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Lori Gutierrez
Deputy Director - Office of Policy
625 Forster Street, Room 814
Health and Welfare Building
Harrisburg, PA 17120
VIA EMAIL to: RA-DHLTCRegs@pa.gov

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; Chapter 201
Deadline: April 18, 2022

Dear Ms. Gutierrez:

Thank you for the opportunity to comment on the proposed regulations addressing nursing homes that were published in the Pennsylvania Bulletin on March 19, 2022.

Background

My firm, David Hoffman & Associates, PC, is a national consulting firm dedicated to ensuring regulatory and clinical compliance and patient/resident safety and, to that end, has served as a Federal and State Monitor for nursing homes that are under Quality Corporate Integrity Agreements with the HHS-Office of Inspector General and state Attorneys' General Offices. Additionally, the firm consults with long-term care providers to assist them in achieving clinical and regulatory compliance. Prior to starting my firm in 2005, I served as an Assistant United States Attorney for the Eastern District of Pennsylvania and started in 1996 what became the Department of Justice's nursing home failure of care initiative. Before joining the DOJ, I was Chief Counsel for the Pennsylvania Department of Aging and in that role, among other responsibilities, was instrumental in implementing the Older Adults Protective Services Act addressing elder abuse and worked closely with the State's Long-Term Care Ombudsman Program.

I am also a Practice Professor of Law at the Kline School of Law at Drexel University and my colleagues, Barry Furrow, Director of the Health Law Program, Robert Field, Director of the JD-Master of Health Program and Hilary Pearsall, JD & MPH Candidate join me in submitting these comments.

Comments on Section 201.12 Application for license of a new facility or change in ownership

We support expanding this section to 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. Specifically, we recommend:

1. **Public Notice and Comment Process Needed.** This section does not include any public notice or public comment process around new facility or change of ownership licensure applications. We feel it is imperative that the Department undertake a meaningful public notice and comment process related to new facility applications or applications for change of ownership. 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.

   Public notice and obtaining public comment on applications is not so dissimilar to the public notice and comment process that was required under the certificate of need system. 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.

2. **Ownership or control interest description.** We support the Department's language that defines as a person who has or will have ownership or control interest to include: "The organization that holds the license or the land or building occupied and used as the facility." We recommend that the Department also include language that requires the applicant to submit the information for anyone who "is the owner of a whole or part interest in any mortgage, deed or 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, it is unclear as written 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). In order to ensure that all of the entities and individuals who will have an ownership or control interest or who will manage the facility are responsible and capable, we recommend clarification that the information in subsections (b)(6)-(10) should be obtained and evaluated for all of the individuals 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 of the individuals identified in subsections 201.12(b)(1)(i)-(ii), (3) and (5).

3. **Definition of "person".** We note that this section now repeatedly refers only to a "person" applying for licensure instead of an applicant. "Person" is not defined in

Section 201.3 of the regulations and recommend that the Department add this 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.

Comments on Section 201.12a; Evaluation of application for license of a new facility or change in ownership.

1. **Criteria for approving or denying applications.** We support the Department's addition of this section. We believe it is important for applicants to 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 to consumers and the public to know the standards to which nursing homes are held.

   Additionally, it is imperative that the regulations include some reasonable factors that warrant automatic exclusion from licensure. Several of these factors, while not all inclusive, should be clearly stated in regulation thereby providing notice to applicants and the public. For this reason, we recommend that the Department, at a minimum, add the following criteria:

- **A facility operated by the person or a facility in which the person owns a 5% or greater interest or acts as a corporate officer or member of the board of directors has been the subject of proceedings that resulted in the suspension, denial or revocation of the license or renewal license of the facility or has been the subject of proceedings that resulted in the denial, cancellation or revocation of the Medicare or Medicaid certification of the facility**
- **The person has a felony conviction or has been convicted of any crime involving physical, sexual, mental or verbal abuse or neglect**
- **The person has been convicted of any crime involving the misappropriation of property or financial abuse**
- **The person has permitted, assisted, or encouraged anyone in the commission of any illegal act against a nursing home resident**
- **A federal, state, or local law enforcement entity has filed an action in any court concerning conditions in any health care facility for which the person was licensed, if that lawsuit resulted in an order or judgment against the person granting damages or any form of equitable relief, including an injunction or declaratory judgment**

Comments on Section 201.13 Issuance of license for a new facility or change in ownership

1. **Inspections.** We 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 regulatory requirements that could not be measured before the licensee was operating the facility.

2. **Provisional Licensure Provisions Should Be Improved, Not Removed.** We recommend that 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 in #1 just above, they should both be subject to onsite inspections during their first 3-6 months of operation.

   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.

Comments on Section 201.13a License Renewal

1. **Periodicity of Licenses Should Be Articulated.** We recommend that the Department delineate the renewal timeframe as follows: 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.

2. **Substantial Compliance is Only the Standard for Full Licenses.** This section states that "The Department will renew a license to operate a facility after a survey is conducted by the Department that indicates the facility is in substantial compliance with section 808(a) of the act (35 P.S. § 448.808(a)) and this subpart." Because the Department may issue a provisional license for a facility that is not in substantial compliance, this section fails to address the standard for determining whether a provisionally licensed facility which has not completely corrected its non-compliance shall be issued another provisional license.

Comments on Section 201.14 Responsibility of Licensee

- **Quarterly Facility Assessments are a key improvement.** We support the requirement that nursing homes conduct the facility assessment (as required in 42 CFR §438.70(e)) on a quarterly basis. This assessment is a valuable tool for evaluating resident acuity, ensuring adequate staffing and meeting the needs of the specific nursing home resident population. In some ways (staffing, change in resident population, resource needs), a facility assessment should be performed on almost a daily basis. As noted in Appendix PP, State Operations Manual, Guidance to Surveyors, 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 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 components.

- **Reportable Incidents.** We recommend expansion of the state reporting requirements at section 201.14(d) as follows:

  (d) In addition to the notification requirements in § 51.3, the facility shall report in writing to the appropriate division of nursing care facilities field office:

  (1) Staffing below state minimum requirements.
  (2) 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, which result or are likely to result in harm to residents.

- **Outline Enforcement Tools.** We recommend that the Department delineate all enforcement steps available to the Department. This is critical for nursing home applicants, residents and their loved ones, the long-term care ombudsman programs, and the general public to understand the licensure and enforcement status of a nursing home.

- **Financial Transparency and Cost Reporting.** Recently, there has been intense scrutiny of the financial relationships and transparency related to nursing homes. 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 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 the following language to Section 201.14 to address these concerns:

(k) an organization that operates, conducts, manages, or maintains a nursing home or nursing homes must prepare and file an annual consolidated financial report. The report shall be reviewed by a certified public accountant or audited, contain a certification of accuracy, shall be filed with the Department and must include the following components:

> **(1) A balance sheet detailing the assets, liabilities, and net worth at the end of its fiscal year.**
>
> **(2) A statement of income, expenses, and operating surplus or deficit for the annual fiscal period, and a statement of ancillary utilization and patient census.**
>
> **(3) A statement detailing patient revenue by payer, including, but not limited to, Medicare, Medicaid, and other payers, and revenue center.**
>
> **(4) A statement of cashflows, including, but not limited to, ongoing and new capital expenditures and depreciation.**
>
> **(5) A combined financial statement that includes all entities reported in the consolidated financial report, unless the organization is prohibited from including a combined financial statement in a consolidated financial report pursuant to a state or federal law or regulation or a national accounting standard. When applicable, the organization must disclose to the Department the applicable state or federal law or regulation or national accounting standard.**

(l) In addition to the information contained in (k), the person must provide an attachment containing the following information:

> **(1) The financial information required by subsection (k) from all operating entities, license holders, and related parties in which the organization has an ownership or control interest of 5 percent or more and that provides any service, facility, or supply to the nursing home.**
>
> **(2) A detailed document outlining a visual representation of the organization's structure that includes both of the following:**
>
> > **(i) All related parties in which the organization has an ownership or control interest of 5 percent or more and that provides any service, facility, or supply to the nursing home and**
> >
> > **(ii) Unrelated parties that provide services, facilities, or supplies to the skilled nursing facility or facilities that are operated, conducted, owned, managed, or maintained by the organization, including, but not limited to, management companies and property companies, and that are paid more than two hundred thousand dollars ($200,000) by the nursing home.**

(m) For purposes of this regulation, a related party may include, but is not limited to, home offices; management organizations; owners of real estate; entities that provide staffing, therapy, pharmaceutical, marketing, administrative management, consulting, and insurance services; providers of supplies and equipment; financial advisors and consultants; banking and financial entities; any and all parent companies, holding companies, and sister organizations; and any entity in which an

immediate family member of an owner of those organizations has an ownership interest of 5 percent or more. Immediate family member includes spouse, natural parent, child, sibling, adopted child, adoptive parent, stepparent, stepchild, stepsister, stepbrother, father-in-law, mother-in-law, sister-in-law, brother-in-law, son-in-law, daughter-in-law, grandparent, and grandchild.

Comments on Section 201.22

Address Pandemic-Prone Infectious Disease Prevention, Control, and Surveillance. We recommend the following language be added in order to address pandemics or outbreaks of infectious diseases:

> **201.22a. Prevention, control and surveillance of Infectious Diseases.**
> **(a) The facility shall have a written infection control plan with established protocols that address training, risk assessment and management, screening and surveillance methods, identification, evaluation, and treatment of residents and employees who have a possible infection or active case of an infectious disease, and reporting to the Department upon experiencing impediments to implementation of the infection control plan. The Infection Preventionist shall monitor federal and state public health advisories at least weekly for outbreaks and emerging infectious diseases.**
> **(b) Recommendations and guidance of the Centers for Disease Control (CDC) and the Centers for Medicare and Medicaid Services (CMS), United States Department of Health and Human Services (HHS) shall be followed in treating and managing persons with confirmed or suspected Pandemic-Prone or other Infectious Disease.**
> **(c) In the response to any outbreak of any infectious virus or disease, the facility shall follow the recommendations, requirements, and guidance of the Centers for Disease Control (CDC), United States Department of Health and Human Services (HHS), and the Department in treating and managing persons with confirmed or suspected cases of the virus or disease.**
> **(d) 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.**

Comments on Section 209.7 Disaster Preparedness

1. **Expand This Section To Include Emergencies, Disasters, and Pandemics.** While the Department is proposing to delete this section because of federal rules requiring disaster preparedness, we believe this section should be expanded to include other emergencies, pandemics, active shooters, etc. Specifically, we propose:
   - Changing the title to cover emergencies, disasters, and pandemics,
   - Requiring each facility to have a written plan to address each of these types of occurrences that gets submitted with license application and annually thereafter for approval by the Department prior to licensure and on an annual basis

- Requiring that in addition to what the regulation already has identified, the Emergency, Pandemic, and Disaster plan that must include the following:

§ 209.7. Emergency, Pandemic, and Disaster Preparedness.
(a) The facility shall have a comprehensive written plan that addresses Emergency, Pandemic, and Disaster Preparedness. The Emergency, Pandemic, and Disaster Plan must:

> **(1) Address fire safety, natural disaster, physical plant disaster, person-made disaster, health outbreak and pandemics, active shooter, and other emergencies.**
> **(2) Be submitted to the Department for prior approval as part of initial licensure and must be available for surveyor review at least annually.**
> **(3) Be developed and maintained with the assistance of qualified fire, safety, infection control, and other appropriate experts.**
> **(4) Be developed based on a facility's risk assessment or a comprehensive evaluation that identifies potential risks and creates plans to address these risks.**
> **(5) Be developed with person-centered planning to ensure residents' physical, psychological, social, and spiritual needs will be met.**
> **(6) Account for the handling of both short and long-term situations. For disasters/emergencies that last more than a day, the Emergency, Pandemic, and Disaster plan must include:**
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> > **(i) How the facility will communicate daily with residents, families, and resident s during the emergency, pandemic, or disaster and at least weekly during periods when the emergency, pandemic, or disaster has subsided but before operations have returned to normal.**
> > **(ii) How the facility will integrate into the community's emergency response system and its regional Health Care Coalition as necessary.**
> > **(iii) Communications plans with the appropriate contacts and how to connect with state and local public health and emergency management agencies along with other relevant entities.**
> > **(iv) How the facility will ensure sufficient supplies to safely and appropriately meet the needs of residents and staff.**
> > **(v) For health-related emergencies, pandemics, or disasters, how the facility will safely and appropriately separate those staff and residents affected or infected from those not or whose status is unknown.**
> > **(vi) How the facility will provide back-up staffing in response to the emergency, pandemic, or disaster.**
> > **(vii) How and when the facility will test their Emergency, Pandemic, and Disaster Preparedness through drills.**
> > **(viii) When the facility will review and update their Emergency, Pandemic, and Disaster Plan.**

(7) Include policies and procedures that reflect evidence-based best practices for infection prevention, detection, control, and surveillance, including ones related to:

(i) Infection control plan – including cleaning and disinfecting.
(ii) Minimum stockpile/stores of supplies to be kept on site at all times.
(iii) Infection control training.
(iv) Administration of vaccinations.
(v) Testing and re-testing policies.
(vi) Contact Tracing policies.
(vii) Staff return to work (post illness) policies.
(viii) Auditing and surveilling infection prevention, detection, and control practices as performed by staff.

Thank you for the opportunity to comment on the third package of nursing home regulations and we look forward to reviewing and commenting on the remaining packages of proposed changes to these important regulations.

Sincerely,

David R. Hoffman, JD, FCPP
Barry Furrow, JD
Robert Field, JD, MPH
Hilary Pearsall, JD & MPH Candidate