DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: December 1, 2023

TO: All Part D Sponsors

FROM: Jennifer R. Shapiro, Director, Medicare Plan Payment Group

SUBJECT: Updates to the Inflation Reduction Act (IRA) Cost Sharing Maximum Reports for Part D Sponsors

The purpose of this memorandum is to announce updates to the Inflation Reduction Act (IRA) Cost Sharing Maximum Reports for Part D sponsors. These monthly reports, which are released via Acumen's Prescription Drug Event (PDE) Analysis web portal, assist Part D sponsors with the identification and correction of benefit year 2023 PDEs that may be misreporting the cost sharing maximum for Part D covered insulins.[1] Beginning December 2023, the IRA Cost Sharing Maximum Reports will include benefit year 2023 PDEs that may be misreporting the cost sharing maximum for adult vaccines as recommended by the Advisory Committee on Immunization Practices (ACIP).

Background

On August 16, 2022, the Inflation Reduction Act (IRA) was signed into law. Section 1860D-2(b)(9) of the Social Security Act (the Act), as added by section 11406 of the IRA, eliminated the deductible and imposed a statutory maximum beneficiary cost sharing of $35 per month's supply for covered Part D insulin products throughout all phases of the Part D benefit effective January 1, 2023. In addition, effective January 1, 2023, the IRA eliminated the deductible and imposed a statutory maximum beneficiary cost sharing of $0 for adult vaccines as recommended by the Advisory Committee on Immunization Practices (ACIP).

On September 26, 2022, CMS released guidance through HPMS titled "PDE Reporting Instructions for Implementing the Cost-Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023." This guidance established background and instructions on implementing the cost-

[1] Per section 1860D-2(b)(9)(C) of the Social Security Act, as added by section 11406(a)(1)(E) of the IRA, a covered insulin is a covered Part D drug covered under a PDP or MA-PD plan that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act and marketed pursuant to such approval or licensure, including any covered insulin product that has been deemed to be licensed under section 351 of the Public Health Service Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and marketed pursuant to such section.

sharing maximums established by the IRA for Part D covered insulin products and ACIP-recommended vaccines on PDEs with dates of service in 2023. The memo also noted that CMS would conduct periodic retrospective reviews to ensure PDE records are consistent with the beneficiary cost sharing and reimbursement requirements.

Updates to the IRA Cost Sharing Maximum Reports

Starting December 2023, PDE records with dates of service on or after 1/1/2023 reporting an ACIP-recommended vaccine are included in the IRA Cost Sharing Maximum Reports when they receive informational edit 902, "If an NDC is an ACIP-recommended vaccine, DOS is on or after 1/1/2023, the Patient Pay Amount must equal zero."

As a reminder, the following actions are expected from sponsors as a participant in this process.

- *Review Notifications*: Authorized PDE Analysis web portal users receive a notification from Acumen when reports are made available for download. Sponsors without PDE records requiring follow up as of the analysis date will not receive a report.

- *Download and Review Reports*: Reports are accessed via the Download Files page of Acumen's PDE Analysis web portal. Each report contains information on the PDE record(s) in question.

- *Research PDEs*: Sponsors are expected to research the PDE records included in the IRA Cost Sharing Maximum Reports to determine the appropriate action that must be taken to address the issue.

- *Take Corrective Action*: Sponsors are required to ensure that the beneficiary is reimbursed for any amount paid for ACIP-recommended vaccines, and then submit an adjustment PDE record once the beneficiary has been reimbursed the difference, as appropriate.

- *Provide a Written Response to Each Ticket in the Report*: Within two weeks of report issuance, sponsors are required to submit responses for each PDE record included in the IRA Cost Sharing Maximum Reports. For each ticket number, the sponsor must provide:

    1. The status of beneficiary reimbursement. The sponsor must confirm whether or not the beneficiary has been reimbursed for any amounts paid for ACIP-recommended vaccines.

    2. The status of the PDE record (valid, or has been/will be adjusted/deleted) and an explanation of the status for each ticket number. The sponsor must also report the date of action by which the PDE record has been or will be adjusted through DDPS.

    3. An explanation of which fields (i.e. Patient Pay Amount, Other TrOOP Amount, etc.) need to be updated if the PDE record still requires an adjustment.

Corrections to the PDE records included in the report are monitored on a regular basis to ensure that action is being taken by the sponsor. Sponsors are required to submit adjustments and

deletions within 90 days following discovery of an issue requiring change per CMS' timeliness standards.[2] Failure to complete the necessary actions in accordance with the timeliness standards may result in compliance action.

General questions regarding the IRA cost sharing maximum provisions should be directed to CMS at PDE-Operations@cms.hhs.gov. Questions regarding the IRA Cost Sharing Maximum Reports or the PDE Analysis web portal should be sent to Acumen at PDEAnalysis@acumenllc.com.

[2] For additional information, please refer to the guidance released through HPMS on October 6, 2011 titled "Revision to Previous Guidance Titled 'Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs.'"