March 1, 2013

Jonathan Blum
Center for Medicare
Center for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, MS:314G
Washington, DC 20201

[Submitted electronically to: AdvanceNotice2014@cms.hhs.gov]

RE: Draft 2014 CMS Advanced Notice and Call Letter to Medicare Advantage and
Part D Prescription Drug Plans

Dear Mr. Blum:

The American Pharmacists Association (APhA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Draft 2014 Advanced Notice and Call Letter to Medicare Advantage (MA) and Part D Prescription Drug Plans (PDPs), released February 15, 2012. 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 offers feedback on the following provisions in Attachment VI: Call Letter 2014.

Star Ratings Changes (Pages 89-101)
APhA supports CMS’ continued utilization of PQA measures as part of the Star Ratings system and clarification/updates/changes to the methodology of current measures, as described for: PQA-endorsed Use of High-Risk Medications in the Elderly measures (HRM), and Medication Adherence for Diabetes Medications (Part D). APhA also supports the proposed new 4-star threshold measures for Part C and D measures as listed in Table 1 related to all-cause readmissions and medication adherence for diabetes, hypertension and cholesterol medications. These measures are important factors in plan ratings because of their impact on beneficiaries’ health outcomes.

We appreciate that CMS specifically references and encourages support for the Million Hearts™ initiative. Both APhA and the APhA Foundation are partners in the initiative and have been
actively engaged in encouraging involvement of pharmacists and student pharmacists from across the country. As CMS outlines, a number of the Start Ratings measures are consistent with the initiatives focus on cardiovascular health and we support CMS’ proposal to encourage plans to engage in the initiative.

APhA recommends that CMS encourage plans to utilize pharmacists in providing medication therapy management (MTM) service and other patient health and wellness services as part of plans’ efforts to meet/improve quality measures and Star Ratings and, as CMS discusses, utilize MTM services to engage in the Million Hearts™ initiative. We are encouraged by CMS’ efforts to further highlight the values of MTM services.

Medication Therapy Management Program Completion Rate for Comprehensive Medication Reviews (Part D) (Page 101)

APhA is very pleased that CMS includes considerable discussion about MTM services in the draft call letter. We support ongoing efforts to improve the program and to expand the number of patients utilizing MTM services. We support continued display of Star Ratings measures specific to Medication Therapy Management Program Completion Rate for Comprehensive Medication Reviews (Part D). We appreciate that the measure is based on the PQA-endorsed measure, *Completion Rate for Comprehensive Medication Review (CMR)*, which, as outlined by CMS, measures the percentage of beneficiaries who met eligibility criteria for the MTM program and who received a CMR.

We also support CMS outlining plans to improve reporting methodologies related to long-term care (LTC) status and MTM program enrollment, aims to integrate LTC reporting into CMR in the future, and plans to further refine the CMR measure calculations. We will continue to support CMS’ efforts to improve the MTM program and ensure that beneficiaries have access to MTM programs covered within the Part D benefit.

Inappropriate shifting of drug coverage from Medicare Part B to Part D (Page 113)

APhA appreciates CMS clarifying Medicare Part B versus Medicare Part D drug coverage payment issues regarding Medicare Advantage (MA) organization activities. We agree with CMS’ statement that a plan cannot require a drug to be covered by Part D and dispensed at a pharmacy and then taken back to a MA provider’s office for administration for a drug that would otherwise be available through Part B at the provider’s office as such an action is the choice of the beneficiary, not the plan. We encourage CMS to discuss this issue in the 2014 Medicare and You Handbook and online information, and in reference materials for health care providers and practice locations discussing Part B versus Part D coverage policy.

Payment for Hospice and ESRD Beneficiaries under Part D (Pages 126-127)

APhA appreciates CMS discussing drug payment issues under Part D for hospice and end stage renal disease (ESRD) beneficiaries. We are aware that some pharmacies, as described by CMS, have had challenges reconciling payment adjudication when hospice and ESRD status and payment requirement is determined after the claim has already been adjudicated/paid by Part D. We agree with CMS on the need to address and resolve payment issues prior to pharmacy claim adjudication when possible. Prior authorization requirements on identified categories of drugs for hospice and ESRD patients may be a potential solution given the challenges to resolve payment
issues. However, we do have concerns that prior authorization requirements may delay patient access to necessary medications. If such a policy is implemented, we recommend CMS ensure that billing transaction reject messages clearly state the claim denial and prior authorization requirement is due to the hospice or ESRD status of the beneficiary.

**Hospital Outpatient Drug Supplies During Observation Services** (Page 129)
We agree with CMS’ efforts to ensure that plans and their customer service representatives are aware that patients have access to their own medications, such as maintenance medications, brought into the hospital per hospital’s policies and procedures.

**Inappropriate Use of Prior Authorization (PA) Forms** (Page 132)
APhA support CMS clarifying the intent and appropriate use of prior authorization forms and that CMS clearly indicates and lists what practices are not permitted and violate Part D regulations. We support efforts to ensure that beneficiaries continue to have access to the pharmacy of their choice.

**Auto-Ship Refill Programs in Part D** (Page 133)
APhA appreciates CMS’ discussion on challenges that some beneficiaries have had related to automatic refill and shipment policies for their Part D drugs. We recognize that improvements can be made in how such programs are managed to limit burden or confusion for the beneficiary and to decrease unintended waste/cost generated from unnecessary refills. However, we do have concerns with the proposal to consider having a beneficiary contacted each time a refill is to be processed. Such a process could generate a significant number of phone calls to a beneficiary if the calls are not coordinated and if refill dates are not coordinated to the extent possible. We recommend CMS consider additional steps in which a beneficiary or their caregiver could select their own preferences for use of an auto-refill/ship program.

**Incremental Fills of Schedule II Controlled Substances Prescriptions** (Page 134)
APhA appreciates CMS explaining challenges with prescription orders for Schedule II controlled substances that appear to be processed as illegal refills for Schedule IIs rather than as permitted partial fills. We support efforts by CMS and appropriate stakeholders to address this issue in billing standards and in plan transaction edits.

**Payment of Extemporaneous Compounds from Pharmacies** (Page 136)
We appreciate CMS clarifying coverage issues for compounded products covered under Part D as those that contain at least one ingredient that independently meets the definition of a Part D drug (with accompanying determination of formulary status and/or if the product is subject to prior authorization requirements) and that only the covered drug ingredient is covered by Part D. We also support efforts to make plans aware that coverage of compounded products should be based on the medical need of the patient and pursuant to a triad relationship between the patient, prescriber, and pharmacist/pharmacy for a product that is generally not commercially available. In addition, we appreciate CMS’ efforts to gather information from stakeholders on pharmacy compounding as CMS looks to ensure safety and quality standards of sterile compounds covered under Part D. As work continues with Congress, the Food and Drug Administration, and states to better define compounding versus manufacturing and to determine appropriate regulatory oversight, adoption of exiting compounding standards across all states will be important and
could be a focus area for CMS. With regards to CMS considering the feasibility of prior authorization for compounded products, we would be interested in having further dialogue with CMS and other pharmacy stakeholders to discuss intended outcomes, potential review criteria and guidance that would be in place for the plans to limit potential impacts on patient access to medically necessary compounded products.

**Million Hearts™ Initiatives (Page 136-7)**
APhA supports CMS efforts to make plans more aware of the Million Hearts™ initiative. As mentioned earlier, APhA and the APhA Foundation are partners in the initiative and have helped to engage pharmacists and student pharmacists to work with patients to improve cardiovascular health, improve adherence, perform screenings, refer patients to medical staff, and other patient care services. We support CMS highlighting utilization of MTM services and targeting beneficiaries who fill one or more prescriptions for antihypertensive medications. Again, we recommend CMS encourage plans to consider how to utilize pharmacists in services and activities as plans consider engagement in the initiative.

In addition, we support CMS encouraging plans to offer MTM services to an expanded population of beneficiaries who may not meet the targeted enrollment criteria but may benefit from the service. Furthermore, APhA supports efforts to expand beneficiary access to MTM services and agrees with CMS’ statement that providing MTM, including a comprehensive medication review, to patients targeted in the initiative could help improve blood pressure control, increase adherence, and empower these beneficiaries to self-manage their medications and their health condition.

**Medication Therapy Management (Page 148 – 154)**
APhA is very supportive of the dialogue CMS included in the draft regarding MTM services and ongoing efforts to improve and expand the Part D MTM program. We applaud CMS for referencing that growing evidence of the value of MTM services to improve beneficiaries’ therapeutic outcomes indicates that more beneficiaries may benefit from these services. We are pleased that CMS refers to the Million Hearts™ initiative section and again advocates for plans to utilize MTM services to engage in the initiative. We also support CMS encouraging plans to optimize their MTM programs to those who may benefit the most and stating that plans may also offer MTM services to an expanded population of beneficiaries who do not meet the eligibly criteria. In addition, APhA is pleased that CMS reports that it is aware of high performing plans using MTM services to improve their Part D Star Ratings which speaks to the values of MTM services.

In addition, it was helpful for CMS to provide background and summary results of their study looking at MTM services for congestive heart failure and COPD patients. We look forward to receiving the final report and potential identification of best practices that could result in more standardization of MTM service definitions and requirements in the future.

**Coordination of Care (Page 150)**
We are very encouraged by CMS’ referencing MTM as it promotes coordination of care. CMS discusses helpful information for eligible beneficiaries to complete their annual CMR and to use their standardized medication action plan and personal medication list as a tool to share with
other providers and in other care settings, including hospital admissions. We appreciate that CMS is planning to include such information and direction about the MTM program in messaging to beneficiaries via the 2014 Medicare & You Handbook and other communication vehicles. In addition, we support CMS outlining that communications from plans should also discuss how MTM services can be used to better coordinate care and how CMRs may be helpful after a transition in care or after a hospitalization.

Regarding transitions of care resources, APhA and the American Society of Health-System Pharmacists (ASHP) are working together on an initiative to improve transitions of care. We have released two resources that may be helpful to CMS as the agency considers additional steps to improve care transitions:

- March 2012: Improving Care Transitions: Optimizing Medication Reconciliation
  Available online at: http://www.pharmacist.com/improving-patient-care-through-better-medications-reconciliation-white-paper
- March 2013: ASHP-APhA Medication Management in Care Transitions Best Practices
  Available online at: www.pharmacist.com/medication-management-care-transitions-best-practices

APhA also supports CMS encouraging plans to adopt standardized health information technology (HIT) for documentation of MTM services. We have long advocated for improved standards and efficiencies in documenting Part D MTM services. We are encouraged that CMS is considering expanding the collection and analysis of data related to the impact of MTM services and concur that adoption coding systems standardization (such as SNOMED) and industry-supported templates would improve functionality of documentation and reporting systems and better align with electronic health record infrastructure. We encourage CMS to have work with the Pharmacy e-HIT Collaborative as they are leading efforts to integrate pharmacist-provided patient care services into the national HIT interoperable framework. Additional information about the Collaborative is available at: www.pharmacyhit.org.

**Optimizing the Delivery of MTM in LTC Settings (Page 151)**

As discussed in the Star Ratings section, we support CMS’ efforts to incorporate CMRs for LTC beneficiaries into plan requirements and into quality measures. We agree that this patient population should benefit from these valuable services. We appreciate the insight CMS offered on how Part D MTM could integrate with the required drug regimen review and approaches to address potential patient cognitive issues and caregiver engagement. However, we do still have concerns with how the services of a Part D MTM would be distinguished from the DRR and expectations of staff to ensure that appropriate separate services are provided and documented. We recommend CMS provide additional guidance on what policies and procedures need to address to ensure compliance with the different programs.

**Promoting Beneficiary Awareness (Page 153)**

APhA is very supportive of CMS’ plan to promote beneficiaries’ awareness of MTM services and enhance information included in the 2014 Medicare & You Handbook and on Medicare.gov. We are eager to see the new MTM tab on the plan finder that will include program eligibility information/requirements, links to MTM program pages for plans, and examples/information about the standardized CMR and personal medication list. Such information will be valuable for
beneficiaries to use as they consider plan options. We also support CMS requiring plans to have a dedicated “Medication Therapy Management Program” page linked from their Medicare drug plan Web site with specific information and descriptions about the MTM program. Again, such information will be helpful for beneficiaries as they consider plan options, become more familiar with the MTM program offerings, and will help increase patient awareness of how they would be contacted if eligible for the program. APhA offers to be a resource to CMS to provide further input as enhanced MTM online content and design is finalized.

**Preferred / Non-Preferred Pharmacy Networks (Page 157)**

We appreciate CMS clarifying the intent of preferred and non-preferred pharmacy networks and how cost-sharing should be managed. In addition, we support ongoing efforts to ensure beneficiaries are aware of what network listings mean on the Plan Finder related to cost sharing and the importance of them understanding potential impacts on the pharmacy of their choice.

In conclusion, APhA thanks you for the opportunity to provide comments on this important issue. We support CMS’ efforts to continue to improve the Medicare Part D program and look forward to continuing to work with CMS on this issue. If you have any questions or require additional information, please contact Marcie Bough, Senior Director of Government Affairs at mbough@aphanet.org or by phone at (202) 429-7538.

Thank you

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

TM/mb

cc: Marcie Bough, PharmD, Senior Director, Government Affairs