August 19, 2021

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 10-221 (Long-Term Care Facilities, Proposed Rulemaking 1)
    28 PA Code Chapters 201-203 and 211
    Deadline: August 30, 2021

To Whom It May Concern:

Both the Center for Advocacy for the Rights and Interests of the Elderly (CARIE) and Community Legal Services of Philadelphia (CLS) have a long history of advocating on behalf of residents in long term care facilities. We are pleased to see that the Department of Health is proposing to update 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. We offer the following comments that were developed in consultation with PA Advocates for Improved COVID-19 Response in LTC Facilities. CLS plans submit additional comments soon.

Comprehensive reform must include the following important priorities:

• **Systemic Changes to Direct Care Staffing** to increase direct care staffing hours and direct care staffing to resident ratios, as well as to adjust direct care staffing upwards from the minimum as needed to address individuals’ assessed needs, overall resident acuity, and other facility-specific factors (such as physical layout features or operation of specialized units).
• **Improvements in Training Requirements** including minimum training hours for direct care and other staff with specific articulated training areas and demonstration of competency.

• **Infection Prevention and Control Requirements** that ensure each nursing home has full-time expert staff on hand to prevent and control infections.

• **Emergency and Pandemic Preparedness Planning Requirements** so that nursing homes must meaningfully plan for how to address emergencies and to prepare for pandemics or other outbreaks.

• **Application for Licensure and for Change of Ownership Procedures** that ensure that the application to operate or purchase a nursing home requires a thorough evaluation of the applicant’s experience, expertise, and financial capacity to provide high quality of care.

• **Residents’ Rights Improvements** to update regulations that are over 20 years old and don’t protect all residents from discrimination or ill treatment.

We understand this proposed rulemaking is one of five that will eventually be combined to make a final, comprehensive regulatory package. This makes it difficult to review these subsections without the context of the remaining sections. There is no way to fully evaluate the impact of proposed deletions to definitions, for example, without reviewing the full regulatory package to consider how and whether those terms are used throughout. Similarly, while we applaud the change in §211.12(i) from 2.7 hours of direct care per resident per day to 4.1 hours, this is only one small piece of more comprehensive change that is critically overdue in Pennsylvania’s nursing homes. Because of this difficulty, we urge the Department of Health to formally commit to accepting comments related to any of the five sections at any time throughout the entirety of the proposed rulemaking process.

**Substantive Comments:**

This first proposed regulatory package includes changes to §§201.1 (Applicability), 201.2 (Requirements), 201.3 (Definitions), and 211.12(i) (Nursing Services).

**201.1 Applicability:**

We query whether this language needs to be clearer in stating that the regulations apply to applicants for licensure as well as to licensed nursing homes.

**201.2 Requirements:**

We are pleased to see the Department makes it a violation of state regulations to violate federal regulations. We urge the Department to expressly articulate that it is a violation of state regulations to violate federal regulations or the State Operations Manual interpreting those regulations.

**201.3 Definitions:**

As noted previously, we cannot fully evaluate the impact of changes to the proposed definitions without seeing revisions to the other sections of this title. As a general rule, we support the deletion of terms that are not used in the regulations. We also typically would
support the reliance on definitions found in the federal regulations, but not where there is a state definition that carries important cross-system meanings.

For example, we have concerns about the impact on state enforcement of Protective Services and associated criminal laws that could result from eliminating state definitions in these regulations of abuse, neglect, exploitation, etc. Deleting terms wholesale instead of aligning them with both federal and state laws, we believe, would pose a new and unnecessary challenge for law enforcement and Protective Services programs. It would be a tragic result to delete state definitions and rely solely on the federal ones if this impacts the ability of protective services programs or law enforcement to pursue state law violations or charge criminal acts of abuse, neglect, and exploitation or if misalignment creates confusion related to reporting and enforcement. Accordingly, we recommend that the definitions of these terms be revised (not deleted) to incorporate both the federal and state definitions by cross referencing to both the federal regulations and the state OAPSA and APSA laws.

We are also concerned that some of the terms being deleted are not definitions but a list of qualifications, which are not found elsewhere in the regulations.

We are glad to see the removal of “locked restraint”. These are inappropriate and unlawful, and we previously recommended the removal of this definition. However, the definition of restraint should remain as it is important to be clear about what is prohibited.

**211.12(i) Nursing Services:**
It is long past time for minimum direct care staffing levels to be set at 4.1 hours of direct care per resident per day. This has been a consistent recommendation from nursing care experts and CMS for over twenty years. We emphatically support this increase in the minimum direct care staffing level. We note, however, that the change to the number of hours per resident per day reflected in the proposed revision to §211.12(i) alone is not sufficient to ensure sufficient staffing to meet each resident’s individual care needs. Other portions of §211 must be revised to ensure that nursing homes can provide quality care for residents.

**We recommend a multidimensional revision to Chapter 211 that:**
1) Raises the minimum direct care staffing hours to 4.1 while prohibiting any concomitant decrease in ancillary staff hours;
2) Adjusts staff to resident ratios to reflect the increase to 4.1 direct care staff hours per resident per day;
3) Requires that each nursing home’s actual direct care staffing hours be determined based on that facility’s residents’ individual needs as determined by their person-centered needs assessments, with 4.1 hours per resident per day as a floor;
4) Requires each nursing facility’s total direct care staffing hours to be adjusted upward from the minimum, as needed, based on facility needs that include needs related to facility layout, operation of specialized units, and overall resident acuity, all of which should be determined by quarterly completion of the facility assessment tool (which
entails requiring that the facility assessment be completed quarterly and not annually as is presently the frequency of assessment).

These recommendations are based on the requirement that care be person-centered, meaning responsive to individual needs, and research that shows that individual resident needs can vary widely. Facilities can differ significantly in their resident composition, physical plant, and administration; these differences should be considered when evaluating how much staffing may be necessary above the minimum requirement. A facility with a disproportionate number of residents with higher acuity compared to other facilities should be required to adjust staffing levels to account for the difference in acuity.

It is important to articulate our belief that two things can simultaneously be true. Truth #1: Quality resident care requires an increase in direct care staffing hours. Truth #2: There is a workforce shortage. The nursing home industry may argue that because there is a workforce shortage, the minimum hours cannot be increased. We argue that there is a workforce shortage and the minimum hours of direct care staffing per resident per day needs to be increased. We were pleased to hear Acting Secretary Beam convey in the July 23, 2021 press conference that the Department is working hard on strategies to address workforce shortages. We believe the industry has indicated that some 7,000 CNAs would be necessary to address the shortage and meet the needs articulated by the 4.1 hour standard. We agree that the state must direct funds such as American Rescue Plan Act dollars and implement other strategies to address the workforce shortage and ensure that the new requirement to provide 4.1 hours per resident per day is achievable.

We also recommend that the Department of Health:

1) Require this change, with our proposed improvements, to be implemented immediately upon the effective date of the final regulations, with no extended phase-in. This change in minimum staffing levels is so overdue that no phase-in should be permitted. Nursing homes will have advance notice before the effective date to allow them to adjust their policies and practices.

2) Work with the Department of Human Services (DHS) to evaluate the adequacy of Medicaid rates to ensure that they support this staffing level increase. We acknowledge that the increase in staffing levels will impact costs and we support increasing Medicaid reimbursement as necessary to support this change. We were pleased to hear Acting Secretary Beam state that the Department is working closely with DHS to address the need for funding to support this change.

There is no question that 2.7 hours of direct care is not enough, and we urge the Department to stand firmly behind their proposed shift to 4.1 hours per resident per day. Over 85% of the nursing homes in Pennsylvania provide more care than 2.7 hours. 334 facilities are providing 3.01-3.49 hours and 134 are providing 3.5-3.99. And importantly, 125 nursing facilities are providing 4.1 hours of care or more already. Increasing the minimum to

---

4.1 hours per resident per day is essential to ensure that all nursing home residents in Pennsylvania receive quality care. Kaiser Family Foundation data show that in 2016, nursing homes in 27 states and the District of Columbia already averaged above 4.1 hours of staffing per resident per day.

Research firmly supports the need to increase the minimum hours of direct care per resident per day from 2.7 to 4.1 hours. The US Department of Health and Human Services (DHHS) and top nursing care experts have long recommended minimum staffing levels higher than what PA has now. A 2001 DHHS study urged the adoption of a minimum of 4.1 nursing hours per resident day (hprd), broken out as .75 RN hours, .55 LVN/LPN hours, and 2.8 CNA hours. The study found this minimum number of hours necessary to ensure consistent, timely care to residents. A 2001 Institute of Medicine report also called for 4.1 hours. These recommendations of a 4.1 hour minimum were confirmed by a 2004 observational study of

---

2 Report released by federal government in support of staffing ratios in nursing homes:

3 The Institute of Medicine Committee on Improving Quality in Long-Term Care, “Improving the Quality of Long-Term Care.” 2001. http://www.iom.edu/~/media/Files/Report%20Files/2003/Improving-the-Quality-of-Long-Term-Care/LTC8pagerFINAL.pdf
nursing home staffing and a 2011 re-analysis by Abt Associates.⁴ A 2016 study on the need for increased minimum staffing standards found that “a number of organizations have endorsed the minimum of 4.1 hprd standard, have recommended that at least 30% of total nursing care hours should be provided by licensed nurses, and have recommended that RNs should be on duty for 24 hours per day. These organizations include the American Nurses Association, the Coalition of Geriatric Nursing Organizations, and the National Consumer Voice for Quality Long-Term Care.”⁵

Some experts have recommended minimum standards even higher than 4.1 (a total of 4.55 hprd) to “improve the quality of nursing home care, with adjustments for resident acuity or case mix”.⁶ The District of Columbia⁷ already has a minimum requirement of 4.1 and several other states are currently considering raising their minimum as well.

Simply changing the minimum number of direct care staffing hours alone is not enough. Our multidimensional recommendations for determining staffing levels, described above, are based on findings from the Center for Medicare Advocacy that that simply changing the direct care staffing hour minimum alone led to nursing homes reducing the hours of ancillary staff and shifting housekeeping and other non-direct care tasks to the workload of direct care staff, effectively undoing the intended resulted of ensuring the delivery of more direct care to residents.

The need to raise staffing levels is supported by research demonstrating that negative outcomes occur where staffing levels are lower than 4.1 hours, and generally don't occur where staffing levels are at or above 4.1 hours per resident per day.⁸

**Other Comments:**
Because the advocacy organizations in our coalition believe so strongly in the need for comprehensive reform, we drafted and submitted to the Department in November 2020 a complete mark-up of the existing regulations, reflecting the comprehensive changes we

---

⁴ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4833431/ citing Schnelle JF, Simmons SF, Harrington C, Cadogan M, Garcia E, Bates-Jensen B. Relationship of Nursing Home Staffing to Quality of Care, Health Serv Res. 2004,
⁵ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4833431/
⁸ Report released by federal government in support of staffing ratios in nursing homes:
http://phinational.org/sites/phinational.org/files/clearinghouse/PhasellVolumeIIofIII.pdf
http://phinational.org/sites/phinational.org/files/clearinghouse/PhasellVolumeIofIII.pdf
believe the Department must make. A link to these recommendations can be found here: https://www.carie.org/wp-content/uploads/2021/01/Cover-Letter-and-NF-Facility-Regulation-Recommendations.pdf. We are hopeful that the remaining sections of the regulations will reflect the overarching reform that is so desperately needed to improve the nursing home regulations for residents and their loved ones.

As a final note, we believe the Department made an error in stating that it was requiring 4.1 hours per resident per shift. The language appears twice in the PA Bulletin package. We don’t believe the Department intended to require 12.3 hours per resident per day, as most nursing homes typically have 3 shifts. While we appreciate and agree in part with the stated intention of not having nursing homes only have direct care staff during day-time hours, we believe that this is better addressed through increasing the established minimum direct care staff ratios and requiring care to be person-centered. We have provided recommendations to this effect.

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

We are dedicated to help 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 the Elderly

Pamela Walz, Supervising Attorney
Community Legal Services

CC: Independent Regulatory Review Commission at irrchelp@irrc.state.pa.us
§ 201.1. Applicability.

This subpart applies to [profit and nonprofit] long-term care nursing facilities [which provide either skilled nursing care or intermediate nursing care, or both, within the facilities under the act] as defined in section 802.1 of the act (35 P.S. § 448.802a).

§ 201.2. Requirements.

(a) The Department incorporates by reference [and thereby requires long-term care facilities to comply with] 42 CFR Part 483, Subpart B of the Federal requirements for long-term care facilities, [42 CFR 483.1—483.75 (relating to requirements for long-term care facilities) revised as of October 1, 1998] (relating to requirements for long-term care facilities), as licensing regulations for long-term care nursing facilities [with the exception of the following sections and subsections:

(1) Section 483.1 (relating to basis and scope).
(2) Section 483.5 (relating to definitions).
(3) Section 483.10(b)(10), (c)(7) and (8) and (o) (relating to level A requirement: Resident rights).
(4) Section 483.12(a)(1), (b), (c)(1) and (d)(1) and (3) (relating to admission, transfer and discharge rights).
(5) Section 483.20(j) and (m) (relating to resident assessment).
(6) Section 483.30(b)—(d) (relating to nursing services).
(7) Section 483.40(e) and (f) (relating to physician services).
(8) Section 483.55 (relating to dental services).
(9) Section 483.70(d)(1)(v) and (3) (relating to physical environment).
(10) Section 483.75(e)(1), (h) and (p) (relating to administration)].

(b) The Department incorporates by reference [and thereby requires long-term care facilities to comply with] the Centers for Medicare & Medicaid State Operations Manual, Chapter 7 and Appendix PP—Guidance to Surveyors for Long-Term Care Facilities.

(c) A facility may apply for an exception to the requirements of this.
subpart under §§ 51.31—51.34 (relating to exceptions).

(d) Failure to comply with the requirements specified in 42 CFR Part 483, Subpart B and the State Operations Manual which interprets the federal regulations shall be considered a violation of this subpart, unless an exception has been granted under §§ 51.31—51.34.

§ 201.3. Definitions.

(a) The Department incorporates by reference all terms defined in 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) and in the Centers for Medicare & Medicaid State Operations Manual, Chapter 7 and Appendix PP—Guidance to Surveyors for Long-Term Care Facilities. The definitions found in these federal sources will govern, except to the extent that a term is differently defined in this section.

(b) The following words and terms, when used in this subpart, have the following meanings, unless the context clearly indicates otherwise:

- **Abuse**—The infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental and psychosocial well-being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish. The term is inclusive of the definitions found in the federal regulations, the State Operations Manual, the Pennsylvania Older Adult Protective Services Act, and the Pennsylvania Adult Protective Services Act and includes the following:
  
  (i) **Verbal abuse**—Any use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend or disability. Examples of verbal abuse include:
   
   (A) Threats of harm.
   
   (B) Saying things to frighten a resident, such as telling a resident that the resident will never be able to see his family again.

  (ii) **Sexual abuse**—Includes sexual harassment, sexual coercion or sexual assault.

  (iii) **Physical abuse**—Includes hitting, slapping, pinching and kicking. The term also includes controlling behavior through corporal punishment.

  (iv) **Mental abuse**—Includes humiliation, harassment, threats of punishment or deprivation.

Commented [AH4]: While we previously recommended shifting wholesale to the federal definition, we are now concerned that the state regulations should also use the state definitions of abuse, neglect, exploitation, etc. as pairs with our state protective services and associated criminal statutes. Deleting terms instead of aligning them with state laws, we believe, poses a new and unnecessary challenge for law enforcement and the Protective Services program. It would be a tragic result deleting the state definition and relying on the federal one impacts the ability of protective services or law enforcement to raise state law violations or charge criminal acts of abuse, neglect, and exploitation.

We recommend that the Department leave the terms and define them as “as inclusive of the definitions found in the federal regs, the State Operations Manual (SOM), the Pennsylvania Older Adult Protective Services Act, and Pennsylvania Adult Protective Services Act.”

Commented [AH5]: These are terms listed within the “abuse” definition in the federal regs but, they are not each defined in the federal regulations or the SOM. Defining these terms is important and we, therefore, recommend leaving these in.
(v) **Involuntary seclusion**—Separation of a resident from other residents or from his room or confinement to his (with/without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs.

(vi) **Neglect**—The deprivation by a caretaker of goods or services which are necessary to maintain physical or mental health.


**Administration of [drugs] Medication**—The giving of a dose of medication to a patient as a result of an order of a practitioner licensed by the Commonwealth to prescribe [drugs] Medications.

**Administrator**—An individual who is charged with the general administration of a facility, whether or not the individual has an ownership interest in the facility and whether or not the individual's functions and duties are shared with one or more other individuals. The administrator shall be currently licensed and registered by the Department of State under the Nursing Home Administrators License Act (63 P.S. §§ 1101—1114.2).

**Alteration**—An addition, modification or modernization in the structure or usage of a building or section thereof or change in the services rendered.

**Ambulatory resident**—An individual who is physically and mentally capable of getting in and out of bed and walking a normal path to safety in a reasonable period of time, including the ascent and descent of stairs without the aid of another person.

**Applicant**—The entity applying for licensure, whether initial licensure for a new facility or transfer of ownership licensure for an existing facility that would, if approved by the Department, be transferred to the new owner.

**Audiologist**—A person licensed as an audiologist by the Pennsylvania State Board of Examiners in Speech-Language and Hearing, or excluded from the requirement of licensure under the Speech-Language and Hearing Licensure Act (63 P.S. §§ 1701—1719).

**Authorized person to administer drugs and medications**—Persons qualified to administer drugs and medications in facilities are as follows:

(i) Physicians and dentists who are currently licensed by the Bureau of
Professional and Occupational Affairs, Department of State.

(ii) Registered nurses who are currently licensed by the Bureau of Professional and Occupational Affairs, Department of State.

(iii) Practical nurses who have successfully passed the State Board of Nursing examination.

(iv) Practical nurses licensed by waiver in this Commonwealth who have successfully passed the United States Public Health Service Proficiency Examination.

(v) Practical nurses licensed by waiver in this Commonwealth who have successfully passed a medication course approved by the State Board of Nursing.

(vi) Student nurses of approved nursing programs who are functioning under the direct supervision of a member of the school faculty who is present in the facility.

(vii) Recent graduates of approved nursing programs who possess valid temporary practice permits and who are functioning under the direct supervision of a professional nurse who is present in the facility. The permits shall expire if the holders of the permits fail the licensing examinations.

(viii) Physician assistants and registered nurse practitioners who are certified by the Bureau of Professional and Occupational Affairs.

*Basement*—A story or floor level below the main or street floor. If, due to grade differences, there are two levels qualifying as a street floor, a basement is a floor below the lower of the two street floors.

*CRNP*—Certified Registered Nurse Practitioner—A registered nurse licensed in this Commonwealth who is certified by the State Board of Nursing and the State Board of Medicine as a CRNP, under the Professional Nursing Law (63 P.S. §§ 211—225) and the Medical Practice Act of 1985 (63 P.S. §§ 422.1—422.45).

*Charge nurse*—A person designated by the facility who is experienced in nursing service administration and supervision and in areas such as rehabilitative or geriatric nursing or who acquires the preparation through formal staff development programs and who is licensed by the Commonwealth as one of the following:

(i) A registered nurse.

(ii) A registered nurse licensed by another state as a registered nurse and who has applied for endorsement from the State Board of Nursing and has received written notice that the application has been received by the State Board of Nursing. This subparagraph applies for 1 year, or until Commonwealth licensure is completed, whichever period is shorter.
(iii) A practical nurse who is a graduate of a Commonwealth recognized school of practical nursing or who has 2 years of appropriate experience following licensure by waiver as a practical nurse.

(iv) A practical nurse shall be designated by the facility as a charge nurse only on the night tour of duty in a facility with a census of 59 or less.

Clinical laboratory—A place, establishment or institution, organized and operated primarily for the performance of bacteriological, biochemical, hematological, microscopical, serological or parasitological or other tests by the practical application of one or more of the fundamental sciences to material originating from the human body, by the use of specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health. The tests are conducted using specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health.

Clinical records—Facility records, whether or not automated, pertaining to a resident, including medical records.

Controlled substance—A drug, substance or immediate precursor included in Schedules I—V of the Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144).

Corridor—A passageway, hallway or other common avenue used by residents and personnel to travel between buildings or sections of the same building to reach a common exit or service area. The service area includes, but is not limited to, living room, kitchen, bathroom, therapy rooms and storage areas not immediately adjoining the resident’s sleeping quarters.

Department—The Department of Health of the Commonwealth.

Dietetic service supervisor—A person who meets one of the following requirements:

(i) Is a dietitian.

(ii) Is a graduate of a dietetic technician or dietetic assistant training program, correspondence course or classroom course approved by the American Dietetic Association.

(iii) Is a member of the American Dietetic Association or the Dietary Managers Association.

(iv) Is a graduate of a State approved course that provided 90 or more hours of classroom instruction in food service supervision and has experience as a

Commented [AH11]: This is not defined in federal regulations or SOM. Additionally, this “definition” lists meaningful qualifications that are not stated elsewhere in the regulations at present. Is the Department planning to state all these qualifications in a new/different section of the revised regulations? We cannot support deletion of these qualifications for these reasons.

Commented [AH12]: Residents not patients.
supervisor in a health care institution with consultation from a dietitian.

(v) Has training and experience in food service supervision and management in a military service equivalent in content to the program in subparagraph (iv).

(vi) Has a baccalaureate degree from a State approved or accredited college or university and has at least 12 credit hours in food service, nutrition or diet therapy and at least 1 year of supervisory experience in the dietary department of a health care facility.

**Dietitian**—A person who is either:

(i) Registered by the Commission on Dietetic Registration of the American Dietetic Association.

(ii) Eligible for registration and who has a minimum of a bachelor’s degree from a United States regionally accredited college or university and has completed the American Dietetic Association (ADA) approved dietetic course requirements and the requisite number of hours of ADA approved supervised practice.

**Director of nursing services**—A registered nurse who is licensed and eligible to practice in this Commonwealth and has 1 year of experience or education in nursing service administration and supervision, as well as additional education or experience in areas such as rehabilitative or geriatric nursing, and participates annually in continuing nursing education. The director of nursing services is responsible for the organization, supervision and administration of the total nursing service program in the facility.

**Drug administration**—An act in which a single dose of a prescribed drug or biological is given to a resident by an authorized person in accordance with statutes and regulations governing the act. The complete act of administration entails removing an individual dose from a previously dispensed, properly labeled container, verifying it with the physician’s orders, giving the individual dose to the proper resident and promptly recording the time and dose given.

**Drug dispensing**—An act by a practitioner or a person who is licensed in this Commonwealth to dispense drugs under the Pharmacy Act (63 P.S. §§ 390-1—390-13) entailing the interpretation of an order for a drug or biological and, under that order, the proper selecting, measuring, labeling, packaging and issuance of the drug or biological for a resident or for a service unit of the facility.

**Drug or medication**—A substance meeting one of the following qualifications: (i) Is recognized in the official United States Pharmacopeia, or official National Formulary or a supplement to either of them.

(ii) Is intended for use in the diagnosis, cure, mitigation, treatment or prevention
of disease in man or other animals.

(iii) Is other than food and intended to affect the structure or a function of the human body or other animal body.

(iv) Is intended for use as a component of an article specified in subparagraph (i), (ii) or (iii), but not including devices or their components, parts or accessories.

<table>
<thead>
<tr>
<th>Elopement—When a resident leaves the facility without the facility staff being aware that the resident has done so.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Existing facility—A long-term care nursing facility or section thereof which was constructed and licensed as such on or before July 24, 1999.</td>
</tr>
<tr>
<td>Exit or exitway—A required means of direct egress in either a horizontal or vertical direction leading to the exterior grade level.</td>
</tr>
<tr>
<td>Facility—A licensed long-term care nursing facility as defined in Chapter 8 of the act (35 P.S. §§ 448.801—448.821).</td>
</tr>
<tr>
<td>[Full-time—A minimum of a 35-hour work week.]</td>
</tr>
<tr>
<td>Interdisciplinary team—An individually-tailored team involved in a resident’s person-centered service planning and service delivery, including the resident’s attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident’s needs, and the resident. If the resident is cognitively impaired and unable to fully participate, the team shall include to the extent practicable, the participation of the resident, and shall also include the resident’s family, a resident representative, a responsible person or the resident’s legal representative.</td>
</tr>
<tr>
<td>Health Care Practitioner—As defined in section 103 of the act (35 P.S. § 448.103). The term &quot;practitioner&quot; when used alone in this subpart is deemed to be synonymous with this definition.</td>
</tr>
<tr>
<td>Intimidation—An act or omission by any person or entity toward another person which is intended to, or with knowledge that the act or omission will, obstruct, impede, impair, prevent or interfere with the administration of this act or any law intended to protect older adults from mistreatment.</td>
</tr>
<tr>
<td>LPN—Licensed practical nurse—A practical nurse licensed to practice under the Practical Nurse Law (63 P.S. §§ 651—667.8) and the regulations of the State Board of Nursing at 49 Pa. Code Chapter 21, Subchapter B (relating to practical nurses).</td>
</tr>
</tbody>
</table>
| Licensee—The individual, partnership, association or corporate entity including a...
public agency or religious or fraternal or philanthropic organization authorized to operate a licensed facility.

[Locked restraints—A mechanical apparatus or device employed to restrict voluntary movement of a person not removable by the person. The term includes shackles, straight jackets and cage-like enclosures and other similar devices.]

Long-term care ombudsman—The local entity serving as designee of the Pennsylvania Office of the State Long-Term Care Ombudsman charged with the functions and responsibilities set forth in 45 CFR §1324.

[Medical record practitioner—A person who is certified or eligible for certification as a registered records administrator (RRA) or a health information technologist/accredited record technician by the American Health Information Management Association (AHIMA) and who has the number of continuing education credits required for each designation by the AHIMA.]

Medication administration—An act in which a single dose of a prescribed medication or biological is given to a resident by an authorized person in accordance with statutes and regulations governing the act. The complete act of administration entails removing an individual dose from a previously dispensed, properly labeled container, verifying it with the physician’s orders, giving the individual dose to the proper resident and promptly recording the time and dose given.

Medication dispensing—An act by a practitioner or a person who is licensed in this Commonwealth to dispense medications under the Pharmacy Act (63 P.S. §§ 390-1—390-13) entailing the interpretation of an order for a medication or biological and, under that order, the proper selecting, measuring, labeling, packaging and issuance of the medication or biological for a resident or for a service unit of the facility.


[Nonambulatory resident—A resident who is not physically or mentally capable of getting in and out of bed and walking a normal path to safety in a reasonable period of time, including the ascent and descent of stairs, without the aid of another person.]

[Nonproprietary drug—A drug containing a quantity of controlled substance or drug requiring a prescription, a drug containing biologicals or substances of glandular origin—except intestinal-enzymes and liver products—and drugs which are administered parenterally.]

Non-prescription medication—An over-the-counter medication legally purchased without a prescription.

Commented [AH20]: We had previous recommended and continue to recommend the addition of a definition for the long-term care ombudsman.

Commented [AH21]: Is this relevant for evacuation requirements?
Nurse aide—An individual providing nursing or nursing-related services to residents in a facility who meets the federal requirements of being a nurse aide and fulfills the following qualifications:

(i) Does not have a license to practice professional or practical nursing in this Commonwealth.

(ii) Does not volunteer services for no pay.

(iii) Has completed 120 hours of training and met the requisite training (aside from total hours) and competency evaluation requirements as defined in 42 CFR 483.75 (relating to administration).

(iv) Appears on the Commonwealth’s Nurse Aide Registry.

(v) Has no substantiated findings of abuse, neglect or misappropriation of resident property recorded in the Nurse Aide Registry.

Nursing care—A planned program to meet the physical and emotional needs of the resident. The term includes procedures that require nursing skills and techniques applied by properly trained personnel.

Nursing service personnel—Registered nurses, licensed practical nurses and nurse aides.

[Occupational therapist—A person licensed as an occupational therapist by the State Board of Occupational Therapy Education and Licensure.

Occupational therapy assistant—A person licensed as an occupational therapy assistant by the State Board of Occupational Therapy Education and Licensure.]

Pharmacist—A person licensed by the State Board of Pharmacy to engage in the practice of pharmacy.

Pharmacy—A place properly licensed by the State Board of Pharmacy where the practice of pharmacy is conducted.

[Physical therapist—A person licensed as a physical therapist by the State Board of Physical Therapy.

Physical therapy assistant—A person registered as a physical therapy assistant by the State Board of Physical Therapy.]
the State Board of Osteopathic Medical Examiners under the Osteopathic Medical Practice Act (63 P.S. §§ 271.1—271.18).

[Practice of pharmacy—The practice of the profession concerned with the art and science of the evaluation of prescription orders and the preparing, compounding and dispensing of drugs and devices, whether dispensed on the prescription of a medical practitioner or legally dispensed or provided to a consumer. The term includes the proper and safe storage and distribution of drugs, the maintenance of proper records, the participation in drug selection and drug utilization reviews and the responsibility of relating information as required concerning the drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease. The term does not include the operations of a manufacturer or distributor as defined in The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144).]

Prescription—A written or verbal order for [drugs] medications issued by a [licensed medical] health care practitioner in the course of [his] professional practice.

[Proprietary drug—A drug which does not contain a quantity of a controlled substance which can be purchased without a prescription and may be purchased from sources other than a pharmacy, and is usually sold under a patented or trade name.]

RN—Registered nurse—[A nurse] An individual licensed to practice [in this Commonwealth] professional nursing under The Professional Nursing Law (63 P.S. §§ 211—225.5) and the regulations of the State Board of Nursing at 49 Pa. Code Chapter 21, Subchapter A (relating to registered nurses).

Resident—A person who is admitted to a licensed long-term care nursing facility for observation, treatment, or care for illness, disease, injury or other disability.

[Resident activities coordinator—A person who meets one of the following requirements:
(i) Is a qualified therapeutic recreation specialist.
(ii) Has 2 years of experience in a social or recreational program, within the last 5 years, 1 year of which was full-time in a patient-resident activities program in a health care setting.

Residential unit—A section or area where persons reside who do not require long-term nursing facility care.

Responsible person—A person who is not an employe of the facility and is responsible for making decisions on behalf of the resident. The person shall be so designated by the resident or the court and documentation shall be available on the resident’s clinical record to this effect. An employe of the facility will be permitted

Commented [AH24]: The preamble says this term is out of date but, we are not sure why it would be out of date. It is critical for resident quality of life that there be meaningful activities and an activities coordinator who plans and runs these activities is important for ensuring that meaningful activities are planned and occur. Also, this is not defined in the federal regulations or SOM and this also articulates qualifications – not just a definition. We recommend against removing it. However, it definitely should be revised to use “resident” instead of “patient”.
to be a responsible person only if appointed the resident’s legal guardian by the court.

Resident representative. The term resident representative means any of the following:
(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;
(2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;
(3) Legal representative, as used in section 712 of the Older Americans Act; or.
(4) The court-appointed guardian of a resident.
(5) An employee of the facility shall not serve as resident representatives for any resident.
(6) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.

Restraint—A restraint can be physical, mechanical, or chemical.

(i) A physical restraint includes any apparatus, appliance, device or garment applied to or adjacent to a resident’s body, which restricts or diminishes the resident’s level of independence or freedom.

(ii) A chemical restraint includes psychopharmacologic drugs that are used for discipline or convenience and not required to treat medical symptoms.

(iii) A physical restraint or “drug used as a restraint” includes psychopharmacologic drugs that are administered for discipline, convenience, or to manage a resident’s behavior in a way that reduces the safety risk to the resident or others, have the temporary effect of restricting the resident’s freedom of movement, and do not reflect a standard treatment for the resident’s medical or psychiatric condition and not required to treat medical symptoms.

[Serious bodily injury.] Injury which creates a substantial risk of death or which causes serious permanent disfigurement or protracted loss or impairment of the function of a body member or organ. (Def. added June 9, 1997, P.L.160, No.13)
“Serious physical injury.” An injury that:
(1) causes a person severe pain; or
(2) significantly impairs a person’s physical functioning, either temporarily or permanently.

Skilled or intermediate nursing care—Professionally supervised nursing care and related medical and other health services provided for a period exceeding 24 hours to an individual not in need of hospitalization, but whose needs are above the level of room and board and can only be met in a long-term care nursing facility on an inpatient basis because of age, illness, disease, injury, convalescence or physical or mental infirmity. The term includes the provision of inpatient services that are needed on a daily basis by the resident, ordered by and provided under the direction of a physician, and which require the skills of professional personnel, such as, registered nurses, licensed practical nurses, physical therapists, occupational therapists, speech pathologists or audiologists.

Social worker—An individual with the following qualifications:
(i) A Bachelor’s Degree in social work or a Bachelor’s Degree in a human services field including sociology, special education, rehabilitation counseling and psychology.
(ii) One year of supervised social work experience in a health care setting working directly with individuals.

Speech/language pathologist—A person licensed as a speech/language pathologist by the State Board of Examiners in Speech-Language and Hearing, or excluded from the requirements of licensure under the Speech-Language and Hearing Licensure Act (63 P.S. §§ 1701–1719).

Commented [AH28]: We want to be sure the state is clear that this doesn’t impact Medicaid eligibility that is tied to these standards.

In order to be eligible for Medicaid for nursing facility (NF) care, a resident must be nursing facility clinically eligible (NFCE). The NFCE definition is below. We think that the 55 Pa Code 1181.2 Medicaid definition contains most of this, but one part which is in NF regulations but not in 1181 is “above the level of room and board”. Do DOH and DHS really want to delete the “above the level of room and board” language? We don’t think this should be deleted.

Nursing Facility Clinically Eligible (NFCE) – The individual has an illness, injury, disability or medical condition diagnosed by a physician; and as a result of that diagnosed illness, injury, disability or medical condition, the individual requires care and services above the level of room and board; and a physician certifies that the individual is NFCE; and the care and services are either a) skilled nursing or rehabilitation services as specified by the Medicare Program in 42 CFR §§ 409.31(a), 409.31(b)(1) and (3), and 409.32 through 409.35; or b) health-related care and services that may not be as inherently complex as skilled nursing or rehabilitation services but which are needed and provided on a regular basis in the context of a planned program of health care and management and were previously available only through institutional facilities.

We recommend that counsel in DHS legal department take a look.

Commented [AH29]: These are qualifications set by PA, not a definition of what is a social worker. These qualifications are not in the federal regulations or the SOM and must be retained in the state regulations.
§ 211.12. Nursing services, Staffing Minimums, and Baseline Staffing Ratios.

(a) The facility shall provide services by sufficient numbers of personnel on a 24-hour basis to provide nursing care to meet the needs of all residents.

The following minimum nursing and nurse aide staffing ratios and minimum staffing levels are minimums. Actual staffing levels, which shall meet or exceed the minimum levels, must be determined specifically for each facility based on the actual needs of each resident as outlined in their comprehensive assessments and person-centered service plans, as well as in accordance with the facility assessment required in 42 CFR 438.70(e), which facilities shall be required to complete quarterly.

(g) In addition to the director of nursing services, the following daily professional staff shall be available.

(1) The following minimum nursing staff ratios are required:

Day shifts.--With respect to a day shift, the nursing facility must have—
- at least 1 registered professional nurse for every 28 residents, with a minimum of 0.29 hours of care provided per resident during each such shift;
- at least 1 licensed practical nurse for every 40 residents, with a minimum of 0.20 hours of care provided per resident during each such shift; and
- at least 1 nurse aide for every 7 residents, with a minimum of 1.14 hours of care provided per resident during each such shift.

Evening shifts.--With respect to an evening shift, the nursing facility must have—
- at least 1 registered professional nurse for every 30 residents, with a minimum of 0.26 hours of care provided per resident during each such shift;
- at least 1 licensed practical nurse for every 40 residents, with a minimum of 0.20 hours of care provided per resident during each such shift; and
- at least 1 nurse aide for every 7 residents, with a minimum of 1.14 hours of care provided per resident during each such shift.

Night shifts.--With respect to a night shift, the nursing facility must have—
- at least 1 registered professional nurse for every 40 residents, with a minimum of 0.20 hours of care provided per resident during such shift;
- at least 1 licensed practical nurse for every 56 residents, with a minimum of 0.14 hours of care provided per resident during such shift; and
- at least 1 nurse aide for every 15 residents, with a minimum of 0.53 hours of care provided per resident during such shift.

Commented [AH30]: We previously recommended adding and continue recommend adding as a new (f) this language.

Commented [AH31]: We previously recommended and continue recommend revising the old (f) (and making it (g)) to read as we revised it.
(g) There shall be at least one nursing staff employee on duty per 20 residents.

(h) At least two nursing service personnel shall be on duty.

(i) A minimum number of general nursing care hours shall be provided for each 24-hour period. The total number of hours of general nursing care provided during each shift spread across all shifts in each 24-hour period shall, when totaled for the entire facility, be a minimum of [2.7] 4.1 hours of direct resident care for each resident. The total minimum of 4.1 hours of general nursing care hours provided per resident per day, with 0.75 hours of care of such total minimum provided by a registered professional nurse, 0.54 hours of care of such total minimum provided by a licensed practical nurse or an RN, and 2.81 hours of care of such total minimum provided by a nursing assistant. A facility shall have, across all shifts during each shift in each 24-hour period, a sufficient number of nursing staff with the appropriate competencies and skill sets to provide nursing care and related services to:

(1) assure resident safety; and

(2) attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.

(j) Nursing personnel shall be provided on each resident floor.

(k) The Department may require an increase in the number of nursing and other personnel from the minimum requirements if specific situations in the facility—including, but not limited to, the physical or mental condition of residents, quality of nursing care administered, the location of residents, the location of the nursing station and location of the facility—indicate the departures as necessary for the welfare, well-being, health and safety of the residents.
(m) The required nursing services and staffing minimums and baseline ratios shall not be interpreted to minimize the facility’s requirement to have sufficient ancillary staff to provide services for the residents other than nursing services. Ancillary staff may include staff who meet the licensure requirements of being RNs, LPNs, dieticians, or skilled professionals but do not provide direct care. Ancillary staff may include activities planners, housekeepers, cooking staff or facilities staff but also staff who conduct assessment, care planning or care management activities or serve as the full-time Infection Preventionist.

(n) Daily, the facility shall conspicuously and publicly post the actual staffing levels for all types of staff as scheduled for the day. This information shall be posted inside and outside the front door of the facility for residents and visitors to see.

§ 211.13. Infection Preventionist
(a) Each facility must employ at least one full-time infection preventionist to plan for, implement, monitor, and oversee all infection control activities.
(b) The infection preventionist must be trained in infection prevention by an accredited training entity and qualified as a nursing professional.

The infection preventionist does not count as direct care, nursing services staff time as their focus is infection prevention.

§ 211.14. Ancillary Staff
The facility shall employ ancillary staff necessary to provide all necessary housekeeping, cooking, cleaning, infection prevention, activities, administrative, and care planning activities. Staff employed for these functions cannot be counted in staffing minimums and baseline ratios outlined in 211.12.

* * * * *