



Optimizing Health by Advancing the Quality of Medication Use

November 30, 2020

Demetrios Kouzoukas
Principal Deputy Administrator & Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS-2020-00933-0002

Dear Mr. Kouzoukas,

The Pharmacy Quality Alliance (PQA) appreciates the opportunity to comment on the Advance Notice of Methodological Changes for Calendar Year (CY) 2022 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II (2022 Advance Notice Part II) and applauds the Centers for Medicare & Medicaid Services (CMS) for providing an earlier-than-anticipated forward look at the Star Ratings program and soliciting input on future measures and concepts to enhance the Star Ratings over time. This may provide plans with more time to prepare their bids, given this unprecedented global health pandemic.

PQA is a national quality organization dedicated to improving medication safety and appropriate use. As a measure developer, researcher, educator and convener, PQA's quality initiatives support better medication use and value-based care. A non-profit organization with 250 diverse members across healthcare, PQA was established in 2006 as a public-private partnership with the Centers for Medicare & Medicaid Services shortly after the implementation of the Medicare Part D Prescription Drug Benefit. [PQA members](#) include community and specialty pharmacy organizations, pharmacists and other healthcare providers, pharmacies, health plans, pharmacy benefit managers, life sciences, technology vendors, government agencies, health information technology partners, academia and researchers.

PQA's comments on the 2022 Advance Notice Part II follow.

- **Statin Use in Persons with Diabetes (SUPD) (Part D) (pp. 80-81).** We are pleased that PQA's non-substantive clarifications and updates to the SUPD measure were implemented by CMS for the 2021 measurement year (2023 Star Ratings).
 - Through PQA's consensus-based measure update process, a requirement was added that the index prescription start date for the SUPD measure should occur

at least 90 days prior to the end of the measurement year to allow reasonable time for interventions to occur to meet the measure's numerator requirements.

- Several new denominator exclusions were added to refine and improve face validity of the measure. The exclusions of pre-diabetes and polycystic ovary syndrome were added to remove individuals who may be using diabetes medications for another indication. Additional denominator exclusions for liver disease, rhabdomyolysis or myopathy, and pregnancy, lactation, or fertility were added to remove individuals who may have a contraindication for use of a statin medication.
- **Drug-Drug Interactions (DDI), Antipsychotic Use in Persons with Dementia – for Community-Only Residents (APD-Comm) and Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer (OHDMP) (Part D) (pp. 81-82).** We support CMS' retirement of the following measures from the display page for 2022 to help reduce sponsors' burden and to focus quality improvement resources:
 - Drug-Drug Interactions (DDI)
 - Antipsychotic Use in Persons with Dementia – for Community-Only Residents (APD-Comm)
 - Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer (OHDMP)

We are pleased that the following measures will remain on the display page:

- Use of Opioids at High Dosage in Persons Without Cancer (OHD)
- Use of Opioids from Multiple Providers in Persons Without Cancer (OMP)
- Overall Antipsychotic Use in Persons with Dementia (APD)
- Antipsychotic Use in Persons with Dementia - for Long-term Nursing Home Residents (APD-LTNH)
- **Polypharmacy: Use of Multiple CNS-Active Medications in Older Adults (Poly-CNS)/ Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH) (Part D) (pp. 83-84).** We support CMS' plans to implement changes to the polypharmacy measures for the 2021 measurement period for the 2023 display measures. These changes were made through PQA's consensus-based measure update process.
 - For both polypharmacy measures, the exclusion of injectable and inhalation routes of administration improves the accuracy in estimating days' supply.
 - The addition of serotonin-norepinephrine reuptake inhibitors (SNRIs) and antiepileptics to the Poly-CNS measure's medication list reflects recommendations in the 2019 AGS Beers Criteria update.¹
 - The addition of the exclusion of beneficiaries with a seizure disorder diagnosis during the measurement year is intended to mitigate potential unintended consequences with the addition of antiepileptic medications to the Poly-CNS measure.

¹ American Geriatric Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. [PMID: 30693946](https://pubmed.ncbi.nlm.nih.gov/30693946/).

- **COVID-19 Vaccination (Part C) (p. 85).** We support the development of measure concepts related to COVID-19 vaccination for the Part C & D display page for potential inclusion in the Star Ratings program, pending rulemaking. Although health plans play an important role to help educate and encourage their members to receive the COVID-19 vaccine, there are important considerations related to COVID-19 vaccine measure development that are worth noting.
 - Prerequisites for evidence-based measure development include availability of FDA-approved or licensed COVID-19 vaccines and clinical guidelines from the Advisory Committee on Immunization Practices (ACIP).
 - Given the nature of the COVID-19 pandemic, evidence, therapeutics, vaccines, indications, and guidelines may rapidly evolve with emerging evidence.
 - Feasibility related to whether the needed data are available to collect and report is another area for consideration. For example, health plans may lack claims or other data on members' COVID-19 vaccine administration. Consistent access and reporting to immunization information systems are essential to ensure appropriate tracking of the COVID-19 vaccine (in addition to all other FDA-approved vaccines).
 - Distribution channels for COVID-19 vaccines may change over time and may vary depending on the geographic region, especially in rural areas.

PQA has exploratory work underway to develop Medication Therapy Management (MTM) immunization measures, which could inform broader development of MTM or pharmacy measures addressing immunization, including a COVID-19 vaccine.

We recommend a collaboration between CMS, PQA and other measure developers, and other key stakeholders to develop and implement new measures that are aligned with equitable access to COVID-19 vaccines.

PQA appreciates CMS' thoughtful consideration of our comments submitted in response to the 2022 Advance Notice Part II.

If you have questions, please do not hesitate to contact us.

Respectfully,



Laura Cranston, RPh
Chief Executive Officer
Pharmacy Quality Alliance
LCranston@PQAalliance.org
(703) 347-7963