

April 29, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Seshamani:

We are writing to express serious concern regarding utilization management tactics that we understand are being employed by Medicare Part D sponsors for vaccine coverage. We are especially alarmed in light of the Administration's policy that all ACIP-recommended vaccines be made available to Medicare beneficiaries with no copay in implementing requirements of the Inflation Reduction Act. We know CMS shares these concerns, previously stating "[w]e urge plans, issuers, and PBMs to check their processes and systems to ensure they are providing full coverage, without cost sharing, of preventive services, as required by federal law."¹ Imposing utilization management tactics on vaccines only serves to obfuscate the Administration's policy intent to make all recommended vaccines more widely available and affordable where CMS has acknowledged "[t]he inappropriate use of these tools can impede access to needed care for people and delay essential treatments, as well as take clinician time away from direct care."² Part D sponsors' utilization management tactics will limit beneficiary access to essential vaccines, undercutting broader efforts to promote the nation's health. **Accordingly, we urge CMS to specifically prohibit Part D sponsors from using utilization management tactics for vaccine coverage and to reject any Part D formulary that suggests utilization management for vaccine coverage.**

The utilization management tactics at issue, such as National Drug Code (NDC) blocks and \$0 reimbursement to pharmacies for "less preferred" ACIP-recommended vaccines pose significant and harmful barriers to timely and equitable access to vaccines for Medicare beneficiaries.

First, these tactics may inappropriately force patients to receive alternative vaccines instead of the one originally prescribed by their healthcare provider, including their trusted pharmacist. This approach disregards the individualized medical needs of patients and undermines the expertise of healthcare professionals in determining the most appropriate

¹ <https://www.cms.gov/newsroom/fact-sheets/cms-letter-plans-and-pharmacy-benefit-managers>

² <https://www.cms.gov/newsroom/fact-sheets/cms-letter-plans-and-pharmacy-benefit-managers>

vaccine based on factors such as age, medical history, risk factors, allergies, and other contraindications.

Second, these Part D sponsor utilization management tactics applied to vaccines could delay access to critical immunizations, compromising the timely protection of vulnerable populations against preventable diseases. The administrative burden imposed by these tactics can lead to delays in patient care, contributing to gaps in vaccination coverage and increasing the risk of outbreaks.

Third, the Part D sponsor utilization management tactics preferring some ACIP-recommended vaccine products over others stands to create serious operational challenges for pharmacies in offering broad vaccination access across the communities they serve. This will also result in increased vaccine waste and increased cold chain burden as pharmacies would potentially have to stock multiple presentations of vaccines used to prevent the same disease (for example Adacel and Boostrix). Additionally, it would give plans the ability to prefer MDV instead of SDV or prefilled syringes, which would add to the operational and financial burden on pharmacies. Pharmacies continue to be a top vaccine access point for Americans. Consider that compared to medical offices, pharmacies provided more than 90% of COVID-19 vaccines during the 2023-2024 season.³ Importantly, the utilization management tactics contemplated would seriously complicate some pharmacies' ability to acquire vaccine products, manage their vaccine inventory, and sustainably support operations and vaccine services.

The tactics contemplated such as \$0 pharmacy reimbursement threaten the convenience of pharmacy-based vaccinations that so many Americans, including seniors, rely upon. For example, consider the scenario where a Medicare Part D beneficiary presents to a pharmacy for a vaccine, and the pharmacy staff bill for a recommended vaccine that is not preferred – either the pharmacy could provide the service only to find out they were reimbursed \$0 for the product and service provided – or if the claim response indicates that another product is preferred, the patient may have to make a return trip in the future to allow the pharmacy time to access the preferred product.

Given the nation's recent experience responding to the COVID-19 pandemic, and the unequivocal importance of efficient scaling of access to vaccines in reopening the nation and saving millions of lives, it is critical for CMS to consider the unintended consequences of the Part D sponsor utilization management tactics. Moreover, the tactics could limit access to full vaccination schedules, leaving patients incompletely protected against diseases that require multiple doses for optimal effectiveness. This not only compromises individual health outcomes but also undermines broader public health efforts to control and prevent the spread of vaccine-preventable diseases.

³ <https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adult-vaccinations-administered.html>

Given the critical role of vaccines in safeguarding public health and reducing healthcare costs associated with preventable diseases, we urge CMS not to allow the use of utilization management tactics by Part D sponsors for vaccine coverage and to specifically deny any Part D formulary that proposes utilization management tactics for vaccine coverage. This would promote equitable access to vaccines for Medicare beneficiaries, and help CMS continue to play a pivotal role in protecting public health and improving health outcomes for millions of Americans.

Thank you for your attention to this important matter. We look forward to your prompt action in addressing these concerns and ensuring that Medicare beneficiaries have access to the vaccines they need to stay healthy.

Sincerely,

American Pharmacists Association (APhA)

National Association of Chain Drug Stores (NACDS)

National Community Pharmacists Association (NCPA)

cc: Jon Blum

Will Harris