March 5, 2018

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies, and 2019 Draft Call Letter

ASHP is pleased to submit comments regarding the proposed changes to Medicare Part D for 2019 (the "Call Letter"). ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's 45,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. ASHP thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the Call Letter. ASHP's comments center on two areas of proposed changes — drug utilization review and quality measures. We address each issue in turn below.

I. Drug Utilization Review (DUR)

ASHP shares CMS's commitment to combatting the opioid crisis. We recognize the challenge of creating workable policy that protects legitimate access to therapy while protecting against misuse and diversion. While we are supportive of CMS's efforts on this front, we encourage the agency to consider revising several of its DUR proposals to ensure that safety and patient access goals are met:

- Opioid Potentiators: ASHP supports the flag for buprenorphine, but we question the necessity of imposing a flag for gabapentin and pregabalin. Both of these drugs are often used as opioid alternatives, and flagging them may undercut efforts to reduce opioid prescribing. Additionally, we recommend that alerts be used sparingly, as flagging too many drugs may result in confusion and/or alert fatigue.

- Concurrent DUR — Hard Edits: ASHP recognizes that hard edits on opioid prescriptions may be helpful in certain instances. Provided that CMS is carefully monitoring access and outcomes, a prior authorization requirement above 90 morphine milligram equivalents (MME) would be acceptable. However, we respectfully request that CMS provide some additional clarification around certain aspects of the proposed policy. For instance, when a hard edit is triggered, will there be a standard protocol for all plans (e.g., a prior authorization request), or will each plan be different? Additionally, if a coverage determination is required, CMS has stated that it expects plans to provide an expedited decision within 24 hours. Will that 24-hour period apply even during weekends? Further, how will coverage determination notifications be made? Will the plan take responsibility for informing patients within 24 hours, or will it fall to the pharmacy? We urge CMS to address these open questions prior to finalizing hard edit requirements.

- Seven-Day Supply Limit for Opioid-Naïve Patients**:** ASHP supports a hard edit for supplies over seven days for acute pain in opioid-naïve patients, as this is consistent with the Centers for Disease Control and Prevention (CDC) guidelines. Generally, we would not support limiting supplies to fewer than seven days. However, we would consider supporting a shorter limit for certain types of procedures (e.g., dental) or a quantity/dosage limit, provided there is sufficient clinical evidence to support the change as well as strong patient safeguards that CMS actively enforces.

- MAT Access: ASHP applauds CMS's proposal to ease authorization restrictions for buprenorphine medication-assisted treatment (MAT) products. Carrying over authorization and requiring a single authorization per year is a smart step toward promoting adherence and ensuring uninterrupted access to MAT. ASHP also strongly encourages CMS to support and expand pharmacists' prescriptive authority through collaborative practice agreements and other means in order to provide pharmacists the ability to fill gaps in patient needs, particularly for MAT related to opioid use disorder and substance abuse disorders.

II. Quality Measures

ASHP appreciates the opportunity to review and comment on the Call Letter's Star Ratings changes as well as new proposed measures. Healthcare quality standards and pharmacy services must be aligned to ensure optimal medication use outcomes and improvements in quality of care.[1] We advocate for the adoption of standard quality measures that are developed with the involvement of pharmacists, that are evidence-based, and that promote the demonstrated role of pharmacists in improving patient outcomes. Such measures would include, but are not limited to, promoting medication adherence, minimizing medication adverse drug events due to drug-drug and drug-disease interactions and polypharmacy, and ensuring the safe and effective use of opioids. ASHP's comments are focused on these quality measure areas:

- Categorical Adjustment Index Considerations: ASHP commends CMS and measure stewards, such as the Pharmacy Quality Alliance (PQA), for carefully calibrating risk adjustment for performance measures in order to account for patient-related sociodemographic factors that influence outcomes. We appreciate efforts to achieve balance between implementation of meaningful quality and measures and recognition of challenges faced by providers serving vulnerable populations. ASHP will continue to monitor policy and measure specification decisions related to the Categorical Adjustment Index from CMS, NQF, and other measure stewards.

- CMS/RAND Technical Expert Panel: ASHP urges CMS to ensure that the Technical Expert Panel includes representatives from pharmacy. Specifically, we ask that CMS work to ensure that hospital and ambulatory clinic-based pharmacists are adequately represented, as their practice models and range of patient-care services may differ substantially from community pharmacy practice.

[1] *See* ASHP Policy 0502: Health Care Quality Standards and Pharmacy Services, *available at* https://www.ashp.org/-/media/assets/policy-guidelines/docs/policy-positions/policy-positions-organization-and-delivery-of-services.ashx?la=en&hash=5B17255F25ED7D5CE895B51980B1DE879A7F93A5.

- Adherence Measures: Medication adherence is essential in improving chronic disease clinical outcomes and reducing patient mortality from chronic conditions. Indeed, nonadherence is associated with increased hospitalizations, morbidity and mortality, and healthcare costs.[2] Team-based care interventions improve patient adherence to medication regimens, especially when pharmacists are fully integrated into the healthcare team.[3]

    - *Statin, Hypertension and Diabetes Measures for Part D*: Overall, ASHP supports the new measure for Part D, Statin Use in Persons with Diabetes, as well as the changes to the medication adherence measures for hypertension, diabetes medications, and cholesterol.

    - *Non-Warfarin Oral Anticoagulants (ADH-NWOA) measure:* We were pleased to see PQA endorsement of the ADH-NWOA measure. Anticoagulation safety is a key priority of the National Action Plan and adherence to this new class of anticoagulants is essential for optimizing efficacy and safety. We encourage CMS to add ADH-NWOA as an adherence measure to the Patient Safety reports to emphasize the importance of adherence and to capture more post-marketing information on these anticoagulant medications. Further, these medications are significantly more expensive than warfarin; therefore, adherence is essential for ensuring continuous anticoagulation and optimizing their value. Although NWOAs have a higher adherence percentage than warfarin, studies indicate that their non-adherent rate is as high as 50% without interventions.[4]

    - *Adherence to Non-Infused Disease Modifying Agents Used to Treat Multiple Sclerosis:* ASHP appreciates consideration of the measure, Adherence to Non-Infused Disease Modifying Agents Used to Treat Multiple Sclerosis. Despite the low prevalence of multiple sclerosis in the Part D contracts evaluated for this measure, this is a disease state with high morbidity and healthcare resource consumption. Adherence to therapy is essential to prevent disease progression; therefore, it is appropriate to measure. We support the inclusion of this measure in quarterly outlier reports and request reconsideration for further incorporation into the Part D program at a later date.

---

[2] *See* M.R. DiMatteo, *Variations in Patients' Adherence to Medical Recommendations: A Quantitative Review of 50 years of Research*, MED. CARE (2004), 200–9; *See also* D.M. Cutler and W. Everett, *Thinking Outside the Pillbox — Medication Adherence as a Priority for Health Care Reform*, N. ENGL. J. MED. (2010), 1553–5; A.O. Iuga and M.J. McGuire, Adherence and Health Care Costs, RISK MAN. HEALTH. POL.(2014), 35–44.

[3] *See* P.M. Ho, A. Lambert-Kerzner, E.P. Carey, *et al*., *Multifaceted Intervention to Improve Medication Adherence and Secondary Prevention Measures after Acute Coronary Syndrome Hospital Discharge: A Randomized Clinical Trial*. JAMA Intern. Med. (2014,186–93; *See also* A.B. Neiman, T. Ruppar, M. Ho, *et al*., *CDC Grand Rounds: Improving Medication Adherence for Chronic Disease Management — Innovations and Opportunities*, MORB. MORTAL. WKLY. REP. (2017), 66, *available at* https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm.

[4] *See* Cate H.Ten, *New Oral Anticoagulants: Discussion on Monitoring and Adherence Should Start Now,* THROMB. J., (2013), 8; *See also* R.A. Rodriguez RA, M.Carrier, and P.S. Wells, *Non-Adherence to New Oral Anticoagulants: A Reason for Concern During Long-Term Anticoagulation?*, J. THROMB. HAEMOST. (2013), 390–394.

- Polypharmacy Measures: ASHP supports adding the following polypharmacy measures to the Patient Safety reports for the 2018 plan year and to the display page and Star Ratings in subsequent years — Polypharmacy: Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH), Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS), and Concurrent Use of Opioids and Benzodiazepines. The Poly-ACH and Poly-CNS measures link to the evidence-based Beers Criteria from the American Geriatrics Society for the purpose of promoting medication safety in older adults, which is particularly important in the Part D population. Highlighting the prevalence of polypharmacy with these measures will provide valuable information to pharmacists and plans and will allow measure performance monitoring before transitioning these measures to the Star Ratings. With respect to the Concurrent Use of Opioids and Benzodiazepines (COB), we agree that this is an important patient safety consideration; it enables adherence to the CDC Guideline for Prescribing Opioids for Chronic Pain, which states that opioid pain medications and benzodiazepines should not be co-prescribed.[5] Overall, we commend PQA for the development of multiple opioid utilization-related quality measures to address opioid overuse in the Part D program. Specifically, we look forward to NQF's endorsement consideration of the COB measure in the near future. Until then, we support the addition of this measure to the Patient Safety report for the 2018 measurement year. Given that the Opioid Management System (OMS) identifies concomitant use of opioids and benzodiazepines and that the Poly-CNS measure also captures this prevalence information, we encourage careful evaluation as to which monitoring mechanism provides the most utility while minimizing related or competing measures in the marketplace. We appreciate CMS's allowance of a soft edit that enables a pharmacist's override in the event of a concurrent opioid and benzodiazepine prescription for those patients with a clear and appropriate indication for both.

Again, ASHP appreciates this opportunity to provide CMS with feedback on the Call Letter. We look forward to continuing to work with CMS to improve care quality and outcomes. Please contact me if you have any questions on ASHP's comments. I can be reached by telephone at 301-664-8696 or by email at jschulte@ashp.org.

Sincerely,

Jillanne Schulte Wall, J.D.
Director, Federal Regulatory Affairs

[5] *See* D. Dowell, T.M. Haegerich, and R.Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain — United States* (2016), available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.