March 1, 2019

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


Dear Administrator Verma:

As participants in the Adult Vaccine Access Coalition (AVAC), we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) 2020 Medicare Advantage and Part D Advance Notice and Draft Call Letter.

We are encouraged that the call letter prioritizes improved access to and utilization of adult immunization services for beneficiaries in Medicare Advantage and Prescription Drug Plans (PDP), including:

- Inclusion of language encouraging Part D sponsors to offer either a $0 vaccine tier or to place vaccines on a formulary tier with low cost-sharing, and we strongly urge maintaining it in the final letter.
- Addition of a Star Ratings Flu Measure, and we request the future addition of an adult immunization composite measure on the display page and for Star Ratings.

In the final Call Letter, we also ask CMS to consider:

- Adoption of the Adult Immunization Status Composite Measure on the Star Ratings Display Page.
- Increased application of MTM programs for the purpose of improving immunization rates among Medicare beneficiaries, particularly those with chronic conditions.

AVAC consists of more than fifty 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 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 a range of stakeholders to have a voice in the effort to improve access 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.\(^1\) In the draft Strategic Plan FY 2018–2022, the Department of Health and Human Services encourages the use of age appropriate vaccines to minimize the burden of vaccine-preventable diseases across the life span.\(^2\) Unfortunately, access to vaccines is not equal across a person’s lifespan.

Despite the well-known benefits of immunizations, more than 50,000 adults die from vaccine-preventable diseases while adult coverage lags behind Healthy People 2020 targets for most commonly recommended vaccines: influenza, pneumococcal, tetanus, hepatitis B, herpes zoster, and HPV. Millions more adults suffer from vaccine-preventable diseases, causing them to miss work and leaving some unable to care for those who depend on them.

Adults seeking access to and coverage for vaccines encounter a confusing health care system that presents multiple barriers, including lack of awareness and information about recommended vaccines, financial hurdles including high cost sharing, as well as technological and logistical obstacles. Socioeconomic and linguistic barriers further challenge the ability of diverse and medically underserved communities from accessing needed immunizations.

**AVAC wishes to offer the following comments with the strong hope that CMS will maintain these important immunization provisions in the final call letter:**

**Improving Access to Part D Vaccines (page 179)**

AVAC greatly appreciates the inclusion of language encouraging Part D sponsors to offer either a $0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing, and strongly urge maintaining it in the final letter.

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1. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm
2. HHS Strategic Plan, FY 2018–2022, Draft, September 2017, page 51
According to the Center for Disease Control and Prevention’s (CDC) Surveillance of Vaccination Coverage Among Adults in the United States, National Health Interview Survey, 2016, vaccination rates remain low for tetanus and diphtheria (Td) and tetanus and diphtheria with acellular pertussis (Tdap) for adults age 65 and older, at 58% and 20% respectively. While the Healthy People 2020 herpes zoster target vaccination rate has been achieved, approximately 70% of adults for whom the vaccine is recommended remain unprotected. In a 2010 Government Accountability Office (GAO) Survey of State Health Insurance Assistance Programs (SHIPS), 40% of SHIPS reported difficulty affording the cost-sharing as a barrier to beneficiaries accessing herpes zoster vaccine. A 2018 study of Tdap and herpes zoster vaccine claims in Part D demonstrated that higher out-of-pocket cost-sharing was associated with higher rates of cancelled vaccination claims, suggesting vaccination was abandoned. In this study, cost-sharing of $51 or greater was associated with a 2 to 2.7-times greater rate of cancelled vaccination claims compared with $0 cost-sharing. In an effort to improve access to these and other Part D vaccines, we continue to encourage Part D sponsors to either offer a $0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing.

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 US 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.

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 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 Tdap and Zoster vaccination claims in their doctor’s office
showed that, compared with no co-pay, beneficiaries who had to pay a co-pay amount of $26–50, $51–75 or $76–100, respectively, are 1.39, 1.66 or 2.07 times as likely to cancel their zoster vaccination.³

- A February 2018 Manatt study showed 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 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.

Removing financial barriers will 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. The Call Letter language sends 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.

**Incentivize Immunization Through Adoption of Evidence Based Measures (113)**

We applaud that the annual flu vaccine has been added as a candidate for the Star Ratings Categorical Adjustment Index (CAI). Influenza is a potentially serious disease that can lead to hospitalization and sometimes even death. Millions of people get the flu every year, hundreds of thousands of people are hospitalized and thousands or tens of thousands of people die from flu-related causes every year. Vaccination has been shown to have many benefits including reducing the risk of flu illnesses, hospitalizations and even the risk of flu-related death in children. According to the Centers for Disease Control and Prevention, 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. The flu accounts for an estimated 8.95 billion, or 65% of the annual economic burden of adult vaccine-preventable diseases.

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

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implementation of adult immunization quality measures CMS will help to reduce barriers to adult immunization by creating incentives for offering vaccines.

While we are encouraged by the addition of the flu measure, we ask that CMS consider the inclusion of the Adult Immunization Stats Composite Measure, which includes four specific vaccines in one (influenza vaccine; tetanus, diphtheria, and pertussis (Tdap) or tetanus and diphtheria (Td) booster vaccine; herpes zoster vaccine; and pneumococcal vaccine). The HHS National Vaccine Program Office (NVPO) and the Centers for Disease Control and Prevention (CDC) in collaboration with the National Adult Immunization and Influenza Summit spearheaded the development of the composite. The immunization composite measure provides a sound, reliable and comprehensive means to assess the receipt of routine adult vaccinations recommended by the Advisory Committee on Immunization Practices (ACIP).

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. In the FY19 Call letter “Potential New Measures for 2020 and Beyond (page 150-151)” CMS laid the groundwork for adoption of this important measure. AVAC strongly supports an adult immunization composite measure and asks that CMS introduce an Adult Immunization Composite Measure on the Star Ratings Display Page.

The addition of an adult immunization composite measure on the display page and for Star Ratings will provide a sound, reliable and comprehensive means to assess the receipt of routine adult vaccinations. Application of the composite measure will provide the foundation for Medicare quality reporting programs and reflect the National Quality Strategy (NQS) "triple aim" of better care, affordable care, and healthy people/communities and serves as an overarching framework for guiding and aligning public and private efforts to improve quality healthcare while the National Prevention Strategy (NPS) serves as the overarching framework for improving quality of life by shifting the focus from sickness and disease to prevention and wellness. At the same time, the composite will help to streamline the patchwork of existing adult immunization measures (see appendix 2) and help to reduce the reporting burden on providers.

Medication Therapy Management Program (146)
AVAC also appreciates language in the call letter encouraging utilization of the Medication Therapy Management (MTM) Program as part of innovations in health care design. Medicare beneficiaries account for a large portion of total prescription drug expenditures and individuals with chronic conditions such as diabetes, heart and lung
disease account for a disproportionate share of Part D spending. MTM programs have been shown to be effective in improving medication adherence, health outcomes and reducing adverse drug events. Enhanced MTM programs offer an additional opportunity for PDPs to innovate prescription drug delivery services with the goal of improving health care quality while lowering costs.

MTM and enhanced MTM programs offer an important, yet underutilized, means to routinely assess the immunization status of eligible beneficiaries and provide counseling as well as administer recommended vaccinations (when permitted by state law). AVAC urges CMS to include additional language in the CY2020 call letter directing PDP and MA plans to encourage increased application of MTM programs for the purpose of improving immunization rates among Medicare beneficiaries, particularly those with chronic conditions.

Thank you for the opportunity to offer our perspective on the 2019 Medicare Advantage and Part D Advance Notice and Draft Call Letter. We hope CMS will maintain strong language in the final letter encouraging Part D plans to include vaccines in the $0 vaccine tier or low-cost sharing tier in the final letter and language supporting efforts to develop and implement a composite quality measure for adult immunizations. We greatly appreciate CMS’ efforts to balance plans’ fiduciary responsibilities and beneficiary access to this important preventive health service.

Please contact an AVAC manager at (202) 540-1070 or 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 Immunization Registry Association (AIRA)
Asian & Pacific Islander American Health Forum (APIAHF)
Association of Immunization Managers (AIM)
Biotechnology Innovation Organization (BIO)
Dynavax
GSK
Hep B United
Hepatitis B Foundation
Immunization Action Coalition (IAC)
Medicago
National Association of Chain Drug Stores (NACDS)
National Association of City and County Health Officials (NACCHO)
National Black Nurses Association
National Foundation for Infectious Diseases (NFID)
National Hispanic Medical Association
Novavax
Pfizer
Pharmacy Quality Alliance
Sanofi
The Gerontological Society of America
Trust for America's Health (TFAH)

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