September 16, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-3347-P
PO Box 8010
Baltimore, MD 21244-1850

Re: Comments on Proposed Rule, Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency and Transparency

Dear Administrator Verma:

Thank you for the opportunity to provide feedback on the Regulatory Provisions to Promote Efficiency and Transparency proposed rule. The mission of LeadingAge is to be the trusted voice for aging. Our 6,000+ members and partners include nonprofit organizations representing the entire field of aging services, 38 state associations, hundreds of businesses, consumer groups, foundations, and research centers. LeadingAge is also a part of the Global Ageing Network, whose membership spans 50 countries. LeadingAge is a 501(c)(3) tax-exempt charitable organization focused on education, advocacy, and applied research.

LeadingAge supports CMS's efforts to simplify and streamline current requirements to eliminate overly burdensome regulations that do not promote quality of care. Our members are dedicated to the well-being of the older adults that they serve and we value opportunities to work collaboratively with CMS to support them in these endeavors. We recognize that the revisions proposed in this rule represent efforts toward administrative burden reduction and increased flexibility for providers. Our comments below focus primarily on opportunities for further clarification and guidance in promoting quality care.

§483.10 Resident Rights
Choice of Attending Physician

LeadingAge supports the proposed revisions to the Choice of Attending Physician requirement. Ensuring that a resident "remains informed" of the name, specialty, and way of contacting the physician is an ambiguous statement that would be impossible to measure for compliance. Revising language to more clearly state that a nursing home is responsible for notifying residents of such information upon admission, upon change, and upon request of such information will meet the needs and support the rights of the resident.

We further support the resident's right to communicate with his or her physician as intended by the requirement. Participating actively in the care planning process ensures the resident and his representative will have knowledge of all providers and the care received. We further suggest the addition of language to the rule to direct that, as active members of the care planning team, residents and/or their representatives have the responsibility to notify the nursing home of any pertinent information exchanged during these discussions.

Grievances

LeadingAge supports many of the proposed revisions to the grievances requirement. We agree that there exists a distinction between a grievance and general feedback provided by a resident or representative and support the addition of such language to the rule. We are concerned, however, by the vagueness of the statement. We encourage our members to heed CMS's directive to include in grievance policies how the distinction will be made between general feedback and grievances and also ask that CMS include in interpretive guidance an explanation similar to that in the proposed rule, as well as examples. We would also recommend the inclusion in interpretive guidance of the expectations outlined in the proposed rule on the specific circumstances in which general feedback would be elevated to the level of grievance.

Similarly, we support the proposal to remove the prescriptive language at §483.10(j)(4)(ii) and §483.10(j)(4)(v), and allow facilities the flexibility to determine how best to manage the grievance process, including grievance decisions, and grievance official roles within their communities. We request that CMS clearly state any expectations for these roles and procedures in interpretive guidance. While the proposal has been made to remove language from the rule, CMS explicitly states that the expectations outlined by the language remain, and it is imperative that this is made clear.

We additionally support the proposed reduction to the record retention requirement from 3 years to 18 months. Beyond the satisfaction of a surveyor's needs, a record retention timeframe is an arbitrary number and we feel that the facility can best determine the need to retain records beyond a survey cycle.

§483.15 Admission, Transfer, and Discharge Rights

LeadingAge supports the proposed changes to send notice of discharge and transfer to the long-term care ombudsman under circumstances of facility-initiated involuntary transfer and discharge only. Recognizing that, per requirement, individuals cannot be discharged to an acute care hospital, we do not feel it would be necessary to require that notice of transfer to an acute care facility is sent to the ombudsman, as a resident who is transferred to the hospital and is unable to return to the nursing home would require an additional discharge notice. At that time, if the discharge is determined to be a facility-initiated involuntary discharge, the ombudsman would be notified according to requirement.

We request clarification in the interpretive guidance, however, to further distinguish voluntary and involuntary transfers and discharges. The current interpretive guidance defines the terms “resident-initiated” and “facility-initiated” but fails to define “voluntary” and “involuntary”. Further, the definitions provided for “resident-initiated” and “facility-initiated” encompass language that would mistakenly render these terms synonymous with “voluntary” and “involuntary.” As defined in Appendix Q of the State Operations Manual:

Facility-initiated transfer or discharge: A transfer or discharge which 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 definition as above unequivocally aligns a facility-initiated discharge with an involuntary discharge. However, there may be circumstances under which a facility initiates a discharge plan to which the resident does not object or that is in alignment with the resident’s stated goals for care and preferences. The result would be a facility-initiated *voluntary* discharge. We request CMS to revise the existing definition for facility-initiated transfer or discharge and provide additional definitions for voluntary and involuntary transfers and discharges in order to recognize the independence of these terms and prevent opportunities for confusion in the interpretation of the requirement.

§483.45 Pharmacy Services

LeadingAge is concerned about the inconsistent and contradictory language used in the proposed rule related to pharmacy services. The proposed rule states that revisions have been made to requirements for extending pro re nata (PRN) psychotropic medications under §483.45(e)(4) and §483.45(e)(5) that would no longer require a physician’s evaluation for the extension of PRN antipsychotic medications. However, this statement is contradicted by a later statement that “§483.45(e)(5) would be revised to require, in addition to the current requirements, that the facility’s policies, standards, and procedures use 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 resident’ [sic] needs for psychotropic drugs.” The phrase “in addition to the current requirements” indicates that the requirement for a physician’s evaluation would remain.

We request clarification on this matter and further recommend that the final rule does, in fact, eliminate the requirement for a physician’s evaluation in order to extend a PRN antipsychotic medication past the 14-day limit. The issue in this matter is not about the use of antipsychotic medications among older adults. We recognize that such medications carry risk and should only be used appropriately and in conjunction with person-centered, non-pharmacologic interventions. Nothing in either the current rule or the proposed rule negates those expectations. The issue at hand is the appropriateness of requiring a physician to visit and evaluate an individual every 14 days for the effectiveness of a medication he may or may not have received in the past 14 days. We believe that the individual physician and the resident’s interdisciplinary team is the best

judge of when an evaluation needs to take place and regulatory requirement for a physician evaluation is simply administrative burden.

We support the proposed revisions that a facility's policies related to the extension of PRN psychotropic medications should use recognized standards of practice and request further guidance related to this requirement. It would be helpful for providers to know CMS's expectations around which set or sets of standards are most appropriate, thus eliminating the opportunity for future disagreement between facilities and regulatory officials on this matter. While LeadingAge does not formally endorse any particular set of standards, we suggest that adopted standards specifically related to geriatric psychiatry would best serve the older adults living in our nursing homes.

§483.60 Food and Nutrition Services

LeadingAge appreciates CMS's efforts to reduce provider burden and agree that the current requirements for Director of Food and Nutrition Services are too stringent. We support the proposed revision that an individual with 2 or more years' experience can be designated as a director of food and nutrition services and support maintaining the requirement that the director must receive frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional.

We have heard from members many opinions on the proposed requirements for individuals designated as Directors of Food and Nutrition Services who have no previous experience in the role. While a "minimum course in food safety" that includes foodborne illness, sanitation procedures, and food purchasing/receiving may not adequately prepare one to serve as a Director of Food and Nutrition Services, most feel that an individual's capability is best determined by the hiring/designating facility and that the flexibility for a facility to make this determination is essential. For this reason, we recommend adoption of the revisions as proposed with special emphasis on the requirement that, in the absence of 2 or more years' experience in the role of Director of Food and Nutrition Services, the individual has completed a course that includes topics integral to managing dietary operations.

We further propose that facilities would have one year from the date that the rule is finalized to meet these requirements. We feel that these requirements will help ensure the safety and well-being of residents through the dining experience without imposing significant burden on providers.

§483.70 Administration

LeadingAge supports the proposed changes to eliminate the requirement at §483.70(e)(3) that each facility must conduct and document a facility-wide assessment for both day-to-day operations and emergencies. We further support the revision of the frequency at which a facility-wide assessment must be completed, but request clarification on a contingency of this revision. The proposed rule states "We believe 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." We request

clarification on what constitutes “high staff turnover” in this reference, and any guidance on how CMS qualifies “as frequently as necessary.”

§483.85 Quality Assurance and Performance Improvement
LeadingAge supports the proposed changes that would eliminate many of the more prescriptive elements of the Quality Assurance and Performance Improvement program. We firmly believe that in order to operate a successful QAPI program, the facility must have the flexibility to determine how best to meet the requirements according to its own unique characteristics. As noted in the proposed rule, we continue to hear concerns from members about the potential for the presentation of the QAPI plan to surveyors to be used as a “gotcha.” While the intent of this requirement is clearly stated in both the proposed rule and the existing interpretive guidance, it seems that further guidance or joint training for surveyors and providers on this topic may help to alleviate any opportunities for confusion and misinterpretation.

§483.80 Infection Control
LeadingAge supports the proposed changes to this section that would eliminate the requirement that the Infection Preventionist work at the facility “at least part-time” and instead require that the Infection Preventionist must have sufficient time at the facility to meet the objectives set forth in the facility’s Infection Prevention and Control Program.

The determination of “sufficient time” should be implicit in that the time is considered sufficient if the facility has met the other requirements of this section—an individual with appropriate education and training has been designated as the Infection Preventionist, the facility has developed and maintained an Infection Prevention and Control Program, and the Infection Preventionist coordinates with the Quality Assessment and Assurance committee.

We further recommend that facilities have the flexibility to provide information supporting the assertion of “sufficient time” in the manner that is most appropriate to the facility which may include, but neither requires nor is limited to, use of the Facility Assessment, the Infection Prevention and Control Program plan, the Quality Assurance and Performance Improvement plan, or Staff Competencies and education.

§483.85 Compliance and Ethics
LeadingAge supports the proposed revisions that would streamline compliance and ethics program requirements and allow facilities the flexibility to determine how best to meet requirements. We note that CMS directs interested parties to the guidance published by the Office of the Inspector General (OIG) in the March 2000 and September 2008 federal registers but feel that this direction has created even more confusion around these requirements.

In the proposed rule, CMS states that they intend to “reduce a majority of the burden currently required under the compliance and ethics program that are not required in the statute,” yet the 2 OIG documents referenced include elements of a compliance program that were not included in the original publication of §483.85. For this reason,

we recommend that the implementation of §483.85 Compliance and Ethics be delayed for one year after the date that the rule is finalized regardless of whether or not the other revisions in this section of the proposed rule are accepted.

§483.90 Physical Environment

LeadingAge supports the changes proposed that §483.90(e)(1)(i) and §483.90(f) would apply only to newly-constructed facilities and newly-certified facilities that had never previously been a long-term care facility. We appreciate CMS's effort to remove any disincentives to purchase or upgrade existing facilities and feel that there should be no sunsetting of these allowances. Sunsetting these allowances in the future only delays the burden and disincentive to that future time.

Further, references to "burden" and "disincentive" do not adequately capture the true issue, which is that the financial burden associated with these changes would be significant enough as to force some facilities to close, such as those whose primary funding comes from Medicaid. These closures would displace residents, eliminate jobs, and eliminate future options for others to receive care in markets that are already limited. Considering these consequences, sunsetting the allowances is not an acceptable option without government funding to offset the costs.

§488.436 Civil Money Penalties: Waiver of Hearing, Reduction of Penalty Amount

LeadingAge supports the proposed changes to replace the written waiver process for reduction of civil money penalty (CMP) with a constructive waiver process, which would allow facilities who choose not to appeal a CMP to receive the 35% penalty reduction while removing the administrative burden for the facility submitting the written request and CMS processing the request. We further encourage CMS to take this opportunity to reevaluate the use of the CMP altogether.

While punishment can be an effective mechanism for reducing unwanted behavior (if used correctly), it assumes that the individual or entity performing the unwanted behavior is aware of the transgression and willingly performs said behavior in favor of other, more appropriate behaviors. The use of CMPs implies an assumption that nursing homes are willfully choosing noncompliance.

The use of CMPs is also an enforcement remedy that requires relatively little investment toward quality improvement. While the use of CMPs does pose far less administrative burden than other enforcement remedies, such as guided plans of correction for example, one could argue that sometimes assuming greater burden in the short term yields a better outcome overall. Perhaps it would benefit us all to assume a little more administrative burden in these circumstances in order to improve nursing home care, rather than enforcing a punishment that does not address the problem and reduces the financial resources that a nursing home desperately needs to address the solution.

Additional Comments

In the proposed rule, the Information Collection Requests (ICR) section includes a reference to Abuse Reporting requirements. No changes to abuse reporting were

proposed in the published version of the rule, which seems to indicate that CMS had considered changes, ultimately decided against any revisions, but neglected to remove this reference from the ICR section. Despite the absence of any proposed changes, we urge CMS to reconsider the 2-hour reporting requirement for allegations of abuse.

LeadingAge supports prompt reporting of abuse and expects our members to comply with the federal statute of the Elder Justice Act that requires reporting reasonable suspicion of a crime, including abuse, to authorities within 2 hours if serious bodily injury occurred and within 24 hours if no serious bodily injury occurred. However, the requirements issued by CMS are not entirely consistent with this law and these inconsistencies pose considerable administrative burden to providers without improving the safety and well-being of residents.

As stated in §483.12(c):

In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:

> *(1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with state law through established procedures.*

According to this requirement, a facility must report within a 2-hour timeframe every allegation, even when the allegation cannot be substantiated and the events of the allegation have not resulted in serious bodily injury. This requires facilities to prioritize paperwork over resident care, misdirecting staff resources away from other residents who may require care and medical treatment and toward the documentation of allegations that do not present emergent situations.

We propose the following language for §483.12(c):

In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:

> *(1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not result in serious bodily injury, to the administrator of the facility and to other*

officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with state law through established procedures.

As stated above, we propose qualifying the 2-hour reporting requirement to apply only to incidents with severe bodily injury. All incidents without severe bodily injury would be required within the 24-hour timeframe. These changes more accurately align the regulatory reporting requirements with the Elder Justice Act while continuing to facilitate the protection of residents.

We once again thank you for your collaborative efforts to improve nursing home quality and operations. Please do not hesitate to reach out to us (Jodi Eyigor jeyigor@leadingage.org) with any questions or requests for further information.

Sincerely,

Jodi Eyigor
Director, Nursing Home Quality & Policy