

March 5, 2018

Center for Medicare & Medicaid Services Department of Health and Human Services Attn: CMS-4182-P

* 1. 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. Formore 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) forthe opportunity to comment on the Call Letter. ASHP’s comments centeron two areas of proposed changes — drug utilization reviewand quality measures. We address each issue in turn below.

# Drug Utilization Review(DUR)

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

* Opioid Potentiators: ASHP supports the flag forbuprenorphine, but we question the necessity of imposing aflag 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/oralert 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, apriorauthorization 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. Forinstance, when ahard edit is triggered, willthere be astandard protocol forall plans (e.g., aprior authorization request), orwill each plan be different? Additionally, if acoverage 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? Willthe plan take responsibility for informing patients within 24 hours, or will it fall to the pharmacy? We urge CMS to address these open questions priorto finalizing hard edit requirements.



* Seven-Day Supply Limit for Opioid-Naïve Patients**:** ASHP supports ahard edit forsupplies overseven 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 considersupporting ashorterlimit forcertain types of procedures (e.g., dental) ora quantity/dosage limit, provided there is sufficient clinical evidenceto support the change as well as strong patient safeguards that CMS actively enforces.
* MAT Access: ASHP applauds CMS’s proposal to ease authorization restrictions forbuprenorphine medication-assisted treatment (MAT) products. Carrying overauthorization and requiring asingle authorization peryearis a smart step toward promoting adherence and ensuring uninterrupted access to MAT. ASHP also strongly encourages CMS to support and expand pharmacists’ prescriptiveauthority through collaborative practice agreements and othermeans in order to provide pharmacists the ability to fill gaps in patient needs, particularly for MATrelated to opioid use disorderand substance abuse disorders.

# Quality Measures

ASHP appreciates the opportunity to reviewand 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 effectiveuse 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), forcarefully calibrating risk adjustment forperformance measures in orderto account for patient-related sociodemographicfactors 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 continueto monitorpolicy and measure specification decisions related to the Categorical Adjustment Index from CMS, NQF, and othermeasure stewards.
* CMS/RANDTechnical 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 theirpractice models and range of patient-care services may differsubstantially from community pharmacy practice.

1 *See* ASHP Policy 0502: Health Care Quality Standards and Pharmacy Services, *available at* https:[//w](http://www.ashp.org/-)ww[.ashp.org/-](http://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 chronicdisease clinical outcomes and reducing patient mortality from chronicconditions. 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 Measuresfor 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 forhypertension, 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 akey priority of the National Action Plan and adherence to this new class of anticoagulants is essential foroptimizing efficacy and safety. We encourage CMS to add ADH-NWOA as an adherence measure to the Patient Safety reports to emphasizethe 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 forensuring continuous anticoagulation and optimizing theirvalue. Although NWOAs have ahigher adherence percentage than warfarin, studies indicate that their non-adherent rate is as high as 50% without interventions.4
  + *Adherenceto 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 multiplesclerosis in the Part D contracts evaluated forthis measure, this is adisease state with high morbidity and healthcare resource consumption. Adherence to therapy is essential to prevent diseaseprogression; therefore, it is appropriate to measure. We support the inclusion of this measure in quarterly outlierreports and request reconsideration forfurtherincorporation into the Part D program at a laterdate.

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:[//w](http://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm)ww[.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm.](http://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 forthe 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 forthe purpose of promoting medication safety in olderadults, 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 thesemeasures 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 adherenceto 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 forthe development of multipleopioid utilization-related quality measures to address opioid overusein the Part D program. Specifically, we look forward to NQF’s endorsement consideration of the COBmeasure in the nearfuture. Until then, we support the addition of this measure to the Patient Safety report forthe 2018 measurement year. Given that the Opioid Management System (OMS) identifies concomitant use of opioids and benzodiazepines and that the Poly-CNS measurealso 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 asoft edit that enables a pharmacist’s override in the event of a concurrent opioid and benzodiazepineprescription forthose patients with aclearand appropriate indication forboth.

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](mailto: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:[//w](http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm)ww[.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.](http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm)