

Comments of the Independent Regulatory Review Commission



Department of Health Regulation #10-221 (IRRC #3312)

Long-Term Care Nursing Facilities

September 29, 2021

We submit for your consideration the following comments on the proposed rulemaking published in the July 31, 2021 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (71 P.S. § 745.5a(a)) directs the Department of Health (Department) to respond to all comments received from us or any other source.

1. Determining whether the regulation is in the public interest; Economic or fiscal impacts; Clarity; Reasonableness; Compliance with the RRA.

Section 5.2 of the RRA (71 P.S. § 745.5b) directs the Independent Regulatory Review Commission (Commission) to determine whether a regulation is in the public interest. When making this determination, the Commission considers criteria such as economic or fiscal impacts and reasonableness. To make that determination, the Commission must analyze the text of the Preamble and proposed regulation and the reasons for the new or amended language. The Commission also considers the information a promulgating agency is required to provide under Section 745.5(a) in the Regulatory Analysis Form (RAF).

The explanation of the regulation in the Preamble and the information contained in the RAF are not sufficient to allow this Commission to determine if the regulation is in the public interest. In the Preamble and RAF submitted with the final-form rulemaking, the Department should provide more detailed and expanded information related to economic or fiscal impacts, impacts on small businesses, and alternative regulatory provisions as required under Section 745.5(a) of the RRA. For example:

- Commenters assert that the Department does not address adequately the fiscal impacts of the proposed regulation. For example, LeadingAge PA states, “The cost burden calculations on the commonwealth and nursing homes are elementary and incomplete. It underestimates and seemingly ignores the cost of staff benefits, the costs to hire and train staff, the cost increases to private pay residents who will more quickly spend down to Medical Assistance (and the consequent costs to the Medical Assistance Program), and makes no effort to calculate the costs to counties.” We address these issues in more detail in comment #4;

- In response to several questions in the RAF, the Department states that the proposed regulation will result in a net cost of approximately \$182.5 million to [the Department of Human Services (DHS)]. The Department states, “DHS does not have sufficient data to determine who will bear the burden of the remaining costs not covered by [Medical Assistance] but believes that at least some of this amount will have to be borne by the regulated community.” We ask the Department to work with DHS to provide additional information related to how the regulated community will be impacted by the \$182.5 million in additional costs, and to explain how this may impact residents in facilities that rely on Medical Assistance and residents in private-pay facilities;
- In addressing potential impacts on small businesses, the Department states that it is “unable to identify which long-term care nursing facilities may be small businesses,” and that “[t]he Department’s responsibility to the health and welfare of all residents in long-term care facilities is not altered by the fact that a long-term care nursing facility may be a small business.” An association states that many of its members are small businesses and asserts that the Department, in conjunction with other state agencies, has the ability and access to data to enable the Department to evaluate potential impacts on small businesses. We ask the Department to calculate and address the impact of the final-form regulation on small businesses as required under the RRA; and
- RAF Question #26 requires an agency to include “a description of any alternative regulatory provisions which have been considered and rejected.” The Department responded that it “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.” However, the Department provided no information on what other increases were considered, nor did the Department explain the factors considered in determining that 4.1 was the least burdensome acceptable alternative. If the Department retains an increase in direct care hours per resident in the final regulation, we ask that the Department amend its response to Question #26 and include a description of its reasoning regarding the other increases that were considered, as well as any subsequent alternative regulatory provisions contemplated in preparing the final-form regulation.

Five Regulatory Packages

The Preamble states that “the Department tentatively intends to promulgate proposed amendments to Part IV Subpart C (relating to long-term care facilities) in five separate parts.” This decision prompted comments of concern from many of those who support the proposed regulation and nearly all of those who oppose it. Several commenters urge the Department to withdraw the proposed regulation, and many commenters would prefer that the Department submit all of its proposed revisions to Part IV Subpart C as one comprehensive package. Commenters state that regulations governing the operation of nursing homes are complex and interrelated, and that the Department should be able to promulgate its revised licensure requirements in a comprehensive, unified, and transparent process. Others express the challenges they will face in trying to understand the full scope and impact of this first package when it is unknown how these changes will correlate with subsequent packages. For example, there is no way to fully evaluate the impact of proposed deletions of definitions without

reviewing the full regulatory package to consider how and whether those terms are used throughout.

Acknowledging the Department's authority to promulgate regulations as it deems appropriate, we ask the Department to consider the significant concerns of the regulated community, and the requests to withdraw this proposed regulation and move forward with one comprehensive regulation. If the Department proceeds with five regulatory packages, we ask the Department to explain why this approach is reasonable given the concerns expressed by the regulated community. We also ask the Department to ensure that the regulations and any amendments are consistent across the packages, and that the interrelation and any impacts between the packages are clearly presented for the regulated community.

2. Section 201.2. Requirements. – Statutory authority; Economic or fiscal impacts; Clarity and lack of ambiguity; Need; Reasonableness of requirements.

Subsection (a) currently states, “The Department incorporates by reference 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**, as licensing regulations for long-term care nursing facilities” [Emphasis added.] The Department proposes to amend Subsection (a) to incorporate by reference the **entirety** of 42 CFR Part 483, Subpart B of the Federal requirements for long-term care facilities.

The Preamble states, “. . . 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 applying the Federal requirements to the three facilities that do not participate in Medicare or Medicaid will be **minimum** [sic] and is vastly outweighed by the need for consistency in the application of standards in long-term care nursing facilities Statewide.” [Emphasis added.] Comments from these private-pay facilities state that they were not represented in the Long-Term Care Work Group, and that the Department neglected to provide an analysis of the impact of the Federal requirements on them. These commenters assert that they will need to hire additional positions, such as a grievance officer, and certify and submit data using software that they will need to purchase since they are not Medicaid/Medicare certified. We ask the Department to amend the final-form Preamble and RAF to provide an analysis of the impacts on private-pay facilities of these additional Federal requirements, including fiscal, reporting, recordkeeping, and other paperwork. We also ask the Department to explain the reasonableness of these requirements for private-pay facilities.

Subsection (b) states, “The Department incorporates by reference the Centers for Medicare & Medicaid State Operations Manual [(SOM)], Chapter 7 and Appendix PP—Guidance to Surveyors for Long-Term Care Facilities [(Appendix PP)].” The incorporation by reference of a Federal manual and guidance document are an improper delegation of the agency's statutory authority. Neither of these documents are subject to Federal regulatory review requirements, and incorporating them by reference removes them from state requirements provided in the Commonwealth Documents Law and the RRA. Changes can be made to these documents without the regulated community and other parties having the opportunity for public comment. We ask the Department to amend the final-form regulation, deleting this language and including

any mandatory provisions from the SOM and Appendix PP in order to establish clear and unambiguous standards that could be predicted by the regulated community. If the Department does not intend to enforce any of the referenced provisions, the Department should explain why it is appropriate to retain this language.

Subsection (d)

Proposed Subsection (d) states, “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.” What is the need for this provision since it is incorporated by reference? By virtue of the new language in Subsection (b), failure to comply with requirements in 42 CFR Part 483, Subpart B is a violation since regulations have the full force and effect of law. This Subsection should be deleted.

If the Department retains the language in Subsection (d) in the final-form regulation, commenters assert that this provision would apply both state and Federal violations resulting in possible double sanctions to the same incidence of noncompliance. LeadingAge PA states that this proposal “appears duplicative, unnecessary, and overly punitive.” We ask the Department to explain in the Preamble of the final-form regulation the need for and reasonableness of this provision.

3. Section 201.3. Definitions. – Protection of public health, safety, and welfare; Clarity.

In the Preamble, the Department states that it proposes to delete several definitions “because they are now incorporated by reference from **either** the Federal regulations **or** the [SOM], **or both** . . .” [Emphasis added.] This proposal from the Department to incorporate by reference definitions from one or more of three sources which will not be identified in the final-form regulation is likely to cause significant confusion for the regulated community and anyone who looks to the Department’s regulations for meanings of these terms. The Department’s explanation in the Preamble of where to find various definitions of the term “abuse” exemplifies the difficulty a person would face if the definition is entirely deleted:

Abuse is defined in 42 CFR 483.5 and in multiple sections of Appendix PP of the [SOM]. Abuse includes verbal abuse, sexual abuse, physical abuse and mental abuse. Verbal abuse is further defined in Appendix PP of the [SOM] in section F600. Sexual abuse is defined separately in 42 CFR 483.5 and further defined in section F600 of Appendix PP of the [SOM]. Physical abuse is defined in section F600 of Appendix PP of the [SOM]. Mental abuse is defined in section F600 of Appendix PP of the [SOM]. Involuntary seclusion, which is included in the existing regulations, is defined in section F603 of Appendix PP of the [SOM]. Neglect is defined separately in 42 CFR 483.5 and in section F609 of Appendix PP of the [SOM].

We recognize that members of the regulated community may be familiar with where to find a deleted definition in Federal regulations; however, these proposed regulations address the care of residents of long-term care nursing facilities and, as such, people who have a family member in a facility and are not familiar with these regulations should have readily available access to the definitions in order to read and understand them. Without this lengthy instructional paragraph,

how would a person know where to find these various definitions? Additionally, commenters express significant concerns because words that are defined in the SOM can be changed by the Centers of Medicare & Medicaid Services (CMS) without any notice or opportunity for comment.

Beyond the likely confusion exists a potential for harm. AARP PA states, “Pennsylvania’s Older Adults Protective Services Act is materially different from [F]ederal regulations. The Department’s adoption of the current [F]ederal regulations (Chapter 7 of the [SOM], and [Appendix PP]) will conflict with relevant state law definitions, will undoubtedly create confusion in the nursing home industry, and will certainly hinder the Pennsylvania Department of Aging’s ability to properly uphold the provisions of the Older Adults Protective Services Act, which is their responsibility.” A joint comment from the Center for Advocacy for the Rights and Interests of the Elderly (CARIE) and Community Legal Services (CLS) states, “[W]e have concerns about the impact on state enforcement of Protective Services and associated criminal laws that could result from eliminating state definitions in these regulations of abuse, neglect, exploitation, etc. Deleting terms wholesale instead of aligning them with both [F]ederal and state laws, we believe, would pose a new and unnecessary challenge for law enforcement and Protective Services programs.”

If the Department intends to rely on Federal regulations to define certain terms, we ask the Department to incorporate by reference those terms or promulgate the text of those terms in the final-form regulations. If the Department intends to rely on definitions found in Federal guidance, we ask the Department to promulgate the text of those definitions in the final-form regulations.

4. Section 211.12. Nursing services. – Economic or fiscal impacts; Protection of public health, safety, and welfare; Clarity; Reasonableness of requirements; Implementation procedures and timetables for compliance.

Subsection (a) states, “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.” The Department states in the Preamble that it proposes to amend Paragraph (i) to add the phrase “for each shift” to ensure that there are proper nursing staff to provide direct care for residents throughout the 24-hour period. The Department also proposes to increase from 2.7 to 4.1 the minimum number of hours of direct care. The proposed language states,

(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 4.1 hours of direct resident care for each resident.

Commenters both for and opposed to this increase question the addition of the language “during each shift.” The joint comment from CARIE and CLS in support of the increase describes this language as “an error,” stating, “We don’t believe the Department intended to require 12.3 hours per resident per day.” We ask the Department to clarify whether this increase is to be per shift or per day.

This proposed increase to 4.1 generated a significant volume of feedback from the regulated community. Comments in support state that this increase is long overdue and essential to ensure that all long-term care nursing facility residents receive quality care, while comments in opposition addressed a range of issues including:

Fiscal or economic impacts

- “[T]his proposal does not include funding for staffing increases beyond the [Medical Assistance] program, nor does it account for employer-paid benefits which could more than double the reported price-tag in the regulatory package.” (Southwestern PA Partnership for Aging (SWPPA))

Protection of public health, safety, and welfare

- “The proposed regulations . . . create the risk of adversely impacting our ability to serve those who most need our assistance by imposing staffing requirements which could drive operating costs to unsustainable levels in a time when there is an acute shortage of qualified staff across the entire facility.” (Delaware County Council)
- “Many nursing homes in the Commonwealth have closed beds because they cannot find enough staff. The Department has not addressed the impact its proposal will have on access to care.” (PELICAN)

Reasonableness of requirements

- “Providers of healthcare and nursing services are in constant and ever-more expensive competition for the same small cohort of eligible and interested workers.” (SWPPA)
- “[N]urses and nurse aides are not the only staff who provide direct care to nursing home residents. CMS recognizes therapists, life enrichment staff, and others who provide care and services that add to the overall wellbeing of residents and complement direct care staff.” (Phoebe Ministries)

Implementation procedures and timetables for compliance

- “If [the Department] disregards other comments relating to the impossible task of hiring direct care staff, [the Department] must offer a compliance period during which providers can work towards increased staffing levels before citations for non-compliance are able to be issued.” (SWPPA)
- “. . . Nursing Assistants are not available in the job market. (Training programs were closed during the pandemic, leading to a significant lack of available recruits.)” (Phoebe Ministries)

If positions remain unfilled when the regulation goes into effect, does the Department see any potential negative impact for residents? Would the public health, safety, and welfare be protected by expanding the definition of direct care staff to align with the Federal definition? Would the Department consider a delayed implementation timetable for compliance?

Ultimately, commenters who support and who oppose this change cite concern for residents’ care as the basis for their comments. Whether the Department retains or amends the minimum of 4.1

hours of direct care in the final-form regulation, we ask the Department to explain how the final-form regulation protects residents of long-term care nursing facilities, while also addressing the impact of the minimum number of direct care hours on facilities. Specifically, we ask the Department to address concerns raised by commenters, as noted above, related to economic or fiscal impacts; protection of public health, safety, and welfare; reasonableness of requirements; and timetable for implementation.

5. RAF. – Clarity.

We ask the Department to amend and clarify the final-form RAF to ensure that the responses are consistent and accurate. For example:

- In response to Question #15 under the heading “Long-Term Care Nursing Facilities,” the Department references 603 facilities that participate in Medical Assistance; however, under the heading “DHS,” 615 facilities are cited as receiving Medical Assistance payments; and
- In response to Question #20, the Department states that there are currently 20 county-owned long-term care nursing facilities. The Department explains further that Allegheny County owns four and then identifies the remaining 15, totaling 19.