Comments of the Independent Regulatory Review Commission

Department of Health Regulation #10-222 (IRRC #3316)

Long-Term Care Nursing Facilities

December 8, 2021

We submit for your consideration the following comments on the proposed rulemaking published in the October 9, 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; Protection of the public health, safety, and welfare; Clarity and lack of ambiguity; Reasonableness.

The Preamble states that the Department tentatively intends to promulgate proposed amendments to Subpart C (relating to long-term care facilities) in five separate parts. 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. This current proposed regulation is Rulemaking Package #2. As with Rulemaking Package #1, the regulated community reiterates 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:

- "The Department claims that promulgating the changes in five separate packages will allow the public greater opportunity to thoroughly examine the proposed amendments and provide detailed comments to the proposed changes. We are in total disagreement with this reasoning, as this fragmented process will only create confusion and undermine the public and regulated community as they seek to understand how each separate package fits together." [Pennsylvania Health Care Association (PHCA)]
- ". . . it is difficult to comment without seeing how the regulations as a whole work to protect residents . . . ." [Pennsylvania Health Funders Collaborative (PHFC)]
- "The regulated community and the public cannot anticipate how the changes to definitions, for example, will impact regulations that have not yet been revealed, nor can they understand how various portions of the regulations will interact with one another." [LeadingAge PA]
- "In the preamble, the Department assumes the incorporation by reference of the Center for Medicare and Medicaid Services (CMS) guidance to surveyors found in the State Operations Manual (SOM), Chapter 7 and Appendix PP – *Guidance to Surveyors for*

Long-Term Care Facilities [(*Appendix PP*)]as proposed in the first rulemaking 10-221. This assumption is troubling and serves to further demonstrate the confusion this fragmented process has created, while also supporting our request for one comprehensive regulatory package." [PHCA]

- "We found it quite challenging and cumbersome to review and comment on both the first and the second regulatory package in isolation of the remaining proposed changes." [AARP PA]
- "Previously, [Disability Rights PA (DRP)] noted our disagreement with the process for disseminating the proposed changes to the public, as well as its process for soliciting public comment."
- "Stakeholders will be unable to provide meaningful public comments, and the Department will not be able to fully understand the impact of its proposed regulations based on stakeholder feedback." [DRP]
- "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. This could happen for any number of reasons; none more important than each package likely requiring individual approval by the Independent Regulatory Review Commission and oversight committees in the General Assembly. This could result in incongruous enactment and confusion that will not further [the Department's] stated goals of improving the quality of care." [LeadingAge PA]
- "LeadingAge PA would respectfully request that [the Department] combine the regulatory packages into one coherent whole before publishing as proposed."

We agree with the significant 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, protects the public health, safety, and welfare, is reasonable, and lacks ambiguity.

The point raised by the commenter above regarding *Appendix PP* is significant and exemplifies our concerns with the Department's intent to continue to deliver individual regulatory packages. In Rulemaking Package #1, the Department proposed to incorporate by reference *Appendix PP* which is an improper delegation of the Department's statutory authority. In our Comment #2 on Rulemaking Package #1, we asked the Department to delete that incorporation by reference and include any mandatory provisions from *Appendix PP* in order to establish clear and unambiguous standards that could be predicted by the regulated community. If the Department deletes the incorporation by reference of *Appendix PP* from Rulemaking Package #1, what is the impact on this proposed regulation? We ask the Department to address the impact in the final-form regulation. The Department's delivery of separate but interrelated regulatory packages has the unintended consequence of complicating the process for the regulated community and this Commission to comment on impacts between the regulatory packages, as well as on the entirety of the changes proposed by the Department.

From the Preamble, we offer examples of the complexity associated with delivering separate proposed rulemaking packages:

- With the **anticipated promulgation** of the amendments to [Section] 201.2 (relating to requirements) **proposed in its first rulemaking**, published at 51 Pa.B. 4074 (July 31, 2021), the Department expects all long-term care nursing facilities in this Commonwealth to comply with the Federal participation requirements, including the requirements in 42 CFR 483.70(l) and (m) (relating to administration). **With these requirements in mind,** the Department proposes the following changes to [Section] 201.23 (relating to closure of facility) . . . . [Emphasis added.]

- Section 203.1 (relating to application of the *Life Safety Code*) is the only section within [Chapter 203 (relating to application of *Life Safety Code* for long-term care nursing facilities)]. The Department proposes to delete [Section] 203.1 and by extension, this Chapter, from the regulations, as part of its process to streamline Federal and State requirements for long-term care nursing facilities. The *Life Safety Code* is incorporated by reference in the Federal requirements for long-term care nursing facilities at 42 CFR 483.73(g)(1) (relating to emergency preparedness). **Because the Department is adopting the requirements in 42 CFR Part 483, Subpart B** as requirements for all long-term care nursing facilities operating in this Commonwealth, it is no longer necessary to have a separate provision within the State requirements regarding the applicability of the *Life Safety Code.* [Emphasis added.]

We emphasize that the amendment to Section 201.2 and the adoption of 42 CFR Part 483, Subpart B referenced above have not yet happened, and are not guaranteed to happen. As noted earlier by a commenter, Rulemaking Package #1 must be reviewed by the Department, this Commission, the General Assembly, and the Attorney General as it continues through the regulatory review process. Having multiple interrelated proposed regulations at the same time creates the opportunity for inconsistencies and errors across the packages. Furthermore, asking the regulated community to keep one proposed regulation—**which is subject to change**—in mind while reviewing another proposed regulation is challenging. Assuming subsequent packages will include similar cross-references, we question whether it is in the public interest or reasonable to expect the regulated community to hold multiple proposed regulations simultaneously in mind while reviewing a proposed regulation.

Because of the continuing concerns of the regulated community, and because the Department's process of issuing separate rulemaking packages raises a serious question as to whether this process is in the public interest, protects the public health, safety, and welfare, and is reasonable, 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 individual rulemaking packages, we ask the Department to explain why this approach is in the public interest and reasonable, and how it protects the public health, safety, and welfare in light of concerns expressed by the regulated community and the demonstrated difficulty that the regulated community likely faces as each subsequent rulemaking package is released. We also ask the Department to:

- Identify in the final-form Preamble any provisions which assume approval of Rulemaking Package #1 as final-form;

- Cross-reference in the final-form Preamble those provisions to the relevant provisions in Rulemaking Package #1; and
- Explain the impact if Rulemaking Package #1 is not approved before or at the same time as Rulemaking Package #2.

We ask that these recommendations be implemented as the Department prepares the subsequent long-term care nursing facilities regulatory packages.

Finally, 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.

2. Section 201.23. Closure of facility. – Protection of the public health, safety, and welfare; Clarity, feasibility, and reasonableness; Need.

Subsection (a)

The Department proposes to delete Subsection (a) which states, "The administrator or owner shall notify the appropriate Division of Nursing Care Facilities field office at least 90 days prior to closure," and add language requiring facilities to comply with 42 CFR 483.70(l) and (m) (relating to administration) which requires notification at least 60 days prior to the date of closure. The Department states that "the deletion of subsection (a) and the adoption of 42 CFR 483.70(l)(1) comports with not only the Federal requirements but also existing State regulations." Commenters across the board are strongly opposed to this proposal. We include the following statements from commenters:

- "The Department's justification is that the federal rules only require 60 days. The state has the authority (is not preempted from requiring 90 days) and the Department clearly chose 90 days in the current regulations for good reason. A safe and orderly transfer of all residents takes time and planning. We urge the Department not to take away what, in essence, is a consumer protection by reducing this time frame to 60 days." [Center for Advocacy for the Rights & Interests of the Elderly/Community Legal Services]
- "Given the tremendous complexity of resident needs and the dangers posed by sudden changes, we believe that 90 days is the minimum appropriate time for notice." [SEIU Healthcare PA]
- "The Department should not use updating of these regulations as a reason to reduce the protections for residents who are being forced to relocate where they live due to no fault of their own." [PHFC]
- "It is not easy to find a quality nursing home placement in a short period of time, particularly when residents are competing against each other for the available beds in the

> region, as during a closure, all facility residents will find themselves in the same position of needing to find an alternative place to live at the same time." [DRP]

Since the requirement which the Department proposes to delete is for a facility to notify the appropriate Division of Nursing Care Facilities field office, does the reduction from 90 days to 60 days affect notice to residents? If this change impacts residents, we ask the Department to explain the reasonableness and feasibility of reducing the notice timeframe, and explain how the final-form regulation protects the health, safety, and welfare of residents. Additionally, we note that Subsection (d) states, "No resident in a facility may be required to leave the facility prior to 30 days following receipt of a written notice from the licensee of the intent to close the facility . . . ." What is the benefit to a resident to have 60 days' notice if the facility can require a resident to leave on day 31? We ask the Department to explain how these provisions work together to protect the public health, safety, and welfare.

Subsection (c)

Regarding Subsection (c), the Preamble states:

> The Department proposes to delete existing subsection (c). Existing subsection (c) requires a long-term care nursing facility to give a resident or the resident's responsible person sufficient time to effectuate an orderly transfer. Under 42 CFR 483.70(l)(3), the administrator of a long-term care nursing facility is required to submit for the Department's review and approval of a plan for the closure of the long-term care nursing facility. The Department **expects** a closure plan, at a minimum, **to meet the requirements set forth by CMS in *Appendix PP*—*Guidance to Surveyors for Long-Term Care Facilities of the State Operations Manual***. Under section F845 of *Appendix PP*, the closure plan must contain . . . . [Emphasis added.]

We emphasize once again that this proposed amendment relies on the Department's expectation that *Appendix PP* will be incorporated by reference in Rulemaking Package #1. As noted in Comment #1, we asked the Department in Rulemaking Package #1 to delete that incorporation by reference. If *Appendix PP* is removed from Rulemaking Package #1, how will that impact requirements for closure plans for long-term care nursing facilities? We ask the Department to clarify in the final-form regulation the requirements for a long-term care nursing facility closure plan.

Additionally, commenters oppose deletion of this provision, asserting that submitting a plan is not the same as guaranteeing a resident the right to receive sufficient time for an orderly transfer. A commenter states that by deleting the requirement, the Department is eliminating this resident right and protection. We note that the existing requirement to provide "sufficient time to effectuate an orderly transfer" offers a protection of the public health, safety, and welfare that is not required under the Federal regulations. If this language is not retained in the final-form regulation, we ask the Department to explain the need for and reasonableness of eliminating this provision, and how the final-form regulation protects the public health, safety, and welfare.

Subsection (g)

In the Preamble, the Department states:

> [Subsection (g)] refers to an outdated requirement that a licensee file proof of financial responsibility with the Department. As outlined previously, a long-term care nursing facility is expected to develop a closure plan in accordance with policies and procedures developed by the facility under the Federal requirements and the State Operations Manual. The closure plan must include, among other things, a plan for continuing payment of salaries and other expenses incurred by the facility during the closure process.

Commenters oppose this deletion, stating that a closure plan is not "proof of financial responsibility" and is not evidence of the ability to pay for salaries and other expenses in accordance with the plan. Commenters are deeply concerned that this provision puts residents and caregivers at risk. We ask the Department to explain the need for eliminating this provision and how requiring a "plan" versus "proof" is reasonable and protects the public health, safety, and welfare.

3. Section 204.1. Application of *Guidelines for Design and Construction of Residential Health, Care and Support Facilities*. – Statutory authority; Clarity and lack of ambiguity.

Subsection (a)

Subsection (a) requires that facility alterations, renovations, and construction approved on or after the date six months after the final regulation is published as a final-form rulemaking shall comply with the 2018 edition of the Facility Guidelines Institute (FGI) *Guidelines for Design and Construction of Residential Health, Care, and Support Facilities* (*Guidelines*). We ask the Department to define "alteration," "renovation," and "construction" to provide clarity for the regulated community.

Regarding the FGI *Guidelines*, we note that the Department states in the Preamble that an earlier edition of the FGI *Guidelines* were included in Federal requirements but then removed in 1984. The Department explains that, at that time, the title was changed to "represent its non-regulatory status." A commenter states the FGI *Guidelines* are not regulatory in nature, and requests that the Department retain the existing language. We ask the Department to explain how requiring facilities to comply with the 2018 FGI *Guidelines* is not an improper delegation of the Department's statutory authority since this document is not subject to regulatory review requirements.

Subsection (c)

Subsection (c) states:

> A facility previously determined by the Department to be in compliance with this subpart will be deemed to be in compliance until the time that the facility completes alterations, renovations or construction. Alterations, renovations or

> construction shall meet the requirements in effect on the date that the facility's plans for alterations, renovations or construction are approved by the Department.

Commenters raise concerns that the language in this provision is ambiguous and suggests that a facility will be considered to be compliant even if it has let buildings deteriorate to the point that they would not meet the standards once met. The Department states in the Preamble that the intent is "to only hold a facility to the standards that were in effect at the time the alteration, renovation or construction was approved." We ask the Department to amend Subsection (c) to clarify under what circumstances facilities will be deemed to be in compliance.

4. Section 204.2. Building plans. – Protection of the public health, safety, and welfare; Clarity, feasibility, and reasonableness.

Subsection (d)

Subsection (d) states, "Any part of a facility that has not been occupied or used for 1 year or more may not be used by the facility for any purpose except as provided for in this section." Commenters raise various concerns regarding this proposed language. What is meant by the phrase "any part?" How does the Department define occupancy and use? Would a room qualify as being "occupied or used" if one item is being stored in it? A commenter expresses concern regarding protecting residents from provider-motivated resident room moves. In other words, providers may be motivated to move residents around to ensure that no space goes unused for a year or more. Commenters also raise concerns as to how facilities would be able to respond rapidly in emergency situations such as the COVID-19 pandemic where it became necessary to isolate people and spread them out to the maximum extent possible. We ask the Department to clarify the language of this provision, and to explain how the final form regulation is reasonable, feasible, and protects the public health, safety, and welfare.

Subsection (e)

Subsection (e) states:

> If a facility intends to occupy or use a space that has been unoccupied or unused for 1 year or more, the occupancy or use shall be considered an alteration, renovation or construction and the facility shall submit architectural plans and blueprints related to its occupancy or use to the Department as required under [Section] 51.3(d). The facility may not use or occupy the space unless approved by the Department.

A commenter states that many nursing facilities are forced currently to limit admission as they struggle to recruit, hire, and retain staff sufficient to provide the level of quality care that residents deserve, and, in many instances, facilities are forced to leave areas and wings vacant. The commenter explains that this requirement could impose the unintended consequence of causing the facility to permanently delicense those beds, causing a reduction in the commonwealth's capacity to serve its aging population. We ask the Department to explain the reasonableness of this requirement, and how the final-form regulation protects the public health, safety, and welfare.

5. Section 204.3. Building; general. – Protection of the public health, safety, and welfare; Clarity, feasibility, and reasonableness.

Subsection (b)

Subsection (b) states in part, "Special authorization **shall** be given by the Department's Division of Nursing Care Facilities **before** a part of the building is to be used for a purpose other than health care." [Emphasis added.] To comply with the *Pennsylvania Code & Bulletin Style Manual*, we ask the Department to follow the language of Section 205.6(a), which states in part, "Special authorization **shall** be given by the Department's Division of Nursing Care Facilities **if** a part of the building is to be used for a purpose other than health care." [Emphasis added.]

6. Section 204.5. Resident rooms. – Protection of the public health, safety, and welfare; Clarity; Reasonableness.

The Department explains in the Preamble that many provisions in Section 204 are carried over from Section 205. However, commenters raise concerns regarding certain provisions of existing Section 205 which are not carried over. For example, language in Section 205.20(d) and (e) (relating to resident bedrooms), establishing minimum square footage requirements for resident rooms, is not addressed in the Preamble or proposed regulation. Commenters raise similar concerns regarding Section 205.23 (relating to location of bedrooms). Commenters acknowledge that these requirements may be covered in the 2018 *FGI Guidelines*. We ask the Department to clarify in the Preamble of the final-form regulation any provisions which are not carried over because they are addressed in the 2018 *FGI Guidelines*.

Subsection (d)

Subsection (d) states, "A resident shall have a choice in the placement of the resident's bed in the room unless the placement presents a safety hazard." A commenter expresses concern that without a definition of "safety hazard," a facility will have too much leeway to deny the residents' choices and preferences. We ask the Department to clarify this provision or explain the reasonableness of retaining this language in the final-form regulation. This comment also applies to Section 205.22 (relating to placement of beds).

7. Section 207.4. Ice containers and storage. – Protection of the public health, safety, and welfare.

The Department states in the Preamble:

> The Department proposes to delete this section. Ice storage and the handling of ice are addressed in the Federal requirements at 42 CFR 483.60(i)(2) (relating to food and nutrition services) and at F812 in [*Appendix PP*]. The Department proposed to adopt the Federal requirements and *Appendix PP* in [Section] 201.2 in the first proposed rulemaking. Under 42 CFR 483.60(i)(2), a facility must store, prepare, distribute and serve food in accordance with professional standards for food service safety. The Department expects, in accordance with this provision and *Appendix PP*, a long-term care nursing facility to engage in

appropriate ice and water handling practices to prevent contamination and waterborne illness.

As discussed in Comment #1, we asked the Department in Rulemaking Package #1 to delete language proposing to incorporate by reference *Appendix PP*. We ask the Department to retain the language of this section in the final-form regulation or amend it to include the specific requirements from *Appendix PP* with which a long-term care nursing facility must comply.

8. 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 addressing potential impacts on small businesses in the RAF, 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." 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. We ask the Department to calculate and address the impact of the final-form regulation on small businesses as required under the RRA.