



October 16, 2018

[Submitted electronically via www.regulations.gov]

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Attention: CMS-1701-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations Pathways to Success [RIN: 0938-AT45]

Dear Administrator Verma:

APhA is pleased to submit comments to CMS’s proposed rule “Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations Pathways to Success” (hereinafter, the “Proposed Rule”). APhA, founded in 1852 as the American Pharmaceutical Association, represents 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, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services. Pharmacists also provide care in accountable care organizations (ACOs), including those participating in the Medicare Shared Savings Program (Shared Savings Program).

ACOs utilize pharmacists in different ways, including monitoring medications as well as the conditions they are used to treat, care coordination and transitions, and preventive health measures. APhA appreciates the opportunity to provide input to CMS’s proposed redesign of the Shared Savings Program and offers the following recommendations based on our members’ feedback, including those working in ACOs, in response to the Proposed Rule.

I. Redesigning Participation Options to Facilitate Transition to Performance-Based Risk (Pgs. 41789-41806)

The Proposed Rule outlines CMS’s approach to restructure the participation options for ACOs applying to participate in the program in 2019 by discontinuing Track 1 (one-sided shared savings-only model), and Track 2 (two-sided shared savings and shared losses model) while maintaining Track 3 (renamed the ENHANCED track). Under the proposed approach, ACOs

would have the option to participate under a BASIC track (offers a path from one-sided models to progressively higher risk-reward potential), or the ENHANCED track (highest level of risk-reward potential). While APhA acknowledges the advantages that can result from increasing ACOs' risks, such as facilitating value-based purchasing, we are aware of challenges ACOs have faced when deciding to accelerate risks. We offer the following points to consider as CMS moves forward.

While a number of APhA members already participate in the advanced Next Generation ACO models, many of these models are in closed health care systems with established infrastructure(s) and greater control over the health care services provided to their attributed beneficiaries. Although APhA appreciates and supports variable models and types of networks, certain options impact ACOs' ability to assume risk, particularly for those Shared Savings Program ACOs with multiple contracted providers. Because there is still a significant amount of provider and beneficiary education needed, APhA recommends CMS pilot the proposed models in different types of systems (e.g., open and closed health care systems), utilizing team-based care (e.g., pharmacists, etc.), to better understand implications, including practitioner responses, to ACO participation and subsequent shifts in risk.

APhA appreciates the increased flexibility CMS is granting ACOs to take on two-sided risk. However, a number of our members stated that their ACOs are also considering becoming Medicare Advantage (MA) plans due to the increased flexibility recently granted to MA plans to request Advanced APM status for certain provider contracts.¹ Accordingly, for planning purposes, APhA asks CMS for clarification if it is the Agency's desire to shift its ACO models to MA models.

II. Program Data and Quality Measures related to Opioids (Pages 41906-41908)

a. Program Data (Pgs. 41907-41908)

APhA appreciates CMS's request for feedback regarding aggregated Medicare Part D data that could be useful to ACOs to combat opioid misuse in their assigned beneficiary population. Generally, APhA encourages data-sharing across the health care system, as there are many different uses for aggregated data by different entities, including ACOs. APhA foresees an opportunity to utilize Part D Claim and Claim Line Feed (CCLF) files to better understand health care expenditures, including the implications of Part D services on other components of Medicare and vice-versa. Such information may also be helpful to ACOs in considering policies to manage their beneficiary population.

APhA's members involved in ACOs indicated real-time data is useful in helping combat opioid misuse in their assigned beneficiary population. ACOs typically rely on real-time data when developing interventions and targeting those interventions. For example, we are aware of ACOs using prescribing data (e.g., examining prescribing frequency and morphine milligram equivalent amounts) to help identify prescribers for additional pain management education.

¹ CMS. Other Payer Advanced APM Determination Process: Medicare Health Plans Fact Sheet. November 2017. Available at: <https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Medicare-Health-Plans-APMs.pdf>

However, because the Part D data CMS shares and proposes to share can be outdated, its usefulness has limitations. Accordingly, APhA requests CMS facilitate ACOs' access to data, such as prescription data, in real-time. Furthermore, APhA recommends CMS examine the formatting of data to effectuate its use and understandability.

b. Federal Information to Share with ACOs (Pg. 41907)

In the Proposed Rule, CMS indicates it will continue to share information highlighting federal opioid initiatives, including the “Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain” and “The Surgeon General's Report on Alcohol, Drugs, and Health”, with ACOs. To better address different facets of the opioid epidemic and patients' pain management needs, APhA encourages CMS to include different types of clinical guidelines and information regarding: pain management, including acute and chronic pain management; naloxone (e.g., “Surgeon General's Advisory on Naloxone and Opioid Overdose”²); treatment of substance use disorder; and stigma (e.g., SAMHSA's “Words Matter: How Language Choice Can Reduce Stigma”³). In addition, APhA recommends CMS share information with ACOs regarding inclusion of pharmacists on care teams, such as CDC's “Advancing Team-Based Care Through Collaborative Practice Agreements”⁴. APhA believes this information, although not opioid-specific, will help ACOs effectively utilize pharmacists' medication expertise when addressing patients' unique medication needs and those of its population more broadly.

c. Quality Measures (Pgs. 41907-41908)

In the Proposed Rule, CMS seeks comments on measures to add to the quality measure set to address the opioid epidemic and addiction. APhA members support adding the NQF-endorsed measures⁵ highlighted in the Proposed Rule to the ACO quality measure set. APhA requests CMS also consider opioid-related measures for persons with polypharmacy⁶ and persons with geriatric syndrome. Should such measures not yet be developed, APhA encourages CMS to work with the Pharmacy Quality Alliance (PQA).

While APhA recognizes CMS's intent to enhance the quality measure set to better address the opioid epidemic and addiction, our members indicate the use of real-time data could be more effective and timelier in addressing the opioid epidemic and managing population health. Accordingly, APhA encourages CMS to perform additional outreach to ACOs to identify

² U.S. Surgeon General. Surgeon General's Advisory on Naloxone and Opioid Overdose. April 5, 2018, available at: <https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html>

³ SAMHSA. Words Matter: How Language Choice Can Reduce Stigma. November 20, 2017, available at: <https://www.samhsa.gov/capt/sites/default/files/resources/sud-stigma-tool.pdf>

⁴ CDC. Advancing Team-Based Care Through Collaborative Practice Agreements A Resource and Implementation Guide for Adding Pharmacists to the Care Team, available at: <https://www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf>

⁵ 83 Fed. Reg. 41789 at 41908, stating CMS' consideration of the following NQF-endorsed measures: NQF #2940 Use of Opioids at High Dosage in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries with a daily dosage of MME greater than 120 mg for 90 consecutive days or longer; NQF #2950 Use of Opioids from Multiple Providers in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies; and NQF #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer.

⁶ As stated in the Proposed Rule, “...a study by MedPAC found that some beneficiaries who use opioids fill more than 50 prescriptions among 10 drug classes annually.”

strategies that use real-time data to address the opioid epidemic and for CMS to consider how it can encourage broader use of such strategies.

III. Promoting Interoperability (Pgs. 41908-41911)

APhA appreciates CMS's continued promotion and encouragement of certified electronic health record technology (CEHRT). In the Proposed Rule, CMS states "...all ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM must certify that at least 50 percent of their eligible clinicians use CEHRT to document and communicate clinical care to their patients or other health care providers." However, CMS's proposal would not adequately incentivize interoperability with and among necessary members of the health care team who are not considered eligible clinicians, including pharmacists, because only eligible clinicians use of CEHRT is counted towards the ACO's certification of at least 50 percent. Therefore, APhA recommends CMS include pharmacists' CEHRT use in calculating ACOs' CEHRT certification goals.

IV. Coordination of Pharmacy Care for ACO Beneficiaries (Pgs. 41911-41912)

APhA is very pleased CMS acknowledges in the Proposed Rule the positive impact pharmacists and their services have on beneficiaries and their care. In the Proposed Rule, CMS requests feedback on ways ACOs, in particular Shared Savings Program ACOs, and Part D sponsors can improve the coordination of pharmacy care to achieve "...better health outcomes, better health care, and lower per-capita expenditures for Medicare beneficiaries." We agree "[i]ncreased collaboration between ACOs and Part D sponsors may facilitate better and more affordable drug treatment options for beneficiaries by encouraging the use of generic prescription medications, where clinically appropriate, or reducing medical errors through better coordination between providers [including pharmacists] and Part D sponsors." Pharmacists already support both ACOs and Part D plans in efforts to improve medication and health outcomes. APhA believes better integrating the pharmacy and medical benefit and data will provide a more comprehensive picture of overall quality, outcomes and costs. Current coverage and payment policies related to medications place incentives on the short-term, focusing on cost containment for the product rather than weighing the overall clinical benefit to the patient and the impact to their medical costs. We concur with CMS that "Part D sponsors may be able to play a greater role in coordinating the care of their enrolled Medicare FFS beneficiaries and having greater accountability for their overall health outcomes, such as for beneficiaries with chronic diseases where treatment and outcome are highly dependent on appropriate medication use and adherence." Therefore, pharmacists look forward to an enhanced role in, but not limited to, the areas mentioned in the Proposed Rule — increasing clinician formulary compliance (when clinically appropriate) and medication compliance; providing pharmacy counseling services from pharmacists; and implementing medication therapy management (MTM).

APhA also wants to ensure CMS's effort to enhance pharmacy care coordination is broader than focusing solely on expanding the use of pharmacy benefit managers⁷ (PBMs) and

⁷ As HHS is aware, there are PBM practices in the Medicare Part D program negatively impacting patient costs, care and access, such as direct or indirect remuneration (DIR) fees and narrow distribution networks. These practices impact the sustainability of community pharmacies and

raw data analysis without utilizing frontline pharmacists to leverage the provider-beneficiary relationship to truly coordinate care. APhA has concerns CMS may not appreciate the difference between Part D MTM and medication management provided through coordinated care models as well as the variability of the MTM benefit within Part D. Medication management services delivered in ACOs and PCMHs focus on comprehensive longitudinal management and monitoring of medications by pharmacists working in coordination with the patient's care team based on individualized patient needs. Follow-up visits are scheduled related to achieving clinical goals with input from other providers. With Part D MTM, there is significant plan variability in beneficiary eligibility for MTM services where Part D Plan sponsors use plan-level data to determine the number of Part D medications, number and types of chronic conditions, and assigned cost thresholds for eligibility.⁸ Thus, a beneficiary may qualify for MTM under one Part D plan's criteria and not under another plan, and it's not clear to providers which of their beneficiaries are eligible for MTM under a given plan. Additionally, eligible beneficiaries qualify for an annual comprehensive medication review, however, follow-up services to address problems and optimize medications varies greatly in delivery format and frequency. Accordingly, APhA strongly recommends any efforts by CMS to improve "pharmacy care coordination" through MTM services address the current barriers to beneficiary access and pharmacist/ pharmacy participation.

V. Incorporating Pharmacists into ACOs

Pharmacists can play a direct role in helping ACOs meet their two primary objectives: achieving quality measures and saving money. Many of those benchmarks require careful attention and monitoring of medications as well as the conditions they are used to treat. Example metrics where pharmacists will likely play a key role include medication reconciliation after discharge from an inpatient facility (ACO-12) and preventive health measures, including influenza immunization (ACO-14); pneumococcal vaccination (ACO-15); preventive care and screening: tobacco use: screening and cessation intervention (ACO-17); statin therapy for the prevention and treatment of cardiovascular (CV) disease (ACO-42); diabetes mellitus: hemoglobin A1c poor control (ACO-27); and falls: screening, risk-assessment, and plan of care to prevent future falls (ACO-47). However, pharmacists are not recognized under Medicare as "eligible clinicians," which impedes their incorporation into health care teams and the effective and efficient delivery of quality care. One immediate solution would be for CMS to use its authority under section 1848(q)(1)(C)(i)(II) [of the Social Security Act] to expand the definition of eligible clinician to include "...such other eligible professionals (as defined in subsection (k)(3)(B)) as specified by the Secretary..."⁹ to pharmacists.

Numerous studies have shown pharmacist-provided patient care services can have a significant impact on lowering costs and improving outcomes for patients with costly chronic

consequently, patient choice and access to care. Accordingly, prior to any discussion of expanding the purview of PBMs within the Medicare program, our organizations recommend CMS first eliminate problematic PBM practices in the Medicare Part D program to maintain patient access to medications.

⁸ CMS. 2017 Medicare Part D Medication Therapy Management (MTM) Programs. Fact Sheet. August 17, 2017. Available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2017-MTM-Fact-Sheet.pdf>

⁹ See, Social Security Act. §1848 (q)(1)(C)(i)(II). Available at: https://www.ssa.gov/OP_Home/ssact/title18/1848.htm

diseases.¹⁰ Given pharmacists' medication expertise and unique access to, and relationship with, the patient community, expanding patient access to pharmacist-provided patient care services can help reduce the possible \$672 billion spent by the U.S. annually on medication-related problems and nonoptimized medication therapy.¹¹ As CMS may know, eighty-nine percent of Americans live within five miles of a community pharmacy.¹² Better utilizing pharmacists in all practice settings to provide care could have a profound, and immediate impact on access, quality, health outcomes and costs for a large portion of the population, particularly in medically underserved communities.

Currently, pharmacists, including those in ACOs, deliver some Medicare services under compliant arrangements with physicians and other providers. However, these services are not attributed to or able to be billed directly by pharmacists, thereby leading to challenges in finding sustainable business models and reaping the benefits from pharmacist-provided patient care services. Consequently, pharmacists often operate as "invisible providers" on patient-care teams, resulting in CMS and other payers being unaware of the vital role pharmacists play in improving patient outcomes. Therefore, APhA strongly recommends CMS take advantage of any regulatory discretion it has to remove barriers recognizing pharmacists as eligible clinicians in ACOs.

Once again, thank you for the opportunity to provide feedback on the Proposed Rule and consideration of our comments. As pharmacists continue to work in collaboration with our physician colleagues as vital members of patient care teams, we are happy to facilitate discussions between CMS and our members who currently provide pharmacist-provided patient care services under ACOs and other Advanced APMs in various practice settings. 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,



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¹⁰ Avalere Health. Exploring Pharmacists' Role in a Changing Healthcare Environment. May 2014. Available at: <http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment>

¹¹ Watanabe, Jonathan H. Et. al. Cost of Prescription Drug-Related Morbidity and Mortality. Annals of Pharmacology. First Published March 26, 2018. Available at: <http://journals.sagepub.com/eprint/ic2iH2maTdI5zfN5iUay/full>

¹² NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.