

Issue Brief

FEDERAL ISSUE BRIEF



Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

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Biden Administration Maps Out Drug Price Negotiation Process

In a 91-page memorandum titled "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments," and in accordance with sections 11001 and 11002 of the **Inflation Reduction Act** (IRA), which created Part E under Title XI of the Act (sections 1191 through 1198), the Secretary of the Department of Health and Human Services is required to establish the Negotiation Program to negotiate maximum fair prices (MFPs) for certain high expenditure, single source Medicare drugs. A copy of this item is available at: <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf>.

With respect to each initial price applicability year, the Centers for Medicare & Medicare Services (CMS) shall (1) publish a list of selected drugs in accordance with section 1192 of the Act; (2) enter into agreements with manufacturers of selected drugs in accordance with section 1193 of the Act; (3) negotiate and, if applicable, renegotiate MFPs for such selected drugs, in accordance with section 1194 of the Act; (4) publish MFPs for selected drugs in accordance with section 1195 of the Act; (5) carry out administrative duties and compliance monitoring in accordance with section 1196 of the Act; and (6) enforce civil monetary penalties (CMPs) in accordance with section 1197 of the Act. Section 1198 of the Act establishes certain limitations on administrative and judicial review relevant to the Negotiation Program.

Starting in April, some Medicare beneficiaries will have lower coinsurance for the 27 prescription drugs that raised prices faster than inflation in the last quarter of 2022. Seniors may see their out-of-pocket costs for these drugs decrease by \$2 to as high as \$390 per average dose starting April 1, 2023.

The 27 drugs subject to Medicare inflation rebates and the coinsurance adjustment rates are below:

| Name | Co-Insurance Percentage (Normally 20.000%) |
|----------------|--------------------------------------------|
| Abelcet | 19.180% |
| Akynzeo | 16.213% |
| Atgam | 17.830% |
| Aveed | 19.239% |
| Bicillin C-R | 18.921% |
| Bicillin L-A | 18.514% |
| Carnitor | 13.918% |
| Cytogam | 18.983% |
| Elzonris | 19.969% |
| Fetroia | 10.274% |
| Flebogamma DIF | 17.655% |
| Folotyn | 19.965% |
| Fragmin | 13.995% |
| Humira | 19.529% |
| Leukine | 19.648% |
| Minocin | 19.288% |
| Mircera | 17.614% |
| Nipent | 17.269% |



| Name | Co-Insurance Percentage (Normally 20.000%) |
|--------------|-----------------------------------------------|
| Padcev | 19.470% |
| Rybrevant | 19.747% |
| Signifor LAR | 18.406% |
| Sylvant | 19.777% |
| Tecartus | 19.958% |
| Winrho SDF | 19.882% |
| Xiaflex | 18.960% |
| Xipere | 18.969% |
| Yescarta | 19.937% |

CMS says copays are subject to change every quarter.

Payments owed by drug manufacturers to Medicare will be in the form of a rebate. Those that fail to pay the rebate will face a penalty equaling 125% of the rebate amount.

The government will start invoicing the companies for the rebates in 2025, but Medicare will start reducing out-of-pocket-costs for members April 1st.