



November 30, 2020

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: 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

Dear Administrator Verma:

As participants of the Adult Vaccine Access Coalition (AVAC), we appreciate the opportunity to comment on Part II of 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.

Specifically:

- AVAC urges CMS to strongly encourage Part D plan sponsors to either offer a \$0 vaccine tier or place vaccines on a formulary tier with low cost-sharing, and to strongly support maintaining it in the final letter. Studies have shown a direct correlation between high cost-sharing and increased abandonment rates of vaccines. Removing financial barriers will greatly improve beneficiary access, utilization, and health outcomes.
- AVAC recommends that CMS encourage Part D plan sponsors to waive or eliminate the 25 percent cost-sharing for vaccine administration fees for beneficiaries in the coverage gap. This additional cost burden is a significant deterrent and presents a burdensome financial challenge for beneficiaries who are already facing increased drug costs.
- AVAC strongly supports the inclusion of the annual flu vaccine star ratings improvement measure. We encourage CMS to consider the development of a COVID-19 vaccination quality measure and we recommend the future addition of the adult immunization status (AIS) composite measure on the display page and for star ratings. This HEDIS measure provides a comprehensive means to assess the receipt of routine adult vaccinations recommended by the Advisory Committee on

Immunization Practices (ACIP). AVAC appreciates the work of NCQA, PQA, and others to develop and test reliable measurement tools that will streamline the patchwork of existing adult immunization measures, has the potential to reduce the reporting burden on providers, and provides meaningful data to the Medicare program on access to this important preventive service.

AVAC consists of over sixty organizational leaders in health and public health who are committed to raising awareness of the importance of adult immunization with the ultimate goal of addressing barriers to adult immunization. Our mission is informed by scientific and empirical evidence that shows that immunization improves health and protects lives against a variety of debilitating and potentially deadly conditions, saving costs to the healthcare system and to society as a whole. AVAC priorities and objectives are driven by a consensus process with the goal of enabling the range of stakeholders to have a voice in the effort to improve access to and utilization of adult immunizations.

Immunizations are a cornerstone of our nation's disease prevention efforts and have a demonstrated track record of success as a cost-effective means of reducing disease burden and saving lives among pediatric populations. The CDC estimates that over 20 years, childhood immunizations prevent 732,000 deaths and 21 million hospitalizations.

In the Strategic Plan FY 2018 –2022, the Department of Health and Human Services (HHS) commits to “support access to preventive services including immunization and screenings, especially for high-risk, high-need populations.” Unfortunately, access to vaccines is not equal across a person's life course. Despite the well-known benefits of immunizations, more than 50,000 adults die every year from vaccine-preventable diseases while millions more suffer the immediate and longer-term negative health impacts of vaccine-preventable diseases. Despite consistently high rates of childhood immunization, adult coverage rates lag behind Healthy People goals for most commonly recommended vaccines: influenza, pneumococcal, tetanus, hepatitis B, herpes zoster, and HPV.

Adults in need of this important preventive service encounter a range of potential challenges, including lack of awareness and information about recommended vaccines, financial hurdles such as high cost-sharing, and technological and logistical obstacles. Socioeconomic and linguistic barriers further challenge the ability of diverse and medically underserved communities from accessing needed immunizations.

A growing body of research illustrates the direct and indirect cost attributable to vaccine preventable disease. A study published in *The Journal of Primary Prevention* found the estimated annual cost of just four major vaccine-preventable diseases among U.S. adults 65 years and older was more than \$15 billion in 2013. Medical costs related to vaccine-preventable diseases (VPD) in older adults are expected to grow substantially in the coming years; one study forecasts U.S. medical costs for Americans ≥65 in the Medicare population to be \$4.74 billion by 2030 for just one VPD.

Immunization coverage for Medicare beneficiaries is segmented between Medicare Part B, which covers vaccinations against influenza, pneumococcal, and hepatitis B for at-risk patients, and Medicare Part D, which covers all other commercially available vaccines when deemed medically necessary to prevent illness. While beneficiaries receive Part B covered

vaccines with no cost-sharing, Part D vaccines are typically subject to cost-sharing requirements.

Previous CMS Part D call letters prioritized and encouraged improved access to and utilization of adult immunization services for beneficiaries in Medicare Advantage and Prescription Drug Plans (PDP). As such, AVAC wishes to offer the following comments:

Section B. USPCC Estimates (p. 10)

AVAC supported recent language in Section 3713 of the CARES Act, which amended section 1852(a)(1)(B) of the Act, prohibiting MA organizations from requiring cost-sharing in excess of Medicare FFS cost-sharing (which is zero) for a COVID-19 vaccine and its administration described in section 1861(s)(10)(A) of the Act. We recommend that CMS go further and strongly encouraged Part D sponsors to offer either a \$0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing for all other ACIP recommended vaccines. AVAC has greatly appreciated the inclusion of similar language in past Medicare Part D call letters, and believes that the language sent an important signal to Medicare Advantage and Prescription Drug Plans that access to Part D vaccines should be a high priority as they develop formulary and cost-sharing tiers.

Financial barriers stand out as one of the most impactful and avoidable barriers to adult immunization. Studies have shown that the variable cost-sharing requirements currently imposed on the majority of Part D vaccines discourage immunization among elderly, disabled, and chronically ill populations who account for a disproportionate percentage of the morbidity and mortality from vaccine-preventable conditions.

- A February 2018 Manatt study found that only 4 percent or less of Medicare Part D enrollees had access to vaccines with no cost-sharing. The variable cost-sharing requirements currently imposed on the majority of Part D vaccines discourage immunization among elderly, disabled, and chronically ill populations who account for a disproportionate percentage of the morbidity and mortality from vaccine preventable conditions.
- A 2017 report by Avalere Health found between 47 and 72 percent of the 24 million Medicare beneficiaries with Part D coverage had some level of cost-sharing for vaccines, ranging from \$35 to \$70 in 2015. Another study found that only 4 percent or less of Medicare Part D enrollees had access to vaccines with no cost-sharing.
- A study evaluating the relationship between vaccine co-pays for Part D beneficiaries and Zoster vaccination claims showed that out-of-pocket cost (OOP) remained the most significant predictor of abandonment. The odds of abandonment were 1.66 times higher for patients with OOP in the \$15-\$34 range compared with those with OOP \leq \$14.99 and odds were much higher—at 5.53 times—for those with OOP in the \$105-\$174.99 range.
- A 2015 report by the Alliance for Aging Research on vaccination rates among older adults found that cost-sharing for vaccines under Part D varies depending on a beneficiary's prescription drug plan or Medicare Advantage plan formulary offerings.

Another study found that patient out-of-pocket cost is one of the most significant predictors of vaccine abandonment, after adjusting for other factors. Removing financial barriers would greatly improve beneficiary access, utilization, and health outcomes among at-risk elderly and chronically ill populations who account for a disproportionate percentage of the morbidity and mortality from vaccine preventable conditions.

Section E. Dispensing Fees and Vaccine Administration Fees for Applicable Drugs in the Coverage Gap (p. 66-68)

AVAC recommends that CMS encourage Part D plan sponsors to waive or eliminate the 25 percent cost-sharing for vaccine administration fees for beneficiaries in the coverage gap. This additional cost burden is a significant deterrent and presents a burdensome financial challenge for beneficiaries who are already facing increased drug costs.

2022 Star Ratings Improvement Measure Updates (p.73)

AVAC is grateful that the advance notice has maintained the annual influenza (flu) vaccine in the Star Ratings Improvement Measures for 2022. Influenza is a serious disease that can lead to hospitalization and sometimes even death. Every year, millions of people get the flu, hundreds of thousands of people are hospitalized, and thousands or tens of thousands of people die from flu-related causes. Flu accounts for an estimated \$8.95 billion, or 65% of the annual economic burden of adult vaccine-preventable diseases. According to the Centers for Disease Control and Prevention (CDC), a 6.2 percent reduction in the adult immunization rate for flu during the 2017-18 influenza season was a contributing factor in the record number of deaths. Vaccination has been shown to have many benefits including reducing the risk of flu-related illnesses, hospitalizations, and even deaths.

Quality measurement, particularly when tied to reporting and payment, serve as a mechanism to incentivize plans, providers, health systems, and other stakeholders to improve immunization rates. By strengthening and enhancing the development and implementation of adult immunization quality measures, CMS will help to reduce barriers to adult immunization by creating incentives for offering vaccines.

COVID-19 Vaccination (Part C) (p. 85)

We appreciate your interest in soliciting comments on a potential new measure concept related to the COVID-19 vaccination for the 2023 Part C & D performance measure display page published in Fall 2022 on CMS.gov and for potential inclusion in the Star Ratings program, pending rulemaking. We support the concurrent development and testing of a question(s) to add to the CAHPS survey administered in early 2022, similar to the flu vaccine. In the Value and Imperative of Quality Measures for Adult Vaccines, renowned vaccine experts explain how quality measures that capture and create incentives for appropriate adult vaccinations can prevent illness and death, reduce caregiving demands, save unnecessary healthcare spending, and set the foundation for healthy aging. We agree that health plans play an important role to help educate and encourage their members to get the COVID-19 vaccine.

Adult Immunization Status (AIS) Measure

AVAC also strongly 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. NCQA added the adult composite measure to their 2019 Healthcare Effectiveness Data Information Set (HEDIS), using the Electronic Clinical Data System (ECDS) reporting domain. Measures in the HEDIS ECDS domain are calculated using electronic data from administrative claims, electronic medical records, case management systems, and registries. Prior to HEDIS, the composite was piloted by the Indian Health Service. This HEDIS measure provides a comprehensive means to assesses the receipt of routine adult vaccinations recommended by the Advisory Committee on Immunization Practices (ACIP). AVAC appreciates the work of NCQA, PQA, and others to develop and test reliable measurement tools that will streamline the patchwork of existing adult immunization measures, have the potential to reduce the reporting burden on providers, and provide meaningful data to the Medicare program on access to this important preventive service.

There is evidence that a composite measure of the adult patient cohort's vaccination schedule, such as those demonstrated by the Northwest Tribal Epidemiology Center and by the National Nursing Home Quality Care Collaborative, can improve outcomes. Such a measure would put vaccination coverage rates into a larger context and encourage a more systematic approach for all vaccines.

Thank you for the opportunity to offer our perspective on the 2022 Medicare Advantage and Part D Advance Notice. We look forward to working with you to further strengthen CMS' commitment to proven preventive health measures and in support of efforts that will help Part D plan sponsors balance fiduciary responsibilities and beneficiary access to important recommended immunizations that protect and preserve health and quality of life.

Please contact an AVAC manager at info@adultvaccinesnow.org if you wish to discuss our comments or adult immunization access and coverage.

Sincerely,

Alliance for Aging Research
American College of Preventive Medicine
American Heart Association
American Immunization Registry Association (AIRA)
Asian & Pacific Islander American Health Forum (APIAHF)
American Pharmacists Association
Association of Asian Pacific Community Health Organizations
Association of Immunization Managers (AIM)
Biotechnology Innovation Organization (BIO)
Dynavax
Families Fighting Flu
GSK
Hep B United
Hepatitis B Foundation
Immunization Action Coalition (IAC)
Medicago
National Association of City and County Health Officials (NACCHO)
National Black Nurses Association

National Consumers League (NCL)
National Foundation for Infectious Diseases (NFID)
National Hispanic Medical Association
National Viral Hepatitis Roundtable
Novavax
Pfizer
Pharmacy Quality Alliance
Sanofi
STChealth
Seqirus
The Gerontological Society of America
Trust for America's Health (TFAH)
Vaccinate your Family

CC: Demetrios Kouzoukas, Principal Deputy Administrator and Director, Center for Medicare