



April 18, 2022

Lori Gutierrez
 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

To Whom It May Concern:

We are pleased to see that the Department of Health is continuing its update of the nursing home licensing regulations. The residents and loved ones we represent are long overdue for improvements in the quality of their care and their surroundings. COVID-19 had a tragically devastating impact on nursing home residents and staff. Moreover, it laid bare gross deficiencies and unconscionable racial disparities in the quality of nursing home care. There can be no doubt that the current regulations are insufficient to protect the lives of residents. Considerable changes are necessary and comprehensive reform is essential. This package of regulations makes positive steps towards addressing outstanding concerns. We offer the following comments.

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

We strongly support expanding this section to include new facility and change in ownership applications. We are happy to see that Section 201.12 has been expanded so that it now will also apply to new/changed ownership. 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 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. We had previously proposed a public notice and hearing process for new licenses and a slightly different public notice and comment process for proposed changes in ownership, with both processes allowing interested members of the public the ability to raise concerns about an application. 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.

We provide recommended edits in our mark-up of the regulations, which is attached.

2. **Ownership or control interest description.** We are pleased that the Department added 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 had previously recommended, however, 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 of trust, note, or other obligation secured (in whole or in part) by the equipment used in the facility or by the land on which or building in which the facility is located." We continue to recommend that the Department include this language. We provide recommended edits to the proposed regulations in our attached mark-up of the proposed regulations.

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 strongly urge you to clarify 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 we strongly urge 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 are happy to see that the Department added this section. We believe it is important to 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.

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

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

1. **Inspections.** We agree with the Department that inspection prior to licensure is not the best use of resources. 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. We believe this should be added into this section and provide draft language in the attached mark-up we have provided of the proposed regulations.
2. **Provisional Licensure Provisions Should Be Improved, Not Removed.** We have concerns about the Department removing the subsection of provisional licenses. We believe 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. Additionally, we generally believe that while enforcement actions are covered in multiple sections of the Health Care Facilities Act, they should be spelled out in the regulations as well. Including a comprehensive discussion of provisional licensure and the other available enforcement actions in the Department's enforcement toolbox is helpful for applicants and nursing home licensees. It sends a message that the Department takes compliance seriously. 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. We have proposed such a section in our mark-up of the proposed regulations, which is attached.

3. **Authority for Increased License Fees Should Be Obtained.** We do not object to the Department's removal of discussion of fees from the regulations, as they exist in the statute. We do worry, however, that applicants should have clear information on what is required in the application process, and it is not readily apparent to us that this information is available elsewhere. We also feel that an increase in initial licensure and licensure renewal fees is long overdue, as the amounts in the statute are terribly outdated and should be increased to a meaningful amount. We urge the Department to ask the legislature to raise the fees in the statute. The increased fees should be used to establish a dedicated unit for vetting applications and to support a new finance unit's review of financial status of applicants, in addition to overall enforcement of the regulations.

Comments on Section 201.13a License Renewal

1. **Periodicity of Licenses Should Be Articulated.** This is a new section which adds language stating that the facility will apply to renew its license, but it does not state the frequency for 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. We strongly recommend that this new section be clearer that every facility must apply to renew its license at least annually but sooner if a provisional license is in place. We supply proposed revisions to the proposed regulations in the mark-up to the proposed regulations, which we have attached.
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. Please see our proposed edits to the proposed regulations in the mark-up to the proposed regulations that we have attached.

Comments on Section 201.14 Responsibility of Licensee

1. **Quarterly Facility Assessments are a key improvement.** We are very pleased that the Department has required that nursing homes conduct the facility assessment (as required in 42 CFR §438.70(e)) on a quarterly basis. This assessment is an important tool for evaluating how best to serve the specific residents in a given facility and how to staff to meet their collective needs. In some ways (staffing, change in resident population, resource needs), a facility assessment should be performed on almost a daily basis. As noted in 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 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.

2. **Reportable Incidents.** Instead of deleting additional state reporting requirements at section 201.14(d), we recommend requiring reporting of the following:
 - Events that cause or result in a resident's death or present an immediate danger of death or serious harm;
 - Events that cause or result in serious injury or significant change in a resident's condition;
 - Staffing below state minimum requirements; and
 - Deaths or serious injuries due to neglect as defined in 42 CFR § 483.5.

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

3. **Require Consolidated Financial Reports.** Recently, there has been intense scrutiny of the financial relationships and transparency related to nursing homes. On February

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

4. **Outline Enforcement Tools Here.** We ask the Department to add to this section language outlining the enforcement steps available to the Department. This is critical for nursing home applicants, their loved ones, the long-term care ombudsman programs, and the general public to understand the licensure and enforcement status of a nursing home. While this information is sprinkled through multiple sections of the Health Care Facilities Act, it would be valuable to have it stated clearly and in one place.

We strongly recommend that the Department outline the steps it could take in response to non-compliance by adding language to §201.14(a). We provide recommended edits in our mark-up of the regulations, which is attached. This addition is important to include in the final regulations.

Comments on Changes to Section 201.17 Location

1. **Clarify the Language Around Co-Location.** The Department proposes to delete the existing section and replace it with language stating that a nursing facility can be co-located in a building that offers other health-related services. We ask that this language be clarified because it is not clear whether the language, as written, means that those other health-related services would be offered as separate services under the nursing home’s license or whether there would be separately licensed providers providing those other health-related services co-located at the same physical location as the nursing facility. We believe the Department intends the latter and not the former but the provision as drafted is not sufficiently clear. We provide recommended language to clarify this point in our attached mark-up to the proposed regulations.

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

1. **Address Pandemic-Prone Infectious Disease Prevention, Control, and Surveillance.** 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 propose additions to the proposed regulations, in the attached mark-up.

Comments on Section 209.7 Disaster Preparedness

1. **Do Not Delete But Instead 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 it is important and needs to be expanded to include other emergencies, pandemics, active shooters, etc. Specifically, we had proposed:
 - 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 and that needs to be approved by the Department prior to licensure and annually and
 - Requiring that, in addition to what the regulation already included, the Emergency, Pandemic, and Disaster plan must include specific items as outlined in our proposed language.

We provide proposed language for how the Department would implement our recommended revisions in our mark-up of the proposed regulations, which is attached.

Comments on Section 209.8 Fire Drills

1. **Expand this Section to Also Cover Safety Drills.** The regulations must be expanded to include all drills for more than just fire events and the section should be renamed to reflect this change. Nursing homes must conduct drills related to all the types of emergencies, disasters, pandemics, etc. events that could happen and would benefit from practice (e.g., active shooter drills). Please see proposed language that we have supplied in our mark-up draft of the proposed regulations.

Section 211.1 Reportable Diseases

1. **Specify Requirement for Reporting of Pandemic-Prone Infectious Diseases.** Clarify obligation to report Pandemic-Prone Infectious Diseases, such as COVID-19, to the Department and other relevant agencies at the Department's direction in the manner, frequency, and format required by the department. Please see proposed language that we have supplied in our mark-up draft of the proposed regulations.

We have attached a marked-up version of Annex A, reflecting all the changes we believe are necessary and identifying where we have specific concerns.

We are dedicated to helping improve the lives of nursing facility residents. We would appreciate the opportunity to meet with your staff in the weeks ahead to further discuss our recommended revisions to the regulations. You can reach us through Pamela Walz at pwalz@clsphila.org or Diane Menio at menio@carie.org.

Sincerely,

Diane A. Menio, Executive Director
Center for Advocacy for the Rights and Interests of Elders

Pamela Walz, Supervising Attorney
Community Legal Services

CC: Independent Regulatory Review Commission at irrhelp@irrc.state.pa.us

ANNEX A

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

SUPBART C. LONG-TERM CARE FACILITIES

CHAPTER 201. APPLICABILITY, DEFINITIONS, OWNERSHIP AND GENERAL

OPERATION OF LONG-TERM CARE NURSING FACILITIES.

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OWNERSHIP AND MANAGEMENT

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§ 201.3 Definitions.

"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.

"Temporary management." The person appointed temporarily by the Department as a substitute facility manager or administrator with authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures and manage the facility to correct deficiencies identified in the facility's operation, with payment to this person being provided by the facility or, at the Department's discretion, from the Department when necessary.

§ 201.12. Application for license of a new facility or change in ownership.

(a) [An application for a license to operate a facility shall be made under section 807 of the act (35 P.S. § 448.807). The application form shall be obtained from the Division of Nursing Care Facilities, Bureau of Quality Assurance, Department of Health.] **(Reserved).**

(a.1) A person may not operate or assume ownership of a facility without first obtaining a license from the Department.

(a.2) A person seeking to operate or assume ownership of a facility shall obtain an application form from the Division of Nursing Care Facilities, Department of Health.

(b) [The following shall be submitted with the application for licensure] In addition to the completed application and fee required under section 807 of the act (35 P.S. § 448.807), a person

seeking to operate or assume ownership of a facility shall submit the following:

(1) [The names and addresses of a person who has direct or indirect ownership interest of 5% or more in the facility as well as a written list of the names and addresses of the facility's officers and members of the board of directors.] The names, addresses, email addresses and phone numbers of any person who has or will have an ownership or control interest in the facility, whether the interest is in its profits or in the land or building occupied and used as the facility, as well as a written list of the names, addresses, email addresses and phone numbers of the facility's officers and members of the board of directors. For purposes of this subsection, a person who has or will have ownership or control interest is:

(i) A person with a direct or indirect ownership interest of 5% or more in the facility.

(ii) The organization that holds the license or owns the land or building occupied and used as the facility.

(iii) The owner of a whole or part interest in any mortgage, deed, 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

(2) If the [owner] person is a nonprofit corporation, a complete list of the [names and addresses] names, addresses, email addresses and phone numbers of the officers and directors of the corporation and an exact copy of its charter and articles of incorporation which are on file with the Department of State as well as amendments or changes.

(3) If the [owner] person is a partnership, the [names and addresses] names, addresses, email addresses and phone numbers of partners.

(4) The name, address, email address, phone number and license number of the administrator.

(5) The names, addresses, email addresses and phone numbers of any persons that have or will have a direct or indirect interest in the management of the facility or the provision of services at the facility.

(6) The person's corporate history.

(7) A list of every licensed facility in any state, the District of Columbia or territory in which the person has or had any percentage of interest in the ownership, management or real property of that facility.

(8) The person's licensing and regulatory history in all jurisdictions where the person has or has had a direct or indirect ownership interest in a facility .

(9) A detailed summary of current, adjudicated, or settled civil actions or criminal actions filed against the person.

(10) Any financial failures involving any persons 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.

(11) Any additional information the Department may request and require applicants to provide, including information responsive to inquiries arising from public comment on the new license or change of ownership licensure application.

(c) In addition to the information required in subsection (b), a person seeking to operate or assume ownership of a facility shall provide the following:

(1) A proposed staffing and hiring plan, which shall include the management and oversight staff, the structure of the facility's governing body and its participants.

(2) A proposed training plan for staff.

(3) A proposed Emergency, Pandemic, and Disaster preparedness plan that meets the requirements of this section and 42 CFR 483.73(a) (relating to emergency preparedness).

(4) Proposed standard admissions and discharge agreements.

(5) A detailed budget for three years of operations, prepared in accordance with generally accepted accounting principles, and evidence of access to sufficient capital needed to operate the facility in accordance with the budget and the facility assessment (as defined in 42 CFR 483.70(e)).

—(d) Once a person submits an application to operate or assume ownership of a facility, the Department shall provide public 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 along with

the name and address of the proposed long-term care facility; name and address of the proposed licensee, if different; and name and address of the owner or owners.

(e) A facility seeking to sell or otherwise change ownership of an existing facility must provide advance written notice to residents, resident representatives, the Office of the State Long-Term Care Ombudsman, the Office of the Local Long-Term Care Ombudsman, the members of the General Assembly who represent the city or town in which the facility is or will be located; and a representative of the local officials of the city, county, or town in which the facility is or will be located. This advance written notice must be provided 30 days in advance of the sale or change of ownership and must outline the specific intention to sell or change ownership of an existing facility as well as the details of the Department's public comment process.

(e)(f) A person who fails, under this section, to demonstrate capacity to operate a facility, will

be given 30 days from the date of the denial of an application to cure the application.

§ 201.12a. Evaluation of application for license of a new facility or change in ownership.

(a) The Department will conduct an evaluation of the application, which will include consideration of the application form and documents submitted under § 201.12 (relating to application for license of a new facility or change in ownership) as well as consideration of any public comment or publicly submitted evidence that the Department has received in response to the public notice provided under § 201.12(d) and allowing a thirty (30) day public comment period.

(b) Upon completion of the evaluation conducted under subsection (a), the Department will approve or deny the application.

(c) The Department will consider the following in determining whether to approve or deny an application:

(1) The person's past performance related to owning or operating a facility in the Commonwealth or other jurisdictions.

(2) The person's demonstrated financial and organizational capacity and capability to successfully perform the requirements of operating a facility based on the information provided under § 201.12.

(3) The person's demonstrated history and experience with regulatory compliance, including evidence of consistent performance in delivering quality care.

(d) Exclusionary factors include but are not limited to each of the following that, in and of itself, constitutes full and adequate ground for deeming an applicant or licensee neither suitable nor responsible to establish or maintain a facility:

(1) 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.

(2) The person has a felony conviction or has been convicted of any crime involving physical, sexual, mental or verbal abuse or neglect.

(3) The person has been convicted of any crime involving the misappropriation of property or financial abuse.

(4) The person has permitted, assisted, or encouraged anyone in the commission of any illegal act against a nursing home resident.

(5) 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 applicant or licensee granting damages or any form of equitable relief, including an injunction or declaratory judgment.

§ 201.13. Issuance of license for a new facility or change in ownership.

(a) [A person may not maintain or operate a facility without first obtaining a license issued by the Department. A license to operate a facility is not transferable without prior approval of the Department.] **(Reserved).**

(b) A license to operate a facility will be issued when the Department [receives the completed application form and the licensure fee and when, after inspection by an authorized representative of the Department, it has been] has determined that the necessary requirements for licensure have been met under § 201.12 (relating to application for license of a new facility or change in ownership) and that issuance of a license is appropriate under § 201.12a (relating to evaluation of application for a new facility or change in

ownership).

(c) [The required fee for a license is:

Regular Licenses (new or renewal) ...	\$250
Each inpatient bed in excess of 75 beds ...	\$2
Provisional I License ...	\$400
Each inpatient bed ...	\$4

Provisional II License ...	\$600
Each inpatient bed ...	\$6
Provisional III License ...	\$800
Each inpatient bed ...	\$8
Provisional IV License ...	\$1,000
Each inpatient bed ...	\$10]

(Reserved).

(d) The license will be issued to the owner of a facility and will indicate the name and address of the facility, the name and address of the owner of the facility, the number [and types] of beds authorized and the date of the valid license.

(e) A regular license will be issued and admissions may begin under a new or changed ownership license when, in the judgment of the Department, there is substantial compliance with the measurable provisions of this subpart. The Department will conduct a survey inspection for any newly licensed facility or facility that has been approved for a license for change in ownership within the first three to six months of operation to confirm substantial compliance with the entire subpart, particularly with the resident service-related requirements that could not be measured prior to admissions. A regular license has a term of 1 year and must be renewed annually.

(f) ~~A~~ provisional license is governed by the following:

(1) A provisional license will be issued if there are numerous deficiencies or a serious specific deficiency and if the facility is not in substantial compliance with this subpart and the Department finds that:

(i) The applicant is taking appropriate steps to correct the deficiencies in accordance with a written plan of correction and timetable for correction submitted by the

applicant and agreed upon by the Department.

(ii) There is no cyclical pattern of deficiencies over a period of 2 or more years.

(2) The provisional license will be issued for a specified period of time not more than 6 months. The provisional license may be renewed, at the discretion of the Department, no more than three times. Upon substantial compliance with this subpart, a regular license will be issued.

~~(3) (Reserved).~~ A provisional license will be granted to a new licensee as its first or initial license. A provisional license will also be granted to a change of ownership licensee as its first or initial license.

~~(3)(4)~~ A provisional license may be granted simultaneously with the imposition of additional enforcement actions, as outlined herein.

(g) [The facility shall have on file the most recent inspection reports, relating to the health and safety of residents, indicating compliance with applicable State and local statutes and regulations. Upon request, the facility shall make the most recent report available to interested persons.] **(Reserved).**

(h) [If the Department's inspection report indicates deficiencies, the facility shall indicate in writing its plans to make corrections and specify dates by which the corrective measures will be completed. The plans are valid only upon approval by the Department.] **(Reserved).**

(i) [The current license shall be displayed in a public and conspicuous place in the facility.] **(Reserved).**

§ 201.13a. License renewal.

(a) A facility shall apply to renew its license on a form prescribed by the Department with the fee required under section 807(b) of the act (35 P.S. § 807(b)). Licenses must be renewed annually for full licenses and at or before the end of the term of the existing provisional license for facilities under a provisional license.

(b) The Department will renew a license to operate a facility after a survey is conducted by the Department. A full license will be granted if the survey indicates that the facility is in substantial

compliance with section 808(a) of the act (35 P.S. § 448.808(a)) and this subpart. A provisional license may be granted if the survey indicates that the facility is not in substantial compliance with section 808(a) of the act (35 P.S. § 448.808(a)) and this subpart but has still achieved sufficient compliance in the opinion of the Department to warrant a provisional license with a plan for correction to achieve substantial compliance. Granting a full or provisional license does not limit the Department's ability to simultaneously take any other enforcement actions as authorized under Chapter 8 of the Act and this subpart.

§ 201.14. Responsibility of licensee.

(a) The licensee is responsible for meeting the minimum standards for the operation of a facility as set forth by the Department and by other Federal, State and local agencies responsible for the health and welfare of residents. This includes complying with all applicable Federal and State laws, and rules, regulations and orders issued by Federal, State or local agencies.

Licensees will be cited for violations of both state and federal requirements. Penalties for violations the Department may impose include but are not limited to:

- (i) Plan of Correction
- (ii) Civil Monetary Penalties
- (iii) Provisional Licensure Status
- (iv) Ban on Admission
- (v) Appointment of Temporary Management
- (vi) Recommendation to the Centers for Medicare and Medicaid Services for Medicare and Medicaid
- (vii) License revocation

(b) If [the] services are purchased for the administration or management of the facility, the licensee is responsible for [insuring] ensuring compliance with [this subpart, and other relevant Commonwealth regulations] all applicable Federal and State laws, and rules, regulations and orders issued by the Department and other Federal, State and local agencies.

(c) The licensee through the administrator shall report within 24 hours to the appropriate Division of Nursing Care Facilities field office serious incidents involving residents [. As] as set forth in § 51.3 (relating to notification). For purposes of this subpart, references to patients in

§ 51.3 include references to residents. Licensees shall also timely comply with all reporting requirements related to hospitalizations or critical incidents as required by Medical Assistance and other payor sources, including Section 1150 B of the Social Security Act, and shall comply with all applicable reporting

requirements outlined in the Older Adult Protective Services Act, the Adult Protective Services Act, and the Child Protective Services Act.

(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) Transfers to hospitals as a result of injuries or accidents. Events that cause or result in a resident's death or present an immediate danger of death or serious harm.

(2) Admissions to hospitals as a result of injuries or accidents.] Events that cause or result in serious injury or significant change in a resident's condition.

(3) Staffing below state minimum requirements.

~~(2)(4)~~ Deaths or serious injuries due to neglect as defined in 42 CFR §483.5. **(Reserved).**

(e) [The administrator shall notify the appropriate division of nursing care facilities field office as soon as possible, or, at the latest, within 24 hours of the incidents listed in § 51.3 and subsection (d).] **(Reserved).**

(f) Upon receipt of a strike notice, the licensee or administrator shall promptly notify the appropriate Division of Nursing Care Facilities field office, the State Long-Term Care Ombudsman Program, the Local Long-Term Care Ombudsman Program, and keep the Department apprised of the strike status and the measures being taken to provide resident care during the strike.

~~—(g) A facility owner shall pay in a timely manner bills incurred in the operation of a facility that are not in dispute and that are for services without which the resident's health and safety are jeopardized. Each facility shall submit annual, fully auditable, consolidated financial reports that show the financial condition of the facility, its parent organization or corporate ownership, and sister entities within the organization or corporate structure. The facility must also comply with Department of Health and Department of Human Services cost reporting and quality reporting requirements.~~

~~—(h) Each facility must annually submit and obtain Department approval of the facility's evidence of compliance with 42 CFR 413.17 "Cost to Related Organizations". Such demonstration of compliance shall be~~

in a manner required by the Department.

~~(i) A facility owner shall pay in a timely manner bills incurred in the operation of a facility that are not in dispute and that are for services without which the resident's health and safety are jeopardized.~~

~~(j) The facility shall report to the Department[, on forms issued by the Department,] census, rate, [and] program occupancy, and any other information [as] the Department may request.~~

(jk) The facility shall have on file the most recent inspection reports, relating to the health and safety of residents, indicating compliance with applicable Federal, State and local statutes and regulations. Upon request, the facility shall make the most recent report available to interested persons.

(k) The facility shall conduct a facility-wide assessment that meets the requirements of 42 CFR 483.70(e) (relating to administration), as necessary, but at least quarterly.

(l) 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.

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

(1) The financial information required by subsection (l) 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.

(n) 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.

§ 201.15. Restrictions on license.

[A license shall apply only to the licensure, the name of the facility and the premises designated therein. It may not be transferrable, in whole or in part, to another licensee or property without prior written approval of the Department.] **(Reserved).**

(a) A license becomes automatically void without notice if any of the following conditions exist:

(1) The [expiration date has been reached] license term expires.

(2) There is a change in ownership and the Department has not given prior approval.

(3) There is a change in the name of the facility, and the Department has not given prior approval [for the transfer of the license].

(4) There is a change in the location of the facility and the Department has not given prior approval.

(b) A final order or determination by the Department relating to licensure may be appealed by the provider of services to the Health Policy Board under section 2102(n) of The Administrative Code of 1929 (71 P.S. § 532(n)).

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§ 201.17. Location.

[The facility shall be operated as a unit reasonably distinct from the other related services, if located in a building which offers various levels of health-related services.] With the approval of the Department, a facility may be located in a building within which there are separately licensed providers that operate and provide other health-related services, such as personal care, home health, or hospice services, and may share services such as laundry, pharmacy and meal preparations. The facility shall be operated as a unit distinct from other health-related services.

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§ 201.22. Prevention, control and surveillance of tuberculosis (TB).

(a) The facility shall have a written TB infection control plan with established protocols which address risk assessment and management, screening and surveillance methods, identification, evaluation, and treatment of residents and [employees] employees who have a possible TB infection or active TB.

(b) Recommendations of the Centers for Disease Control and Prevention (CDC), United States Department of Health and Human Services (HHS) shall be followed in screening, testing and surveillance for TB and in treating and managing persons with confirmed or suspected TB.

(c) [A baseline TB status shall be obtained on all residents and employees in the facility.]

(Reserved).

(d) [The intradermal tuberculin skin test is to be used whenever skin testing is done. This consists of an intradermal injection of 0.1 ml of purified protein derivative (PPD) tuberculin containing 5 tuberculin units (TU) using a disposable tuberculin syringe.] **(Reserved).**

(e) [The 2-step intradermal tuberculin skin test shall be the method used for initial testing of residents and employees. If the first test is positive, the person tested shall be considered to be infected. If the first test is negative, a second test should be administered in 1—3 weeks. If the second test is positive, the person tested shall be considered to be previously infected. If the

second test result is negative, the person is to be classified as uninfected.] **(Reserved)**.

(f) [Persons with reactions of ≥ 10 mm or persons with symptoms suggestive of TB regardless of the size of the test reaction, shall be referred for further diagnostic studies in accordance with CDC recommendations.] **(Reserved)**.

(g) [A written report of test results shall be maintained in the facility for each individual, irrespective of where the test is performed. Reactions shall be recorded in millimeters of induration, even those classified as negative. If no induration is found, “0 mm” is to be recorded.] **(Reserved)**.

(h) [Skin test “negative” employees having regular contact of 10 or more hours per week with residents shall have repeat tuberculin skin tests at intervals determined by the risk of transmission in the facility. The CDC protocol for conducting a TB risk assessment in a health care facility shall be used to establish the risk of transmission.] **(Reserved)**.

(i) [Repeat skin tests shall be required for tuberculin-negative employees and residents after any suspected exposure to a documented case of active TB.] **(Reserved)**.

(j) [New employees shall have the 2-step intradermal skin test before beginning employment unless there is documentation of a previous positive skin reaction. 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.] **(Reserved)**.

(k) [The intradermal tuberculin skin test shall be administered to new residents upon admission, unless there is documentation of a previous positive test.] **(Reserved)**.

(l) [New tuberculin positive reactors (converters) and persons with documentation of a previous positive reaction, shall be referred for further diagnostic testing and treatment in accordance with current standards of practice.] **(Reserved)**.

(m) [If an employee’s chest X-ray is compatible with active TB, the individual shall be excluded from the workplace until a diagnosis of active TB is ruled out or a diagnosis of active

TB is established and a determination made that the individual is considered to be noninfectious.

A statement from a physician stating the individual is noninfectious shall be required.]

(Reserved).

(n) [A resident with a diagnosis of TB may be admitted to the facility if:

- (1) Three consecutive daily sputum smears have been negative for acid-fast bacilli.
- (2) The individual has received appropriate treatment for at least 2—3 weeks.
- (3) Clinical response to therapy, as documented by a physician, has been favorable.]

(Reserved).

201.22a. Prevention, control and surveillance of Infectious Diseases.

(a) The facility shall have a written infection control plan with established protocols which 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.

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CHAPTER 209. FIRE PROTECTION AND SAFETY PROGRAMS FOR LONG-TERM

CARE NURSING FACILITIES.

FIRE PROTECTION AND SAFETY

§ 209.1. [Fire department service.

The telephone number of the emergency services serving the facility shall be posted by the telephones in each nursing station, office and appropriate place within the facility.] **(Reserved).**

§ 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:

- (i) Address fire safety, natural disaster, physical plant disaster, person-made disaster, health outbreak and pandemics, active shooter, and other emergencies.
- (ii) Be submitted to the Department for prior approval as part of initial licensure and must be available for surveyor review at least annually.
- (iii) Be developed and maintained with the assistance of qualified fire, safety, infection control, and other appropriate experts.
- (iv) Be developed based on a facility's assessment or a comprehensive evaluation that identifies potential risks and creates plans to address these risks.
- (v) Be developed with person-centered planning to ensure residents' physical, psychological, social, and spiritual needs will be met.
- (vi) 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:
 - a) How the facility will communicate daily with residents, families, and resident 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.
 - b) How the facility will integrate into the community's emergency response system and its regional Health Care Coalition as necessary.
 - c) 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.
 - d) How the facility will ensure sufficient supplies to safely and appropriately meet the needs of residents and staff.
 - e) 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.
 - f) How the facility will provide back-up staffing in response to the emergency, pandemic, or disaster.
 - g) How and when the facility will test their Emergency, Pandemic, and Disaster Preparedness through drills.

- h) When the facility will review and update their Emergency, Pandemic, and Disaster Plan.
- (vii) Include policies and procedures that reflect evidence-based best practices for infection prevention, detection, control, and surveillance, including ones related to:
 - a) Infection control plan – including cleaning and disinfecting
 - b) Minimum stockpile/stores of supplies to be kept on site at all times
 - c) Infection control training
 - d) Administration of vaccinations
 - e) Testing and re-testing policies
 - f) Contact Tracing policies
 - g) Staff return to work (post illness) policies
 - h) Auditing and surveilling infection prevention, detection, and control practices as performed by staff

~~(ii)~~(viii) ~~It shall~~ include procedures for prompt transfer of casualties and records, instructions regarding the location and use of alarm systems and signals and fire fighting equipment, information regarding methods of containing fire, procedures for notification of appropriate persons and specifications of evacuation routes and procedures. The written plan shall be made available to and reviewed with personnel, and it shall be available at each nursing station and in each department. The plan shall be reviewed periodically to determine its effectiveness.

- (b) A diagram of each floor showing corridors, line of travel, exit doors and location of the fire extinguishers and pull signals shall be posted on each floor in view of residents and personnel.
- (c) All personnel shall be instructed in the operation of the various types of fire extinguishers used in the facility. ~~-(Reserved)-~~

§ 209.8. Fire and Safety drills.

- (a) Fire drills shall be held monthly. Fire drills shall be held at least four times per year per shift at unspecified hours of the day and night.
- (b) A written report shall be maintained of each fire and safety drill which includes date, time required for evacuation or relocation, number of residents evacuated or moved to another location and number of personnel participating in a fire drill. ~~-(Reserved)-~~
- (c) Emergency, Pandemic, and Disaster response drills shall be held in accordance with the

facility's approved Emergency, Pandemic, and Disaster Plan.

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CHAPTER 211. PROGRAM STANDARDS FOR LONG-TERM CARE NURSING FACILITIES.

§ 211.1. Reportable diseases.

(a) When a resident develops a reportable disease, the administrator shall report the information to the appropriate health agencies and appropriate Division of Nursing Care Facilities field office. Reportable diseases, infections and conditions are listed in § 27.21a (relating to reporting of cases by health care practitioners and health care facilities).

(b) Cases of scabies [and] or lice or bed bug infestations shall be reported to the appropriate Division of Nursing Care Facilities field office.

(c) Significant nosocomial outbreaks, as determined by the facility's medical director, Methicillin Resistant Staphylococcus Aureus (MRSA), Vancomycin-Resistant Staphylococcus Aureus (VRSA), Vancomycin-Resistant Enterococci (VRE) and Vancomycin-Resistant Staphylococcus Epidermidis (VRSE) shall be reported to the appropriate Division of Nursing Care Facilities field office.

(e)(d) Outbreaks of COVID-19, other state or federally declared pandemics, or infectious disease outbreaks shall be reported to Department of Health and other agencies at the direction of the Department of Health in the manner, frequency, and format required by the Department of Health. Outbreaks shall be defined as one or more cases of resident or staff infection.