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Submitted by e-mail to: [RA-DHLTCRegs@pa.gov](mailto:RA-DHLTCRegs@pa.gov); [irrc@irrc.state.pa.us](mailto:irrc@irrc.state.pa.us)

Ann Chronister  
Director, Bureau of Long-Term Care Programs  
PA Department of Health  
625 Forster Street, Room 814  
Health and Welfare Building  
Harrisburg, PA 17120

October 24, 2022

Dear Ms. Chronister:

LeadingAge PA, an association representing more than 370 mission-driven providers of senior services, appreciates the opportunity to offer comments on Final Form Rulemaking 10-223 (Long-Term Care Facilities, Rulemaking 3) found on the Independent Regulatory Review Commission (IRRC) [website](http://www.Irrc.state.pa.us).

We begin by thanking the Department of Health (DOH) for responding to our suggestions on several items in this regulatory package, however, we must note that additional changes are needed. In addition, we agree with the Department that efficiency and consistency of inspections can be improved with the consistent adoption and application of Federal requirements, and we look forward to continuing to work with DOH to assure that providers and surveyors are “on the same page” regarding compliance with the regulations.

We appreciate that several requirements that have needed updates have been addressed, such as:

- The addition in 201.14(h) that DOH will provide advance notice of new reporting requirements, except in instances of an emergency.
- Language in 201.15(b)(1) regarding license term expiration, making an exception to the expiration if it is due to a departmental delay, a federal emergency or state disaster emergency.
- Changes to Section 201.22, Prevention, control, and surveillance of tuberculosis, to update procedures to align with the recommendations of the Centers for Disease Control and Prevention (CDC).

Nonetheless, we continue to have serious concerns about the following changes, and LeadingAge PA vehemently requests that DOH withdraw this Final Form Rulemaking to make the appropriate revisions.

**Added requirement for full compliance with section 808 for license renewal without opportunity for clarification is concerning.** In the section on license renewal (201.13c(D)), we are concerned about the change from substantial to full compliance with section 808 of the Health Care Facilities Act. It is concerning that this change was made without the opportunity to provide comment or receive clarification of what will be required.

**Additional required documentation for CHOW submission must be coupled with timely review by DOH.**

LeadingAge PA understands and supports the desire of the DOH to improve the efficacy of their review of requests for changes of ownership (CHOW). We understand that this may require additional documentation, but we must continue to suggest that timelines and protections be included to assure both selling and purchasing facilities of prompt attention to their submissions. The timeliness of DOH's decisions is critical to preventing closures of nursing facilities that are under significant stress and ensuring that residents receive the best care possible during what is hoped to be a speedy and efficient transition to new ownership. With this additional documentation, we hope DOH will feel they are equipped to limit sales of facilities to providers with poor records of care but also recognize that additional documentation is not enough. DOH must act to deny acquisitions by providers with poor records. We would respectfully request that DOH not only outline the criteria it will use to evaluate CHOWs but also be explicitly committed to providing timely decisions.

LeadingAge PA had initially suggested that applications for CHOW be published in the *Pennsylvania Bulletin* with a brief comment period like the DOH regulatory exception process. However, upon further consideration, we are seriously concerned that a poorly timed public announcement could move the focus of operations away from resident care and potentially cause an exodus of staff. After further discussion and consideration, LeadingAge PA would respectfully request that the nursing facility administration be allowed to determine the timing and methods for notifying residents, staff, and the community rather than leave this important action to a concurrent notice requirement by DOH. We continue to agree that transparency is necessary and desirable, but given the stressful situation, it is best to leave the notification timing and particulars to the nursing facility so that they can continue to provide uninterrupted care for residents as they work through the process of the CHOW. Finally, LeadingAge PA would continue our request that DOH's acquisition of documentation for a CHOW not be unlimited, and therefore continue to request that section 201.12(11) be changed from "Any additional information the Department may require" to reflect that the information be reasonably related to the review of the applicant's history related to the finance and operation of facilities or other human service endeavors.

DOH has stated their intent to maintain resident safety as the reason for pursuit of additional documentation review in advance of a CHOW, but to preserve resident safety, it is imperative that this process of review by DOH be completed in a timely manner. We sincerely appreciate the Commonwealth's increase to Medical Assistance rates in the last budget, but facilities serving Medical Assistance residents continue to be underfunded by the state's program and in financial peril. The decision to seek new ownership for a facility is rarely taken lightly. Therefore, it is incumbent upon DOH to impose timeliness standards for document request, review, and decision. LeadingAge PA requested but DOH has not yet provided reasonable timelines for its review of CHOWs. This lack of timelines for DOH concerns us because the potential for delays in review by DOH is very high, with negative consequences to the facilities involved. Additionally, the number and complexity of CHOWs continues to increase, which may further delay decisions by DOH. We propose that DOH complete an initial review of the selling facility for stability and resident wellbeing within 5 days of receipt of application for CHOW. A temporary determination should then be rendered to the *selling* facility within 10 business days of original CHOW application submission. Full document submission by the *purchasing* facility must be completed within 10 days of the original CHOW application, and DOH must request any additional documentation within 15 business days of the original application. A final determination should be offered to both the selling and purchasing facility by DOH within 30 days of the original application submission.

The regulated community sees significant increased burdens in this section relating to document submission, yet the process for review and approval or denial remains obscured. While we appreciate that DOH requires some flexibility for making determinations, we fear these additional requirements may not result in meaningful CHOW denials, where warranted, and will simply add to the paperwork burden on the facilities involved. We strongly urge DOH to establish and communicate the parameters for which denials of CHOWs may occur. In addition, to improve clarity, LeadingAge PA would request that DOH discuss what happens when a CHOW is in process on the effective date of the regulation.

**Consideration of Continuing Care Retirement Communities (CCRCs) in newly required annual audit submissions for license renewal.** Section 201.13c, License Renewal in the final form regulations would newly require that a facility must submit audited annual financial reports with its application form for license renewal. As this proposal was not yet discussed with the regulated community, LeadingAge PA would respectfully request that DOH consider CCRCs that may have a combined audited annual financial report and not require these entities to separate out the nursing facility, since that would be an administrative and cost burden to complete each time the license is renewed.

**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.** LeadingAge PA was disappointed that DOH did not remove its proposal that facilities complete three additional facility assessments each year. Requiring additional facility assessments is an undue burden on an industry already desperate to hire additional staff. Especially considering the minimum staffing requirements included in the final form regulations, and the current Federal requirement for an annual facility assessment, it is difficult to comprehend how quarterly assessments will contribute to quality and improve care of nursing home residents. In response to commentator questions regarding what evidence there is that additional facility assessments would improve resident care, DOH offered that quarterly assessments would be used to determine what resources are needed to care for residents, provide a timely indication of any system problems at a facility and assist with identifying areas for improvement. Analyzing the resident population every quarter is intended to provide a snapshot as to the overall conditions of the residents at that time, including the most common diseases, conditions, and diagnoses during that time period, and if the facility has the appropriate staff and equipment to take care of those residents, particularly if a trend is found among those residents. However, LeadingAge PA respectfully reminds DOH that several timely indicators are already available to provide this information, including the Payroll Based Journal for staffing information (updated quarterly), the Quality Measures that provide information on a range of resident conditions and experiences (updated quarterly for the public), DOH's own required incident reporting for selected incidents and diseases (reported immediately), and the Federal requirement that facilities have a quality assurance/performance improvement (QAPI) program.

LeadingAge PA respectfully requests that DOH offer an honest assessment of the time, energy and commitment required to complete and utilize a facility assessment, especially since the Centers for Medicare and Medicaid Services (CMS), recognizing the administrative burden of the assessment and noting that the characteristics of the facility reviewed in a facility assessment rarely change, only requires that it be conducted annually unless significant changes are made. LeadingAge PA requests deletion of the quarterly facility assessment from the regulatory package unless DOH can produce empirical evidence that more frequent completion of facility assessments results in improved quality outcomes.

**DOH's review of the fiscal impact on facilities lacks effort and meaningful analysis of costs on the regulated**

**community and ignores the potential impacts on the three license-only nursing facilities, small businesses and the elderly.** Additional documentation submission for acquiring facilities coupled with increased staffing burdens for completion of quarterly facility assessments will have associated costs for facilities. The department's analysis of "nominal fiscal impact due to the increase in required frequency" appears to indicate that DOH is not serious about its requirement to identify the costs of its proposal to the regulated community. Simply bringing required information together does not include a comprehensive review of documents to assure proper care, services, and policies are in place to assure resident and staff safety. The CHOW documentation requirements appear to be extensive. Even if the facility already has these documents, compiling them will likely take more than the few hours DOH seems to think are needed. Additionally, these requirements come at a time when all or nearly all nursing facilities in our membership are limiting admissions because of an inability to find, recruit, hire, and retain adequate staff.

The Regulatory Review Act requires a statement of the paperwork/forms required. Just because DOH is not requiring a specific form for the facility assessment or the CHOWs does not mean that it is not additional reporting, recordkeeping, or other paperwork that will be required for implementation of the regulation. Additionally, the DOH did not explain any measures which have been taken to minimize these requirements.

In the Regulatory Analysis Form, item 23 lists costs to the regulated community and the agency. While DOH provided estimated costs for itself to review the CHOWs, it does not appear to recognize there will be added costs to the regulated community. While there is a recurring reference to the cost per facility estimate based on nominal review of information provided by the Department of Military and Veterans' Affairs, the analysis is incomplete.

LeadingAge PA thanks the Department for now recognizing that most nursing facilities are small businesses, however, there has still been a failure to address the implications of these changes on small business providers in a meaningful way. We continue to be concerned about the financial impacts the final form regulations will likely have on all nursing facilities, but particularly those that are small businesses - and this is true of each of the nursing facility regulatory packages DOH has submitted. Instead of attempting to estimate the regulatory burden on any of the regulated community, much less attempt to discern its impact on the many nursing homes that are considered small businesses, DOH asserts that it does not need to consider the impact since almost all nursing facilities are small businesses. In addition, since at least two of the license-only homes are small businesses, continuing to ignore the significant impact on these homes seems to be a serious omission of required information. Although DOH states that it asked about financial impacts and specifically financial impacts on small businesses at a stakeholder meeting, the calculation of the increased costs is not something a provider can offer without analysis, which is likely why the department did not receive immediate response to the question at a meeting. In addition, it would have been difficult to estimate the costs before the final regulatory package was known.

Further, the Regulatory Review Act requires DOH to provide a description of any special provisions which have been developed to meet the particular needs of affected groups and persons, including minorities, the elderly, small businesses, and farmers. The DOH has not addressed the potential access issues the final form regulations may have on elderly persons who need nursing facility care. LeadingAge PA appreciates the actions by the administration and General Assembly to increase the Medical Assistance rates in conjunction with the proposal to increase staffing requirements, however, it will be important to continue to review whether the new regulations will compound existing business challenges and to make adjustments quickly to

address access issues. LeadingAge PA also reminds DOH and the administration of the need for additional commensurate Medical Assistance (MA) funding to meet the year two staffing increases reflected in Package 4.

Finally, the significant changes that would be required of the three private pay facilities are not taken into account by DOH, nor does DOH provide any compelling reason to require changes of these facilities. In the Regulatory Analysis Form (RAF), DOH touts that there have been expanded requirements for emergency preparedness, quality assurance and infection control, abuse, neglect and exploitation protections, and admission and discharge protections to ensure the health and safety of residents, noting that these three facilities had a reported, combined census of 79 residents for the Department's 2020-2021 annual report. DOH states that it believes, pertinent to this rulemaking, that residents, and their family members, will benefit from the adoption of the Federal requirements for infection prevention and control and fire safety and emergency preparedness. LeadingAge PA notes that DOH provides no data or analysis to back up its claim that requiring these three facilities to adopt the Federal requirements rather than continuing to address the health and safety of residents in a way that meets resident needs and preferences will positively affect the resident. It also offers no compelling issue to be addressed by requiring these three facilities to comply with the Federal requirement. These homes have exemplary records of compliance with DOH requirements and have been selected by residents for their unique ability to offer person-centered care not focused on documentation for Federal reimbursement. DOH states, and we agree, that for the most part, "...the regulated community will benefit from the efficiency of the consistent adoption and application of the Federal requirements for health and safety at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities)...", but this anticipated efficiency does not justify upending the lives of the residents of these three homes.

**Release of regulatory package in sections lacks reasonableness, transparency, and clarity.** Despite requests by LeadingAge PA and other stakeholders, DOH has continued along the path of releasing the final form regulations in four separate regulatory packages to update nursing facility regulations. This process has created an excessive burden on stakeholders and especially the regulated community to piece together various related aspects of the regulations that are contained over several regulatory packages. Further, many changes were made between proposed and final form, which stakeholders have not had the opportunity to review or discuss until publication of the final form, which does not offer adequate ability to make changes where needed. The department is to be commended for listening to stakeholder input and adding some of the suggested changes, but stakeholders are faced with commenting *during the final form stage of the rulemaking* to definitions and significant sections of the regulations that are newly stated in the final form regulations. As we stated before, without view of the comprehensive package in advance of final form, neither the regulated community nor the public could assess the full scope of changes promulgated as final, nor do we have the ability we should have to request changes that would improve the regulations. Finally, moving the regulations through the process separately with each package requiring individual approval by the Independent Regulatory Review Commission and oversight committees in the General Assembly could result in incongruous or partial enactment and confusion that will not further DOH's stated goals of improving the quality of care. LeadingAge PA would respectfully request that it would be reasonable and in the public interest for DOH to withdraw the regulatory packages and combine them into one coherent whole before enacting as final form.

The Nursing Home Taskforce previously met on a number of occasions and worked extensively with DOH and the administration towards common ground and viable regulatory changes, however the proposed regulations have been issued without further consultation of the Taskforce despite repeated requests by many of the participants. We note that DOH has disregarded our repeated requests to reconvene the

Nursing Home Task Force to discuss the proposed or final form regulatory packages in pieces or once complete. We continue to recommend that DOH convene the Nursing Home Task Force even though it is too late to offer input into the regulations, recognizing that it would be useful as a sounding board to discuss interpretive guidelines when clarification is needed, how public/private partnerships could help to elevate long-term care in the future, how DOH can assist nursing homes in complying with the regulations, and offering advice on potential avenues to address the workforce crisis.

LeadingAge PA appreciates that DOH has, in response to our concerns and those of other commenters, changed the immediate effective date of the proposed regulations to allow until July 1, 2023 for most of the required changes. This change, while appreciated, still provides a challenging timeframe for most facilities to comply. More time to reach compliance would be appreciated. If this cannot be provided given where we are in the regulatory process, an educational and flexible approach to survey and citations will be needed as the regulated community learns what is required and how to achieve it. Compliance with new regulations takes time to become aware of the required changes and will require planning to initiate the staffing and budget changes to achieve compliance. We request that the three license-only homes be exempted from changes in the final form regulations. If they are not exempted, it is unreasonable to assume that these facilities will be able to implement significant changes in adapting to federal regulations with which they need not currently comply, so it would be necessary to provide them with additional time beyond July 1, 2023 to learn the many new processes and requirements.

LeadingAge PA appreciates the opportunity to offer comments on the final form regulations and we look forward to working with the department as facilities strive to understand and implement the regulations. The members and staff of LeadingAge PA are always ready to assist you with any issues or questions relating to caring for our seniors. We look forward to working with you so the Commonwealth's seniors have quality long-term care services and supports should they be needed.

Please feel free to contact me if you have any questions regarding these comments or if we can be a resource to the department.

Sincerely,

A handwritten signature in black ink, appearing to read 'G. Pezzano', with a stylized, flowing script.

Garry Pezzano  
President and CEO, LeadingAge PA  
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