CRA Insights: Life Sciences

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November 2022

Inflation Reduction Act: Increasing healthcare coverage, reducing healthcare prices. How will it impact manufacturers?

Part 1: Expanding patient access to healthcare

The Inflation Reduction Act (IRA) of 2022, signed into law on August 16, contains some of the most significant changes in healthcare regulation since the introduction of the Medicare Modernization Act of 2003. There are many healthcare-related policy changes contained in the IRA, which can be categorized into three major sections:

1. Expansion of patient access to affordable insurance
2. Adjustments to medication pricing and reimbursement
3. Reforms to patient cost-sharing

Over the coming weeks, CRA will briefly summarize some of the most important changes associated with the IRA and highlight implications for life science manufacturers. In this installment, we tackle provisions related to expanding patient access to healthcare. We welcome any feedback or questions you might have about our analysis and look forward to discussing how your products and organization may be impacted.

There are at least three important changes within the IRA impacting patient access to health insurance.

- **Extending Affordable Care Act (ACA) tax credits**

  The ACA created subsidies, also known as Premium Tax Credits (PTC), for individuals or families living near the federal poverty level (FPL) that cap the premiums associated with ACA-qualified health plans purchased within the Health Insurance Marketplace. These subsidies work on a sliding scale, providing Americans near the FPL with subsidies continuing but at decreasing levels up to 400% of the FPL. The American Rescue Plan Act of 2021 (also called the COVID-19 Stimulus Package) expanded these subsidies, providing additional support to those closer to the FPL and ensuring that a person at any income level would not pay more than 8.5% of their income in health insurance premiums. These changes were set to expire in 2023 but have been extended by the IRA for three years until January 1, 2026. Had these tax

credits expired, it is estimated that five million Americans would have lost their health insurance within the ACA marketplace[1].

- **Medicare Part D premium stabilization**

  Increases to premiums for Medicare Part D plans will be capped at 6% year-over-year from 2024 through 2029[2]. In 2030 and beyond, premium calculations will revert to their previous computation which relies on competitive bidding. To the extent that health plans were to increase premiums by more than 6%, the Government would cover the difference for the period from 2024-2029[3]. It is worth noting that in recent years Medicare Part D monthly premiums have not increased at an annual rate of 6% and, in fact, have fallen 19% from a high of $32 in 2018 to $26 in 2021[4]. The Medicare Part D premium stabilization could stave off any major increases in premiums resulting from recent inflationary pressures throughout the economy.

- **Expanding eligibility of low-income subsidies (LIS) under Medicare Part D**

  LIS individuals qualify for Medicare Part D plans that have very low cost-sharing and limited to no premiums. This section of the IRA expands eligibility of individuals who qualify for LIS from 135% of the FPL to 150% of the FPL starting January 1, 2024. This change will increase the number of individuals that qualify based on income by six million compared to the 56 million that fall below 135% of the FPL[5]. However, the total number of LIS enrollees was only 14 million in 2019[6] (e.g., due to not meeting other LIS-qualifying requirements), suggesting that the income-based eligibility expansion could impact far fewer than six million individuals.

In summary, the IRA has extended the subsidies provided to many families with the COVID-19 stimulus package, limited the ability for plans to raise premiums to patients higher than 6% per year, and opened the opportunity for more patients to qualify for low-income subsidies.

Implications for life sciences companies

- As with any provision that increases the number of insured patients, **these provisions bolster the number of patients that can access critical healthcare services**, including medications. This tends to increase overall market size for many healthcare products with a more significant impact in certain diseases that disproportionately impact low-income individuals and families (e.g., metabolic, cardiovascular, and renal disease)[7].
- Stability in Medicare Part D premiums could lead to **less switching during open enrollment periods**, and **less pressure for patients to move out of higher premium plans** that tend to have more generous benefits and formularies. Patients staying on plans for longer may mean that manufacturers with drugs that have a longer-term health economic benefit may be viewed more favorably by Part D payers.
- The expansion of the LIS population may result in a **moderate increase in patients with minimal out-of-pocket cost obligations** which could be beneficial for manufactures selling or developing high-cost medications in therapeutic areas where LIS coverage is more common.

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[1] https://www.urban.org/research/publication/what-if-american-rescue-plan-act-premium-tax-credits-expire.

[2] Inflation Reduction Act, Page 194, https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_of_2022.pdf

[3] https://www.cbo.gov/system/files/2022-08/58355-Prescription-Drug.pdf, p. 3.

[4] https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-premiums-and-cost-sharing-in-2021/.

[5] https://www.census.gov/data/tables/time-series/demo/income-poverty/cps-pov/pov-01.html.

[6] https://www.kff.org/medicare/state-indicator/number-of-low-income-subsidy-lis-enrollees/.

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5171223/.

While this change will undoubtedly be impactful for those patients that are newly eligible for the LIS program, additional provisions within the IRA are dedicated to reforming cost-sharing for even more non-LIS Medicare patients.

- One possible side-effect: **if plans face a margin squeeze**, due to rising healthcare costs, higher beneficiary utilization of healthcare, and reforms to patient cost sharing, **plans may look to other avenues to limit expenditures such as considering increased utilization management** or maybe even fewer products included on the formulary.

In our next installment we will cover new rules governing the pricing and reimbursement of pharmaceuticals, including provisions enabling price negotiations for Medicare products, reimbursement policies for biosimilars, and mandatory rebates tied to inflation rates.

Part 2: Adjustments to medication pricing and reimbursement

The Inflation Reduction Act (IRA) of 2022, signed into law on August 16, contains some of the most significant changes in healthcare regulation since the introduction of the Medicare Modernization Act of 2003. There are many healthcare-related policy changes contained in the IRA, which can be categorized into three major sections:

4. Expansion of patient access to affordable insurance
5. Adjustments to medication pricing and reimbursement
6. Reforms to patient cost-sharing

Over the coming weeks, CRA will briefly summarize some of the most important changes associated with the IRA and highlight implications for life science manufacturers. In this installment of CRA's review of the IRA of 2022 we cover a variety of provisions influencing drug pricing, primarily via rebates paid to Medicare, and one change to how physicians are reimbursed. To review our prior installment, which covered the expansion of access for consumers, **click here**. We welcome any feedback or questions you might have about our analysis and look forward to discussing how your products and organization may be impacted.

There are four notable provisions that relate to pricing and reimbursement:

- **Medicare Drug Price Negotiation**

  The most extensive change to pharmaceutical pricing in the IRA is a mandate that the Secretary of Health and Human Services (HHS) shall establish a Drug Price Negotiation Program (Program). This Program will empower Medicare to negotiate directly with manufacturers for the first time and, once price is negotiated, these drugs will appear on all Medicare formularies. As part of the Program, the HHS Secretary will publish a list of drugs for negotiation, enter into agreements to negotiate with manufacturers, negotiate "maximum fair prices", and monitor and enforce compliance of the Program.[8]

  Initially, this Program will be limited to a set number of high expenditure drugs paid for by Medicare, but a variety of criteria will determine the drugs selected:

  - Single-source drugs that were in the top-50 total expenditure drugs for Medicare Part B or D in the prior year
  - FDA-approved drugs which have been approved for at least seven years and for which no generics have been approved (authorized generics do not count)
  - FDA-approved biologics which have been approved for at least 11 years and for which there are no biosimilars (authorized biosimilars do not count and a delay in negotiation is possible if there is a "high likelihood" that a biosimilar will be approved in the next two years)

  Notably, the Program excludes:

  - Qualifying orphan drugs, being those that have been designated as a drug for a single rare disease or condition – drugs with multiple indications could be included in the Program

[8] IRA, p. 42, https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_of_2022.pdf

- Low-spend Medicare Drugs, being those with Medicare expenditures less than $200 million in 2023 increased by the Consumer Price Index for all Urban Consumers (CPI-U) for each subsequent year
- Biologic products derived from human blood or plasma
- For 2026 through 2028, drugs sold by small biotech manufacturers which are defined by having one product that accounts for most (>80%) of their revenue and less than 1% of Medicare spend

Table 1 below identifies by year how many additional drugs are to be selected for negotiation and under which benefit.

Table 1: Drug Negotiation Implementation Schedule[9]

Negotiation year	Implementation year	# of Products	Benefit
2023/4	2026	10 Drugs	Part D only
2025	2027	15 Additional drugs	Part D only
2026	2028	15 Additional drugs	Part B and D
2027 and beyond	2029 and beyond	20 Additional drugs	Part B and D

The first list of products for negotiation will be published on September 1, 2023, with subsequent lists published on February 1 of each following year. Presumably the first year begins earlier to give more time for manufacturers and HHS to acclimate to the Program. Table 2 below provides a timeline by which negotiation or renegotiation is expected to follow.

Table 2: Drug Negotiation Process Calendar[10]

Activity	First year timing	Subsequent years
HHS publishes selected drugs	September 1, 2023	February 1
Manufacturers enter into agreement to negotiate	October 1, 2023	February 28
Manufacturers submit the non-Federal Average Manufacturer Price (non-FAMP) and any other information required by HHS to negotiate	October 2, 2023	March 1
HHS provides an initial offer; after which manufacturers can provide counteroffers	February 1, 2024	June 1
Negotiations must conclude; a maximum fair price is agreed upon and eventually published by HHS	August 1, 2024	November 1

HHS is expected to establish a consistent negotiation process which aims to achieve the lowest maximum fair price but the IRA states that HHS should consider factors such as:

[9] IRA, p. 48, https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_of_2022.pdf

[10] IRA, p. 69, https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_of_2022.pdf

- research and development costs,
- current unit production and distribution costs,
- prior federal financial support for discovery and development,
- data on pending and approved patent applications and exclusivities,
- market/revenue/sales volume data, and
- alternative treatment options and comparative effectiveness.

HHS and the manufacturer must agree to a maximum fair price which is less than a ceiling price multiplied by a defined percentage. These amounts are defined as follows in Table 3.

Table 3: Maximum Fair Price Calculation Fundamentals[11]

Ceiling price (Lowest of the below benchmarks)	X	Defined percentage (Whichever of the below qualify)
The average non-FAMP for 2021 inflated by CPI-U to the year prior to the selection year		Long-monopoly drugs: 40% for drugs which have been approved for at least 16 years
Starting with the second year of the Program and later, the average non-FAMP for the year prior to selection		Extended-monopoly drugs: 65% for drugs which have been approved for 12 through 16 years
For Part D drugs: An enrollment-weighted average of the plan-specific net negotiated price amounts for each Medicare Prescription Drug Plan (PDP) and Medicare Advantage Prescription Drug Plan (MA-PDP) for the most recent year for which the data are available		Short-monopoly drugs and vaccines: 75% for drugs and vaccines approved less than 12 years
For Part B drugs: The lesser of the drug's Average Sales Price (ASP) or Wholesale Acquisition Cost (WAC)		Extended- and long-monopoly vaccines: 75% for vaccines approved 12+ years

To ensure that manufacturers reach a negotiated agreement, a significant excise tax is to be applied during any period of noncompliance with the above-mentioned timelines. The excise tax is initially set at 65% of all US drug sales and increases to 95% of all US drug sales if a manufacturer remains out of compliance. Additional penalties are specified for providing false information, failing to provide the maximum fair price, and several other potential violations.

Once a product has reached a negotiated maximum fair price with HHS, this price remains in effect until the year beginning nine months after a generic or biosimilar has entered into the market. The maximum fair price will be increased annually by the CPI-U and after the first two years of the Program, the Secretary may decide to renegotiate with drug manufacturers. Renegotiations are triggered by either:

- a change in monopoly status (e.g., from extended to long monopoly) or
- the approval of new indications or other material changes if the renegotiation is expected to result in a significant change in the maximum fair price.

Once a manufacturer has reached a negotiated maximum fair price, the Program will ensure that drugs for which prices have been negotiated are included on all Part D formularies and that

[11] IRA, p. 72, https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_of_2022.pdf

Part B drugs are reimbursed at 106% of the maximum fair price (subject to sequestration). Further, the maximum fair price can set Medicaid Best Price but will not be part of Average Manufacturer Price (AMP) calculations. Finally, there is a provision whereby a manufacturer must offer the maximum fair price to 340B entities; however, the 340B entity much choose either the maximum fair price or their 340B discount.

- **Drug inflation rebates**

  The IRA will require manufacturers of certain single-source drugs to issue rebates to HHS for Medicare Part B and D expenditures on any drug that increases price faster than the CPI-U. The bill distinguishes between products covered under Medicare Part B and D as outlined below:

  - *Medicare Part B:*

    No later than 6 months after each calendar quarter, beginning January 1, 2023, HHS will provide manufacturers with a quarterly report detailing the number of units paid for during a relevant period, the excess increase in average sales price (ASP) relative to the inflation rate, and the rebate due to HHS. This provision of the IRA may begin on January 1, 2023, but HHS has the option to delay implementation for up to two years. Drugs launched after 2020 will have the rebate applied once ASP is established, which will occur on the sixth full calendar quarter after the drug is first marketed. These inflation rebates will be excluded from many forms of government price reporting (e.g., ASP, Best Price, AMP).
  - *Medicare Part D:*

    No later than nine months after each calendar year (defined as October 1 – September 30), beginning October 1, 2022, HHS will provide manufacturers with an annual report detailing the amount of excess annual price increase for each dose strength and form, and the rebate amount due to HHS. Like Medicare Part B, HHS may delay this first rebate period by up to two years and these rebates will be excluded from government price reporting (e.g., Best Price, AMP).

- **Delay of the pharmacy benefit manager safe harbor rebate rule**

President Trump signed an executive order in 2020 directing the Secretary of HHS to remove the discount safe harbor protections in connection

Part 3: Reforms to patient cost-sharing

The Inflation Reduction Act (IRA) of 2022, signed into law on August 16, contains some of the most significant changes in healthcare regulation since the introduction of the Medicare Modernization Act of 2003. There are many healthcare-related policy changes contained in the IRA, which can be categorized into three major sections:

7. Expansion of patient access to affordable insurance
8. Adjustments to medication pricing and reimbursement
9. Reforms to patient cost-sharing

In the third installment of CRA's review of the Inflation Reduction Act (IRA) of 2022 we cover several reforms to patient cost-sharing for Medicare Part D Plans (PDP) and Medicare Advantage Prescription Drug (MA-PD) Plans. Our first installment covered the expansion of access for consumers and can be viewed **here**. Our second installment discussed the implementation of medication pricing and reimbursement rules, which can be viewed **here**.

We welcome any feedback or questions you might have about our analysis and look forward to discussing how your products and organization may be impacted.

- **Medicare Part D out-of-pocket cap**

  Patient cost sharing for Medicare Part D drugs has gone through a variety of revisions since the introduction of the Medicare Modernization Act in 2003. Many changes have focused on reducing or eliminating the donut hole where consumers were initially responsible for the full payment of medications. However, patients have always been responsible for 5% co-insurance once they reached the catastrophic phase of their benefit. The IRA will remove patient responsibility for the catastrophic phase starting in 2024.[12] Further, in 2025 the IRA will establish an annual out-of-pocket cap of $2,000 for all Part D beneficiaries and will finally eliminate the "donut hole" such that there is only an initial coverage phase from a patient perspective.

  To assist in paying for these changes to patient out-of-pocket costs the IRA will sunset the existing Medicare Coverage Gap Discount Program and create a new discount program which will require manufacturers to pay a 10% rebate in the initial coverage phase and a 20% rebate in the catastrophic phase. Similar to the previous program, these rebates will apply to branded drugs, biologics, and biosimilars on the Part D benefit. It also appears that these rebates will apply to drugs that have negotiated a maximum fair price, further eroding net price.

- **Monthly Part D out-of-pocket caps to smooth cost sharing**

  At the start of each year, PDP and MA-PD beneficiaries who are taking high-cost medications typically see a significant out-of-pocket burden as they pay their deductible during initial coverage and in the coverage gap. As part of the IRA, starting in 2025, consumers can smooth their out-of-pocket expenses over the course of the year. This would be implemented at any point in the year by dividing the amount of money the beneficiary owes the plan sponsor by the remaining months in the year. Pharmacies would still be paid in full by the plan sponsor at the time of sale. If a beneficiary fails to pay their smoothed out-of-pocket costs in any month, their participation in the cost smoothing program would be terminated, they would owe the full out-of-pocket cost amount, and they would not be allowed to participate in the cost-smoothing program

[12] IRA, p. 162, https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_of_2022.pdf

in the next year. This smoothing of cost-sharing is expected to ease payment for many patients, especially those living on fixed incomes.

- **Insulin out-of-pocket caps**

  The rising cost of insulin to consumers has been a target of criticism in recent years; the IRA seeks to limit insulin out-of-pocket costs for Medicare beneficiaries. For the plan years of 2023 and 2024, the standard Part D deductible will not apply to insulin and insulin out-of-pocket cost will be limited to $35 per month. [13]Starting in 2025, the deductible will apply, but cost sharing will remain limited to $35 per month. Finally, in 2026 and beyond, cost sharing will be limited to the lesser of:

  - $35 per month,
  - 25% of the maximum fair price (see installment 2 here if you'd like to understand more about this new negotiated price), or
  - 25% of the negotiated price of the product under the beneficiary's plan.

- **Eliminating cost-sharing for vaccines**

  Most vaccines are covered under Medicare Part D with the major exceptions of influenza, pneumonia, hepatitis B, COVID-19, and post-exposure prophylaxis vaccines (e.g., tetanus and rabies) all of which are covered under Medicare Part B. There are already provisions which ensure that vaccines provided under Medicare Part B have no patient cost-sharing, but that has typically been untrue for vaccines covered under Medicare Part D. The IRA eliminated cost-sharing for Part D covered vaccines that have been recommended by the Advisory Committee on Immunization Practices (ACIP). It further provides a temporary (2023-2025) subsidy to plans to assist in paying for the expected increased uptake of vaccinations for Medicare beneficiaries.

In summary, the IRA provides several mechanisms to help reduce the out-of-pocket burden on Medicare Part D and Medicare Advantage Prescription Drug Plan beneficiaries.

Implications for life sciences companies

- Certain high-cost Part D products faced patient affordability challenges due to the uncapped 5% catastrophic co-insurance. **Removal of catastrophic co-insurance combined with the removal of the coverage gap and the institution of out-of-pocket cost caps may help more patients afford their medications**, which could increase prescription and compliance rates for high-cost therapies.
- All else equal, **lower out-of-pocket costs for patients could cause upward pressure on drug prices**, as manufacturers face less price-sensitivity, especially for products with high Medicare exposure.
- **Upward price pressure is likely limited to the inflation rate** as any additional price increase would need to be paid back to CMS in the form of inflation rebates (as covered in Part 2 (link) of this series of articles).
- Due to reduced need, there will likely be **reduced contributions to non-profit copay foundations** dedicated to assisting Medicare patients paying for high-cost medications.

Part D sponsors will need to adjust their bid prices, premiums, benefit designs, and/or utilization management strategies to pay for the reduced contributions from patients. Another possibility

[13]IRA, p. 229, https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_of_2022.pdf

would be that we see **fewer plans offered in the Medicare space** with fewer options for consumers to choose from. In either case, **manufacturers will need to consider the implications of benefit design changes on their target patients as they consider their own Part D contracting strategies.**

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