



January 27, 2025

Jeff Wu  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services,  
Attention: CMS-4208-P, Mail Stop C4-26-05,  
7500 Security Boulevard, Baltimore, MD 21244-1850  
<https://www.regulations.gov/document/CMS-2024-0345-0006>

Dear Acting Administrator Wu:

On behalf of members of the Adult Vaccine Access Coalition (AVAC), we appreciate the opportunity to offer comments on the proposed rule, “Medicare and Medicaid Programs: Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.”

Specifically:

- Support codifying that any ACIP-recommended adult vaccine is exempted from all beneficiary cost sharing for Calendar Year (CY)2026 and beyond.
- Support codifying the definition of an “ACIP-recommended adult vaccine”.
- Appreciate the proposal to enable enrollees who submit direct member reimbursement (DMR) requests for ACIP-recommended adult vaccines accessed at either out-of-network pharmacies or providers, or at in-network pharmacies or providers to receive the benefit with no added cost sharing.
- Encourage Part D and Medicare Advantage plans to avoid utilization management strategies that hinder a provider or pharmacy’s ability to choose to stock and offer vaccines to Part D beneficiaries.
- Appreciate the proposal clarifying that Part D plans must provide coverage without cost sharing once a new or revised recommendation is adopted by the CDC Director and posted on the CDC website.

AVAC consists of more than seventy-five organizational leaders in health and public health who are committed to legislative and regulatory policy solutions to improve access to adult vaccines. 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 society. 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 the ecosystem for adult immunizations.

Research shows that utilization of recommended vaccines minimizes the burden of vaccine-preventable diseases across the life course. However, despite the well-known benefits of immunizations, approximately 50,000 adults die each year from vaccine-preventable disease in the United States, while adult coverage remains below federal goals for most commonly recommended vaccines. 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.

AVAC greatly appreciates the proposed rule seeks to codify language that any ACIP-recommended adult vaccine is exempted from all beneficiary cost sharing, including the annual deductible or any other fees in all phases of the benefit for Calendar Year (CY)2026 and beyond. Studies have shown a direct correlation between high cost sharing and increased abandonment rates of vaccines in Medicare Part D. Removing cost and other barriers to Medicare beneficiary access will encourage more individuals take advantage of this important preventive benefit, which will drive improved immunization rates for Medicare populations and will ultimately lead to improved direct and indirect health outcomes and lower costs.

In addition to codifying immunization coverage for Medicare Advantage and Prescription Drug Plan beneficiaries without cost-sharing requirements, it is also vitally important to support a robust network of community qualified providers that is available and accessible to offer and administer vaccines. Vaccines are not equally available across communities, and as such, remain a consistently underutilized, yet valuable prevention tool.

It is vital that CMS provide simple and clear guidance on immunization coverage to Medicare Advantage and Part D plans, their beneficiaries, as well as the range of providers who serve them. AVAC is appreciates that CMS seeks to build on past regulations and guidance, as described in the proposed rule, by codifying an explicit definition of an “ACIP-recommended adult vaccine”. The proposed rule defines it, “as a vaccine licensed by the FDA for use in adults and administered in accordance with ACIP recommendations.” Furthermore, the proposed rule specifies that routine vaccines that are included on the ACIP “Adult Immunization Schedule”<sup>1</sup> as well as, vaccines recommended by the ACIP through shared clinical decision making or recommended for specific population subgroups are all required to be covered by Medicare Advantage and Part D plans at no cost to the beneficiary. Codification of this definition and these requirements in the final rule will help ensure that plans continue to provide beneficiary Part D coverage at no cost for routine adult vaccines, vaccines recommended through shared clinical decision-

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<sup>1</sup> <https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-schedule-vaccines.html>

making, as well as vaccines that may be recommended to a beneficiary for specific travel reasons or due to an occupational risk.

AVAC also supports the CMS proposal to enable enrollees who submit direct member reimbursement (DMR) requests for ACIP-recommended adult vaccines accessed at either out-of-network pharmacies or providers, or at in-network pharmacies or providers, that are otherwise a covered benefit to receive them with no added cost sharing, as required by law. Furthermore, we would urge CMS to also finalize the requirement that Part D plans reimburse the enrollee for the full cash price paid to the pharmacy or provider for an ACIP-recommended adult vaccine in instances where there is a potential difference between the cash price and plan allowance for DMRs.

Furthermore, AVAC urges CMS to strongly encourage Part D and Medicare Advantage plans to avoid utilization management strategies (for example, prior authorization) that would otherwise hinder a provider or pharmacy's ability to choose to stock and offer vaccines that best serve the needs of their patients. The proposed rule notes that "Section 30.2.7 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, Part D sponsors may only use utilization management strategies to assess the necessity of vaccines that are less commonly administered in the Medicare population, facilitate the use of vaccines in line with ACIP recommendations, and evaluate potential reimbursement of vaccines that could be covered under Part B. <sup>(11)</sup>" For instance, a provider will want to ensure they are carrying vaccines that meet the clinical needs a beneficiary, based on their age and any potential health conditions. The employment of utilization management strategies across different Part D and Medicare Advantage plans can complicate and add unnecessary costs to providers who wish to stock and offer vaccines to beneficiaries.

AVAC also appreciates the proposed rule seeks to ensure that Part D beneficiaries have timely access to recommended vaccines. Specifically, the proposed rule would codify that once a new or revised recommendation is adopted by the CDC Director and posted on the CDC website, Part D and Medicare Advantage plans sponsors must provide coverage for dates of service on or after the "Effective date of the ACIP recommendation". This important clarification will help reduce beneficiary and provider confusion and delays in access and plan coverage of recommended vaccines. We appreciate the proposed rule also directs plans to reimburse beneficiaries for any recommended vaccines that may have been administered after the ACIP recommendation effective date but prior to the recommendation being posted on the CDC website and also provides guidance to Medicare Advantage and Part D plans on vaccine coverage and cost sharing when ACIP modifies a previous recommendation to ensure it remains aligned with FDA medically accepted indications.

Again, thank you for the opportunity to share our perspective on the proposed rule. Please contact an AVAC Coalition Manager at [lfoster@adultvaccinesnow.org](mailto:lfoster@adultvaccinesnow.org) if you wish to further discuss our comments.