DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: June 5, 2023

TO: All Part D Sponsors

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

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

The purpose of this memorandum is to announce the upcoming release of the Inflation Reduction Act (IRA) Cost Sharing Maximum Reports for Part D sponsors. The purpose of these reports is to 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] The reports will be released on a monthly basis beginning June 2023 via Acumen's Prescription Drug Event (PDE) Analysis web portal. Part D sponsors will have two weeks from the date of posting to provide a response to CMS regarding each PDE that is posted for review.

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).

Subparagraph (E) of section 1860D-2(b)(9) of the Act allowed for a 3-month grace period (January 1, 2023 through March 31, 2023) for plans to fully implement the insulin cost sharing maximum at the point of sale.[2] This means that beneficiaries may have paid the 2023 plan cost

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[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.

[2] The statute does not allow a grace period for plans to implement the changes to cost sharing for ACIP-recommended vaccines.

sharing previously established in the 2023 bid for covered insulin products at the point of sale through March 31, 2023. The statute requires plans to have reimbursed beneficiaries for any amount paid above $35 for a month's supply within 30 days. Beginning with dates of service on or after April 1, 2023, beneficiaries must not pay more than $35 for a month's supply of covered insulin products at the point of sale.

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 provided background and instructions on implementing the cost-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 not be issuing edits around cost sharing amounts for Part D covered insulin products during the grace period and instead is conducting periodic retrospective reviews to ensure PDE records are consistent with the beneficiary cost sharing and reimbursement requirements. After the grace period, the Drug Data Processing System (DDPS) issues informational Edit 904 when the Patient Pay Amount reported on the PDE record is greater than $35 for a month's supply for covered insulin products.

IRA Cost Sharing Maximum Reports

The IRA Cost Sharing Maximum Reports contain the details of PDE records reporting cost sharing amounts for Part D covered insulin products that may be inconsistent with the IRA's cost sharing and beneficiary reimbursement requirements.

PDE records with dates of service on or after 1/1/2023 reporting a Part D insulin product are included in the report in instances when:

- The PDE record was submitted during the grace period (January 1, 2023 through March 31, 2023), and as of the release date of the report, the PDE record continues to report a Patient Pay amount that exceeds $35 * number of months' supply, indicating that the beneficiary may not have been reimbursed for any amount paid in excess of $35 per month's supply.

- The PDE record was submitted on or after 4/1/2023, and the PDE record reports a Patient Pay amount that exceeds $35 * number of months' supply as of the release date of the report, where a month is defined as a 30-day supply, where a month is defined as a 30-day supply. This category includes PDE records that received informational Edit 904, which is effective as of 4/1/2023.[3]

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.

[3] While, as of the release of this memorandum, for informational Edit 904, a month is defined as a 28-day supply, for the IRA Cost Sharing Maximum Reports, CMS is defining a month as a 30-day supply. Therefore, while most of the PDE records in this category will be ones that have received informational Edit 904, there will be others in this category that did not receive the edit.

Sponsors without PDE records requiring follow up for the above-mentioned reasons 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 above $35 for a month's supply, and then submit an adjustment PDE record once the beneficiary has been reimbursed the difference, as appropriate, per our September 2022 HPMS guidance. For PDEs with dates of service between 1/1/23 and 3/31/23, sponsors are required to reimburse the beneficiary within 30 days of the date of service.

- *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 amount that exceeds $35 * number of months' supply and the date that the reimbursement has been or will be provided.

    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. [4] 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.

[4] 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.'"