Foulkeways at Gwynedd
1120 Meetinghouse Road
Gwynedd, PA 19436

August 26, 2021

Lori Gutierrez
Deputy Director, Office of Policy
625 Forster Street, Room 814
Health and Welfare Building
Harrisburg, PA 17120

Dear Ms. Gutierrez:

This document represents our strong opposition to the proposed Department of Health Regulations that replace 28 PA. Code Chapters 201 and 211. As these regulatory changes will affect the future survival of our Nursing Facility, we believe an in-person discussion is warranted and necessary.

PROPOSED REGULATION:

DEPARTMENT OF HEALTH
[28 PA. CODE CHS. 201 AND 211] Long-Term Care Nursing Facilities

PROPOSED REGULATION

The Department of Health (Department), after consultation with the Health Policy Board, proposes to amend §§ 201.1—201.3 and 211.12(i), to read as set forth in Annex A.

The Department began the process of updating the current long-term care regulations in late 2017. The Department sought review, assistance and advice from members of a long-term care work group (LTC Work Group) consisting of relevant stakeholders. The members of the LTC Work Group were drawn from a diverse background and included representatives from urban and rural long-term care facilities and various stakeholder organizations and consumer groups that work in the area of resident care and delivery of services

This is the first rulemaking packet developed as a result of the previous discussions. The purpose of this rulemaking is to create consistency between Federal and State requirements for long-term care nursing facilities by expanding the adoption of the Federal requirements to include all the requirements set forth in 42 CFR Part 483, Subpart B (relating to requirements for long term care facilities). This proposed rulemaking also updates existing definitions applicable to long-term care nursing facilities by adding, updating and deleting definitions as fully explained as follows. Finally, this proposed rulemaking increases the number of direct care hours that long-term care

nursing facilities are required to provide to residents, per shift, while also clarifying that nursing staff providing such care must possess the appropriate competencies and skills necessary to do so.

II. *Description of Proposed Amendments*

Comments:

The 3 non-Medicare and/or Medicaid Nursing Facilities that are most effected by these proposed regulations and referenced in these proposed changes were not represented in any of the long-term care work groups (LTC Work Group). No financial or paperwork analysis was conducted related to these 3 facilities.

No interviews of the Licensed Nursing Home Administrators or Board Members was conducted. The subjective allegations that there will be no paperwork or financial burdens on these facilities is without merit or evidenced based data.

IV. **According to the following:**

PROPOSED REGULATION

Statutory Authority

Sections 601 and 803 of the HCFA (35 P.S. §§ 448.601 and 448.803) authorize the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the HCFA. Section 801.1 of the HCFA (35 P.S. § 448.801a) seeks to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities. The minimum standards are to assure safe, adequate and efficient facilities and services and to promote the health, safety and adequate care of patients or residents of those facilities. In section 102 of the HCFA (35 P.S. § 448.102), the General Assembly has found that a purpose of the HCFA is, among other things, to assure that citizens receive humane, courteous and dignified treatment. Finally, section 201(12) of the HCFA (35 P.S. § 448.201(12)) provides the Department with explicit authority to enforce its rules and regulations promulgated under the HCFA.

The Department also has the duty to protect the health of the people of this Commonwealth under section 2102(a) of the Administrative Code of 1929 (71 P.S. § 532(a)). The Department has general authority to promulgate regulations under section 2102(g) of the Administrative Code of 1929.

Comments:

The minimum standards are to be applied to assure safe, adequate and efficient facilities and services and to promote the health, safety and adequate care of patients or residents of those facilities. There is no evidence that the current Long-Term Care Nursing Facilities regulations were not meeting the Statutory Authority for the Department of Health (DOH).

Pennsylvania Nursing Facilities demonstrate no less safe, adequate and efficient facilities and services than other states.

Since the DOH has noted repeatedly in these proposed regulations that ONLY 3 Pennsylvania Nursing Facilities are not currently subject to these Federal regulations by virtue of their Medicare and/or Medicaid certification status and associated reimbursement, these proposed regulations are punitive and not apply the "minimum standards" to the 3 nursing facilities that are not Medicare and/or Medicaid certified (Resident Funded).

The current Title 28 Health and Safety Part IV, Chapter 201 regulations are providing the minimum standards for Resident Funded facilities and our facilities have demonstrated consistent quality care for our Residents.

In the case of Foulkeways at Gwynedd:

- **In 2010 Foulkeways was given the "Pathways to Greatness" award by Leading Age for meeting Quality First standards.**
- **Foulkeways was awarded the 2012 "Excellence in Health Care Compliance" Pennsylvania Department of Health first time recognition in the Commonwealth for having met quality standards and three Medicare recertification and licensure surveys in a row without deficiencies.**
- **In 2012 Foulkeways was also selected as one of ten nursing facilities out of 16,000 in the United States to participate in the "Best Practices" Review of High Performing Nursing Homes for the purposes of launching a National Quality Improvement Collaborative, led by CMS and the Quality Improvement Organizations (QIOs) across the county.**
- **In 2017 Foulkeways decertified in the Medicare program after a DOH deficiency free Medicare re-certification survey**

Since 2017 Foulkeways has been DOH surveyed under Title 28, Part IV, Chapter 201, the Montgomery County DOH surveyors have followed the 45 pages of regulations for our annual licensure survey. By proposing to use the full scope of the Federal Medicare/Medicaid regulations for Resident Funded nursing facilities exceeds the Minimum standards condition.

In addition, the proposed regulation may violate PA state law. The proposed regulations may violate the Regulatory Review Act in that it incorporates by reference federal guidance or interpretations (State Operations Manual, Chapter 7 and Appendix PP) issued by the Centers for Medicare and Medicaid Services (CMS). This guidance may be changed by CMS at any time without notice or public process. This approach raises both due process and precedential questions and concerns.

CMS makes it clear that these guidance or interpretations are only to be referenced by surveyors in assisting them with the survey process, and that they are not statutory or regulatory in nature.

By reference to these CMS guidance, DOH regulations could change without going through any sort of process including PA legislative review or oversight as outlined in the Regulatory Review Act.

PROPOSED REGULATION

§ 201.1. Applicability
The proposed changes to directly reference the definition of ''long-term care nursing facility'' add clarity and promote consistency in the application of the act and in the application and scope of this subpart to long-term care nursing facilities.

Comments:

The 3 Resident Funded Nursing Facilities should not be subject to regulations designed to meet the Federal Conditions of Medicare and Medicaid for reimbursement when they purposely do not accept those funds. By proposing to apply onerous regulations, that cannot be met, will place unrealistic financial, staffing and operational burdens on organizations that are being funded by older adults on fixed incomes.

PROPOSED REGULATION

§ 201.2. Requirements

The Department proposes to break § 201.2 (relating to requirements) into four subsections. The existing language will move into subsection (a), with some changes. Specifically, the Department proposes to update the citation to the Federal requirements and delete the exceptions to the Federal requirements that are currently listed in this section. The effect of this change will be to adopt the Federal requirements in 42 CFR Part 483, Subpart B in their entirety. In subsection (b), the Department proposes to incorporate by reference Chapter 7 and Appendix PP—Guidance to Surveyors for Long-Term Care Facilities from the Centers of Medicare & Medicaid Services (CMS) State Operations Manual. Chapter 7 and Appendix PP are the parts of the State Operations Manual that are applicable to the implementation of 42 CFR Part 483, Subpart B. The Department proposes to add language in subsection (c) to clarify that a long-term care nursing facility may still apply for an exception under §§ 51.31—51.34 (relating to exceptions). The Department proposes to add language in subsection (d) to clarify that a violation of the Federal requirements will be considered a violation at the State level as well, unless an exception has been granted under §§ 51.31—51.34.

The Department's surveyors survey long-term care nursing facilities for compliance with both the State and Federal regulations for long-term care nursing facilities. With respect to the Federal regulations, the Department is designated as the State Survey Agency for CMS. As such, the Department is responsible for conducting surveys of facilities, including long-term care nursing

facilities, for compliance with the participation requirements for Medicare and Medicaid[1]. The Federal participation requirements for long-term care nursing facilities are located at 42 CFR Part 483, Subpart B. Presently, only three long-term care nursing facilities licensed by the Department do not participate in either Medicare or Medicaid. The remaining facilities participate in either Medicare or Medicaid, and as such, are already required at the Federal level to comply with the Federal requirements. See 42 CFR 483.1 (relating to basis and scope). Requiring all long-term care nursing facilities to comply with the Federal requirements across the board at the State level, without exceptions, will make the survey process more efficient and will create consistency and eliminate confusion in the application of standards for all long-term care nursing facilities that are licensed in this Commonwealth. In addition, all long-term care nursing facilities licensed by the Department were and are already required to comply with some of the Federal requirements based on the existing language in this section. Thus, any negative impact in applying the Federal requirements to the three facilities that do not participate in Medicare or Medicaid will be minimum and is vastly outweighed by the need for consistency in the application of standards in long-term care nursing facilities Statewide.

Comments:

"Requiring all long-term care nursing facilities to comply with the Federal requirements across the board at the State level, without exceptions, will make the survey process more efficient and will create consistency and eliminate confusion in the application of standards for all long-term care nursing facilities that are licensed in this Commonwealth" is wrong. The DOH surveyors currently have an efficient, consistent DOH standards to follow during survey for the 3 Resident funded facilities. There is nothing confusing about the DOH regulations. There is less burden on the DOH surveyors to apply the 45 pages of DOH regulations and application guidelines than the hundreds of pages of regulations found in Appendix PP State Operations manual.

§ 211.12. Nursing services

Comments:

The proposed regulations seek to require nursing homes to increase the requirements for staff from 2.7 nursing Hours Per Patient Day (NHPPD) to 4.1 NHPPD on each shift. While we currently exceed the daily NHPPD we are unable to staff shift each at 4.1 hours per day. As the result of the ongoing COVID pandemic and the lack of available nursing home staff, now is not the time after 24 years to suddenly implement a requirement that cannot be achieved. Long term care providers have not had the benefit of working from home during the ongoing COVID pandemic. We are dealing with staff burnout, unprecedented overtime and the stigma of working in facilities that require special dedication during non COVID pandemic conditions. Imposing one size fits all NHPPD at a time of extreme staff fatigue combined with the worst staffing crisis of our time is ignorance of the conditions at best.

A one size fits all NHPPD does not equal quality. Each nursing home has unique qualities such as acuity of residents, training, competency and tenure of staff, and characteristics of the building.

The DOH should allow the facility assessment and resident care plans to determine appropriate staffing instead of 4.1 NHPPD, which does not necessarily equate to quality care.

The federal government chose not to mandate a minimum staffing hour PPD. One of the reasons given was that they did not want to stifle innovation.

Nurses and nurse aides are not the only staff that provide care to nursing home residents. Therapists, life enrichment staff, and others provide care and services that add to the overall wellbeing of residents. The Centers for Medicare and Medicaid Services (CMS) even recognizes this in their definition of direct care staff. DOH should modify their proposal to include other staff that provide care and services to residents in the calculation of the 4.1 staffing proposal.

III. *Fiscal Impact and Paperwork Requirements*

Comments:

The DOH has determined there are no additional paperwork or financial burdens placed on the 3 Resident funded facilities. This is categorically wrong. We will need to add a RNAC-RN for a job that does not exist, certifying and submitting the Minimum Data Set (MDS) electronically to a CMS website that we do not have and cannot gain access to. We will need to add positions such as the Grievance Officer.

Software costing thousands of dollars and will need to be purchased to collect MDS data to submit to CMS which will not accept our submission. We will need to increase documentation requirements associated with Medicare and Medicaid funding, which we do not receive, in other words, dead end documentation performed by professional who should be spending time with Residents as they are currently doing, rather than meeting bureaucratic regulations.

There was a reason why Foulkeways decertified in the Medicare program in 2017, our staff wanted to spend more time with Residents providing care, therapy, treatments, hand holding, family support, end of life care, providing walks outside, staff education, competency building, emotional and spiritual support of our Residents rather than sitting at a computer documenting for dollars.

We have been successful in achieving our goals. Our Residents are our Quality Control, if our care was substandard we would not be at full occupancy. We would not have survived the peak of the COVID pandemic when there were no COVID vaccines or COVID treatments with low COVID cases and deaths. Check out our DOH survey Resident Council

comments, we are meeting and exceeding Standards of Care without being subject to excessive regulations found in 42 CFR 483.5.

BASIS FOR PROPOSED REGULATION

Regulated community

The proposed amendments to the regulations will apply to all 689 licensed long-term care nursing facilities in this Commonwealth. These facilities provide health services to more than 72,000 residents. The existing regulations of the Department already incorporate many of the Federal requirements and any burden by the expansion, in § 201.2, to incorporate the remaining Federal requirements in 42 CFR Part 483, Subpart B will only impact those long-term care nursing facilities that do not participate in Medicare or Medicaid. There are currently only three long-term care nursing facilities that do not participate in either Medicare or Medicaid. Requiring a long-term care nursing facility to comply with the Federal requirements across the board, without exceptions, will make the survey process more efficient and will create consistency and eliminate confusion in the application of standards to long-term care nursing facilities, which will benefit all long-term care nursing facilities. Any negative impact on the three facilities that do not participate in Medicare or Medicaid will be minimum as they are already required by existing § 201.2 to comply with the majority of the requirements in 42 CFR Part 483, Subpart B. Any negative impact is also vastly outweighed by the need for consistency and efficiency in the application of standards for long-term care nursing facilities in this Commonwealth.

The increase in direct nursing care hours from 2.7 to 4.1 will directly impact 603 of the total 689 licensed long-term care nursing facilities licensed by the Department. Of the three private pay facilities, two already exceed the proposed 4.1 ratio; one does not exceed the proposed ratio. The annual cost to the single private pay facility is estimated to be $10,205. The Department believes that the increase in quality of life and safety for the approximately 67,500 residents in the impacted long-term care nursing facilities outweighs any additional cost to the regulated community.

Comments:

Again, the DOH is wrong. DOH has not consulted with the 3 Resident Funded Nursing Facilities, there has been no analysis of the financial or paperwork burden on the 3 Resident Funded Nursing Facilities. Where is the data that supports this assertion? There is none.

There will be a significant paperwork and financial burden on Foulkeways. We were participants in the Medicare program since its inception, we withdrew from the Medicare program in 2017 for a reason, to allow staff to spend time with Residents rather than spending time jumping through regulatory hoops. If we are subject to these regulations, it will cost our Residents more money and our staff more time. We know the statement, "Any negative impact is also vastly outweighed by the need for consistency and efficiency in the application of standards for long-term care nursing facilities in this Commonwealth." means in 3 cases the DOH surveyors will have to continue to apply fewer unnecessary and unreimbursed regulations during one annual survey to 3 Resident Funded Nursing Facilities.

PROPOSED REGULATION

Annex A
TITLE 28. HEALTH AND SAFETY
PART IV. HEALTH FACILITIES
Subpart C. LONG-TERM CARE FACILITIES
CHAPTER 201. APPLICABILITY, DEFINITIONS, OWNERSHIP AND GENERAL OPERATION OF LONG-TERM CARE NURSING FACILITIES
GENERAL PROVISIONS

The following comments will reference some of the regulations that the 3 Resident Funded Nursing Facilities will be unable to comply and therefore, be placed in a regulatory noncompliance status perpetually. We will be forced to be subject to perpetual fines, sanctions and potential closure due to our inability to meet the proposed requirements.

PROPOSED REGULATION

§ 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 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:

483.1 Basis and scope.

(a) *Statutory basis.* (1) Sections 1819(a), (b), (c), (d), and (f) of the Act provide that—

(i) Skilled nursing facilities participating in Medicare must meet certain specified requirements; and

(ii) The Secretary may impose additional requirements (see section 1819(d)(4)(B)) if they are necessary for the health and safety of individuals to whom services are furnished in the facilities.

(2) Section 1861(l) of the Act requires the facility to have in effect a transfer agreement with a hospital.

(3) Sections 1919(a), (b), (c), (d), and (f) of the Act provide that nursing facilities participating in Medicaid must meet certain specific requirements.

(4) Sections 1128I(b) and (c) require that—

(i) Skilled nursing facilities or nursing facility have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations.

(ii) The Secretary establish and implement a quality assurance and performance improvement program for facilities, including multi-unit chains of facilities.

(5) Section 1150B establishes requirements for reporting to law enforcement crimes occurring in federally funded LTC facilities.

(b) *Scope.* The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a Skilled Nursing Facility in the Medicare program, and as a nursing facility in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid.

Comments:

The 3 Resident Funded Nursing Facilities do not comply with this basis and scope regulation as we do not accept Medicare or Medicaid reimbursement. This regulation is in direct conflict with the proposed DOH regulation where it is embedded.

PROPOSED REGULATION

§483.20 Resident assessment.

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

(a) *Admission orders.* At the time each resident is admitted, the facility must have physician orders for the resident's immediate care.

(b) *Comprehensive assessments*— (1) *Resident assessment instrument.* A facility must make a comprehensive assessment of a resident's needs, strengths, goals, life history and preferences, using the resident assessment instrument (RAI) specified by CMS. The assessment must include at least the following:

(i) Identification and demographic information.

(ii) Customary routine.

(iii) Cognitive patterns.

(iv) Communication.

(v) Vision.

(vi) Mood and behavior patterns.

(vii) Psychosocial well-being.

(viii) Physical functioning and structural problems.

(ix) Continence.

(x) Disease diagnoses and health conditions.

(xi) Dental and nutritional status.

(xii) Skin condition.

(xiii) Activity pursuit.

(xiv) Medications.

(xv) Special treatments and procedures.

(xvi) Discharge planning.

(xvii) Documentation of summary information regarding the additional assessment performed on the care areas triggered by the completion of the Minimum Data Set (MDS).

(xviii) Documentation of participation in assessment. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

(2) *When required.* Subject to the timeframes prescribed in §413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2) (i) through (iii) of this section. The timeframes prescribed in §413.343(b) of this chapter do not apply to CAHs.

(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)

(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

(iii) Not less often than once every 12 months.

(c) *Quarterly review assessment.* A facility must assess a resident using the quarterly review instrument specified by the State and approved by CMS not less frequently than once every 3 months.

(d) *Use.* A facility must maintain all resident assessments completed within the previous 15 months in the resident's active record and use the results of the assessments to develop, review, and revise the resident's comprehensive plan of care.

(e) *Coordination.* A facility must coordinate assessments with the preadmission screening and resident review (PASARR) program under Medicaid in subpart C of this part to the maximum extent practicable to avoid duplicative testing and effort. Coordination includes—

(1) Incorporating the recommendations from the PASARR level II determination and the PASARR evaluation report into a resident's assessment, care planning, and transitions of care.

(2) Referring all level II residents and all residents with newly evident or possible serious mental disorder, intellectual disability, or a related condition for level II resident review upon a significant change in status assessment.

(f) *Automated data processing requirement*-(1) *Encoding data.* Within 7 days after a facility completes a resident's assessment, a facility must encode the following information for each resident in the facility:

(i) Admission assessment.

(ii) Annual assessment updates.

(iii) Significant change in status assessments.

(iv) Quarterly review assessments.

(v) A subset of items upon a resident's transfer, reentry, discharge, and death.

(vi) Background (face-sheet) information, if there is no admission assessment.

(2) *Transmitting data.* Within 7 days after a facility completes a resident's assessment, a facility must be capable of transmitting to the CMS System information for each resident contained in the MDS in a format that conforms to standard record layouts and data dictionaries, and that passes standardized edits defined by CMS and the State.

(3) *Transmittal requirements.* Within 14 days after a facility completes a resident's assessment, a facility must electronically transmit encoded, accurate, and complete MDS data to the CMS System, including the following:

(i) Admission assessment.

(ii) Annual assessment.

(iii) Significant change in status assessment.

(iv) Significant correction of prior full assessment.

(v) Significant correction of prior quarterly assessment.

(vi) Quarterly review.

(vii) A subset of items upon a resident's transfer, reentry, discharge, and death.

(viii) Background (face-sheet) information, for an initial transmission of MDS data on a resident that does not have an admission assessment.

(4) *Data format.* The facility must transmit data in the format specified by CMS or, for a State which has an alternate RAI approved by CMS, in the format specified by the State and approved by CMS.

(5) *Resident-identifiable information.* (i) A facility may not release information that is resident-identifiable to the public.

(ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

(g) *Accuracy of assessments.* The assessment must accurately reflect the resident's status.

(h) *Coordination.* A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals.

(i) *Certification.* (1) A registered nurse must sign and certify that the assessment is completed.

(2) Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.

(j) *Penalty for falsification.* (1) Under Medicare and Medicaid, an individual who willfully and knowingly—

(i) Certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than $1,000 as adjusted annually under 45 CFR part 102 for each assessment; or

(ii) Causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty of not more than $5,000 as adjusted annually under 45 CFR part 102 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

(k) *Preadmission screening for individuals with a mental disorder and individuals with intellectual disability.* (1) A nursing facility must not admit, on or after January 1, 1989, any new resident with—

(i) Mental disorder as defined in paragraph (k)(3)(i) of this section, unless the State mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority, prior to admission,

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services; or

(ii) Intellectual disability, as defined in paragraph (k)(3)(ii) of this section, unless the State intellectual disability or developmental disability authority has determined prior to admission—

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services for intellectual disability.

(2) *Exceptions.* For purposes of this section—

(i) The preadmission screening program under paragraph (k)(1) of this section need not provide for determinations in the case of the readmission to a nursing facility of an individual who, after being admitted to the nursing facility, was transferred for care in a hospital.

(ii) The State may choose not to apply the preadmission screening program under paragraph (k)(1) of this section to the admission to a nursing facility of an individual—

(A) Who is admitted to the facility directly from a hospital after receiving acute inpatient care at the hospital,

(B) Who requires nursing facility services for the condition for which the individual received care in the hospital, and

(C) Whose attending physician has certified, before admission to the facility that the individual is likely to require less than 30 days of nursing facility services.

(3) *Definition.* For purposes of this section—

(i) An individual is considered to have a mental disorder if the individual has a serious mental disorder as defined in §483.102(b)(1).

(ii) An individual is considered to have an intellectual disability if the individual has an intellectual disability as defined in §483.102(b)(3) or is a person with a related condition as described in §435.1010 of this chapter.

(4) A nursing facility must notify the state mental health authority or state intellectual disability authority, as applicable, promptly after a significant change in the mental or physical condition of a resident who has a mental disorder or intellectual disability for resident review.

Comments: We have no ability to transmit MDS data to CMS. We would have to purchase software for thousands of dollars to transmit data to an agency that will not provide access. In addition, the data is used in the Federal survey process to select Residents for review, we will be unable to comply. We will be in perpetual noncompliance with regulations.

PROPOSED REGULATION

§483.80 Infection control.

(g) *COVID-19 reporting.* The facility must—

(1) Electronically report information about COVID-19 in a standardized format specified by the Secretary. This report must include but is not limited to—

(i) Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19;

(ii) Total deaths and COVID-19 deaths among residents and staff;

(iii) Personal protective equipment and hand hygiene supplies in the facility;

(iv) Ventilator capacity and supplies in the facility;

(v) Resident beds and census;

(vi) Access to COVID-19 testing while the resident is in the facility;

(vii) Staffing shortages;

(viii) The COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events; and

(ix) Therapeutics administered to residents for treatment of COVID-19.

(2) Provide the information specified in paragraph (g)(1) of this section at a frequency specified by the Secretary, but no less than weekly to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.

(3) Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must—

(i) Not include personally identifiable information;

(ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and

(iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: Each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

(h) *COVID-19 Testing.* The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

(1) Conduct testing based on parameters set forth by the Secretary, including but not limited to:

(i) Testing frequency;

(ii) The identification of any individual specified in this paragraph diagnosed with COVID-19 in the facility;

(iii) The identification of any individual specified in this paragraph with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;

(iv) The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;

(v) The response time for test results; and

(vi) Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.

(2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;

(3) For each instance of testing:

(i) Document that testing was completed and the results of each staff test; and

(ii) Document in the resident records that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test.

(4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19.

(5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.

(6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

Comments: We have no ability to transmit COVID-19 data to CMS. We will be in perpetual noncompliance with these regulations. There are too many specific regulations with which we are unable to comply to note in this document, however, DOH is placing our facility in a no-win compliance situation because we do not accept Federal or State funds as Resident Funded Nursing Facilities.

PROPOSED REGULATION

Survey Process

(b) The Department incorporates by reference 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 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

Comments: This proposed regulation adds language that states that a violation of Federal regulations will also be a violation of state regulations. This is a significant change in position for the state regulations. In the past, federal regulations had been incorporated but the state regulation did not make the statement that federal violations would also be considered state violations. This could result in both state and federal fines for the same incidences.

Federal fines in particular are already very expensive and may not lead to the desired outcome of increasing quality in poor providers. Explain that providers should not see duplicative fines and penalties for citations, especially the 3 Resident Funded Nursing Facilities that do not accept Federal funds are not subject to Federal survey. Also, Foulkeways could be subject to Federal fines under state law when we do not participate in the Federal Medicare or Medicaid programs.

Please consider the impact of forcing unnecessary regulations on a Nursing Facility that has exceeded gerontological care giving standards without regulatory constrain or government funds for years.

Sincerely,

Mary T. Knapp

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