

Regulatory NewsBREAK

CMS Revision of Section 11401 of the Inflation Reduction Act

On July 24, 2023, the Centers for Medicare and Medicaid Services (CMS) issued a memorandum titled "Revision - Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines" (Revised Guidance).

The Inflation Reduction Act requires \$0 cost sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP). An "adult vaccine recommended by [ACIP]" is a covered Part D drug that is a vaccine under section 351 of the Public Health Service Act for use by adult populations and administered in accordance with ACIP recommendations.

Previously, CMS issued guidance on September 26, 2022 that any ACIP-recommended adult vaccine available in a plan year and supported by Part D must apply the \$0 cost-sharing requirements for dates of services after ACIP's issued recommendation. On April 4, 2023, CMS clarified that an ACIP recommended vaccine for adult use must be approved by the Director of the Center for Disease Control and Prevention (CDC and published in the CDC's Morbidity and Mortality Weekly Report (MMWR).

CMS will now no longer use the MMWR date of publication for approved vaccines as the effective date of an ACIP recommendation. Sponsors must provide \$0 cost-sharing for specific ACIP-recommended adult vaccines as of the date the CDC Director adopts and posts ACIP's recommendation on the CDC website. If the CDC Director adopts an ACIP recommendation for an adult vaccine without a specified effective date, sponsors must provide the \$0 cost-sharing starting the day after the last day of the ACIP meeting during which the recommendation was approved. As an example, if ACIP's recommendations are adopted during the meeting scheduled for October 24-26, 2023, but an effective date is not specified, sponsors will need to provide the \$0 cost sharing effective October 27, 2023.

Part D sponsors should note that the CDC Director's adoption of an ACIP recommendation might not get published on the same day that the approval is effective. This means that Part D sponsors will have to provide \$0 cost-sharing for applicable

vaccines that enrollees receive on or after the effective date but prior to when this recommendation was posted as officially adopted by the CDC Director.

• Effective immediately.

See the Revised Guidance for additional details.

More on This Topic:

- Revised Guidance
- https://www.cdc.gov/vaccines/acip/recommendations.html

For questions, please reach out to <u>Tyler Thorne</u>.

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