DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE

DATE: August 31, 2023

TO: All Part D Sponsors

FROM: Vanessa S. Duran

Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: **REMINDER -** Contract Year 2023 Program Guidance Related to Inflation

Reduction Act Changes to Part D Coverage of Vaccines

The purpose of this memorandum is to remind Part D sponsors of the CMS memorandum released July 24, 2023, entitled "REVISION - Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines," which announced revised program guidance related to determining when \$0 cost sharing applies for adult vaccines covered under Part D. Specifically, in the revised guidance, CMS instructed that the effective date of the \$0 cost-sharing requirement for a new adult vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) must align with the date on which the CDC Director adopts the respective recommendation, as published on the CDC website, or the date after the last day of the ACIP meeting at which the recommendation was approved, if no date is published on the CDC website. While this CMS guidance revision became effective as of the date of the memorandum, July 24, 2023, we clarify that it retroactively applies to commercially available ACIP-recommended adult vaccines adopted by the CDC Director during previous 2023 ACIP meetings.

In addition, we remind Part D sponsors of the CMS memorandum released September 26, 2022, entitled "Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin," which requires Part D sponsors to apply \$0 cost sharing for new Part D vaccines that become available during the plan year and have an ACIP-recommended use in the adult population, regardless of whether a Part D sponsor adds such vaccines to the formulary midyear or the enrollee obtains the vaccine via a formulary exception. If Part D sponsors add such vaccines to their formulary with utilization management requirements, CMS will review such requirements to ensure they are consistent with section 30.2.7 of Chapter 6 of the Prescription Drug Benefit Manual.

Adherence to the revised program guidance and section 30.2.7 of Chapter 6 of the Prescription Drug Benefit Manual is particularly important as new ACIP-recommended adult vaccines with wide public health implications become available, including new vaccines for Respiratory Syncytial Virus (RSV), and sponsors should add these high-priority vaccines to their formularies as quickly as possible.

Questions about this memorandum may be submitted to PartDPolicy@cms.hhs.gov.