



June 27, 2022

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Harrisburg, PA 17120

VIA EMAIL to: RA-DHLTCRegs@pa.gov

Re: Rulemaking 10-224 (Long-Term Care Facilities, Proposed Rulemaking 4) 28 PA Code Sections 201.18-21, 201.24-31, 207.2, 209.3, 211.2-211.17
Deadline: June 27, 2022

To Whom It May Concern:

Thank you for the opportunity to provide comments relating to the fourth package of proposed changes to the Pennsylvania nursing home licensing regulations.

Background

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

I am also a Practice Professor of Law at the Kline School of Law at Drexel University who focuses on patient safety and compliance.

Introduction

I am pleased to see that the Department of Health is continuing its update of the nursing home licensing regulations. There is no doubt that the current regulations are insufficient to protect the lives of some of our most vulnerable members of society, our nursing home residents. Considerable changes are necessary and comprehensive reform is essential. **The Department is to be commended for moving forward with this reform initiative and these comments are offered in the spirit of enhancing what has been proposed by the Department.**

General Recommendations:

(A) The substitution of federal regulation in areas where state licensing regulations can better protect residents is concerning. In some instances, the deletion of existing state regulations that improved oversight of nursing homes is problematic. Additionally, the Department has the opportunity to enhance federal regulation in appropriate areas, to the protection of nursing home residents, and should do so.

(B) All facilities must comply with the requirements of 42 CFR Section 483 if the state is going to cross reference it, not just the facilities participating in Medicare and/or Medicaid. I am concerned that since the federal regulations found at 42 CFR Section 483 establish conditions of participation for the Medicare and/or Medicaid program, facilities that are solely private pay are not bound by these requirements. While there are not many in Pennsylvania, they do exist. The Department's intention to extend the federal regulations to these facilities through cross referencing the federal regulations may not be adequate to ensure the federal regulations apply and possibly may not sustain any legal challenges. I also question how likely these facilities' personnel are to be familiar with both the federal regulations and all applicable interpretative guidance documents.

(C) The nursing home licensing regulations should specify the services that must be delivered by the nursing home facility to its residents. I propose that the licensure regulations clearly delineate the following services: **medical, social, nursing, pharmacy, dementia care, activities, protective supervision, cueing, and other services to meet the physical health, behavioral health, skilled nursing, nursing, psychosocial, emotional, cognitive, social, personal care, nutritional, rehabilitative, technological, equipment, transportation, Medicaid eligibility, and other needs and preferences of each individual resident and as may be required of a person who meets the nursing facility level of care. Facilities must also assist residents with activities of daily living and instrumental activities of daily living and in preparing for transition out of the nursing facility.**

Specific Regulatory Section Comments:

(1) Comments on Section 201.18 – Management

The "Governing body" refers to individuals such as facility owner(s), Chief Executive Officer(s), or other individuals who are legally responsible to establish and implement policies regarding the management and operations of the facility. *State Operations Manual, Appendix PP - Guidance to Surveyors for Long Term Care Facilities*, p. 616. This entity plays a critical role in ensuring that nursing homes operate in a compliant manner and as such, greater detail is warranted than what appears in federal regulation.

Moreover, the role of the administrator should be set forth in greater detail in this section, to include involvement in the financial decisions in the facility in conjunction with the governing body. Specifically, the following language is offered for Section 201.18 in its entirety:

(a) The facility shall have an effective governing body functioning with full legal authority and responsibility for the operation of the facility.

(1) The Facility shall maintain written documentation to evidence how the governing body was created and by whom and maintain a listing of all current and past members.

(2) The governing body is legally responsible for establishing and implementing policies regarding the management and operation of the facility. All entities providing management and operational activities shall report monthly to the governing body on findings, recommendations and performance improvement activities.

(3) The governing body shall report monthly to the licensee on operational activities including, at a minimum, the items identified in 201.18(b).

(4) The governing body appoints the administrator of the facility.

(5) The governing body shall be actively engaged in the establishment of all policies and procedures governing the facility and oversee the Quality Assurance Performance Improvement process. The administrator shall present, at least quarterly, a detailed description of the QAPI projects being performed by facility staff and the results of QAPI projects completed. The governing body shall review the projects, provide oversight and analyze outcomes to ensure that the QAPI program is performing effectively.

(b) The governing body shall adopt effective administrative and resident care policies and bylaws governing the operation of the facility in accordance with legal requirements. In addition to the requirements set forth in 42 CFR 483.70(d) (relating to administration), the governing body of a facility shall adopt and enforce rules relative to:

(1) The health, care, and safety of the residents.

(2) Protection of personal and property rights of the residents, while in the facility, and upon discharge or after death, and return of any resident property remaining at the facility within 10 business days after discharge or death.

(3) The general operation of the facility.

(c) The governing body shall report to the Department within 30 days changes to the information that was submitted with the facility's application for licensure under section 201.12 (relating to application for license of a new facility of change in ownership).

(d) The administrative and resident care policies and bylaws, established and implemented by the governing body under 42 CFR 483.70(d), shall be in writing, dated and made available to the members of the governing body, which shall ensure that they are operational, Additionally, review and revision of policies and bylaws shall be reviewed on an annual basis and revised, in writing, as necessary. The

policies and bylaws shall be available upon request, to residents, and resident representatives.

(e) The administrator appointed by the governing body under 42 CFR 483.70(d)(2) shall be currently licensed and registered in this Commonwealth and shall be employed full-time in facilities that have more than 25 beds. Facilities with 25 beds or less may share an administrator provided that:

(1) The Department is informed of this arrangement.

(2) There is a plan in the event of an emergency when the administrator is not working.

(3) There is a readily available method for residents to contact the administrator should they find it necessary.

(4) The director of nursing services has adequate knowledge and experience to compensate for the time the administrator is not in the building.

(5) The sharing of an administrator shall be limited to two facilities.

(f) The administrator's work schedule, including what days and times the administrator will be physically present in the facility, shall be publicly posted in the facility along with the daily posting of staffing numbers and levels for all types of staff.

(g) The Administrator shall report to the governing body on an at least monthly basis, in writing, regarding the operation of the facility to include survey results, allegations of abuse or neglect, complaints, or any other information relevant to risks, safety and security of the facility's residents. The governing body shall respond in writing to the administrator's report within thirty (30) days acknowledging receipt and development of a plan to address any non-compliant conduct.

(h) The administrator shall also be responsible to report, on a monthly basis, information regarding the facility's management and operation through the use of audits, review of budgets, projected and actual staffing tools, supplies available, in order to ensure compliance with regulatory requirements and meet the needs of the residents.

(i) The facility assessment process shall include a detailed review of the assessment of the operations by the governing body and documentation of said review as part of the facility assessment.

(j) The administrator's responsibilities shall include the following:

(1) Enforcing the regulations relative to the level of health care and safety of residents and to the protection of their personal and property rights.

(2) Planning, organizing and directing responsibilities obligated to the administrator by the governing body.

(3) Engaging in an analysis of all financial information relevant to the operation of the facility and participating in the development of the facility's budget in conjunction with the governing body and licensee.

(4) Ensuring satisfactory housekeeping in the facility and maintenance of the building and groups.

(5) Maintaining an ongoing relationship with the governing body, medical and nursing staff and other professional and supervisory staff through meetings and periodic reports.

(6) Studying and acting upon recommendations made by committees.

(7) Appointing, in writing and in concurrence with the governing body, a responsible employee to act on the administrator's behalf during temporary absences.

(8) Assuring that appropriate and adequate relief personnel are utilized for those necessary positions vacated either on a temporary or permanent basis.

(9) Developing a written plan to assure the continuity of resident care and services in the event of a strike in a unionized facility.

(10) Communicating to residents and resident representatives any updates about the composition of or decisions made by the governing body.

(k) A written record shall be maintained on a current basis for each resident with written receipts for personal possessions and funds received or deposited with the facility and for expenditures and disbursements made on behalf of the resident. The record shall be available for review by the resident or resident representative upon request.

(l) The governing body shall disclose, upon request, to be made available to the public, the licensee's current daily reimbursement under Medical Assistance and Medicare as well as the average daily charge to other insured and noninsured private pay residents.

(m) When the facility accepts the responsibility for the resident's financial affairs, the resident or resident representative shall designate, in writing, the transfer of the responsibility. The facility shall provide the residents with access to their money within 1 day of the request and in the form—cash or check—as requested by the resident. The facility shall process a request for electronic transfer of funds, if requested, within one day of the request.

(4) Comments on Section 201.19 – Personnel Records

I recommend additional language be added to personnel records including a record of all training, all background checks, and all credentials; a copy of the employment application; documentation of any monitoring, performance, or disciplinary action related to the employee; and a record of the employee's receipt of required vaccinations.

**(5) Comments on Section 201.20 – Staff Development
Staff development section requires additional language.**

(1) Education Topics Need to be Added.

- While the federal regulations at 42 CFR 483.95 include education on what constitutes abuse, the procedures to report it, and abuse prevention, the federal regulations do not require training on detection (which is critically important) nor on mandatory reporting laws. Therefore, detection and reporting requirements should be added.
- The federal regulations do not require education on the topics of (1) Disability competency, (2) LGBTQ Cultural Competency, (3) Implicit Bias, (4) Non-discrimination, or (5) Understanding dementia and effective communication skills with people living with dementia and how to apply that to residents of the facility. These topics should be added.
- Additionally, each facility should educate all direct care staff in dementia care and treatment including: (1) understanding Alzheimer’s disease and dementia; (2) person-centered care; (3) assessment and care planning; (4) activities of daily living; and (5) dementia-related behaviors and communication.

(2) Demonstration of Competency is Required. The regulations do not require that direct care staff demonstrate competency which is an important component to ensuring that quality care is delivered consistently. Therefore, language should be included to address this issue.

(3) Resident-Specific Training is Essential and Should be Added. Direct care staff need resident-specific education before they can begin independent work in a facility. Residents are all unique and the approach to care must be tailored to each resident. Knowing how one resident is most safely transferred or knowing how another resident’s skin is most successfully protected from pressure injuries is knowledge that should be conveyed to new staff so that they can meet the regulatory requirements governing care delivery and promote the health and well-being for residents.

(4) Annual Training Should Be Strengthened Not Removed. The Department should require that annual education be at least 16 hours per year and expand on the topics that should be covered in the annual training. Additionally, education must be provided by individuals who have the expertise required to ensure staff proficiency.

**(6) Comments on Section 201.21 – Use of Outside Resources
Eliminating most of this section is unwarranted.**

I believe that facilities should be held accountable for ensuring that the outside resources or related parties with whom they contract are appropriately qualified to provide high-quality services. I also believe that facilities must be required to use contracted services if they cannot directly provide the required services through their own employees. Therefore, I believe that the Department should not delete Sections (a) through (c). Additionally, I recommend adding language that requires that facility contracts with outside resources obligate them to cooperate with state-funded programs, demonstrations, or partnerships with local hospitals or health systems or other entities (similar to those created in response to COVID-19) that are designed to provide quality of care for residents.

(7) Comments on Section 201.24 – Admission Policy

Resident protections within the admissions process should be enhanced.

- In Section 201.24 of the proposed regulations, language that prohibits a facility from requiring a resident from designating a representative has been removed. Designating a representative is a resident choice and should not be mandated by a facility.
- Additionally, a facility employee should not be named as the representative of a resident and language setting forth this resident protection should be added. The proposed regulations would also remove language that protects a resident from being forced to sign a waiver of rights, which should not occur.
- Facilities should not be allowed to require a resident representative or other third party to sign an admissions agreement or to otherwise attempt to financially bind that resident's representative or third party personally for a resident's care. The prohibition needs to be included in the regulatory language.
- The proposed regulations remove language that prohibits facilities from making residents release a facility from liability for failure to fulfill its duties. This language should not be deleted.

(8) Comments on Resident admissions- Section 201.24(c)

I recommend revising this section to state:

(c) A facility shall provide nursing facility level of care as residents require. A facility shall admit only residents whose individual needs can be provided by the staff and facility. A facility must have and follow a written admission policy that outlines admission procedures, criteria for admission, and what nursing care and physical needs they can and cannot provide. This policy must

- 1) be pre-approved by the Department and any revisions must be approved by the Department before being implemented;**
- 2) be compliant with the Americans with Disabilities Act and all other non-discrimination laws and regulations, including provisions in 201.29 (Residents Rights);**
- 3) not permit discrimination on the basis of payor source;**
- 4) be publicly posted on the facility website and within the facility; and**
- 5) be applied uniformly by the facility.**

Next, facilities should be required to maintain records on whom they are denying admission to for purposes of ensuring that the Department can exercise its authority to prevent discriminatory practices. Residents should receive a written denial notice stating the basis for such denial.

Finally, I urge the Department to create a standard admissions agreement detailing exactly what must be included in the agreement. This standard agreement would create a level of uniformity that would benefit both parties to the admission process.

(9) Comments on Section 201.25 – Discharge Policy

Discharge protections should not be deleted from the regulations.

The Department proposes to delete language requiring discharge and transfer planning for residents. For years, residents have lacked adequate protections against unjust and unsafe discharge or transfers to other settings. Robust protections must be articulated to prevent residents from being arbitrarily and carelessly evicted from their home. I believe that nursing facilities should be required to follow a Department-approved discharge policy and that regulatory language should establish that obligation.

(10) Comments on Section 201.29 – Resident Rights

State regulations such as section 201.29(e) often provide more specificity than the federal regulations. For example, 42 CFR 483.10(g)(18) requires facilities to inform a resident before changes in charges, while the state regulations at 201.29(e) require the facility to inform the resident **verbally and in writing** of changes in charges. This added resident protection, perfectly permissible under federal preemption rules, should not be eliminated.

Similarly, state regulations should not provide less protection than the federal regulations. Accordingly, I support the revisions to 201.29(e) of the language requiring 30 day advance notice because federal regulations at 42 CFR 483.10(g)(18)(i) and (ii) require at least 60 days advance notice of charges not covered under Medicare or Medical Assistance. But, the federal regulations only address changes due to charges not being covered by Medicare or Medical Assistance and the Department's wholesale deletion of a requirement of at least 30 days advance notice is inappropriate. The Department could extend the 60 days' notice requirement to all potential changes in charges or could clarify that changes in coverage for items and services covered under Medicare and Medical Assistance must be made at least 60 days in advance in accordance with 42 CFR 483.10(g)(18)(i) and (ii) while 30 days' notice must be provided for all other changes in charges.

(11) Comment on Experimental research or treatment- Section 201.29(o)

I believe nursing home residents need more protection than just a basic requirement for informed consent before initiation of experimental research or treatment in a nursing home. The need for enhanced protection was evident during the early phases of the pandemic. Residents have the right to participate or not in any experimental research or treatment. If the facility is involved in the experimental research or treatment, the facility must have Department approval, IRB approval or other similar, written, safety protocols like the ones the IRB requires and these must be provided to residents, and written approval based on a meaningful informed consent process.

Therefore, I recommend the following language to be included in Section 201.29(o) in its entirety:

(o) A resident has the right not to be required to participate in any experimental research or treatment while in a facility, whether by the facility or as guided by their doctor. The resident has the right to participate in experimental research or treatment with their doctors, only after a fully documented and legally compliant informed consent process has occurred, and informed consent is obtained by the resident and/or their legal representative. Experimental research or treatment

involving a resident in a facility whether conducted by the facility or by any doctor under contract with or employed by the facility may not be carried out:

(1) without the approval of the Department,

(2) without IRB approval or other written, safety protocols that are provided to the resident and resident representative, if applicable, and,

(3) without the written approval and informed consent of the resident, or resident representative, obtained prior to participation and initiation of the experimental research or treatment. The resident, or resident representative, shall be fully informed of the nature of the experimental research or treatment, the safety protocols, and the possible consequences of participating. The resident, or resident representative, shall be given the opportunity to refuse to participate both before and during the experimental research or treatment. For the purposes of this subsection, "experimental research or treatment" means a treatment or procedure that is:

(a) Not a generally accepted treatment, procedure, or practice in the medical community, and

(b) Exposes or has the potential to expose the resident to pain, injury, unknown risks, or invasion of privacy or asks the resident to surrender autonomy, such as a drug study.

(4) An experimental research or treatment often involves the development, testing and use of a clinical treatment, such as an investigational drug or therapy that has not yet been approved by the U.S. Food and Drug Administration (FDA) or medical community as effective and conforming to medical practice. It can also involve such things as nursing or social science exploration of new approaches to providing assistance with activities or daily living or addressing social isolation.

(12) Comments on Section 201.31 – Transfer Agreement

I do not agree with the deletion of this section. I believe this section should be revised to reflect that residents have a choice in which hospital they are sent to and that facilities must work in concert with the resident's insurance so that admissions are consistent with Community HealthChoices or other insurance plan provider network limitations.

(13) Comments on Section 211.2- Medical Director

The role of the facility Medical Director is critically important since this professional is responsible for overseeing the care of all of the residents, regardless of whether the Medical Director is acting as the treating physician. The federal regulations do not provide the specificity required to ensure that the medical care delivered to residents is compliant on a consistent basis. I am also concerned that the preamble would allow consultant medical directors to be used and to apply their own interpretation of the nursing home regulations in their role as medical director.

Therefore, I offer the following language related to Section 211.2 in its entirety:

(a) The attending physician shall be responsible for the medical evaluation of the resident and shall prescribe a planned regimen of total resident care.

(b) The facility shall have available, prior to or at the time of admission, resident information which includes current medical findings, diagnoses and orders from a physician for immediate care of the resident. The resident's initial medical assessment shall be conducted no later than three (3) calendar days after admission and include a summary of the prior treatment as well as the resident's rehabilitation potential.

(c) In addition to the requirements of 42 CFR 483.70(h) (relating to administration), the medical director of a facility shall be licensed as a physician in this Commonwealth and who and shall complete at least four hours annually of continuing medical education (CME) pertinent to the field of medical direction or post-acute and long-term care medicine. The medical director may serve on a full- or part-time basis depending on the needs of the residents and the facility and may be designated for single or multiple facilities. There shall be a written agreement between the physician and the facility.

(d) The medical director's responsibilities shall include at least the following:

(1) Overall coordination of the medical care in the facility to ensure the adequacy and appropriateness of the medical services provided to the residents.

(2) Documented review of incidents and accidents in order to evaluate and address the need for further care delivery interventions on a systemic and individualized resident basis and to address the health and safety hazards of the facility. The medical director shall evaluate the incidents and accidents for need in a change in residents' care plans and possible systems modifications to avoid future incidents and accidents. The administrator shall be given appropriate information from the medical director to help insure a safe and sanitary environment for residents and personnel.

(3) Development of written policies that are approved by the governing body that relate to resident medical care and delineate the responsibilities of attending physicians. The medical director shall, on at least an annual basis, evaluate the care being delivered by attending physicians to ensure consistency with the facility's clinical practices and standards of care. This evaluation shall identify performance expectations for attending physicians as well as facilitating feedback based on performance and practices. If a health care practitioner is providing care inconsistent with current standards of care, the medical director must intervene as appropriate.

(4) Participate in quality assurance and performance improvement meetings and the Quality Assessment and Assurance Committee (QAA) meetings.

- (5) Utilize evidence-based best practices related to the care of nursing home residents and how to oversee and communicate with other health care practitioners.**
- (6) Assist with developing and implementing staff education.**
- (7) Identify potential conflicts of interest and implement steps to mitigate any such conflicts. Conflicts of interest should be reviewed and addressed through the facility's Compliance and Ethics Program.**
- (e) Medical director communication and interactions with residents and resident representatives shall be person-centered and conducted in a manner easily understood by the specific resident, and provided in the form, format, and language of the resident's need or preference.**

(14) Comments on Section 211.8 – Restraints

I propose that the following language be adopted to address the risks associated with the use of physical, mechanical and chemical restraints:

211.8 Restraints

- (a) Residents have the right to be free of physical, mechanical, and chemical restraints.**
- (b) Restraints are prohibited unless
 - (i) authorized in accordance with state and federal law,**
 - (ii) ordered by a physician as appropriate to treat the individual's medical condition,**
 - (iii) consented to by the resident or resident's representative, and**
 - (iv) approved by the resident's person-centered service planning interdisciplinary team as part of the resident's written person-centered service plan and must include a written demonstration that less restrictive alternative means of controlling movement or behavior do not work. The person-centered service plan must outline how and when restraints are approved.****
- (c) Restraints may not be used for discipline, convenience, or in lieu of staff effort or adequate staffing levels to meet residents' needs.**
- (d) Locked restraints or any mechanical apparatus or device, such as shackles, straightjackets, cage-like enclosures or other similar devices, employed to restrict voluntary movement of a person that is not removable by that person may not be used.**
- (e) Restraints may not be used or applied in a manner which causes injury to the resident.**
- (f) Physical and mechanical restraints shall be removed at least 10 minutes out of every 2 hours during the normal waking hours to allow the resident an opportunity to move and exercise. Except during the usual sleeping hours, the resident's position shall be changed at least every 2 hours. During sleeping hours, the position shall be changed as indicated by the resident's needs.**
- (g) If restraints are used, a facility shall ensure that appropriate interventions are in place to safely and adequately respond to resident needs.**
- (h) A signed, dated, written physician order from a physician or physician's delegee authorized under 42 CFR 483.30(e) (relating to physician services), shall be required for a restraint. This includes the use of chest, waist, wrist, ankle, drug or**

other form of restraint. The order shall include the type of restraint to be used. It shall include the period for which the restraint is being authorized and the circumstances under which the restraints may be used. All other circumstances are prohibited and a violation of the resident's right to be free of restraints.

(i) The physician, or physician's delegatee authorized under 42 CFR 483.30(e), shall document the reason for the initial restraint order and shall review the continued need for the use of the restraint order by evaluating the resident. If the order is to be continued, the order shall be renewed by the physician, or physician's delegatee authorized under 42 CFR 483.30(e), in accordance with the resident's total program of care.

(j) Every 30 days, or sooner if necessary, the interdisciplinary team shall review and reevaluate the use of all restraints ordered by physicians. Residents' person-centered services plan shall be updated to reflect the outcomes of these reviews.

(k) Any chemical restraints must be closely monitored to ensure no adverse reactions.

(l) The facility shall document daily all uses of restraints, including dates and times and staff persons involved. These documents shall be stored and made available for inspection by the Department and others authorized to view these records.

(15) Comments on Section 211.12 - Nursing Services

Nursing staffing ratios serve as the floor, not the ceiling related to the number of nurses needed to meet regulatory requirements. The following language should be added to address this fact:

(f) 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.

Next, a methodology for evaluating staffing that meets the needs of nursing home residents on a consistent basis must be implemented. In package 1, the Department previously proposed a minimum number of hours set at 4.1 of direct care per resident per day which I supported. However, the Department should require staffing levels with a specific minimum required breakout of RN, LPN, and CNA time. Ratios alone are simply not enough. For example, it is extremely time-consuming to dispense medications in a nursing home. This fact has to be accounted for as part of the staffing methodology used by a facility in ensuring care delivery in a timely fashion. Finally, the Department should ensure that only RNs, LPNs, and CNAs who are providing direct care to residents are counted when meeting regulatory staffing requirements. Ancillary staff cannot and should not be included in the calculation for purposes of compliance with staffing level and ratio requirements.

(16) Comments on Section 211.15 – Dental Services

This section should be improved not deleted. I do not agree with the deletion of this section. Facilities must help residents access dental services. The Department should strengthen this section to ensure facilities assist residents in accessing outside providers when needed or preferred.

(17) Comments on Section 201.27 Advertisement of Special Services

I believe that some important additions to this section are needed. They are as follows:

(1) an express requirement that facilities comply with the requirements of the Unfair Trade Protection and Consumer Protection Law when advertising and marketing, and

(2) an express prohibition on facilities advertising their services in a manner that misrepresents their scope of services as being greater or lesser than their licensure and certification covers.

The decision in PA Supreme Court case, *Commonwealth of Pennsylvania Acting by Attorney General, Josh Shapiro, Appellant v. Golden Gate National Senior Care LLC; GGNSC Holdings LLC et al.* provides support for modifying this regulation.

Proposed New Regulatory Sections:
Dementia Care/Memory Care Units

Nursing homes promote expertise in dementia care yet there is no clear regulatory requirements associated with the provision of this care. Interestingly, Pennsylvania requires personal care homes and assisted living facilities to comply with criteria for memory care units but nursing homes do not. I believe that specific regulatory language should be included as follows:

(a) A Dementia Care or Memory Unit is a unit or portion of a facility that has submitted an application to and been approved by the Department as a Dementia Care or Memory Unit that provides one or both of the following:

(1) Specialized care and services for residents with Alzheimer’s disease or dementia in the least restrictive manner consistent with the resident’s person-centered services plan to ensure the safety of the resident and others in the residence while maintaining the resident’s ability to receive the care and services they need.

(2) Intense neurobehavioral rehabilitation for residents with severely disruptive and potentially dangerous behaviors as a result of brain injury in the least restrictive manner consistent with the resident’s rehabilitation and person-centered services plan to ensure the safety of the resident and others in the facility.

(b) Only a facility authorized by the Department as a Dementia Care or Memory Unit may so advertise, regardless of what terminology the facility uses to describe their unit. The Department will consider the licensee’s demonstration that:

(1) Staff collaboratively assess, plan, and provide care that is consistent with current advances in dementia care practices.

(2) Staff have the qualifications, skills, training, and education to assess and provide care for a resident population with memory impairment.

- (3) The facility provides activities that match the resident’s cognitive ability, memory, attention span, language, reasoning ability, and physical function.**
- (4) Non-pharmacological interventions are used as an alternative to antipsychotic medication use.**
- (5) The organization has a designated physical environment to promote safety and minimize confusion and overstimulation.**

Compliance and Ethics Program Effectiveness Review

Pursuant to federal regulation, nursing homes are required to have a compliance and ethics program that is “reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care.” 42 CFR Section 483.85(1). The key to measuring success of this program is through an “effectiveness” review. In addition to specifically delineating the federal compliance and ethics language into our state licensing regulations, I propose that the elements of the **effectiveness review** be set forth as well in our licensing regulations. This review should be modeled on the “U.S. Department of Justice Criminal Division Evaluation of Corporate Compliance Programs(Updated June 2020). <https://www.justice.gov/criminal-fraud/page/file/937501/download>. At a minimum, the DOJ requires an answer to the following questions:

- (1) Is the corporation’s compliance program well designed?;
 - (2) Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?; and
 - (3) Does the corporation’s compliance program work in practice?
- See Justice Manual 9-28.800.

The Department should use these questions and the DOJ evaluation document as the basis for including regulatory language to ensure that facilities’ compliance and ethics programs are, in fact, “effective” and not just a bunch of policies in a binder without any systemic impact on compliance and quality care delivery to our frail and vulnerable nursing home residents.

Conclusion

Thank you for the opportunity to comment on the fourth package of nursing home licensing regulations and I look forward to reviewing and commenting on the Department’s final submission for these important regulations.

Sincerely,

David Hoffman, JD, FCPP

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