HINMAN STRAUB PC
ATTORNEYS AT LAW

121 State Street
Albany, New York 12207-1693
Tel: 518-436-0751
Fax: 518-436-4751

TO: **Memo Distribution List**

LeadingAge New York

FROM: Hinman Straub P.C.

RE: CMS Proposed Regulation Revising Nursing Home Conditions of Participation

DATE: August 26, 2019

NATURE OF THIS INFORMATION: This memorandum solicits your comments or responses on new proposals or pending action.

DATE FOR RESPONSE OR IMPLEMENTATION: CMS is accepting comments on the proposed regulation through September 16, 2019. Please provide any comments on the proposed regulation by September 9, 2019.

HINMAN STRAUB CONTACT PEOPLE: Sean Doolan, Michael Paulsen and Kimberly Philip

THE FOLLOWING INFORMATION IS FOR YOUR FILING OR ELECTRONIC RECORDS:
Category: #9 Medicaid and Medicare Suggested Key Word(s):

The Centers for Medicare and Medicaid Services (CMS) recently published a proposed rule that would make significant revisions to the requirements that skilled nursing and nursing facilities (also referred to as LTC facilities) must meet to participate in the Medicare and Medicaid programs, which were substantially revised in 2016. The proposed rule revises requirements that CMS has identified as unnecessary, obsolete, or excessively burdensome, and reduces the frequency of certain required activities. The proposed rule would also delay the implementation date for certain Phase 3 requirements for an additional year.

CMS is accepting comments on the proposed rule through September 16, 2019. If you would like to submit comments for consideration by CMS, please provide comments by Monday, September 9, 2019.

The following is a high-level summary of the revisions contained in the proposed rule:

- Modify the grievance process to allow facilities to designate complaints as a grievance or general feedback, with general feedback not subject to the facility's grievance process, and to remove the specific duties of a facility's Grievance Officer (Section A);
- Modify the requirement for facilities to send transfer or discharge notices to the State Long-Term Care Ombudsman to only apply to facility-initiated involuntary transfers or discharges (Section B);
- Allow orders for anti-psychotic medication to be extended beyond the 14-day limit in the same manner as psychotropic medication and no longer requiring the prescriber to evaluate the resident (Section F);
- Modify the qualifications of the director of food and nutrition services to allow an individual with 2 or more years of experience in the position of a director of food and nutrition services or has completed a minimum course of study in food safety (Section G);
- Modify the facility-wide assessment to no longer require the assessment to be conducted for emergencies and to change the frequency of the assessment from annually to biennial (Section H);
- Remove specific QAPI Program requirements to allow facilities to design their QAPI program to fit their facility-specific needs (Section I);
- Remove the requirement that a facility's infection preventionists (IPs) work at least part-time at the facility, and delay the implementation of the requirement to designate an IP for one year (Section J); and
- Modify the requirements for an operator's Compliance and Ethics Program, and delay the implementation date for an operator to have in place a Program for one year (Section K).

Additional information regarding each item can be located in the section of this memorandum that is cited following each item, along with other changes to the federal requirements.

## Background

In 2016, CMS adopted a final rule that made comprehensive revisions, from both a structural and a content perspective, of the existing Medicare and Medicaid requirements for participation for LTC facilities[1] (the "2016 final rule"). Broadly, the 2016 final rule resulted in significant changes

[1] 42 CFR part 483, subpart B.

to current facility operations, impacting clinical practices, administration, and quality of care oversight. The revised LTC requirements for participation were implemented in three phases. Phases 1 and 2 were implemented in November of 2016 and 2017, respectively.[2] Phase 3 includes additional regulatory provisions that are scheduled to be implemented on November 28, 2019.

Following the adoption of the 2016 final rule and the FY 2018 Skilled Nursing Facility Prospective Payment System (SNF PPS) proposed rule, CMS received feedback from LTC stakeholders regarding areas of burden reduction and cost savings in LTC facilities. CMS conducted an internal review of the LTC conditions of participation, as revised by the 2016 final rule, in light of stakeholder feedback, to develop this proposed rule. Specifically, consideration was given to each recommendation and the potential of reducing the burden on LTC facilities without sacrificing the health and safety of the residents. The ultimate goal of the proposed rule is to reduce the burden for facilities and residents, improve the quality of care, decrease costs, and ensure that residents, their providers and physicians are making the best health care choices possible.

**Phase 3 Implementation Delayed**

CMS has proposed to delay the implementation of certain Phase 3 requirements that are directly impacted by the proposed changes in the regulation to one year following the effective date of this proposed rule, if finalized. The Phase 3 requirements that would be delayed and modified as a result of the proposed rule are:

- Designation of an infection preventionist (IP) responsible for the facility's IPCP;
- Specific requirements for the operation of a compliant QAPI Program; and
- Implementation of a Compliance and Ethics Program.

All other Phase 3 requirements are not being delayed as a result of the proposed rule. Notable Phase 3 requirements, which are required to be implemented by November 28, 2019, include:

- Ensure that residents who are trauma survivors (including Holocaust survivors, survivors of abuse, military veterans with post-traumatic stress disorder, and survivors of other trauma) receive care and treatment that is trauma-informed, takes into consideration the resident's experiences and preferences in order to avoid triggers that may cause re-traumatization, and meets professional standards of practice;
- Require that the services provided or arranged by the facility be culturally-competent and trauma-informed;
- Ensure that a resident who displays or is diagnosed with mental or psychosocial adjustment difficulty, or who has a history or trauma and/or post-traumatic stress disorder, receives appropriate treatment and services to correct the assessed problem or to attain the highest practicable mental health and psychosocial well-being; and
- Modify resident call system to allow residents to call for staff assistance through a communication system from the resident's bedside.

[2] CMS previously adopted an 18-month transition period for the implementation of Phase 2 requirements, including an 18-month moratorium on the imposition of civil money penalties, discretionary denials of payment for new admissions and discretionary termination where the remedy is based on a deficiency finding of the certain Phase 2 requirements.

## Proposed Revisions to Conditions of Participation

A. Resident Rights (§ 483.10)

1) Current regulations require that facilities keep residents informed of the name, contact information, and specialties of the physician and other primary care professionals that are responsible for their care. CMS proposes to modify the requirement to require that residents be informed of only their primary care physicians' information at admission, with any change of provider information, and upon the residents' request.

2) The 2016 final rule extensively expanded the grievance process in LTC facilities. CMS proposes a number of changes to the revised grievance process:
   - The proposed rule clarifies that general feedback may not rise to the level of an official grievance under the facility's grievance process. In describing this proposed change, CMS states "general feedback or complaints stem from general issues that can typically be resolved by staff present at the time a concern is voiced, while grievances are more serious and generally require investigation into allegations regarding the quality of care." Thus, the proposed rule would permit facilities to designate concerns by a resident or resident representative as general feedback and not be subject to the facility's grievance process. However, CMS states that the facility would have the responsibility to include how they made the determination as to whether a complaint was a grievance or general feedback as part of their grievance policy and ensure that residents were fully informed of such determination.
   - The 2016 final rule required facilities to identify a Grievance Officer and establish specific duties of the Grievance Officer. The proposed rule would remove the specific duties of the Grievance Officer to allow facilities greater flexibility in determining how their facility will ensure that grievances are fully addressed.[3] CMS also notes that the existing regulation permits facilities to designate existing staff as the Grievance Officer and that facilities can assign multiple individuals to assist the grievance official in the oversight of the facility's grievance process.
   - The 2016 final rule required facilities to ensure that all written grievance decisions include specific information, including the date the grievance was received, a summary of the grievance, and any corrective action taken. The proposed rule would remove the specific requirements for all written grievance decisions, replacing it with a requirement for facilities to ensure that any written grievance decisions include any pertinent information including but not limited to a summary of the findings or conclusions and any corrective actions. While this change appears to reduce the requirements for a formal grievance plan, the elements required under the 2016 final rule are likely to be considered pertinent and should continue to be included even if this proposed change is adopted.

[3] The proposed rule removes the following language: "receiving and tracking grievances through to their conclusion; leading any necessary investigations by the facility; maintaining the confidentiality of all information associated with grievances, for example, the identity of the resident for those grievances submitted anonymously; issuing written grievance decisions to the resident; and coordinating with state and federal agencies as necessary in light of specific allegations"

- The 2016 final rule required facilities to maintain evidence demonstrating the resolution of complaints and grievances for at least 3 years. The proposed rule would limit the retention period to 18 months from the issuance of the grievance decision.

B. Admission, Transfer, and Discharge Rights (§483.15)

The 2016 final rule requires facilities to send transfer or discharge notices to the State Long-Term Care Ombudsman. The proposed rule modifies this requirement to require facilities to send a copy of a transfer or discharge notice to a representative of the Office of the State Long-Term Care Ombudsman only in the event of facility-initiated involuntary transfers or discharges. A "Facility-initiated" transfer or discharge is intended to mean a transfer or discharge that the resident objects to, did not originate through a resident's verbal or written request, and/or is not in alignment with the resident's stated goals for care and preferences. This change would exclude from this requirement transfers at the request of a resident or emergency transfers to an acute care facility when return is expected.

C. Quality of Care (§483.25)

The 2016 final rule requires facilities to attempt to use appropriate alternatives to bed rails prior to installing a side or bed rail, and if a side or bed rail is used, the facility must ensure the correct installation, use and maintenance. The proposed rule would remove references to the ''installation'' of bed rails and replace with the ''use'' of bed rails. This change is intended to clarify that facilities may use beds purchased with bed rails already installed, and are not required to remove the bed rails when not in use.

D. Nursing Services (§483.35)

Current regulations require facilities to post daily nurse staffing data and to maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by state law, whichever is greater. The proposed rule reduces the timeframe from 18 months to 15 months, or as required by state law, whichever is greater.

New York regulations governing nursing home general record keeping requirements do not include a minimum timeframe that records must be retained for. If the proposed change is adopted, facilities would be permitted to use the 15 month timeframe for maintaining daily nurse staffing data.

E. Behavioral Health Services (§483.40)

The 2016 final rule included a new requirement for facilities to provide each resident with the necessary behavioral health care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, including any medically-related social services. The 2016 final rule required facilities to have sufficient staff who provide direct services to the residents with the appropriate competencies and skill sets to provide nursing related services. The proposed rule, in concluding that this requirement is duplicative of the requirements under Nursing Services, is proposing to remove the requirement for staff to have appropriate competencies and skills from

the behavioral health services regulation. This change is not expected to have any practical impact as facilities would continue to be required to employ staff members with competencies and skills sets to meet the behavioral health needs of residents for whom the facility has assessed and developed care plans.

F. Pharmacy Services (§483.45)

The 2016 final rule established specific requirements for the use of psychotropic drugs by nursing home residents. Specifically, the 2016 final rule limited prescriptions for psychotropic drugs to 14 days. To extend beyond the 14 day limit, the attending physician or prescribing practitioner may document their rationale in the resident's medical record and indicate the duration of the PRN order. This exception does not apply to anti-psychotic medications, unless the attending physician or prescribing practitioner evaluates the resident for the medication, as set forth in current regulations at § 483.45(e)(5).

The proposed rule would apply the same standard for both psychotropic and anti-psychotic medications, allowing for an order to be extended beyond the 14-day limit in accordance with the facility's policy if the prescriber documents his or her rationale in the resident's medical record and indicates the duration for the PRN order. The proposed rule would further require facilities to revise policies and procedures related to prescribing psychotropic and anti-psychotic medications to include recognized standards of practice, including the circumstances upon which PRN orders for psychotropic drugs could be extended beyond the 14-day limitation; and that the facility take into consideration individualized residents' needs for psychotropic drugs. As a result of the proposed rule, facilities would not be required to have the attending physician or prescribing practitioner evaluate the resident to extend the 14-day order for anti-psychotic medications.

G. Food and Nutrition Services (§483.60)

The 2016 final rule extensively revised the requirements related to food and nutrition services, including a requirement that a facility must designate a person to serve as the director of food and nutrition services if the facility does not employ a full-time qualified dietitian or other clinically qualified nutrition professional. The 2016 final rule established minimum requirements for the director of food and nutrition services, requiring that the director be a certified dietary manager or certified food service manager as evidenced by meeting national certification standards, or hold an associate's or higher degree in hospitality or food service management.

The proposed rule would revise the educational requirements for a director of food and nutrition services, replacing the current standards. Under the proposed rule, an individual would be eligible to serve as the director of food and nutrition services if he or she has 2 or more years of experience in the position of a director of food and nutrition services or has completed a minimum course of study in food safety that includes topics integral to managing dietary operations such as, but not limited to, foodborne illness, sanitation procedures, and food purchasing/receiving. The proposed rule would retain the requirement that the director receive frequently scheduled consultation from a qualified dietitian or nutrition professional.

H. Administration (§483.70)

The 2016 final rule requires facilities to perform a documented, annual facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The assessment is to be used by the facility for multiple purposes, including, but not limited to, activities such as determining staffing requirements, establishing a QAPI program and conducting emergency preparedness planning.

The proposed rule would remove the requirement that the facility-wide assessment be conducted for emergencies. CMS has concluded that this requirement is duplicative of existing requirements applicable to LTC facilities to develop and maintain an emergency preparedness plan that must be based on a documented facility-based and community-based risk assessment, utilizing an all-hazards approach.

CMS is also proposing to change the minimum frequency in which a facility should conduct a facility wide assessment under this requirement from an annual assessment to a biennial facility-wide assessment. CMS notes that this change does not preclude facilities from conducting an assessment more frequently than every 2 years, and believes that in facilities with a high staff turnover, assessments should take place as frequently as necessary and the issue should be addressed in the QAPI plan.

I. Quality Assurance and Performance Improvement (QAPI) (§483.75)

The 2016 final rule requires every facility to develop, implement, and maintain an effective, comprehensive, data-driven QAPI program, reflected in its QAPI plan. CMS has reviewed the QAPI requirements included in the 2016 final rule and concluded that the level of specificity may limit a facility's ability to design their QAPI program to fit their individual needs and hinder a facility's QAPI program from being a valuable tool in promoting quality care.

The proposed rule retains the requirement that each facility develop a QAPI program, present the QAPI plan at each annual recertification survey and upon request during any other survey and to CMS upon request, and lastly must present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with the program requirements to a State Survey Agency, federal surveyor, or CMS upon request. However, the proposed rule would revise the QAPI requirements to allow facilities more flexibility in developing their QAPI program.

The proposed rule would remove the specific requirements that facilities must include in their QAPI program, but maintains the requirement that a QAPI program include the following:

- Be ongoing, comprehensive, and address the full range of care and services provided by the facility;
- Include written policies and procedures for feedback, data collection systems, and monitoring, including adverse event monitoring; and
- Require facilities to take actions aimed at performance improvement and, after implementing those actions, measure its success, and track performance to ensure that improvements are realized and sustained.

J. Infection Control (§483.80)

The 2016 final rule required facilities to designate one or more individual(s) as infection preventionists (IPs) who are responsible for the facility's infection prevention and control program (IPCP), and required such designated IP to work at least part-time at the facility. The proposed rule would remove the requirement that IPs work at the facility at least part-time, and replace this with a requirement that the IP must have sufficient time at the facility to meet the objective's set forth in the facility's IPCP.

K. Compliance and Ethics Program (§483.85)

The 2016 final rule required the individual or entity that operates a facility to have in effect a compliance and ethics program that has established written compliance and ethics standards, policies and procedures that are capable of reducing the prospect of criminal, civil, and administrative violations, and promoting quality of care. The 2016 final rule included minimum requirements for the compliance and ethics program. The proposed rule would remove a majority of the minimum requirements, concluding that they are not statutorily required and that existing requirements establish the appropriate safety and quality standards to support compliance and ethics requirements.

Specifically, the proposed rule would remove the following requirements:

- Designate a compliance officer and a designated compliance liaison[4];
- Designate a compliance and ethics program contact person to which individuals may report suspected violations; and
- Annual review of the compliance and ethics program;

In modifying the structure of the compliance and ethics program, the proposed rule would require that facilities develop a compliance and ethics program that is appropriate for the complexity of the organization and its facilities and that each facility assign a specific individual within the high-level personnel of the operating organization with the overall responsibility to oversee compliance. The program must include written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations. While facilities are not required to specify a compliance and ethics contact person, facilities are required to designate an appropriate person to be responsible for all aspects of the program and to maintain a method of reporting suspected violations anonymously.[5]

The implementation of a compliance and ethics program was a Phase 3 requirement under the 2016 final rule, thus requiring compliance by November 28, 2019. The proposed rule would delay the implementation of this requirement for 1 year from the date the proposed rule is enacted.

L. Physical Environment (§483.90)

[4] The compliance liaison is applicable to operating organizations with five or more facilities.

[5] CMS expects that facilities will designate an individual who has appropriate authority to assure compliance with the program, but will not dictate who facilities should hire to comply.

The 2016 final rule implemented new physical environment requirements at § 483.90 related to space and accommodations within the facilities. Specifically, the regulations require newly constructed, re-constructed, or facilities first certified after November 28, 2016 to accommodate no more than two residents in a bedroom and for each resident room to have its own bathroom that has a commode and sink. Although CMS is not proposing to entirely remove these requirements, CMS is proposing to revise these requirements to apply only to newly constructed facilities that have never previously been a long-term care facility. CMS is soliciting comments as to whether it would be appropriate to sunset the exception proposed to provide for buildings that were previously long-term care facilities.

CMS is also proposing to allow LTC Facilities certified prior to July 5, 2016 that have previously used the FSES to determine equivalent fire protection levels, to continue to use the 2001 FSES mandatory values when determining compliance for containment, extinguishment and people movement requirements.