January 21, 2011

Dr. Donald Berwick
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave, SW, Room 445-G
Washington, DC 20201

Re: CMS-4144-P

Dear Dr. Berwick:

The American Association of Homes and Services for the Aging (AAHSA) appreciates the opportunity to comment on the Proposed Rule (published in the Federal Register November 22, 2010) **"Medicare Program; Proposed Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Proposed Changes."**

AAHSA is an association of 5,500 not-for-profit organizations dedicated to expanding the world of possibilities for aging. These organizations, 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.

AAHSA has comments on **Section II.B.11, "Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities under PDPs and MA-PD Plans (§ 423.154)."** We begin with a brief introduction and overview, followed by specific issues and recommendations.

I. Introduction and Overview

CMS proposes "to require all pharmacies servicing long-term care facilities…to dispense brand-name medications to [Medicare Part D] enrollees in such facilities in no greater than 7-day increments at a time…. The provisions of this regulation will apply to all organizations and sponsors offering Part D including stand alone Part D plans, MA organizations, EGWP contracts, and PACE plans." This provision implements Section 3310 of the Affordable Care Act ("ACA"), which directs the Secretary of Health and Human Services to require Medicare Part D prescription drug plan sponsors "to utilize specific, uniform dispensing techniques …when

dispensing covered Part D drugs to enrollees who reside in long-term care facilities in order to reduce waste associated with 30-day fills."

AAHSA appreciates the opportunities CMS provided as it was developing the proposed rule to ask questions, participate in meetings, and offer comments and suggestions. From the outset, AAHSA has applauded efforts to reduce pharmacy waste, but has expressed concerns about the potential unintended consequences and negative effects of Section 3310 of ACA. Among other things, many of our nursing home members are quite concerned about the increase in nursing staff time required by shorter pharmacy cycles which will require the use of very scarce professional nursing time reordering, receiving and reconciling medications, and managing medications in the medication cart, taking away from time spent with patients. We thus have applauded CMS efforts to minimize the potential negative consequences of Section 3310 of ACA. In the stakeholder meetings that CMS held, we joined others in supporting the proposal CMS was considering (and now has formally proposed) to limit the short cycle requirements to brand name drugs. As CMS notes, "During our discussions with the industry, multiple parties reported that 75 percent to 80 percent of the cost of drug wastage arises from only 20 percent of the drugs. That 20 percent is made up exclusively of brand-name medications." AAHSA continues to believe that limiting the new requirement to selected drugs is an excellent step towards finding a way to achieve the goals of Section 3310 of the ACA ("reducing pharmacy waste") without inadvertently subverting the underlying goal of that provision, which is to reduce overall *costs* associated with pharmacy waste. Since publication of the proposed rule, however, AAHSA has had the opportunity to obtain and review more detailed information about the potential impact of CMS' proposal. We believe that the rule, as written, is more likely to increase costs than to reduce them and to have other negative and unintended consequences. We thus respectfully propose the changes discussed below.

II. Issues and Recommendations

ISSUE: <u>Need to Delay implementation for Further Study to Assure Cost Savings and Minimize Disruptions</u>

CMS proposes that the regulation take effect January 1, 2012, less than a year from the time the final rule will be published and admittedly (by CMS) in the absence of data to substantiate desired savings or the best way to achieve them. The studies cited by CMS in the proposed rule are all very small and fail to consider fully all the relevant costs; nearly all are at least 20 year old. We therefore agree with CMS' conclusion that "only when data has been systematically collected will the extent of waste of Part D drugs be quantifiable on other than an anecdotal basis."

CMS proposes simultaneously implementing its "best shot rule," at the same time beginning to collect data required to construct a reasonable rule. In our view, this puts the cart before the horse with potentially very serious unintended consequences. Among other things, to the best of our knowledge, there is no published or otherwise widely-available, methodologically-acceptable study that includes the cost to nursing homes of new staff resources that would be

required, or how those costs might be mitigated by appropriate alternative procedures. It has been accurately noted that some SNFs do use less than 30 day normal drug cycles for Part A patients (where homes share in the cost savings), which might suggest that a short cycle requirement for Part D (in which nursing facilities would bear the new costs, but not accrue savings) could save money. However, since the types of patients (and the drugs they use) differ between Part A and Part D in nursing facilities, such an assumption requires actual study. Furthermore, even if there would be "immediate" savings to Medicare, costs to nursing homes must be included in the analysis as ultimately these costs are part of the costs borne by Medicare and Medicaid, however tenuous the immediate relationship under existing payment rules.

RECOMMENDATION: **Delay the final rule and implementation until reasonable studies are completed to assure that only a feasible, truly cost-effective approach is required. Conduct the needed studies, including the cost to nursing homes of implementing any proposed changes.**

ISSUE: Need for Alternative/Exception in States that Permit Return for Credit and Reuse of Unused Drugs

CMS considered return and use systems already in place but "decided that return for credit and reuse would not be the optimal solution to address drug waste generated by LTC facilities under Part D." CMS further explains "although return for credit and reuse is not prohibited by CMS, we recognize limitations to this approach since return for credit and reuse is not permitted in all states, often excludes lower cost generic drugs, and is frequently limited to a subset of drugs in unused or specially approved packaging." Since the current proposed rule also excludes lower cost generic drugs and others, CMS's reasoning does not appear to be relevant in states that do permit return and reuse. AAHSA is concerned that in some, and perhaps all of these states, implementation of the proposed rule will be counterproductive, increasing costs rather than reducing them. AAHSA heard from members in some of these states where systems are already in place to minimize waste safely.

As an example, we quote below extensively from comments received from a small independent pharmacy in Kansas (which allows and encourages return and reuse) serving AAHSA members. We hope the details provided will help CMS better understand not only the reason why creating an exception in states which permit return and reuse is feasible and important, but also why exceptions for small, independent pharmacies in other places may also require exceptions and/or waivers.

> **"**The purpose of this regulation is to save money; less medication dispensed should result in less cost. However, in Kansas we are required to credit for any unit dose medications except narcotics which are returned from the nursing home. We are currently doing this. Therefore, there will be NO cost savings, absolutely NONE, should these new regulations be enforced. All states who credit SHOULD BE EXEMPT from the short-cycle dispense regulations.
>
> To implement these new regulations will be very costly, time consuming, decrease our efficiency; it may increase our med error rate both for the pharmacy and the nursing home without any cost savings. It may be so costly as to force us to stop

dispensing to nursing homes altogether, causing a reduction in employees by one pharmacist and two pharmacy techs. At this time we employ three RPH's and six techs. Our business is 40% NH. Losing the NH would prevent us from buying enough volume to get the best prices on retail medications.

We currently dispense to one NH in our town with 150+ beds, with an additional 40 assisted living which fall outside these guidelines. We have been using the Opus 14-day system. This requires one pharmacist and one pharmacy tech working closely together to fill cassettes every two weeks and we barely accomplish the task before the next switch of meds. We deliver and exchange medication cassettes every other Wednesday. It takes two people about three hours to load, exchange, and unload the cassettes. We also, at the request of the NH, do the same Opus 14-day system for the 40 assisted living residents. These people do not pay extra for this service, and we are not reimbursed for the unit dose system by the Plan-D's. Many NH's require their assisted living people to have the same unit dose system as full nursing care. This is because they may decline in health and be moved into health care at any time. Also the NH's have less med errors, less loss of meds on transfer, less missing doses if residents are on the same system. Nursing only has to learn one system. If the transfer occurs at 10 p.m. at night, and the pharmacy is 15-30 miles away, the NH must locate all residents' meds, inventory them, and return them to pharmacy, where the pharmacist then must review, repackage, re-dispense, and redeliver. Then the NH must recheck each med with MAR before the resident can receive it, which causes delays in the patient receiving the drug. If both A.L. and Nursing Care are on the same system, all medication including narcotics could be transferred just as they are, correctly packed for nursing care.

It has been said that those on Opus 14-day cassettes have little change to make, just place 7 days down one side of the cassette and blank out the other side and fill more often. The 14-day cassettes are labeled by the day and go left to right not down the side. We will always be starting in the middle of the cassette. Every time we get a new order, that dispensing will start somewhere in the middle of the cassette and can be confusing. It takes just as much time to fill a 7-day cassette as it does to fill a 14-day cassette, and just as much time for the pharmacist to check.

Procedure**:** -Tech pulls bottle from shelf
-Lays out cassette with correct bottle
-Writes down lot number, expiration dates

If it is a daily order, the tech fills 2 cassettes; one to send, one for flip. If it is a QID order the tech fills 8 cassettes; 4 to send, 4 for flip. On the new 7-day system, to save time and prevent errors we would need to fill for daily orders 4 weekly cassettes at the same time. For QID each order, 16 cassettes at the same time. This will double the number of cassettes we need, double the number of bins to store, double number of lids, double labels, double liners, and double the space needed to store cassettes. Not to mention the time spent on hand-washing liners which then must air-dry, and the time spent pulling old labels, auxiliary labels, and expiration dates off the returned cassettes. On DC'ing daily orders, we would need to pull 3 cassettes for each dose, while waiting for the one to return from NH before crediting. For QID orders, pull 12 cassettes.

The average number of drugs per resident is 11. If all were BID doses, this would require 44 cassettes on the old system. On the new 7-day system it would require 88 cassettes. This would only give us 4 days to fill twice as many cassettes. It currently takes us 8 days to fill 44 cassettes per person, thus creating twice the amount of work and only giving us half the time to do it. Crediting for daily orders would also be more

difficult with 4 cassettes to count. If the dose is 4 times a day, you would have 16 cassettes total to credit.

The cassettes are $2.10 each. This is no small investment to double our cost of everything. We would have to hire another full time tech to work exclusively on NH to get this done.

- 40 hour week @ $10/hr x 52 weeks = $20,800
- Insurance $4,740/year
- TOTAL = $25,540/year

With the Opus 14 day system, the cassettes are switched out every other Wednesday, whether the pills are used or not. Unused pills come back each month. No extra work switching. We fill the pills off an individual patient Mar, which lists the lot number. When refilling the next month, any pills that are returned are logged on the Mar & subtracted from the next months billing. Only if the drug is discontinued, do we reverse and rebill. Our computer company charges us $0.06 to bill, Credit, & rebill or $0.18. Some of the Plan Ds, also charge us between $0.05 (CCRx) up to $0.25 (Humana) to submit & Credit & rebill (between $0.15-0.75). Medicaid's rule is if the cost of the medication returning is less than $5.00 we don't have to credit. In our system, most of these returns are taken out of the next months billing avoiding the credit & rebilling fees, which really add up. If a full cassette, or almost full cassette returns, of a drug we use frequently, we add more pills & relabel for the next patient. Our margin of profit is so small, we save every way we can. However, for the bubble pack 30 day calendar cards, to be forced to dispense weekly, this will increase the cost of our packaging 4x, increase the cost of delivery 4x (these NHs are 10 to 12 miles from our pharmacy). We may have to give up these homes. We would lose money to dispense weekly with the current packaging."

RECOMMENDATION: **AAHSA recommends that CMS develop an exceptions process or similar alternative to the 7 days or less dispensing requirement that relies instead on the efficiencies already achieved by return, credit, and reuse systems in states that permit this.**

ISSUE: Proposal to Waive 7 days or less Dispensing Requirements for Particular Types of LTC Pharmacies-need for additional extensions and/or waivers

CMS proposes waiving requirements for facilities serving those with mentally retardation and developmental disabilities (ICFs MR/DD), institutes for mental disease (IMDs), and for LTCFs utilizing Indian Health Service or Tribal facilities. CMS further proposes to allow an independent community pharmacy that is a primary provider of the Part D covered drugs to a LTCF located in a rural community to dispense a 14-day supply through December 31, 2012. AAHSA supports (at a minimum) those policies, but believes that further exceptions are required to assure that the new requirements do not inadvertently reduce needed access to appropriate services, particularly those provided by small, independent pharmacies.

AAHSA believes that CMS needs to be particularly careful not to implement regulations that reduce important competition in the nursing home pharmacy business, which is already highly

concentrated. Small, independent pharmacies play an essential role for our members and the entire field, particularly in rural areas. While many of our members do have contracts with larger, national long term care pharmacies (and recognize the benefits many offer), preserving options for choice is essential to quality, resident satisfaction, and ultimately overall costs and access. A recent study conducted for CMS, for example, found that while it is very common to facilities to have a pharmacy contract with only one provider, "the use of a single pharmacy reduces the ability of a beneficiary to choose his or her preferred vendor, and limits the ability to shop for the best available price. This is not generally a concern for beneficiaries covered by Medicaid, but can be an issue for private pay patients." The study goes on to say this:

> "Generally, nursing facilities discuss this with residents when they are first admitted, and will support a resident's use of their pharmacy of choice if the pharmacy selected by the resident provides the same labeling and packaging services provided by the facility's primary pharmacy provider… We found that in rural areas and in a small number of states –- Arkansas, Kansas, Mississippi, Minnesota, Oklahoma, and Texas –- nursing facilities report working with multiple pharmacies… At least 17 states have enacted legislation to assure consumers freedom of choice among all sources of pharmaceutical services, such as the local community pharmacy or mail order facility that best suits their needs."[1]

We quoted extensively above from comments we received from a small, independent pharmacy in Kansas about the problems the proposed regulation would impose on them. If CMS does not waive or create an exception process for states like Kansas that do permit return and reuse, the pharmacy and the homes and residents it serves would be harmed. In addition, that small pharmacy, while located in a place that is rural by many characteristics, misses by 3 miles the definition of "rural" CMS proposes in this alternate exception to the 7 day rule.

We heard from other small, independent pharmacies that would also be negatively affected. For example, we heard from a member in Waukesha County, Wisconsin, which is a not-for-profit organization of skilled and assisted living facilities with its own pharmacy. They expressed considerable concerns about the proposed rule including this note:

> "The pharmacy will have increased costs associated with packaging.
> We use a punch card system. Even though there are some 7 day cards
> available there is not a significant difference in the costs of 7 day vs. 30 day cards. So, our cost for the packaging materials will increase unless we can find some alternate supplier. Any new cards we would go to may not be compatible with our heat sealing machines which cost approximately $4000.00 each. If it is necessary to go to a totally different type of dispensing system I would have no way of estimating what the cost of conversion would be but it would be significant."

Additional examples of potential problems cited by AAHSA reviewers included locations where the only pharmacy may be a distance and/or hours away from the facility; where small pharmacies continue to fill prescriptions via a hand count rather than an automated process and therefore require more time and labor to complete the fill; and/or rural areas where weather events, e.g., blizzards, can impede or prevent travel from these pharmacies for 48 hours or

[1] The Lewin Group, "CMS Review of Current Standards of Practice for Long-Term Care Pharmacy Services" (Dec. 30, 2004) (prepared for CMS).

more. AAHSA members responding from these areas expressed concern that these are conditions that present challenges even now, i.e., under 30-day prescription cycles, and that the need for more frequent fill and delivery can only serve to increase the potential for delay times four.

RECOMMENDATION: **At a minimum, retain and extend the proposed deadline for implementing the proposed rule for small, independent pharmacies in rural areas. In addition, develop an exception process or other alternative to address circumstances particular to small, independent pharmacies, including those that may be close to (but not meet) CMS' proposed definition of "rural."**

ISSUE: Exclusion of Schedule II Medications from 7-Day or Less Dispensing

Today's nursing facility populations are comprised largely of long-term residents, many of whom have multiple chronic conditions; post-surgery and/or post-acute patients; and residents, including those electing hospice, who are at or approaching end of life. Because virtually all of these individuals are at high risk for significant pain, a facility's ability to assure appropriate relief, including timely access to schedule II medications, is essential. Recognizing adequate pain management as a critical component of treatment and services, current federal requirements for long-term care facilities cite failure to provide timely and appropriate pain management as constituting substandard quality of care.

Under federal requirements facilities are also explicitly charged with accountability for the use and management of controlled medications. The facility, not the pharmacist, remains responsible for implementing and maintaining a system of accountability, i.e., the pharmacist's role "…is to evaluate and determine that the facility maintains an account of all controlled medications and completes the reconciliation according to its procedures, consistent with State and federal requirements."

- The Requirements of Participation for LTC Facilities as contained in the State Operations Manual, Appendix PP, 483.60 - Pharmacy Services, mandate that facilities "…provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident."
- The Interpretive Guidelines section, "CONTROLLED MEDICATICATIONS", [483.60(d) Labeling of Drugs and Biologicals; and (e) Storage of Drugs and Biologicals], reiterates the requirements that facilities "…have a system to account for the receipt, usage, disposition, and reconciliation of all controlled medications, and that the system include, but not be limited to:

    - Records of receipt of all controlled medications with sufficient detail to allow reconciliation (e.g., specifying the name and strength of the medication, the quantity and date, received, and the resident's name)...

- Records of usage and disposition of all controlled medications with sufficient detail to allow reconciliation (e.g., the medication administration record [MAR], proof-of-use sheets, or declining inventory sheets), including destruction, wastage, return to the pharmacy/manufacturer, or disposal in accordance with applicable State requirements; and
- Periodic reconciliation of records of receipt, disposition and inventory for all controlled medications (monthly or more frequently as defined by facility procedures or when loss is identified)… Because diversion can occur at any time, the reconciliation should be done often enough to identify problems…"

The receipt, reconciliation, and management of Schedule II medications is more complex than for other prescriptions, requiring additional documentation and dedication of at least two staff at any given point to verify counts, etc. Inclusion of these controlled medications in the 7-day or less requirements can mean up to a four-fold increase in related administrative duties. The end result can be a compromise in the time spent bedside by licensed nursing staff and potential delays in meeting resident needs related to pain management.

RECOMMENDATION: **AAHSA recommends that Schedule II medications be excluded from the 7-day or less dispensing requirement.**

ISSUE: "How Soon the Industry Can Transition to Include Generic Drugs in the 7-day or Less Requirement."

CMS states that it is "postponing" inclusion of generic drugs in the 7-day or less dispensing process and asks for comments regarding how soon this might be accomplished. We are unable to answer this question precisely, but note that AAHSA reviewers were quite concerned that CMS might contemplate including generic drugs prematurely. Concerns centered mainly on the overall 4-fold increase in staff time and labor that will be required for medication-related administrative and management duties, with negligible compensating reduction in product costs.

AAHSA, through activities of its Center for Aging Services Technology ("CAST"), promotes the development and adoption of new technologies (such as automated dispensing machines) that may ultimately provide optimal solutions that could include generic drugs. In a recent review of the literature, we found a dearth of needed studies on these newer, promising technologies. Anecdotal evidence suggests, however, that these technologies do not appear fully ready at this time for optimally wide adoption. Some of our members who have tried them have had problems with the particular models available to them at this time, though many remain very enthusiastic about the potential. We note that CMS support of related research (including cost-effectiveness studies) could substantially speed the development and adoption process.

RECOMMENDATION: **At a minimum, retain the exclusion of generic drugs from the short cycle requirements until detailed study proves that adding generic drugs would be feasible, desirable, and fully cost-effective for all concerned. Support the development of new technologies that can eventually provide this enhanced efficiency.**

ISSUE: Proposed Exclusion of Those Drugs that are Difficult to Dispense in a 7-Day or Less Supply. Types of Dosage Forms and Drugs that Should be Excluded

AAHSA agrees that requiring certain types of drugs to be dispensed in 7-day or less increments could result in safety or efficacy concerns or could be counterproductive to the effort to reduce drug waste. While AAHSA's reviewers concurred with CMS' decision to exclude antibiotics, concern was expressed that the transfer of other liquids, i.e., injectables, to smaller prescription bottles or oral syringes could be problematic. CMS states "some in the industry have suggested that we exclude liquids from the requirements; however, we believe most liquids can be transferred to smaller amber prescription bottles or oral syringes to accommodate 7-day-or-less dispensing, so we decline to propose the exclusion of all liquids." One group of AAHSA reviewers noted that insulin is already packaged in small bottles, and that transfer to containers based on the 7-day or less dispensing system will mean "they will be small enough to pick up with tweezers…"

RECOMMENDATION: **Exclude all injectables from the 7-day or less dispensing requirement where smaller packaging is impractical.**

Again, AAHSA appreciates the opportunity to comment on the CMS Proposed Rule, "Medicare Program; Proposed Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Proposed Changes." 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
American Association of Homes
and Services for the Aging