Comments of the Independent Regulatory Review Commission

Department of Health Regulation #10-223 (IRRC #3335)

Long-Term Care Nursing Facilities

May 18, 2022

We submit for your consideration the following comments on the proposed rulemaking published in the March 19, 2022 *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; Protection of the public health, safety, and welfare; Reasonableness.**

The Department has submitted this proposed regulation as one of four rulemaking packages which promulgate comprehensive amendments to Subpart C (relating to long-term care facilities). Proposed Rulemaking Package #1 (regulation #10-221) was published in the *Pennsylvania Bulletin* on July 31, 2021, and this Commission issued comments on September 29, 2021. Proposed Rulemaking Package #2 (regulation #10-222) was published in the *Pennsylvania Bulletin* on October 9, 2021, and this Commission issued comments on December 8, 2021. This current proposed regulation is Rulemaking Package #3. As with the previous two rulemaking packages, the regulated community again states its opposition to the delivery of separate proposed regulations. We include a sampling of the statements made by the regulated community as taken from the submitted comments:

- "Without view of the comprehensive package, neither the regulated community nor the public can assess the full scope of changes that may be promulgated as final." [LeadingAge PA]
- "This fragmented process is and will continue to create confusion and undermine the public and regulated community as we seek to understand how each separate package fits together." [PA Health Care Association (PHCA)]
- "For example, in this proposed rulemaking, there are provisions regarding the conducting of a facility assessment. The facility assessment is designed as a tool to be used by facilities to determine the resources, staffing levels and staff competencies needed to properly care for the residents residing in their facility. This provision overlaps with the staffing hours proposed in rulemaking package 1, as well as the provisions that the Department intends to address in rulemaking package 4 (related to staffing ratios and staff development)." [PHCA]

- "We understand that the Department plan is to submit all four final-form regulatory packages . . . on the same day. Although this does provide the opportunity to review all four separate packages at the same time, at this point in the Regulatory Review Process, the only recourse is to offer written comments to [the Independent Regulatory Review Commission (Commission)] and/or offer comments during a public hearing. The comments offered are not required to be addressed by the Department in any meaningful way and will have no reflection in the final regulation unless [the Commission] disapproves the package(s)." [PHCA]
- ". . . we found it quite challenging and cumbersome to review and comment on three different regulatory packages in isolation. . . " [American Association of Retired Persons – PA Chapter];
- "Separate packages make it impossible for stakeholders and the general public to provide meaningful feedback, as no one can understand the full impact of each proposed rulemaking without seeing what is in the entire package. Individual subsections of regulations cannot be read in a vacuum; they must be read collectively." [Disability Rights PA]

We agree with the continuing concerns of the regulated community and question whether the presentation of this regulation as a separate regulation rather than as part of a comprehensive regulatory package is in the public interest, is reasonable, and protects the public health, safety, and welfare. We encourage the Department to reevaluate its approach to the promulgation of these rulemakings and consider submitting one comprehensive regulatory package regarding long-term care nursing facilities.

If the Department proceeds with separate regulatory packages, we recommend that the Department deliver each of the individual packages as final regulations on the same day, which would give the regulated community an opportunity to review the separate final regulations at the same time. We want to make clear that doing so is not the equivalent of withdrawing and submitting one comprehensive regulatory package, which would include a public comment period, providing both the regulated community and this Commission an opportunity to provide feedback on the entirety of the Department's proposed changes regarding long-term care nursing facilities.

Further, if the Department proceeds on this course, we suggest that the Department consider issuing an Advance Notice of Final Rulemaking (ANFR) to assist in reaching consensus. Section 2(a) of the RRA states, "To the greatest extent possible, this act is intended to encourage the resolution of objections to a regulation and the reaching of a consensus among the [C]ommission, the standing committees, interested parties and the agency." 71 P.S. § 745.2(a). An ANFR would provide the regulated community with an opportunity to offer input on the entirety of the four regulatory packages prior to the Department's delivery of the final-form versions of the regulations.

2. Compliance with the RRA – Determining whether the regulation is in the public interest; Economic and fiscal impacts; Reasonableness; Implementation.

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

The information contained in the Preamble and RAF is 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, we ask the Department to provide more detailed information required under Section 745.5(a) of the RRA, addressing the fiscal impacts of the regulation. Specifically, we ask the Department to provide additional information related to the following:

- Questions 15 and 17 require the Department to identify the types and number of small businesses which will be affected by the regulation, and the financial, economic, and social impact of the regulation on small businesses. The Department did not provide an estimate of the number of small businesses impacted by the proposed regulation, and further states that it "does not have sufficient data to estimate with any certainty the cost impact of requiring additional assessments." Does the Department, in conjunction with other state agencies, have the ability to access data to enable the Department to evaluate potential impacts on small businesses? For example, the Department of Labor may be able to provide information on the number of employees. Also, since Pennsylvania disburses Medicare and Medicaid reimbursement to these facilities, information is available to estimate facility revenue. Also, we ask the Department to work with the regulated community to calculate and address the economic impact of additional quarterly assessments on the long-term care nursing facilities, particularly those that are small businesses.
- Questions 19 and 23 require the Department to provide a specific estimate of the costs and/or savings to the regulated community and an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community. The Department responds to Question 19 that the proposal to require a facility to complete a facility assessment on at least a quarterly basis "may impose some financial burden on facilities" but then responds to Question 23 by stating a $0 cost for the current year and five subsequent years for the regulated community. We ask the Department to ensure that its responses to the RAF questions are consistent and to address the specific costs for implementation and compliance for the regulated community.
- Question 29 requires the expected effective date of the final-form regulation. The Department states that it intends to set the same effective date for all four rulemaking packages. A commenter states that implementation upon publication in the *Pennsylvania Bulletin* is not reasonable. The commenter explains that compliance with new regulations takes time to become aware of the required changes and requires planning to initiate the staffing and budget changes to achieve compliance. We ask the Department

to address these concerns regarding implementation and explain why the timeframe for implementation is reasonable.

We will review the Department's amended RAF to determine whether the final regulation is in the public interest.

3. **Section 201.12. Application for license of a new facility or change in ownership. – Protection of public health, safety, and welfare; Clarity; Reasonableness; Implementation.**

Commenters raise various questions related to aspects of application for license of a new facility or change in ownership that are not addressed in the proposed regulation including the following:

- Should the Department require notification of sale or change in ownership to be provided to residents, their families, employees, and the public, and, if so, when would notice be provided?
- What is the process for receiving public feedback and input on an application for license of a new facility or change in ownership?
- Will there be set timelines for document requests?
- What happens if an application for license of a new facility or a change in ownership is in process when the regulation is published in the *Pennsylvania Bulletin* and goes into effect?

We ask the Department to amend the final regulation and address these implementation questions in the Preamble to the final regulation.

Also related to implementation, we note that in response to RAF Question 12, the Department proposes to include a public notice and comment requirement. The Department states:

> Massachusetts is the most comprehensive of the states that the Department researched. In Massachusetts, prospective owners are subject to an evaluation process that considers factors such as financial stability and compliance history. . . . . in Massachusetts, prospective owners are also subject to a public notice requirement, a public comment period, and where requested, a hearing. 105 CMR 153.007 and 153.022.

The Department states that amendments, such as the public notice and comment requirement, "are necessary to ensure that prospective owners are properly vetted in order to safeguard the health and safety of residents in long-term care nursing facilities." Commenters note their support for such a requirement, but we do not see the language for this requirement in the proposed regulation. Is this provision intended to be a part of the regulation? If not, we ask the Department to explain how the public health, safety, and welfare will be protected without a requirement for a public notice and comment period. We ask the Department to explain the reasonableness of not soliciting feedback from persons who may have direct knowledge of a potential owner's history or administration of a long-term care nursing facility.

Subsection (b)

Subsection (b) requires a person seeking to operate or assume ownership of a facility to submit various information. Paragraph (b)(5) requires "[t]he names, addresses, e-mail addresses and phone numbers of any persons that have or will have a direct or indirect interest in the management of the facility or the **provision of services** at the facility." [Emphasis added.] Paragraph (b)(6) requires "[t]he person's corporate history." We ask the Department to clarify what is meant by "provision of services" and "corporate history."

We note inconsistencies that may lead to confusion in the provisions under Subsection (b). Specifically, we note inconsistent tenses and use of the phrase "direct and indirect," as well as varying references to percentages in Subsections (b)(1)(i), (b)(7), and (b)(8). We ask the Department to carefully review this Subsection in the final regulation to clarify the requirements and make them consistent where appropriate.

Regarding requirements for application, a commenter raises concerns regarding interlocking private equity fiscal arrangements, stating, "Because private equity ownership can involve 8 or more interlocking entities all trying to maximize profit for each of their spheres of influence, it is critical that the Department have the financial information to understand the underlying cash flows and ownership and to assure that adequate funds remain for residents' services and supports." We ask the Department to amend the final regulation to require submission of information related to interlocking private equity fiscal arrangements, or to explain in the Preamble how the final regulation protects the public health, safety, and welfare without this requirement.

Likewise, commenters express the need for the Department to expand Paragraph (b)(1) to include any related business of the owner or operator of the facility which conducts business with any level of the corporate structure of the facility, its parent, or related businesses, the building, or the land on which the facility operates. Would the public health, safety, and welfare be better protected by such a requirement, as well as a visual representation of the organization's structure including all related parties in which the organization has an ownership or control interest of five percent or more and that provides any service, facility, or supply to the long-term care nursing facility? We ask the Department to amend the final regulation to include these provisions, or to explain how the final regulation protects the public health, safety, and welfare without these requirements.

Subsection (c)

Subsection (c)(4) requires a person seeking to operate or assume ownership of a facility to provide "[p]roposed standard admissions and discharge agreements." We ask the Department to clarify what is meant by "discharge agreements."

4. Section 201.12a. Evaluation of application for license of a new facility or change in ownership. – Implementation.

Commenters raise various questions related to aspects of the evaluation of application for license of a new facility or change in ownership that are not addressed in the proposed regulation including the following:

- Will there be set timelines for document reviews and decisions?
- Does the Department have criteria that would result in automatic denial of the application which could be placed in the regulation?
- Would the Department produce a publicly available report outlining the Department's position on approval or rejection of an application for license, including any underlying concerns and additional oversight requirements as a condition for licensure if warranted?
- Is there a process for appeal of a denial of an application for licensure or a change in ownership, and, if so, what is it?

We ask the Department to address these implementation concerns in the final regulation.

5. Section 201.13. Issuance of license for a new facility or change in ownership. – Protection of the public health, safety, and welfare; Clarity; Implementation.

Subsection (b) is being amended to state, "A license to operate a facility will be issued when the Department has determined that the necessary requirements for licensure have been met under [Section] 201.12 (relating to application for license of a new facility or change in ownership) and [Section] 201.12a (relating to evaluation of application for a new facility or change in ownership)." Will the license issued be a regular license without conditions or could this license also be a provisional license? If this also refers to a provisional license, we ask the Department to clarify this possibility and include a reference to Section 812 of the Health Care Facilities Act (Act) (35 P.S. § 448.812). Also, we note that the length of time that the license is valid is not addressed, and ask the Department to make a clarification by including the timeframe or a reference to Section 809(a) of the Act (relating to term and content of license) (35 P.S. § 448.809(a)).

Commenters raise concerns that new licensees and changes in ownership warrant a heightened level of oversight in the initial months of operation. The commenters suggest that new licensees under this Section be subject to a survey inspection within their first 3-6 months of operation so that the Department can confirm substantial compliance with requirements that could not be measured before the licensee was operating the facility. We suggest that the Department consider including such an inspection in the final-form regulation. If such an inspection is not implemented in the final regulation, we ask the Department to explain how it will ensure protection of the public health, safety, and welfare without heightened oversight in the initial months of operation.

6. Section 201.13a. License renewal. – Clarity; Implementation.

This Section addresses renewal of license, but does not indicate what the renewal timeframe is. We ask the Department to clarify implementation of when and how a licensee must apply for renewal of a license.

Subsection (b) states, "The Department will renew a license to operate a facility after a survey is conducted by the Department that indicates the facility is in substantial compliance with [S]ection 808(a) of the [A]ct (35 P.S. § 448.808(a)) and this subpart." We ask the Department to clarify in the final-form regulation what standards will define whether a facility is in "substantial compliance" with Section 808(a) and this subpart. If a facility is not in substantial compliance, would the Department issue a provisional license? If so, we ask the Department to include a reference to Section 812 of the Act (35 P.S. § 448.812).

7. Section 201.14. Responsibility of licensee. – Economic or fiscal impacts; Protection of the public health, safety, and welfare; Need; Implementation.

Subsection (j) states, "The facility shall conduct a facility-wide assessment that meets the requirements of 42 CFR 483.70(e) (relating to administration), as necessary, but at least quarterly." The Department states in the Preamble, "Currently, under the Federal requirements, a facility must conduct and document a facility-wide assessment... as necessary, and at least annually." While the Department states in response to RAF Question 15 that "a facility **may** be able to identify cost saving measures during the course of the assessment which would benefit both the facility and the residents and would offset any cost associated with conducting the assessment more often," we note that the Department does not provide a need for this provision. [Emphasis added.] While several commenters support this change as "an important tool for evaluating how best to serve the specific residents in a given facility and how to staff to meet their collective needs," others oppose the provision. A commenter states that requiring facilities to complete three additional facility assessments each year is an undue burden on an industry already desperate to hire additional staff. The commenter asserts that completion of facility assessments on a quarterly basis will not contribute to increased care quality but will burden staff and facilities with additional documentation and review. Another commenter asserts that this requirement is "excessive." We ask the Department to explain the need for the provision, and how the benefits of this new requirement for quarterly facility-wide assessments outweigh the economic impacts.

Subsection (h) requires long-term care nursing facilities to report "any other" information that the Department may request. We ask the Department to amend the final regulation to ensure that facilities are provided advance notice of any additional reporting requirements prior to implementation of that requirement.

Several commenters suggest that nursing homes should be required to submit annual consolidated financial reports from each facility, to include any parent organization or related entities providing goods or services, and that such financial reports should be reviewed by a certified public accountant or audited. We ask the Department to amend the final-form regulation to include such submission of annual consolidated financial reports, or to explain how the public health, safety, and welfare would be protected if such a requirement is not included.