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Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code CMS – 4144 – P, Comments to CMS' Proposed Rule Regarding "Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract 2012 and other Proposed Changes," published in the *Federal Register* on November 22, 2010.

Dear Administrator Berwick:

Thank you for the opportunity to respond to the proposed rule regarding "Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract 2012 and other Proposed Changes." The American Health Care Association (AHCA) is the nation's leading long term care (LTC) organization representing more than 11,000 non-profit and proprietary facilities. Our members deliver the professional, compassionate, quality long term and post-acute care that more than 1.5 million of America's seniors and persons with disabilities rely on each day. While the proposed rule addresses numerous provisions within Medicare Part C and D, we have limited our comments to those provisions that directly impact nursing facilities and the patients whom we serve. Our recommendations, summarized below, are followed by a more detailed discussion of our issues and comments.

I. Summary of AHCA Recommendations

1. Seven-Day or Less Dispensing in Long Term Care Facilities (§423.154): AHCA strongly recommends that Centers for Medicare & Medicaid Services (CMS) postpone implementation of this rule until at least January 1, 2013 to ensure that nursing facilities have sufficient time to evaluate dispensing system options; pharmacies have sufficient time to secure capital and retool; and Part D Plans (PDPs) are able to fully incorporate into their bids the real, additional costs of 7-day or less dispensing technologies that reflect the choices of nursing facilities. Even if the effective date is postponed to 2013, CMS could still encourage and support voluntary conversion to 7-day or less dispensing by encouraging PDPs to adequately adjust pharmacy dispensing fees for early adopters that have converted to 7-day or less dispensing for both brand and generic drugs. Without a delay and without adequate compensation to pharmacies, the reality is that implementation of this rule will result in most pharmacies converting existing 30-day punch card systems to 7-day punch card systems. Use of 7-day punch cards, even if initially limited to brand drugs, will quickly overburden our facilities, increase our costs and harm our patients.

2. Safeguards Against Cost Shifting & Provision of Adequate LTC Pharmacy Network: AHCA strongly believes that the regulatory impact statement is flawed because CMS has failed to properly analyze the financial impact of the short-cycle rule on pharmacies and long term care facilities. Further, in light of the considerable risk that negotiated dispensing fees will not be adequate to cover pharmacies' increased costs, AHCA seeks assurances that such costs will not be passed on to nursing facilities. AHCA also seeks assurances that the initial and ongoing implementation of this rule will not adversely affect nursing facility patients' access to Medicare Part D drugs by disrupting or diminishing long term care pharmacy networks. Specifically, AHCA asks that CMS increase scrutiny of Part D sponsors' long term care pharmacy networks to ensure that Part D sponsors have in fact contracted with long term care pharmacies that meet CMS' performance and service criteria and that their networks are adequate to meet nursing facility patient needs.

3. Excluded Drugs (§ 423.154(b)): In order to avoid ambiguity about what drugs are excluded and to ensure clinical appropriateness for patients and uniformity within each nursing facility, CMS should promulgate a regulation that requires Part D Plans to exclude drugs identified by CMS, in consultation with stakeholders, in guidance to be issued in advance of the rule's effective date and as needed. Such a list, unlike a regulation, could be updated when new drug information becomes available. AHCA's specific recommendations for excluded drugs are included in the more detailed analysis below.

4. Transition Fill Notices (§423.120 (b)(3)(iii)(B)): Part D Plans must be required to send a copy of the initial written transition fill notice to the patient's nursing facility within three days of the date of initial adjudication and at least every 28-30 days thereafter during the transition period. CMS also must require Part D Plans to provide accurate codes to pharmacies so that pharmacies will know that a patient has received a transition fill of a non-formulary drug.

5. Disposition of Unused Drugs (§423.154(f)): To avoid conflicts with other federal and state environmental and controlled substances laws, CMS should withdraw its proposal to require that all unused drugs be returned to the pharmacy to be counted and reported to the Part D sponsor. AHCA urges CMS to consult with other federal and state authorities to develop a single, clear, consistent and cost-effective standard for disposal of all unused, dispensed drugs, regardless of payor source.

6. Definition of Dispensing (§423.100): CMS must amend the definition of dispensing fees to clarify that dispensing fees for drugs dispensed in LTC facilities include the costs associated with "techniques, as chosen by each facility, to minimize the dispensing of unused drugs."

7. Refill Too Soon: To reduce the risk of increased medication errors due to medication unavailability, CMS should issue guidance to Part D Plans requiring them to turn off "refill too soon" reject codes for drugs dispensed to nursing facilities upon the effective date of this rule.

8. Dissemination of Part D Plan Information (§423.128(7)(iii)): AHCA supports the recommendation that network pharmacies be required to provide beneficiaries with a customized printed notice at point of sale explaining how the enrollee can request a coverage determination from the plan sponsor. For nursing facility patients, we urge CMS to require that a copy of the notice be sent directly to the patient with a copy to the nursing facility. We also urge CMS to ensure the accuracy of information sent to pharmacies by Part D Plans regarding rejected claims and transition fills.

9. Medication Therapy Management (423.153(d)(1)(vii)(D)(5)): AHCA does not support requiring that Part D sponsors contract with all nursing facilities in which their patients reside to coordinate Medication Therapy Management (MTM) services with the monthly Drug Regimen Reviews (DRRs). We believe it is duplicative and unnecessary. We urge CMS to give serious consideration to exempting nursing facility patients from MTM under Medicare Part D.

10. Grievance, Coverage Determinations & Appeals (Subpart M): AHCA supports strengthening requirements for grievance, coverage determinations and appeals. For Medicare Part D enrollees who are nursing facility patients, AHCA urges CMS to require Part D Plans to send copies of all notices to the patient's facility and to allow nursing facilities to make oral and written requests for exceptions, coverage determinations and appeals on behalf of their patients.

11. Cost-sharing for Individuals Receiving Home- & Community-based Services: AHCA supports CMS' proposed amendments to implement Section 3309 of the *Affordable Care Act* which eliminates cost-sharing for individuals receiving certain Medicaid-funded home- and community-based services. AHCA also supports CMS' decision to implement these changes by January 1, 2012, the earliest date allowed by law.

12. Co-payments: We recommend that at minimum, CMS specify that enrollees in long term care facilities cannot be charged more than one copayment per prescription regardless of how many dispensing events occur in one month.

13. Enforcement: Scant attention has been paid to the issue of enforcement. In light of the potential that LTC pharmacy networks could be disrupted, we urge CMS to convene stakeholders to identify safeguards needed to minimize potential unintended but adverse impacts on our facilities and patients in the event that enforcement action is taken against a plan or pharmacy for violating this rule.

II. Detail Comments and Discussion of Issues

1. Appropriate Dispensing of Prescription Drugs in Long Term Care Facilities

To implement Section 3310 of the *Affordable Care Act* (ACA), in §423.154, CMS proposes requiring all pharmacies servicing long-term care facilities to dispense brand name medications to enrollees in no greater than 7-day increments at a time. CMS is limiting initial implementation to brand name drugs because brand drugs, which represent only about 20 percent of drugs dispensed in long-term care, represent 75 to 80 percent of the cost associated with waste medications. By limiting initial implementation to brand drugs only, CMS seeks to target the drugs resulting in the most financial waste while lessening the additional burden on facilities for ordering and stocking during the transition from 30-day to 7-day supplies. However, CMS also makes clear that it remains committed to extending the requirement for 7-day-or-less dispensing to generic drugs at a future date.

AHCA and its members share CMS' concern with the need to reduce pharmaceutical waste and to ensure proper disposition and disposal of unused medications. We also appreciate CMS' sensitivity to the burdens placed on facilities and staff during transition. However, even with a transitional approach, we remain deeply concerned about the impact of this rulemaking on our facilities and patients.

Our concerns center on the potential for:

- Placing additional administrative burdens on nursing staff that reduce time for patient care;
- Increasing medication errors and the risk of missed doses;
- Shifting costs to long term care facilities and beneficiaries; and
- Disrupting the long term care market in such a way that we end up with fewer Part D Plans and fewer long term care pharmacies in Part D pharmacy networks, resulting in inadequate capacity to serve our facilities and provide quality care to our patients.

Implementation Should be Postponed to Allow for More Time To Address Critical Infrastructure Issues and Minimize Adverse Impacts

As facility operators and clinicians, our members spend considerable time working with both in-house and contract pharmacists to develop and implement systems that ensure regulatory compliance. We also are accustomed to responding to changes in law and regulations. However, the proposed short-cycle rule presents special challenges. First, the rule is scheduled to go into effect January 1, 2012. Because publication of the proposed rule was delayed by several months, it is unlikely that the final rule will be published before the middle or end of March 2012. Such a schedule leaves just nine (9) months for facilities to make decisions about new dispensing methodologies and systems; pharmacies to purchase and deploy new equipment; Part D Plans to reformulate bids; all parties to renegotiate contracts; and PDPs, pharmacies and facilities to reprogram, retool and train staff.¹

We appreciate that CMS' acknowledges that nursing facilities have unique needs and that, under the rule, each long term care facility and its preferred pharmacy, not the Part D Plan, define the uniform dispensing technique that is most appropriate for that facility. Indeed, the preamble states that "Part D sponsors must permit their contracted pharmacies to implement the uniform dispensing technique selected by each LTC facility and may *not* require the use of a different packaging system or technology than that selected by the facility through its contracted LTC pharmacy."² CMS is very clear that the rule is intended to accommodate various 7-day or less dispensing techniques from 7-day blister packs, to "2-2-3" day dispensing, "4-3" dispensing, daily dispensing as well as automated shift or dose dispensing.

Given the flexibility allowed by the rule, it would be logical to presume that facilities would be interested in a variety of techniques and would seek to utilize those systems that offer the greatest amount of safety and control without increasing staff time on non-nursing tasks. Such dispensing techniques include newly emerging automation technologies that produce medication compliance packs (multiple medications in a single pouch) dispensed by patient time of administration that reduce waste and nursing labor costs.

¹ Implementation is complicated by the fact that virtually no objective, peer-reviewed evidence exists to guide pharmacies and facilities in making decisions about the various dispensing methodologies available in the market place today. Also there is no research regarding the most cost-effective ways to deploy this technology in a nationwide roll out, and little, if any, data or information about how short-cycle dispensing in Medicare Part D affects medication error rates and the overall quality of patient care. Lacking such basic information means that pharmacies and facilities risk making mistakes that could drive implementation costs even higher.

² 75 *Federal Register* 71207. (Emphasis added).

Yet, in reality, even CMS acknowledges that few pharmacies are likely to convert to automated compliance pack dispensing systems due to the high cost of capital acquisition.³ Instead, CMS anticipates that most pharmacies will follow the path of least resistance and lowest cost and simply convert from existing 14- or 30-day punch card systems to 7-day punch card systems. We agree with CMS. Without financial incentives and given the timetable for implementation, pharmacies that currently use 30-day punch cards – including the two largest pharmacies representing 60 percent of the total market – likely will merely convert to 7-day punch cards.⁴

For nursing facilities, the use of 7-day punch cards exponentially increases the amount of time nurses must spend on administrative tasks such as checking in medications, restocking medication carts, creating countdown sheets for controlled drugs, and reordering - all of which takes away from direct patient care. The average nursing home patient takes 10 prescriptions per day and a 100-bed nursing facility orders and receives an average of about 800 oral solid prescriptions per month. With 7-day dispensing, the average nursing facility would have to handle 3,200 prescriptions per month, a net increase of 2,400 prescriptions per month. To handle the additional administrative tasks associated with 2,400 additional prescriptions, the average 100-bed nursing facility would need to hire 1.25 Full-time Equivalents (FTEs). Given the more than 15,000 nursing homes nationwide, we estimate, conservatively, that the potential increase in labor costs for nursing facilities is \$600 million per year.

The use of 7-day punch cards also increases the risk of medication errors due to missed doses or because of medication unavailability. Such errors are more likely to occur because, when using 7-day punch cards, nurses will have to coordinate four times the number of order refills per month.

While the decision to limit the initial phase only to brand name drugs limits the number of medications that must be dispensed in 7-day increments, that decision merely postpones, but does not eliminate, the increased costs and burdens on nursing facilities. It also means that, during this initial phase, nursing homes will be handling approximately 20 percent more orders placed and received which will result in less direct patient care staff time and contribute to medication errors. Once the program is expanded to generics, nursing facility costs for licensed nursing staff will increase significantly without discernible benefit to patients. Although CMS recognizes that “automated dose dispensing . . . is likely the most efficient dispensing methodology and the most effective in reducing waste,”⁵ once PDPs and the LTC pharmacy market leaders comply with the rule by adopting brand name, 7-day punch card dispensing - absent incentives - there is little likelihood that the pharmacy industry will voluntarily move toward more effective technology solutions such as automated compliance pack dispensing. In sum, given the structure of the rule and the timetable for implementation, nursing facilities, in reality, will have little choice but to accept the least acceptable dispensing methodology – a methodology that will drive up facility costs, take nurses away from patient care and increase medication error rates. This is a recipe for disaster.

AHCA commends CMS for considering ways to ease the burden of transition on facilities. However, we feel strongly that patients and the industry would be better served if CMS postponed implementation of this rule until at least January 1, 2013. Postponement is needed to

³ New technology companies also may have difficulty scaling up to meet national demand by January 1, 2012.

⁴ Part D sponsors, that have no responsibility for patient outcomes in nursing facilities and have no contractual or other relationship to our facilities are likely to view 7-day punch cards as the least costly and simplest solution.

⁵ 75 *Federal Register* 71207.

ensure that nursing facilities have sufficient time to evaluate dispensing system options and that pharmacies have sufficient time to secure capital and create the infrastructure to support full deployment of the dispensing systems chosen by nursing facilities. With the proper technology in place, it would then be possible to transition all drugs, brand and generic, to 7-day or less dispensing. Additional time is also needed to ensure that Part D Plans are able to fully evaluate and incorporate into their bids the real, additional costs of 7-day or less dispensing technologies that reflect the choices of nursing facilities. It is critical that CMS makes clear in its final rule that, if a facility chooses more sophisticated dispensing technology, then Part D sponsors are expected to increase dispensing fees to reflect the additional costs associated with that technology (see additional comments below regarding the definition of dispensing fees).

Even if the effective date is postponed to 2013, CMS could still encourage and support existing and voluntary conversion to 7-day or less dispensing by encouraging Part D Plan sponsors to adequately adjust the pharmacy dispensing fees for early adoptors, who together with their facilities, have converted or will be converting to 7-day or less dispensing for both brand and generic drugs. Further, CMS must make clear that PDPs must not limit short-cycle dispensing fees to brand name drugs. If a facility chooses to convert all brand and generic medications to 7-day dispensing, the pharmacy must be reimbursed for all dispensing events for all drugs.

Encouraging PDPs to differentiate and compensate pharmacies for the capital investment required to implement new technologies that better serve long term care facilities than 7-day punch cards will result in savings that will benefit all parties by reducing costs and improving the growth environment for new pharmacy operators and help fuel technological advances. Without a delay and without adequate compensation to pharmacies, implementation of this rule will quickly overburden our facilities, reduce the number of pharmacy operators and negatively impact adoption of new and developing technologies that will reduce our costs and improve quality of care.

Costs – Who will pay?

We strongly believe that CMS has failed to properly analyze the financial impact of the short-cycle rule on pharmacies and long-term care facilities, many of which would be characterized as “small entities” for purposes of the required Regulatory Impact Analysis (RIA) under the *Regulatory Flexibility Act* (RFA).⁶ CMS’ RIA largely focuses on Medicare Advantage organization and Part D sponsor costs due to the need to renegotiate various contracts.

With respect to pharmacies, CMS states that “pharmacies may have up-front costs associated with software upgrades, packaging and hardware changes and ongoing costs associated with transaction fees and additional deliveries.”⁷ CMS anticipates that long term care facilities will be impacted by an increase in the number of medication check-ins and that staff will require varying amounts of additional training.⁸ Although, no effort is made to quantify these costs,

⁶ The *Regulatory Flexibility Act* (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has significant impact on a substantial number of small entities. According to CMS, the great majority of hospitals and health care providers are small entities either because they are nonprofit or they meet the Small Business Administration definition of a small business (having revenue of less than \$7.0 million to \$34.5 million in any one year). However, CMS declined to undertake an RFA analysis on small businesses because it only considered the impact on MA organizations and Part D sponsors. These organizations generally are not considered small business entities. (See *75 Federal Register* 71254). Inexplicably, CMS did not consider the impact of this rule on any other health care providers including long-term care pharmacies and facilities.

⁷ *75 Federal Register* 71257

⁸ *75 Federal Register* 71259

CMS terms all of these costs “marginal” and projects that dispensing fees to pharmacies serving LTC facilities will be 50 percent to 100 percent higher for contract year 2012 than in previous contract years with increases in the lower end for the large majority of claims.⁹

In reality, however, pharmacy costs are likely to increase by at least 400 percent since a 7-day or less dispensing quadruples the number of dispensing events per month. Assuming that the costs of a dispensing event are fixed, even if pharmacies are successful in negotiating a 100 percent increase in dispensing fees, they will still only be paid for 50 percent of the dispensing events in a single month under the short-cycle rule. Short-cycle dispensing also requires new claims processing codes and reprogramming of systems. CMS has not factored in the time and personnel needed for additional claims processing and collecting and reporting proposed new data elements such as the dispensing methodology used for each dispensing technique.

CMS also has failed to identify costs associated with the requirement that Part D sponsors require that pharmacies take-back previously dispensed, unused medications, inventory these drugs and report back to the Part D Plans. Aside from the legal issues associated with the collection and disposal of unused medications (see below), this new requirement will shift some costs from facilities to pharmacies as facilities are currently responsible for disposal of unused medications. It is unclear, however, which entity - the pharmacy or the facility - will bear the costs of properly classifying drugs to ensure that controlled drugs and hazardous waste are not being transported in violation of local and federal laws. Further, since a pharmacy will be collecting unused medications from multiple sites, the volume of waste collected could reclassify them from a Small Waste Generator (SWG) to a Large Waste Generators (LWG) under the (*Resource Conservation and Recovery Act* (RCRA)). As a LWG, pharmacies would be subject to the full extent of RCRA-generated regulations, further driving up costs. Finally, since CMS is requiring that pharmacies count the drugs and report back to individual plans, pharmacies will need to look up every returned prescription to ensure that information is reported to the correct payor. This too will add to pharmacy costs. Consequently, pharmacies and facilities will both experience significant cost increases to implement this rule.

We presume that Part D Plans will use their considerable bargaining position to hold the line on dispensing fees when negotiating pharmacy network contracts and will try to keep dispensing fees in line with or lower than CMS’ projections. If this happens, we have identified two possible scenarios. First, pharmacies may seek to recoup costs by increasing facility fees for pharmaceutical services, including delivery of other costs. Second, if unable to be paid a fair dispensing fee or recoup costs from facilities, long term care pharmacies could simply reject Part D contracts or be forced to leave the market. We could see an erosion of LTC pharmacy networks. For example, if the LTC pharmacy market leaders reject unfavorable terms offered by plans serving the Low Income Subsidy (LIS) market, facility operators will need to engage individual pharmacies to serve the patients enrolled in those plans. As facility operators, we could find ourselves dealing with multiple pharmacies. This would greatly increase our costs and disrupt process workflows designed to minimize medication errors – in other words, chaos. We are also concerned that smaller, independent pharmacies could be forced to leave the market if dispensing fees are not adequate to cover their increased costs. Overall, 7-day or less dispensing could significantly disrupt the long term care pharmacy market, resulting in fewer long-term care pharmacies and decreased competition, leaving long term care patients without adequate access to Part D drugs.

⁹ 75 *Federal Register* 71257

We believe that the regulatory impact statement is flawed. In addition to the reasons cited above, CMS must postpone implementation of the rules for 7-day or less dispensing to conduct a proper analysis of the rule's true costs, as well as the economic impact on pharmacies and facilities. Further, since CMS cannot interfere in contract negotiations between plans and pharmacies, and long term care facilities are not parties to these contracts, AHCA members seek clarification regarding what costs, if any, can be passed on to the nursing facility. We also need assurances that the initial and ongoing implementation of this rule will not adversely affect nursing facility patients' access to Part D drugs by disrupting or diminishing long term care pharmacy networks. Specifically, we ask that during the contract approval process, CMS increase scrutiny of Part D sponsors' long term care pharmacy networks to ensure that Part D sponsors have in fact contracted with long term care pharmacies that meet CMS' performance and service criteria and that their networks are adequate to meet nursing facility patient needs.

Exclusions

In 42 C.F.R. § 423.154(b), CMS is proposing that the short-cycle rule apply initially to all brand name drugs except for drugs that are:

. . . difficult to dispense in supply increments of 7-day or less, such as drugs that must be dispensed in the original packaging including, but not limited to eye drops, nasal sprays, inhalational products, ear drops, reconstituted antibiotics and, in general, drugs with a parenteral route of administration, and topical preparations; or [d]rugs dispensed for acute illnesses including, but not limited to a 10- or 14-day course of antibiotics." In preamble language, CMS states that liquids would not be excluded because most "can be transferred to small amber prescription bottles or oral syringes to accommodate 7-day or less dispensing.

AHCA is concerned that the proposed regulatory language regarding excluded brand name drugs could be interpreted as giving individual plan sponsors discretion to decide what brand drugs will or will not be excluded. If CMS were to permit Part D Plans to make determinations about excluded drugs on a plan basis, there will be variations in how the same drugs are classified for patients within the same home. We are also concerned that there may be a need to update or modify the list of excluded drugs following implementation. Accordingly, we recommend that CMS promulgate a regulation that requires Part D plans to exclude drugs identified by CMS, in consultation with stakeholders, in guidance to be issued in advance of the rule's effective date. Such a list, unlike a regulation, could be updated as needed.

We further recommend that CMS include on such list at least the following drugs:

- eye and ear drops,
- nasal sprays,
- inhalation products and inhalers,
- insulin and diabetic supplies,
- all antibiotics,
- all controlled substances regardless of class,
- all liquids
- contraceptives,
- patches,
- limited distribution drugs,
- drugs packaged as kits,

- topical preparations,
- drugs with a parenteral route of administration,
- drugs (including solid dosage forms) where the manufacturer recommends keeping the medication in the original container,
- drugs dispensed for an acute illness as determined by the beneficiary's treating physician.
- injectables.
- limited distribution drugs.
- Boniva® monthly,
- Femring vaginal ring,
- Premphase®/Prempro®, and
- Steroid bursts (dispensed for limited period of time)
- Weekly meds like Vitamin D3 (mega dose) and Fosamax®
- Powdered meds like Miralax®

Regarding our recommendation with respect to controlled substances, it is important to consider that all controlled substances, regardless of class, are subject to additional security controls, including special handling at delivery, storage in double-locked storage compartments and count sheets that enable two licensed staff to inventory all controlled drugs at the end of each shift. We are also concerned that more frequent delivery of controlled drugs to our facilities in smaller quantities could increase the risk of diversion. We include all liquids, because repackaging of liquids into smaller amber prescription bottles or oral syringes adds costs, storage challenges and increases the risk of contamination. Also determining exact quantities of liquids to be dispensed is difficult, since the patients using this dosage form frequently have difficulty taking medications and frequently repeat dosing is necessary if medication is spilled or expectorated by the patient.

Transition Fills

In 42 C.F.R. §423.120 (b)(3)(iii)(B), CMS proposes to change the duration during which a Plan Sponsor must provide an enrollee with a temporary supply of a non-formulary drug from 93 days to 91 days when the 7-day or less supply provision applies. In addition for patients in long-term care facilities, CMS is proposing that written notice only be provided within 3 business days after *adjudication* of the first temporary fill. This would be the only written notice required during the entire 91- day transition period.

AHCA does not object to changing the duration of the transition period from 93 to 91 days to conform to the 7-day or less cycle fill requirement for brand drugs. However, we are concerned that the proposed notice provision for long term care patients is inadequate for several reasons. First, long term care patients' transition fill notices currently are sent only to the beneficiary or to the address currently on file with the Social Security Administration. Second, pharmacies currently are receiving incomplete reject codes or no reject codes at the time of a transition fill dispensing from Part D plans and are often unaware that a patient's prescription order has been approved only as a transition fill. As a result, the pharmacy, and therefore the facility, is often unaware that a patient's drug is not on formulary until the end of the transition period when it is too late to file an appeal.

An additional problem occurs when a pharmacy bills Part D plans retrospectively. Retrospective or post-consumption billing requires a pharmacist to submit a test claim at the time of dispensing to determine coverage, then reverse the claim and resubmit it for payment for the actual drugs consumed after 30 days. Pharmacists however often are not informed that the beneficiary has

received a transition fill until the transition period is exhausted and the medication is reordered by the facility, creating a crisis for the patient that the pharmacy and facility must resolve. Problems associated with retrospective billing and transition fills likely will increase with 7-day or less dispensing because it is anticipated that more pharmacies will be billing retrospectively once the rule goes into effect.

Accordingly, to ensure that long-term care facility patients receive timely notice of transitions fills and to ensure appropriate steps are being taken to either transition patients to formulary drugs or to file an appeal, ACHA recommends the following:

1. In addition to sending notice to the beneficiary, Part D Plans must be required to send a copy of the written transition fill notice to the patient's nursing facility.
2. The initial written transition fill notice needs to be sent within three days of the date of initial adjudication, whether for reimbursement or coverage validation in the case of retrospective billing.
3. Given the length of the transition period, written transition fill notices should be sent to the patient and the nursing facility at least every 28-30 days during the transition period after the initial notice is sent.
4. CMS must require Part D Plans to provide accurate codes to the pharmacy so that pharmacies also will know that a patient has received a transition fill of a non-formulary drug.

Disposition of Unused Drugs

In 42 C.F.R. §423.154(f), CMS proposes to require that Part D sponsors' contracts with long term care pharmacies include terms that require any unused drugs originally dispensed to the Part D sponsor's enrollees to be returned to the pharmacy (not necessarily for reuse) and reported to the sponsor. The contracts must also address contractual obligations for disposal in accordance with Federal and State regulations. CMS has asked for comments on any federal or state regulatory barriers.

Currently, nursing homes already are required by federal regulation to have policies and procedures in place for disposal of medications.¹⁰ Our member facilities work with pharmacists or pharmacy provider to remove outdated and unused medications, account for medications awaiting final disposition and document the actual disposition of medications.

In addition to CMS requirements, as health care facilities, facilities are subject to rules governing the collection, handling and disposition of hazardous waste under Resource Conservation and Recovery Act (RCRA). Depending on the amount of waste generated, a facility will be classified as a conditionally-exempt small quantity generator (CSESQG) or a small quantity generator (SGQ). While CSESQGs have the least stringent requirements, a CSESQG still can only send hazardous waste to approved facilities. If a facility qualifies as an SGQ, more restrictions apply. For example, hazardous waste can only be transported in approved containers by an authorized hazardous waste transporter and transported to permitted hazardous waste treatment, storage, and disposal facilities. Hazardous waste must be segregated from non-hazardous waste and cannot be collected with biohazardous waste (red bag) for sterilization. In addition, we must comply with

¹⁰ Centers for Medicare & Medicaid Services *State Operations Manual*, Appendix PP, (hereinafter "*State Operations Manual*"), FTAG 425, 42 C.F.R. §483.60, Pharmacy Services, available at http://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf

local rules regarding the handling and disposition of hazardous waste. Accordingly, we are concerned that CMS' proposed rule requiring that all unused drugs be returned to the pharmacy conflicts with our obligations under RCRA and could place both facilities and pharmacies at risk of incurring fines and penalties for violations.

A further concern is the treatment of controlled substances. Here again, nursing facilities and pharmacies must comply with the *Controlled Substances Act* (CSA). Under the CSA, nursing facilities are strictly prohibited from returning controlled drugs to the pharmacy because nursing facilities are not DEA registrants. While Congress recently enacted the *Secure and Responsible Drug Disposal Act of 2010* (Pub. L. 111-273) to address this issue, until DEA issues regulations, nursing facilities cannot return controlled drugs to the pharmacy for disposal. Finally, we are concerned that sending drugs back to the pharmacy for disposal could increase the potential for fraud by adding one more change of custody prior to actual destruction of discontinued medications.

Overall, the biggest impediments to effective and safe pharmaceutical waste management practices in long-term care are (1) the lack of clear, uniform standards due to the multiplicity of competing authorities, e.g., (EPA, DEA, FDA, State Environmental Agencies, etc) that enforce laws and regulations which often conflict with each other and (2) the lack of reimbursement for providers who handle drug disposition. We believe that CMS' new proposal only adds to the confusion without solving either problem. We also believe that due to the need to sort and handle drugs differently, our costs could actually increase. Rather than impose a new and potentially conflicting requirement, we urge CMS to consult with DEA, EPA, FDA, ODCDCP and other federal and state authorities, including those that pay for large quantities of prescriptions drugs such as CMS, the Veterans Administration (VA), the Department of Defense (DOD) and State Medicaid Agencies, to develop a single, clear, consistent, cost effective standard for disposal of all dispensed, unused drugs regardless of payor source.

Definition of Dispensing

In 42 C.F.R. § 423.100, CMS is proposing a new definition of "dispensing fee." The new definition includes any reasonable costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee including, but not limited to "special packaging, salaries of pharmacists and other pharmacy workers, as well as the costs associated with maintaining the pharmacy facility and acquiring and maintaining technology and equipment necessary to operate the pharmacy."¹¹ The new definition further states that dispensing fees should take into consideration the number of dispensing events in a billing cycle, the incremental costs associated with the type of dispensing methodology, and "with respect to Part D drugs dispensed in LTC facilities, the techniques to minimize dispensing of unused drugs." Dispensing fees may also take into account restocking fees associated with return for credit and reuse when it is allowed by state law and by the contract between the Part D sponsor and the pharmacy.

While AHCA supports CMS' new definition of dispensing fees, we note that the actual dispensing fee paid to a pharmacy is the result of negotiations between the pharmacy (or the pharmacy's agent) and the plan. As discussed, AHCA is concerned that dispensing fees will not be adequate to cover the increased pharmacy costs attributable to new dispensing technologies and that some of these costs could be passed on to nursing facilities. We are also concerned that inadequate dispensing fees could lead to adoption of dispensing techniques with the lowest acquisition costs such as 7-day punch cards. We recommend that CMS amend slightly the

¹¹ 42 C.F.R. §423.100 *Dispensing fees* (2) (proposed), 75 *Federal Register* 71286.

definition of dispensing fees in 42 C.F.R. §423.100 so that it is clear that dispensing fees for drugs dispensed in LTC facilities include the costs associated with “the techniques, *as chosen by each nursing facility*, to minimize the dispensing of unused drugs.”

In addition, we urge CMS to clarify in the preamble to the final rule that if a facility chooses more sophisticated dispensing technology, then Part D Plans are expected to increase dispensing fees to reflect the additional costs associated with that technology. CMS must also clarify that if a nursing facility voluntarily chooses to convert all drugs to 7-day or less dispensing during any transition period, Part D Plans are expected to reimburse pharmacies for all dispensing events associated with 7-day or less dispensing for both brand and generic products.

We also note that the definition of dispensing makes no mention of the costs associated with the new, proposed requirement that all unused drugs be returned to the pharmacy to be counted and reported to the Part D Plan and that contracts address proper disposal of the medications. If these costs are not part of the dispensing fee, does CMS anticipate that Part D Plans will pay pharmacies a separate fee for these new responsibilities? We ask CMS to clarify who is responsible for paying these costs.

Refill Too Soon

Today, to minimize excessive use, waste and stock-piling of medications, Part D Plans routinely use “refill too soon” policies to reject claims if an attempt is made to refill the prescription before a certain percent of the day supply of the previous fill has been used. All Part D Plans have their own policies, but typically refills will not be allowed before 80 percent of the drug has been used. In an environment where drugs are being dispensed on 30-day cycle fills, “refill too soon” policies generally still allow sufficient time for pharmacies and nursing staff to order, fill, deliver and restock medications before a patient runs out. In a 7-day dispensing cycle environment, however, a “refill too soon” policy that generates a reject code when 80 percent or less of the drug has been used, leaves at maximum, only 72 hours to resolve the reject code and then prepare, dispense, deliver, receive and restock the medication for the patient’s use. We believe that the continued use of “refill too soon” codes for Part D drugs dispensed in 7-day or less increments for long term care facility patients could result in an increase in missed doses due to medication unavailability. We urge CMS to issue guidance to Part D Plans requiring them to turn off this Drug Utilization Review (DUR) edit for drugs dispensed to nursing facility patients upon the effective date of this rule.

2. Improvements to Medication Therapy Management Programs

In 42 CFR § 423.153, CMS is proposing to require Part D sponsors to contract with all long term care facilities in which their Part D enrollees reside to provide appropriate Medication Therapy Management (MTM) services in coordination with consultant pharmacist evaluation and monitoring. CMS estimates that the first year costs associated with this requirement will be \$96,709, 680 for Part D sponsors; annual costs thereafter will be \$32,236,560. All of these costs are attributable to contracting, not to service provision. Notably, CMS has not estimated costs to nursing facilities either for contracting or for services. However, should this proposed rule be implemented, nursing facilities would also have costs associated with contracting and with the on-going management and execution of contracts with multiple Part D sponsors. Given the turnover among Part D Plans serving dual eligibles and the annual process for auto-assigning beneficiaries to LIS plans, the on-going administrative burden and costs to facilities could be considerable.

While AHCA appreciates CMS' interest in improving coordination between Part D Plan MTM services and the monthly drug regimen reviews conducted by consultant pharmacists, AHCA strongly opposes this proposal.

- First, we are unclear what CMS expects nursing facilities to do under these new contracts or what nursing facilities can expect from Part D Plans, especially since the only costs associated with these contracts are the costs associated with contracting and not service provision.
- Second, we are skeptical that merely mandating that Part D Plans contract with nursing facilities will contribute to improved patient outcomes. Currently, as mandated by CMS regulations and survey guidelines, consultant pharmacist monthly Drug Regimen Reviews (DRR) are more comprehensive and more clinically focused than Part D medication therapy management services. Consultant pharmacists have expertise in geriatric pharmacotherapy and when conducting reviews, have access to the patient's entire medical chart, including the patient's medical history and lab reports. Unlike the Part D MTM assessments, which are only communicated to the patient, consultant pharmacists' recommendations are made to the patient's treating physician and per regulation, must be responded to by the attending physician. Our experience with Part D MTM to date is that Part D assessments are more focused on reducing drugs costs and improving formulary compliance and less on assessing the total clinical picture of the patient.
- Third, Medicare and Medicaid are already providing reimbursement for consultant pharmacist reviews through payments to the nursing facility or to the pharmacy. We believe that paying Part D sponsors to undertake a more limited assessment is duplicative and could create opportunities for fraud.

In sum, AHCA does not support requiring that Part D sponsors contract with all nursing facilities in which their enrollees reside to coordinate Medication Therapy Management services with the monthly Drug Regimen Reviews. We believe it is duplicative and unnecessary. Indeed, we urge CMS to give serious consideration to exempting Part D enrollees from Part D MTM while they are residing in a nursing facility.

3. Dissemination of Part D Plan Information

In §423.128, CMS is proposing that Part D plans provide a "system that transmits codes to network pharmacies so that the network pharmacy is notified to populate and/or provide a printed notice at the point-of-sale to an enrollee explaining how the enrollee can request a coverage determination by contacting the plan sponsor's toll-free customer service line or by accessing the plan sponsor's website."

We support the electronic transmission codes at the point of sale to enable pharmacies to provide coverage determinations to enrollees. For nursing facilities, we urge CMS to require that a copy of the notice be sent directly to the patient with a copy to the nursing facility. We also urge CMS to ensure the accuracy of information sent to pharmacies by Part D Plans regarding rejected claims and transition fills.

4. Grievance, Coverage Determinations & Appeals

CMS is proposing in 42 C.F.R. § 423.562 a number of provisions to improve and streamline the grievance, coverage determination and appeals process. AHCA supports these provisions. However, for Part D enrollees who are nursing facility patients, we urge CMS to require Part D plans to send copies of all notices to the patient's facility and to allow nursing facilities to make oral and written requests for exceptions, coverage determinations and appeals on behalf of their patients.

5. Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home- and Community-Based Services

To implement Section 3309 of the ACA, which eliminates co-payments for full benefit dual eligibles receiving home and community-based services under specified Medicaid waiver or state plan programs, CMS is proposing to: (1) amend 42 C.F.R. §423.772 to establish the definition of "individual receiving home and community-based services," and (2) amend 42 C.F.R. § 423.782(a)(2)(ii) to reflect that these individuals will have no cost-sharing. CMS is also proposing to make these amendments effective on January 1, 2012. AHCA supports these proposed amendments.

6. Co-Payments

Moving from 30-day to 7-day dispensing will lead to changes in copayment methodology. CMS anticipates that copayment methodologies are likely to vary within plans depending on the billing and dispensing methodologies. Although the number of patients in long term care who are responsible for co-payments is relatively small, we are concerned that the failure to specify a single methodology or to include safeguards for beneficiaries could lead to confusion and abuse. For example, beneficiaries could be charged a co-pay for each dispensing event within a single month. Accordingly, we recommend that at minimum, CMS specify that enrollees residing in a long term care facility cannot be charged more than one-copayment per prescription regardless of how many dispensing events occur in one month.

7. Impact on Low-Income Subsidy Plan Availability and LTC Pharmacy Network Adequacy

In 2011, there will only be 332 plans serving Low-Income Subsidy (LIS) eligible beneficiaries. This represents a 48 percent reduction since 2007.¹² We are concerned that given the additional costs to the Part D sponsor of having to staff up, retool, reprogram and quadruple the number of claims transactions for enrollees in long term care, and given that long term care patients are a very small segment of their overall market, more Part D Sponsors may choose not to serve dual eligibles. In other words, we believe there is risk that 7-day or less dispensing could drive even more LIS plan sponsors out of the LIS market.

8. Enforcement

The proposed rule is silent regarding enforcement or penalties for failure to comply with the rule. If an LTC network pharmacy is unable to comply by the effective date or violates the 7-day or

¹² *Medicare Part D Spotlight, Part D Plan Availability in 2011 and Key Changes Since 2006*, Kaiser Family Foundation, October 2010, available at <http://www.kff.org/medicare/8107.cfm>.

less dispensing rule by dispensing non-excluded drugs in 30-day supplies, we assume that Part D Plans could disallow the claims or perhaps even terminate its contract with the pharmacy. If this should happen, nursing facilities could find that their contracted pharmacy is no longer able to serve those who were members of that plan. While these contingencies may be unlikely, there has been virtually no discussion of how the 7-day or less dispensing rule will be monitored or enforced and no discussion of how to minimize adverse impacts on nursing facilities. We are very concerned about potential disruption of pharmacy services to our patients. We urge CMS to convene stakeholders to identify safeguards needed to minimize potential unintended but adverse impacts on our facilities and our patients.

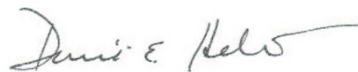
III. Conclusion

AHCA urges CMS to adopt these recommendations. In particular, CMS must conduct a more thorough analysis of the impact of the proposed rules for 7-day or less dispensing on pharmacies and facilities. Adequate analysis and recognition of costs is critical to ensuring that 7-day or less dispensing is not implemented in a way that creates an unfunded mandate and adoption of less-than-optimal dispensing technologies that increase cost and diminish our ability to provide quality care.

We believe that it is in the best interests of all parties involved to postpone implementation of 7-day or less dispensing in long-term care facilities to at least January 1, 2013. Postponement is needed not only to give CMS more time to conduct its analysis of costs, but to give the industry sufficient time to evaluate options, secure capital and create the infrastructure to support full implementation of short-cycle dispensing for both brand and generic drugs. Additional time also is needed to ensure that Part D Plans are able to incorporate the real costs of 7-day or less dispensing technologies into their bids. Without a delay and without adequate compensation to pharmacies, the reality is that implementation of this rule will quickly overburden our facilities, increase our operating costs and place our patients at risk.

Thank you again for the opportunity to provide comments on this important rule.

Sincerely,



David E. Hebert
Senior Vice President, Policy and Government Affairs

cc: Dr. Jeffrey A. Kelman
Tracy McCutcheon