version of this article). Increased nurse staffing included more RN HPRDs and RN staffing skill mix, LPN HPRDs, LPN/licensed vocational nurse (LVN) skill mix, CNA skill mix, and more licensed nursing hours. Resident outcomes positively related to nurse staffing were activity (bed rest, activities of daily living), exercise and repositioning, infection (pressure ulcers, urinary tract infection), medication errors, better eating patterns, pain, bladder/bowel incontinence, fractures, and psychotic status. Berlowitz et al. (1999) and Johnson-Pawlson and Infeld (1996) did not support the concept that an increased number of RNs positively affects resident outcomes. Bostick's (2004) findings did not support the hypothesis that an increased number of LPNs positively affect resident outcomes. Rantz et al. (2004) and Wan (2003) reported that, overall, nursing staff was significantly related to positive resident outcomes. Although the majority of studies supported the contribution of nursing staff, some (4 of 28; Berlowitz et al., 1999; Bostick, 2004; Johnson-Pawlson & Infeld, 1996; Wan, 2003) did not. More detailed relationships between each type of nursing staff and outcomes are presented below.

*RN.* The majority ( $n = 13$ ) of studies examined the contribution of nursing care provided by RNs to resident outcomes. Overall, increased RN staffing hours were found to be positively related to resident outcomes (Table A). RN levels (FTE, number, or hour) usually were used to measure RN staffing, and some studies examined RN HPRD specifically. Excluding stud-

ies by Berlowitz et al. (1999) and Johnson-Pawlson and Infeld (1996), RNs' contribution was supported in aggression, use of restraints, infection, pressure ulcers, weight loss and eating pattern, catheter use, exercise, mental health, pain management, and general QOL/QOL measures.

**LPN.** Eight studies found positive contributions of LPNs to resident outcomes. Consistent with the impact of RNs on outcomes, elevated LPN levels (FTE, number, or hour) were reported to have better resident outcomes in QOC, such as pressure ulcers, activity, feeding assistance, incontinence, eating patterns, exercise, pain management, and restraint use.

**CNA.** In the same vein as RN and LPN levels, all studies except Wan's (2003) found positive relationships between CNA staffing and resident outcomes, including exercise, out-of-bed engagement, incontinence, feeding assistance, eating patterns, pressure ulcers, physical restraints, pain management, and general QOC and QOL (8 studies).

**Skill Mix and Total Nursing Staff.** Six studies examined the relationship between nursing skill mix and resident outcomes. As shown in Table A, overall, more licensed nursing staff and increased total nursing staff levels (FTE, number, or hours) were positively related to resident outcomes. Additionally, GAPNs using organizational-level interventions were effective in decreasing depression and improving morale for residents (Krichbaum et al., 2005).

Only four studies used total nursing staff in relation to resident outcomes. In Rantz et al.'s (2004) study, there were no differences in staffing or staff mix in NHs with good, average, and poor resident outcomes, based on the 23 quality indicators of the Minimum Data Set. Although staffing hours were not significantly different among the three groups, there were basic care differences among the three

groups (Rantz et al., 2004). The ratio of RNs to residents did not have a statistically significant influence on the total Centers for Medicare & Medicaid Service (CMS) deficiency index, whereas total nursing staff had a significant inverse effect on the overall CMS deficiency index (Johnson-Pawlson & Infeld, 1996). The relationship between total nursing staff and total deficiencies was statistically significant: The more total nursing staff NHs had, the fewer deficiencies (Johnson-Pawlson & Infeld, 1996). That is, more nursing hours contribute to better outcomes. However, an increase of RNs did not contribute to better resident-rights outcomes (Johnson-Pawlson & Infeld, 1996). This study did not examine what RNs actually do, so the results could be different if RNs' actual processes were considered.

**Turnover.** Castle and Engberg (2007) and Castle and Anderson (2011) investigated the impact of RN, LPN, and CNA turnover on the quality indicators of Minimum Data Set 2.0. Interestingly, a higher turnover rate of RNs was related to better resident outcomes, whereas LPN and CNA turnover were not statistically significant (Castle & Engberg, 2007). The more recent study (Castle & Anderson, 2011) showed that increased turnover of RNs and CNAs would deteriorate some quality indicators but that of LPNs was not statistically significant. More research is urgently required to confirm the relationships.

**Stability.** Castle and Engberg (2007) examined a new concept of staffing—stability, which is differentiated from turnover. They defined staffing stability as long-tenured staff, not calculating only the turnover rate. They found that CNA stability was related to improved resident outcomes.

**Use of Agency Staff.** Studies about use of agency nursing staff on outcomes are mixed, and further research is required. Castle and Eng-

berg (2007) investigated use of agency nursing staff on outcomes; the use of agency RNs and CNAs did not contribute to improved outcomes; only the use of LPN agency staff was related to better outcomes. Also, Castle, Engberg, and Men (2008) reported that use of agency CNAs in NHs with more than 25 FTEs deteriorated resident outcomes. Castle and Anderson (2011) also supported that the use of agency RN and CNA staff was related to deteriorated quality, whereas the use of LPN agency staff was not significant.

### **Risk Adjustment/Control Measures Used**

To control for alternative explanations of resident outcomes, studies used several variables as covariates in the examination of the relationship between nurse staffing and resident outcomes. These adjustments included resident characteristics and facility/market characteristics. Depending on data analysis strategies, researchers used these covariates before they compared NH quality or actually included them in the multivariate analysis model as covariates. The ultimate purpose of including these variables was to reduce errors and find unbiased relationships between nurse staffing and resident outcomes. To control for residents' health status or acuity status, case-mixed residents' outcomes have often been used (Krichbaum et al., 2005; Rantz et al., 2004; Weech-Maldonado et al., 2004). Other measures that might affect nurse staffing and quality outcomes have also been used, including activities of daily living performance, mobility, diagnoses, age and sex, race/ethnicity, resident payment source, risk-adjusted outcomes, patient acuity, length of stay, body mass index, nutrition and medication, and total dependence at admission. Intuitively, NHs with a higher case mix or higher acuity require higher staff-

ing and have a greater chance to have lower NH quality. There are consistent results about the association between these resident characteristics and quality outcomes. For example, those residents who have multiple clinical diagnoses (Harrington, Carrillo, et al., 2000; Kang, 2008) and are older (Bates-Jensen et al., 2004) and male (Bliesmer, Smayling, Kane, & Shannon, 1998) reported lower quality.

Facility or market characteristics have been used in research about staffing and QOC. Facility size has been correlated with QOC and tended to be the popular covariate, followed by ownership, payer mix, location, cost, and certification status. County per capita income was used to control market characteristics (Weech-Maldonado et al., 2004). From our review, there are no consistent study findings regarding the relationship between facility characteristics and NH quality.

## LIMITATIONS

This review has several limitations. A variety of resident outcomes and the heterogeneity of staffing variables and samples limited the consolidation of findings. A comprehensive search strategy was used for this review. However, the search terms for nurse staffing, QOC, and QOL might not include all of the terms that will capture the studies in this area. Future studies need to use all possible terms to capture greater numbers of studies in this area.

This review has shown that each study examined different aspects of staffing and different resident or organizational outcomes. It is difficult to determine the appropriate staffing level to produce superior resident outcomes. The reviewed studies have not clearly defined the relationship between differing levels of nurse-staffing skill mix and specific structural, process, outcome, and composite indicators of quality. Therefore, the inconsistent findings suggest that more research is needed in this area.

## IMPLICATIONS FOR RESEARCH

In this review of current studies on nurse staffing and resident outcomes in NHs, we found that better outcomes were related to higher levels of nurse staffing, but most studies depended heavily on cross-sectional and observational study designs and failed to differentiate RNs from other nursing staff. Furthermore, each study examined different aspects of staffing and different resident or organizational outcomes, making determination of appropriate staffing levels difficult. This finding is consistent with results from a previous study (Maas & Specht, 1999). The research that examined the relationship between total nursing staff levels and process and outcome quality indicators did not clearly define the relationship between differing levels of nursing staff skill mix and specific structural, process, outcome, and composite indicators of quality (Dellefield, 2000). This inconsistency in findings suggests that further investigation is needed using a longitudinal design, including nursing staff skill mix as an independent variable, and QOL beyond QOC as a dependent variable.

Several recommendations were suggested from this review to advance knowledge in this area. In the design and analysis of studies, it is necessary to use a longitudinal study design to examine the impact of nurse staffing on resident outcomes because it provides data by sequence to identify the causal relationship of nurse staffing to outcomes. In measurements of nurse staffing, few studies differentiated RN staff from other nursing staff. Legal authority (Baldwin, Roberts, Fitzpatrick, While, & Cowan, 2003) and nursing staff's educational preparation (Bostick, 2002) to provide care are different from each other, which leads to a difference in process and outcome measures of residents (Harrington, O'Meara, Collier, & Schnelle, 2003). Also, nursing staff may have different areas of interest in the health care

of older adults. Researchers need to investigate this issue using different measures of nurse staffing.

In measures of resident outcomes, nutrition issues with weight loss are major concerns for NH residents because many studies and government reports have addressed undernutrition and weight loss as serious problems (Abbasi & Rudman, 1993; Blaum, Fries, & Fiatarone, 1995; Kayser-Jones & Schell, 1997; Kayser-Jones et al., 1999; Morley & Kraenzle, 1994; Rudman & Feller, 1989; Starkey & Ryan, 1996; Wang et al., 2004; White, Pieper, & Schmadder, 1998; Zahler, Holdt, Gates, & Keiser, 1993). The U.S. General Accounting Office and the Health Care Financing Administration (now CMS) identified these as serious problems for NH residents (Findorff, Wyman, Croghan, & Nyman, 2005). In 2005, 9% of NH residents experienced weight loss, according to the Nursing Home Compare website (Findorff et al., 2005) and 60% of residents experienced undernutrition (Clarke, Wahlqvist, & Strauss, 1998). Approximately 30% to 50% of residents have symptoms related to protein-calorie malnutrition (Abbasi & Rudman, 1993). In addition, weight loss is highly related to mortality (White et al., 1998). This review also found that nutrition was the most studied outcome, and studies continue to investigate the nutrition issue.

In the relationship between nurse staffing and resident outcomes, staffing has usually been considered a structural variable (Bowers et al., 2000). However, based on their study's results, Bowers et al. (2000) found that staffing can be a process variable. Relevant process variables may include (a) how nursing staff spend their time and what nursing staff actually do, and (b) how nursing staff interact with other staff, residents, and families. Future studies need to examine whether staffing is a process or a structural variable. Another consideration can be that

if staffing is a strong predictor variable for resident outcomes, studies should consider whether the impact of staffing is greater than the impact of other factors on resident outcomes. In this review, we found several covariates, including resident characteristics and facility/market characteristics, that control alternative explanations of outcomes. Other factors that could affect outcomes may include nurse work environment, such as supervisor support and communication with peers. These factors have not yet been examined by researchers and need to be investigated. Additional research should also focus on new ways to measure quality of staffing because it is questionable whether QOC or QOL are only influenced by the quantity of nursing staff; rather, they may develop from the effectiveness of the professional nursing staff (Bowers et al., 2000). The effectiveness of the professional nursing staff could be measured through an understanding of comprehensive nurse staffing characteristics. Increased levels of nursing staff should be ensured to sustain the well-being and health of NH residents.

### IMPLICATIONS FOR PRACTICE

From this review of studies, it is evident that more nursing staffing is required to provide optimum QOC and QOL for NH residents. In particular, RNs practice independently in the role of nurses with professional and advanced skills and knowledge of gerontology. RNs' contribution in NHs is explicit and paramount; they provide independent and leadership responsibilities, including providing assistance to residents; supervising staff; recognizing significant changes of residents; screening for disease; teaching staff and caregivers; and being involved in staffing, delegation, communication, quality assurance, and advocacy issues (Harrington et al., 2003; Heath & Masterson, 2001; Masterson, 2004). However, NHs employ less licensed nursing staff

(RNs/LPNs/LVNs) and more unlicensed nursing staff (CNAs) due to financial pressures (Harrington, 2005). Moreover, the Balanced Budget Act of 1997 initiated Medicare prospective payment systems, which was not required to reveal specific staff levels (Harrington, 2005). Thus, after the Balanced Budget Act of 1997 was set up, the RN level and overall HPRD were decreased, leading to worse resident outcomes (Harrington, 2005; Konetzka, Yi, Norton, & Kilpatrick, 2004).

The report to Congress by CMS (2001) also failed to identify RNs' diverse and specific roles in NHs (Mohler, 2001). Recently, Harrington (2005) reported that the number of RNs in long-term care facilities decreased by approximately 25% between 1999 and 2003, which means the HPRD decreased from 0.8 to 0.6. In the same study, Harrington (2005) also reported that the HPRD of LVNs/LPNs was consistent at 0.7, whereas HPRD of CNAs increased from 2.1 to 2.5. It is likely that the staff shortage problem will worsen with the aging population and nationwide nursing shortage problems (Evans, 2001). Thus, the reported residents' outcomes with more RN staffing from reviewed studies will contribute to legisla-

tion that NH residents will have more RNs to attain better QOC and QOL. Therefore, future studies should differentiate between RN nursing staff and other nursing staff.

To establish and improve the QOC in NHs by establishing legal minimum staffing ratios and minimum levels of total nursing care hours, it is important to explore and define RNs' contribution to the QOC in NHs. RNs' unique contribution to resident outcomes versus alternative nursing staffing requires further research to determine which staffing mix maximizes desirable outcomes for residents. Optimal levels of each nursing staff and staffing mix to provide health care to residents might also vary depending on residents' acuity levels. As the older adult population grows and future long-term care settings require more RNs, further studies are needed to examine these research questions. This will provide policy makers, clinicians, and managers with better knowledge of staffing strategies, including minimum staffing standards (at the state and federal levels) (Harrington, Swan, & Carrillo, 2007; Mueller et al., 2006).

Another issue is related to GAPNs. As the needs of NH residents become more diverse, the

### KEYPOINTS

Shin, J.H., & Bae, S.-H. (2012). Nurse Staffing, Quality of Care, and Quality of Life in U.S. Nursing Homes, 1996-2011: An Integrative Review. *Journal of Gerontological Nursing*, 38(12), 46-53.

- 1 This study reviewed recent studies that systematically focused on nurse staffing and resident outcomes, including both quality of care and quality of life in U.S. nursing homes from 1996 to 2011.
- 2 In this review, better resident outcomes were related to higher levels of nurse staffing, but most studies depended heavily on cross-sectional and observational study designs and failed to differentiate RNs from other nursing staff.
- 3 RNs' unique contribution to resident outcomes requires further research to determine which staffing mix maximizes desirable outcomes for residents. Optimal levels of nursing staff and staffing mix might also depend on residents' acuity levels.

competency of nurse staffing in NHs becomes more demanding (Castle & Engberg, 2008). Although many studies agreed on the contributions of GAPNs to cost effectiveness, decreased hospital length of stay, and decreased use of emergency departments, these studies were limited to anecdotal evidence. The concept of using nurse practitioners in NHs (e.g., Evercare) is highly recommended (Lawrence, 2009). GAPNs play diverse and important roles in NHs, which may be summarized as collaborators, clinicians, care managers, coordinators, coach/educators, counselors, and communicators (Abdallah, 2005). GAPNs in NHs were reported to have more advanced knowledge and skills than RNs: They can observe residents closely and regularly and can take action in the residents' physical or psychological situation in an appropriate time period. Because physicians seldom visit NHs, NH residents have not been treated quickly, and meeting time with physicians has been very limited (Abdallah, 2005). Nurses should be encouraged to develop their career, role, and activities with the educational opportunities offered to nurse practitioners. More qualified nursing staff is required to meet complex and urgent needs of quality.

## CONCLUSION

Nurse staffing is a key factor to improve QOC and QOL for NH residents. Original studies of 28 articles during the past 10 years were reviewed. The findings reported inconsistent findings of the relationship between nurse staffing and resident outcomes. Further research is needed, including investigating the relationship between nurse staffing and QOC or QOL and developing integrative review papers to have a higher level of evidence that can be used for determining optimized nurse staffing levels.

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Table A

*Summary of Relationship between Nursing Staffing and Resident Outcomes*

Nursing categories	Nurse staffing variables	Resident outcomes	Study design	Source
Registered Nurse	RN HPRD	Verbal aggression Physical aggression Disruptive behavior Restraints Decubitus Contractures Dehydration Urinary tract infection Fracture	Cross-sectional, observational	Anderson et al., 1998
	RN HPRD	QOL deficiencies	Cross-sectional, observational	Akinci & Krolikowski, 2005
	RN HPRD	Pressure ulcers	Cross-sectional, descriptive	Bostick, 2004
	RN hours	QOC deficiencies QOL deficiencies Administrative deficiencies	Cross-sectional, observational	Harrington, Zimmerman et al., 2000
	RN HPRD	Pressure ulcers Hospitalization Urinary tract infections Weight loss Catheterization ADLs	Cross-sectional, observational	Horn et al., 2005
	RNs/100 beds	Dignity and respect NG tubes Accommodation of individual needs and preferences ADL Pressure sores Urinary catheters Bladder incontinence Nutrition Hydration Drugs Medication errors	Longitudinal, quasiexperimental	Wan, 2003
	RN number	Better eating pattern	Anthropological	Kayser-Jones & Schell, 1997
	RN FTE	HCFA deficiencies index	Cross-sectional, observational	Johnson-Pawlson & Infeld, 1996
	RN number/resident	Exercise and repositioning	Descriptive comparative	Schnelle, 2004
	RN number/resident	Incontinence care	Descriptive comparative	Schnelle, 2004
	RN number/resident	Feeding assistance	Descriptive comparative	Schnelle, 2004
	RN FTE/100 beds RN FTE/100bed	Pressure Ulcer Quality Indicators in MDS 2.0	Descriptive Exploratory factor analysis	Berlowitz et al., 1999 Castle & Engberg, 2007

Nursing categories	Nurse staffing variables	Resident outcomes	Study design	Source
	RN FTE	Physical restraint use Catheter use Pain management Pressure sores	Cross-sectional observational	Castle & Anderson, 2011
	RN FTE/100 bed	Mental health deficiencies	Longitudinal observational	Castle & Myers, 2006
Licensed Practical Nurse	LPN HPRD	QOC deficiencies Other deficiencies	Cross-sectional, observational	Akinci & Krolikowski, 2005
	LPN HPRD	ADL loss Pressure ulcers	Cross-sectional, descriptive	Bostick, 2004
	LPN level	Pressure ulcers	Cross-sectional, descriptive	Horn et al., 2005
	LVN number/resident	Out-of-bed engagement	Descriptive comparative	Schnelle, 2004
	LVN number/resident	Feeding assistance	Descriptive comparative	Schnelle, 2004
	LVN number/resident	Incontinence care	Descriptive comparative	Schnelle, 2004
	LPN/100 beds	Retardations Dignity and respect NG tubes Accommodation of individual needs and preferences ADL Pressure sores Urinary catheters Bladder incontinence Nutrition Hydration Drugs Medication errors	Longitudinal, quasiexperimental	Wan, 2003
	LVN number	Better eating pattern	Anthropological	Kayser-Jones & Schell, 1997
	LVN number/resident	Exercise and repositioning	Descriptive comparative	Schnelle, 2004
	LPN FTE/100bed	Quality indicators in MDS 2.0	Exploratory factor analysis	Castle & Engberg, 2007
	LPN FTE	Physical restraint use Catheter use Pain management Pressure sores	Cross-sectional observational	Castle & Anderson, 2011
	LPN FTE/100 bed level	Mental health deficiencies	Longitudinal observational	Castle & Myers, 2006
Certified Nursing Assistant	CNA number/resident	Exercise and repositioning	Descriptive comparative	Schnelle, 2004
	CNA number/resident	Out of bed engagement	Descriptive comparative	Schnelle, 2004
	CNA number/resident	Incontinence care	Descriptive comparative	Schnelle, 2004
	CNA number/resident	Feeding assistance	Descriptive comparative	Schnelle, 2004
	CNA HPRD	QOC deficiencies Other deficiencies	Cross-sectional, observational	Akinci & Krolikowski, 2005

Nursing categories	Nurse staffing variables	Resident outcomes	Study design	Source
	CNA/100 beds	Retardations Dignity and respect NG tubes Accommodation of individual needs and preferences ADL Pressure sores Urinary catheters Bladder incontinence Nutrition Hydration Drugs Medication errors	Longitudinal, quasiexperimental	Wan, 2003
	CNA number	Better eating pattern	Anthropological	Kayser-Jones & Schell, 1997
	CNA level	Pressure ulcers	Cross-sectional, observational	Horn et al., 2005
	CNA FTE	Physical restraint use Catheter use Pain management Pressure sores	Cross-sectional observational	Castle & Anderson, 2011
	CNA FTE/100bed	Mental health deficiencies	Longitudinal observational	Castle & Myers, 2006
	CNA hours	QOC deficiencies QOL deficiencies Administrative Deficiencies	Cross-sectional, observational	Harrington, Zimmerman et al., 2000
	CNA, other care staff	QOL deficiencies	Cross-sectional, observational	Harrington, Zimmerman et al., 2000
	CNA, research staff feeding assistance	Food/fluid intake	Experimental	Simmons et al., 2001
	Workload Supervision constraints Poor relationship between nurses and CNAs Needs of food intake	Food intake	Cross-sectional, observational	Crogan & Shultz, 2000
	Better relationship between CNAs and residents	Better resident outcomes	Cross-sectional, observational	Bowers et al., 2000
Skill Mix	Licensed hours $\geq$ unlicensed hours	Discharge to home Death Functional ability (total dependence score) Resident assessment deficiencies Physical restraints Antipsychotic drugs Pressure ulcers Mood decline Cognitive decline	Historical cohort design Historical cohort design Historical cohort design Cross-sectional, observational Cross-sectional, observational	Bliesmer et al., 1998 Bliesmer et al., 1998 Bliesmer et al., 1998 Moseley & Jones, 2003 Weech-Maldonado et al., 2004

Nursing categories	Nurse staffing variables	Resident outcomes	Study design	Source
		Physical restraint use Pressure sore QOL deficiencies	Descriptive	Kang, 2008
		Pressure ulcers	Cross-sectional, observational	Hickey et al., 2005
		Physical restraint use Catheter use Pain management Pressure sores	Correlational	Castle & Anderson, 2011
Turnover	RN turnover	Quality Indicators in MDS 2.0	Exploratory factor analysis	Castle & Engberg, 2007
	RN turnover	Physical restraint use Catheter use Pain management Pressure sores	Correlational	Castle & Anderson, 2011
	LPN turnover	Quality Indicators in MDS 2.0	Exploratory factor analysis	Castle & Engberg, 2007
	LPN turnover	Physical restraint use Catheter use Pain management Pressure sores	Correlational	Castle & Anderson, 2011
	CNA turnover	Quality Indicators in MDS 2.0	Exploratory factor analysis	Castle & Engberg, 2007
	CNA turnover	Physical restraint use Catheter use Pain management Pressure sores	Correlational	Castle & Anderson, 2011
Stability	RN stability	Quality Indicators in MDS 2.0	Exploratory factor analysis	Castle & Engberg, 2007
	LPN stability	Quality Indicators in MDS 2.0	Exploratory factor analysis	Castle & Engberg, 2007
	CNA stability	Quality Indicators in MDS 2.0	Exploratory factor analysis	Castle & Engberg, 2007
Agency use	RN	Quality Indicators in MDS 2.0	Exploratory factor analysis	Castle & Engberg, 2007
	RN	Physical restraint use Catheter use Pain management Pressure sores	Correlational	Castle & Anderson, 2011
	RN	Quality Indicators in MDS 2.0 (NHs less than 14 FTES	Correlational	Castle et al., 2008
	RN	Quality Indicators in MDS 2.0		Castle et al., 2008
	CNA	Quality Indicators in MDS 2.0	Exploratory factor analysis	Castle & Engberg, 2007
	CNA	Physical restraint use Catheter use Pain management Pressure sores	Correlational	Castle & Anderson, 2011
	LPN	Quality Indicators in MDS 2.0	Exploratory factor analysis	Castle & Engberg, 2007
	LPN	Physical restraint use Catheter use Pain management Pressure sores	Correlational	Castle & Anderson, 2011

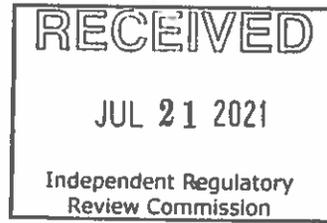
Nursing categories	Nurse staffing variables	Resident outcomes	Study design	Source
Total nursing staff	Total nursing staff	HCFA deficiencies index	Cross-sectional, observational	Johnson-Pawlson & Infeld, 1996
	Total nursing staff	Out of Bed	Cross-sectional, observational	Bates-Jensen et al., 2004
	Total nursing staff	Pressure ulcers	Cross-sectional, observational	Hickey et al., 2005
	Nursing HPRD	QOC deficiencies	Cross-sectional, observational	Akinci & Krolikowski, 2005
		Other deficiencies		
Etc.	More qualified staff	Fluid intake	Quasiexperimental, perspective	Kayser-Jones et al., 1999
	Differences of NHs in staffing, skill mix among good, average, and poor resident outcomes	21 MDS QIs	Cross-sectional, exploratory	Rantz et al., 2004
	Organization level interventions by Gerontological Advanced Practice Nurses	Health function	Quasiexperimental, repeated measures	Krichbaum et al., 2005
	Administrator turnover	Health and safety deficiencies	Descriptive	Christensen & Beaver, 1996
	Administrative staff hours	Administrative deficiencies	Cross-sectional, observational	Harrington, Zimmerman et al., 2000
	Use of contract nursing staff	Physical restraint use Pressure sore QOL deficiencies	Descriptive	Kang, 2008
	Changes in staffing patterns	Pressure ulcers	Cross-sectional, observational	Hickey et al., 2005

*Note.* + Staffing variables contribute to residents' outcomes; - Staffing variables did not contribute to residents' outcomes. ADL = activities of daily living; CNA = certified nursing assistant; FTE = full-time equivalent; HCFA = Health Care Financing Administration; HPRD = hours per resident day; LPN = licensed practical nurse; LVN = licensed vocational nurse; MDS = minimum data set; NG = nasogastric; NS = not significant; QOC = quality of care; QOL = quality of life; RN = registered nurse.

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NOTICE OF PROPOSED 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; 211.12(i)

LONG-TERM CARE NURSING FACILITIES

The Department of Health (Department), after consultation with the Health Policy Board, proposes to amend 28 Pa. Code §§ 201.1 (relating to applicability), 201.2 (relating to requirements), 201.3 (relating to definitions) and 211.12(i) (relating to nursing services), to read as set forth in Annex A.

Due to the projected length of the complete revisions to the Department's regulations and given that few if any changes have been made to the existing regulations over the last 24 years, the Department tentatively intends to promulgate proposed amendments to Title 28, Part IV (relating to health facilities), Subpart C (relating to long-term care facilities) in five separate parts. The Department believes that promulgating the changes in this way will allow the public a greater opportunity to thoroughly examine the proposed amendments and provide detailed comments to the proposed changes. It will also allow the Department to focus more closely on those comments and provide a more considered and cogent response to questions and comments. This proposed rulemaking is the first set of amendments to be proposed.

The Department tentatively proposes to promulgate the amendments to Subpart C in the following sequence. The actual contents of each proposed rulemaking packet are subject to change as the Department develops each packet.

*Proposed Rulemaking 1*

Section 201.1. Applicability.

Section 201.2. Requirements.

Section 201.3. Definitions.

Section 211.12(i). Nursing Services.

*Proposed Rulemaking 2*

Section 201.23. Closure of facility.

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

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

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

Section 207.4. Ice containers and storage.

*Proposed Rulemaking 3*

Section 201.11. Types of ownership.

Section 201.12. Application for license.

Section 201.13. Issuance of license.

Section 201.15. Restrictions on license.

Section 201.17. Location.

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

Section 209.1. Fire department service.

Section 209.7. Disaster preparedness.

Section 209.8. Fire drills.

Section 211.1. Reportable diseases.

*Proposed Rulemaking 4*

Section 201.14. Responsibility of licensee.

Section 201.18. Management.

Section 201.19. Personnel policies and procedures.

Section 201.20. Staff development.

Section 201.27. Advertisement of special services.

Section 201.30. Access requirements.

Section 201.31. Transfer agreement.

Section 207.2. Administrator's responsibility.

Section 211.2. Physician services.

Section 211.4. Procedure in event of death.

Section 211.5. Clinical records.

Section 211.6. Dietary services.

Section 211.7. Physician assistants and certified registered nurse practitioners.

Section 211.9. Pharmacy services.

Section 211.12. Nursing services.

Section 211.15. Dental services.

Section 211.16. Social services.

*Proposed Rulemaking 5*

Section 201.21. Use of outside resources.

Section 201.24. Admission policy.

Section 201.25. Discharge policy.

Section 201.26. Power of attorney.

Section 201.29. Resident's rights.

Section 209.3. Smoking.

Section 211.3. Oral and telephone orders.

Section 211.8. Use of restraints.

Section 211.10. Resident care policies.

Section 211.11. Resident care plan.

Section 211.17. Pet therapy.

**I. Background and Need for Amendments**

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%. Pennsylvania also has a higher percentage of older adults when compared to other states. In 2017, Pennsylvania 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 (aged 65 or older) for every 100-working age Pennsylvanians (15 to 64 years of age). Penn State Harrisburg, Pennsylvania State Data Center. *Population Characteristics and Change: 2010 to 2017 (Research Brief)*. <https://pasdc.hbg.psu.edu/data/research-briefs/pa-population-estimates> (last visited: November 25, 2020). 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 today has an almost 70% chance of needing some type of long-term nursing care during the remainder of their lifetime. U.S. Department of Health and Human Services. *How Much Care Will You Need?* <https://longtermcare.acl.gov/the-basics/how-much-care-will-you-need.html> (last visited: December 4, 2020). Currently, there are more than 72,000 Pennsylvanians residing in 689 long-term care nursing facilities licensed by the Department.

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

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

The Department began the process of updating the current long-term care regulations in late 2017. The Department sought review, assistance and advice from members of a long-term care work group (LTC Work Group) consisting of relevant stakeholders. The members of the LTC Work Group were drawn from a diverse background and included representatives from urban and rural long-term care facilities and various stakeholder organizations and consumer groups that work in the area of resident care and delivery of services. The LTC Work Group members consisted of representatives from the following organizations: American Institute of Financial Gerontology; Baker Tilly Virchow Krause, LLP; Berks Heim and Rehabilitation; Fulton County Medical Center; Garden Spot Community; HCR ManorCare; Inglis House; Landis Communities; Leading Age; Legg Consulting Services; LIFE Pittsburgh; Luzerne County Community College; The Meadows at Blue Ridge; Mennonite Home, Lutheran Senior Life Passavant Community; PA Coalition of Affiliated Healthcare and Living Communities; Pennsylvania Home Care Association; University of Pittsburgh; and Valley View Nursing Home. The following State agencies participated: Department of Aging; the Department of Human Services (DHS); and the Department of Military and Veteran's Affairs (DMVA).

The members of the LTC Work Group met regularly during 2018 with the LTC Work Group's primary focus being the simplification and modernization of the existing long-term care regulations. Upon completion of the LTC Work Group's discussions, the Department conducted an internal review of the recommended changes. While the Department accepted most of the language and substantive changes proposed by the LTC Work Group and attempted to

incorporate them in this proposed rulemaking, the Department is proposing additional changes to language and additional substantive changes, as well.

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

This is the first rulemaking packet developed as a result of the above discussions. The purpose of this 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 all the requirements set forth at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). This proposed rulemaking also updates existing definitions applicable to long-term care nursing facilities by adding, updating and deleting definitions as fully explained below. Finally, this proposed rulemaking increases the number of direct care hours that long-term care nursing facilities are required to provide to residents, per shift, while also clarifying that nursing staff providing such care must possess the appropriate competencies and skills necessary to do so.

## **II. Description of Proposed Amendments**

### *Section 201.1. Applicability.*

The Department proposes to delete the phrases “profit and nonprofit” and “which provide either skilled nursing care or intermediate nursing care, or both, within the facilities under the act.” These phrases are presently used in this section to describe the types of long-term care

nursing facilities to which Title 28, Part IV (relating to health facilities), Subpart C (relating to long-term care facilities) applies. The Department proposes, with the above deletions, to add the phrase “as defined in section 802.1 of the act (35 P.S. § 448.802a)” 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 proposed changes to directly reference the definition of “long-term care nursing facility” add clarity and promote consistency in the application of the act and in the application and scope of this subpart to long-term care nursing facilities.

*Section 201.2. Requirements.*

The Department proposes to break section 201.2 (relating to requirements) into four subsections. The existing language will move into subsection (a), with some changes. Specifically, the Department proposes to update the citation to the Federal requirements and delete the exceptions to the Federal requirements that are currently listed in this section. The effect of this change will be to adopt the Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) in their entirety. In subsection (b), the Department proposes to incorporate by reference *Chapter 7* and *Appendix PP – Guidance to Surveyors for Long-Term Care Facilities* from the Centers of Medicare & Medicaid Services (CMS) *State Operations Manual*. Chapter 7 and Appendix PP are the parts of the State Operations Manual that are applicable to the implementation of 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). The Department proposes to add language in subsection (c) to clarify that a long-term care nursing facility may still apply for an

exception under sections 51.31 through 51.34 (relating to exceptions). The Department proposes to add language in subsection (d) to clarify that a violation of the Federal requirements will be considered a violation at the State level as well, unless an exception has been granted under sections 51.31 through 51.34.

The Department's surveyors survey long-term care nursing facilities for compliance with both the State and Federal regulations for long-term care nursing facilities. With respect to the Federal regulations, the Department is designated as the State Survey Agency for CMS. As such, the Department is responsible for conducting surveys of facilities, including long-term care nursing facilities, for compliance with the participation requirements for Medicare and Medicaid<sup>1</sup>. The Federal participation requirements for long-term care nursing facilities are located at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). Presently, only three long-term care nursing facilities licensed by the Department do not participate in either Medicare or Medicaid. The remaining facilities participate in either Medicare or Medicaid, and as such, are already required, at the Federal level, to comply with all of the Federal requirements. *See* 42 CFR § 483.1 (relating to basis and scope). Requiring all long-term care nursing facilities to comply with all of the Federal requirements across the board at the State level, without exceptions, will make the survey process more efficient and will create consistency and eliminate confusion in the application of standards for all long-term care nursing facilities that are licensed in the Commonwealth. In addition, all long-term care nursing facilities licensed by the Department were and are already required to comply with some of the Federal requirements based on the existing language in this section. Thus, any negative impact in

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<sup>1</sup> In Pennsylvania, Medicaid is referred to or known as Medical Assistance (MA).

applying all of the Federal requirements to the three facilities that do not participate in Medicare or Medicaid will be minimum and is vastly outweighed by the need for consistency in the application of standards in long-term care nursing facilities statewide.

*Section 201.3. Definitions.*

The Department proposes to divide section 201.3 (relating to definitions) into two subsections. In subsection (a), the Department proposes to incorporate all terms that are defined in 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) to be consistent with the adoption of the Federal requirements in section 201.2. The incorporation of terms in subsection (a) includes all terms specifically defined in 42 CFR § 483.5 (relating to definitions), as well as all other terms that are defined throughout Subpart B. The Department also proposes to incorporate all terms that are defined in the *State Operations Manual, Chapter 7* and *Appendix PP – Guidance to Surveyors for Long-Term Care Facilities*, issued by CMS. The Department proposes to delete existing terms that are incorporated in subsection (a). The Department also proposes to delete definitions that are outdated or for which ordinary dictionary definitions apply. In subsection (b), the Department proposes to retain, update or add certain definitions that are not defined in either the Federal requirements or the *State Operations Manual*. The changes are as follows:

1. *As explained in more detail below, the following definitions will be deleted because they are now incorporated by reference from either the Federal regulations or the State Operations Manual, or both:* abuse (including verbal abuse; sexual abuse; physical abuse; mental abuse; involuntary seclusion; and neglect); administrator; charge nurse; clinical laboratory; dietician; director of nursing services; elopement; exit or exitway; full-time;

interdisciplinary team; nurse aide, restraint (including physical restraint and chemical restraint); and social worker.

Abuse is defined in 42 CFR § 483.5 (relating to definitions) and in multiple sections of *Appendix PP* of the *State Operations Manual*. Abuse includes verbal abuse, sexual abuse, physical abuse and mental abuse. Verbal abuse is further defined in *Appendix PP* of the *State Operations Manual* in section F600. Sexual abuse is defined separately in 42 CFR § 483.5 (relating to definitions) and further defined in section F600 of *Appendix PP* of the *State Operations Manual*. Physical abuse is defined in section F600 of *Appendix PP* of the *State Operations Manual*. Mental abuse is defined in section F600 of *Appendix PP* of the *State Operations Manual*. Involuntary seclusion, which is included in the existing regulations, is defined in section F603 of *Appendix PP* of the *State Operations Manual*. Neglect is defined separately in 42 CFR § 483.5 (relating to definitions) and in section F609 of *Appendix PP* of the *State Operations Manual*.

Administrator is defined at 42 CFR § 483.70(d)(2). Charge nurse is a licensed nurse designated by a long-term care nursing facility to serve in this capacity under 42 CFR § 483.35(a)(2). Laboratory services are covered under 42 CFR § 483.50(a). A facility that provides its own laboratory services or performs any laboratory tests directly must have a certificate pursuant to the Clinical Laboratory Improvement Amendments (CLIA) (42 U.S.C. § 263a). The term “clinical laboratory” is defined in CLIA.

A dietician is referred to as a qualified dietician under the Federal requirements and is defined at 42 CFR § 483.60 (relating to food and nutrition services). A director of nursing services is a registered nurse designated by a long-term care nursing facility to serve in this capacity under 42 CFR § 483.35(b)(2). Elopement, which refers to a resident leaving the

premises or a safe area without authorization, is defined in section F689 of *Appendix PP* of the *State Operations Manual*.

Exit is defined in section F906 in *Appendix PP* of the *State Operations Manual*. Full-time is defined in *Appendix PP* of the *State Operations Manual*, sections F727 and F801, as working more than 35 or more hours a week. Interdisciplinary team is defined at 42 CFR § 483.21(b)(2)(ii). Nurse aide is defined at 42 CFR 483.5. Restraint refers to both physical and chemical restraints, 42 CFR § 483.12 (relating to freedom from abuse, neglect and exploitation). Physical restraints and chemical restraints are defined in *Appendix PP* of the *State Operations Manual* in sections F604 and F605, respectively. Social worker is defined at 42 CFR § 483.70(p).

2. *The Department proposes to delete the following definitions because they are outdated and will no longer be used in this subpart:* existing facility; locked restraints; medical record practitioner; resident activities coordinator; residential unit; responsible person; and skilled or intermediate nursing care.

3. *The Department proposes to delete the following definitions because they are not used in this subpart, and therefore, a definition is not necessary:* audiologist; dietetic service supervisor; occupational therapist; occupational therapy assistant; physical therapist; physical therapy assistant; practice of pharmacy; and speech/language pathologist.

4. *The Department proposes to delete the following definitions because the ordinary dictionary definition applies:* ambulatory resident and nonambulatory resident. The terms “ambulatory” and “nonambulatory” are understood to have their ordinary dictionary definitions when applied to describe a resident who is able to walk or not able to walk in a long-term care

nursing facility. Separate definitions for “ambulatory resident” and “nonambulatory resident” are not necessary and could result in conflict and confusion if they remained in this subpart.

*5. The Department proposes to delete the following definitions, and replace them with new terms and definitions in subsection (b):*

The definition of “proprietary drug” will be deleted and 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 will also be changed to reflect common usage of this term to refer to an over-the-counter medication that is purchased without a prescription.

The definition of “nonproprietary drug” will be deleted. The use of the word “prescription” more accurately reflects the current terminology that is used. The existing definition of the word “prescription” will be updated to: (1) replace the word “drugs” with the word “medications” to reflect current terminology; (2) replace the words “licensed medical” with “health care” before the word “practitioner” for consistency with the use and meaning of the term “health care practitioner” in this subpart; and (3) delete the word “his” to make this definition gender neutral.

*6. The Department proposes to update the following definitions, and include them in subsection (b):*

The citation to HCFA in the definition of “act” will be updated to reflect the proper citation that encompasses all provisions of the act.

The definition of “licensed practical nurse” will be updated to add the acronym “LPN” and to include a citation to the regulations of the State Board of Nursing to more accurately describe an individual licensed in this capacity under the Practical Nurse Law.

The terms “drug” and “drugs” will be replaced with “medication” and “medications” in the definitions for “administration of drugs,” “drug administration” and “drug dispensing” to reflect current terminology used to describe the process of administering medications to residents in long-term care nursing facilities. The Department is not proposing any substantive changes to these three definitions. However, as a result of these changes, the definitions for “medication administration” and “medication dispensing” will be moved so that they appear in alphabetical order in section 201.3(b).

The definition of “registered nurse” will be updated with minor changes to the phrasing of the definition for clarity. This includes the addition of the acronym “RN” and a citation to the regulations of the State Board of Nursing to more accurately describe an individual licensed in this capacity under the Professional Nursing Law.

7. *The following definitions will be retained and included in subsection (b) with no changes:* alteration; authorized person to administer drugs and medications; basement; CRNP – certified registered nurse practitioner; clinical records; controlled substance; corridor; department; drug or medication; facility; licensee; NFPA; nurse aide; nursing care; nursing service personnel; pharmacist; pharmacy; physician assistant; and resident.

8. *The Department proposes to add the following definition to subsection (b):*

The Department proposes to add the definition of “health care practitioner” from the act for consistency in the application of the term to long-term care nursing facilities and to recognize the range of health care professionals that provide care to residents in long-term care nursing facilities. The term “practitioner” when used as a standalone term in this subpart is considered to be synonymous with those individuals defined as a “health care practitioner” under the act.

*Section 211.12. Nursing services.*

The Department proposes to amend subsection (i) to add the phrase “for each shift” to ensure that there are proper nursing staff to provide direct care<sup>2</sup> for residents throughout the 24-hour period. The Department is concerned that without this clarification, a facility might attempt to meet the requirement for the minimum number of direct care hours by frontloading the required hours during one part of the day, leaving residents without adequate care for the remainder of the 24-hour period. This addition also aligns with the Federal requirements that long-term care nursing facilities post on a daily basis the number of nursing staff directly responsible for resident care on a “per shift” basis. *See* 42 CFR § 483.35(g)(1)(iii).

The Department also proposes to increase the minimum number of direct resident care hours from 2.7 to 4.1. Numerous studies, including a study by CMS in 2001, have found a direct correlation between the quality of resident care, quality of resident life, and the number of direct care hours that the resident receives. Benefits of higher staffing ratios include improved activity levels, lower mortality rates, fewer infections, less antibiotic use, fewer pressure ulcers and fewer catheterized residents, improved eating patterns and pain levels, and improved mental health. Juh Hyun Shin, PhD, RN & Sung-Heui Bae, PhD, MPH, RN. *Nurse Staffing, Quality of Care, and Quality of Life in U.S. Nursing Homes, 1996-2011*, 38 *Journal of Gerontological Nursing* 46 (2012). In its 2001 study, CMS suggested that a minimum of 4.1 hours of direct care per resident day would improve the quality of care provided to a resident, and that anything below that amount could “result in harm and jeopardy to residents.” *Medicare and Medicaid*

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<sup>2</sup> Pursuant to the Federal requirements, which are adopted by the Department in section 201.2 (relating to requirements), direct care refers to assisting a resident, through interpersonal contact, with care and services that allow the resident to attain or maintain the highest practicable physical, mental and psychosocial well-being. 42 CFR § 483.70(q)(1).

*Programs; Reform of Requirements for Long-Term care Facilities*, 80 Fed. Reg. 42168, 42202 (July 16, 2015).

Despite this finding, CMS declined to include a minimum number of direct care hours when it proposed to update the Federal requirements in 2015. CMS agreed that the existing staffing requirements needed to be clarified but believed that it did not have sufficient information at that time to require a specific number of staffing hours. *Id.* at 42201. CMS was also concerned that requiring specific numbers would conflict with requirements already established by states and “would limit flexibility and innovation in designing new models of person-centered care delivery to residents.” *Id.* at 42175.

Instead, CMS proposed language that would require nursing staff to possess the appropriate competencies and skills to provide health care and services to residents in long-term care facilities. CMS also proposed that long-term care facilities use a facility assessment to determine direct care staff needs. *Id.* at 42171. In the final rulemaking, CMS responded to concerns about its failure to implement required minimum staffing hours, by reiterating that it was concerned that a mandated ratio could have unintended consequences such as staffing to a minimum, input substitution (hiring for one position by eliminating another), task diversion (assigning non-standard tasks to a position) and the stifling of innovation. *Medicare and Medicaid Programs; Reform of Requirements for Long-Term care Facilities*, 81 Fed. Reg. 68688, 68753-68759 (October 4, 2016). The lack of a Federal requirement has left it up to states to determine and set a required minimum number of direct care hours.

Nationally, in 2016, the number of reported actual total direct care nursing hours (including RNs, LPN/LVNs and NAs) was, on average, on par with the recommended 4.1 hours per resident day. However, there was wide variation among states with some states such as

Florida, Alaska, Idaho, Oregon and Utah exceeding 4.5 hours per resident day. Kaiser Family Foundation. *Nursing Facilities, Staffing, Residents and Facility Deficiencies: 2009 through 2016*. (2018). <https://www.kff.org/report-section/nursing-facilities-staffing-residents-and-facility-deficiencies-2009-through-2016-staffing-levels/> (last visited: March 19, 2021).

However, minimum requirements set by states continued to be lower than the recommended 4.1 hours of direct care per resident day. *Id.*

The Department reviewed the regulations of the surrounding states of New York, New Jersey, Maryland, Delaware, Ohio and West Virginia to determine if those states have set a minimum requirement for direct care nursing hours. A review of New Jersey, Maryland, Delaware, Ohio and West Virginia regulations reflects minimum requirements from 2.25 hours to 3.67 hours. New York does not have a minimum level, but instead merely provides that sufficient staffing is required. N.Y. Comp. Codes R. & Regs. tit. 10 § 415.13(a). West Virginia has the lowest minimum requirement of direct care resident hours with a required minimum of 2.25 hours. W. Va. Code. R. § 64-13-8. Ohio and New Jersey require a minimum of 2.5 hours, Maryland requires a minimum of 3.0 hours, and Delaware has the highest requirement at 3.67 hours of care. Ohio Admin. Code 3701-17-08; N.J. Admin. Code § 8:85-2.2; Md. Code Regs. 10.07.02.19; 16 Del. Admin. Code § 3201-5.0.<sup>3</sup>

Momentum is gaining, however, for states to act regarding nursing staff ratios in long-term care nursing facilities as the COVID-19 pandemic has heightened awareness of this issue. Legislation was recently introduced in New York that, if passed and enacted, will establish a

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<sup>3</sup> See also, Harrington, Charlene, Ph.D. *Nursing Home Staffing Standards in State Statutes and Regulations*. (2010). <https://theconsumervoicework.org/uploads/files/issues/Harrington-state-staffing-table-2010.pdf> (last visited: March 19, 2021) (state-by-state summary of statutes and regulations pertaining to nursing home staffing requirements).

minimum requirement of 4.85 direct care nursing hours. Safe Staffing for Quality Care Act, Assembly Bill 108, 244<sup>th</sup> State Assembly Reg. Sess. (N.Y. 2021). Legislation has also been introduced in Connecticut that, if passed and enacted, will establish a minimum requirement of 4.1 direct care nursing hours. Raised S.B. 1030, General Assembly Reg. Session (Conn. 2021). The Rhode Island Senate also recently passed a bill, which, if enacted, will require all nursing facilities to provide a minimum daily average of 4.1 hours of direct nursing care per resident, per day. Nursing Home Staffing and Quality Care Act, S.B. 0002, General Assembly Reg. Session (R.I. 2021).

The Department has a duty to protect the health of all Pennsylvanians, including those who are 65 and older. Given that a significant number of the population in Pennsylvania consists of individuals aged 65 and older, with an expected increase in that population in the next several years, it is even more important that the Department act to ensure the health and safety of this vulnerable population. The Department has carefully considered the impact that requiring an increase in direct care staffing hours will have on long-term care nursing facilities. The Department strongly believes that increasing the number of direct care staffing hours from 2.7 to 4.1 will have a positive impact on the quality of life and quality of care for every resident in a long-term care nursing facility, as proven by the many studies on this issue. While there will be an impact on long-term care nursing facilities as a result of this increase, the Department feels strongly that the benefits to older Pennsylvanians now and in the future outweighs those costs.

Finally, the Department proposes to add language to section 211.12(i), from the Federal requirements at 42 CFR § 483.35 (relating to nursing services), to indicate that a facility shall have a sufficient number of 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. The addition of this language addresses CMS's concerns that a mandated ratio could result in unintended consequences by clarifying that the increase to 4.1 direct resident care hours per shift will be a minimum requirement and will not excuse a long-term care nursing facility from CMS's requirement that the facility have adequate staff with the appropriate competencies and skill sets to care for residents.

### **III. Fiscal Impact and Paperwork Requirements**

#### ***Fiscal Impact***

##### ***A. Commonwealth***

###### ***1. 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. Rather, the proposed amendments, in particular the adoption of the Federal requirements without exceptions, 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.

The Department is also the State agency charged with administering and overseeing the Nurse Aid Registry for the Commonwealth. Pursuant to Federal law, any individual who works in a long-term care nursing facility as a nurse aide must meet the statutory requirements to be

included on the State's Nurse Aide Registry. 42 U.S.C. § 1396r(b)(5)(c). The Department is required to handle the administrative hearings related to the annotation process for nurse aides accused of abuse. There is currently a total of 335,792 nurse aides on the registry. The Department is not able to quantify the impact that the proposed regulations will have on its management of the Nurse Aide registry. The Department's proposal to increase the number of direct care hours will most likely result in the hiring of additional nurse aides, which may increase the number of nurse aide annotations. However, it is the Department's position that an increase in the number of nurse aides hired at a long-term care nursing facility would increase the level of care provided to residents and thus should decrease the number of abuse allegations.

## 2. *DHS*

The proposed amendment to the number of direct care hours will increase costs to the Medical Assistance, or Medicaid, program (MA) in DHS. DHS determined the cost impact of the Department's proposed increase in direct care hours. Although the Department currently licenses a total of 689 long-term care nursing facilities, for its analysis, DHS excluded the six long-term care nursing facilities that are operated by DMVA. Of the 683 remaining long-term care nursing facilities that are operated by DMVA. Of the 683 remaining long-term care nursing facilities, a total of 615 receive MA payments. Of these 615 long-term care nursing facilities, 595 are private facilities and 20 are county facilities. The median hourly rate for a nursing staff assistant was determined to be \$22.91. The total additional nursing assistant staff hours needed to bring each MA facility up from 2.7 to 4.1 direct care hours is 15,986,835. To provide the most accurate estimate, DHS considered actual nursing staff assistant costs for each MA facility, rather than the median hourly rate. The additional nursing assistant staff hours needed for each MA long-term care nursing facility multiplied by the facility-specific hourly rate results in \$385.7 million in additional costs across all MA long-term care nursing facilities

(\$355.7 million for the 595 private facilities and \$30.0 million for county facilities). The Federal MA Program match in Federal fiscal year 2022 is 52.68% of this \$385.7 million, or \$203.2 million, which results in a net cost to DHS of approximately \$182.5 million. DHS does not have sufficient data to determine who will bear the burden of the remaining costs not covered by MA, for the MA facilities, but believes that at least some of this amount will have to be borne by the regulated community. Nonetheless, the Department feels strongly that the increase in quality of life and safety for the approximately 67,500 residents in the impacted long-term care nursing facilities outweighs any additional costs to either the MA program in DHS or the regulated community.

### 3. *DMVA*

DMVA operates six veterans' homes across the state with more than 1,300 residents and employs more than 2,000 clinical and professional staff. An increase in direct care nursing hours to 4.1 requires the Bureau of Veterans Homes to add staff to the direct care complement resulting in an additional 235 employees. The average cost to DMVA for one direct care provider is \$105,207.42. This cost includes salary and benefits. The total overall estimated cost to DMVA for the increase will be \$24,723,743.70. This will also be a cost-to-carry for subsequent fiscal years. The Federal MA Program rate will apply to these direct care workers. This increase in staff (\$12.9 million) could be implemented over a 3-year period, and with an estimated Federal MA Program rate of 52%, would be an increase of approximately \$4.3M in state funding per year.

### 4. *Department of State (DOS)*

DOS has jurisdiction to investigate complaints related to health care practitioners. The proposed amendments will not have any identifiable fiscal impact on DOS. Requiring all long-

term care nursing facilities to comply with the Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) will provide consistency and will assist DOS' investigators and prosecutors in enforcing standards for nursing home administrators. Additionally, because the increase in direct care nursing hours is expected to improve the quality of life and care of residents in long-term care nursing facilities, DOS may see a decrease in the number of complaints.

*B. Local government*

There are currently 20 county-owned long-term care nursing facilities which account for approximately 8 percent (8,706 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 Medicare or Medicaid, and thus, will not be impacted by the Department's incorporation of all of the Federal requirements in section 201.2 (relating to requirements).

None of the 20 county-owned long-term care nursing facilities meet or exceed the proposed increase in direct care nursing hours. This will impact the 16 counties which own nursing homes. The Department does not have the necessary data to calculate what the exact cost to these counties will be. However, based on the analysis performed by DHS, some of this cost (\$30.0 million) will be covered by MA.

*C. Regulated community*

The proposed amendments to the regulations will apply to all 689 licensed long-term care nursing facilities in the Commonwealth. These facilities provide health services to more than

72,000 residents. The existing regulations of the Department already incorporate many of the Federal requirements and any burden by the expansion, in section 201.2 (relating to requirements), to incorporate the remaining Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) will only impact those long-term care nursing facilities that do not participate in Medicare or Medicaid. There are currently only three long-term care nursing facilities that do not participate in either Medicare or Medicaid.

Requiring all long-term care nursing facilities to comply with all of the Federal requirements across the board, without exceptions, will make the survey process more efficient and will create consistency and eliminate confusion in the application of standards to long-term care nursing facilities, which will benefit all long-term care nursing facilities. Any negative impact on the three facilities that do not participate in Medicare or Medicaid will be minimum as they are already required by existing section 201.2 to comply with the majority of the requirements in 42 CFR Part 483, Subpart B. Any negative impact is also vastly outweighed by the need for consistency and efficiency in the application of standards for all long-term care nursing facilities in the Commonwealth.

The increase in direct nursing care hours from 2.7 to 4.1 will directly impact 603 of the total 689 licensed long-term care nursing facilities licensed by the Department. The 603 impacted facilities provide care to approximately 67,500 residents. To determine this number, the Department utilized data extracted in January 2020. It was determined by the Department that this data would be more accurate than data from 2020 as there was concern that 2020 data may be skewed because of the COVID-19 pandemic and its impact on long-term care nursing facility staffing. DHS determined the cost impact on facilities that participate in MA. The median hourly rate for a nursing staff assistant was determined to be \$22.19. The total additional

nursing assistant staff hours needed to bring each MA facility up from 2.7 to 4.1 direct care hours is 15,986,835. To provide the most accurate estimate of the cost impact on MA facilities, DHS considered actual nursing staff assistant costs for each facility, rather than the median hourly rate. The additional nursing staff hours needed for each MA nursing facility multiplied by the facility-specific hourly rate results in \$385.7 million in additional costs across all MA long-term care nursing facilities (\$355.7 million for the 595 private facilities and \$30.0 million for county facilities). The Federal MA match in Federal fiscal year 2022 is 52.68% of this \$385.7 million, or \$203.2 million, which results in a net cost to DHS of approximately \$182.5 million. DHS does not have sufficient data to determine who will bear the burden of the remaining costs not covered by MA but believes that at least some of this amount will have to be borne by the regulated community.

Of the long-term care nursing facilities that do not participate in MA, the Department identified 65 long-term care nursing facilities that accept only Medicare as payment and three facilities that are “private pay only.” Medicare is an insurance program managed by the Federal government. According to Medicare.gov, direct care services, *i.e.*, assistance with activities of daily living in long-term care nursing facilities, are generally not covered. Medicare Part A may cover care in a certified skilled nursing facility if it is deemed medically necessary. The Department does not have sufficient data to determine whether any of the direct care services being provided to long-term care nursing residents is medically necessary, and thus, covered under Medicare. Of the 65 Medicare-only facilities, in January 2020, 40 were above the proposed staffing ratio of 4.1, five did not have any residents, and 20 were operating below the proposed 4.1 staffing ratio. In an attempt to determine the most accurate estimate, the Department excluded the five facilities that did not have residents in January 2020 and estimated

costs based on the 20 facilities that were operating below the proposed 4.1 ratio. Assuming that the direct care services provided by nursing staff in the Medicare-only facilities are not covered by Medicare, the Department estimates that the cost to the 20 impacted facilities will be \$183,450 annually. Of the three private pay facilities, two already exceed the proposed 4.1 ratio; one does not exceed the proposed ratio. The annual cost to the single private pay facility is estimated to be \$10,205. The Department believes that the increase in quality of life and safety for the approximately 67,500 residents in the impacted long-term care nursing facilities outweighs any additional cost to the regulated community.

*D. General public*

There are expected to be no additional costs to the general public. The more than 72,000 residents in the 689 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 Medicare or Medicaid. It is expected that the proposed increase in direct care hours provided to residents will improve the quality of life and care of approximately 67,500 Pennsylvanians who reside in the 603 long-term care nursing facilities mentioned above, as will all older Pennsylvanians who may need long-term care nursing in the future.

*Paperwork Requirements*

The proposed amendments do not impose any additional paperwork requirements on any of the above entities.

**IV. 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, 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)).

#### **V. Effectiveness/Sunset Date**

The regulations will become effective upon their publication in the *Pennsylvania Bulletin* as final regulations. A sunset date will not be imposed. The Department will monitor the regulations and update them as necessary.

#### **VI. Regulatory Review**

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on July 21, 2021, the Department submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Health and Human Services Committee and the House Health Committee. A copy of this material is available to the public upon request.

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

#### **VII. Contact Person**

Interested persons are invited to submit comments, suggestions or objections to the proposed regulations within 30 days after publication of this notice in the *Pennsylvania Bulletin*. The Department prefers that comments, suggestions or objections be submitted via email to [RA-DHLCReqs@pa.gov](mailto:RA-DHLCReqs@pa.gov). Persons without access to email may submit comments, suggestions or objections to Lori Gutierrez, Deputy Director, Office of Policy, (717) 317-5426, at the following address: 625 Forster Street, Rm. 814, 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 ATT&T Relay Service at (800) 654-5984[TT]. Persons who require an alternative format of this document may contact Lori Gutierrez at the above address or telephone number so that necessary arrangements can be made. Comments should be identified as pertaining to rulemaking 10-221 (Long-Term Care Facilities, Proposed Rulemaking 1).

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] 42 CFR §§ 483.1 – 483.95 (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)].

(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.]

*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 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. 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).]

\* \* \* \* \*

*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).]

\* \* \* \* \*

*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.

(ii) A registered nurse licensed by another state as a registered nurse 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.]

*[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.]

\* \* \* \* \*

*[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.]*

[*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.]

\* \* \* \* \*

[*Elopement*—When a resident leaves the facility without the facility staff being aware that the resident has done so.]

[*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.]

\* \* \* \* \*

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

*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.

*[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.]*

*Licensed practical nurse or LPN—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).*

\* \* \* \* \*

*[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 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.

\* \* \* \* \*

[*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 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.]

\* \* \* \* \*

[*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.]

\* \* \* \* \*

[*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.]

\* \* \* \* \*

[*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).]

*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.]

*Registered nurse or RN*—[A nurse] An individual licensed to practice professional nursing [in this Commonwealth] 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 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.]

[*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.

(ii) A chemical restraint includes psychopharmacologic drugs that are used for discipline or convenience and not required to treat medical symptoms.]

*[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).]

\* \* \* \* \*

**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. 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. 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.

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

\* \* \* \* \*

(l) The Department may require an increase in the number of nursing personnel from the minimum requirements if specific situations in the facility—including, but not limited to, the physical or mental condition of residents, quality of nursing care administered, the location of residents, the location of the nursing station and location of the facility—indicate the departures as necessary for the welfare, health and safety of the residents.



COMMONWEALTH OF PENNSYLVANIA  
OFFICE OF THE SECRETARY OF HEALTH

July 21, 2021

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

Re: Department of Health – Proposed Regulation No. 10-221  
Long-Term Care Nursing Facility Regulations  
28 Pa. Code §§ 201.1—201.3; 211.12(i)

Dear Mr. Sumner:

Enclosed are proposed regulations for review by the Independent Regulatory Review Commission (Commission) in accordance with the Regulatory Review Act (71 P.S. §§ 745.1-745.15).

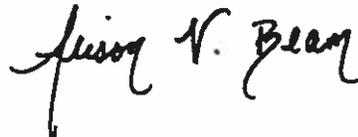
The purpose of this proposed rulemaking is to create consistency between Federal and State requirements for long-term care nursing facilities by expanding the adoption of the Federal requirements to include all the requirements set forth at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). This proposed rulemaking also updates existing definitions applicable to long-term care nursing facilities by adding, updating and deleting definitions. Finally, this proposed rulemaking increases the number of direct care hours that long-term care nursing facilities are required to provide to residents, while also clarifying that nursing staff providing such care must possess the appropriate competencies and skills necessary to do so.

Section 5(g) of the Regulatory Review Act, 71 P.S. § 745.5(g), provides that the Commission may, within 30 days after the close of the public comment period, convey to the proposing agency and the Standing Committees any comments, recommendations and objections to the proposed regulations. The Department expects the regulations to be published on July 31, 2021. A 30-day public comment period is provided.

As required by Section 5(c) of the Regulatory Review Act, 71 P.S. § 745.5(c), the Department will provide to the Commission a copy of any comment received pertaining to the proposed regulations, within 5 business days of receipt. The Department will also provide the Commission with any assistance it requires to facilitate a thorough review of the proposed regulations.

If you have any questions, please contact David Toth, Director of the Office of Legislative Affairs, at (717) 787-6436.

Sincerely,

A handwritten signature in black ink that reads "Alison V. Beam". The signature is written in a cursive style with a large, stylized initial 'A'.

Alison V. Beam, JD  
Acting Secretary of Health

Enclosures

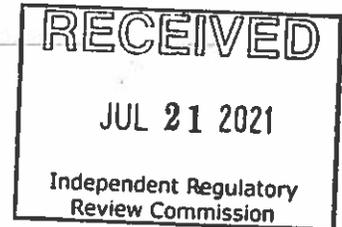
**From:** Bradbury, Joan  
**To:** Smith, Pamela (Health); Brooks, Senator Michele  
**Subject:** Re: Proposed Long-Term Care Nursing Facilities Regulations # 10-221  
**Date:** Wednesday, July 21, 2021 8:57:22 AM

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**From:** Smith, Pamela (Health) <pamesmith@pa.gov>  
**Sent:** Wednesday, July 21, 2021 8:14:20 AM  
**To:** Brooks, Senator Michele <mbrooks@pasen.gov>  
**Cc:** Bradbury, Joan <jbradbury@pasen.gov>  
**Subject:** Proposed Long-Term Care Nursing Facilities Regulations # 10-221



**CAUTION : External Email**

Good morning,

Attached is a proposed regulatory package from the Department of Health for long-term care nursing facilities.

The Regulatory Review Act requires delivery of the proposed regulatory package to the Standing Committees of the General Assembly, the Legislative Reference Bureau (LRB) and the Independent Regulatory Review Commission (IRRC) **on the same day**, with IRRC receiving the package last. Confirmation of receipt by the Standing Committees and LRB is required for delivery to IRRC.

Please respond as soon as possible to this email indicating that you have received the attached proposed regulatory package so that I can deliver the package to IRRC **today, July 21, 2021**.

Thanks,  
Pam

**Pamela G. Smith** | Assistant Counsel  
Pennsylvania Department of Health | Office of Legal Counsel  
625 Forster Street, Room 825 | Harrisburg, PA 17120  
Phone: 717.783.2500 | Fax: 717.705.6042  
[www.health.state.pa.us](http://www.health.state.pa.us)

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**From:** [Fricke, Erika L.](#)  
**To:** [Smith, Pamela \(Health\)](#); [Frankel, Dan](#)  
**Subject:** Re: Proposed Long-Term Care Nursing Facilities Regulations # 10-221  
**Date:** Wednesday, July 21, 2021 9:12:16 AM

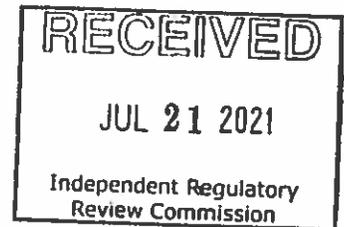
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**From:** Smith, Pamela (Health) <pamesmith@pa.gov>  
**Sent:** Wednesday, July 21, 2021 8:18:03 AM  
**To:** Frankel, Dan <DFrankel@pahouse.net>  
**Cc:** Fricke, Erika L. <EFricke@pahouse.net>  
**Subject:** Proposed Long-Term Care Nursing Facilities Regulations # 10-221



Good morning,

Attached is a proposed regulatory package from the Department of Health for long-term care nursing facilities.

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Thanks,  
Pam

**Pamela G. Smith** | Assistant Counsel  
Pennsylvania Department of Health | Office of Legal Counsel  
625 Forster Street, Room 825 | Harrisburg, PA 17120  
Phone: 717.783.2500 | Fax: 717.705.6042  
[www.health.state.pa.us](http://www.health.state.pa.us)

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**From:** [Whitney Metzler](#)  
**To:** [Smith, Pamela \(Health\)](#)  
**Subject:** Read: Proposed Long-Term Care Nursing Facilities Regulations # 10-221  
**Date:** Wednesday, July 21, 2021 10:44:04 AM  
**Importance:** High

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Your message

To:  
Subject: Proposed Long-Term Care Nursing Facilities Regulations # 10-221  
Sent: Wednesday, July 21, 2021 2:44:03 PM (UTC+00:00) Monrovia, Reykjavik  
was read on Wednesday, July 21, 2021 2:43:59 PM (UTC+00:00) Monrovia, Reykjavik.



**From:** Freeman, Clarissa  
**To:** Smith, Pamela (Health); Haywood, Senator Art  
**Subject:** Re: Proposed Long-Term Care Nursing Facilities Regulations # 10-221  
**Date:** Wednesday, July 21, 2021 8:28:10 AM

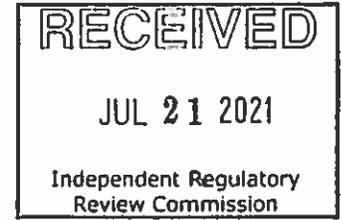
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Received.  
Thank you,  
Clarissa

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**From:** Smith, Pamela (Health) <pamesmith@pa.gov>  
**Sent:** Wednesday, July 21, 2021 8:16:09 AM  
**To:** Haywood, Senator Art <Art.Haywood@pasenate.com>  
**Cc:** Freeman, Clarissa <Clarissa.Freeman@pasenate.com>  
**Subject:** Proposed Long-Term Care Nursing Facilities Regulations # 10-221



■ EXTERNAL EMAIL ■

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Good morning,

Attached is a proposed regulatory package from the Department of Health for long-term care nursing facilities.

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Thanks,  
Pam

**Pamela G. Smith** | Assistant Counsel  
Pennsylvania Department of Health | Office of Legal Counsel  
625 Forster Street, Room 825 | Harrisburg, PA 17120  
Phone: 717.783.2500 | Fax: 717.705.6042  
[www.health.state.pa.us](http://www.health.state.pa.us)

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**From:** Bulletin  
**To:** Smith, Pamela (Health)  
**Subject:** [External] RE: Proposed Long-Term Care Nursing Facilities Regulations # 10-221  
**Date:** Wednesday, July 21, 2021 9:37:44 AM

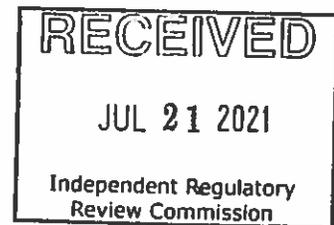
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Good Morning Pamela:

Thank you for sending PRM 10-221. Someone from our office will contact you regarding the publication date in the *Pennsylvania Bulletin*. Have a nice day.

Corinne Marut  
Editorial Assistant  
**Legislative Reference Bureau**  
*Pennsylvania Code & Bulletin Office*  
647 Main Capitol Building  
Harrisburg, PA 17120-0033  
717-783-1530  
[cmarut@palrb.us](mailto:cmarut@palrb.us)



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**From:** Smith, Pamela (Health) <pamesmith@pa.gov>  
**Sent:** Wednesday, July 21, 2021 9:24 AM  
**To:** Bulletin <bulletin@palrb.us>  
**Subject:** Proposed Long-Term Care Nursing Facilities Regulations # 10-221  
**Importance:** High

Good morning,

Attached is a proposed regulatory package from the Department of Health for long-term care nursing facilities. The entire package is attached as a .pdf with Word versions of the Annex and Preamble.

The Regulatory Review Act requires delivery of the proposed regulatory package to the Standing Committees of the General Assembly, the Legislative Reference Bureau (LRB) and the Independent Regulatory Review Commission (IRRC) **on the same day**, with IRRC receiving the package last. Confirmation of receipt by the Standing Committees and LRB is required for delivery to IRRC.

Please respond as soon as possible to this email indicating that you have received the attached proposed regulatory package so that I can deliver the package to IRRC **today, July 21, 2021**.

Thanks,  
Pam

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