March 4, 2016

[Submitted electronically to AdvanceNotice2017@cms.hhs.gov]

Centers for Medicare & Medicaid Services
U.S. Dept. of Health & Human Services
Attention: CMS-4159-P
P.O. Box 8013
Baltimore, MD 21244-8013


Dear Sir/Madam:

The American Pharmacists Association (“APhA”) is pleased to submit our comments on the Centers for Medicare & Medicaid Services’ (“CMS”) CY 2017 Call Letter (the “Call Letter”). Founded in 1852 as the American Pharmaceutical Association, APhA 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, physicians’ offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services. We appreciate CMS’s continued efforts to increase transparency and to enhance meaningful data collection from Medicare Part D plans in order to improve patient care.

I. Star Ratings Measures

APhA thanks CMS for the opportunity to offer our comments regarding enhancements to the Star Ratings in CY 2017. APhA’s member pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians are committed to continuous quality improvement. Our comments below echo the feedback we submitted in December 2015 to CMS’s “Request for Comments: Enhancements to the Star Ratings for CY 2017 and Beyond.”

A. Changes to Measures for 2017

i. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) measure (Part D) (p. 104)

APhA strongly supports the development of meaningful measures for medication therapy management (“MTM”) services and is encouraged by CMS’s addition of the Comprehensive Medication Review (“CMR”) completion rate to the 2017 Part D Star ratings. APhA commends
CMS’s continued efforts to identify outcomes-based MTM measures that can serve as companion measures to the CMR completion rate as more robust MTM measures are needed to effectively measure the value of MTM services.

APhA supports CMS’s approach of adding a detailed file during each Health Plan Management System (“HPMS”) plan preview period to list each contract’s underlying denominator, numerator, and Data Validation score.

ii. High Risk Medications in the Elderly measure (HRM) (p. 105)

APhA agrees with CMS’s proposal to move the High Risk Medications in the Elderly (“HRM”) measure from a Star Ratings measure to a Display Measure in 2017. The need to incorporate updates to the Beers’ Criteria, the efforts to better understand the unintended consequences when plans lack access to clinical data, and the need to analyze the associations between low-income status and the use of high-risk medications in the elderly are all important reasons to move the HRM measure to display status.

B. 2017 CMS Display Measures

APhA supports CMS’s proposal to add four new Part C and one new Part D measure to the 2017 Display Measures: the Medication Reconciliation Post Discharge (Part C), the Hospitalizations for Potentially Preventable Complications (Part C), the Statin Therapy for Patients with Cardiovascular Disease (Part C), the Asthma Measures (Part C), and the PQA-endorsed Statin Use in Persons with Diabetes (“SUPD”) measure (Part D). These measures address important health care issues where there is opportunity improve the quality of care. APhA would support moving these measures from display measures to Star Ratings measures in the future if experience and assessment merit their inclusion in the Star Ratings program.

i. Care Coordination (Part C) (p. 142)

APhA appreciates and thanks CMS for its efforts to identify meaningful care coordination measures. As CMS considers the activities that best represent care coordination, APhA requests that CMS consider examining the contributions of pharmacists to appropriate care coordination, especially as it relates to optimizing medication therapies. Medication-related problems often occur due to lack of care coordination, and pharmacists can play an important role in managing medications across multiple providers, including communicating medication information and exchanging reconciled medication lists. APhA recommends that the activities of pharmacists be included in the exploration of new care coordination measures.

II. Part D Benefit Review and Plan Requirements

A. Medication Therapy Management (MTM): Annual MTM Eligibility Cost Threshold (p. 181)

APhA appreciates CMS’s continued support for MTM programs, which improve medication-related and overall health outcomes. Studies indicate that for every $1 spent on MTM services, anywhere from $4 up to $12 is saved—in addition to cost savings, patients also realize significant improvements in key health measures. Despite clear evidence supporting the value of pharmacist-led MTM services, these programs continue to be significantly
underutilized. We strongly encourage CMS to revisit the cost threshold for CY 2017—the current $3,507 threshold excludes many beneficiaries with complex conditions, but smaller drug spends, who could benefit from MTM services. This point is reinforced by the fact that the United States spends $300 billion annually on medication-related problems.\(^1\) APhA appreciates CMS’s ongoing efforts to expand and enhance MTM, including the Enhanced MTM Model test, and we hope CMS will continue to work collaboratively with pharmacists, plans, and beneficiaries to improve and streamline MTM eligibility criteria (including the number of medications and chronic conditions) in order to maximize the services’ benefits to both patients and the larger health care system.

B. Network Access

i. General Network Access

While we applaud CMS’s efforts to improve access—including its decision to maintain the current plan outlier criteria for CY 2017—we believe there is room for improvement. APhA applauds CMS’s previous transparency and information-sharing reforms, which have offered beneficiaries more information with which to make informed choices. However, we believe that if additional pharmacies are offered the opportunity to participate in Part D plans, patients will have increased access to benefits and services, which may result in improve outcomes from their medications. Thus, APhA continues to advocate for the imposition of a requirement that Part D plans contract with any pharmacy willing to accept their contractual terms and conditions. We believe that patients would further benefit if certain network adequacy standards were introduced. APhA supports network adequacy standards that recognize and include pharmacists as essential providers. In contracting with community pharmacies, plans create opportunities for patients to interact with pharmacists in a way that improves outcomes while controlling costs.

ii. Access to Preferred Cost-Sharing Pharmacies (p. 185)

APhA strongly supports CMS’s commitment to providing patients with access to both affordable medication and the clear, accurate information regarding plans’ benefits that beneficiaries need to make informed plan selections. APhA, like CMS, advocates for better transparency and supports the concept of plans offering patients access to preferred cost-sharing pharmacies (“PCSPs”), which have the potential to increase patient access to affordable medications. APhA was pleased to see the reported increases in PSCP access for urban, rural, and suburban beneficiaries. However, the Call Letter’s analysis of PSCP access indicates that plans in the lowest decile are still close to 20 percentage points removed from reaching CMS’s convenient access standard for urban beneficiaries. As a result, APhA remains concerned that while current plan networks include PCSPs, beneficiaries may encounter logistical hurdles in actually accessing PSCPs. We encourage CMS to continue to monitor beneficiary access to PCSPs closely and to require plans to provide patients with up-to-date information on real-world access to PCSPs advertised by their plans.

C. Tier Labeling and Composition; Benefit Review (p. 186-189)

APhA applauds CMS for addressing the ongoing issues beneficiaries face in determining how a plan’s cost-sharing requirements will be applied to their medications. We appreciate

\(^1\) NEHI, *Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Adherence for Chronic Disease* (August 2009).
CMS’s continued focus on improving transparency by requiring that the names of formulary tiers accurately reflect their composition. APhA has consistently advocated for empowering beneficiaries by providing them with plan information that allows them to make informed health care decisions. We are pleased that in addition to tier labeling, CMS will be focusing on the cost-sharing associated with non-preferred drug tiers, stating that it will “continue to evaluate the type of level of cost sharing that is most appropriate for this tier and that balances the Part D sponsor’s ability to mix brand and generic drugs within a tier while maintaining transparency and a meaningful benefit offering for beneficiaries…”.

APhA commends CMS for emphasizing the importance of the adult immunization benefit. Offering full coverage of vaccines with very low or no beneficiary cost-sharing requirement will incentivize many beneficiaries to stay up-to-date with their immunizations. Immunizations are vital to public health, and higher rates of adult immunization will improve patient health while reducing health costs associated with preventable conditions. Pharmacists are important members of the immunization neighborhood and improve patient access to vaccinations recommended by the Centers for Disease Control and Prevention’s (“CDC’s”) Advisory Committee on Immunization Practices (“ACIP”). Therefore, CMS should encourage plans to maximize the inclusion of pharmacists as in-network clinicians providing vaccines in accordance with the National Vaccine Advisory Committee (“NVAC”) Adult Immunization Standards and as authorized under state practice acts.

D. Opioid Utilization

i. Formulary-Level Cumulative Opioid Point-of-Sale Edits in CY 2017 (p. 202)

APhA was pleased to see CMS’s data regarding the decrease in opioid overutilization in Part D plans. We have long been strongly supportive of programs that effectively target and deter prescription drug abuse and misuse, provided these programs are narrowly tailored and carefully structured to ensure that patients with a legitimate need have access to medications. APhA appreciates that CMS’s proposal to require point-of-sale (“POS”) edits on the basis of cumulative morphine equivalent dose (“MED”) is based on the positive results of a pilot project. APhA supports such evidence-based interventions, but we caution that expanding the requirements to all Plan D sponsors may initially result in confusion and possible beneficiary access issues. While CMS notes that the pilot project did not produce any beneficiary access issues or complaints, the sample size was very small. Because plans will have some flexibility in designing these POS edits, variable criteria could prevent some legitimate prescriptions from being filled. While we understand the need for flexibility, variation in plan criteria may result in confusion, particularly as beneficiaries transition between plans, while numerous alerts related to POS edits may create technical issues for pharmacies. Given the small sample size of the original pilot, we encourage CMS and plan sponsors to consider expanding the original pilot to include more plans in order to troubleshoot any issues associated with deviations in POS edit criteria that could compromise patient access before rolling out POS edits for all plans. As the plan sponsors develop their POS edits, APhA encourages plans and CMS to engage with pharmacists and prescribers to craft edits that can proactively prevent overutilization without compromising patient access to medically-necessary opioids.

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ii. Access to Medication-Assisted Therapy (p. 204-205)

As noted above, APhA recognizes the importance of developing and implementing programs to identify, prevent, and treat prescription drug abuse. As such, APhA supports access to, and coverage for, evidence-based medication-assisted therapy (“MAT”) for opioid use disorders. Limitations on dispensing and coverage can adversely impact patient access to MAT and we encourage policymakers to implement policies that reduce or eliminate these barriers, to the extent possible.

iii. Centers for Disease Control and Prevention (CDC) Guidelines for Prescribing Opioids for Chronic Pain (p. 205-206)

APhA supports the use of evidence-based guidelines to assist in developing CMS’s overutilization guidance and the Overutilization Monitoring System (“OMS”) opioid overutilization methodology. However, given that the CDC guidelines have not yet been finalized, we believe it is premature to make reference to their incorporation prior to finalization and response from the marketplace. Additionally, many states are adopting their own sets of guidelines, so CMS must consider the current environment and the immediate desire of policymakers to understand and implement effective approaches that balance legitimate need with the prevention of drug abuse and misuse. Thus, we suggest CMS consider a variety of evidence-based guidelines when establishing policy.

Thank you for the opportunity to provide comments on the Call Letter. We support CMS’s efforts to continue to improve the Medicare Part D program and look forward to continuing to work with CMS to reach that goal. If you have any questions or require additional information, please contact Jillanne Schulte, JD, Director of Regulatory Affairs, at jschulte@aphanet.org or by phone at (202) 429-7538.

Sincerely,

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Executive Vice President and CEO

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs