

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

DATE: April 15, 2024

TO: All Part D Plan Sponsors

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

SUBJECT: Submitting Other TrOOP Amount Information for 2023 Part D Payment Reconciliation of the Inflation Reduction Act Subsidy Amount (IRASA)

The purpose of this memorandum is to provide additional information to Part D sponsors regarding the process and associated file formats necessary to reconcile Inflation Reduction Act Subsidy Amounts (IRASA) during the 2023 Part D Payment Reconciliation. The five file formats described in this memorandum are included as attachments and posted at www.csscooperations.com → Prescription Drug Event → IRASA Reconciliation.

Please submit questions about the IRASA reconciliation to PDE-Operations@cms.hhs.gov.

Background:

Sections 11401 and 11406 of the Inflation Reduction Act of 2022 (IRA) amended section 1860D-2 of the Social Security Act (“the Act”), effective January 1, 2023, to mandate that no deductible applies to covered insulin products or to adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Part D; to cap enrollee cost sharing for each covered insulin product at \$35 per month supply; and to cap enrollee cost sharing at \$0 for ACIP-recommended adult vaccines.¹ Further, sections 11401 and 11406 of the IRA amended section 1860D-15(h) of the Act to require that Part D sponsors receive a temporary retrospective subsidy for the elimination of the deductible and reduction in cost sharing regarding ACIP-recommended adult vaccines and covered insulin products with dates of service (DOS) in 2023.²

A September 26, 2022 memorandum 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,” described the temporary retrospective subsidy mandated by section 1860D-15(h) of the Act as the Inflation Reduction Act Subsidy Amount

¹ See Act § 1860D-2(b)(8) and (9).

² See Act § 1860D-15(h) as amended by IRA §§ 11401(c)(1) and 11406(c).

or “IRASA.”³ IRASA is available only for Prescription Drug Event (PDE) records reporting DOS in 2023 and consists of “the difference between the beneficiary cost sharing for the covered insulin, or ACIP-recommended vaccine, under the plan’s 2023 benefit design, and the applicable statutory maximum cost sharing (\$35 for insulins and \$0 for vaccines).”⁴

Section 11401(c)(2) of the IRA amended the statutory definition of “incurred costs” to include IRASA.⁵ As a result, all IRASA counts toward meeting the annual out-of-pocket (OOP) threshold. To operationalize counting IRASA toward meeting the annual OOP threshold, the Centers for Medicare and Medicaid Services (CMS) instructed Part D sponsors to report IRASA in the Other TrOOP Amount field on PDE records for covered insulin products with DOS in 2023.⁶ Since the Other TrOOP Amount field may contain non-IRASA Other TrOOP (i.e., payments from another TrOOP-eligible payers) further reducing cost sharing for covered insulin products to below \$35, CMS defined additional codes to report on PDE records when the Other TrOOP Amount field contains IRASA. CMS repurposed and renamed the Type of Fill Code field as the Other TrOOP Amount Indicator field to report the type of Other TrOOP Amount dollars populated within that field.⁷ An “S” in the Other TrOOP Amount Indicator field indicates the amount in the Other TrOOP Amount field consists of IRASA only and a “B” in the Other TrOOP Amount Indicator field indicates the amount in the Other TrOOP Amount field includes both IRASA and non-IRASA Other TrOOP amounts. A blank in the Other TrOOP Amount Indicator field indicates any amount in the Other TrOOP Amount field does not include IRASA.⁸

The 2023 Part D Payment Reconciliation will include a cost-based reconciliation of IRASA. Therefore, each Part D sponsor must submit a supplemental file that reports both the IRASA and the non-IRASA Other TrOOP amounts included in the total dollars reported in the Other TrOOP Amount. Part D sponsors will receive a subsidy equal to the total reported in Other TrOOP Amount fields on all final action, non-delete PDE records reporting the Other TrOOP Amount Indicator equal to “B” or “S,” minus the non-IRASA Other TrOOP amounts for PDEs on which the Other TrOOP Amount Indicator equals “B.”

IRASA Reconciliation Process Flow and Reports:

The Drug Data Processing System (DDPS) will generate a report, Report 45, which contains a detail (DET) record for every final action, non-delete PDE record with DOS in 2023 for a covered insulin product, that reports “B” in the Other TrOOP Amount Indicator field of the PDE record and is accepted by the 2023 Part D Payment Reconciliation PDE record submission deadline of June 28, 2024. Sponsors should be proactively reviewing the monthly Report 44, the Other TrOOP Amount Indicator Summary Report, to ensure final action PDE records identified on this report are accurate

³ Centers for Medicare and Medicaid Services published “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,” (September 26, 2022 Memorandum) on the Health Plan Management System (HPMS). The September 26, 2022 memorandum is available at <https://www.cms.gov/files/document/2023-pde-reporting-instructions.pdf>

⁴ September 26, 2022 Memorandum at p. 2.

⁵ See Act § 1860D-2(b)(4)(C)(iii)(I)(dd) (*two items designated as (dd) so in law*) as amended by IRA § 11401(c)(2)(B).

⁶ See fn. 4.

⁷ *Id.*

⁸ September 26, 2022 Memorandum at p. 3.

and make any adjustments or deletions as appropriate prior to the cut-off date. Any changes to PDE records after the cutoff date will not be reflected in Report 45 and will be captured during a future reopening of the 2023 Part D reconciliation.

The information provided by Report 45 enables Part D sponsors to identify the dispensing events associated with each included PDE record and shows amounts reported in the Other TrOOP Amount field of the submitted PDE records. DDPS will send Report 45 to the Prescription Drug Front-end System (PDFS), which then distributes the report to Part D sponsors. PDFS will transmit Report 45 on or about July 15, 2024, and a listserv announcement from the Customer Service and Support Center (CSSC) will notify Part D sponsors when Report 45 becomes available.

After determining the individual PDE-level IRASA and non-IRASA Other TrOOP amounts reported in the Other TrOOP Amount field of PDE records included in Report 45, Part D sponsors will use the Report 46 format to transmit this information back to PDFS. The Report 46 format resembles that of Report 45 but includes two additional fields added to the end of the DET record for separately reporting the IRASA and non-IRASA Other TrOOP amounts. Each record included within Report 46 must correspond to an associated record in Report 45. Further, the first 216 characters of the DET record populated by the Part D sponsor on Report 46 must match exactly to the first 216 characters of a DET record on Report 45.

Part D sponsors may provide multiple Report 46 submissions to respond to the Report 45 records. Additionally, Part D sponsors may resubmit previously accepted records that contain an error or errors requiring correction. CMS will determine the IRASA and non-IRASA Other TrOOP amounts for 2023 Part D Payment Reconciliation based on the final Report 46 DET record accepted as of 11:59pm Eastern Time on September 30, 2024.

DDPS will process and store records from Report 46 and will generate Report 47, a return file communicating acceptance or rejection of each Report 46 DET record submitted. PDFS will distribute Report 47 to Part D sponsors who will correct rejected records and resubmit a new Report 46 to PDFS. The possible Report 47 reject reason codes are:

Edit Code	Edit Description
300	DET record not found.
301	Data has changed within fields other than the Actual Other TrOOP Amount and the IRA Subsidy Amount on the DET record.
302	Actual Other TrOOP Amount <= \$0 on the DET record.
303	IRA Subsidy Amount <= \$0 on the DET record.
304	Other TrOOP Amount <> Actual Other TrOOP Amount + IRA Subsidy Amount on the DET record.

Part D sponsors may submit, and PDFS will accept, Report 46 records until 11:59pm Eastern Time on September 30, 2024. CMS will monitor submission and acceptance of Report 46 records and may contact Part D sponsors with Report 45 records that lack accepted, corresponding Report 46 records.

After the Report 46 submission window closes, DDPS will aggregate and calculate IRASA

reconciliation. CMS will determine the non-IRASA Other TrOOP amount based on the most recently accepted Report 46 record as of September 30, 2024, and will subtract this amount from the sum of the Other TrOOP amounts reported on PDE records where the Other TrOOP Amount Indicator equals “B” or “S.” This occurs during 2023 Part D Payment Reconciliation in the calculation of IRASA payment.

At the conclusion of the 2023 Part D Payment Reconciliation, DDPS will generate two new Part D Payment Reconciliation reports for distribution via PDFS to Part D sponsors alongside the existing Part D Payment Reconciliation reports. The new IRASA reconciliation reports consist of Report 48, the IRASA Reconciliation Inputs report, and Report 49, the IRASA Reconciliation Results report.

Part D plan sponsors should note the IRASA reconciliation process described by this memorandum will carry forward for any subsequent reopening of the 2023 Part D Payment Reconciliation.