December 12, 2011

Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-4157-P: Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities; **-- Submitted electronically**

Dear Ms. Tavenner:

LeadingAge (formerly AAHSA) appreciates the opportunity to comment on this proposed regulation. The members of LeadingAge (www.LeadingAge.org) serve as many as two million people every day through mission-driven, not-for-profit organizations dedicated to expanding the world of possibilities for aging. Our 5,700 members, many of which have served their communities for generations, offer the continuum of aging services: adult day services, home health, community services, senior housing, assisted living residences, continuing care retirement communities and nursing homes. Together, we advance policies, promote practices and conduct research that supports, enables and empowers people to live fully as they age. LeadingAge's commitment is to create the future of aging services through quality people can trust.

We provide comments below on sections of the proposed rule (1) dealing with proposed new benefit flexibility for fully-integrated dual eligible special needs plans and (2) related to CMS considering changes to the conditions of participation for long term care facilities (independent consultant pharmacy services).

New Benefit Flexibility for Fully-Integrated Dual Eligible Special Needs Plans (FIDE SNPs) (§ 422.102)

CMS proposes "amending § 422.102 to add a new paragraph (e) specifying that, subject to CMS approval, and as specified annually by CMS, certain FIDE SNPs may offer additional

supplemental benefits beyond those other MA plans may offer where CMS finds that the offering of such benefits could better integrate care for the dual eligible population."[1] CMS proposes this change in the interest of helping "prevent health status decline in the dual eligible population, and [reducing] the quantity and cost of future health care needs." CMS also notes "in circumstances where a State reduces coverage of a Medicaid benefit, we believe that the ability to offer additional Medicare supplemental benefits to full-benefit dual eligible enrollees is particularly critical in order to ensure continuity of care." LeadingAge concurs.

As examples of benefits that could be offered under this proposed rule, CMS lists "personal care services in the home, non-skilled nursing activities in the home, custodial care, and in-home food delivery for vulnerable beneficiaries." Research indicates that adult day services can effectively provide personal care and nursing services that help prevent health status decline in the dual eligible population and reduce the quantity and cost of future health care needs.[2] We believe that it should be included as a supplemental benefit offered by Fully Integrated Special Needs Plans.

> RECOMMENDATION**: <u>LeadingAge supports this proposal, encourages CMS to finalize it, and recommends including adult day services as a potential supplemental benefit.</u>**

Independence of LTC Consultant Pharmacists: CMS Considering Changes to the Conditions of Participation for Long Term Care Facilities

In this proposed regulation, CMS reports the agency is considering changing the conditions of participation for LTC facilities (SNFs and NFs) to require that "LTC consultant pharmacists be independent of the LTC facility pharmacy, pharmaceutical manufacturers or distributors, or any affiliate of these entities." Prominent among the evidence CMS offers that some type of action is needed are statistics regarding high use of anti-psychotics in nursing homes. CMS asks for public comment on the new regulations it is considering, though has not drafted.

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[1] CMS explains "Assuming that this proposal is finalized, we would issue guidance in our annual Call Letter and in Chapter 4 of the Medicare Managed Care Manual—to provide guidance on the applicability of this provision, as well as examples of the specific additional supplemental benefits flexibilities that could be afforded under this initiative.

[2] Gaugler JE and Zarit SH, "The effectiveness of adult day services for disabled older people," *J Aging Soc Policy*, 2001:12(2):23-47.

LeadingAge shares CMS' dedication to better assuring appropriate use of pharmaceuticals for nursing home residents[3] and strongly believes that ethical professional consulting pharmacist services are an important component of optimal nursing home care. However, we disagree with CMS' conclusion that "a requirement under consideration that LTC consulting pharmacists be independent would be appropriate and prudent because it would ensure that financial arrangements did not influence the consultant pharmacist's clinical decision making to the detriment of LTC residents." For reasons explained more fully below, we believe that CMS has failed at this time to make the case that the option they are considering should be developed into a formal regulatory proposal. Appropriate studies are needed and feasible in a reasonable amount of time and may suggest better remedies (more clearly related to identified goals and with less potential for negative consequences) should problems be confirmed. We appreciate CMS' asking for input before proceeding further.

ISSUE: **CMS is considering new regulations in substantial part because it is concerned that improper behavior--already prohibited by regulations and law-- may be occurring, but does not demonstrate that new regulations are necessary or that the benefits of the new regulations would likely outweigh the costs and potential unintended negative consequences.**

CMS states (though does not support with independent research) that "LTC pharmacies typically provide the consultant pharmacists to nursing homes at rates that are well below the LTC pharmacy's cost and below fair market value." This, they say, raises concerns "that these arrangements may be used to entice nursing homes to enter into contracts with the LTC pharmacy for pharmacy dispensing services and the purchase of prescription drugs," which raises additional concerns when coupled with "financial arrangements that involve payments from pharmaceutical manufacturers directly or indirectly to LTC pharmacies and LTC consultant pharmacists for encouraging physicians to prescribe the manufacturer's drug(s) for residents." CMS is further concerned that these arrangements "may lead to recommendations that steer nursing home residents to certain drugs. This steering could result in the overprescribing of medications, the prescribing of drugs that are inappropriate for LTC residents, or the use of unnecessary or inappropriate therapeutic substitutions. Such potential outcomes can pose serious jeopardy to nursing home residents' health and safety."

[3] See, for example, the recent testimony to the Senate Special Committee on Aging of LeadingAge Senior VP Dr. Cheryl Phillips regarding reducing the inappropriate use of antipsychotics in the nursing home and improving the care of individuals with Alzheimer's Disease and related dementia. See: http://aging.senate.gov/events/hr240cp.pdf

CMS is rightly concerned that consulting pharmacists not make recommendations tainted by improper financial considerations that result in "overprescribing of medications, the prescribing of drugs that are inappropriate for LTC residents, or the use of unnecessary or inappropriate therapeutic substitutions." But such behavior is already prohibited by regulation and law. Indeed, the evidence that CMS cites that their concerns "are not merely theoretical," involves a case successfully prosecuted to settlement by the Justice Department in which, as described by CMS, "claims brought by qui tam relators under the False Claims Act alleging that, for instance, an LTC pharmacy received quarterly payments styled as rebates from the pharmaceutical manufacturer to engage in an active intervention program to convince physicians to prescribe a manufacturer's antipsychotic agent to the physicians' nursing home patients and to authorize all competitive products only after the failure of the manufacturer's product."

CMS does not provide evidence that proper enforcement of current law (e.g., the Anti-Kickback Act) and regulations cannot root out the prohibited behavior that concerns CMS. In addition, the agency's proposed action--piling on broad regulations that will for sure disrupt arrangements that are ethical and working very well--appears to us a scatter-shot approach with potentially excessive collateral damage and no assurance of actually netting more miscreants.

CMS inadequately supports its conclusion that new regulations would actually be an effective way to achieve stated goals of better resident care through differently-organized consulting pharmacy services. For example, if the problem stems ultimately from profit opportunities in the US market-based health care system that some people may now be abusing, what is the evidence that requiring "independence" of consulting pharmacists would (as CMS states would be the case) "ensure that financial arrangements did not influence the consultant pharmacist's clinical decision making to the detriment of LTC residents"?

Among other things, CMS should provide detailed analysis of the New Jersey situation, where "independent" consulting pharmacy services are required. How is it similar and different from the model of "independence" CMS is considering? Have goals been achieved in New Jersey? What problems were encountered (if any) in implementation? How were they resolved? What works and doesn't work in that system?

Finally, it is important to note that CMS acknowledges the regulations being considered would up-end an entire industry but also acknowledges it cannot get reliably close to estimating the cost of this and asks for help from stakeholders. While CMS stipulates that new costs would be incurred by nearly every nursing home (i.e., a likely net increase in costs), the first-cut estimates provided raised credibility concerns with many of our members. Among other things, it appears that the approach CMS used in its estimates did not include any overhead costs for the new independent consultant pharmacists. What magnitude of transaction costs would be involved in

totally reorganizing this industry (e.g., forming new independent consultancy businesses, new marketing and billing operations, etc)? Who would pay for that and how? What would be the change in drug costs? Further, while we agree that there may be associated cost savings to the health care system—if the new regulations did produce better pharmacy services—it is critical to determine how net costs would change for nursing facilities separately from more global considerations. How would the net cost increases to nursing facilities be paid for? If money is necessarily shifted from nursing staff to a new way of buying (more costly) independent consultant pharmacy services, what is the probability that patient/resident care will be improved (or harmed)? Thoughtful, independent, studies are required to address such questions.

> RECOMMENDATION**: CMS should not at this time (if at all) proceed to drafting formal proposed regulations discussed as "under consideration." The information required on this important topic cannot be met simply by reviewing stakeholder comments (useful as they may be). Rather, CMS should assure that needed independent studies (including cost analyses) are conducted before determining how best to proceed.**

ISSUE: **CMS is considering new requirements regarding the independence of consulting pharmacists in part because CMS is concerned that prescribing physicians and nursing homes "generally are unaware of any financial interests that can bias the pharmacist's drug recommendations," but better remedies to enhance transparency have not been sufficiently considered.**

In support of its proposed new requirements, CMS relies heavily on a 2008 study conducted by The Office of the Inspector General (OIG).[4] Among other things, CMS notes that the study reported 80 percent of the "nursing home administrators interviewed for the study indicated the consultant pharmacists performing their facility's drug regimen reviews were employed by the nursing home's LTC pharmacy." CMS further notes "this report states that 54 percent of the 79 pharmacy directors interviewed for the study reported that their pharmacy receives rebates from pharmaceutical manufacturers that are frequently based on market share or volume. However, only three of the pharmacy directors reported providing rebate information to the LTC facility. Thus, in delegating responsibility for avoiding use of unnecessary drugs to consultant pharmacists, nursing homes generally are unaware of any financial interests that can bias the pharmacist's drug recommendations. Consultant pharmacists perform monthly drug regimen reviews for all LTC facility residents. During this review, the consultant pharmacist may recommend a medication change. In making a decision whether to accept the recommended

[4] US Department of Health and Human Services, Office of the Inspector General, *Availability of Medicare Part D Drugs to Dual-Eligible Nursing Home Residents,* June 2008.

change, prescribing physicians are likewise generally unaware of the LTC pharmacy rebate arrangements with pharmaceutical manufacturers that may influence the recommendation."

LeadingAge concurs with CMS' concerns regarding lack of transparency regarding financial interests. But we believe that OIG's targeted recommendation regarding this in the referenced report is better than the overly-broad, scatter-shot remedy that CMS proposes. OIG's recommendation, and CMS' objection to it is given below:

> **"**Consider methods to encourage long-term care pharmacies to disclose to physicians information about rebates that they receive from drug manufacturers**.** We recognize that CMS does not have the authority under Part D to require long-term care pharmacies to disclose the rebates that they receive from drug manufacturers. However, CMS can consider methods to encourage long-term care pharmacies to disclose to physicians information about their rebates. Because long-term care pharmacists can influence the drugs that are prescribed to residents in nursing homes, it is important that physicians be aware of any potential financial incentives that pharmacists may have to recommend one drug over another" "….CMS did not concur with our fourth recommendation to consider methods to encourage long-term care pharmacies to disclose to physicians information about rebates that they receive from drug manufacturers. CMS stated that it does not have authority under Part D to require long-term care pharmacies to disclose their rebates to physicians. CMS noted that to ensure that the rebates received by long-term care pharmacies do not create incentives that are contrary to a Part D plan's formulary, it currently requires Part D sponsors to collect and review information regarding rebates received by their network long-term care pharmacies. We recognize that CMS does not have the authority to require pharmacies to disclose their rebates to physicians. However, we continue to recommend that CMS consider additional ways to encourage pharmacies to disclose this information to physicians so that they are aware of any potential financial incentives that pharmacists may have to recommend one drug over another."
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> RECOMMENDATION: **CMS should contract for an independent study to analyze possible methods that could be used to encourage long-term care pharmacies to disclose to nursing homes and physicians information about rebates that they receive from drug manufacturers.**

ISSUE**: CMS proposes a very broad definition of "independence," which appears unworkable. The agency recognizes that if the regulation(s) they are considering were finalized, exceptions would be needed, but struggles unsuccessfully to define clear criteria for those exceptions. These problems further suggest a different approach is needed**.

CMS is considering using a very broad definition of "independence," given below:

> "We are considering requiring that long term care facilities employ or directly or indirectly contract the services of a licensed pharmacist who is independent. We also are considering including a definition of the term ''independence'' to mean that the licensed pharmacist must not be employed, under contract, or otherwise affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities.…We do not believe it necessary to define the terms ''affiliate'' or ''affiliated'' as we believe the meaning should be broadly interpreted to cover all relationships that incent overprescribing and inappropriate prescribing in LTC facilities." [Emphasis added]

We disagree with CMS as we do believe it would certainly be necessary to define the terms "affiliate" and "affiliated." In our view, it is inappropriate to boundlessly prohibit "all relationships that incent overprescribing and inappropriate prescribing in LTC facilities." What about a nursing home that hired a consulting pharmacist who also served (for compensation) as editor of a pharmacy journal that was substantially supported by the pharmaceutical industry? The definition of affiliation has to be specific enough to provide a bright line test that is easy to apply but has to be workable in the real world.

While CMS says they do not want to define that bright line, they do say they are looking for examples of "the specific relationships that should be permitted," explaining thusly: "We do not intend…for any of the changes under consideration to prohibit any relationships that would be inherently free of conflict of interest." They offer an example of "Indian Tribes and Tribal organizations own LTC facilities that serve their members and that the Tribe may also own the pharmacy that serves the facility. We believe that the Tribal-owned LTC facility may employ the services of a pharmacist to provide consultation and perform drug regimen reviews who is also employed by the facility's pharmacy without violating the independence requirement. In these instances, because the LTC facility and pharmacy are commonly owned by the Tribe, the consultant pharmacist's incentives for prescribing are aligned with the best interests of not only the Tribal members who are LTC residents, but also the Tribe."

Similarly, we believe that a LTC facility that has its own in-house pharmacy and employed pharmacists presents a case with incentives as aligned (or sufficiently similarly aligned) as the one above to warrant an exception, should CMS proceed with the regulations it is considering. As described below by one of our members, a very large SNF, with its own pharmacy, this situation presents minimal incentives for improper pharmacy recommendations. Because of the close relationship between the facility and the pharmacy, there is more than enough accountability for the pharmacist; the contractual privity between the facility and the pharmacy is the same as if the facility were to hire an "independent" consultant pharmacist to work with a contracted LTC pharmacy.

> "The Parker Jewish Institute for Health Care and Rehabilitation, located in New Hyde Park, NY, opposes the change in CMS-4157-P….Parker's in-house Pharmacy…. is self-contained. Its formulary is determined by the Institute's Pharmacy and Therapeutic Committee, comprised of clinicians employed by the facility. Additions or deletions of drugs are made by the Committee, based exclusively upon an objective evaluation of the

> efficacy of the drug in question. There is no financial incentive, or quid pro quo, as inferred by the proposed rule change. In fact, the notion that a given facility is capable of influencing a particular drug's market share is patently naïve. The proposed rule change ignores the proven professionalism of in-house pharmacists and their critical role as collaborators in providing excellent patient care. At Parker, and similar long term care organizations, the in-house clinical pharmacists are able to work closely with physicians and nurses employed by the facility. In the course of drug reviews, the in-house pharmacist's constant and, if needed, immediate access to medical staff is in the manifest best interests of the patient, and reflects contemporary best practices encouraging rapid, on-site communication."

Finally, we concur with CMS that the proposed regulations would be particularly problematic in rural areas, where "independent" alternatives (as described by CMS) are not available. Thus, should CMS proceed with this proposal, we would strongly recommend an exception for rural areas.

> RECOMMENDATION: **If CMS were to proceed with this proposal, a clear definition of "independence" would be needed and terms CMS is considering including like "affiliated" would also need clear definition. The definition of prohibited relationships has to be specific enough to provide a bright line test that is easy to apply but has to be workable in the real world. If CMS proceeds, we also recommend exceptions for self-contained in-house pharmacies and for rural areas where there are no alternatives (or insufficient ones to provide some margin of choice).**

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Again, LeadingAge appreciates the opportunity to comment on this proposed rule. We hope our comments will be helpful to you.

Please do not hesitate to contact us if you have any questions or would like further discussion. We look forward to our continued work with you on this and related issues.

Sincerely,

Barbara B. Manard, Ph.D.
Vice President, LTC Health/Strategies
Leading Age
BManard@leadingAge.org