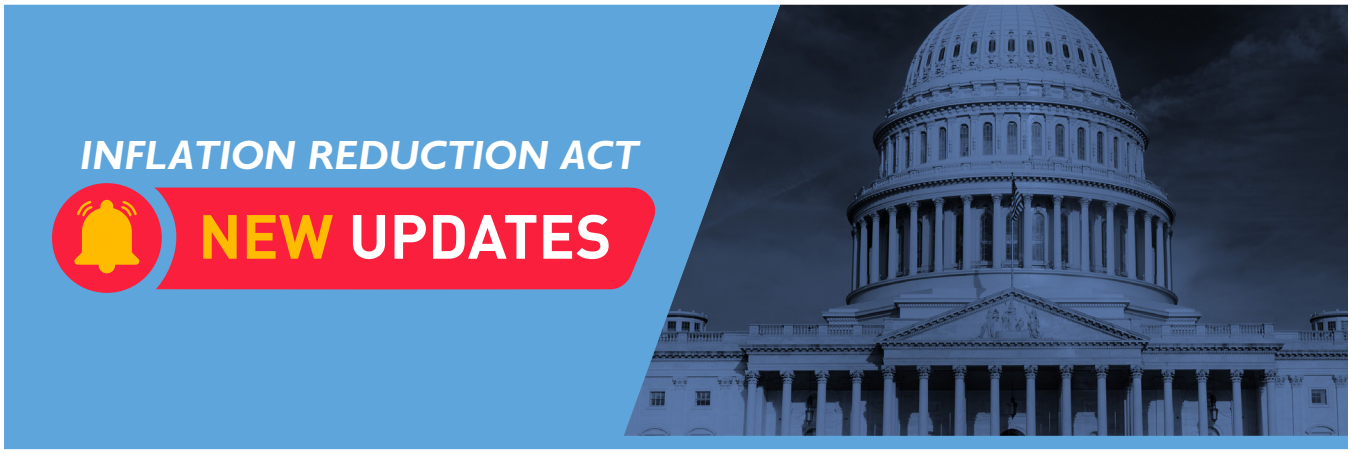
Prescription Analytics, Inc.
121 S Wilson Avenue, Hartford, WI 53027
Tel: 414-306-8200
prescriptionanalytics.com



UPDATE – INFLATION REDUCTION ACT REBATE PROVISIONS FOR PHARMA MANUFACTURERS

Inflation Reduction Act – new updates!

On August 16th, 2022, the Inflation Reduction Act (IRA) of 2022 was signed into law, creating potential impacts for drug manufacturers in the way of inflation rebates. Pertinent information and a timeline for changes surrounding the legislation can be found in our "Inflation Reduction Act Likely to Have a Negative Financial Impact On Many Drug Manufacturers" blog.

On February 9th, 2023, CMS released additional guidance related to the inflation rebates that will be billed to manufacturers with brand drugs and biologic products for Medicare Part B and Part D utilization soon.

The guidance released provides some consolidated insight and details into how these rebate calculations will work. This is helpful for manufacturers as companies work to accrue for potential liabilities. Here are key takeaways we had following our review of these documents:

- **Medicare Part D Inflation Rebates**
  - Manufacturers that do not have a CMS agreement (and likewise a 340B agreement), will not be required to enter into an agreement with the Secretary of HHS following the implementation of this program
  - Line Extensions will follow an alternate rebate, similar to current Medicaid URA calculations
    - *This formula has yet to be finalized*
  - It's not yet clear if benchmark values will be required to be shared among manufacturers when they acquire the rights to market a drug that has been previously marketed
  - The billing process will consist of a preliminary invoice (similar to the Branded Prescription Drug Fee), followed by a final rebate invoice with provisions that allow for a final true up billing approximately one year following the initial invoice
    - *Further clarification is still needed on how manufacturer restatements that go back further than this will be handled or if there is an option to restate these in that event*

- **Medicare Part B Inflation Rebates**
  - Benchmark values and rebates will be calculated at the HCPCS J-Code level using the Medicare Payment limit calculated (a derivative of ASP and/or WAC)
    - This means rebate amounts may not be driven by an individual manufacturer's activities
  - For new drugs, rebates will start the 6th full calendar quarter after the day on which the drug was first marketed, but the benchmark period will be the third full calendar quarter after the day on which the drug was first marketed

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- Aligned with ASP rules, drugs excluded from rebates are select vaccines for Influenza, pneumococcal disease, hepatitis B, and COVID-19
- The billing process will consist of a preliminary invoice (similar to the Branded Prescription Drug Fee), followed by a final rebate invoice with provisions that allow for one final true up billing approximately one year following the initial invoice
  - *Further clarification is required on how manufacturer restatements that go back further than this will be handled or if there is an option to restate*

ACTION REQUIRED FOR PHARMA MANUFACTURERS

The initial billing may not be sent to manufacturers until 2025, however it's imperative that manufacturers start planning for this change now as this has the potential to have serious impacts on manufacturers' financials for periods being accrued now.

For support in understanding the implications of inflation rebates and other legislation from the Inflation Reduction Act, contact the experts at Prescription Analytics today.

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SOURCES:

Part D Guidance: https://www.cms.gov/sites/default/files/2023-02/2.9.2023%20Part%20D%20Inflation%20Rebate%20Guidance.pdf

Part B Guidance: https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf