



American Pharmacists Association[®]
Improving medication use. Advancing patient care.

March 3, 2017

[Submitted electronically to AdvanceNotice2018@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

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter

Dear Sir/Madam:

The American Pharmacists Association (APhA) is pleased to submit our comments on the Centers for Medicare & Medicaid Services' (CMS) Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter (the "Call Letter"). Founded in 1852 as the American Pharmaceutical Association, APhA represents 64,000 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, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

I. Star Ratings and Display Measures

APhA's members are committed to continuous quality improvement and support the development and use of meaningful measures that help patients achieve optimal health and medication outcomes. APhA thanks CMS for the opportunity to offer our comments regarding enhancements to the Star Ratings and display measures in CY 2018.

A. New Star Ratings measures

i. Medication Reconciliation Post Discharge (Part C) (p. 79)

APhA supports the addition of this measure to help determine MA-PD's star ratings and looks forward to working with CMS to add it to a broader set of future measures related to care transitions. Inclusion of the medication reconciliation post-discharge measure in the MA-PD star ratings program is consistent with measures used in other CMS programs such as the ACO measures in the Medicare Shared Savings

Program (MSSP) and the quality measures in the Merit-based Incentive Payment System (MIPS) within the Quality Payment Program (QPP).¹ APhA and its members are very grateful for CMS's continued recognition of the value of pharmacists and implementation of policies that promote pharmacists' involvement in patient care, including the Medication Reconciliation Post Discharge measure that references pharmacists.

In addition to recognizing the strong role that pharmacists can play in the post-discharge care of beneficiaries, APhA strongly urges CMS to implement policies which facilitate pharmacists' involvement in a patient's care coordination process other than at discharge. Better, as well as earlier, incorporation of pharmacists and their medication expertise in patient care is consistent with the movement to coordinated care^{2,3} and other team-based care models to more effectively maximize the members of the health care team and benefit patients.

B. Removal of Star Ratings measures

i. High Risk Medications in the Elderly measure (Part D) (pgs. 82, 99-100)

APhA agrees with CMS's proposal, based upon statements from the Pharmacy Quality Alliance (PQA) and the American Geriatrics Society, to move the High Risk Medications in the Elderly (HRM) measure from a Star Ratings measure to a display measure in 2018. We appreciate the change is due to concerns that the measure should not be punitive as medications on the HRM list are not contraindications and are only recommendations and considerations.⁴

C. 2018 CMS display measures

While not included in the plan ratings, CMS and plans use "display measures," to facilitate quality improvement. All previous 2017 display measures will continue as display measures for 2018. However, some of the measures contain specification changes, and there are new measures proposed. In general, APhA supports the following display measures highlighted below that relate to pharmacists and pharmacist services. APhA would also support moving these measures from display measures to Star Ratings measures in the future if experience and assessment merit their inclusion.

i. Pneumococcal Vaccination Status for Older Adults (Part C) (pgs. 97-98)

APhA supports CMS's efforts to explore better ways (e.g., claims, case management systems, medical records, registries and electronic health records) to assess pneumococcal vaccination status, other than through CAHPS survey data. Relying upon

¹ See, CMS, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017, Final Rule. 81 FR 80170. Pg. 80485. November 15, 2016. Available at: <https://www.federalregister.gov/documents/2016/11/15/2016-26668/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions>

² See, The Patient-Centered Primary Care Collaborative. "Integrating Comprehensive Medication Management to Optimize patient Outcomes." June 2012. Available at: <https://www.pcpcc.org/guide/patient-health-through-medication-management>

³ See, American College of Physicians (ACP) – Practice Advisor. Collaborative Medication Management. Module. 2017. Available at: <https://www.practiceadvisor.org/Modules/improving-clinical-care/collaborative-medication-management/login>

⁴ CMS. Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Pgs. 115-116. April 4, 2016. Available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvntgSpecRateStats/Downloads/Announcement2017.pdf>

patient recall and understanding regarding which pneumococcal vaccine(s), if any, a patient might have received is an unreliable method to determine immunization status. Encouraging all immunization providers to report vaccines administered to patients will provide a comprehensive database from which to measure patient immunization status.

ii. Statin Therapy for Patients with Cardiovascular Disease (Part C) (p. 98)

APhA is unclear what is meant by CMS's statements, "[s]ince the HEDIS statin measures overlap with the measures developed by the PQA, CMS included only one of the HEDIS measures on the 2017 display page and will retain it on the 2018 display page. After gaining experience with the new treatment guidelines and metric, we plan to include this measure in the 2019 Star Ratings." We ask for clarity which HEDIS measure(s) overlaps with which PQA measure(s) and also verification that CMS plans to use the HEDIS statin measure in the Part C Star Rating program and the PQA Statin measure (Statin Therapy in Persons with Diabetes) in the Part D Star Ratings program.

iii. Drug-Drug Interactions (Part D) (pgs. 100-101)

APhA continues to support this measure as CMS is planning to implement the revised measure drug list, which PQA updated, for the 2019 display measures using 2017 data.

iv. Antipsychotic Use in Persons with Dementia (APD) (Part D) (p. 101)

Generally, APhA supports measuring the percentage of Medicare Part D beneficiaries 65 years or older with dementia who received prescription fills for antipsychotics without evidence of a psychotic disorder or related condition. As CMS is aware, pharmacists have extensive medication-related experience and training, and can assist in helping treat seniors with dementia. Pharmacists can also help address a number of concerns for care transitions for patients with dementia (i.e., medication reconciliation, comprehensive medication reviews, etc.).⁵ Therefore, we reiterate our call to CMS to implement measures and policies that encourage team-based care, and effectively optimize pharmacists and other practitioners' skills to improve patient care.

v. Use of Opioids from Multiple Providers (OHDMP) and/or at High Dosage (OHD) in Persons without Cancer (Part D) (pgs. 101-102)

APhA supports addressing and improving opioid prescribing and management, while recognizing the need for patients to have access to "safer, more effective chronic pain treatment"⁶ and remembering the millions of patients with chronic pain in need of legitimate access to appropriate prescription pain medications. APhA supports CMS's proposal to implement the PQA's recently-approved changes to these measures.⁷ We also

⁵ Burke, Robert. Et. al. Dementia in Care Transitions. The Society for Post-Acute and Long-Term Care Medicine. White Paper M16. Introduced in March 2016. Available at: <http://www.paltec.org/sites/default/files/M16-%20TOC%20Dementia%20White%20Paper.pdf>

⁶ CMS. Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Pg. 216. April 4, 2016. Available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf>

⁷ Changes include: The treatment period for OHD and opioids at high doses from multiple providers must be 90 days or more. MED is changed to morphine milligram equivalents. ICD-9, 10 codes will be changed to align with the American Medical Association Physician Consortium for Performance Improvement cancer value set. All buprenorphine products indicated for medication-assisted treatment (MAT) will be excluded.

support efforts continuing to refine these measures using the best available scientific evidence. Accordingly, APhA supports CMS’s proposal to not add these measures to Star Ratings at this time.

vi. Statin Use in Persons with Diabetes (Part D) (pgs. 102-103)

APhA supports this PQA-endorsed measure of patients between 40 – 75 years old who received at least two diabetes medication fills and received a statin medication during the measurement period (excluding ESRD and hospice patients). We also support this measure becoming a Star Ratings measure for 2019 as it will facilitate increased management of statin therapy in persons with diabetes.

D. Measures for 2019 and beyond

i. Telehealth and Remote Access Technologies (p. 104)

APhA appreciates that CMS welcomes feedback on the appropriateness of including telehealth and/or remote access technology encounters (including behavioral health) as allowed under the current statutory definition of Medicare covered telehealth services and/or as provided by an MA plan as a supplemental benefit, as eligible encounters in various future Part C quality measures. As CMS understands, Medication Therapy Management (MTM) under Part D can be delivered in a telehealth format. Therefore, as CMS facilitates its telehealth delivery criteria, APhA urges CMS to continue to improve the exchange of clinical information between health care practitioners in all its policies or programs, including pharmacists.

Pharmacists regularly provide services to improve safe and appropriate medication use; adherence for the elderly and other populations; medication reconciliation; wellness and prevention; chronic disease management programs; and case management for beneficiaries with multiple medications that require complex medication dosing regimens. However, pharmacists are frequently blocked from the electronic exchange of relevant clinical information, which is critical to maximize the benefit of coordinated team-based care. Therefore, we also encourage CMS’s continued help in facilitating the electronic exchange of clinical information between pharmacists and other health care providers to improve the delivery of coordinated, team-based care and benefit patients.

ii. Care Coordination (Part C) (pgs. 104-106)

APhA thanks CMS for its efforts to identify meaningful care coordination measures and supports its efforts to consider them as an immediate outcome measure. As CMS and its contractors⁸ consider the activities that best represent care coordination measures for MA and MA-PD plans, starting with the 2019 star ratings, 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

⁸ Impaq International. CMS Awards IMPAQ Contract to Support Quantifiable Care Coordination Measures for Medicare Advantage Plans. November 10, 2015. Available at: <http://www.impaqint.com/media-center/press-releases/cms-awards-impaq-contract-support-quantifiable-care-coordination>

information and exchanging reconciled medication lists. Therefore, APhA recommends that as CMS explores new care coordination measures, measured activities include the contributions of pharmacists.

iii. Transitions of Care (Part C) (pgs. 106-107)

APhA is pleased that CMS understands the vital role that pharmacists can play in ensuring safe transitions of care. APhA appreciates that Medication Reconciliation is included as one of the 4 indicators under the new Transitions of Care measure. In addition to the Medication Reconciliation indicator for this measure, CMS should consider pharmacists' roles in the Notification of Inpatient Admission, Receipt of Discharge Information, and Patient Engagement after Discharge indicators. As the first health care practitioner patients often encounter post-discharge, pharmacists could benefit greatly from better inclusion in the sharing of pertinent clinical information and often are the health care practitioner coordinating medication-related information between the hospital and primary care physician. Pharmacists/pharmacies can act as access points for sharing of medication information vital to appropriate medication reconciliation during any care transition a patient experiences to improve care and reduce costs. For example, connectivity of the community pharmacist with the hospital pharmacist and primary care physicians under the Hawaii CMS Innovation Center (CMMI) project reduced the medication-related hospitalization rate of individuals aged 65 and older by 36.5% than in nonintervention hospitals with an estimated \$6.6 million in annual avoided admissions.⁹ Therefore, APhA requests that CMS consider the role of pharmacists when developing the indicators for this new Transitions of Care measure.

iv. CMS' Expectation for Hard Formulary-Level Cumulative Opioid MED POS Safety Edits in CY 2018 (pgs. 148-149)

APhA has long been strongly supportive of programs that effectively target and deter prescription drug abuse and misuse. APhA supports CMS's efforts to help address this epidemic, provided its policies are scientifically- based and carefully structured to ensure that patients with a legitimate need have access to medications. APhA appreciates CMS's proposal to require point-of-sale (POS) edits based on the cumulative morphine equivalent dose (MED).

APhA understands the difficulty in setting an MED upper limit for a hard edit. Our members tell us that the majority of beneficiaries that reach 200 mg likely have a combination of short and long acting pain medications and have had to choose whether to fill them to avoid hitting the limit. Imposing hard edits can result, in some cases, plans rejecting, at least temporarily, the medically necessary prescriptions of beneficiaries with legitimate needs. Adding to the complexity, many patients whose legitimate medical needs requires opioids at an upper limit that may trigger a hard edit, and receive prescriptions that indicate the date that they are allowed to fill it written on the script itself—a date that is chosen because it is the day they will run out of their medication. Often a hard edit, or the time necessary to receive prior authorization may exceed the prescription date forcing patients to unnecessarily return to see their physicians. APhA

⁹ Pellegrin, Karen. Et. al. Reductions in Medication-Related Hospitalizations in Older Adults with Medication Management by Hospital and Community Pharmacists: A Quasi-Experimental Study. *Journal of the American Geriatrics Society*. October 7, 2016. Available at: <http://onlinelibrary.wiley.com/doi/10.1111/jgs.14518/full>

appreciates CMS’s acknowledgement that plans should account for “high-dose opioid usage previously determined to be medically necessary such as through case management or the coverage determination and appeals process.” We strongly recommend that plans establish a process, prior to implementing hard edits, to proactively address the appropriate authorization for patients who are receiving high doses of opioids for legitimate needs, particularly those patients who are currently receiving these medications long-term.

In addition, prescribers often switch medications instead of completing prior authorizations for POS edits thinking that will take care of the issue, which, again, is causing patients to make trips back and forth to the doctor's office, which may cover significant distances. APhA members have informed us that patients often come back with another prescription and pharmacists encounter the exact same problem. APhA members believe the POS edits need to be a clearly defined, in a consistently applied process that will allow overrides, if appropriate, to be completed on the same day given the fact that the prescriptions are written only allowing the fill process to occur on the very last day that patients will run out of medication(s). In addition, setting “hard stops” may lead to an increase in the volume of patients seeking relief through illegal methods. As the plans implement POS edits, APhA encourages both the plans and CMS to engage with pharmacists and prescribers to craft evidence-based POS edits that can proactively prevent overutilization without compromising patient access to medically-necessary opioids. To assist these efforts, CMS and the plans should support the policy adopted by APhA’s House of Delegates (HOD) for automation and technology in pharmacy practice that “supports nationwide integration of prescription drug monitoring programs (PDMP) that incorporate federal, state, and territory databases for the purpose of providing health care professionals with accurate and real-time information to assist in clinical decision making when providing patient care services related to controlled substances.”¹⁰

II. Part D Requirements

A. *Medication Therapy Management (MTM): Annual MTM Eligibility Cost Threshold* (pgs. 110-111, 135-136)

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.¹¹ Despite clear evidence supporting the value of pharmacist-led MTM services, these programs continue to be significantly underutilized. As APhA has previously stated, we strongly encourage CMS to revisit the cost threshold, as the current \$3,919 threshold, which increased \$412 from the previous year, excludes many beneficiaries with complex conditions, but smaller drug spends, potentially through the use of generic medications, 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.¹² While APhA appreciates CMS’s ongoing efforts

¹⁰ APhA. HOD. Current Adopted Policy Statements 1963-2016. 2015 Integrated Nationwide Prescription Drug Monitoring Program. Pg. 16. 2016. Available at: <http://pharmacist.com/sites/default/files/files/Current%20Adopted%20Policy%2016088.pdf>

¹¹ Isetts, BJ. Et. al. Clinical and economic outcomes of medication therapy management services: the Minnesota experience. J Am Pharm Assoc. 2008; 48(2):203–11. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/18359733>

¹² NEHI. Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Adherence for Chronic Disease. August 2009. Available at: http://www.nehi.net/writable/publication_files/file/pa_issue_brief_final.pdf

to expand and enhance MTM, including the Enhanced MTM Model test, we hope that 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. Access to Preferred Cost-Sharing Pharmacies (PSCP) (pgs. 139-140)

APhA, like CMS, advocates for increasing patient access to affordable medications. APhA was pleased to see, through CMS's efforts to increase transparency within the Medicare program, the reported increases in PSCP access for urban, rural, and suburban beneficiaries for 2018 and the requirement for outlier plans to disclose in marketing materials, including websites, that their plans' may offer lower access to PSCP networks. However, APhA remains concerned that while current plan networks include PCSPs, beneficiaries may still encounter logistical hurdles in actually accessing PSCPs. APhA believes that if CMS offers additional pharmacies the opportunity to participate in Part D plans, patients will have increased access to benefits and services, which may result in improved outcomes from their medications. Thus, APhA continues to advocate for a requirement that Part D plans contract with any pharmacy willing to accept their contractual terms and conditions.

Thank you for the opportunity to provide comments on the draft Call Letter. We support CMS's ongoing efforts to continue to improve Medicare's prescription drug programs and look forward to continuing to work with CMS to reach that goal. If you have any questions or require additional information, please contact Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,



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

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs, APhA
The Honorable Tom Price, M.D., Secretary, U.S. Department of Health and Human Services