

THE INFLATION REDUCTION ACT – MEDICARE DRUG UPDATES

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INFLATION REDUCTION ACT OF 2022

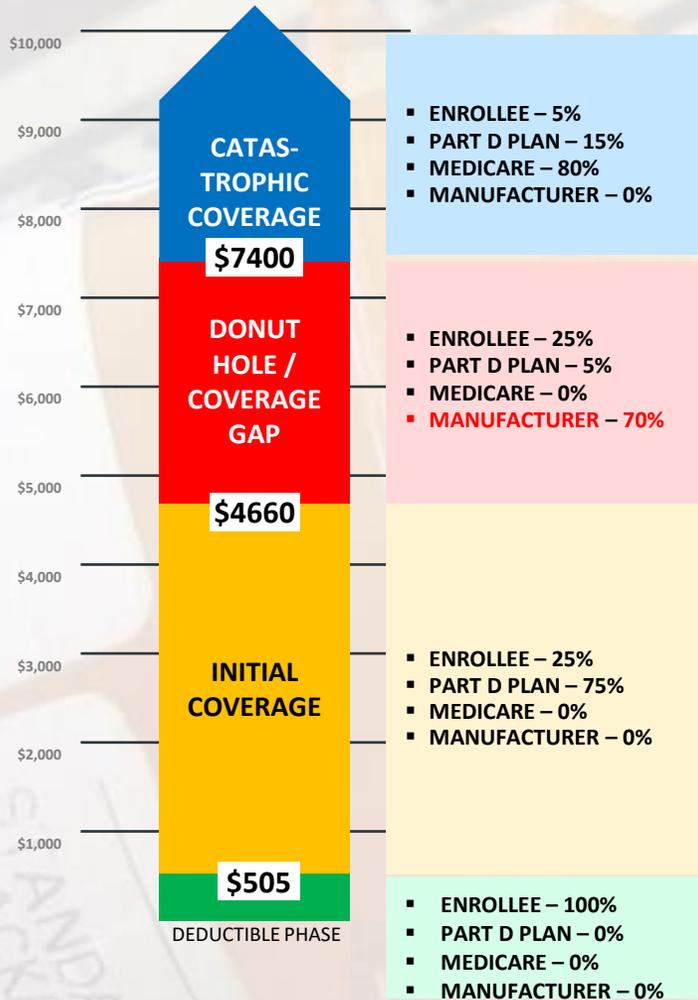
AT CORE OF THE IRA:

- REDESIGN OF THE MEDICARE PRESCRIPTION DRUG BENEFIT
- MEDICARE DRUG PRICE NEGOTIATION PROGRAM
- INFLATION-BASED REBATES
- PBM RULE DELAYED UNTIL 2032
- TEMPORARY INCREASE IN BIOSIMILAR REIMBURSEMENT

PART B – FEE-FOR-SERVICE	▪ <u>ADMINISTERED</u> IN THE OUTPATIENT SETTING / PHYSICIAN OFFICE
PART D – PRESCRIPTION DRUG PLANS	▪ <u>DISPENSED</u> BY A PHARMACY
PART D – PRESCRIPTION DRUG PLANS	▪ ADMINISTERED BY PRIVATE INSURANCE COMPANIES ▪ THE “NON-INTERFERENCE CLAUSE”

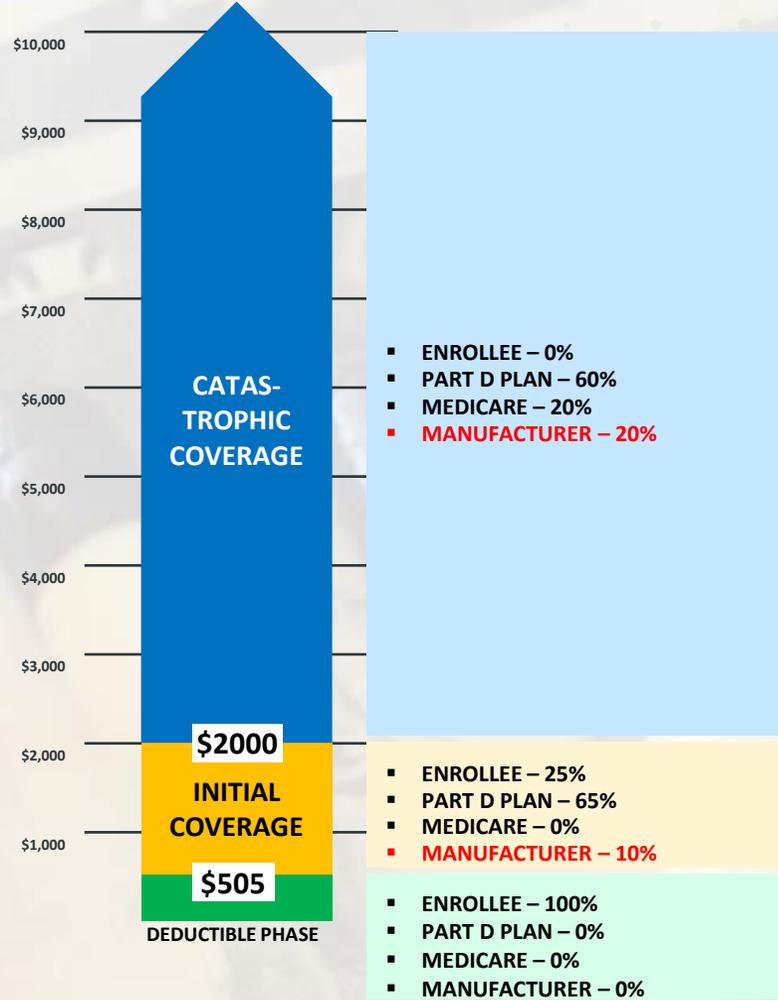
PART D PRESCRIPTION DRUG BENEFIT REDESIGN

CURRENT – UNTIL DEC. 31, 2024



FUTURE – EFF. JAN. 1, 2025

PATIENT OUT-OF-POCKET SPENDING PER YEAR ↑



OTHER CHANGES

- Premium Stabilization** – Premium growth capped at 6% per year
- Expansion of Low-Income Subsidy** – LIS benefits available to incomes lower than 150% FPL (previously 135%)
- Vaccines** – First dollar coverage
- Insulin Costs** – \$35/month

DRUG PRICE NEGOTIATION PROGRAM

→ INITIAL PRICE APPLICABILITY YEAR —
STARTS JAN. 1, 2026

→ CMS SELECTED FIRST 10 DRUGS
EARLIER THAN THE SEPT. 1, 2023
DEADLINE – ALL PART D

\$50.5 billion

- ELIQUIS
- JARDIANCE
- XARELTO
- JANUVIA
- FARXIGA
- ENTRESTO
- ENBREL
- IMBRUVICA
- STELARA
- FIASP

DRUG PRICE NEGOTIATION PROGRAM – SELECTION PROCESS

QUALIFYING SINGLE-SOURCE DRUGS

- Brand-name; no generic or biosimilar competition

Small Molecule	Potentially selected 7 years after 1st approval	Price controls go into effect approximately 2 years after selection
Large Molecule	Potentially selected 11 years after BLA	

- ✗ Orphan Drugs; Low Medicare Spend (<\$200M)

NEGOTIATION-ELIGIBLE DRUGS

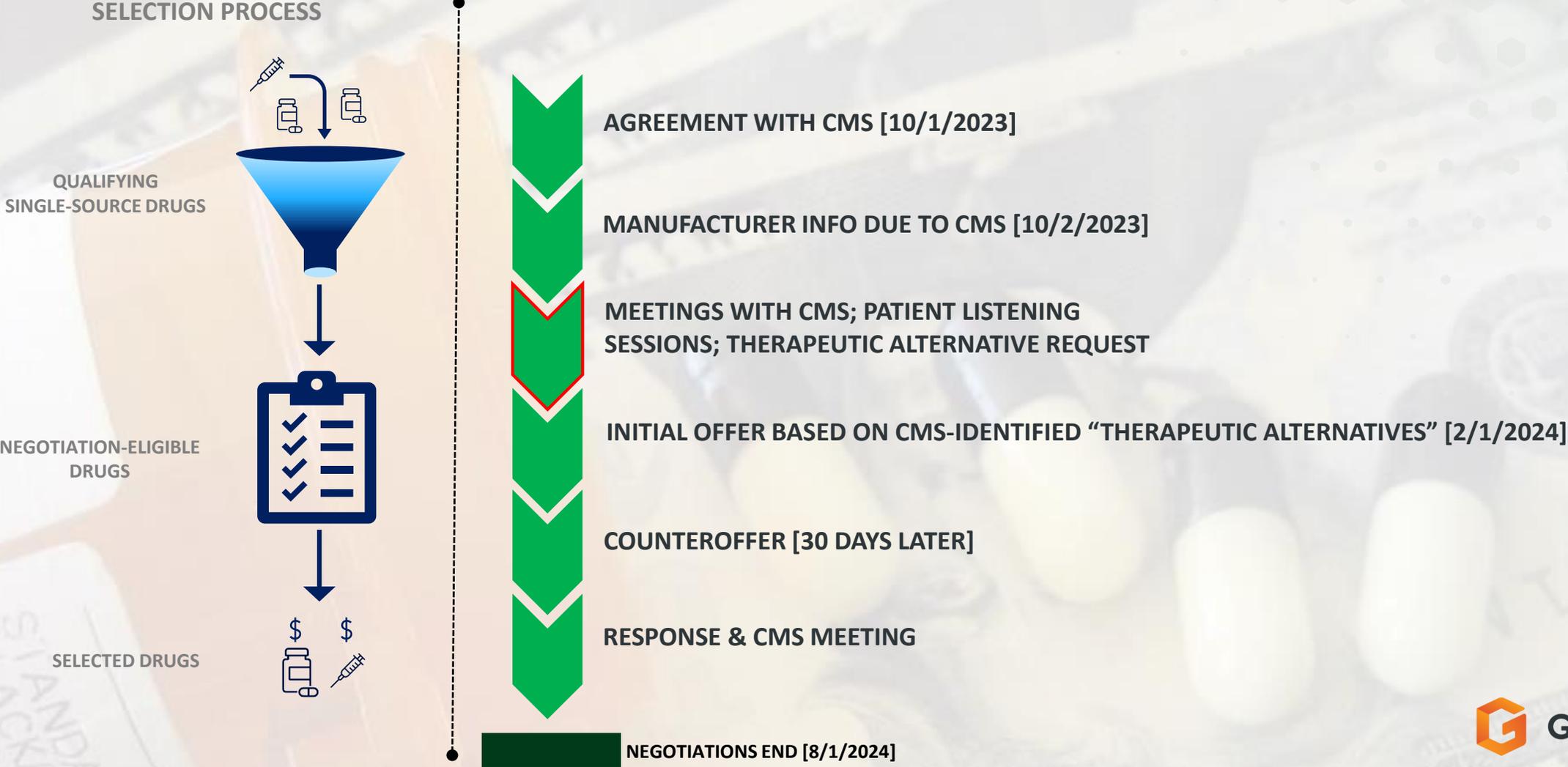
- Top 50 Drugs Ranked by Spend
- ✗ Small Biotech Drugs (2026-2028)

SELECTED DRUGS

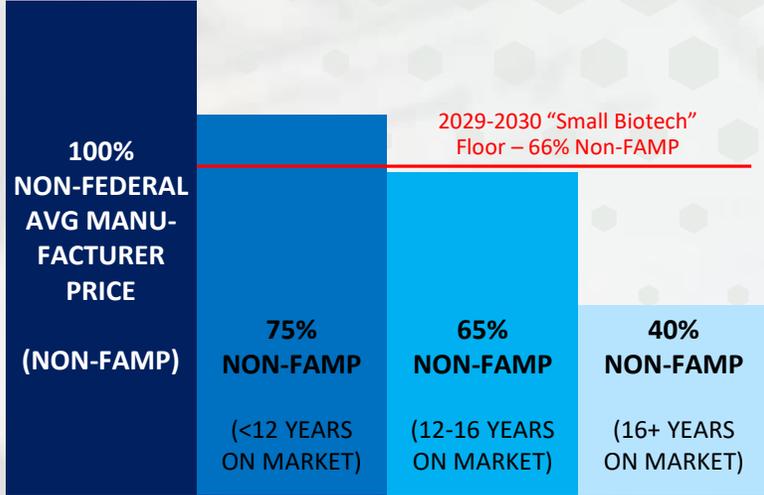
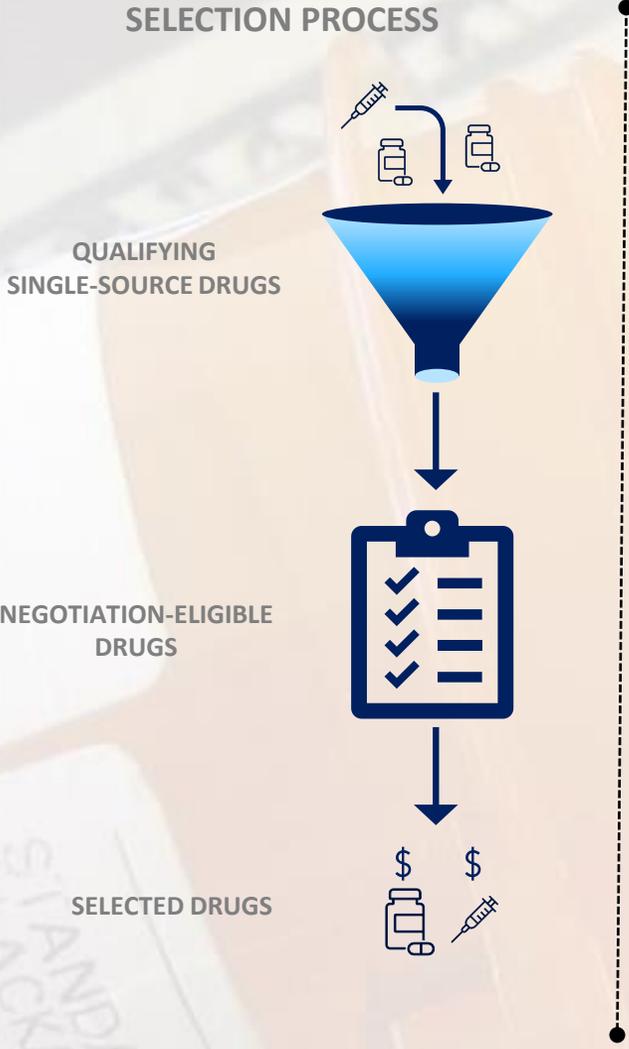
- Top 10 negotiation-eligible drugs
- First selection date: **September 1, 2023**, for price year **2026**



DRUG PRICE NEGOTIATION PROGRAM – NEGOTIATION PROCESS



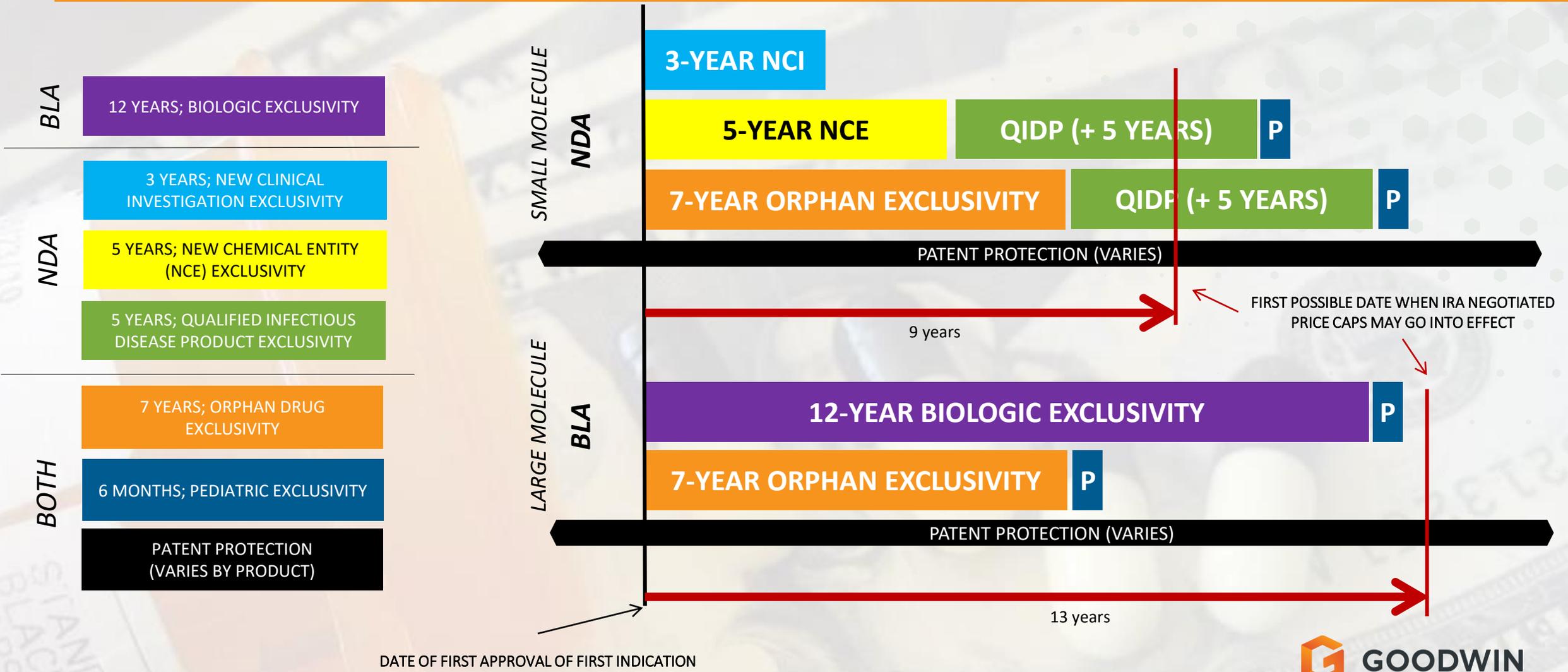
DRUG PRICE NEGOTIATION PROGRAM – MAXIMUM FAIR PRICE



- PUBLISHED [9/1/2024]
- EFFECTIVE DATE: JANUARY 1, 2026
- RENEGOTIATION
- 106% MFP – PART B
- MFP + DISPENSING FEE – PART D
- PRIMARY MANUFACTURER ADMINISTRATIVE RESPONSIBILITIES

POTENTIAL FDA EXCLUSIVITIES & PATENT PROTECTIONS

– VS. IRA'S MEDICARE ROI CLIFF



DRUG PRICE NEGOTIATION PROGRAM



How to Submit the 2023 Public Submission Form for Reporting Evidence about Selected Drugs and Their Therapeutic Alternatives

What Information is Requested

For the first time, the Inflation Reduction Act of 2022 (P.L. 117-169) allows Medicare, through CMS, to directly negotiate the prices of certain high expenditure, single source prescription drugs that have no generic or biosimilar competition with the drug's manufacturer. CMS is asking the public to provide information about these drugs, including personal experience taking these drugs and their therapeutic alternatives.

- **All questions, instructions and definitions are available in the [Information Collection Request Form for the Negotiation Data Elements](#).** You only need to look at Sections I and J, Questions 26 through 32 starting on page 36. *Certain manufacturers may answer more questions found in Sections A–H.*
- **Helpful Definitions:**
 - **Selected drugs:** drugs selected by CMS for potential negotiation; CMS selected 10 drugs for the first year of price negotiation with any negotiated prices effective starting in 2026.

DRUG PRICE NEGOTIATION PROGRAM

EXCISE TAX

FAILURE TO . . .

- ENTER A NEGOTIATION AGREEMENT
- AGREE TO THE MFP
- SUBMIT REQUIRED DATA

OR ELSE TERMINATE M/M PARTICIPATION
FOR ALL DRUGS

DAYS NON-COMPLIANT	TAX
1-90	1.85 X SALES PRICE
91-180	3 X SALES PRICE
181-270	5.67 X SALES PRICE
271+	19 X SALES PRICE

CIVIL MONETARY PENALTIES

VIOLATION	CIVIL MONETARY PENALTY
FAILING TO OFFER THE MFP	10 X THE DIFFERENCE BETWEEN SALE PRICE AND MFP
VIOLATING THE NEGOTIATION AGREEMENT	\$1M / DAY
KNOWINGLY PROVIDING FALSE INFORMATION RE: SMALL BIOTECH EXCEPTION & BIOSIMILAR DELAY	\$100M / FALSE ITEM

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