1100 Bent Creek Boulevard, Mechanicsburg, PA 17050
O: 717-763-5724 | F: 717-763-1057 | www.LeadingAgePA.org

Submitted by e-mail to: RA-DHLTCRegs@pa.gov; 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 10-221 (Long-Term Care Facilities, Rulemaking 1), listed on the Independent Regulatory Review Commission (IRRC) website as IRRC # 3312.

We begin by thanking the Department of Health (DOH) for responding to our suggestions on several items in this regulatory package, but we must also reiterate some remaining significant concerns with this regulation. Our comments on the final form again fall into two categories: process issues and operational issues.

Initially, we must put our comments into context, first addressing the environment that surrounds the proposed regulations: a pandemic, a workforce crisis and the extremely difficult financial conditions that have many high-quality nursing homes contemplating or already taking action towards reducing the numbers of residents they serve or total closure of their building. The proposed regulations have been released at a time when nursing home providers continue to battle a once-in-a-century pandemic during the midst of the most critical workforce shortage they have ever seen. Nursing facilities have been doing the best they can to protect their residents and staff under previously unimaginable conditions. Further, we are grateful that the budget this year finally offered a rate increase in the Medical Assistance (MA) Program after nearly a decade without a rate increase during which providers have been challenged to finance their operations on an increasingly thin shoestring. However, despite their mission-driven commitment to provide high quality care and services to seniors, they are tired, underfunded, and discouraged.

LeadingAge PA appreciates that DOH has heard the distress of providers, who, with hundreds of vacant staff positions open and no takers, were extremely concerned about the Department of Health's (DOH's) proposal to increase the minimum staffing requirements by 50%; a demand which would have been impossible for many facilities to meet. We will discuss the updated final form staffing requirements in regulatory package #4, where they have been moved in the final form regulations. While we outline our concerns in detail below, we continue to urge DOH to look at the context of the environment, consider the significance of the changes we are now discussing at the final form part of the process, and consider withdrawing these changes to the regulations until after the pandemic has subsided and commentators have had a fair chance to review, discuss, and respond to the comprehensive set of proposed changes.

Process Concerns:

For LeadingAge PA, the final form regulations raise multiple concerns, not the least of which relate to process for the regulatory package, and which are outlined in more detail below:

- The regulatory package is divided into four sections and stakeholders have only now had the opportunity to review the packages as a whole. LeadingAge PA would respectfully request the DOH withdraw the four regulatory packages and resubmit as one complete package, with a public comment period.
- The final form packages incorporate significant new definitions, language, and concepts for which stakeholders have not had the opportunity to evaluate or provide input. In addition, DOH has rephrased or added back sections that were deleted in the proposed rules that commentators may have desired to comment on had they known the section would be added back into the final form.
- LeadingAge PA appreciates that DOH has spelled out the State Operations Manual (SOM) guidance it intends to use in state regulations, rather than incorporating by reference the entire 162-page Chapter 7 of the State Operations Manual (SOM) and the 702-page Appendix PP as was proposed, which made it difficult to anticipate and comment on which sections DOH intended to include specifically. However, LeadingAge PA recommends that DOH remove the SOM language from the final form regulations altogether because it was difficult for the regulated community to discern which specific elements of the SOM to comment on during the proposed stage, and because, in S&C Letter 08-10, the Centers for Medicare and Medicaid Services (CMS) makes it clear that these guidances or interpretations are only to be referenced by surveyors to assist them with the survey process, and that they are not statutory or regulatory in nature. We ask that the language from the SOM be removed from the regulations. One example is found in Rulemaking 2, where guidance from the SOM is incorporated into final form regulations regarding closure of a facility.
- LeadingAge PA appreciates that DOH has moved the overall implementation timeline back to July 1, 2023, recognizing that the proposed changes would require significant planning, budgeting, and hiring decisions on the part of the regulated community. However, LeadingAge PA requests that DOH provide an additional 6 months for nursing facilities to study the regulations, identify changes that must be made, plan, budget, change policies and procedures, and hire staff to comply with the new regulations. Moving the effective date to allow an additional six months would allow nursing facilities a more appropriate amount of time to prepare and come into compliance. If DOH is not able to change the effective date in the regulations, we would respectfully request that at least during the first year of implementation for each phase of the regulation, the focus be on education and technical assistance rather than on sanctions for noncompliance with the new requirements, as providers and surveyors learn the new regulations and make the myriad changes that will be required.
- DOH states in its commentary that the incorporation of Federal requirements at Title 28, section 201.2 allow the Department to continue to cite Federal noncompliance with both state and Federal sanctions. At our request, DOH did remove one of the sections that allowed duplicative sanctions for the same incident of noncompliance, but the issue continues due to the language in 201.2. LeadingAge PA views citing both state and Federal sanctions for the same infraction to be duplicative, unnecessary, and overly punitive. We recognize that DOH has been doing this for some time, but it is not conducive to improving resident care and, if monetary penalties are applied, takes much-needed resources away from resident care. We would respectfully request that DOH discontinue this practice and cite only for either the state or the Federal requirement when the requirements are duplicative.

- DOH's cost burden calculations on nursing homes continue to be incomplete, except for the direct costs to the Medical Assistance (MA) Program. LeadingAge PA appreciates the addition of MA cost information and the inclusion of some estimate of employee benefits to the cost calculation for additional staffing requirements. Further, LeadingAge PA appreciates the collaborative process with stakeholders, the Administration, and the General Assembly that led to finally increasing the MA rates for nursing facilities. The cost estimates, however, continue to underestimate the costs to hire and train new staff, pay increases that will likely be needed for current staff as new staff are added, and most importantly, the cost increases to private pay residents. In addition, the costs to the Department of Human Services are underestimated because private pay residents will more quickly spend down to MA as the nursing facility will have little choice but to pass along the costs to implement the new requirements to these residents.

Release of Regulatory Package in Sections Lacks Transparency and Clarity. This final form rule is the first in a series of four related rulemaking packages that DOH expects will eventually update the current nursing facility regulations. This first set of regulations changes definitions that are to be used in the other three regulatory packages, which the public was not able to review at the same time during the proposed stage. Changes have been made to definitions as well as the sections in which some definitions are used, but the regulated community is only now able to comment on the interplay of the definitions and the sections of regulations to which they apply.

The entire existing state regulations under review relating to nursing facility providers are 48 pages in total, including the interpretive guidelines. These are no more cumbersome than many other regulations that have moved forward in a complete package so that stakeholders can reasonably review and comment on the complete regulatory package. Dividing the regulatory package in this way lacks clarity and does not allow the regulated community or the general public a fair opportunity to review the regulations and provide comment until now, when the regulations are in final form.

Definition Changes Should Have Received More Opportunity for Input and Discussion. Any term newly defined in Rulemaking 1 was not able to be fairly assessed by the impacted community without seeing simultaneously any instance of its application in the other three packages. It would be impossible to determine what a new definition truly meant until a later rulemaking was issued. Further, definitions are now included in Final Form that are different or entirely new compared to the Proposed Regulation, including, for example, the new definition of *Full compliance,* which means total compliance. Since licenses are issued and sanctions are calculated based on this terminology, it would have been important to discuss this with stakeholders to determine if there are important implications for this definition. LeadingAge PA encourages DOH to invite discussion on new definitions and provisions as the regulations are implemented so that unanticipated issues can be addressed promptly.

The term *Sexual abuse* appears to have inadvertently omitted the term "sexual" from the Federal definition. It should be defined as "non-consensual SEXUAL contact of any type with a resident, including sexual harassment, sexual coercion or sexual assault." We would encourage DOH to correct this oversight.

The term *Substantial compliance* is used for important actions such as issuing a license. The new definition included in the final form rulemaking is based on the definition from the hospital setting (28 Pa. Code section 101.92(b)) and was not in the proposed rulemaking and therefore the regulated community had no opportunity to discuss its merits. LeadingAge PA does not have an issue with the definition at this time but is concerned that such an important definition would be introduced in the final form and would request that DOH be ready to hold discussions with stakeholders and make any necessary changes if issues or unintended consequences arise.

A new definition of *Construction Alteration or Renovation* was issued with little opportunity for stakeholders to discuss it with DOH. We note also that the definition of *Alteration* is removed, and a new definition of *Construction, alteration or renovation* has been added to the final form. The new definition, while used in Title 28, Chapter 51, is not defined. The new definition does not appear to reflect the prior definition of *Alteration*. As the new definitions are used, it will be important to address unforeseen issues, especially since the regulated community has had no opportunity to comment or discuss the new definitions and their implications.

Regulations Should Not Duplicate Federal Sanctions. The regulations propose to apply both state and Federal violations and sanctions to the same incidence of noncompliance. This proposal is duplicative, unnecessary, and overly punitive. Considerable doubt remains whether financial penalties are the most effective method of improving compliance for most facilities. This practice often causes more harm than good by taking resources from struggling facilities that could otherwise use those funds to hire additional staff or improve resident care in other ways. LeadingAge PA requests that DOH apply State sanctions to state-only infractions rather than adding to the punishment inflicted by the significant Federal Civil Monetary Penalty sanctions. Federal fines are already very expensive without exhibited results of improving quality.

LeadingAge PA would further request that DOH consider education, information, training, and interpretive guidance to encourage compliance. These supports are more effective than sanctions and do not impose financial hardship on a nursing facility that is struggling to comply. LeadingAge PA commends DOH for a program it began planning prior to the pandemic to share promising practices. LeadingAge PA would encourage DOH to reenergize such educational and collaborative efforts to assess their effectiveness before determining that simply duplicating Federal sanctions will hold the key to compliance which still may have no positive effect on resident care quality.

Rulemaking Shows Lack of Concern for the Three License-Only Facilities and their Residents. We are concerned that DOH has chosen to require all PA nursing homes to comply with the Federal requirements for nursing homes certified to receive Medicare or Medicaid. DOH dismisses concerns about the overwhelming nature of these Federal regulations by saying it believes it will be better for the residents and that there are only three such facilities in the Commonwealth. DOH neglected to consider that the residents in these facilities are paying privately for their care and have selected these nursing homes specifically for the services they offer. Two of these are small businesses by any definition: one of the three license-only Pennsylvania nursing facilities (NFs) referenced by DOH is a 30-bed nursing home, another is a 20-bed home. DOH should instead be concerned that these facilities may close their doors rather than change their entire program to meet the voluminous Federal regulations and guidance that they simply cannot comply with for a number of technical reasons including systems access to Federal data sharing portals. We appreciate that DOH has recognized in this final form regulation that there are Federal requirements such as completion of Minimum Data Sets (MDSs) that are not available to facilities that aren't Medicare and Medicaid certified and in the final form has exempted these facilities from completing the MDS, however, these facilities should at least be exempted from the additional Federal requirements, especially those related to reimbursement, that are proposed in this series of updates to DOH's nursing facility rules.

Operational Concerns:

This initial package of the four final form regulations proposed by DOH raises a number of operational concerns for the regulated community and our Commonwealth's public. There are areas of overlap with our process concerns, which we will mention in passing. Our operational concerns include:

- DOH continues to include new Federal requirements for the license-only homes. There has been no indication of a systemic problem with these homes and DOH has not otherwise justified why these homes should be included in Federal requirements of participation for Medicare and Medicaid when these homes do not accept reimbursement from these sources.

- DOH has missed an opportunity to expand the definition of direct care staff to align with the Federal definition and to recognize these staff contributions in the NHPPD minimum thresholds. The definition of included staff should be altered to include all staff providing resident care, not simply clinical care. Resident wellbeing is a function of adequate clinical care coupled with exceptional person-centered programming like music and occupational therapies, games and activities, and meal experiences.
- The proposed regulation does not allow for innovation or for career advancement, another missed opportunity to attract and retain caring workers who need and want to advance within their long-term care profession, rather than out of it due to lack of opportunities. LeadingAge PA encourages DOH to work collaboratively with LeadingAge PA and other stakeholders, such as other state agencies, to encourage and support initiatives to increase the long-term care workforce.

The following are discussions of the issues highlighted above and a detailed list of issues and concerns with Rulemaking 1.

DOH Should Exempt the License-Only Homes from Rulemaking 1-4. While we agree with DOH that the regulated community will generally 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), it is not tenable that the interests of bureaucratic efficiency would be placed before the needs and preferences of residents of the three private pay facilities. The residents of these homes have strongly indicated their preference for patient-centered care, even to the point of foregoing their Medicare benefits to select a nursing home that provides care in the way they prefer. DOH should recognize the interests of the residents of these homes and exempt them from having to comply with any additional Federal regulations that are incorporated by reference in the final form regulations. Further, the implication that these homes may not have updated their practices since 1998 is incorrect. These homes have chosen to deliver care in a way that is responsive to resident needs and preferences, establishing practices that focus staff time on resident care rather than on compliance with the stacks of documentation and paperwork required to comply with reimbursement regulations that dictate so much of the way care is delivered for homes that accept Medicare and Medicaid. Finally, there has been no indication of any systemic problem in these homes that additional regulations would address. Even DOH states, in its discussion of the fiscal impact to these communities, that "…based on the Department's experience with facilities' compliance with existing regulatory requirements, these facilities already comply with various provisions, such as infection prevention and control measures, emergency preparedness and planning, food service safety, and homelike environment requirements. Therefore, it is unlikely that the facilities would reach the maximum estimated costs." Of what benefit is it to residents of these facilities that the administration now be required to provide documentation of compliance? It is not in the public interest to force these homes to comply with Federal regulations that are irrelevant to their programs and residents. These homes should be exempt from complying with additional Federal requirements imposed through this update to our state regulations.

The Definition of Staff Should Include All Staff Providing Resident Care: A more appropriate model would be to adopt the CMS definition of direct care staff that can be counted toward minimum staffing thresholds. Nursing staff are not the only individuals that provide care and services to nursing facility residents. Adopting the following definition of Direct Care from Federal regulation 42 CFR 483.70 would encompass the full scope of staff providing meaningful care to residents and would be more in tune with true quality improvement: "Direct Care Staff are those individuals who, through interpersonal contact with residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Direct care staff does not include individuals

whose primary duty is maintaining the physical environment of the long-term care facility (for example, housekeeping)." We believe it was a missed opportunity to recognize the holistic nature of addressing the requirement in 42 CFR 483.24 that "…each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident's comprehensive assessment and plan of care."

The Proposed Regulation Does Not Allow for Innovation or for Career Advancement: As we stated in our 2018 comments on staffing to the DOH long-term care workgroup, we believe in a multifaceted approach to identify and recruit staff in more innovative ways, retain and support those who enter the field, address the stigma of working in the field of long-term care, and allow innovative staffing models and new technologies, including substitutions that make sense. This will take collaboration by many agencies and private entities, but it is necessary to develop the workforce we need now and into the future. It takes a special person to provide care and services to older adults; it takes care and compassion and a willingness to listen and continue learning as advances are made in the field of caregiving.

LeadingAge PA continues to strongly recommend that DOH provide more regulatory flexibility in roles and education of direct care workers, who would benefit from career paths such as medication technician. These trained and certified individuals could administer medications for long-term residents with stable conditions. We would recommend that DOH add ix) *Medication technician*, under the definition of *Authorized person to administer medications* in Section 201.3 Definitions. The definition or a separate section in Rulemaking 4 could indicate the training and supervision that would be required, as well as indicating any restrictions on medication administration such as administering only to long-stay residents with stable conditions.

We are disappointed that DOH appears not to have addressed our request as the regulations do not appear to recognize the need for various career paths, nor do they provide the necessary flexibility in the definitions or content of the regulations. To the extent that DOH will allow for innovation in roles, duties, and career advancement for staff, we would be delighted to work with DOH to discuss and establish attractive career ladders and engagement opportunities for nursing home workers to advance in their careers.

Conclusion

In summary, LeadingAge PA remains concerned about the following issues included in Rulemaking 1 (10-221):

- DOH has neglected to accurately calculate the costs of the proposal. The regulations financially burden private pay residents who may not need or want the additional requirements imposed, yet DOH fails to recognize these costs in their calculation.
- It unfairly impacts small businesses, who must now hire and pay new staff and comply with additional paperwork requirements.
- Even with the much-appreciated exceptions for MDS data transmission and the provisions of 42 CFR 483.1 relating to basis and scope, the remaining provisions are likely to have devastating impacts on the three non-certified nursing homes, two of which are quite small and are considered small businesses.
- It appears to have needlessly circumvented reasonable public comment on closely interrelated regulations that have been issued separately.
- It contains significant new material between proposed and final form stages which stakeholders have not had the opportunity to review and obtain needed changes prior to issuance in final form.

LeadingAge PA strongly urges DOH to withdraw this final form regulation and propose a single complete regulatory package that meets the requirements of the Regulatory Review Act.

LeadingAge PA is concerned that this regulation does not serve the public interest given the lack of information provided about the costs of the proposal and the many new concepts, definitions and sections of regulation that were not present during the proposed stage. We are seriously concerned that Rulemaking 1 contained most of the definitions to be used in related regulatory packages that were not introduced until *after the comment period ended* for this section. During the public comment period of the proposed stage, commentators had no idea how a definition would be used later in the yet-to-be proposed rulemakings 2 through 4. We sincerely appreciate that DOH has made some changes based on the comments received, but these changes also inhibit the ability of stakeholders to review the comprehensive set of four rules, as so much of the content is new as well. We cannot stress enough how important it will be, once the regulations are in place, to collaboratively work through the issues that will arise. LeadingAge PA is ready to assist DOH in identifying and understanding unanticipated issues that occur and working together to reach solutions.

We reiterate our recommendation that the Commonwealth, including DOH, use a collaborative approach to encourage more working age people to consider long-term care as a career. Initiatives to attract caring individuals to the long-term care workforce would be in the public interest, and many such initiatives would not require a regulatory process in order to proceed. LeadingAge PA has several workforce initiatives underway and would appreciate the opportunity to work with DOH and other stakeholders to attract new workers into this rewarding field.

The members and staff of LeadingAge PA are always ready to assist you with any issues or questions relating to caring for 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.

Sincerely,

Garry Pezzano
President and CEO, LeadingAge PA
gpezzano@leadingagepa.org