



October xx, 2015

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3260-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

**RE: CMS-3260-P: Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities**

Dear Sir/Madam:

I write on behalf of the membership of LeadingAge New York to comment on the above-captioned proposed rule. LeadingAge NY represents nearly 500 not-for-profit and public providers of long term care and senior services throughout New York State, including approximately 230 nursing homes. Our national affiliate, LeadingAge, is an association of 6,000 not-for-profit organizations providing long term care services and supports throughout the United States.

Since the publication of the proposed regulations in July we have worked diligently to educate our member nursing homes, and to solicit their input, as adoption of these regulations would significantly impact care delivery systems, deployment of staff, federal/state oversight and compliance costs.

Leading Age NY members have long been at the forefront of delivering person-centered care and, as such, we are generally supportive of efforts that fully promote and sustain environments within which residents make decisions and have control over their lives. However, we are concerned that a number of requirements included in this proposed rulemaking are unrealistic, ambiguous and/or contrary to sound standards of practice, and would entail potentially significant costs without provision for payment. For example, many of the proposed changes related to staffing requirements and qualifications would place a particular hardship on facilities located in rural and other workforce shortage areas.

Our comments on various aspects of the proposed rule follow.

**Transitions of Care (§ 483.15)**

There is a proposed requirement for a facility to exchange specific information/data elements (e.g., demographic information, history of present illness including active diagnoses, functional status, medications, reason for transfer and past medical/surgical history) with the receiving provider. This requirement will be extremely difficult to meet in a time-effective and accurate manner without interoperable health information exchange. In fact, the rule states, “[w]e encourage facilities to explore

how the use of certified health IT can support their efforts to electronically develop and share standardized discharge summaries.”

In spite of the costs entailed in deploying interoperable health IT, the federal government has not provided any health IT meaningful use incentives to nursing homes and other post-acute providers. Unless this aspect of the proposed rule is addressed and meaningful use incentives or other funding is provided to support electronic exchange of this information, we must oppose this requirement as proposed.

#### **Baseline Interim Care Plan (§ 483.21)**

We are concerned about the proposed 48-hour timeframe within which facilities would be required to develop a baseline care plan for each newly-admitted resident. While the proposed rule indicates that the baseline plan is supposed to facilitate effective and person-centered care that meets professional standards of quality care, it provides only minimal details as to the expected content of such a plan. When, for example, an individual is admitted on a Friday afternoon (which is not uncommon) or a holiday, a 48-hour requirement to have such a plan in place seems particularly unreasonable given the more limited availability of medical and other personnel on weekends and holidays. If the goal is to have an interim care plan in place at a point in time earlier than 21 days, we would recommend extending the 48-hour timeframe to a more reasonable period of time such as within 5 days of admission.

#### **Interdisciplinary Team (§ 483.21)**

We believe that input from direct-care staff is critical to the care of the resident. However, we do not support the proposal to require certified nursing assistants (CNAs) to attend interdisciplinary team (IDT) meetings. Further requirements to include qualified mental health professionals for residents who are diagnosed with mental health conditions or prescribed psychotropic drugs; social workers; and food and nutrition services staff in IDT meetings will also add to facility compliance costs. These individuals will be unavailable for resident care activities during IDT meeting times, causing logistical and scheduling issues and resulting in additional facility costs associated with backfilling their time with other staff members. Furthermore, prescribing the involvement of additional individuals in the IDT could also conflict with IDT composition requirements under federal Financial Alignment Initiative demonstrations such as New York’s Fully Integrated Duals Advantage program.

The individual facility should have the flexibility to determine how best to obtain input from CNAs and other direct-care staff in a manner that is not disruptive to resident care activities. For example, a facility could put into place a process that elicits input from direct-care staff and conveys the information about the resident to IDT meeting participants outside of the formal IDT meetings.

In the facility assessment and competency based approach narrative contained in the proposed rule, CMS reflects upon approaches that are prescriptive and limit flexibility and innovation. In this light, requiring the attendance of specific direct-care staff at IDT meetings does not recognize that there are other effective, less costly and more practical ways to exchange resident-specific information.

### **Pharmacy (§§ 483.21, 483.45, 483.70)**

The time commitment that is expected of the pharmacist based on the requirement for the review of antibiotics (in addition to antipsychotics) is unrealistic, and we urge that this section of the proposed rule be reconsidered or significantly modified. In addition, the increased review of the resident's medical chart at least every 6 months and when the resident is new, or returns from the hospital will also require more pharmacist time. Finally, facilities also must assure that a drug reconciliation will be performed upon admission and at discharge. Collectively, these requirements will significantly affect existing pharmacy arrangements and increase facility costs dramatically. For some providers, this level of additional pharmacy involvement will simply not be available due to geography and other factors.

We also question the proposed 48-hour limit on PRN use of antipsychotic medications and availability of physicians to meet this requirement. The requirement to include in the review of psychotropic drugs "any drug that affects brain activities associated with mental processes and behavior" would greatly increase the number of drugs subject to review, could interfere with prescribing needed medications such as anti-depressants, and would result in increasing the level of pharmacist involvement beyond what is reasonable. In some rural and geographically isolated facilities, the pharmacist may only be available one day a month.

### **In-Person Evaluation (§ 483.30)**

While LeadingAge NY is supportive of efforts to reduce avoidable hospital use, we strongly oppose this proposed requirement. The proposed regulations do not define an "emergency situation" or the determining factors for requiring an in-person evaluation. Our most significant concern is the potential for a resident to deteriorate significantly in a situation when a physician or physician extender is unavailable to assess the resident when needed, particularly in rural areas where a physician may not be accessible within a realistic timeframe.

In addition, under the terms of New York State's approved Medicaid Section 1115 Waiver, *the Partnership Plan*, Medicaid beneficiaries are being required to enroll in Medicaid managed care plans. Those managed care plans that are responsible for the acute care benefit have their own protocols related to pre-approval of hospitalization that may be different than what is proposed in the regulations, which could create confusion and duplication.

We believe there are more pragmatic approaches to addressing concerns about avoidable hospital use. For example, a Registered Nurse (RN) is qualified to assess the condition of the resident and share the findings of his/her assessment with the physician; take orders for additional assessments or tests to be performed; and/or communicate the urgent need for transfer to an acute care setting when the RN is uncomfortable with the condition of the patient despite the lack of actionable findings on assessment.

Furthermore, there is no provision in the proposed rule for telehealth consultations, which growing numbers of facilities are utilizing for off-site physician visualization and assessment of the resident in real-time. Telehealth assessments would allow for better telephonic assessments and physician input in a timelier manner when needed.

### **Nursing Services (§ 483.35)**

As noted in the proposed rule, CMS considered but chose not to propose establishing minimum staffing requirements such as nurse hours per resident day, nurse to resident ratios, extended RN presence and RN on-call provisions. The rule further indicates that CMS welcomes comment on all of these options. LeadingAge NY agrees that minimum staffing requirements should not be included in this rule.

Staffing is obviously important in nursing homes and is a cornerstone of providing quality resident care. Nursing homes are already required to develop staffing plans tailored to individual patient care needs. However, arbitrary “one-size-fits-all” minimum staffing ratios would eliminate the flexibility needed to adapt nursing assignments to diverse and quickly changing resident needs, and ignore the different levels of experience and preparation of nurses and other members of the multi-disciplinary care team. Furthermore, mandatory nurse staffing ratios are not supported by empirical evidence. The latest peer-reviewed studies on California’s mandatory staffing ratios have not found a direct link between specified, mandated statewide staffing ratios and improved patient outcomes.

To ensure effective and reliable patient-centered care, staffing decisions must remain with individual nursing homes and health care professionals. Mandated ratios could jeopardize access to care – limiting patient access if sufficient numbers of staff are not available at all times – and could be prohibitively expensive to residents/patients, their families and governmental payers.

### **Behavioral Health Services (§ 483.40)**

The proposed rule includes a new section outlining facility requirements to provide the necessary behavioral health care and services to residents in accordance with their comprehensive assessment and plan of care. Under the requirements, facilities would be required to determine their direct care staff needs based on the “facility’s assessment,” and facility staff must have the “appropriate competencies and skills” to provide behavioral health care and services to residents with mental and psychosocial illnesses.

The proposed rule is unclear as to the specific elements of the assessment the facility will be required to conduct to determine its direct care staff needs; the expectations of facilities to determine the competencies and skills to provide behavioral health services; and whether facilities will need to ensure expanded access to outside professional behavioral health services (which are costly and already difficult to access in rural and geographically underserved areas). Furthermore, facilities would incur potentially significant costs to provide required behavioral health training to their entire staff under the proposed § 483.95(i).

### **Dental Services (§ 483.55)**

The requirement that a dental referral for lost or damaged dentures take place within a 3-business day timeframe is overly prescriptive. Referral timeframes may be affected by dental office schedules; transportation availability; and any applicable insurer pre-authorization requirements. We recommend retaining the nursing home’s responsibility to make a dental referral in such instances, but modifying the requirement to reflect a more reasonable timeframe such as 5-7 business days.

### **Facility-Wide Assessment (§ 483.70)**

Nursing homes typically engage in a number of initiatives to validate that the needs of residents are being met. Staffing, education, equipment and care-related products are continuously evaluated to assure they are appropriate in number and scope and sufficient in quality to meet the needs of residents. We are very concerned about the surveyor use of this newly created, undefined and stand-alone regulatory requirement and the potential for surveyors to create a linkage between the facility-wide assessment and any other non-compliant area. It is impossible to evaluate this requirement in the absence of any interpretive guidelines and, as such, we would propose that it be eliminated until such time as CMS is prepared to provide far greater clarity on what would constitute facility compliance in this area.

### **Administration (§ 483.70)**

The proposed rule would add a new requirement for the nursing home administrator to report to and be accountable to the governing body. While we understand and appreciate the need for the governing body to be kept apprised of the operations and management of the facility, we do not support a regulatory requirement prescribing that the facility administrator report to and be directly accountable to the governing body. Many of our not-for-profit member organizations have management structures that include a Chief Executive Officer (CEO) who is not the administrator of record of the nursing home. Under the bylaws and governance structure of these organizations, the CEO is directly accountable to the board of directors and responsible for hiring and supervising the facility administrator and other executive staff. Requiring the administrator to report to and be directly accountable to the governing body in these circumstances would supplant the governance policies of these organizations and undermine the relationship of the CEO to the board of directors.

We recommend that this requirement be eliminated in its entirety. Alternatively, the requirement could be modified to require that the organization's senior management keep the governing body apprised of the operations and management of the facility, while leaving it up to the organization to designate the individual who would be responsible for this function.

### **Quality Assurance Performance Improvement (QAPI) (§ 483.75)**

The proposed regulation states that the surveyor will have access to, "...systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events." We are opposed to this provision based on our concern that it would confer broad and unlimited access to QAPI documentation on the survey team. This creates the potential for the facility's own QAPI activities to be used to identify or possibly support findings of non-compliance.

Under longstanding federal law, documents are privileged from disclosure if they are generated by a facility's quality assessment and assurance (QAA) committee and used in the facility's quality assurance processes. The rationale for this privilege is that QAA committees are key internal mechanisms that allow nursing homes opportunities to address quality concerns in a confidential manner that can help them sustain a culture of quality improvement. We are concerned that this aspect of the proposed regulation may have a chilling effect on advancing QAPI efforts, and should be reconsidered.

### **Infection Control (§ 483.80)**

The proposed regulations set mandated qualifications for a number of existing and new positions, including the Infection Prevention and Control Officer. This new designation and the additional expertise that is being required to function in the position will increase facility costs. In rural and other areas where this expertise may not be available, compliance would be difficult, if not impossible. Accordingly, we oppose this requirement not only based on access to the required expertise and potentially significant compliance costs, but because it runs counter to CMS's assertions that in the proposed rule, "[w]e considered prescriptive approaches, such as requiring specific numbers and types of staff...", but instead decided on a "competency-based approach".

In this vein, we believe a more reasonable approach would be to detail the standards for infection control, and allow the nursing home to make a determination as to whether the individual responsible for this function possesses the competency and expertise to function in the position.

### **Compliance and Ethics Program (§ 483.85)**

Many facilities are already subject to requirements to have corporate compliance programs in place. However, we do not believe that these existing programs contain all of the components proposed in this rule, or that all of these proposed elements are documented or included in facilities' standards, policies, or procedures.

Accordingly, facilities would need to review their current programs and possibly revise or, in some cases, develop new sections for their programs in order to comply with the proposed requirements, and have these programs reviewed by legal counsel to ensure they are in conformity with these requirements and other state/federal compliance program requirements and guidelines. Furthermore, facilities would need to develop policies and procedures to implement the program; develop materials for dissemination to all staff, volunteers and contractors; and conduct training as needed. Facilities may need to involve legal counsel and/or consultants in these activities as well.

Given the scope of all of these activities, the proposed one-year timeframe within which to establish a compliance and ethics program in conformity with the regulations is inadequate. Designation of a compliance contact/officer will result in costs for creation of the position, in addition to the compliance costs associated with all of the aforementioned activities.

### **Physical Environment (§ 483.90)**

As set forth in the proposed regulations, any facility construction or reconstruction plan would require that each resident room in the newly constructed/reconstructed space must have its own bathroom equipped with at least a toilet and sink, with the added requirement of a shower. We oppose this proposal on the basis of utility, feasibility and cost. The definition of "reconstruction" is also somewhat unclear in this context.

As acknowledged in the rule, the nursing home population is more medically complex, frail and debilitated today than in the past. The clinical and functional status of many residents calls into

question the extent to which in-room showers would actually be utilized and raises safety issues. In older facilities undergoing reconstruction, the building configuration and existing resident room spaces may not be conducive to adding showers to each resident room given other square footage and code requirements applicable to resident spaces. These shower/bathrooms would have to be of substantial size to enable entrance into the shower stall for residents for whom a lifting device is required, as well as to accommodate a shower chair or gurney in the shower. Finally, we are concerned that the costs associated with imposing such a requirement – which may be prohibitively high – could create a significant disincentive for facility operators to update and modernize resident rooms, contrary to the overall intent of the proposed rule.

### **Short-Stay Residents**

In the rule, CMS invites comments on how to modify the requirements to better address the unique needs of short-stay residents:

“In addition, because we also received comments regarding the need to specifically address the needs of short stay residents, we solicit comments on how the requirements could acknowledge the special needs of short stay residents. We are particularly interested in any suggestions to improve existing requirements, within the authority of existing statute, where they make serving [the] population difficult or less effective. The most useful comments will be those that offer suggestions to amend specific sections of the existing requirements or offer particular additions.”

### **LEADINGAGE NY SEEKS INPUT ON SPECIFIC EXAMPLES OF EXISTING OR PROPOSED REQUIREMENTS THAT SHOULD BE MODIFIED OR ELIMINATED TO FACILITATE THE DELIVERY OF SHORT-TERM CARE.**

### **Implementation and Compliance Costs**

This proposed rule would make major changes to the nursing home requirements affecting multiple areas of facility operations, at a time of major shifts in federal and state payment policies, quality expectations and provider-payer relationships. These changes will necessitate significant revisions to facility policies and procedures; developing and conducting training; hiring or otherwise acquiring needed expertise; assessing preparedness; and planning for all associated compliance costs.

Given the significant changes underway and the sheer magnitude of the proposed changes contemplated in this rule, we strongly recommend a five-year phase-in of the regulatory revisions, with prioritization of certain requirements based on the level of importance and facility/government preparedness for implementation. For example, QAPI information has been available to providers for a number of years and many facilities have already integrated QAPI into their QAA programs.

If the proposed regulations were to be implemented in their totality without an extended phase-in period, we would most certainly have added concerns about compliance cost, training and coordination challenges for facilities. Regulators will also need time to understand the proposed changes, develop interpretive guidance, modify survey processes, train surveyors and otherwise be in a position to objectively and consistently evaluate facility compliance.

We are also concerned about the cumulative compliance costs associated with the many changes proposed in the regulations, and believe that these costs have been significantly under-estimated by CMS. The regulatory impact analysis indicates that the estimated first-year cost of the proposed rule averages approximately \$46,491 per facility and \$40,685 per facility in subsequent years. **LEADINGAGE NY IS WORKING ON AN ANALYSIS TO SHOW THAT THE ACTUAL COSTS OF COMPLIANCE WILL BE HIGHER THAN THE CMS ESTIMATES.**

The additional staffing, credentialing, training, systems and contractual relationships that will be required for compliance will add to the financial stresses that nursing homes are experiencing from ongoing Medicare and Medicaid cuts, unless such compliance costs are funded by federal and state governments. Ironically, the proposed requirements could force facilities to divert limited financial and staffing resources from resident care to the increased administrative requirements this rule would impose.

Upon issuance of a final rule, CMS will need to develop sub-regulatory requirements including interpretive guidelines to provide much greater detail and guidance on the regulatory revisions. LeadingAge NY strongly recommends that provider organizations and association representatives be involved in the development of these specific requirements and guidelines to ensure they are consistent with sound practice, pragmatic in approach, sufficiently flexible, cost effective and representative of the current realities of providing nursing home care to an increasingly complex and diverse resident population.

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Thank you for the opportunity to provide input on the proposed rule. If you have any questions on our comments, please contact me at (518) 867-8383 or [dheim@leadingageny.org](mailto:dheim@leadingageny.org).

Sincerely,



Daniel J. Heim  
Executive Vice President