Inflation Reduction Act Data Collection Provisions

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Contents

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Introduction: Medicare Drug Price Negotiation Program

The enactment of the Inflation Reduction Act (IRA) in 2022 empowers Medicare (CMS) to negotiate directly with pharmaceutical companies for high-expenditure, sole-source medications lacking generic or biosimilar alternatives

CMS selected 10 Part D drugs for the first cycle of "negotiation," price applicability year 2026

Ten Medicare Part D Drugs Selected for Price "Negotiation" in 2023 for 2026 Price Applicability

Drug name	Manufacturer	Used for	Year of FDA approval	Total Gross Medicare Spending, June 2022-May 2023*
Eliquis	Bristol Myers Squibb	Blood thinner	2012	$16,482,621,000
Enbrel	Amgen	Rheumatoid arthritis, psoriasis	1998	$2,791,105,000
Farxiga	AstraZeneca	Diabetes, heart failure	2014	$3,268,329,000
Fiasp/Novolog	Novo Nordisk	Diabetes	2000	$2,576,586,000
Entresto	Novartis	Heart failure	2015	$2,884,877,000
Imbruvica	Pharmacyclics (AbbVie) and Janssen (Johnson & Johnson)	Leukemia, lymphoma	2013	$2,663,560,000
Januvia	Merck	Diabetes	2006	$4,087,081,000
Jardiance	Boehringer Ingelheim and Eli Lilly	Diabetes, heart failure	2014	$7,057,707,000
Stelara	Janssen (Johnson & Johnson)	Psoriasis, Crohn's disease	2009	$2,638,929,000
Xarelto	Janssen (Johnson & Johnson)	Blood thinner	2011	$6,031,393,000
Total				**$50,482,188,000**

CMS selection of drugs for negotiation will increase over time:

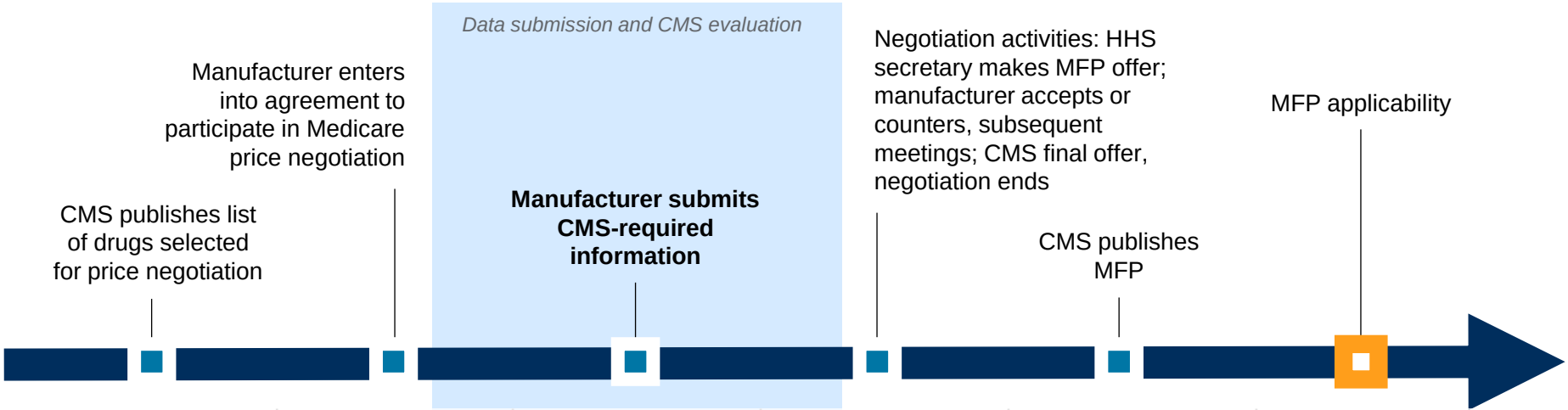
Price applicability years shown

- **2026:** 10 Medicare Part D drugs
- **2027:** 15 Medicare Part D drugs
- **2028:** 15 drugs covered under Medicare Part D or Part B
- **2029+:** 20 drugs covered under Medicare Part D or Part B

SOURCE: KFF. NOTE: *Total gross spending includes Medicare, plan, and beneficiary payments, not excluding any manufacturers' rebates or other price concessions as CMS is prohibited from publicly disclosing such information. CMS Notification: Centers for Medicare & Medicaid Services, Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026, August 29, 2023
CMS=Centers for Medicare & Medicaid Services.

Medicare Drug Price Negotiation Program Timeline

Negotiation process for selected drugs begins approximately two years before “Maximum Fair Price” (MFP) applicability*



By February 1, 2025 *15 Part D drugs*	By February 28, 2025	By March 1, 2025	By June 1 - By November 1, 2025	By November 30, 2025	**January 1, 2027**
By February 1, 2026 *15 Part D or Part B drugs*	By February 28, 2026	By March 1, 2026	By June 1 - By November 1, 2026	By November 30, 2026	**January 1, 2028**
By February 1, 2027 *20 Part D or Part B drugs*	By February 28, 2027	By March 1, 2027	By June 1 - By November 1, 2027	By November 30, 2027	**January 1, 2029**

***Selection continues through 2029, MFPs for drugs selected in 2029 will go into effect in 2031.** Dates may be subject to change based on CMS guidance and requirements.
Source: CMS, “CMS Implementation Timeline,” Link. Biotechnology Innovation Organization, “Understanding the Prescription Drug Provisions of the Inflation Reduction Act,” link.
CMS=Centers for Medicare & Medicaid Services. HHS=Health & Human Services.

Objectives & Methods

Non-compliance with the IRA's stringent data collection mandates can lead to significant penalties, including civil fines and a substantial excise tax (65%-95% of US sales)

We analyzed IRA guidelines and processes to understand the following:

- Data collection specifics (including elements and sources)
- Submission procedures (utilizing designated portals and templates)
- Audit details (timing and particularities)
- Implications of noncompliance, confidentiality issues, and associated compliance costs

IRA=Inflation Reduction Act.

IRA Data, Evidence Generation and Submission Requirements*

Research and development costs	US Market and sales data	Unit production and distribution costs	Comparative clinical effectiveness and therapeutic value	Budget impact
Total direct and direct development costs, including the direct and indirect costs of preclinical and clinical research, manufacturing, and post-marketing surveillance; and the extent to which the manufacturer has recouped such costs†	Sales volume, revenue data, and pricing across various channels like Medicare, Medicaid, and commercial markets	The current costs of producing and distributing the drug, including the costs of raw materials, labor, equipment, packaging, transportation, and storage	The extent to which the drug represents a therapeutic advance compared to other available treatments *(including clinical effectiveness; cost-effectiveness; budget impact; unmet medical needs, and improvements in health outcomes)*	Budget impact analysis of the drug on different global payers *(many variables may impact estimates, including complexity and variability of pricing arrangements, number of applicable countries)*
~$100,000 / drug	~$35,000 - $100,000 / drug	~ $50,000 / drug	~$235,000 - $900,000 / drug	≤ ~$5M

Low-end estimate: ~$500,000 *Costs based on publicly-available estimates* **High-end estimate: ~$6.4M**

Notes:

- Data accuracy, completeness, and/or relevance will be assessed by HHS; additional information or documentation may be requested from the manufacturer or the auditor; HHS will conduct random audits of a sample of manufacturers each year.
- The cost of required reports, audits, reviews, and related compliance may vary depending on the complexity and volume of the data; the quality of the review; requirements associated with data sources and review methodology; availability and accessibility of the data; the complexity and variability of the pricing arrangements; and, the frequency and timeliness of the reporting.

*For full data requirements, see Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act (cms.gov)
†Submission requirements also include pending and approved patent applications and exclusivities, and prior federal financial support for discovery and development.
HHS=U.S. Department of Health and Human Services. IRA=Inflation Reduction Act.

Considerations for Real-World Evidence Generation

- Given the 9- and 13-year lag period for small molecules and biologics respectively prior to negotiated Maximum Fair Price going into effect for selected drugs,* manufacturers have the **opportunity to develop real-world evidence in advance** to capture effectiveness data versus competitors.

- When developing comparative real-world evidence, it is critical to consider the **broad definition of therapeutic alternatives**, and the **focus on the Medicare population**.

*Small molecules eligible for selection 7 years post FDA approval with price applicability in year 9, vs biologic at 11 years post approval with price applicability in year 13

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Regulatory and Compliance Implications of the IRA

It's critical to evaluate internal preparedness for IRA compliance, optimize data and analytics for submissions, refine clinical development strategies, assess enterprise-wide impacts, and address other relevant factors

Readiness for Compliance

Conduct a gap analysis against IRA requirements, review current compliance frameworks, evaluate internal processes.

Data and Analytics Capabilities Assessment

Examine existing data management systems, data quality, analytics tools, and data governance practices.

Strategy for Early Clinical Development Optimization

Analyze current clinical development plans, evaluate the potential financial and regulatory impact of the IRA.

Enterprise-wide Impact Assessment

Perform a cross-functional analysis involving finance, operations, strategy, and regulatory affairs.

Other Relevant Factors

Leverage market research, competitive intelligence, and stakeholder interviews to gather insights.

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Expanded Clinical Development: Impact on Medicare Spending

Illustration for Product X with a baseline spending of ~$1B and 2027 eligibility for selection for negotiation*

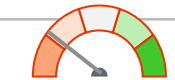
Approval Scenario A

Indication 3
Indication 4
Indication 5

Population: 7K

Total potential impact on annual Medicare expenditure:

$154M



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Indications in consideration for development (estimated size of target population / expected market share for product X):

- Indication 1 (1,100,000 – 10%)
- Indication 2 (500,000 – 20%)
- Indication 3 (5,000 – 60%)
- Indication 4 (40,000 – 25%)
- Indication 5 (60,000 – 40%)

$1.03B

…..Overall increase in Medicare spending…..

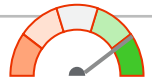
Approval Scenario B

Indication 1
Indication 3
Indication 5

Population: 25K

Total potential impact on annual Medicare expenditure:

$573M



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Key Considerations

- ❖ **Population size & attributes**
- ❖ **Channel mix (Med vs. Comm)**
- ❖ **Benefit (Part D vs. Part B)**
- ❖ **Estimated market share**
- ❖ **Pricing and production costs**
- ❖ **Rebates / discounts**
- ❖ **IRA exclusions**

Assumptions: 18.7% of eligible patients are expected to be covered by Medicare

**Product X is a hypothetical example not based on any material reference or source, used solely for the purposes of this example calculation*

Strategic Considerations

Unique challenges and opportunities presented by the IRA call for organization to develop a specialized, holistic approach

1	**Specialized Expertise**	In-depth of knowledge in IRA compliance, market access strategies, and healthcare policy that complements prior strengths and experiences. This expanded expertise is critical for uncovering nuanced regulatory insights and strategic opportunities that might be overlooked.
2	**Objective Perspective**	Approach internal evaluations with an objective perspective to illuminate blind spots and challenge assumptions, ensuring a robust strategy that is comprehensive and adaptable with goals of ensuring compliance and supporting value demonstration in the competitive landscape.
3	**Resource Optimization**	Tackling the IRA's implications requires dedicated focus. Teams will need to tackle these challenges while remaining free to concentrate on their core functions—driving innovation and operational excellence.
4	**Rapid Response to Regulatory Changes**	The IRA's regulatory landscape is evolving. Organizations will need to stay abreast of changes, interpreting these swiftly to adjust strategies in real-time, a proactive approach that internal teams, given their broad responsibilities, may find challenging to replicate.
5	**Data and Analytics Solutions**	Enhancing data capabilities, not just for compliance, but as a strategic asset for decision-making may increase reliance on cutting-edge tools and methodologies to unlock insights from data, offering clarity in a complex environment.

Conclusion and recommendations: The IRA enhances the role of value demonstration and evidence generation, which requires organizational adaptation

Intricate data requirements and substantial compliance costs make proactive strategic planning an imperative, starting as early as asset selection phase, to ensure full and efficient compliance

Evaluate infrastructure and readiness to understand areas of strength, gaps, and needed enhancements

- **Documentation Review**: Examine existing policies, procedures, and documentation to ensure they meet IRA standards
- **Strategic Roadmap**: Develop a detailed roadmap outlining steps to achieve full compliance with IRA data submissions, including timelines and responsible parties

Assess capabilities and develop recommendations for improving data systems and enhancing analytics capabilities

- **Data Inventory**: Create a comprehensive inventory of existing data sources, formats, and systems to identify gaps and redundancies
- **Technology Assessment**: Evaluate current analytics tools and IT infrastructure against the needs for IRA compliance and strategic decision-making
- **Data Governance Framework**: Implement a data governance framework to ensure data quality, security, and compliance with regulatory requirements

Review clinical development strategies and consider adjustments required for optimization

- **Pipeline Analysis**: Analyze the current product pipeline to identify opportunities based on IRA provisions and market access strategies
- **Clinical Trial Design Consultation**: Work with clinical teams to incorporate cost-effectiveness and value considerations into clinical trial designs
- **Impact Modeling**: Model the financial and market access implications of different clinical development scenarios under IRA provisions

IRA=Inflation Reduction Act.

Q&A