



March 1, 2019

[Submitted electronically to www.regulations.gov]

The Honorable Seema Verma
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services (CMS)
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter (Docket Number: CMS-2018-0154)

Dear Administrator Verma:

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) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 draft Call Letter (hereinafter "Call Letter"). Founded in 1852 as the American Pharmaceutical Association, APhA represents nearly 60,000 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. APhA would like to provide feedback on the following areas included in the Call Letter.

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 2020.

A. Measure Updates for 2020 Star Ratings

i. Statin Use in Persons with Diabetes (SUPD) (Part D).

APhA supported this PQA-endorsed measure becoming a Star Ratings measure for 2019 to facilitate increased focus on the evidence-based use of statin therapy in persons with diabetes. Accordingly, we support CMS's proposal, for the 2020 Star Ratings (based on 2018 data) and

subsequent years, to assign a weight of 3 (intermediate outcomes) to this measure as it is standard practice and due to the clinical importance of this measure in improving health outcomes of persons with diabetes.

ii. Improvement measures (Part C & D)- Table 1: 2020 Star Ratings Improvement Measures.

i. Annual Flu Vaccine Process Measure C (1).

APhA supports adding the annual flu vaccine to the 2020 Star Ratings for Part C plans. According to the Centers for Disease Control and Prevention (CDC), a 6.2 percent reduction in the adult immunization/ vaccination rate for flu during the 2017-18 influenza season was a contributing factor in the record number of deaths.¹ Thanks to changes in state laws, pharmacists are playing an increasingly critical role in increasing influenza-vaccination rates across the United States, with an additional 4.1 million additional adults vaccinated in 2013 because states allowed pharmacists to administer the flu vaccine, which would have resulted in between 81,000-134,000 fewer influenza infections among adults in that year, depending on vaccine effectiveness. Additionally, the odds that an adult would receive the flu shot increased by 7.8 percent in states that allowed pharmacists to be immunizers.² APhA urges CMS to aggregate data from MA prescription drug plans (MA-PD) and Part D plan sponsors to better monitor, measure and attribute the impact different providers, including pharmacists, have on vaccination rates of Medicare beneficiaries.

ii. Getting Needed Prescription Drugs D (1.5) (CAHPs measure).

APhA appreciates CMS recognizing the importance of patient access to medications and supports the addition of this measure. However, not only is access to the product important, patient choice and their relationship with their pharmacist is critical to optimizing the impact of prescription medications.

B. New 2020 Display Measures

i. Transitions of Care (Part C).

APhA appreciates “Medication Reconciliation Post-Discharge” is retained as one of the 4 indicators collected and reported under the new Transitions of Care display measures with the intent to propose this measure for inclusion in the Star Ratings in the future. CMS should also consider pharmacists’ roles in the Notification of Inpatient Admission, Receipt of Discharge Information, and Patient Engagement after Discharge indicators. As CMS understands by adding the medication reconciliation measure, the review can be conducted by a pharmacist. Pharmacists are often the first health care practitioner patients often encounter post-discharge and the provider generally responsible for coordinating medication-related information between the hospital and primary care physician. Accordingly, patients could benefit greatly if

¹ CDC. Estimates of Influenza Vaccination Coverage among Adults—United States, 2017–18 Flu Season. Page last reviewed: November 5, 2018, available at: <https://www.cdc.gov/flu/fluview/coverage-1718estimates.htm>

² Drozd EM, Miller L, Johnsrud M. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates Across States. Clin Ther. 2017 Aug 3. pii: S0149-2918(17)30771-3, available at: <https://www.ncbi.nlm.nih.gov/pubmed/28781217>

pharmacists were better included in transitioning patients from an inpatient setting to home. 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, including transitional care services. For the Transitions of Care measure, the medication reconciliation information must be found in the same medical record that is used for the reporting of the other three indicators within the measure, which should be that of the primary care practitioner or ongoing care provider who is managing the patient's care. If pharmacists had access to relevant information in the patient's record, including discharge information, pharmacists could have a more effective role in helping a patient transition between care settings. APhA also requests CMS clarify how the efforts of community pharmacists in delivering medication reconciliation services would be captured since the primary provider's database is the one that is used for the data in calculating this measure.

ii. Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C).

APhA supports CMS's proposal to add to the 2020 display page a new HEDIS measure assessing follow-up care provided after an emergency department visit for patients with multiple chronic conditions. As CMS states "[p]atients with multiple chronic conditions are more likely to have complex care needs and follow-up after an acute event, like an emergency department visit, can help prevent the development of more severe complications." Pharmacists can provide several follow-up services with patients with chronic conditions and play a vital role in MA issuers achieving success on this measure. This measure could also be useful in providing information for transitional care management services.

C. Changes to Existing Display Measures

i. Use of Opioids at High Dosage and from Multiple Providers (OHDMP) and Antipsychotic and Use in Persons with Dementia (APD) (Part D).

For accurate measurement, APhA supports CMS's proposal to implement the PQA-approved measure updates for the 2020 display page measures (based on 2018 data) that calculate total days supply. We remain pleased the reporting of these measures to Part D plan sponsors is still through Patient Safety reports, with only the OHDMP measure added to the 2019 display page. APhA urges CMS to continue to monitor the application of these measures for unintended consequences to patients with legitimate pain needs using the best available scientific evidence.

D. Potential Changes to Existing Star Ratings and Display Measures

i. Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS) (Part D).

APhA supports CMS’s decision to begin reporting these three PQA-developed measures in the Patient Safety reports for the 2018 measurement year, and to add them to the display page for 2021 (2019 data) and 2022 (2020 data). We also support CMS considering these measures for the 2023 Star Ratings (2021 data).

ii. Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer.

In 2017, APhA supported CMS’s proposal to implement the PQA’s approved changes to these measures to better align with the CDC Guideline for Prescribing Opioids for Chronic Pain.³ We continue to support efforts refining these measures using the best available scientific evidence as CMS implements these revisions in the Patient Safety reports for the 2019 measurement year and considers including them on the 2021 display page (2019 data). APhA also recommends CMS monitor this measure for any negative and unintended consequences to patients, such as lack of access to necessary medications.

E. Potential New Measure Concepts

i. Interoperability Measures (Part C).

APhA appreciates CMS’s effort to gain feedback on ways to measure health plans’ progress in maximizing their capabilities to exchange health information with other plans, health care providers, and others. APhA encourages CMS to review the Pharmacy Health Information Collaborative’s report, “Integrating Pharmacists into Health Information Exchanges -- Update Version”⁴ to learn more about the pharmacy community’s health information exchange (HIE) related goals.

Should CMS consider adapting Merit-based Incentive Payment System (MIPS) measures to more directly measure interoperability for Part C, APhA recommends explicitly including pharmacists and pharmacies in definitions and terms where their eligibility may be unclear (e.g., healthcare provider, setting of care). For example, the Quality Payment Program electronic prescribing measure defines prescription as “the authorization by a MIPS eligible clinician to a pharmacist to dispense a drug that the pharmacist could not dispense to the patient without such authorization.”⁵ While the Summary of Care measure does not explicitly include pharmacies in the term “setting of care” or specify whether pharmacists are considered “healthcare providers.”⁶ APhA believes clearly including pharmacists and pharmacies in such terms and measures will

³ 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.

⁴ Pharmacy Health Information Technology Collaborative, Integrating Pharmacists into Health Information Exchanges -- Update Version, last updated February 9, 2018, available at: <http://www.pharmacyhit.org/pdfs/workshop-documents/WG3-Post-2018-01.pdf>.

⁵ See Centers for Medicare & Medicaid Services (CMS), Quality Payment Program, Merit-Based Incentive Payment System (MIPS) Advancing Care Information Performance Category Measure, 2018 Performance Period, available at: https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2018.MIPS%20ACI%20Measure_e-Prescribing.pdf, last accessed: February 20, 2019.

⁶ See Centers for Medicare & Medicaid Services (CMS), Quality Payment Program, Merit-Based Incentive Payment System (MIPS) Advancing Care Information Performance Category Measure 2018 Performance Period, available at: https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2018.MIPS%20ACI%20Measure_Request-Accept%20Summary%20of%20Care.pdf, last accessed: February 20, 2019.

limit confusion and encourage health plans to maximize their capabilities to exchange information across the range of health care practitioners providing care to patients in different settings, including pharmacists.

In the Call Letter, CMS highlights Part C and D “interoperability-sensitive” measures (e.g., HEDIS Medication Reconciliation Post-Discharge measure) which specifically reference pharmacists and therefore, facilitate their inclusion in these services. APhA encourages CMS to work with NCQA to more explicitly include pharmacists and community pharmacies in other HEDIS measures, such as HEDIS Transitions of Care. As pharmacists become more involved in team-based care and implementation specifications⁷ advance, it is becoming increasingly important that interoperability incentives similarly advance to include and recognize pharmacists.

ii. Patient-Reported Outcome Measures (Part C).

APhA agrees with CMS that “[p]atient engagement is key to achieving high quality care,” “[p]atients are the ultimate source of information on patient outcomes,” and “Patient-Reported Outcome Measures (PROMs or PROs) have the potential to capture aspects of quality that are best, or perhaps only, assessed by plan members themselves.” As CMS notes, a number of the CDC’s over 1,800 Patient-Reported Outcomes Measurement Information System (PROMIS) measures for use in adults, such as sleep and depression, are already collected through current patient survey efforts, while others are not. APhA urges CMS to include pharmacists as a core member of the integrated review teams to determine PRO measures as pharmacists are easily accessible to patients and have important perspectives on how patients view their care.

iii. Pain Management (Part C).

The Call Letter indicates NCQA is exploring the development of new measures assessing the use of non-opioid therapies (pharmacologic and non-pharmacologic) for pain and PROs (e.g., functional status, quality of life) to manage care for patients with chronic pain. In assessing the use of non-opioid therapies, APhA encourages CMS through their work with measure developers to consider medication-related services provided by pharmacists to optimize medications and limit risks to patients.^{8,9,10,11} APhA believes inclusion of such services in an NCQA measure may

⁷ See Office of the National Coordinator for Health Information Technology, Interoperability Standards Advisory: Documenting and Sharing Medication-Related Care Plans by Pharmacists, *NCPDP Pharmacist eCare Plan Version 1.0 Guidance on the Use of the HL7 CDA Consolidated Templates for Clinical Notes R2.1 Care Plan and HL7 CDA® R2 Implementation Guide: Pharmacist Care Plan Document, Release 1 - US Realm, Volume 1*, available at: <https://www.healthit.gov/isa/documenting-and-sharing-medication-related-care-plans-pharmacists>, last accessed: February 20, 2018.

⁸ See Fan, T. & Elgourt, T. (2008). Pain management pharmacy service in a community hospital, *American Journal of Health-System Pharmacy*, 65(16), 1560-1565, available at: <https://academic.oup.com/ajhp/article/65/16/1560/5127962>

⁹ See also, Wells, D.L., Popish, S., Kay, C., Torrise, V. & Christopher, M. (2016). Program Profile: VA Academic Detailing Service: Implementation and Lessons Learned, *Federal Practitioner* (May 2016), available at: https://mdedge-files-live.s3.us-east-2.amazonaws.com/files/s3fs-public/issues/articles/038_FP0516_WEB.PDF, last accessed: February 20, 2019.

¹⁰ See Dole, E.J., Murawski, M.M., Adolphe, A.B., Aragon, F.D. & Hochstadt, B. (2007). Provision of pain management by a pharmacist with prescribing authority, *American Journal of Health-System Pharmacy*, 64(1), 85-89, available at: <https://academic.oup.com/ajhp/article/64/1/85/5134842>

¹¹ See also, Hadi, M.A., Alldred, D.P., Briggs, M., Munyombwe, T. & Closs, J.S. (2014). Effectiveness of Pharmacist-led Medication Review in Chronic Pain Management: Systematic Review and Meta-analysis, *The Clinical Journal of Pain*, 30(11), 1006-1014, available at: <https://www.ncbi.nlm.nih.gov/pubmed/24480911>

encourage patient uptake and consequently, improved outcomes as a result of non-opioid therapies when appropriate.

iv. Adherence to Antipsychotic Medications for Individuals with Schizophrenia (Part C).

As CMS is aware, pharmacists have extensive medication-related experience and training, and can assist in helping treat seniors with schizophrenia.¹² Pharmacists can also help address a number of concerns for care transitions for patients with schizophrenia (i.e., medication reconciliation, comprehensive medication reviews, etc.). 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. Antibiotic Utilization Measures (Part C).

CMS is considering possible future reporting on the CMS display page measures focusing on antibiotic prescribing practices related to three of the most common acute respiratory conditions (acute bronchitis, upper respiratory infections, and viral pharyngitis). Expanding antibiotic stewardship in the community is likely one of the most influential ways to battle the untoward effects of widespread antibiotic misuse, including resistance, superinfection, and medication-related adverse effects. Accordingly, APhA urges CMS to consult, incorporate and acknowledge pharmacists when designing and implementing measures and strategies for antibiotic stewardship in outpatient settings, as well as other settings (e.g., hospitals and long-term care settings, etc.). Pharmacists play a unique and essential role in antibiotic stewardship because of their knowledge of antimicrobial therapy, particularly the selection of nonantibiotic symptomatic therapy alternatives, pharmacokinetics and pharmacodynamics, adverse effects, and drug–drug interactions. Pharmacists bring value in the development and implementation of stewardship strategies by counseling, providing educational resources, and tracking, reporting, and assessing the effectiveness of services.

vi. Diabetes Overtreatment (Part C).

APhA is supportive of the development of a new measure for assessing overtreatment. For certain older adults (e.g., those with multiple comorbidities or functional impairment), there is growing recognition that the harms of pursuing intensive A1c targets may outweigh the benefits. For example, the American Diabetes Association recommends relaxing A1c goals for older adults with multiple coexisting chronic illnesses, cognitive impairment, or functional dependence.

¹² Hashimoto, Yasuhiko and Masami Tensho. Effect of pharmacist intervention on physician prescribing in patients with chronic schizophrenia: a descriptive pre/post study. BMC Health Serv Res. 2016; 16: 150. Published online 2016 Apr 26, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4847190/>

F. Innovations in Health Plan Design

i. Part D Enhanced Medication Therapy Management (MTM) Model.

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.¹³ Despite clear evidence supporting the value of pharmacist-led MTM services, these programs continue to be significantly underutilized. While APhA appreciates CMS's ongoing efforts to expand and enhance MTM, including the Part D Enhanced MTM model, we hope that CMS will continue to work collaboratively with pharmacists, plans, and beneficiaries to improve MTM services for greater consistency and uptake and to maximize the services' benefits to both patients and the larger health care system. APhA also encourages CMS to publicly share the progress of the Enhanced MTM program beyond the brief 2017 report on spending thresholds.¹⁴

APhA has also previously expressed 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. Additionally, there is significant plan variability in beneficiary eligibility for MTM services.¹⁵ 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, including pharmacists, which of their beneficiaries are eligible for MTM under a given plan. Furthermore, while eligible beneficiaries qualify for an annual comprehensive medication review, follow-up services to address problems and optimize medications vary greatly in delivery format and frequency. Accordingly, APhA strongly recommends any efforts to measure and improve MTM services address the current barriers to beneficiary access and a comprehensive MTM benefit.

II. Part C

A. Medicare-covered Opioid Treatment Program Services Beginning in CY 2020

As noted in the Call Letter, the *Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Public Law No. 115-271)* establishes opioid use disorder treatment services¹⁶ furnished by Opioid Treatment Programs (OTPs) as a Medicare Part B service beginning in 2020. APhA is a strong proponent of accessible opioid use disorder treatment services because of their proven evidence in patient outcomes. APhA urges CMS to use this law and any regulatory discretion to increase Medicare

¹³ 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>

¹⁴ CMS. Part D Enhanced Medication Therapy Management Model First Year Performance Based Payment Results Fact Sheet. 2017, available at: <https://innovation.cms.gov/Files/x/mtm-firstyrresults-fs.pdf>

¹⁵ 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>

¹⁶ As noted in the Call Letter, “Opioid use disorder treatment services include: FDA-approved opioid agonist and antagonist treatment medications and the dispensing and administration of such medications; substance use counseling; individual and group therapy; toxicology testing; and other items and services that CMS determines appropriate (excluding meals and transportation).”

beneficiaries' access to needed opioid recovery and treatment services by utilizing pharmacists and services within their scope of practice. With nearly 90 percent of Americans living within five miles of a community pharmacy, pharmacists are often an underutilized health care provider.¹⁷

B. Non-Opioid Pain Management Supplemental Benefits

APhA appreciates CMS's efforts to encourage MA organizations to consider Part C benefit designs for supplemental benefits that address medically-approved non-opioid pain management and complementary and integrative treatments. APhA encourages CMS to expand upon the list of examples enumerated in the Call Letter to include pharmacist-provided services which help patients better manage pain or obtain treatment, such as medication management services focused on non-opioid medications.

C. Provider Directories

It is generally recognized in the health care field and verified by industry surveys conducted by credentials verification organizations and other entities that between 20-40 percent of the time provider directories in both the private and public sector are inaccurate or out-of-date. To address this situation, credential verification organizations are attempting to use a variety of strategies, including technological innovations, telephonic interventions, penalties, etc. Pharmacist and pharmacy-specific directories currently suffer from the same shortcomings as physician and other health provider directories with missing, inaccurate or out-of-date data. As pharmacists are being recognized in more and more states as health care providers with expanded scope and authority, the maintenance of accurate directories of pharmacists with accurate information is critical. However, presently pharmacists are facing challenges in effectively documenting and maintaining their professional credentials for use by public and private payer entities.

To address this situation, APhA, through a subsidiary entity Pharmacy Profiles LLC, has launched a nationwide platform designed to securely centralize a database of U.S. pharmacist providers and their advanced credentials. The system is designed to automate the retrieval of professional credentials information on pharmacists, verify that information, and engage pharmacists regularly to keep it up-to-date. Pharmacy Profiles works in collaboration with industry partners to effectively coordinate and share information leveraging and linking to existing databases. The Pharmacy Profiles system intends to enable pharmacists to manage all of their professional information in one place and participate as seamlessly as possible in provider directories going forward. APhA is willing to meet with CMS to further discuss Pharmacy Profiles and its benefits to Medicare and Medicaid.

¹⁷ NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

III. Part D

A. *Improving Access to Opioid-Reversal Agents and Co-Prescribing*

APhA appreciates CMS's recognition of pharmacists' abilities to improve access to naloxone by highlighting, "49 states permit non-patient specific prescriptions through pharmacy standing orders, collaborative practice agreements, or protocol orders to authorize pharmacists to dispense naloxone without a separate prescription written from the provider."¹⁸ While CMS encourages plans to consider innovative approaches to increase co-prescribing, such as patient-specific pharmacy messaging, APhA believes CMS should consider how to better utilize pharmacist services related to naloxone dispensing, such as screening and counseling, as reimbursable services. In addition to prescriber and patient education, APhA notes it would also be beneficial for plans to educate pharmacists regarding naloxone and state-specific authorities.

Currently, when pharmacists co-prescribe naloxone, patients require additional services, such as assessment and in-depth education. While other health care practitioners can bill payers, such as Medicare Part B, for these services as part of the office visit, pharmacists are precluded. Therefore, to help increase access to naloxone, decrease prescription abandonment and increase patient understanding, APhA recommends CMS develop mechanisms to enable pharmacists to bill for services that must be performed when furnishing naloxone for certain high-risk patients.

B. *Formulary and Benefit Designs*

APhA agrees that if CMS wants to improve beneficiary access to naloxone, encouraging plans to cover it at a \$0 or lower cost-sharing will help remove a significant barrier – cost. We are supportive of federal and state efforts to increase patients' access to naloxone.

C. *Access to Medication-Assisted Treatment*

Like CMS, APhA believes Medicare beneficiaries' appropriate access to medication-assisted treatment (MAT) is imperative. APhA appreciates CMS's efforts to stop plans from implementing prior authorization (PA) criteria duplicative of requirements in the FDA Risk Evaluation and Mitigation Strategies (REMS) and Drug Addiction Treatment Act of 2000 (DATA). To discourage plans from developing more stringent prior authorization criteria, APhA recommends CMS clarify its intent to stop PA criteria duplicative of, or more stringent than the requirements of REMS and DATA. APhA believes such clarity will help improve efficiency and minimize practitioners' administrative burdens associated with MAT. Further, by reducing such burdens, health care practitioners may be more willing to provide MAT, including related services.

In the Call Letter, CMS acknowledges that additional requirements (REMS and DATA waiver) must be fulfilled when providing MAT. However, these requirements tend to be

¹⁸ See, SAMHSA. Preventing the Consequences of Opioid Overdose: Understanding Naloxone Access Laws. Developed under the Substance Abuse and Mental Health Services Administration's Center for the Application of Prevention Technologies task order. Reference #HHSS283201200024I/HHSS28342002T. For training use only. January 20, 2018, available at: <https://www.samhsa.gov/capt/sites/default/files/resources/naloxone-access-laws-tool.pdf>.

associated with the regulatory or legal components of prescribing and dispensing of MAT products (e.g., buprenorphine), as opposed to the patient care services which are also part of MAT. APhA urges CMS to encourage plans to cover MAT-related services provided by pharmacists in community and other out-patient settings. APhA believes such coverage would significantly improve patient access to MAT, especially where pharmacists operating under collaborative practice agreements or statewide protocols have authority to provide a broader array of MAT services but are inaccessible to patients due to coverage barriers.

D. Medication Therapy Management (MTM)-Annual Eligibility Threshold

As APhA has stated previously, we strongly encourage CMS to revisit the cost threshold, as the current \$4,044 threshold excludes many beneficiaries with complex conditions, but smaller drug spends, who could benefit from MTM services.

E. Comprehensive Medication Review Summary Standardized Format

CMS is proposing “...revisions to the standardized format with the intent of optimizing the utility of the CMR summary for beneficiaries while reducing burden on Part D sponsors. The revised format will be available for public comment through the PRA process before submission to OMB for approval in 2020.” APhA strongly supports revisions to the standardized format so it is more user friendly for the beneficiary and the pharmacists providing the service and look forward to the release of the revised format for public comment. Additionally, the revisions should provide flexibilities in how the standardized format can be delivered to beneficiaries.

F. Improving Access to Part D Vaccines

APhA is pleased the Call Letter continues to include language encouraging Part D plans to offer vaccines in the \$0 vaccine tier or to place vaccines on a formulary tier with low cost-sharing. We share CMS’s concern that vaccination rates remain low for tetanus and diphtheria with acellular pertussis (Tdap), and that approximately 70% of adults for whom the herpes zoster vaccine is recommended remain unprotected. A 2016 report by Avalere Health found between 47 and 72 percent of the 24 million Medicare beneficiaries with Part D coverage had some level of cost sharing for vaccines, ranging from \$35 to \$70 in 2015.¹⁹ The variable cost sharing requirements currently imposed on the majority of Part D vaccines discourage immunization among elderly, disabled and chronically ill populations who account for a disproportionate percentage of the morbidity and mortality from vaccine preventable conditions. Removing this financial barrier could have a significant impact on improving beneficiary access to and utilization of vaccines and will also help drive reductions in hospitalizations and avoidable medical expenditures in other parts of the Medicare program. 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 CDC’s Advisory Committee on Immunization Practices (ACIP). Therefore, CMS should

¹⁹ Pearson, Caroline. Et. al. Medicare Has the Potential to Avoid Preventable Illnesses by Encouraging Broader Coverage for Adult Vaccines. February 18, 2016, available at: <http://avalere.com/expertise/managed-care/insights/medicare-has-the-potential-to-avoid-preventable-illnesses-by-encouraging-br>

encourage plans to recognize and compensate / reimburse pharmacists as they do physicians and other immunization providers and maximize the inclusion of pharmacists as in-network clinicians providing vaccines in accordance with the National Vaccine Advisory Committee (NVAC) Adult Immunization Standards, ACIP recommendations, and as authorized under state practice acts. Additionally, as mentioned previously, APhA urges CMS to aggregate data from MA-PD and Part D plan sponsors to better monitor, measure and attribute the impact different providers, including pharmacists, have on vaccination rates of Medicare beneficiaries.

G. Improving Access to Generic and Biosimilar Medicines

APhA appreciates CMS's deliberation of effective formulary policies to encourage use of the lowest-cost preferred therapeutic option such as generic and biosimilar medicines. In evaluating policy options related to biosimilars, APhA notes the variable state laws regarding the pharmacists' ability to substitute interchangeable biosimilar products even though there has yet to be an interchangeable biosimilar approved by the FDA. APhA encourages CMS and plans provide additional education and resources to health care practitioners to make them aware of its policy changes and steps to ease any access barriers.

In addition, APhA notes, at times, the pharmacy may spend more money to acquire the medication than the reimbursement amount provided through Medicare. As CMS moves forward in lowering drug costs by improving access to generic and biosimilar medicines, APhA encourages CMS to consider how pharmacy reimbursement, acquisition costs and costs associated with additional services related to dispensing are impacted by such policies. Moreover, it is critical for CMS to consider separately the cost of the product from any associated service.

CMS is also considering discouraging or prohibiting plan sponsors from placing generics and/ or biosimilars on brand formulary tiers and brand drugs on a generic formulary tier and eliminating the non-preferred drug tier. CMS data reveals "[i]n 2011, 71% of generic drugs were placed on tier 1, the lowest tier in the formulary. By 2015, 19% of covered generics were placed on tier 1, while 46% were placed on tier 2 and 35% were placed on tier 3 or higher."²⁰ This shift represents a 52-percentage point decrease in the number of generics being placed on the lowest tier between 2011 and 2015. New analysis shows the introduction of the "non-preferred drug" tier in 2017 led to the percentage of covered generics on that tier increasing from 18 percent in 2016 to 25 percent in 2019, a 7-percentage-point increase.²¹ Accordingly, APhA urges CMS to analyze whether issuers' placement of generics on higher cost sharing tiers affects patient access to necessary medications and publicly share plans' justifications for such actions. Unfortunately, recently, pharmacists and patients have also experienced large increases in the cost of generics in the marketplace. These price spikes negatively impact patient access and, in some cases, patient adherence and thus, patients' health outcomes. APhA appreciates any steps CMS can take to increase transparency regarding generic pricing and out-of-pocket cost to patients.

²⁰ Avalere Health. Seniors Pay More for Medicare Part D Generics Despite Stable Prices. Press Release. May 22, 2018, available at: <https://avalere.com/press-releases/seniors-pay-more-for-generics-in-medicare-prescription-drug-plans-despite-stable-prices>

²¹ Avalere Health. Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs. February 2019, available at: <https://avalere.com/wp-content/uploads/2019/02/20190228-White-Paper-Part-D-Generic-Tiering.pdf>

H. Improving Drug Utilization Review Controls in Medicare Part D

i. Medicare Part D Opioid Overutilization Policy.

APhA appreciates CMS's decision not to implement new opioid safety edits for 2020 and encourages CMS to carefully evaluate the impact, including any unintended consequences, of current edits on prescribers' and pharmacists' workflow, and most importantly, on patients. For example, APhA believes CMS should consider whether the safety edits, such as the opioid care coordination edit, meaningfully improve care coordination and patient treatment plans, and the amount of time devoted to resolving such measures to obtain improvements. In addition, we encourage CMS to also use metrics beyond patients' MME to determine the effectiveness of the safety edits.

APhA appreciates the recommendation to include a threshold of two or more opioid prescribers in these edit specifications as we believe this will help reduce the frequency of alerts and better focus communications between pharmacists and prescribers, until the effectiveness of these alerts can be evaluated. However, APhA wants to emphasize the difficulties pharmacists experience when trying to override safety alerts, particularly the new opioid care coordination alert. APhA believes the logic underpinning these safety alerts improperly presume pharmacists and prescribers can easily communicate in real time. CMS may not fully appreciate the barriers that exist when pharmacists, particularly community pharmacists, try to obtain the needed information from prescribers to make a clinical decision regarding the safety alert in a timely manner. Such communications are made even more difficult when patients attempt to fill medications outside of prescriber office hours and because pharmacists often lack access to patients' electronic health records (EHRs). While APhA supports clinically meaningful prescriber-pharmacist communications to improve patient care and safety, we are sensitive to both the workflows and workload of prescribers and pharmacists. Given breadth of these ad hoc safety alerts and wide range of patients impacted, APhA is concerned the requirements to override edits do not sufficiently recognize the current health care environment and delay patient access to medications. APhA encourages CMS to consider how opioid overutilization policies can be made more flexible to help pharmacists, patients and prescribers overcome these barriers while maintaining patient safety.

ii. Drug Management Programs.

Consistent with our previous comments, APhA urges CMS to monitor the impact of drug management programs (DMPs) on patients. Failure to capture and address unintended consequences of DMPs, such as out-of-pocket opioid purchases by patients, will result in skewed quality measure results and negatively-impacted patient care, among other concerns. As DMPs are currently being voluntarily implemented, APhA believes CMS can learn from these experiences and consider mechanisms to improve DMPs before plans are required to have them pursuant to the *SUPPORT for Patients and Communities Act*.

I. New Draft 2020 Call Letter Proposals to Address the Opioid Epidemic

Please, refer to our comments in the Improving Access to Opioid-Reversal Agents section, under Part D; Non-Opioid Pain Management Supplemental Benefits section, under Part C; and Enhancements to the 2020 Part C & D Star Ratings and Future Measurement Concepts, under Parts C & D.

J. Future Changes to the Overutilization Monitoring System (OMS) Criteria

APhA urges CMS to prioritize studying the impact and effectiveness of current OMS policies before seeking methods to expand the OMS criteria to identify potential at-risk beneficiaries. As noted above, APhA is concerned well-intentioned policies to curb the opioid epidemic may have unintended consequences that negatively impact patient care, including access to opioids by patients with legitimate needs and placing patients who are dependent, not addicted, into inappropriate withdrawal from the medication. In addition, prior to developing future policies, CMS should analyze the results from the significant efforts underway to address the opioid epidemic. Should CMS offer any new changes, APhA recommends those changes be proposed to stakeholders with ample opportunity to provide feedback before any new requirements are implemented.

K. Opioid Potentiator Drugs

APhA recognizes concurrent use of some medications with opioids can pose risks to patients, including those between opioids and “potentiator” drugs, such as gabapentin and pregabalin. In addition, our members indicated that alerts can be helpful, but that it is important to be mindful of the quantity of alerts received in the pharmacy. While CMS seeks to enhance the OMS by adding additional flags for potentiator drugs, APhA recommends CMS develop a framework to identify potentiator drugs or clarify how the Office of the Inspector General is identifying these medications as potentiator drugs. APhA believes it is important for causation, not just correlation, to be considered when identifying potentiator drugs.

However, APhA does recognize patients prescribed opioids and certain other medications may be vulnerable to additional risks. APhA applauds CMS for recognizing the importance of offering MTM services to beneficiaries who are at risk of adverse events due to opioid overutilization or opioid users who are also taking potentiator drugs. APhA agrees these beneficiaries may benefit from MTM services including a CMR, targeted medication reviews, and interventions with their prescribers. In addition, APhA recommends that CMS consider requiring appropriate follow-up services as part of the MTM service for beneficiaries. Beneficiaries may need more rigorous monitoring than is currently being delivered, especially in those prescription drug plans (PDPs) using the minimum quarterly targeted review as the design for their MTM program. APhA encourages CMS to clarify plan coverage of MTM services provided by pharmacists, including community pharmacists, and for plans to provide and make clear patient eligibility for MTM services and additional coverage details (e.g., what codes to use and how to submit the claim).

L. Part D Mail Order Auto-Ship Modifications

CMS is proposing, starting in 2020, to permit interested Part D sponsors to offer an opt-in voluntary auto-ship program for refills of established therapies that a beneficiary has been on for at least 4 consecutive months. CMS expects sponsors implementing an auto-ship program for refills of established therapies will include no less than two shipping reminders prior to sending. The Call Letter states “CMS is not recommending a specific method for how the pharmacy provides the two reminders but recognizes that such notification could be achieved by phone, email, text, direct mailing, or other comparable means of communication (including in an alternative language if needed) and should be based on the beneficiary’s stated preference.” APhA recommends CMS clarify this policy further prior to considering implementation in order to receive appropriate feedback.

While APhA believes current consent forms and procedures for auto-ship are cumbersome and difficult for patients to fully comprehend, more clarity is needed with regard to how or who is responsible for obtaining consent and whether the notice procedures contained in the Call Letter are sufficient. In addition, we are concerned the term “opt-in voluntary auto-ship program” is misleading as it appears the patient does not participate voluntarily nor do they need to “opt-in,” but rather the plan can enroll the beneficiary in auto-shipment without any action by the beneficiary. Further, there are laws and safety issues preventing the return and reuse of medication. Accordingly, if CMS goes forward with this program, APhA urges the agency to provide reimbursement to pharmacies following this policy and its processes for any actual cost associated with the shipped/ returned product as well as the resources associated with processing and disposing of the returned product by beneficiaries.

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,



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