



Provider Alert

To: Sharp Health Plan Medicare Providers and Provider Office Staff
From: Sharp Health Plan
Date: June 30, 2023
Subject: Sharp Health Plan Inflation Reduction Act (IRA) Guidance

Hello Plan Partners,

We have attached the Sharp Health Plan's Inflation Reduction Act (IRA) Guidance memo regarding certain drugs identified by CMS that may have reduced cost share due to inflation and the risk that the medical groups hold for the listed drugs.

Thank you for your continued partnership in providing the best care possible for our members. If you have any questions, please contact a Provider Account Specialist at provider.relations@sharp.com or 1-858-499-8330. We are available to assist you Monday – Friday, 8 a.m. to 5 p.m.

Best regards,
Sharp Health Plan
Provider Account Management
Provider.Relations@sharp.com
Tel: 1-858-499-8330 | Fax: 1-858-303-9049

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SHARP Health Plan

8520 Tech Way, Suite 201
San Diego, CA 92123-1450

April 19, 2023

RE: Sharp Health Plan Inflation Reduction Act (IRA) Guidance

Under the Part B Rebatable Drug Coinsurance Adjustment provision, beginning April 1, 2023, coinsurance for Part B rebatable drugs will be reduced, if the drug's price has increased at a rate faster than the rate of inflation.

Beginning April 1, 2023, the MA enrollee cost sharing for a Part B rebatable drug must not exceed the coinsurance amount of the original Medicare adjusted beneficiary coinsurance for that Part B rebatable drug. Part B rebatable drugs may be in either of the categories "Chemotherapy administration services to include chemotherapy/radiation drugs" or "Other drugs covered under Part B of original Medicare" listed in § 422.100(j)(1)(i).

Currently, all of Sharp Health Plan's cost share benefits for Part B drugs are the same or less than original Medicare's coinsurance.

Table 1 – Sharp Medicare Advantage 2023 plans

Plan	Gold	Plat	VIP	SHC Basic EGWP	SHC Prem EGWP	CalPERS EGWP	SDPEBA EGWP	Extra EGWP
Part B Coin	20% coin	20% coin	20% coin	20% coin	15% coin	No cost share	No cost share	10% coin

The table below lists the affected drugs and plans and what cost share changes need to occur. No changes are currently needed to the CalPERS, SDPEBA or Extra EGWP plan benefits for Part B drugs.

Table 2 – Rebatable Drugs New Coinsurance

HCPCS Code	Description	Gold, Plat, VIP & SHC Basic EGWP	SHC Prem EGWP
J0287	Abelcet	19.180%	15%
J8655	Akynzeo	16.213%	15%
J7504	Atgam	17.830%	15%
J3145	Aveed	19.239%	15%
J0558	Bicillin C-R	18.921%	15%
J0561	Bicillin L-A	18.514%	15%
J1955	Carnitor	13.918%	13.918%
J0850	Cytogam	18.893%	15%

SHARP Health Plan

HCPCS Code	Description	Gold, Plat, VIP & SHC Basic EGWP	SHC Prem EGWP
J9269	Elzonris	19.969%	15%
J0699	Fetroja	10.274%	10.274%
J1572	Flebogamma DIF	17.655%	15%
J9307	Folotyn	19.965%	15%
J1645	Fragmin	13.995%	13.995%
J0135	Humira	19.529%	15%
J2820	Leukine	19.648%	15%
J2265	Minocin	19.288%	15%
J0888	Mircera	17.614%	15%
J9268	Nipent	17.269%	15%
J9177	Padcev	19.470%	15%
J9061	Rybrevant	19.747%	15%
J2502	Signifor LAR	18.406%	15%
J2860	Sylvant	19.777%	15%
Q2053	Tecartus	19.958%	15%
J2792	Winrho SDF	19.882%	15%
J0775	Xiaflex	18.960%	15%
J3299	Xipere	18.969%	15%
Q2041	Yescarta	19.937%	15%



CENTER FOR MEDICARE

DATE: November 7, 2022

TO: All Organization Types and Stakeholders

SUBJECT: Inflation Reduction Act Changes to Cost Sharing for Part B Drugs for Contract Year 2023 Medicare Advantage and Section 1876 Cost Plans

This memorandum provides Medicare Advantage (MA) organizations and Section 1876 Cost Plan sponsors with guidance on the beneficiary cost sharing protections under section 11101 (Part B drugs with prices increasing faster than inflation) and section 11407 (Monthly cost-sharing cap for insulin furnished under Part B benefit) of the Inflation Reduction Act (IRA, P.L. 117-169), enacted on August 16, 2022. The cost sharing changes discussed in this memorandum become effective on April 1, 2023 for Part B drugs with prices increasing faster than inflation (referred to as the Part B Rebatable Drug Coinsurance Adjustment in this memorandum) and July 1, 2023 for the monthly cost-sharing cap for insulins furnished under Part B (referred to as the Part B Insulin Cost Sharing Cap in this memorandum).

This guidance is specific to Contract Year (CY) 2023. CMS will issue separate guidance regarding future contract years at a later date.

Medicare Advantage Plans

IRA Section 11101: Part B Rebatable Drug Coinsurance Adjustment

Background: Under the Part B Rebatable Drug Coinsurance Adjustment provision, beginning April 1, 2023, coinsurance for Part B rebatable drugs will be reduced, if the drug's price has increased at a rate faster than the rate of inflation. CMS will publish the adjusted beneficiary coinsurance for each Part B rebatable drug in the quarterly pricing files posted on the CMS website, as a 0-20% effective coinsurance of the Medicare-approved payment amount. The list of Part B rebatable drugs as well as the effective beneficiary coinsurance for those drugs could change each quarter.

Requirements: Beginning April 1, 2023, the MA enrollee cost sharing for a Part B rebatable drug must not exceed the coinsurance amount of the original Medicare adjusted beneficiary coinsurance for that Part B rebatable drug. Part B rebatable drugs may be in either of the categories "Chemotherapy administration services to include chemotherapy/radiation drugs" or "Other drugs covered under Part B of original Medicare" listed in § 422.100(j)(1)(i).

In applying this effective coinsurance percentage, MA plans may continue to base enrollee cost sharing off of the total MA plan financial liability for that Part B drug. For example, if the original Medicare adjusted beneficiary coinsurance for a Part B rebatable drug is 18% for the

calendar quarter beginning April 1, 2023, then the MA plan may use an enrollee coinsurance for that Part B rebatable drug during the calendar quarter beginning April 1, 2023 that does not exceed 18% of the total amount due for the drug for the specific encounter. MA plans that currently have a copayment for “Chemotherapy administration services to include chemotherapy/radiation drugs” or “Other drugs covered under Part B of original Medicare” do not need to make an adjustment so long as the copayment complies with the cost sharing rules in the April 2022 final rule.¹

CMS will specify the adjusted beneficiary coinsurance amount for each Part B rebatable drug in the quarterly pricing files (e.g., the Average Sales Price (ASP) files posted on this website prior to the applicable quarter: <https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice>²). MA organizations must ensure their cost sharing does not exceed the original Medicare adjusted beneficiary coinsurance as shown in the applicable quarterly ASP pricing file. The quarterly ASP pricing file will include an identifier or note in the “Notes” column for Part B rebatable drugs and will show the adjusted beneficiary coinsurance as a percentage with three decimal places (for example, 18.000) in a new column. The beneficiary coinsurance adjustment may change quarterly or not apply in a subsequent quarter.

See below for implementation instructions.

IRA Section 11407: Part B Insulin Cost Sharing Cap

Background: Insulin furnished under Part B on or after July 1, 2023, through an item of durable medical equipment covered under section 1861(n) (i.e., a medically necessary traditional insulin pump), is subject to a beneficiary coinsurance cap for a month’s supply of such insulin (that does not exceed \$35 and the Medicare Part B deductible does not apply).

Requirements: Beginning July 1, 2023, MA plans must cover Part B insulin at or below the original Medicare coinsurance cap of \$35 for a one-month’s supply of insulin without applying a service category or plan level deductible, pursuant to § 422.100(j)(1)(i)(F). Because original Medicare cost sharing is set as an absolute cap on cost sharing for Part B insulin, both MA coinsurance and copayments must not exceed that amount.

Section 1876 Cost Plans

The cost sharing charged by Section 1876 Cost Plans must not exceed the effective original Medicare coinsurance percentage for a Medicare Part B rebatable drug when such a drug is in the “Chemotherapy administration services to include chemotherapy/radiation drugs” category. This requirement is the same as described in the Medicare Advantage section above. See below for implementation instructions.

¹ See for example § 422.100(f)(6) as well as § 422.100(j).

² For calendar quarters beginning April 1, 2023 and beyond, the ASP pricing files will include a column for beneficiary coinsurance.

We also note that the Part B Rebatable Drug Coinsurance Adjustment and Part B Insulin Cost Sharing Cap of the IRA apply to Section 1876 Cost Plan enrollees who access health care benefits via original Medicare instead of through the cost plan's network in the same manner as they apply to original Medicare beneficiaries.

CY 2023 Part B Rebatable Drug Coinsurance Adjustment Implementation (MA Plans and Section 1876 Cost Plans)

Beginning April 1, 2023, MA plans and Section 1876 Cost Plans must implement the Part B Rebatable Drug Coinsurance Adjustment at the point-of-service or through an enrollee refund. Implementation at point-of-service means that when the plan uses coinsurance, the enrollee is charged no more than the dollar amount of the adjusted coinsurance percentage that applies to the specific Part B rebatable drug they received, based on the date of service.

Given the limited time for plans to implement the coinsurance adjustment for Part B rebatable drugs, CMS will consider timely refunds to enrollees (per §§ 417.456 and 422.270) of any excess coinsurance paid by the enrollee for a Part B rebatable drug as compliance with the applicable requirements for MA plans and Section 1876 Cost Plans. This means that if an enrollee pays more than the adjusted coinsurance percentage for a Part B rebatable drug based on the date of service, the plan must issue a refund to that enrollee. The refund amount to the enrollee must equal the difference between: (1) the dollar amount of the coinsurance paid by the enrollee for that Part B rebatable drug and (2) the dollar amount of the adjusted coinsurance percentage that applied on the date of service for that specific Part B rebatable drug. This implementation flexibility is only for CY 2023.

Note: Additional guidance specific to dually eligible enrollees will be forthcoming.

CY 2023 Medicare Plan Finder and Communication Materials (MA Plans and Section 1876 Cost Plans)

The CY 2023 Medicare Plan Finder (MPF) will reflect Part B drug cost sharing amounts that MA organizations and Section 1876 Cost Plans submitted in their 2023 bids. CMS is considering ways in which to educate beneficiaries about the cost sharing changes discussed in this memorandum on MPF.

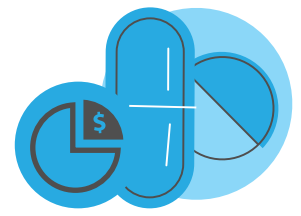
MA organizations' and Section 1876 Cost Plans' communication materials (including the Evidence of Coverage (EOC), the Annual Notice of Change (ANOC), and the Summary of Benefits) must reflect the changes in their cost sharing limits related to the IRA provisions discussed in this memorandum. For example, MA plans may use the ANOC or EOC errata model to communicate these changes if updating the hard copy ANOC or EOC is not practicable. In other instances, plans may use an addendum or a notice to communicate changes.

Consistent with CMS's guidance in the *Updates to Part D Member Materials for Contract Year 2023 Health Plan Management System (HPMS)* memorandum, dated September 6, 2022, which addressed updates to various communications materials to ensure that information pertaining to

coverage of insulin and vaccines was accurate in light of the changes to Part D benefits outlined in sections 11401 and 11406 of the IRA, plans are not required to resubmit any materials previously submitted to CMS, through the HPMS marketing module, that are edited based on the guidance set forth in this memorandum. Plans also are not required to resubmit any errata, notices, or addenda created for any of the materials based on the guidance set forth herein. CMS will not take any compliance actions for the changes to communication materials required in this memorandum.

Additionally, MA organizations and Section 1876 Cost Plans must have updated enrollee communication materials on their websites. MA and Section 1876 Cost Plans should also review other communication materials under §§ 422.428, 422.2260 and 423.2260 to ensure that information and guidance for enrollees related to coverage of Part B rebatable drugs and Part B insulin are accurate in light of the guidance in this memorandum.

Reduced Coinsurance for Certain Part B Rebatable Drugs under the Medicare Prescription Drug Inflation Rebate Program



Applicable April 1 – June 30, 2023

President Biden’s historic Inflation Reduction Act requires drug companies to pay rebates to Medicare when prescription drug prices increase faster than the rate of inflation for certain drugs furnished to people with Medicare. This new inflation rebate applies to Medicare Part B rebatable drugs, which are single source drugs and biological products, including certain biosimilar biological products, beginning January 1, 2023.

The federal government intends to invoice drug manufacturers for 2023 and 2024 Part B inflation rebates no later than fall 2025. The rebates will be deposited into the Medicare Trust Fund. In addition, beginning April 1, 2023, people with Medicare may see lower out-of-pocket costs for certain Part B drugs and biologicals with prices that have increased faster than the rate of inflation. For these drugs and biologicals, the beneficiary coinsurance will be 20% of the inflation-adjusted payment amount, which will be less than what the beneficiary would pay in coinsurance otherwise.

CMS posts payment information each quarter for separately payable Part B drugs, including the Part B rebatable drugs subject to the coinsurance adjustments, in the Medicare Part B Quarterly Sales Pricing (ASP) file, which is publicly available on CMS.gov. For the first time, the April 2023 ASP public file will also include the coinsurance adjustments for certain Part B rebatable drugs as required by the Inflation Reduction Act. The Part B drugs impacted by a coinsurance adjustment may change quarterly.

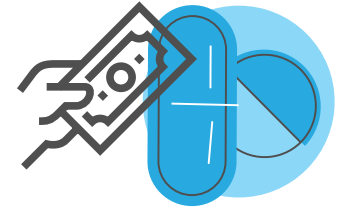
For the time period of April 1 to June 30, 2023, 27 Part B rebatable drugs have an adjusted coinsurance rate based on the inflation-adjusted payment amount. People with Traditional Medicare and Medicare Advantage who use these drugs may, depending on other health coverage they may have, pay a reduced amount for their coinsurance during this specific quarter. For the quarter April 1-June 30, 2023, people with Medicare may experience coinsurance amounts that are lower than what they would have paid before the new law passed by as much as \$2 to \$390 per average dose.

Below is the list of drugs with adjusted coinsurance amounts for the quarter April 1-June 30, 2023. Learn more about the **Medicare Prescription Drug Inflation Rebate Program** including a fact sheet on the Part B rebatable drug coinsurance reduction.

HCPCS Code	Short Description	Inflation-Adjusted Coinsurance Percentage (Normally 20.000%)
J0287	Abelcet	19.180%
J8655	Akynzeo	16.213%
J7504	Atgam	17.830%
J3145	Aveed	19.239%
J0558	Bicillin C-R	18.921%
J0561	Bicillin L-A	18.514%

HCPCS Code	Short Description	Inflation-Adjusted Coinsurance Percentage (Normally 20.000%)
J1955	Carnitor	13.918%
J0850	Cytogam	18.983%
J9269	Elzonris	19.969%
J0699	Fetroja	10.274%
J1572	Flebogamma DIF	17.655%
J9307	Folotyn	19.965%
J1645	Fragmin	13.995%
J0135	Humira	19.529%
J2820	Leukine	19.648%
J2265	Minocin	19.288%
J0888	Mircera	17.614%
J9268	Nipent	17.269%
J9177	Padcev	19.470%
J9061	Rybrevant	19.747%
J2502	Signifor LAR	18.406%
J2860	Sylvant	19.777%
Q2053	Tecartus	19.958%
J2792	Winrho SDF	19.882%
J0775	Xiaflex	18.960%
J3299	Xipere	18.969%
Q2041	Yescarta	19.937%

Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Initial Guidance



In August 2022, President Biden signed the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169) into law. Among many other provisions, this landmark law will lower the cost of health insurance for American families and give peace of mind to 50 million seniors and people with disabilities by placing an annual out-of-pocket cap on Medicare prescription drug costs.

The new law makes improvements to Medicare that will expand benefits, lower drug costs, keep prescription drug plan premiums stable, and improve the sustainability of the Medicare program. The law provides meaningful financial relief for millions of people with Medicare by improving access to affordable treatments and strengthening Medicare both now and in the long-run.

Q: What is the Medicare Prescription Drug Inflation Rebate Program?

The new drug law requires drug companies to pay a rebate if they raise their prices for certain drugs faster than the rate of inflation. This rebate is paid to Medicare and will be calculated and invoiced by the Centers for Medicare & Medicaid Services (CMS). The law establishes Medicare Part B prescription drug inflation rebates for single-source drugs and biologics with prices increasing faster than the rate of inflation, and provides for lower Part B beneficiary cost sharing on these drugs and biologics. In addition, the law establishes Medicare Part D prescription drug inflation rebates for certain drugs and biologics with prices increasing faster than the rate of inflation. Collectively, this program to implement these rebates is referred to as the Medicare Prescription Drug Inflation Rebate Program, or the Inflation Rebate Program.

Q: How will this new program improve Medicare?

The Medicare Prescription Drug Inflation Rebate Program will lead to a stronger Medicare program for current and future enrollees and discourage runaway price increases by drug companies. The rebates paid by drug companies will be deposited in the Federal Supplementary Medical Insurance Trust Fund. The Inflation Rebate Program was authorized under the Inflation Reduction Act, which

lowers out-of-pocket drug costs for people with Medicare and improves the sustainability of the Medicare program for current and future generations.

Q: How will people with Medicare benefit under the Medicare Prescription Drug Inflation Rebate Program?

The Medicare Prescription Drug Inflation Rebate Program may discourage drug companies from increasing their prices faster than the rate of inflation. Beginning April 1, 2023, people with Medicare may see lower out-of-pocket costs for certain Part B drugs and biologics with prices that have increased faster than the rate of inflation. For these drugs and biologics, the beneficiary coinsurance will be 20% of the inflation-adjusted payment amount, which will be less than what the beneficiary would pay in coinsurance otherwise.

Q: What's included in the initial program guidance for the Medicare Prescription Drug Inflation Rebate Program?

The initial program guidance issued on February 9, 2023 specifies the initial requirements and procedures for implementation of the new Medicare Prescription Drug Inflation Rebate Program.

CMS is seeking comment for the implementation of the Part B inflation rebates on topics such as:

- the process CMS intends to use to determine the number of drug units for calculating rebates;
- the process CMS intends to use to identify and remove 340B units for calculating rebates;
- the process CMS intends to use to identify and remove units for which a Medicaid drug rebate was paid for a covered outpatient drug;
- operational considerations related to the inclusion of units furnished to beneficiaries who are enrolled in Medicare Advantage plans;
- the processes CMS intends to use to reduce or waive the rebate amount in the case of a drug shortage or severe supply chain disruption;
- the process CMS intends to use to allocate the financial responsibility for the rebate amount for a calendar quarter where there is more than one manufacturer of the Part B rebatable drug; and

- the process CMS intends to use to ensure the integrity of the rebate determination process.

CMS is seeking comment for the implementation of the Part D inflation rebates on topics such as:

- options to identify the Part D rebatable drug billing units on the prescription claim and PDE file to assure that manufacturers are being accurately billed for Part D drug inflation rebates;
- options for methods to identify 340B units to exclude them from Part D rebatable drug units beginning in 2026;
- options to bill manufacturers in the future for Part D inflation rebates for Part D rebatable drugs of manufacturers that do not have an agreement in effect under the Medicaid Drug Rebate Program (MDRP), as well as Part D rebatable drugs that are not covered outpatient drugs under the MDRP;
- the processes CMS intends to use to reduce or waive the rebate amount in the case of a drug shortage or severe supply chain disruption;
- the mechanisms CMS intends to use to ensure integrity of the Part D drug inflation rebate invoicing process, including the use of Preliminary Rebate Reports and Preliminary True-Up Reports; and
- the process CMS intends to use to impose Civil Monetary Penalties (CMPs) on manufacturers that fail to pay rebates
- penalties on manufacturers that fail to pay rebates.

More information on how to submit comments can be found in the initial guidance. Comments received by March 11, 2023, will be considered.

Q: Can the public provide input on this new program?

Public feedback is critical to the success of the Medicare Prescription Drug Inflation Rebate Program, and this initial guidance is one tool, among many, CMS will use to ensure interested parties know when and how they can make their voices heard on implementation of the new drug law.

More information:

[CMS.gov/inflation-reduction-act-and-medicare](https://www.cms.gov/inflation-reduction-act-and-medicare)

Q: What are the key dates for implementation of this new program?

- **October 1, 2022** – The start of the first 12-month period for which drug companies will be required to pay rebates to Medicare if their prices for certain Part D drugs increase faster than the rate of inflation over the 12-month period.
- **December 20, 2022** – CMS issued its first inflation rebate guidance for Medicare providers and suppliers regarding reporting the 340B modifier for the Part B inflation rebates.
- **January 1, 2023** – The start of the first quarter for which drug companies will be required to pay rebates to Medicare if prices for certain Part B drugs increase faster than the rate of inflation.
- **February 9, 2023** – CMS issues initial guidance with a 30-day comment period on key topics to implement the Medicare Prescription Drug Inflation Rebate Program.
- **March 11, 2023** – The 30-day comment period on key topics to implement the Medicare Prescription Drug Inflation Rebate Program closes.
- **April 1, 2023** – Beginning on this date, people with Traditional Medicare and Medicare Advantage may pay a lower coinsurance for certain Part B drugs if the drug’s price increased faster than the rate of inflation in a benchmark quarter.
- **Q4 2023** – CMS expects to issue revised guidance to implement the Medicare Prescription Drug Inflation Rebate Program. Timing may be adjusted as necessary.
- **September 30, 2025** – The date by which CMS must invoice drug companies for the Part B inflation rebates they owe Medicare for calendar quarters in 2023 and 2024.
- **December 31, 2025** – The date by which CMS must invoice drug companies for the Part D inflation rebates they owe Medicare for the 12-month periods beginning October 1, 2022 and October 1, 2023.

