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DATE: July 24, 2023

TO: All Part D Sponsors

FROM: Vanessa S. Duran, Acting Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: **REVISION** - Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines

The purpose of this memorandum is to update CMS guidance with respect to the effective date of new Advisory Committee on Immunization Practices (ACIP) recommendations for purposes of determining when \$0 cost sharing applies for new adult vaccines covered under Part D.

Section 11401 of the Inflation Reduction Act (IRA, P.L. 117-169¹) amended the Social Security Act (the Act) by adding paragraphs (b)(8) and (c)(5) to section 1860D-2 to require that, effective January 1, 2023, no deductible or cost sharing shall apply for adult vaccines recommended by the ACIP (referred generally to as \$0 cost sharing in this memorandum). For purposes of section 1860D-2(b)(8) of the Act, the IRA defined “adult vaccine recommended by the [ACIP]” as meaning a covered Part D drug that is a vaccine licensed under section 351 of the Public Health Service Act for use by adult populations and administered in accordance with recommendations of the ACIP.

On September 26, 2022, CMS released guidance via the Health Plan Management System (HPMS) memorandum titled “Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin,” in which we instructed that for any new ACIP-recommended adult vaccine that becomes available during a plan year, Part D sponsors must apply the \$0 cost-sharing requirements in section 1860D-2(b)(8) of the Act to applicable claims with dates of service after ACIP’s issued recommendation.

On April 4, 2023, CMS clarified in the HPMS memorandum titled “Final Contract Year (CY) 2024 Part D Bidding Instructions” that, in addition to meeting the statutory definition of “adult vaccine recommended by the [ACIP],” as well as CMS’ interpretation of “adult vaccine” and “recommended” in the September 2022 memorandum,² in order for a vaccine to be considered

¹ <https://www.congress.gov/bill/117th-congress/house-bill/5376/text>

² In the September 2022 memorandum, for the purposes of section 1860D-2(b)(8) of the Act, we interpreted “adult vaccine” and “vaccine ... for use by adult populations,” to mean a covered Part D drug that is a vaccine licensed by the US Food and Drug Administration under section 351 of the Public Health Service Act for use by adult populations and recommended for adult use by the ACIP, such as in the CDC/ACIP Adult Immunization Schedule

“ACIP recommended” for adult use, it must be both approved by the Director of the Centers for Disease Control and Prevention (CDC) and published in the CDC’s Morbidity and Mortality Weekly Report (MMWR).

Based on updated instruction from the CDC with respect to the effective date of new ACIP recommendations, we are revising CMS guidance, effective immediately, to align the effective date of the \$0 cost-sharing requirement for an applicable vaccine with the date on which the CDC Director adopts the respective ACIP vaccine recommendation, as published on the CDC website at <https://www.cdc.gov/vaccines/acip/recommendations.html>. Whereas the CDC previously specified that recommendations adopted by the CDC Director would become official once published in the MMWR, CDC now states under the “Meeting Recommendations” section of this webpage³ the date on which meeting recommendations have been adopted by the CDC Director and are immediately official. Accordingly, with this update, CMS is no longer using the date of the MMWR publication of approved vaccines as a factor in the effective date of an ACIP recommendation or in our interpretation of the term “ACIP recommended,” and we are removing the reference to the MMWR from our program guidance. This revision to guidance means that sponsors must provide \$0 cost sharing for a specific ACIP-recommended adult vaccine as of the date the CDC Director adopts the ACIP’s recommendation and it is posted as official on the CDC website, rather than the date that the adopted recommendation is published in the MMWR. In the event that the CDC Director’s adoption of an ACIP recommendation for an adult vaccine is posted as official on the CDC website but an adoption date is not specified, sponsors must provide \$0 cost sharing for such vaccine starting the day after the last day of the ACIP meeting at which the recommendation was approved. For example, the next ACIP meeting is scheduled to be held October 24-26, 2023. If an ACIP recommendation is officially adopted by the CDC director during that meeting but an adoption date is not specified on their website, sponsors must provide \$0 cost sharing effective October 27, 2023.

The ACIP holds three regular meetings annually, in addition to emergency sessions, for the purpose of reviewing scientific data and voting on vaccine recommendations. We call Part D sponsors’ attention to the fact that the CDC Director’s adoption of an ACIP recommendation might not be published on the CDC website on the exact date the approval is effective. Consequently, Part D sponsors will need to retroactively provide \$0 cost sharing for applicable vaccines that enrollees receive on or after the effective date but prior to when such recommendation was posted as officially adopted by the CDC Director. Such retroactive \$0 cost sharing will allow enrollees to receive the ACIP-recommended vaccines they need in a timely manner without financial barriers and in accordance with section 1860D-2(b)(8) of the Act.

Except for the revision described above, the instructions set forth in the September 26, 2022 and April 4, 2023 memoranda still apply.

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

(<https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html>) or other applicable ACIP recommendations. We also interpreted “recommended” to include all categories of ACIP recommendations, such as those based on shared clinical decision-making or those provided for use in limited populations and circumstances, in accordance with ACIP Vaccine Recommendations and Guidelines (<https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>).

³ <https://www.cdc.gov/vaccines/acip/recommendations.html>