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Independent Regulatory Review Commission

From: Gail Weidman
To: DH, LTCRegs
Cc: Zach Shamberg; Peter Tartline; Chris Fisher; Gail Weidman
Subject: [External] Comment Letter Re: Proposed rulemaking 10-222 (Long-Term Care Nursing Facilities. Proposed Rulemaking 2)
Date: Wednesday, November 3, 2021 10:26:15 AM
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PHCA Comment Letter Regulatory Package 2 11-3-21.pdf

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Good Morning,

Please accept the attached comment letter regarding the DOH proposed rulemaking 10-222, being submitted on behalf of PHCA and the long term care facilities we represent.

Thank you for the opportunity to provide comment.

Sincerely,
Gail

Gail Weidman
Director of Policy & Regulatory Affairs
Pennsylvania Health Care Association
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November 3, 2021

Lori Gutierrez
Deputy Director, Office of Policy
Department of Health
625 Forster Street, Room 814
Harrisburg, PA 17120

Re: Proposed Rulemaking No. 10-222 (Long-Term Care Facilities, 28 Pa Code §§ 201.23 and 207.4; Chapters 203, 204 and 205)

Dear Deputy Director Gutierrez,

We are writing today regarding the Department of Health, Long-Term Care Facilities, Proposed Rulemaking 10-222, published in the *Pennsylvania Bulletin* on October 9, 2021.

Please accept these comments on behalf of the Pennsylvania Health Care Association (PHCA), and the more than four-hundred long-term care facilities we represent throughout the commonwealth, including nursing homes, personal care homes and assisted living communities.

This proposed rulemaking is the second of a series of five separate rulemakings that the Department of Health (Department) intends to release, and we must reiterate our objection regarding the process.

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.

PHCA continues to urge the Department to reconsider the use of this fragmented process and issue one comprehensive proposed package. If, however, the Department insists on moving forward, PHCA requests that subsequent to the publication of all five individual regulatory packages, a comprehensive package be published, as proposed, with a new 30-day public comment period. This will provide the public and regulated community the opportunity to review all chapters and interconnected sections of the nursing facility licensure regulations in a cohesive and comprehensive manner.

In addition to the process objections, PHCA has concerns regarding some of the responses provided by the Department in the Regulatory Analysis Form (RAF). One requirement within the RAF is that the state agency provide a schedule for review of the regulation, including the date(s) on which any public meetings or hearings will be held. In response to this specific question (Question # 17), the Department asserts that "The proposed regulations were presented to the Health Policy Board on October 29, 2020." The same assertion was provided in the RAF for Rulemaking 10-221. If both rulemakings were presented to the Health Policy Board on the same day in 2020, this brings into question the Department's rationale for failing to publish one comprehensive rulemaking package.

Furthermore, the Department, once again, has not given adequate attention to the financial and economic impact of the regulation on small business, nor those nursing facilities, business partners and/or suppliers that are small businesses. Nursing facilities are a major employer and purchaser in their local communities. Simply stating the requirements apply to all nursing facilities, regardless of whether they are a small business, is not an analysis. And the assertion that the commonwealth does not have access to data to determine which nursing facilities fall into the small business category is simply not accurate.

Consequently, before this rulemaking or any of the other four rulemakings are approved, it is imperative that the access to care impacts of the proposed regulatory changes be adequately assessed and considered.

In addition to these issues, PHCA has concerns regarding references included in the preamble and amendments proposed in the annex of rulemaking, as outlined below.

Preamble References to State Operations Manual and Appendix PP.
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* 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.

Once again, we raise our overall objection to the incorporation by reference of the SOM, Chapter 7, and Appendix PP. The information contained in the SOM are interpretive guidelines and can be changed by CMS at any time without notice or public input. Incorporating the SOM by reference circumvents the regulatory review process and may go as far as violating the Regulatory Review Act.

Moreover, in S&C Memorandum 08-10, CMS makes it abundantly clear that the interpretive guidelines provided in these documents are not statutory or regulatory in nature and are only to be referenced by surveyors to assist them with the survey process.

Of specific concern are the references in the preamble to the guidance contained in Appendix PP of the SOM related to § 201.23 (relating to closure of facility) on pages 9 – 12, and § 207.4 (relating to ice containers and storage) on page 30.

In the discussion regarding § 201.23 (relating to closure of facility), the Department states "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*". The Department goes on to reference Section F845 of Appendix PP and list closure policies and procedures provisions. As previously noted, the guidance contained in Appendix PP are not requirements, and F845 is not a section – it is a Federal Tag number that is associated with compliance to regulatory provisions set forth in the Federal regulations. In fact, the **Guidance** that is being referenced in the preamble as requirements set forth by CMS are not listed under F845, but under "GUIDANCE §483.70(m)".

In the discussion regarding § 207.4 (relating to ice containers and storage), the Department notes the expectation that nursing facilities engage in appropriate ice and water handling practices to prevent contamination and waterborne illness in accordance with 42 CFR §483.60(i)(2) AND Appendix PP at

F812. Guidance related to F-tag 812 in Appendix PP is seventeen pages long, and the specific guidance the Department refers to in the preamble is contained on one of the seventeen pages.

Once the regulatory provisions have been promulgated, the preamble is not promulgated or readily available. As a result, the nursing facility will need to search through the 702-page Appendix PP to access the language they will be required to adhere to. This is an unreasonable expectation and a terrible use of already-limited time.

Under both of these sections, if the Department's intent is to require nursing facilities to comply with the guidance contained in Appendix PP that is referenced in the preamble, the specific language that a nursing facility must adhere to should be promulgated in the regulatory Chapter under the relevant section to provide clarity and full disclosure.

Consequently, PHCA requests that the Department remove the incorporated references to the SOM, Chapter 7 and Appendix PP – *Guidance to Surveyors for Long-Term Care Facilities* in this proposed rulemaking, as well as proposed rulemaking 10-221 and all subsequent rulemakings. Any guidance from the SOM that the Department intends to require nursing facilities to comply with must be promulgated under the appropriate section in 28 Pa. Code Part IV, Subpart C (relating to long-term care facilities).

2018 edition of the Facility Guidelines Institute (FGI) Guidelines for Design and Construction of Residential Health, Care and Support Facilities.
Although PHCA supports the Department's proposal to adopt the 2018 edition of the FGI as the minimum standard for alterations, renovations, or construction, we do have concerns related to the provisions contained in §204.2 (relating to building plans) as noted below. In addition, PHCA commends the Department for utilizing the regulatory review process to incorporate any future editions of the FGI.

Section 204.2 (relating to building plans).
Based on our review of subsection (e) of this section, it is our understanding that if a nursing facility has a unit, wing, or floor that has been unoccupied for one year or more, the facility would be required to submit architectural plans and blueprints, and the occupancy or use will be considered new construction, an alteration, or renovation, in order for the unit, wing or floor to be reopened. The nursing facility would then be required to comply with the provisions contained in § 204.1 (relating to application of guidance for design and construction of residential health, care and support facilities), which, based on the approval date, would require the unoccupied space to come into compliance with the 2018 edition of the Facility Guidelines Institute *Guidelines for Design and Construction of Residential Health, Care and Support Facilities*.

Many nursing facilities across the commonwealth have addressed severe staffing shortages throughout the past twenty months by temporarily closing units, wings, or floors until they have adequate staff to accommodate the use of the space. This allows nursing facilities to operate and deploy their existing staff more efficiently and ensure quality care to the residents residing in their facilities.

Given the number of staffing vacancies, there is a high probability that some of these spaces will be unoccupied for a year or more. As written, this provision will be one more barrier that a nursing facility must overcome to return to full operation and provide access to those individuals in need of services.

While we recognize the need to ensure the health and safety of residents, we are compelled to ask: if the space was previously safe for resident occupancy, is licensed, and it complies with requirements established by the Department, what would render it 'unsafe' now? It is incumbent on the Department to make allowances for these types of situations so that nursing facilities can occupy these spaces without going through the expense of meeting the 2018 edition of the FGI.

Once again, PHCA strongly urges the Department to bring stakeholders and industry experts together to develop a strategy and a comprehensive regulatory package that will support the needs of residents, caregivers, and providers throughout Pennsylvania. PHCA and our members stand ready to work with the Department on this initiative.

Thank you for the opportunity to share our comments.

Sincerely,

Zachary Shamberg
President and CEO