January 11, 2011

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4144-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

[Submitted online at: www.regulations.gov]


Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule on program changes to the Medicare Advantage (MA) plan (Part C) and the Medicare Prescription Drug Benefit program (Part D) for contract year 2012 and other proposed changes, published November 22, 2010 (75 FR 71190). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA supports CMS’ effort to revise the Medicare Part D program based on lessons learned from the years of implementing the program and to implement provisions enacted through the Affordable Care Act (ACA, P.L. 111-148). APhA appreciates that CMS continually aims to improve the Medicare Part D program and build on feedback often received from stakeholders, including pharmacists, physicians, other health care providers, beneficiaries, and advocacy organizations and their members. APhA’s comments on the proposed rule will following provisions: enrollment election period, quality of plans, appropriate dispensing in long-term care facilities (LTCFs) (short-cycle dispensing), uniform exceptions and appeals forms and claims messaging/printing, preventive services, improvements to medication therapy management (MTM) programs, revisions to MTM in LTCFs, coverage gap information, definition of pharmacist, and electronic transactions for compounded prescription orders.
II. Provisions of Proposed Regulations

B. Changes to Implementing the Provisions of the Affordable Care Act

*Simplification of Beneficiary Election Periods* (p. 71198)
APhA supports simplifying the Medicare Part D beneficiary annual open enrollment election period and the revised dates of October 15 – December 7 starting in 2012. APhA has advocated for an earlier closing date to better ensure that correct beneficiary enrollment information is available at the pharmacy beginning January 1 of a plan year. We encourage CMS to provide continued beneficiary education and outreach about the revised enrollment dates.

*Authority to Deny Bids* (p. 71200)
APhA supports CMS’ efforts to streamline plan bid submissions to have a high quality, meaningful difference between plans. Such changes should reduce confusion and help beneficiaries select the most appropriate plan for their prescription drug coverage needs. If there are challenges with specific plans during a plan year, APhA is willing to continue to work with CMS to provide appropriate information to pharmacists.

*Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities under PDPs and MA-PD Plans* (p. 71205)
APhA supports CMS’ efforts to reduce medication waste in any setting. As outlined in the proposal, we appreciate CMS’ intent to implement the ACA provision to reduce financial and physical medication waste by reducing 30-day dispensing fills to 7-day or less dispensing fills (or short-cycle dispensing) in long-term care facilities (LTCFs) for beneficiaries with Part D or MA plans. However, we are concerned that implementing the 7-day or less dispensing method for Medicare Part D branded medications could create significant changes in LTCFs, institutional facilities, and pharmacy workflow that could create increased and undue administrative or financial burdens on pharmacists and pharmacies if not implemented correctly. Specifically, we are concerned with the increased staffing needs, workload and logistics to input, process, fill/package, and dispense an increased number of prescription orders, resulting in an increased number of prescription orders delivered and managed at a LTCF. APhA is interested in meeting with CMS to further discuss our concerns to better ensure a successful implementation of this ACA provision.

To address the various provisions in the proposal, APhA encourages CMS to consider the following issues:

*Implementation Deadline*

- Similar to other stakeholders, **APhA recommends delaying the implementation of the proposal from January 1, 2012 to January 1, 2013**. Such a delay would allow LTCFs more time to:
  - Make the necessary staffing and workflow adjustments/training to implement the provision to ensure patient safety is not compromised when changing from the current system;
  - Navigate necessary capital investment and funding options to transition the LTCFs dispensing model to include a 7-day or less dispensing method, such as automated dispensing systems, packaging equipment, and computer software changes;
• Determine the business feasibility of implementing the provision for brand-only Medicare Part D covered drugs (as discussed in the proposal and estimated to be 20% of LTCFs dispensed medications) versus utilizing capital investment to make a full transition of 7-day dispensing for all Medicare Part D covered medications; and
• Ensure time for business negotiations to include estimated additional costs in dispensing fee negotiations between LTCFs and Medicare Part D plan sponsors.

Dispensing Fee

• APhA supports revising the dispensing fee definition (as discussed on page 71244) to allow for adjustments that include “acquisition, maintenance, and technology costs” accrued by the pharmacy to implement this provision. However, we are concerned that the definition change may not go far enough to ensure that LTCFs have the opportunity to negotiate adequate dispensing fees in their contracts with Medicare Part D plans in order to fully cover additional labor and delivery costs associated with 7-day or less fills.
• APhA maintains that a full dispensing fee must be paid for each prescription dispensed, regardless of the number of dosage units dispensed, as the process and costs for dispensing each prescription remains the same. Therefore, **APhA recommends that CMS clearly state that a full dispensing fee must be paid with every prescription dispensed, including dispensing of 7-day or less fills.**
• We are aware that the long-term care industry is currently collecting data to determine costs associated with 7-day or less dispensing. However, we are concerned that adequate, current data regarding actual dispensing costs associated with 7-day or less dispensing may not be fully collected, analyzed or available to Medicare Part D plans, CMS or the LTC industry to accurately predict costs for the upcoming 2012 plan year. Such concerns further support the need to delay implementation for until 2013.

Pharmacy Dispensing Transactions

• APhA is concerned with CMS’ proposal for plans to capture one prescription drug event (PDE) per month to be reported to CMS. PDEs reports must account for each pharmacy dispensing transaction, regardless of the number of doses dispenses per fill. Otherwise, the number of prescriptions (and thus correlating workload and correlating costs) associated with dispensing 7-day or less fills could be significantly underreported. This reporting schedule also complicates transactions that have been changed and must be re-billed. For these reasons, **APhA recommends that CMS require plans to report a PDE for each fill per month, including any 7-day or less fill.**
• Furthermore, we are concerned with CMS’ statement that existing National Council for Prescription Drug Programs (NCPDP) electronic transaction standards can accommodate all aspects of the proposed new requirements. It is our understanding that NCPDP needs additional time to ensure that the functionality of the proposal can be fully implemented.

Excluded Medications

• APhA appreciates that CMS is proposing to exclude certain medications from the 7-day or less fills (as discussed on page 71205) due to dispensing difficulties, routes of administration, safety and efficacy concerns, and acute illness. As discussed in the proposal, we support excluding eye drops, ear drops, inhalers and inhalation drugs, nasal sprays, reconstituted antibiotics and other drugs with parenteral routes of administration, drugs that must remain in their original container, and topical medications. In addition, **APhA recommends that CMS consider adding compounded drugs to the excluded**
list and that CMS consider how to incorporate clinical appropriateness when determining if a Medicare Part D covered medication is appropriate for 7-day or less dispensing.

Return and Reuse of Medications

- **APhA recommends that CMS consider the impact of Drug Enforcement Administration (DEA) regulations that prevent the return/reuse of controlled substances from a LTCF to a pharmacy. APhA also recommends that CMS recognize revised DEA regulations related to disposals of controlled substances if available upon the implementation of the short-cycle provision** (DEA meeting notice: *Procedures for the Surrender of Unwanted Controlled Substances by Ultimate Users*; published December 22, 2010; 75 FR 80536). DEA’s future regulations could provide additional options for LTCFs and institutional pharmacies to properly dispose of unused controlled substances and reduce waste outside of short-cycle dispensing.
- **Based on information from NCPDP, APhA also recommends that CMS consider delaying implementation of return/reuse and restocking requirements until such standards are finalized by NCPDP and functionality is adopted by pharmacy.**

Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans (p. 71210)
APhA supports CMS’ efforts to require a streamlined and uniform exceptions and appeals process for plans. Such changes should reduce confusion and better facilitate a beneficiary’s ability to begin an exceptions or appeals process to address plan formulary issues. We also support efforts to work with the pharmacy industry, specifically NCPDP, on standards to facilitate the on-demand printing of electronic claims denial messaging that specifically includes general plan information for beneficiaries to start an exceptions and/or appeals process for requesting drug coverage. Such information will be helpful for beneficiaries and will supplement the information that pharmacies are required to post regarding beneficiary rights to exceptions and appeals. We encourage CMS to work with pharmacy, including APhA and other pharmacy organizations, to develop and provide educational information to pharmacists on the requirement of the provision and the logistics for printing such messages for beneficiaries.

Cost Sharing of Medicare-Covered Preventive Services (p. 71212)
APhA supports efforts to extend the elimination of beneficiary cost-sharing for preventive services within Original Medicare to the MA programs and the implementation of an annual wellness visit for beneficiaries. **We recommend that CMS ensure that beneficiaries continue to have access to covered preventive services, such as immunizations, provided by pharmacists. We further recommend that in the future CMS consider adding a “Welcome to Medicare, Medication Check-Up” as a covered preventive service for all beneficiaries.**

Improving the Medication Therapy Management (MTM) Programs (p. 71213)
APhA greatly appreciates CMS’ continued efforts to make significant improvements to the Medicare Part D MTM program requirements through the previous 2010 Final Call Letter and in the final regulations effective for plan year 2011 (published April 15, 2010; 75 FR 19678). We agree with CMS that these changes to MTM programs will improve and help maximize beneficiary access to such services. As outlined in the proposed rule, we agree that many of the improvements to MTM program provisions enacted under ACA already exist in regulation. In addition, we agree with CMS that some revisions are needed to the existing regulations to ensure
consistency with several of the ACA provisions. Specifically, we support revising the existing regulations to address:

- Clarifying that plans perform quarterly assessments of all “at risk” individuals not already enrolled in an MTM program;
- Defining telehealth technologies as used in the provision that MTM services offered to targeted beneficiaries that include, at a minimum, an annual comprehensive medication review (CMR), may be furnished person-to-person or via telehealth technologies. Furthermore, we recommend that CMS track the types of telehealth technologies being utilized by plans to ensure that telehealth is not limited to telephonic interventions; and
- Clarifying that Medicare Part D MTM programs are required to use a standardized format for a written summary and action plan that may result from a comprehensive medication review provided as part of the required MTM benefit for targeted beneficiaries. APhA is interested in working with CMS on the development and/or testing of a standardized format that will work with a variety of pharmacy operating and MTM documentation systems.

**MTM Requirements in LTCFs**
Specific to CMS’ proposed revisions to MTM services furnished in LTCFs (p. 71214), APhA appreciates that CMS is concerned that Medicare Part D MTM service requirements may not be made available to all targeted beneficiaries living in LTC facilities. We agree that if MTM is provided, it may not be coordinated with the monthly medication regimen review (MRR) required to be conducted by the LTCFs consultant pharmacist according to federal conditions of participation for Medicare and Medicaid certified facilities. We agree with CMS’ statement in the proposal that the lack of coordination between series may lead to conflicting recommendations related to medication management. In addition, it is our position that Medicare Part D MTM programs/services are distinctly different from those of a facility-required MRR. Therefore, **APhA recommends that CMS ensure that systems are in place to comply with required and separate documentation of the distinct MTM and MRR services.** Whether Medicare Part D MTM services are provided by the same consultant pharmacist who performs a beneficiary’s MRR or provided by a different pharmacist, such services and assessment should be coordinated.

Furthermore, while we support CMS’ intent to require plans to coordinate their MTM program with the MRR performed by the LTCFs consultant pharmacist, we are concerned that the proposal suggests that the contract be between the LTC facility and the Medicare Part D plan rather than the plan and the consultant pharmacist or affiliated pharmacy. Therefore, **APhA recommends CMS revise the proposal to indicate that a contractual relationship should be between the Medicare Part D plan and the LTCFs consultant pharmacist, the affiliated pharmacy, or independent pharmacist practitioner providing the facility with Medicare Part D MTM services.** Pharmacists and pharmacies rather than individual facilities are better equipped to engage directly with plans to perform MTM and contract for these services.

**Changes to Close the Medicare Part D Coverage Gap** (p. 71214)
APhA appreciates the Agency’s efforts to provide coverage gap program implementation tip sheets and resources for pharmacist and beneficiaries. Such information has been very helpful for implementing the program in plan year 2011 and helped clarify that discount information would be available through a beneficiary’s monthly explanation of benefits, not through the pharmacy prescription claim message. We will continue to provide feedback to CMS from our
members on the implementation of this program. APhA also encourages the Agency to continue to provide information to stakeholders through program implementation.

**C. Clarification of Various Program Participation Requirements**

**Definition of pharmacist** (p. 71224)
APhA supports amending the definition of “pharmacist” to reflect pharmacists needing to have a valid license to practice pharmacy issued by the appropriate regulatory authority of any of the states or territories of the United States or District of Columbia. We appreciate CMS addressing this issue based on your findings from a recent sponsor audit that found non-US licensed pharmacists were being utilized to make clinical judgments associated with the administration of the Medicare Part D benefit.

**E. Strengthening Our Ability to Distinguish for Approval Stronger Applicants for Part C and Part D Program Participation and to Remove Consistently Poor Performers**

**Requiring Use of Electronic Transaction Standards for Multiple-Ingredient Drug Compounds; Payment for Multi-Ingredient Drug Compounds** (p. 71239)
APhA supports the utilization of the HIPAA compliant NCPDP Telecommunication Standard Version D.0 for the electronic transaction standards for multiple-ingredient drug compounds as it has functionality to support electronic claims submission for compounded drugs. We support CMS’ ongoing work with NCPDP to ensure implementation of this provision and appropriate revisions to the proposal as needed.

**Conclusion**
Finally, APhA would like to reiterate our support for CMS’ efforts to implement ACA provisions and improve the Medicare Part D program. We encourage CMS to delay the implementation of 7-day or less dispensing on LTCFs until 2012, work with the pharmacy profession on creating a standard template for MTM action plans, and revise proposed changes to MTM programs in LTCFs. Specific to 7-day or less dispensing, APhA supports CMS’ intent to reduce medication waste in LTCFs but we must work together with other stakeholders to ensure that waste reduction initiatives are neither administratively nor financially burdensome to pharmacists and pharmacies.

Thank you again for the opportunity to provide comments on these important issues. Again, we welcome the opportunity to further discuss our concerns and recommendations with CMS. If you have any questions or require additional information, please contact Marcie Bough, PharmD, Director of Federal Regulatory Affairs, at (202) 429-7538, or at mbough@aphanet.org.

Sincerely,

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Executive Vice President and CEO

TM/mb

cc: Brian Gallagher, BSPharm, JD, Senior Vice President, Government Affairs
    Marcie A. Bough, PharmD, Director, Federal Regulatory Affairs