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Subject: [External] PHLP's Comments on Proposed Rulemaking 10-223 (Long-Term Care Facilities, Proposed Rulemaking 3)
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Attachments: [PHLP 2022-04-18 Comments on LTC Facility Proposed Rulemaking.pdf](#)

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Attached please find the Pennsylvania Health Law Project's comments on the Department of Health's proposed rulemaking 10-223 (Long-Term Care Facilities, Proposed Rulemaking 3).

Thank you for your consideration of these comments.

Very truly yours,

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April 18, 2022

VIA EMAIL (RA-DHLTCREGS@PA.GOV)

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

**RE: Rulemaking 10-223
(Long-Term Care Facilities, Proposed Rulemaking 3)
28 PA Code Sections 201.12-201.17, 201.22, 209.1, 209.7, 209.8 and 211.1**

Dear Ms. Gutierrez:

The Pennsylvania Health Law Project (PHLP) is one of the few non-profit law firms in the country exclusively focused on health care. We have deep expertise in the local, state, and federal laws and regulations that govern eligibility for and delivery of health care services. We also have a long history advocating on behalf of residents in long-term care facilities. The backbone of our work is helping eligible and low-income Pennsylvanians 1) obtain and keep Medicaid and 2) obtain medically necessary services and supports from their Medicaid managed care plan. PHLP counsels and represents Pennsylvanians in every county and opens more than 2,500 cases per year.

The COVID-19 pandemic has spotlighted the challenges facing Pennsylvania's nursing homes and the profound need to update the Commonwealth's long-term care regulations. With the long-term care system now in the spotlight the moment has indeed arrived to take meaningful actions to improve nursing homes.

Below are PHLP's specific comments on and recommendations regarding the third packet of proposed rules related to long-term care facilities. In addition to these comments, we fully endorse the specific language recommendations and comments Center for Advocacy for the Rights & Interests of the Elderly (CARIE) and Community Legal Services (CLS) provided in their mark-up of the proposed regulations which is attached to their comments submitted to the Department today.

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PHLP's COMMENTS

1) Section 201.12 Application for license of a new facility or change in ownership

We strongly support the decision to expand section 201.12 to include new facility and change in ownership applications. It is critical that the regulations clearly delineate the requirements for a change in ownership licensure applicant and the proposed regulations take important steps to accomplish this. We additionally recommend the following:

A. Provide a public notice and comment process.

It is imperative that the Department add a meaningful public notice and comment process related to new facility applications and applications for change of ownership, which proposed Section 201.12 does not currently include. This is important for transparency, accountability, and ensuring that applications are considered in context with public feedback regarding whether applicants meet the criteria to receive a license. We therefore urge the Department to:

- Publish on its website a notice of the applicant's intent to open or change operators of a nursing facility, with details of the public comment process.
- Require applicants to notify residents, resident representatives, the LTC Ombudsman, staff, and others in writing about a sale or change of ownership.
- Receive and review comments from the public on whether the applicant meets the criteria for licensure, and consider the comments in its decision to approve or deny a license, which may include taking action to investigate any issues raised in public comments.

B. Revise the ownership or control interest description.

We are pleased the Department added language defining "a person who has or will have ownership or control interest" to include "[t]he organization that holds the license or the land or building occupied and used as the facility." However, we recommend the Department also include language requiring the applicant to submit information for anyone who "is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the equipment used in the facility or by the land on which or building in which the facility is located."

In addition, as written, it is unclear whether "person" in section 201.12(b)(6)-(10) applies solely to the "person" seeking to operate or assume ownership of a facility pursuant to subsection 201.12(b) or whether it also applies to the persons identified in subsections (b)(1)(i)-(ii), (3) and (5). To ensure that all entities and individuals who will have an ownership or control interest or who will manage the facility are responsible and capable, we strongly urge the Department to clarify that the information in subsections (b)(6)-(10) should be obtained and evaluated for all individuals and entities identified in subsections (b)(1)(i)-(ii), (3) and (5). Similarly, in section 201.12a(c), it should be clarified that "person" refers to all

individuals and entities identified in subsections 201.12(b)(1)(i)-(ii), (3) and (5).

C. Define “person.”

We note that this section now repeatedly refers only to a “person” applying for licensure instead of an applicant. However, “person” is not defined. We strongly urge the Department to add the below definition from the Health Care Facilities Act to the definitions included in Section 201.3:

"Person." A natural person, corporation (including associations, joint stock companies and insurance companies), partnership, trust, estate, association, the Commonwealth, and any local governmental unit, authority and agency thereof.

2) Section 201.12a Evaluation of application for license of a new facility or change in ownership

We are pleased the Department added this section. We believe it is important that applicants have a clear understanding of what criteria the Department will apply in deciding whether to approve or deny a new license or change of ownership request. We also believe it is important for consumers and the public to know the standards to which nursing homes are held.

While we support the Department’s articulation in 201.12a(c)(1)-(3) of criteria the Department will apply in evaluating an application, it is imperative that the regulations include some factors that warrant automatic exclusion from licensure. These should be clearly stated, known to applicants and the public. For this reason, we recommend that the Department add the criteria outlined in the CARIE and CLS’s mark-up of the proposed regulations.

3) Section 201.13 Issuance of license for a new facility or change in ownership

A. Conduct survey inspections within the first months of operation.

We agree with the Department that inspection prior to licensure is not the best use of resources. However, we believe facilities with new initial and change of ownership licenses warrant some heightened level of oversight in the initial months of operation. We strongly recommend that new license applicants and change of ownership applicants be subject to a survey inspection within their first 3-6 months of operation so the Department can confirm substantial compliance with requirements that could not be measured before the licensee was operating the facility.

B. Provisional licensure provisions should be improved, not removed.

We have concerns about the Department removing the subsection on provisional licenses. We believe both new licensees and change of ownership licensees should receive a provisional license lasting no longer than 6 months as their first license and, as stated above, they should both be subject to onsite inspections during their first 3-6 months of operation. Additionally, we believe that while

enforcement actions are covered in multiple sections of the Health Care Facilities Act, they should be spelled out in the regulations as well. Including a comprehensive discussion of provisional licensure and the other available enforcement actions in the Department's enforcement toolbox is helpful for applicants and nursing home licensees. It sends a message that the Department takes compliance seriously; ensures that facilities understand the consequences of non-compliance and the enforcement action steps which the Department may take; and helps consumers, their loved ones, the long-term care ombudsmen, and the public to understand what different enforcement actions mean in the grander scheme of oversight.

Because we believe the regulations should include more enforcement requirements (concerning provisional licenses, fines/penalties, the entire progressive enforcement approach and plans of correction) and not less, we recommend that the Department improve rather than remove this section and add a section specifically related to enforcement.

C. Authority for increased license fees should be obtained.

We do not object to the Department's removal from the regulations of the list of fees because that information exists in the statute. However, we feel that applicants need clear information on what is required in the application process, and it is not readily apparent to us that fee information is available elsewhere.

We feel an increase in initial licensure and licensure renewal fees is long overdue as the amounts in the statute are terribly outdated and should be increased to a meaningful amount. We urge the Department to ask the legislature to raise the fees in the statute. Increased fees should be used to establish a dedicated unit for vetting applications and to support a new finance unit's review of the financial status of applicants, in addition to overall enforcement of the regulations.

4) Section 201.13a License Renewal

A. Periodicity of licenses should be articulated.

New Section 201.13a requires license renewals but does not state the frequency for such renewal. We strongly recommend that this new section be clearer that every facility must apply to renew its license at least annually and at the end of the term of a provisional license (which cannot exceed 6 months).

B. Add information on the standard for extending a provisional license.

Because, consistent with our recommendations above, the Department may issue a provisional license to a facility that is not in substantial compliance, this section should address the standard for determining whether a provisionally licensed facility that has not completely corrected its non-compliance shall be issued another provisional license. Please see our proposed edits to the proposed regulations in the mark-up to the proposed regulations that we have attached.

5) Section 201.14 Responsibility of Licensee

A. Quarterly Facility Assessments are a key improvement.

We are pleased that the Department is requiring nursing facilities to conduct the facility assessment (as required in 42 CFR §438.70(e)) on a quarterly basis. This assessment is an important tool for evaluating how best to serve the specific residents in a facility and how to staff to meet their collective needs. In some ways (staffing, change in resident population, resource needs), a facility assessment should be performed on almost a daily basis. As noted in State Operations Manual, Guidance to Surveyors, Appendix PP, related to the facility assessment regulation:

The facility assessment will enable each nursing home to thoroughly assess the needs of its resident population and the required resources to provide the care and services the residents need. It should serve as a record for staff and management to understand the reasoning for decisions made regarding staffing and other resources, and may include the operating budget necessary to carry out facility functions.

Nursing home resident populations change with some frequency so the value of performing a facility assessment on a quarterly basis (at a minimum) is enormous. Additionally, performing a meaningful facility assessment on a quarterly basis will improve internal quality assurance and will identify possible areas of regulatory non-compliance. The notion that this proposed regulatory requirement is simply a burdensome paperwork requirement misses the importance of an effective ethics and compliance program that integrates a quality assurance component.

B. Expand reportable incidents.

Instead of deleting additional state reporting requirements at Section 201.14(d), we recommend requiring reporting of the following:

- Events that cause or result in a resident's death or present an immediate danger of death or serious harm;
- Events that cause or result in serious injury or significant change in a resident's condition;
- Staffing below state minimum requirements; and
- Deaths or serious injuries due to neglect as defined in 42 CFR § 483.5.

These additions will promote the reporting of events, including the provision of inadequate care, that result or are likely to result in harm to residents.

C. Require consolidated financial reports.

Nursing facilities should be required to submit annual consolidated financial

reports from each facility, including any parent organization or related entities providing goods or services. Such financial reports should be reviewed by a certified public accountant or audited.

Recently, there has been intense scrutiny of the financial relationships and transparency related to nursing homes. On February 3, 2022, CARIE hosted a webinar on “Private Equity Investors as Nursing Home Owners: Impact on Quality of Care and Lack of Accountability.” On April 1, 2022, the Kline School of Law at Drexel University held a conference regarding the impact of private equity on health care, especially nursing homes. It was apparent from the expert panelists at both events that nursing home ownership and financial transparency are critically important to ensuring that public funds are used appropriately and protecting nursing home residents.

Therefore, we recommend requiring submission and review of financial information from all operating entities, license holders and related parties in which the organization has an ownership or control interest of 5% or more and that provides any service, facility, or supply to the nursing facility. The Department should also require a detailed document providing a visual representation of the organization’s structure including all related parties in which the organization has an ownership or control interest of 5% or more and that provides any service, facility, or supply to the nursing facility.

D. Outline enforcement procedures in this section.

We ask the Department to add to Section 201.14(a) language outlining the enforcement steps available to the Department in cases of non-compliance. This is critical for nursing home applicants and residents, their loved ones, the long-term care ombudsman programs, and the general public to understand the licensure and enforcement status of a nursing home. While this information is sprinkled through multiple sections of the Health Care Facilities Act, it would be valuable to have it stated clearly and in one place.

6) Section 201.17 Location

A. Clarify language around co-location.

The Department proposes to delete the existing section and replace it with language stating that a nursing facility can be co-located in a building that offers other health-related services. We ask that the proposed language be clarified because it is not clear whether the co-located health-related services would be offered as separate services under the nursing home’s license or whether there would be separately licensed providers providing other health-related services co-located at the same physical location as the nursing facility. We believe the Department intends the latter but the provision as drafted is not sufficiently clear.

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

Address pandemic-prone infectious disease prevention, control, and surveillance.

The proposed regulations need to be revised to include a section that mirrors the tuberculosis section but broadly applies to any pandemics or outbreaks, such as we have experienced with COVID-19. Among other things, this should require that in the event of any pandemic or outbreak, the nursing facility is required to follow all currently applicable state and federal regulations and protocols.

8) Section 209.7 Disaster Preparedness

Do not delete but instead expand Section 209.7 to include emergencies, disasters, and pandemics.

While the Department is proposing to delete this section because of federal rules requiring disaster preparedness, we believe it is important not only to keep but to expand the section to include other emergencies, pandemics, active shooters, etc. Specifically, we propose:

- Changing the section title to cover emergencies, disasters, and pandemics.
- Requiring each facility to have a written plan addressing each of these types of occurrences which must be submitted with the license application and annually, and approved by the Department prior to licensure and annually.
- Requiring, in addition to what the regulation already include, that the Emergency, Pandemic, and Disaster plan include specific items as specified in CARIE and CLS's mark-up of the proposed regulations.

9) Section 209.8 Fire Drills

Expand this section to cover other types of safety drills.

Section 209.8 must be expanded to include all types of safety drills and renamed to reflect this change. Nursing facilities must be required to conduct drills related to any type of emergency, disaster or pandemic (e.g., active shooter drills).

10) Section 211.1 Reportable Diseases

Specify requirement for reporting of pandemic-prone infectious diseases.

Clarify the obligation to report Pandemic-Prone Infectious Diseases, such as COVID-19, to the Department and other relevant agencies at the Department's direction in the manner, frequency, and format required by the Department.

We are hopeful that the remaining sections of the proposed regulations and the entirety of the final regulations will reflect the overarching reform that is so desperately needed to improve the nursing home regulations for residents and their loved ones. PHLP looks forward to reviewing and commenting on the additional upcoming releases of the nursing home regulatory package and reserves our ability to submit additional comments on the first, second and third packages in light of those new proposals.

Thank you for giving us the opportunity to comment.

Very truly yours,

/s/

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