



From: [Jennifer Garman](#)
To: [DH, LTCRegs](#)
Subject: [External] Proposed Rulemaking 10-223, Long-term Care Nursing Facilities, Proposed Rulemaking 3
Date: Monday, April 18, 2022 3:56:22 PM
Attachments: [Disability Rights Pennsylvania Comments on NH Regulation Package 3.pdf](#)

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Good Afternoon,

Attached please find comments from Disability Rights Pennsylvania.

Sincerely,

Jennifer Garman

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VIA EMAIL

April 18, 2022

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

**Re: Proposed Rulemaking 10-223 (Long-term Care Nursing Facilities,
Proposed Rulemaking 3)**

Disability Rights Pennsylvania (DRP) is the federally mandated, state designated Protection and Advocacy (P&A) system for persons with disabilities in Pennsylvania, and it has been providing legal and advocacy services to Pennsylvanians with disabilities for over 40 years. We are pleased to be given the opportunity to comment on package three of the Department of Health's (DOH) proposed rulemaking updating the Commonwealth's nursing home regulations.

While we are pleased to see DOH has combined the planned fourth and fifth packages into one final package, we nonetheless continue to believe that the Department should have issued all the proposed changes at once. 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.

Although the Department now states that “if a commentator believes that an amendment in [a] proposed rulemaking . . . does not align with amendments that were proposed in [an earlier] proposed rulemaking . . . , the commentator may comment on this during the 30-day public comment period for [the later] proposed rulemaking[.]” this does not align with prior IRRC guidance. The IRRC has said that commenters cannot offer feedback pertaining to all five sections throughout the entire commenting process, and that if they do so, comments that pertain to earlier sections will be ignored. This means that unless IRRC has changed its position, DOH has created a process where, if commenters’ feedback on an earlier section changes once read in conjunction with a later section, they are without a forum to express this. Stakeholders are therefore unable to provide meaningful public comments, and DOH will not be able to fully understand the impact of its proposed regulations.

Finally, we appreciate that the Department will hold meetings with stakeholders after each public comment has ended. We note the concern that during the updating and development of the regulations starting in 2017, the list of stakeholders that DOH met with did not include any advocates from the aging or disability community, nor did it include any organizations that provide the resident perspective, it only focused on the health care perspective and nursing home operators. As noted in the Background to the regulations, Pennsylvania is an aging state and the need for long-term care services is growing every year. Engaging stakeholders with a variety of perspectives is necessary and important to ensure that all views are considered in the regulations.

Section 201.12 Application for License of a New Facility or Change in

Ownership: DRP supports the proposed changes to this section. We believe it is necessary for the Department to require prospective new owners to demonstrate their fitness for operating a long-term care facility through the application process, in the same fashion as is required of new facilities. A change in ownership can often mean fundamental changes in how a facility operates, and these can result in negative impacts to residents’ care, and in turn, their health and safety.

In addition, we believe it is important for the Department to understand which individuals and entities will have a direct or indirect ownership interest in the facility, because such information can provide clues as to whether they will ultimately put profits before people, thus compromising

residents' well-being. Thus, we fully support the new requirements related to disclosing ownership interests, as well as information about present and past ownership of other long-term care facilities, licensing and regulatory history related to said ownership, a detailed summary of current or settled civil actions or criminal actions, and any financial failures involving any individuals or entities identified in the application that resulted in a bankruptcy, receivership, assignment, debt consolidation or restructuring, mortgage foreclosure, corporate integrity agreement, or sale or closure of a nursing facility, the land it sits on or the building in which it is located.

While we support the new proposed requirements in subsection (c), related to, among other things, staffing, training, hiring, and emergency preparedness plans and budgets, we would encourage the Department to be more specific about what information should be included in said plans and budget. Both prospective new owners of existing facilities and applicants for new facilities should be required to make clear how they will, for example, train and recruit staff, and they should be held accountable if they end up failing to carry out their DOH approved plan.

We do not object to offering applicants an opportunity to cure a defective application. However, we believe the opportunity to cure defects should only be offered once. An applicant should not be allowed to repeatedly amend an application until DOH decides it has demonstrated the ability to successfully operate a facility, as the need for repeated amendments suggests that the applicant is not capable of doing so. The regulations should be explicit that the opportunity for amendment is only available *once* after the initial defective application.

Throughout this section, the Department uses the term "person" to describe applicants for a license. To avoid any confusion about what constitutes a person for the purposes of these regulations, we urge the Department to include the definition provided in the Health Care Facilities Act, found at 35 P.S. § 448.103, directly in the regulations, or, at a minimum reference said definition, such as by saying that the term "person" has the same definition as provided by the Act.

Finally, we note with concern that this section does not include any public notice or public comment process around new facility or change of ownership licensure applications. We feel this is imperative that the Department undertake a meaningful public notice and comment process

related to new facility applications or applications for change of ownership. The Department must include a public notice and comment process. 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. Giving public notice and taking public comment on applications is not so dissimilar to the public notice and comment process that was required under the certificate of need system the Department once operated. We urge the Department to:

- Publish a notice of the applicant's intent to open or change operators of a nursing facility on the Department's website, with details of the public comment process.
- Require applicants to notify the 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, considering the comments in its decision whether to approve or deny a license, which may include taking action to investigate any issues raised in public comments.

Section 201.12a Evaluation of Application for License of a New Facility or Change in Ownership: We agree the Department should indicate in the regulations how it plans to evaluate an application for licensure or a change in ownership. It is important that applicants know and understand the criteria on which their applications will be assessed. When assessing applications, we would encourage DOH to give the most weight to whether applicants have demonstrated "evidence of consistent performance in delivering quality care[,]" and make the importance of this factor apparent in the regulation.

In addition, we feel the regulations must explicitly indicate what types of events or findings in the Department's review of an applicant's past performance owning or operating a facility, capacity to operate a facility, or regulatory compliance would result in their application being denied. We agree with the suggestions put forth by CARIE and urge the Department to add the specified events and findings to the regulation.

Section 201.13 Issuance of License for a New Facility or Change in Ownership

§ 201.13(b): We agree that extensive inspections prior to the opening of a new facility do not provide the Department with much useful information. However, there should be inspections of the building itself to ensure that it is physically accessible to residents, staff, and visitors with disabilities and that the space complies with the ADA. Given that many nursing home residents have physical disabilities and use assistive devices to ambulate, it is vital that the building be fully accessible. The regulations should provide for an inspection of the physical space prior to the opening of a new facility.

We do believe, however, that brand new licensees and change of ownership new licensure warrants 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 that the Department can confirm substantial compliance with requirements that could not be measured before the licensee was operating the facility. The regulations should establish such an inspection.

§ 201.13(f): DRP does not support the Department's proposed elimination of the discussion of provisional licenses. We agree applicants who wish to open new facilities should not be granted a license if they fail to comply with the requirements put forth in these regulations. However, we do agree that applicants who are seeking a license pursuant to a change in ownership should be given a provisional license if there are non-compliance issues that existed prior to the change in ownership. This gives the new owners time to fix things. Provisional licensure should be temporary, and there should be a short amount of time to make improvements.

Additionally, 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. It also ensures that facilities understand the consequences of non-compliance and the

enforcement action steps which the Department may take. It is also helpful for 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.

Section 201.13a License Renewal

§ 201.13a(a): We believe the Department needs to specify a timeframe for when owners must apply for licensure renewal. It should be clearly stated that the renewal timeframe is: 1) annually for full licenses and 2) at the end of the term of the provisional license (which cannot exceed 6 months) for facilities under a provisional license. Licenses should be renewed annually, as this allows the Department the opportunity to conduct regular oversight. Facilities operating pursuant to a provisional license should be required to seek renewal within 6 months to ensure that issues have been resolved related to the provisional license.

§ 201.13a(b): This section requires facilities to be in “substantial compliance” with the regulations and 35 P.S. § 448.808 in order for their license to be renewed. This is a very subjective standard. More specifics are needed here, so that it is clear what standards a facility and its owners will be required to meet before their license will be renewed. In addition, if only “substantial compliance” is needed for renewal of full license, what is required for renewal of a provisional license? This information and clarifications are important so that residents, families, and stakeholders understand what standards are being applied for license renewal.

Section 201.14 Responsibility of Licensee

§ 201.14(d): 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.

§ 201.14(i): We support requiring facilities to keep inspection reports on file and providing them to parties who request to see them. This increases transparency and helps consumers and their families to make better informed decisions when looking for a long-term care facility, particularly for families and individuals who may not have internet access to review information on the CMS site.

§ 201.14(j): We are pleased the Department has required nursing homes to conduct facility assessments quarterly. 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. 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 quality assurance component.

Finally, we offer a general comment for Responsibilities of Licensee, and request that the Department require Consolidated Financial Reports of Licensees. Recently, there has been intense scrutiny of the financial relationships and transparency related to nursing homes. Recently, the advocacy community in Pennsylvania held trainings related to private equity in the Nursing Home industry. It was apparent from the expert panelists at these events that nursing home ownership and financial transparency are critically important to ensuring that public funds are used appropriately and the safety of nursing home residents protected. To that end, 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. Such financial reports should be reviewed by a certified public accountant or audited.

Therefore, we recommend requiring submission 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. We propose recommended language in our attached mark-up of the regulations.

Section 201.22 Surveillance of Tuberculosis (TB): The Department must add a corresponding section of the regulations which addresses pandemics or outbreaks, such as COVID-19. Unfortunately, we can expect similar viral outbreaks in the future, and facilities must be prepared to handle them. By establishing requirements related to infection control, the Department would help ensure that facilities are ready for the next pandemic.

The proposed regulations need to be revised to include a section that mirrors the specific TB 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 home is required to follow all currently applicable state and federal regulations and protocols. We suggest that the Department adopt the following language:

201.22a. Prevention, Control and Surveillance of Pandemic-Prone Infectious Diseases

(a) The facility shall have a written Pandemic-Prone Infectious Disease infection control plan with established protocols which address risk assessment and management, screening and surveillance methods, identification, evaluation, and treatment of residents and employees who have a possible Pandemic-Prone infection or active case of a Pandemic-Prone infectious disease and

report to the Department upon experiencing impediments to implementation of the infection control plan.

(b) Recommendations of the Centers for Disease Control (CDC) and United States Department of Health and Human Services (HHS) shall be followed in treating and managing persons with confirmed or suspected Pandemic-Prone Infectious Disease.

(c) A baseline Pandemic-Prone Infectious Disease status shall be obtained on all residents and employees in the facility.

(d) A CDC approved or recommended test is to be used whenever Pandemic-Prone Infectious Disease testing is done.

(e) A written report of test results shall be maintained in the facility for each individual, irrespective of where the test is performed.

(f) Pandemic-Prone Infectious Disease “negative” employees shall have repeat Pandemic-Prone Infectious Disease tests at intervals determined by the risk of transmission in the community and facility. The CDC protocol for conducting a Pandemic-Prone Infectious Disease risk assessment in a health care facility shall be used to establish the risk of transmission.

(g) Repeat Pandemic-Prone Infectious Disease tests shall be required for Pandemic-Prone Infectious Disease-negative employees and residents after any suspected exposure to a documented case of active Pandemic-Prone Infectious Disease.

(h) New employees shall have a Pandemic-Prone Infectious Disease test before beginning employment. Test results shall be made available prior to assumption of job responsibilities. CDC guidelines shall be followed with regard to repeat periodic testing of all employees.

(i) The Pandemic-Prone Infectious Disease test shall be administered to new residents upon admission.

(j) A resident with a diagnosis of Pandemic-Prone Infectious Disease may be admitted to the facility if:

(1) The facility has a DOH approved plan for safely isolating the new resident who is infected, including plans for co-horting staff and residents to prevent cross-contamination.

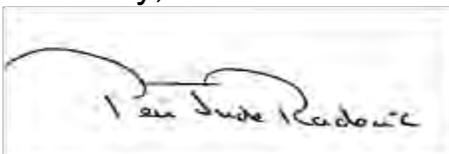
(k) In the response to any outbreak of any infectious virus or disease, the facility shall follow the recommendations, requirements, and guidance of the CDC, HHS, and the Department in treating and managing persons with confirmed or suspected cases of the virus or disease.

(l) The facility must undertake evidence-based best practices for infection prevention, detection, control, and surveillance. These must be outlined in their Emergency, Pandemic, and Disaster Preparedness Plan, as outlined in Section 209.7.

Section 211.1 Reportable Diseases: We believe the Department must clarify the obligation of facilities to report Pandemic-Prone Infectious Diseases, such as COVID-19, to the Department and other relevant agencies. A subsection should be added to this part requiring facilities to report diseases at the Department's direction in the manner, frequency, and format required by the Department.

We thank you for consideration of our concerns and suggestions. Please contact Jennifer Garman, Director of Government Affairs at 717-236-8110 ext. 327 with questions.

Sincerely,

A rectangular box containing a handwritten signature in black ink. The signature appears to read "Peri Jude Radecic".

Peri Jude Radecic
Chief Executive Officer