



March 6, 2020

[Submitted electronically to [www.regulations.gov](http://www.regulations.gov)]

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

**Re: Advance Notice of Methodological Changes for Calendar Year 2021 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and Payment Policies – Part II - Draft Call Letter (Docket Number: CMS-2020-0003)**

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”) 2021 for Medicare Advantage (“MA”) Capitation Rates, Part C and Part D Payment Policies – Part II (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, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

**I. General Comments**

*A. Require Plans to Share Price Concessions with Patients*

The annual Call Letter sets forth changes in Medicare payment methodology for Part D/ MA plans as well as benefit parameters for the defined standard benefit received by Part D plan beneficiaries. In short, it is annual information used for plan sponsors to submit bids to participate under the Part D and MA-PD programs. Historically, CMS has utilized the Call Letter to incorporate a number of policy changes into Part D sponsor contracts. Recently, HHS has clearly emphasized in both the Office of Inspector General (“OIG”) <sup>1</sup> and CMS proposed rules<sup>2</sup>,

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<sup>1</sup> CMS. Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. Proposed Rule. February 2, 2019, available at: <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>

<sup>2</sup> CMS. Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. Proposed Rule. November 30, 2018, available at: <https://www.regulations.gov/document?D=CMS-2018-0149-0002>

that direct and indirect remuneration (“DIR”) fees and other retractive fees utilized by PBMs are now being used beyond their original purpose to retroactively adjust pharmacies’ payment months after the sale, sometimes below the price paid by the pharmacy. As a stark example, CMS pointed out the alarming 45,000 percent increase in pharmacy price concessions (i.e., DIR fees) between 2010-2017,<sup>3</sup> an increase that is unsustainable for pharmacies, patients and Medicare. Therefore, pursuant to CMS’ statutory authority, APhA reiterates our strong support for HHS to implement the proposed rules by both OIG and CMS in the final Call Letter and accompanying Part D rule to require Part D plan sponsors to eliminate DIR and give these discounts to patients.

*B. Fix DIR Before Developing Pharmacy Performance Measures/ Determining Applicability to Star Metrics*

CMS codified information collection requirements for Part D sponsors in regulation at §423.514. In the accompanying Part D proposed rule to the Call Letter, CMS is utilizing this authority to amend the regulatory language at § 423.514(a) to establish a requirement for Part D sponsors to disclose to CMS the “pharmacy performance measures” they use. APhA strongly supports this proposal. We also appreciate CMS encouraging “...industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency and fairness.” APhA agrees with CMS that “[c]ollecting pharmacy performance measures used to determine whether a financial reward or penalty is incurred by a pharmacy after the point-of-sale (POS) will enable CMS at a minimum to better understand the extent to which the measures are applied, whether it be uniformly or specific to pharmacy type. This effort may also explain if there is a pharmacy performance problem, as pharmacy price concessions (financial penalties incurred) after the POS have continued to grow annually. Knowledge of the industry’s pharmacy performance measures would also provide transparency to the process and likely confirm or dispel the idea that many of the measures may not provide appropriate metrics across all types of pharmacies.” We also strongly support publishing the list of pharmacy performance measures to increase public transparency. We also agree this information is essential due to “...the growing use of pharmacy performance measures in determining the final cost of a drug under Part D and the impact of these recoupment practices on the amount a beneficiary pays for a Part D drug at the POS is essential “...if there is to be predictable reimbursement for pharmacies and cost sharing for beneficiaries.” Thus, it is imperative that CMS first fix the growing and runaway misuse of price concessions (i.e., DIR fees) in the Call Letter before developing pharmacy performance measures in the accompanying Part D proposed rule. APhA also appreciates CMS soliciting “...comment on the principles that Part D pharmacy performance measures should adhere to, including potential burden or hardship of performance measures on small, independent, and/or rural pharmacies, and recommendations for potential Part D Star Ratings metrics related to these measures.”<sup>4</sup> Once DIR has been fixed, APhA looks forward to working with other stakeholders to determine a standard set of pharmacy performance reporting measures and their applicability to Part D Star metrics.

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<sup>3</sup> 83 Fed. Reg. 62,174 (Nov. 30, 2018).

<sup>4</sup> CMS. Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly. Proposed Rule. February 18, 2020, available at: <https://www.federalregister.gov/documents/2020/02/18/2020-02085/medicare-and-medicaid-programs-contract-year-2021-and-2022-policy-and-technical-changes-to-the>

APhA also continues to remind HHS when developing “pharmacy performance measures,” to separately consider the reimbursement of the product, which is fixed for pharmacists, from the cost of dispensing and any related patient care service or performance incentive payment. To maintain beneficiary access to medications, it’s essential to provide adequate reimbursement under a sustainable business model that improves and does not disrupt our nation’s medication distribution system. Unfortunately, the current system still fails to provide coverage for the true cost of the medication and any payment for pharmacists to provide needed patient care services.

## **II. Section F. Dispensing Fees and Vaccine Administration Fees for Applicable Drugs (Pgs. 50-51)**

In the Call Letter, CMS restates its policy for liability for dispensing and vaccine administration fees, as described in the Announcement of the CY 2013 MA, Capitation Rates and MA and Part D Payment Policies and Final Call Letter. However, the Call Letter does not recognize CMS has also identified a misvaluation of the code (CPT code 96372) associated with vaccine administration reimbursement in the 2020 physician fee schedule (“PFS”) final rule<sup>5</sup> to physicians and other practitioners, such as pharmacists, for provision of the immunization administration. This threatens access to vaccinations, particularly in rural and medically underserved areas. In the PFS final rule, CMS stated “[w]e recognize that it is in the public interest to ensure appropriate payment to physicians and other practitioners for provision of the immunization administration services that are used to deliver vaccines and plan to review the valuations for these services to ensure appropriate payment.” CMS decided to maintain the CY 2019 national payment amount for immunization administration services for CY 2020 while preparing a longer-term correction. As such, APhA urges CMS to restore reimbursement rates from Part D sponsors for the CPT codes for vaccine administration to the 2017 (Practice Expense (PE) Relative Value Unit (RVU) of .54)<sup>6</sup> in the final Call Letter to ensure reimbursement accounts for the cost of the service and continues to encourage providers to offer Medicare beneficiaries Centers for Disease Control (“CDC”) Advisory Committee on Immunization Practices (“ACIP”)-recommended immunizations at the clinical point-of-care.

In the 2020 Medicare Advantage and Part D Rate Announcement and Final Call Letter CMS also recognized that CDC found that vaccination rates remain low for tetanus and diphtheria (Td) and tetanus and diphtheria with acellular pertussis (Tdap) for adults age 65 and

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<sup>5</sup> CMS, .Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements. Final Rule. November 15, 2019, available at: <https://www.federalregister.gov/documents/2019/11/15/2019-24086/medicare-program-cy-2020-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other> - which found “while we did not make any specific proposals in the CY 2020 PFS proposed rule to change payment for these administration services, we did receive comments noting a decrease in payment for these services. These comments noted the linked crosswalk between CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug) subcutaneous or intramuscular) and a number of the immunization services, and the impact that a proposed reduction to 96372 would have on payment for some practices that offer immunization services. We recognize that it is in the public interest to ensure appropriate payment to physicians and other practitioners for provision of the immunization administration services that are used to deliver vaccines and plan to review the valuations for these services to ensure appropriate payment. In the interim, given our concern about public access to vaccines and in light of recent public health events, we are maintaining the CY 2019 national payment amount for immunization administration services for CY 2020.”

<sup>6</sup> See, CMS, Addendum B – Relative Value Units and Related Information Used in CY 2020 Proposed Rule. August 14, 2019, available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-P.html> - which proposed a PE RVU of .22, representing a 44% decrease from 2017, when this service was paid at \$25.84 (PE RVU of .54). A review of the practice expense cost files does not support this reduction. Practice expense costs were unchanged in 2018 and increased in both 2019 and 2020. In addition, there is no evidence of decreases in any cost component.

older, at 58% and 20% respectively.<sup>7</sup> The 2020 Final Call Letter also cites a 2018 study of Tdap and herpes zoster vaccine claims in Part D that demonstrated higher out-of-pocket cost-sharing was associated with higher rates of cancelled vaccination claims, suggesting vaccination was abandoned. In this study, cost-sharing of \$51 or greater was associated with a 2 to 2.7-times greater rate of cancellation.<sup>8</sup> Addressing cost-sharing and reimbursement issues with Part D vaccines is critical to ensuring that Medicare beneficiaries have access to vaccines that have the potential to prevent serious disease. To help in addressing current low vaccination rates, APhA strongly urges CMS to require Part D sponsors to offer a \$0 vaccine tier in the 2021 final Call Letter. 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. As CMS understands, 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 ACIP. As a reminder, ACIP and CDC “...defines a health care provider as anyone who provides or administers vaccines: primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists.”<sup>9</sup> Therefore, CMS should 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, APhA urges CMS to require Part D sponsors to submit and 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.

### **III. 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 2021.

#### *A. Changes to Existing Star Ratings and Display Measures:*

##### **i. Improvement measures (Part C & D)- Table 1: 2021 Star Ratings Improvement Measures (Pgs. 59-60)**

###### **a. Annual Flu Vaccine Process Measure C (1).**

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<sup>7</sup> Available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf>

<sup>8</sup> Yan, S., DerSarkissian, M., Bhak, R.H., Lefebvre, P., Duh, M.S., & Krishnarajah, G. (2018) Relationship between patient copayments in Medicare Part D and vaccination claim status for herpes zoster and tetanus-diphtheria acellular pertussis, *Current Medical Research and Opinion*, 34:7, 1261-1269, DOI: 10.1080/03007995.2017.1416347, available at: <https://www.tandfonline.com/doi/full/10.1080/03007995.2017.1416347>

<sup>9</sup> CDC. ACIP Shared Clinical Decision-Making Recommendations. Frequently Asked Questions. Last reviewed: February 10, 2020, available at: <https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html>

APhA supports continuing to include the annual flu vaccine in the 2021 Star Ratings for Part C plans. According to the CDC, a 6.2 percent reduction in the adult immunization/vaccination rate for flu during the 2018-19 influenza season was a contributing factor in the record number of deaths.<sup>10</sup> In the 2018-2019 season, CDC estimated that increasing coverage by five percentage points could have prevented another 4,000 to 11,000 hospitalizations, depending on the severity of the season.<sup>11</sup> Thanks to changes in state laws, pharmacists are playing an critical role in increasing influenza-vaccination rates across the United States, with an additional 4.1 million additional adults vaccinated in 2013 because states authorized 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.<sup>12</sup> APhA also supports and urges CMS to seriously consider the future addition of an adult immunization status (“AIS”) composite measure on the display page and as a Star Ratings measure. The National Committee for Quality Assurance (“NCQA”) added the adult composite measure to their 2019 Healthcare Effectiveness Data Information Set (“HEDIS”) using the Electronic Clinical Data System (“ECDS”) reporting domain. In addition, as stated above, APhA urges CMS to use the final Call Letter to require data from MA-PD and attribute the impact different providers, including pharmacists, have on vaccination rates of Medicare beneficiaries.

b. Getting Needed Prescription Drugs D (1.5) (Consumer Assessment of Healthcare Providers & Systems (“CAHPS”) patient experience survey measure)

APhA appreciates CMS recognizing the importance of patient access to medications and supports continuing 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. APhA urges CMS to modify this CAHPS measure to attribute the impact pharmacists have on Medicare beneficiaries getting access to their prescription drugs.

ii. Controlling High Blood Pressure (Part C) (Pg. 68)

APhA appreciates and supports CMS and NCQA looking at providing a minimum six-month window for interventions that might assist in bringing beneficiaries’ blood pressure under control. However, APhA emphasizes that such measures should also acknowledge and attribute the contributions of pharmacists helping to reduce patients’ high blood pressure as part of primary care teams. For example, we encourage CMS to reference the 2012 Hypertension Control Champions, Kaiser Permanente Colorado and Ellsworth Medical Clinic of western Wisconsin, who were announced by the Million Hearts campaign, which is co-led by CMS and CDC working alongside other areas of HHS and the U.S. Department of Veterans Affairs. APhA and the APhA Foundation are active partners in the Million Hearts campaign to prevent 1 million

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<sup>10</sup> 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>

<sup>11</sup> CDC. Flu Vaccination Coverage, United States, 2018–19 Influenza Season. Last Reviewed: September 26, 2019, available at: <https://www.cdc.gov/flu/fluview/coverage-1819estimates.htm>

<sup>12</sup> 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>

heart attacks and strokes. Both Kaiser Permanente’s and Ellsworth Medical Clinic’s health care providers relied upon pharmacists to help achieve hypertension control rates of more than 80% among their patients with high blood pressure.<sup>13</sup> We also urge CMS and NCQA to work with pharmacists and other stakeholders on the National Hypertension Control Roundtable (“NHCR”)<sup>14</sup> to improve national hypertension control rates in any updated Star Ratings and display measures for MA-PD plans.

iii. Transitions of Care (Part C). (Pg. 69)

For the Transitions of Care measure, NCQA proposes to revise the requirement of using one medical record from a specific provider to, instead, allow numerator information to be captured from “the outpatient medical record as well as other information accessible to the primary care provider (PCP) or ongoing care provider.” This change is intended to help the specification capture additional communication forms (e.g., admissions, discharges, and transfers (“ADT”) feeds, shared electronic medical records (“EMRs”)) that occur regularly in the field and meet the intent of the measure. The change attempts to ensure that scores for the measure and the standalone Medication Reconciliation Post-Discharge (“MRP”) measure would match. Pharmacists are often the first health care practitioner patients encounter post-discharge and the provider generally responsible for coordinating medication-related information between the hospital and primary care and specialist physicians. Patients could benefit greatly if data from pharmacies was better included in the data capture of patients transitioning from an inpatient setting to home. Yet, pharmacy data is not accounted for in this measure and is 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. Accordingly, if pharmacists had access to relevant information in the patients’ record, including discharge information, pharmacists could have a more effective role in helping patients transition between care settings. Pharmacists’ services should also be attributed and captured under an updated version of this measure. Accordingly, APhA requests CMS clarify for MA-PD plans in the final Call Letter how the efforts of pharmacists in community pharmacies in delivering medication reconciliation services would be captured in calculating this measure.

iv. Patient-Used Device Data for HEDIS (Part C). (Pg. 69)

APhA appreciates that NCQA is continuing to add additional sources of data to meet the numerator requirements of their HEDIS measures. One HEDIS advancement is incorporating data from patient-used devices. The Call Letter states “[f]or example, for the Controlling High Blood Pressure measure, readings are allowed from home blood pressure machines (which digitally store and transfer data on patient’s blood pressure) to be used to fulfill the numerator of the measure.” A 2013 study of 450 people with high blood pressure at eight different health clinics found that 72 percent of patients who received pharmacist-guided home blood pressure monitoring had their high blood pressure under control compared to 45 percent of the normal care group.<sup>15</sup> Home monitoring and pharmacist managements are two powerful interventions to

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<sup>13</sup> <https://www.pharmacist.com/pharmacists-team-hypertension-control>; <https://www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdf>

<sup>14</sup> <https://www.cdc.gov/dhdsp/programs/hypertension-roundtable.htm>

<sup>15</sup> Marqolis, KL. Et. al. Effect of home blood pressure telemonitoring and pharmacist management on blood pressure control: a cluster randomized clinical trial. JAMA. 2013 Jul 3;310(1):46-56. doi: 10.1001/jama.2013.6549, available at: <https://www.ncbi.nlm.nih.gov/pubmed/23821088>

control high blood pressure. As such, APhA encourages CMS and NCQA to work together to better incorporate data from pharmacist-provided patient care services in HEDIS measures with the wider use of other technologies that facilitate the incorporation of patient data into clinical data repositories in the future.

- v. Concurrent Use of Opioids and Benzodiazepines (COB), Use of Opioids at High Dosage in Persons Without Cancer (OHD), Use of Opioids from Multiple Providers in Persons Without Cancer (OMP), and Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer (OHDMP) (Part D) (Pg. 71).

APhA supports CMS implementing the sickle cell disease exclusion added to the Pharmacy Quality Alliance (“PQA”) opioid measures. This change reflects the recommendations in the CDC Guideline for Prescribing Opioids for Chronic Pain.<sup>16</sup> Researchers supported by the National Heart, Lung, Blood Institute (“NHLBI”) ultimately want to find a widely available cure for sickle cell disease, which would eliminate not just the pain, but the disease itself. In the meantime, NHLBI researchers state it is critical to find relief for the many patients who suffer untenable pain on a daily basis. We continue to support efforts refining these measures using the best available scientific evidence as CMS implements these revisions. However, APhA also strongly recommends CMS monitor these measures for any negative and unintended consequences to patients, such as lack of access to necessary medications.

- vi. Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D). (Pg. 72)

APhA supports CMS considering implementation of PQA’s sociodemographic status (“SDS”) risk adjustment recommendations for the 2022 measurement year/ beyond for PQA’s three adherence measures used in the Part D Star Ratings. We agree the measure rates should be risk adjusted for SDS characteristics to adequately reflect differences in patient populations; adjusted for the following beneficiary-level SDS characteristics: age, gender, dual eligibility/Low-Income Subsidy (LIS) status, and disability status; and stratified by the beneficiary-level SDS characteristics to allow health plans to identify disparities and understand how their patient population mix is affecting their measure rates.

#### *B. Potential New Measure Concepts*

- i. Prior Authorizations (Part C). (Pg. 73)

In the Call Letter, “CMS recognizes that when processes are not in place to quickly review and approve requests for tests, services and supplies that may be medically necessary for the beneficiary, this can affect access to needed patient care.” Accordingly, APhA appreciates that CMS is working to develop a measure for the display page related to prior authorizations

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<sup>16</sup> CDC. CDC Guideline for Prescribing Opioids for Chronic Pain. Last Reviewed August 28, 2019, available at: <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>

and consideration for potential future Star Ratings that could assess the performance of plans related to how well they administer and automate electronic prior authorizations.

As CMS moves forward with this effort, APhA encourages consideration of prior authorization measurement for the Part D program. Areas of focus could be beneficiary access time for medications requiring prior authorization and medication abandonment due to prior authorization delays. In addition, APhA encourages CMS to measure provider, including pharmacist, administrative burden from prior authorization processes in Part C and Part D when evaluating prior authorization programs for effectiveness and efficiencies.

ii. Cardiac Rehabilitation (Part C). (Pg. 74)

As a member of the Million Hearts Campaign, APhA supports the proposed development of a plan-level HEDIS measure based on the American College of Cardiology (“ACP”) / American Heart Association (“AHA”) claims-based quality measure for cardiac rehabilitation participation in HEDIS for the 2020 measurement year.

iii. Diabetes Overtreatment (Part C). (Pg. 75)

APhA is supportive of CMS’ interest in a new measure assessing diabetes overtreatment in patients with Type II diabetes and NCQA’s work on a measure that, depending on development timeline, could be implemented in HEDIS in 2021. 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.

Two measure concepts are under consideration, one that “assesses whether clinically complex members with type 2 diabetes are being overtreated (as defined by A1C level and medications),” and another “outcome measure that focuses on the identification of hospitalizations, emergency department visits, and observation stays among diabetic adults due to hypoglycemia as an alternative way to assess diabetes overtreatment.” APhA supports examination of a measure focused on hospitalizations, emergency department visits, etc. due to hypoglycemia. It is important to deprescribe agents in people with type 2 diabetes who are at risk of hypoglycemia, such as those taking insulin.

For the measure using A1C and the number of medications as a marker for over-treatment, APhA recommends clarifying if an age restriction is being considered in the development of the measure or if the measure is for all persons with type II diabetes 65 years and older. The older patients with diabetes become, they should have more screening for hypoglycemia and medication-polypharmacy as stated in the 2020 ADA Standards for diabetes care. Another important consideration is that medications such as GLP-1 agonists and SGLT2 inhibitors have many cardiovascular benefits and are now encouraged to be used in patients with cardiovascular disease (“CVD”) even if A1C is already at target. A 66-year-old patient with CVD taking metformin, a GLP-1 agonist, and SGLT2 inhibitor with A1C of 6.5% may not be a good candidate for a measure focused on diabetes overtreatment based on A1C and number of medications. Finally, consideration of a measure that includes the use of continuous glucose

monitoring (“CGM”) to track “time in range” could be a more effective mechanism to measure diabetes control. Because of the individualized nature of effective diabetes management, it will be important to consider these factors and others in developing any measure of diabetes overtreatment.

iv. Generic Utilization (Part D). (Pgs. 75-76)

APhA supports CMS in determining whether and how measures of generic and biosimilar utilization in Medicare Part D could help achieve goals related to prescription drug costs and patient access. However, generic utilization is a complex issue with a variety of factors that could impact any potential measures’ feasibility or lead to unintended consequences. For example, a 2016 Government Accountability Report (“GAO”) looked at nearly 1,400 “established” generic drugs covered by Medicare Part D and found that overall prices declined between 2010 and 2015, but that more than 300 of them had at least one “extraordinary” price increase (meaning an increase of 100 percent or more).<sup>17</sup> Therefore, APhA recommends CMS delay measure development and work with an experienced, multi-stakeholder and consensus-based organization to study and evaluate the role of formularies, plan designs, rebates and state substitution rules (among other factors) as well as the role of the physician-pharmacist-patient relationship to help determine the most effective measures.

v. Initial Opioid Prescribing (IOP) Measures (Part D). (Pgs. 76-78)

APhA generally supports CMS’ plans to begin reporting the Initial Opioid Prescribing for Long Duration (“IOP-LD”) measure in the Patient Safety reports for the 2020 measurement year. As CMS considers this measure for the display page for 2023 and 2024, and potentially the Star Ratings in the future, APhA recommends that CMS continue to monitor this measure for any negative and unintended consequences to patients, such as lack of access to necessary medications.

Thank you for the opportunity to provide comments on the draft Call Letter. We support CMS’ ongoing efforts to continue to improve Medicare’s prescription drug programs (Parts C and D) 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](mailto:mbaxter@aphanet.org) or by phone at (202) 429-7538.

Sincerely,



Ilisa BG Bernstein, PharmD, JD  
Senior Vice President, Pharmacy Practice and Government Affairs

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<sup>17</sup> GAO. Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases. GAO-16-706: Published: Aug 12, 2016, available at: <https://www.gao.gov/products/GAO-16-706>

cc: Demetrios Kouzoukas, Principal Deputy Administrator & Director of the Center for Medicare, CMS