LeadingAge Wisconsin
Better Services for Better Aging

October 8, 2015 **Submitted Electronically**

Andy Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

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

Dear Mr. Slavitt:

LeadingAge Wisconsin, an affiliate of LeadingAge, is a statewide membership association of not-for-profit organizations principally serving seniors and persons with a disability. Membership is comprised of 195 religious, fraternal, private and governmental organizations which own, operate and/or sponsor 185 nursing homes, 6 intermediate care facilities for the intellectually disabled, 182 assisted living facilities, 114 apartment complexes for seniors and over 300 community service agencies which provide programs ranging from Alzheimer's support, adult and child day care, home health, home care and hospice to Meals on Wheels. LeadingAge Wisconsin members employ over 38,000 individuals who provide compassionate care and service to over 48,000 residents/tenants/clients each day.

Before commenting on the specifics of CMS-3260-P, LeadingAge Wisconsin members would like to point out the obvious but apparently ignored disconnect between a proposed rule which CMS estimates will add first-year costs of $46,491 per facility and subsequent annual costs of $40,685 per facility to the financial plight of Wisconsin nursing homes, which in 2013-14 (the most recent data available), on average, lost $52.11 per day for each Medicaid resident they served, or an average annual Medicaid loss of just under $1.1 million per facility. Over 40 Wisconsin nursing facilities have closed in the past decade because of Medicaid underfunding.

In Wisconsin, 65% of the residents of nursing homes are Medicaid recipients, 23% are private payors, and 12% are Medicare beneficiaries. Nursing home operators historically have turned to private pay and Medicare residents to subsidize this Medicaid underfunding but that cost shifting ability has been declining rapidly for years. To address this insufficient Medicaid funding, private pay nursing home residents in Wisconsin currently pay rates that average just under $100 per day more than the average facility Medicaid payment rate of $161.12 per day for virtually the same care a Medicaid resident receives.

On the Medicare side, the Affordable Care Act (ACA) reduced expenditures for skilled nursing facilities (SNF) by $14 billion through 2020. Additional SNF reimbursement cuts went into effect on October 1, 2011; the average Wisconsin SNF experienced a 12.6% Medicare rate reduction that year. Finally, under federal sequestration, Medicare provider payments were reduced by an additional 2% on April 1, 2013 and will continue to be reduced 2% annually through 2024.

The situation continues to worsen. Under 2015 Wisconsin Act 55, the state's 2015-17 state budget, nursing homes did not receive an increase in their Medicaid payment rates and, for the first time in the previous two biennial budgets, received no acuity adjustments, either. Because of the formula used to distribute Medicaid funding to Wisconsin nursing homes, approximately 80% of the state's 373 facilities actually will receive a Medicaid rate cut in 2015-16.

Because of these realities, the ability to cost shift in Wisconsin (and we suspect throughout the country) has all but disappeared.

Therefore, it borders on being disingenuous to propose an unfunded mandate on nursing facilities that already are struggling financially. Disingenuous, because those facilities are caring for your clients, individuals who are eligible for funding under the federal-state Medicaid program. If the improvement of nursing home resident quality of care and quality of life, the purported goal of these proposed revisions (and one LeadingAge Wisconsin members support), is truly what the Administration seeks to achieve by promulgating this proposed rule, it ought to "put its money where its mouth is" and pay for these proposed changes, laudable as many of them are. If the end result of implementing these modifications is facility closures or compromised care because of the inability to staff sufficiently, how do these changes benefit the nursing home resident?

The following are the key provisions in CMS-3260-P which LeadingAge Wisconsin members urge the CMS to address further:

1. Quality Assurance and Performance Improvement (QAPI) – 42 CFR 483.75

Proposed Regulation**:** It is at best unclear the level of access that the survey team will have to a facility's QAPI documentation. 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." (42 CFR 483.75(h)(2)(i))

LeadingAge Wisconsin Response: Members are concerned that with access to this information, surveyors would be able to use the facility's own documentation and identification of problems to cite the facility. Under state and 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. **The proposed CMS rule may have a chilling effect on advancing QAPI efforts, and should be deleted or substantially modified.**

2. Infection Control – 42 CFR 483.80

Proposed Regulation: Under 42 CFR 483.80(a) of the proposed rule, CMS mandates the creation of an Infection Prevention and Control Program (IPCP) which will require significant staff training and additional "expertise." 42 CFR 483.80(b)-(c) requires a facility to designate an Infection Prevention and Control Officer (IPCO) to oversee the IPCP and serve as a member of the facility's quality assessment and assurance (QAA) committee. CMS is proposing that facilities be required to establish a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon its facility assessment and following accepted national standards (42 CFR 483.80(a)(1)).

LeadingAge Wisconsin Response: The proposed regulations set mandated qualifications for a number of positions, including the IPCO. This 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. **LeadingAge Wisconsin members believe that a more reasonable approach would be to better define the standards for infection control in a detailed manner, and allow the nursing home to make a determination as to whether the individual responsible for this function has the competency and expertise to effectively serve in that position.**

In addition, a question has been raised as to whether the reference to "s. 483.75(e)" in s. 483.80(a)(1) of the proposed rule should be "s. 483.70(e)."

3. Physical Environment – 42 CFR 483.90

Proposed Regulation: CMS proposes to require facilities that receive approval of construction or reconstruction plans from state and local authorities or are newly certified after the effective date of the final rule to have a bathroom in each resident room that is equipped with a toilet, sink and shower. In the Comments section of the proposed rule, CMS states "reconstruction" means that the facility undergoes reconfiguration of the space such that the space is not permitted to be occupied, or the entire building or an entire occupancy within the building, such as a wing of the building, is modified.

LeadingAge Wisconsin Response: It is the goal of all LeadingAge Wisconsin members to offer all residents a private room with their own bathroom. However, some older facilities may not be able to meet this goal and yet desire to create separate resident rooms with a shared bathroom (i.e., one bathroom shared by two residents). Under 42 CFR 483.90(e), the proposed rule states that for facilities that receive approval of construction or reconstruction plans, "each resident room must have its own bathroom equipped with at least a toilet, sink and shower." This provision could stop a facility from undertaking renovation or remodeling projects to improve an older building because the cost of creating separate bathrooms could be prohibitive. **LeadingAge Wisconsin members urge the CMS to apply this provision to new construction only**.

4. Nursing Services – 42 CFR 483.35 and Administration – 42 CFR 483.70

Proposed Regulation: Under s. 483.70(e) of the proposed rule, facilities would be required to conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility assessment must address or include the facility's resident population (that is, the number of residents, overall types of care and staff competencies required by the residents, and cultural aspects), resources (e.g., equipment, and overall personnel), and a facility-based and community-based risk assessment.

LeadingAge Wisconsin Response: **This section should be deleted since outcomes of existing requirements stand as evidence of adequate facility assessment**. LeadingAge Wisconsin members question the need to spend precious time writing and documenting a facility-wide assessment that surveyors will use to interpret whether sufficient staff is available. The current regulations already appropriately require resident-centered and specific care plans designed to attain and maintain the resident's highest practicable physical, mental and psycho-social well-being. This individualized planning and attention to each person's needs is a more appropriate way to assess allocation of resources than another documentation endeavor. A general requirement of this nature invites a tremendous amount of subjectivity into the survey process when surveyors already have F-Tags and interpretive guidelines at their disposal to address insufficient staffing, substandard quality of care and a wide range of other issues that could arise during a facility inspection.

5. Physician Services – 42 CFR 483.30

Proposed Regulation: Under 42 CFR 483.30(e) of the proposed rule, CMS would require an in-person evaluation by a physician, physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) before an unscheduled resident transfer to a hospital that is not an emergency.

LeadingAge Wisconsin Response: This proposal is poorly thought out, unrealistic, and could in fact result in harm to facility residents. Wisconsin already is facing a shortage of physicians willing to serve nursing home residents; this proposed regulation only serves to fuel this shortage. If this proposed rule goes forward, residents may need to wait before necessary care and services can be provided. Some "non-emergency" transfers to the hospital could prove to be life saving. Please let the clinicians practice their professions**. LeadingAge Wisconsin respectfully requests this provision be dropped from the proposed rule.**

6. Laboratory, Radiology and Other Diagnostic Services – 42 CFR 483.50

Proposed Regulation: CMS proposes to clarify that the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist be notified of abnormal laboratory results when they fall outside of clinical reference ranges, in accordance with facility policies and procedures

for notification of a practitioner or per the ordering physician's orders (42 CFR 483.50(a)(2)(ii) of the proposed rule).

LeadingAge Wisconsin Response: Members believe this proposed requirement will impose an undue burden on facility clinical staff and on the ordering physicians, physician assistants, nurse practitioners and clinical nurse specialists. Instead, we recommend that CMS consider amending this proposal to state that the ordering practitioner should be notified when results fall outside a critical value, which is defined by every laboratory based on the reference range. This will avoid calls to the ordering practitioner when a lab result falls outside the clinical reference range, but the trend of the result is going in the correct direction for the resident.

7. Pharmacy Services – 42 CFR 483.45

Proposed Regulation: CMS has proposed to clarify and distinguish ''antipsychotic'' drugs from ''psychotropic'' drugs. Under s. 483.45(c)(3) of the proposed rule, a psychotropic drug "is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories": anti-psychotic; anti-depressant; anti-anxiety; hypnotic; opioid analgesic; and any other drug that results in effects similar to those drugs. 42 CFR 483.45(e) of the proposed rule states that, based on a comprehensive assessment of a resident, the facility must ensure that: 1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record; 2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs; 3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and 4) PRN orders for psychotropic drugs are limited to 48 hours and cannot be continued beyond that time unless the resident's physician or primary care provider documents the rationale for this continuation in the resident's clinical record.

LeadingAge Wisconsin Response: Wisconsin currently ranks fifth in the country in reducing the use of antipsychotic medications in nursing homes. LeadingAge Wisconsin members believe that CMS and the States already have the authority (and have used that authority) under existing regulations and F-Tag interpretive guidelines to cite facilities for the use of any drug if the drug is deemed to be unnecessary or to not have an appropriate indication for its use. We do not believe CMS should go so far as to expand the definition of psychotropic drugs to include any drug that affects brain activities associated with mental processes and behavior. Further, we disagree that PRN orders should be limited to 48 hours; if CMS believes a limit is necessary, then we recommend that the limit be 72 hours. This will provide both a reasonable amount of time for the clinical team to work together on alternate solutions, especially after a weekend, while allowing the resident to remain in the facility and not be transferred to an emergency room because of behavioral health symptoms that present a danger to the resident and/or others, including staff. Further, **if** CMS decides to finalize this proposal, then LeadingAge Wisconsin members request the following:

- Exclude anti-depressants and opioids from the definition of psychotropic drugs. Discouraging the treatment of depression or pain through the use of appropriate

medications (anti-depressants and opioids, respectively) seems to be the opposite of what is needed.

- Expand the list of excluded diagnoses from the limited set of exclusions currently in use with regard to antipsychotic medications.

8. Behavioral Health Services – 42 CFR 483.40

Proposed Regulation: CMS proposes to require facilities to provide the necessary behavioral health care and services to residents in accordance with their comprehensive assessment and plan of care. Specifically, s. 483.40(a) of the proposed rule requires the skills set of a facility's direct care staff to include, but not be limited to, knowledge of and appropriate training and supervision for: (1) Caring for residents with mental illnesses and psychosocial disorders, as well as residents with a history of trauma or post-traumatic stress disorder, that have been identified in the facility assessment; and (2) Implementing non-pharmacological interventions. CMS further proposes to require the facility to ensure that a resident who has a mental or psychological adjustment difficulty, or who has a history of trauma and//or post-traumatic stress disorder, receives appropriate treatment and services to correct the assessed problem or to attain the highest practicable mental and psychosocial well-being, and that a resident who did not have such a diagnosis does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors unless the resident's clinical condition demonstrates that this was unavoidable.

LeadingAge Wisconsin Response: Members request that CMS clarify how this new section intersects with the current pre-admission screening and resident review (PASARR) process, particularly with respect to the Level II screening when it results in a finding that a resident would require specialized behavioral health services. Historically, nursing homes have not been expected to admit residents with these needs and Medicaid per diem rates for the most part do not include payment to a nursing home for specialized behavioral health services. We believe caring for residents with psychiatric illnesses is complex and requires a thoughtful plan that does not rely solely upon nursing homes to fill in gaps in the behavioral health system of care for older adults. **LeadingAge Wisconsin respectfully requests that CMS drop this provision and work with State survey agencies and providers to address how residents with complex behavioral challenges can best be served**.

9. Specialized Rehabilitative Services – 42 CFR 483.65 and Outpatient Rehabilitation Services – 42 CFR 483.67

Proposed Regulation: Under s. 483.65(a) of the proposed rule, CMS adds respiratory services to the list of specialized rehabilitative services and clarifies what constitutes rehabilitative services for mental illness and intellectual disability. Under s. 483.67 of the proposed rule, the CMS creates a new section relating to outpatient rehabilitation services, which among other things would establish new health and safety standards for the provision of outpatient rehabilitative therapy services and delineate the personnel and required qualifications of those responsible for the provision of outpatient rehabilitation services.

LeadingAge Wisconsin Response: Members believe a nurse with the appropriate training can provide the necessary respiratory services in most instances. It is difficult to discern if the proposed rule would require facilities providing rehabilitative services to do so solely through respiratory therapists but it is quite clear that if that is the case, it would be nearly impossible to find enough respiratory therapists to provide the services described in the proposed rule. It also would be cost prohibitive to do so, especially if in most cases a nurse could have provided the same services to the residents.

10. Dental Services – 42 CFR 483.55

Proposed Regulation: Under s. 483.55(a)(3) of the proposed rule, CMS would prohibit facilities from charging a Medicare resident for the loss or damage of dentures determined to be the facility's responsibility.

LeadingAge Wisconsin Response: The proposed rule should clarify that the facility's responsibility for lost dentures does not extend to the loss of dentures resulting from resident actions and/or failure to (repeatedly) abide by facility policies. **LeadingAge Wisconsin respectfully requests that this provision either be clarified or removed from the proposed rule.**

11. Comprehensive Person-Centered Care Planning – 42 CFR 483.21

Proposed Regulation: Under s. 483.21(b)(2)(ii) of the proposed rule, CMS requires that a nurse aide with responsibility for the resident, a member of the food and nutrition services staff, and a social worker be part of the interdisciplinary team (IDT) responsible for developing a comprehensive care plan for each resident.

LeadingAge Wisconsin Response: This requirement would add to the current duties of each of these staff members and, therefore, would be a new economic cost to each facility. The federally-prescribed composition of the IDT should remain unchanged. While LeadingAge Wisconsin members believe that input from direct-care staff is critical in the care of each resident, the individual facility should have the flexibility to determine how best to obtain this input in a manner that is not disruptive to resident care. For example, a facility could put into place a process that elicits input from direct-care staff and conveys the information about the resident outside of the formal IDT meetings. Mandating attendance of direct-care staff at the actual IDT meetings raises cost and logistical issues.

12. Facility Responsibilities – 42 CFR 483.11

Proposed Regulation: Under s. 483.11(d)(1) and (2) of the proposed rule, CMS proposes to revise visitation requirements consistent with the requirements established for inpatient hospitals.

LeadingAge Wisconsin Response: Members believe that if the rule's intent is to permit "open visitation" similar what is permitted in hospitals, there are some important distinctions between hospitals and nursing homes that should be considered. Most nursing homes do not employ distinct security personnel, or if they do employ security personnel, they are typically not present around the clock. It is more common for a nursing home to have a receptionist at the main entrance who welcomes and guides visitors. Generally, reception staff are present until early evening hours. Around the clock visitation would require increased staffing, at a minimum. This did not seem to be included in CMS' estimate of costs per facility for implementation of these rules.

Another concern is that the privacy and conditions of other residents must be a consideration in an "open visitation" environment. Currently, facilities accommodate visitors at any time when a request is made or the clinical situation of the resident is such that the presence of visitors is essential. This provides everyone involved with the time to prepare and to accommodate everyone's needs. Mandatory "open visitation" in what is both a home and a health care facility means there will be more unanticipated visitors, and this could lead to facility resources being diverted to quickly arrange for an appropriate visiting environment for all involved, as opposed to attending to other needs. **LeadingAge Wisconsin urges CMS to clarify this section of the proposed rule to ensure that facilities maintain the ability to limit visitations if those limitations are based on clinical or safety considerations that are outlined in the facility's policies and procedures and shared with each resident.**

13. Transitions of Care – 42 CFR 483.15

Proposed Regulation: Under s. 483.15(b)(2)(iii)(A)-(R) of the proposed rule, CMS requires facilities seeking to transfer or discharge a resident to provide 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) to the receiving provider.

LeadingAge Wisconsin Response: This requirement will be difficult to meet in a timely and accurate manner without interoperable health information exchange. Unfortunately, the federal government has not provided any health information technology "meaningful use" incentives to nursing homes and other post- acute care providers. LeadingAge Wisconsin members do not see how this requirement could be met without either increasing staff or deploying an electronic medical record system with interoperability. The federal government should provide "meaningful use" incentives to nursing homes if this requirement is included in the final rule.

14. Training Requirements – 42 CFR 483.95

Proposed Regulation: CMS proposes to add a new section to 42 CFR 483 that sets forth all the requirements of an effective training program that facilities must develop, implement, and maintain for all new and existing staff, individuals providing services under a contractual arrangement, and volunteers, consistent with their expected roles. The proposed training topics that would be required to be provided include the following:

- **Communication:** CMS proposes to require facilities to include effective communications as a mandatory training for direct care personnel.
- **Resident Rights and Facility Responsibilities**: CMS proposes to require facilities to ensure that staff members are educated on the rights of the resident and the responsibilities of a facility to properly care for its residents as set forth in the regulations.
- **Abuse, Neglect, and Exploitation**: CMS proposes to require facilities, at a minimum, to educate staff on activities that constitute abuse, neglect, exploitation, and misappropriation of resident property, and procedures for reporting these incidents.
- **QAPI & Infection Control**: CMS proposes to require facilities to include mandatory training as a part of their QAPI and infection prevention and control programs that educate staff on the written standards, policies, and procedures for each program.
- **Compliance and Ethics**: In accordance with Section 6102 of the Affordable Care Act, CMS would require the operating organization for each facility to include training as a part of their compliance and ethics program. CMS proposes to require annual training if the operating organization operates five or more facilities.
- **In-Service Training for Nurse Aides**: In accordance with Section 6121 of the Affordable Care Act, CMS proposes to require dementia management and resident abuse prevention training to be a part of the 12 hours per year in-service training for nurse aides.
- **Behavioral Health Training**: CMS proposes to require that facilities provide behavioral health training to its entire staff, based on the facility assessment requirement under s. 483.70(e) of the proposed rule.
- **Trauma-Informed Care:** CMS proposes staff training requirements would need to include culturally competent, trauma-informed care.

LeadingAge Wisconsin Response: Members are seriously concerned with the fiscal and administrative burdens associated with such expansive requirements when it is already challenging to meaningfully address currently-required training topics. Facilities need flexibility to determine how to best train staff on these and a myriad of other issues. **LeadingAge Wiscosin members recommend the list of added training topics be evaluated by a provider-CMS workgroup and a staggered, 5-year phase-in of any new training requirements be considered.**

Concluding LeadingAge Wisconsin Recommendations:

- Given the significant changes underway and the sheer magnitude of the proposed changes contemplated in this rule, **LeadingAge Wisconsin strongly recommends a five-year phase- in of these regulatory revisions**, with prioritization of certain requirements based on the level of importance and facility/government preparedness for implementation.

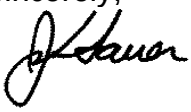
- LeadingAge Wisconsin members also are **concerned about the cumulative compliance costs** associated with the many changes proposed in the regulations. The additional staffing, credentialing, training, systems and contractual relationships that will be required for compliance will add to the financial stresses that nursing homes are experiencing from ongoing Medicare and

Medicaid cuts. In addition, we believe the CMS cost estimates to comply with these proposed changes are understated significantly.

- 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.

Thank you for this opportunity to offer comments, concerns and recommendations on this important rule proposal on behalf of the LeadingAge Wisconsin membership.

Sincerely,



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