APhA
American Pharmacists Association

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[Submitted electronically via regulations.gov]

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Director, Center for Medicare
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) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (CMS-2022-0021)

Dear. Dr. Seshamani:

The American Pharmacists Association (APhA) is pleased to submit our comments on the Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

APhA is the only organization advancing the entire pharmacy profession. As the voice of pharmacy, APhA leads the profession and equips members for their role as the medication expert in team-based, patient-centered care. APhA inspires, innovates, and creates opportunities for members and pharmacists worldwide to optimize medication use and health for all. Our expert staff, and strong volunteer leadership, including many experienced pharmacists, allow us to deliver vital leadership to help pharmacists, pharmaceutical scientists, student pharmacists and pharmacy technicians find success and satisfaction in their work, while advocating for changes that benefit them, their patients and their communities.

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CMS Needs to Update the Payment Methodology from MA and Part D Plans to Cover the Necessary Costs for Pharmacy Dispensing of COVID-19 Oral Antivirals

The Advance Notice provides updates for changes in, and adoption of, payment and risk adjustment policies for MA and Part D plan payment policies.

CMS must use this opportunity to take immediate action to require MA, MA-PD and Part D plans provide adequate and appropriate pharmacists' payment for all pharmacy dispensing costs for COVID-19 oral antivirals to ensure success of the significant investment the government has made in purchasing these products for U.S. patients.

MA and Part D health plans and PBMs have set pharmacist dispensing fees for COVID-19 oral antivirals as low as $1.00, far below pharmacies' necessary costs to conduct patient safety checks to dispense these lifesaving medications—a process that can take up to one hour (average time of 15 minutes, up to 60 minutes for patients with complex medication regimens and conditions).

In November, APhA warned[1] that CMS' decision to only "encourage"[2] but not require payment of additional pharmacist costs necessary for dispensing oral COVID-19 antiviral drugs would set up the distribution program for failure. As a result, health plans and PBMs have rushed to the bottom for reimbursement below dispensing costs and unnecessarily forced many pharmacies to choose not to participate in the dispensing of these medications.

CMS needs to finalize an Announcement that clearly requires MA, MA-PD and Part D plans to cover the full costs necessary to ensure patient safety for pharmacists' dispensing of COVID-19 oral antivirals.

The federal government has made it clear we need all-hands-on-deck to defeat COVID-19 and advance health equity by very clearly authorizing pharmacists to order and administer select COVID-19 therapeutics under the Ninth Amendment to the

[1] https://pharmacist.com/APhA-Press-Releases/pharmacy-groups-cms-guidance-sets-up-oral-antivirals-for-failure-limiting-patients-access-to-covid-19-treatments
[2] https://www.cms.gov/files/document/oralantiviralguidance11232021.pdf

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Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19.[3]

Without hesitation, throughout the pandemic, our nation's frontline pharmacists have stepped up to meet the public health needs of our patients. CMS must act, now, to ensure MA, MA-PD and Part D plans do not prevent these medications from reaching patients immediately to save lives and preserve precious health care resources for patients with more severe infections.

2023 Star Ratings Improvement 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 measures in CY 2023.

There are a number of measures on the Part C and Part D Star Ratings list that pharmacists can meaningfully impact. APhA offers specific comments on the following measures included in the calculation for the 2023 improvement measures in the table below, excerpted from Table IV-1:

Part	Measure	Measure Type	Weight	Improvement Measure	APhA Comments
C	Annual Flu Vaccine	Process Measure	1	Yes	APhA urges CMS to gather data from MA prescription drug plans (MA-PD) plans to better monitor, measure and

[3] https://www.federalregister.gov/documents/2021/09/14/2021-19790/ninth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical

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					attribute the impact different providers, including pharmacists and pharmacies, have on vaccination rates of Medicare beneficiaries.
C	Medication Reconciliation Post-Discharge	Process Measure	1	Yes	As CMS understands, the medication reconciliation review can be conducted by a pharmacist. APhA requests CMS clarify how the efforts of 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.
C	Care Coordination	Patients' Experience and Complaints Measure	4	Yes	Pharmacists are often the first health care provider generally responsible for coordinating medication-related information on patient-care teams. APhA recommends CMS add CAHPs questions to attribute the coordinated care Medicare beneficiaries receive from pharmacists.
D	Getting Needed Prescription Drugs	Patients' Experience and Complaints Measure	4	Yes	APhA appreciates CMS recognizing the importance of patient access to medications. 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. CMS needs to establish mechanisms for understanding the contributions of pharmacists in providing access to medications.
D	Medication Adherence for Diabetes Medications	Intermediate Outcome	3	Yes	Pharmacists and pharmacies working with individuals with diabetes are in a key position to assess risks for nonadherence, to develop strategies to facilitate medication taking, and to

					provide ongoing support and assessment of adherence at each visit. Intervention trials show the use of pharmacists improves adherence.[4]
D	Medication Adherence for Hypertension (RAS antagonists)	Intermediate Outcome	3	Yes	Pharmacist intervention at pharmacies can significantly increase disease-related knowledge, blood pressure control and medication adherence in patients with hypertension.[5]
D	Medication Adherence for Cholesterol (Statins)	Intermediate Outcome	3	Yes	Studies have shown that pharmacists at pharmacies play a crucial role in reducing cardiovascular

[4] Hennessey, Erin. Et. al. Medication Adherence in Patients With Type 2 Diabetes. July 5, 2019, available at: https://journalce.powerpak.com/ce/medicationadherenceinpatientswithtype2diabete

[5] Saleem, Fahad. Et. al. Pharmacist intervention in improving hypertension-related knowledge, treatment medication adherence and health-related quality of life: a non-clinical randomized controlled trial. Health Expect. 2015 Oct; 18(5): 1270–1281. Published online 2013 Jun 20, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5060860/

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					disease (CVD) risk by improving adherence to statins.[6]
D	MTM Program Completion Rate for Comprehensive Medication Review (CMR)	Process	1	Yes	There is significant plan variability in beneficiary eligibility for MTM services. 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

[6] Bui, Arden. Et. al. Overcoming Barriers to Statin Adherence. US Pharm. 2019;44(6):19-22, available at: https://www.uspharmacist.com/article/overcoming-barriers-to-statin-adherence

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					comprehensive medication review, follow-up services to address problems and optimize medications vary greatly in frequency and delivery format Accordingly, APhA strongly recommends any efforts to measure and improve MTM services address the current barriers to beneficiary access and a comprehensive MTM benefit.

Changes to Existing Star Ratings Measures in 2023 for Future Years

As codified at §§ 422.164(c)(2)–(4), 423.184(c)(2)–(4), 422.164(d)(2), and 423.184(d)(2), new measures and measures with "substantive specification changes" must remain on the display page for at least two years prior to becoming a Star Ratings measure.

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

The Pharmacy Quality Alliance (PQA) modified several exclusions related to the SUPD measure in their draft 2022 measure manual (liver disease exclusion to include only beneficiaries with a diagnosis of cirrhosis, removed dapagliflozin and empagliflozin single ingredient from the measure National Drug Code (NDC) medication list) with no change to the intent of the measure or the target population. APhA supports CMS' plans to implement these non-substantive measure specifications for the 2022 measurement year (2024 Star Ratings).

Medication Adherence for Diabetes Medication/Medication Adherence for Hypertension (RAS Antagonists)/ Medication Adherence for Cholesterol (Statins) Measures/ Statin Use in Persons with Diabetes (SUPD) Measure (Part D)

PQA removed the Risk Adjustment Processing System (RAPS) RxHCC codes from all of its measures, including these 3 medication adherence and SUPD measures, in their draft 2022 measure manual for better alignment of the diagnosis codes used for exclusions and the National Drug Code (NDC) Medication Value Sets. APhA supports CMS' plans to implement the non-substantive measure specifications for the 2022 measurement year (2024 Star Ratings).

Medication Adherence for Diabetes Medication/Medication Adherence for Hypertension (RAS Antagonists)/ Medication Adherence for Cholesterol (Statins) Measures (Part D)

CMS is currently testing the risk adjustment for socioeconomic status (SES) or sociodemographic status (SDS) and soliciting feedback on moving forward when applying the SDS risk adjustment for the medication adherence measures. CMS is considering whether to no longer use member-years of enrollment. Instead, CMS would align with PQA's measure specifications of continuous enrollment as defined by the treatment period and exclude beneficiaries with more than 1-day gap in enrollment during the treatment period. According to PQA, a beneficiary may meet the requirements of enrollment in more than one contract in a measurement year but will not be adjusted using the member-years methodology. APhA supports CMS' proposal

to fully align with the PQA-endorsed specifications which do not include these adjustments.

Adult Immunization Status (Part C).

This measure assesses the receipt of influenza, Td/Tdap, zoster, and pneumococcal vaccines. CMS is considering changing the data source used to capture influenza vaccination to use the Healthcare Effectiveness Data and Information Set (HEDIS) results for the influenza and pneumococcal indicator of adult immunization status instead of the Consumer Assessment of Healthcare Providers & Systems (CAHPS) survey.

While the HEDIS measure is likely to capture more adult immunizations than the CAHPs survey, as stated above, APhA urges CMS to better monitor, measure and attribute the impact different providers, including pharmacists and pharmacies, have on vaccination rates of MA beneficiaries. For example, as CDC data clearly shows, pharmacies are consistently responsible for administering more influenza vaccines than physician medical offices.[7]

In the 2022 Advance Notice, CMS also solicited comments on a potential new measure concept related to COVID-19 vaccination for the Part C and D performance measure display page on CMS.gov and for potential inclusion in the Star Ratings program based on rulemaking. For 2023, CMS is again welcoming feedback on the utility and feasibility of a vaccination measure for MA plans.

APhA supports a potential new measure concept related to the COVID-19 vaccination for the 2023 MA performance measure display page published on CMS.gov and for potential inclusion in the Star Ratings program, pending rulemaking. As you know, HHS has authorized state-licensed pharmacists to order and administer[8], and state-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer COVID-19 and seasonal influenza vaccinations.[9] Therefore,

[7] https://www.cdc.gov/flu/fluvaxview/dashboard/vaccination-dashboard.html
[8] HHS. HHS Statements on Authorizing Licensed Pharmacists to Order and Administer COVID-19 Tests. April 8, 2020. https://www.hhs.gov/about/news/2020/04/08/hhs-statements-on-authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.html
[9] https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx

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CMS should add a pharmacist modifier on COVID-19 vaccination administration claims and create a similar mechanism for all pharmacist-involved Medicare claims in Parts B, C (MA), and D to provide greater visibility into the scope and outcomes of the Medicare services pharmacists currently provide.

CMS should also encourage MA plans to maximize the inclusion of pharmacists as in-network clinicians providing COVID-19 and other Advisory Committee on Immunization Practices (ACIP)-recommended vaccines.

CMS also previously planned to concurrently develop and test question(s) to add to the CAHPS survey, similar to the flu vaccine.[10] Such question(s) may ascertain whether a beneficiary received the COVID-19 vaccine during a specified timeframe to measure the percent of beneficiaries who received the COVID-19 vaccine, which would be most useful if we get to a point where dosing is stabilized like an annual influenza vaccine. As such, APhA recommends CMS add specific provider and site-of-care to the CAHPS survey questions to gain insight into satisfaction with COVID-19 vaccines administered by pharmacists and at pharmacies.

Due to the trusting relationships between pharmacists and their patients, pharmacists have ample opportunities to advance public health through immunization advocacy. Pharmacists are important members of the immunization neighborhood, and that trust will be important in addressing vaccine hesitancy for our nation's vulnerable populations—which is an invaluable asset that should be emphasized by CMS and the health plans.

APhA agrees with CMS that health plans play an important role in helping to educate and encourage their members to get vaccinated. Accordingly, APhA strongly recommends CMS and health plans implement a fully-funded component for pharmacists and other accessible health care practitioners to conduct coordinated and consistent community- based education and outreach campaigns supporting recommended vaccinations. These campaigns should focus on eliminating stigma, fostering vaccine confidence, and improving prevention and health outcomes for high priority and vulnerable patient populations.

[10] https://www.cms.gov/files/document/2022-advance-notice-part-ii.pdf

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Concurrent Use of Opioids and Benzodiazepines (COB)/Initial Opioid Prescribing for Long Duration (IOP-LD)/Use of Opioids at High Dosage in Persons without Cancer (OHD)/Use of Opioids from Multiple Providers in Persons without Cancer (OMP) (Part D).

PQA updated the measure specifications in their draft 2022 measure manual to exclude beneficiaries in palliative care during the measurement period for all of the opioid measures to align with the CDC's Guideline for Prescribing Opioids for Chronic Pain since beneficiaries receiving palliative care have unique therapeutic goals and the risks and benefits associated with opioid use in palliative care may be different from the broader population. APhA supports adding the palliative care exclusion to the opioid display measures for the 2022 measurement year (2024 display page).

APhA also encourages CMS to monitor for release of the updated CDC guideline for any impact on opioid-related measures in the Star Ratings Program. The draft CDC Clinical Practice Guideline is currently posted in the Federal Register for public comment.[11]

Potential New Measure Concepts and Methodological Enhancements for Future Years

Health Equity Index (Part C and D).

CMS is seeking feedback on the development of a Health Equity Index it might incorporate into MA and Part D star-ratings systems to condense how effective plans are at providing for enrollees with social risk factors (SRFs) into a single score.

CMS is also considering replacing the current reward factor added to the overall or summary ratings with the Health Equity Index.

CMS Office of Minority Health has been working to create the Health Equity Summary Score (HESS) which differs from the health equity index potentially being developed for the Star Ratings program in that it currently focuses on CAHPS and HEDIS measures,

[11] https://www.cdc.gov/media/releases/2022/s0210-prescribing-opioids.html

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while the Health Equity Index would focus on all of the Part C and D measures in the Categorical Adjustment Index (CAI) and CAHPS measures.

APhA strongly supports efforts to improve data on beneficiaries' race, ethnicity, and social determinants of health, as well as methods to address health disparities such as the Health Equity Index.

Value-based Care (Part C).

CMS is interested in how MA organizations are transforming care and driving quality through value-based contracts with providers.

APhA is aware that some MA plans are starting to contract with pharmacies to improve access to care for beneficiaries and close care gaps for plan metrics. It's important for CMS to be aware that pharmacists/pharmacies are contracting with MA plans and consider mechanisms for including pharmacists and pharmacies in efforts to evaluate the involvement of contracted providers in the care of MA beneficiaries.

Persistence to Basal Insulin (PST-INS) Measure (Part D).

APhA supports CMS aligning with the PQA's continuous enrollment specification for PST-INS (excludes individuals with more than a 1-day gap in enrollment during the treatment period). APhA also supports CMS beginning reporting of the PST-INS measure in the Patient Safety reports to gain experience for the 2022 measurement year.

Conclusion

Thank you for the opportunity to provide comments on the Advance Notice. We support CMS' 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, Senior Director of Regulatory Policy, at mbaxter@aphanet.org or by phone at (202) 459-8963.

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Sincerely,

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Senior Vice President, Pharmacy Practice and Government Affairs

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