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Prescription Drug Pricing Reform

Inflation Reduction Act of 2022

Signed into law on August 16, 2022

The Inflation Reduction Act of 2022 (IRA) establishes new measures and regulatory authorities to control drug costs across the Medicare program

"The IRA is a historic piece of legislation. There hasn't been such consequential legislation addressing drug costs since the passage of the Medicare Modernization Act in 2003, establishing the original drug benefit in Medicare nearly 20 years ago."

- Anne Phelps, Principal
US Health Care Policy Leader
Deloitte & Touche LLP

Drug Price Negotiation

For the first time in the history of the Medicare drug program, the Centers for Medicare and Medicaid Services (CMS) will now be required by law to negotiate directly with pharmaceutical manufacturers to control the rising prices of certain high-cost drugs in Medicare Parts B and D

Inflationary Price Caps

To help control the rising cost of medication for Medicare beneficiaries, **the law's inflationary provisions on Parts B and D drugs "cap" drug price annual growth rates** benchmarked against the Consumer Price Index for All Urban Consumers (CPI-U)

Medicare Beneficiaries

The law's drug pricing provisions aim to help Medicare beneficiaries by instituting measures to control rising drug costs while **lowering the existing maximum out-of-pocket under Part D, thus closing the so-called Medicare "donut hole" created under the original law in 2003**

The drug pricing provisions under the IRA are divided into five parts

Part 1

Drug Price Negotiation

Beginning in 2023 with an initial price applicability year of 2026, CMS will be required to negotiate prices for select high-cost Part D drugs, expanding to Part B drugs, directly with manufacturers

Part 2

Drug Inflation Rebates

Beginning in 2023, drug manufacturers will be required to pay Medicare a rebate for Parts B and D drugs when prices increase faster than inflation

Part 3

Part D Benefit Redesign

Beginning in 2025, out-of-pocket drug costs for Medicare beneficiaries will be capped at $2,000, and a Manufacturer Discount Program replaces the current Medicare Coverage Gap Discount Program

Beginning in 2024 through 2029, premium growth for Medicare Part D beneficiaries will be limited to 6% per year

Part 4

Rebate Rule

Continues delay of the rule to end the anti-kickback safe harbor protections for prescription drug rebates until 2032

Part 5

Beneficiary Coverage

Insulin: Institutes a $35/month supply copay cap on covered insulin products for Medicare Advantage – Prescription Drug (MA-PD) and Part D

Vaccines: Institutes vaccine coverage with no cost-sharing or deductible under Medicare Part D, Medicaid, and CHIP* starting in 2023

Low Income Subsidies: Institutes low-income subsidy under Part D for seniors earning less than 150% of the Federal Poverty Level (FPL) starting in 2024

In a separate section of the law, Congress extended premium tax credits for individuals with ACA exchange coverage through 2025

*"CHIP" – Children's Health Insurance Program

The major drug pricing provisions should be analyzed together to understand full impact

Drug Price Negotiations

The Secretary of Health and Human Services (the Secretary) is required to examine and rank 100 high-cost drugs to select the specific drugs for negotiation each year. The number of selected drugs starts with 10 in 2026 and expands to 15 in 2027, 15 in 2028, and 20 in 2029. If a negotiated drug comes off the list and new drugs are selected year-over-year, there may be up to 60 selected drugs by 2029.

Inflation Rebates

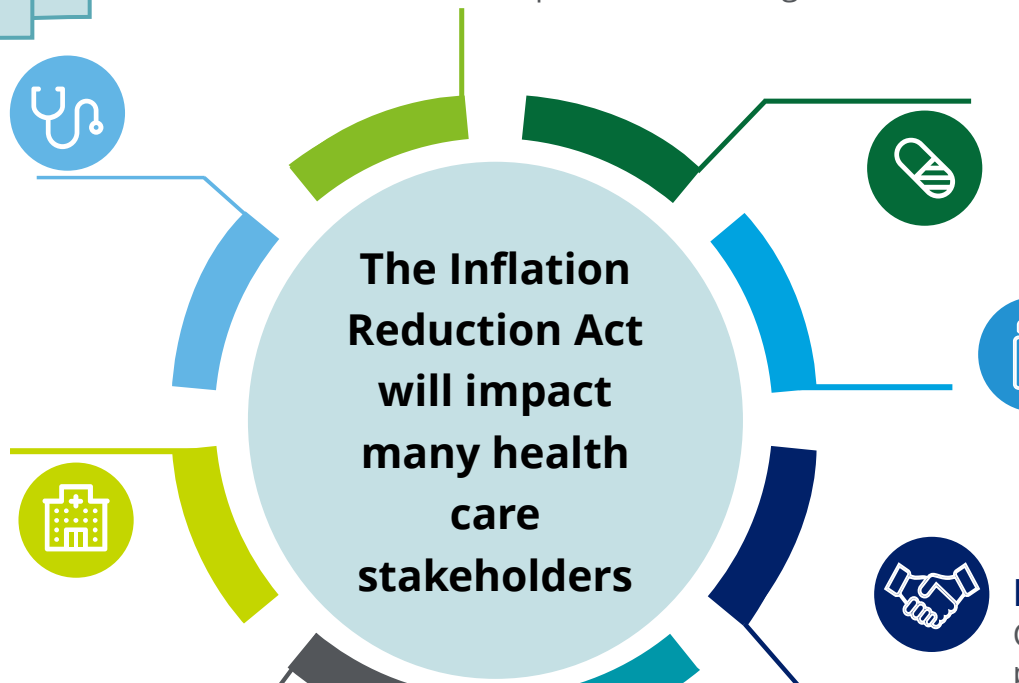
Beginning in 2023, drug manufacturers will be required to pay Medicare a rebate for Parts B and D drugs when prices increase faster than inflation. This applies to all Parts B and D drugs (with some exceptions). This will also apply to drugs when they come off the high-cost negotiated list, setting a benchmark for future years.

Benefit Redesign

Setting the maximum out of pocket cost for Medicare beneficiaries at $2,000 means beneficiaries will be able to afford more of their medicines but will also require CMS and private health plans to manage the catastrophic drug benefit and increased insurance risk.

** after program implementation*
*** annual increases continue by the current Part D methodology*

IRA's BROADER IMPACT



DRUG MANUFACTURERS
Implications for drug manufacturers of high-cost medications will be critical focus, in addition to inflation rebates. Manufacturers will need to establish processes to assess financial impact, conduct negotiations with CMS, and adjust agreements with customers.

HEALTH PLANS
MA, MA-PD, and PDP* plans will be able to forecast drug cost impact on premiums, including future inflationary increases, and plan for increased costs in catastrophic coverage for beneficiaries.

PHARMACEUTICAL BENEFIT MANAGERS (PBMs)
Price provisions and new negotiations may cause PBMs to assess potential price shifts across Parts B, D and commercial markets.

HOSPITALS / PROVIDERS
Reduction in high-price drug costs may benefit purchasing prices, while potentially decreasing revenue / margin for certain providers with higher Part B drug utilization (e.g., HOPDs**, infusion centers). Additionally, 340B programs will have to assess maximum fair price negotiations against existing 340B discounts.

PHARMACIES
Purchasing and supply chain impacts may benefit pharmacies, while price constraints could have longer-term impacts to revenue growth.

EMPLOYERS
Commercial plans are not included in the drug pricing provisions. Medicare price reductions may cause cost shift and/or reevaluation of drug prices in the commercial market.

HOME HEALTH
Providers administering home infusion or other medications may need to examine Part B revenue implications.

MEDICARE BENEFICIARIES
Out-of-pocket costs for Parts B and D generally reduced and future increases to the growth of base premiums are limited to 6% per year.

CMS

- CMS is appropriated $3B to establish the Drug Price Negotiation Program, almost double current program management funding.
- CMS will need to issue regulations as soon as late 2022 / early 2023 to meet legislative timelines.

*Medicare Advantage plans, Medicare Advantage Prescription Drug Plans, and Medicare Part D prescription drug plans
**Hospital Outpatient Departments

The IRA fundamentally changes aspects of Medicare Parts B and D

	MEDICARE PART B TODAY	MEDICARE PART D TODAY	IRA CHANGES[8]
General Coverage	Doctors' services, outpatient care, home health services, physician-administered drugs	Outpatient prescription drugs[5]	No changes
Covered Drugs	Drugs administered in an outpatient setting or physician's office. In certain situations, self-administered outpatient drugs are covered as well.[3]	Medication for beneficiaries, including at least 2 drugs in each category used to treat the same condition and all drugs in protected classes.[5]	No changes
How services / drugs are negotiated & priced	Most separately payable Part B drugs are paid based on the Average Sales Price (ASP). A manufacturer's ASP and volume sold of a given drug is calculated by the manufacturer every quarter and submitted to CMS. Medicare pays 106 percent of ASP (ASP+6 percent) for most Part B drugs.[3]	Noninterference clause prohibits government from interfering in negotiations between insurers, drug manufacturers, and pharmacies.[6] Negotiated price concessions take the form of rebates from a manufacturers' list prices for brand name drugs. There is no central formulary. Coverage requirements for each plan, and most sponsors offer alternative plans with tiered formularies (generic, brand, specialty).[5]	**Parts B and D**: CMS given authority to negotiate the price of prescription drugs directly with manufacturers, creating an exception to the noninterference clause. **Parts B and D:** In 2023, rebates by manufacturer paid to CMS if prices are raised faster than inflation.
Beneficiary out-of-pocket spending	After meeting the yearly deductible, beneficiaries pay 20% of the Medicare-approved amount for most healthcare services that they receive under Part B. There is no out-of-pocket limit for Part B.[2]	Enrollees enter catastrophic coverage after reaching $7,050 in out-of-pocket costs for covered drugs, which triggers a 5% co-insurance per payment.[7] No monthly out-of-pocket cap.	**Part D:** If a beneficiary's annual out-of-pocket expenses for covered drugs reaches $2,000, the 5% co-insurance costs will be eliminated, as Part D will pay 20% of the cost of brand-name drugs and 40% of the cost of generic drugs. Insurers and drug manufacturers will bear the remaining costs[5] A monthly cap of $35 on insulin costs. Expansion of low-income subsidies to 150% of the FPL.

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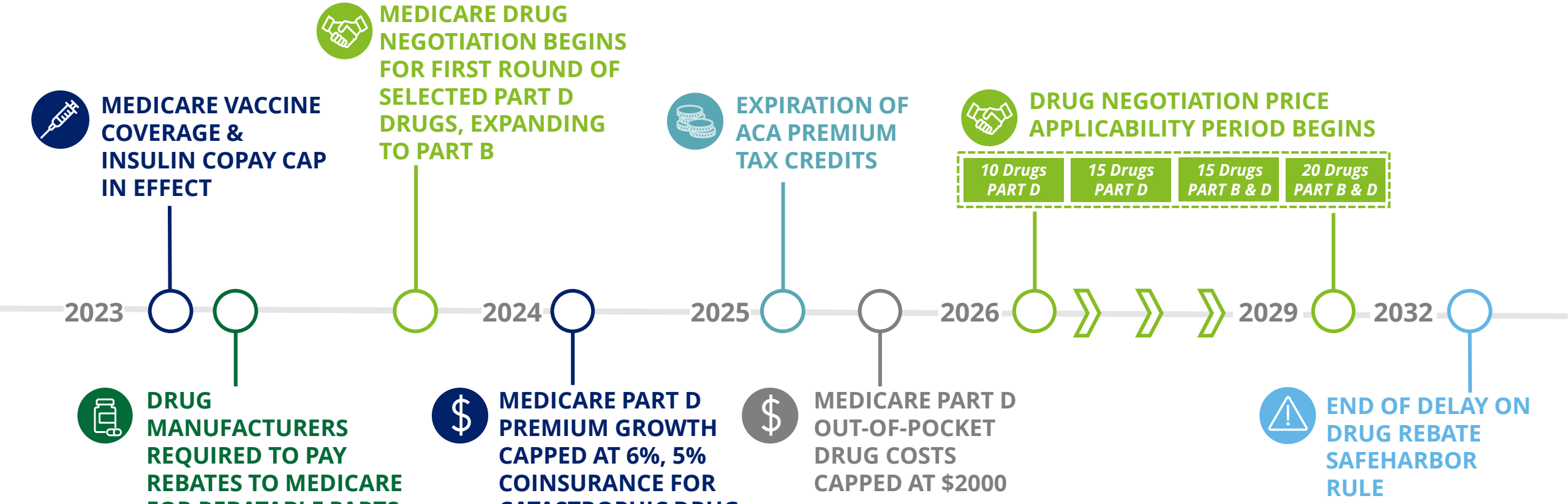
Implementation begins immediately

Based on the timelines under the IRA, stakeholders across the industry will see revenue impact beginning in 2023



The clock is ticking…..

Stakeholders across the industry should begin analyses and preparations in 2022

Drug Price Negotiations

June 1, 2022 to May 31, 2023 – Total Expenditures of Negotiation Eligible Drugs used for initial rankings of high spend drugs

October 1, 2023 – Deadline to enter into agreements with manufacturers of selected drugs for the initial price applicability period

Inflation Rebates

January 1, 2021 – Initial Parts B & D Benchmark Period: CPI-U used to calculate future inflation rebates

October 1, 2022 – Part D drugs furnished on or after this date subject to inflation rebates (1st rebate report issued July 1, 2023)

January 1, 2023 – Part B drugs furnished on or after this date subject to inflation rebates (1st rebate report issued July 1, 2023)

Other Provisions

January 1, 2023 – No cost share for adult vaccines; subsidies for retroactive reimbursement for PDP plan sponsor and Medicare Advantage to begin 18 months following the end of the applicable plan year

January 1, 2023 – Insulin copay cap capped at $35

Specific questions for health care stakeholders

Life Sciences

Begin Analyses

- What drugs do you manufacture that are subject to Part B & D provisions?
- Which drugs are considered selected or high-cost drug now and in the future?
- What are the revenue implications from the inflationary caps and rebates?

Start Preparing

- How will you prepare for drug negotiations with CMS?
- How will negotiations affect spending allotment and cost containment? (e.g., G&A, R&D, advertising, etc.)
- How will you prepare to offset revenue impacts due to negotiations and inflation rebates?

Health Plans

Begin Analyses

- What high-cost drugs are on your formularies for your MA, MA-PD, and PDP plans? What is the volume of claims?
- How will inflation caps and rebates affect your actuarial calculations?
- What is your exposure for catastrophic coverage above the new $2000 cap for beneficiaries?

Start Preparing

- What processes do you need to assess lower drugs costs and actuarial impact to annual premiums?
- What processes do you need to assess new catastrophic limits and plan coverage?
- How can you increase members based on expanded drug coverage?

Health Care Providers

Begin Analyses

- What high-cost drugs covered under Parts B & D are most widely administered at your facilities?
- How much revenue is coming from your Hospital Outpatient Departments for Part B drugs that will be subject to negotiation and inflations caps?
- How will these pricing provisions affect revenue and margin from drug pricing programs such as 340B?

Start Preparing

- What processes do you need in place to assess revenue exposure and associated risk? Supply chain impacts?
- How are you continuing to monitor reimbursement changes stemming from this legislation?

Think about your partners: How will these changes affect your relationships or contracts with other health care stakeholders?

Contact us:

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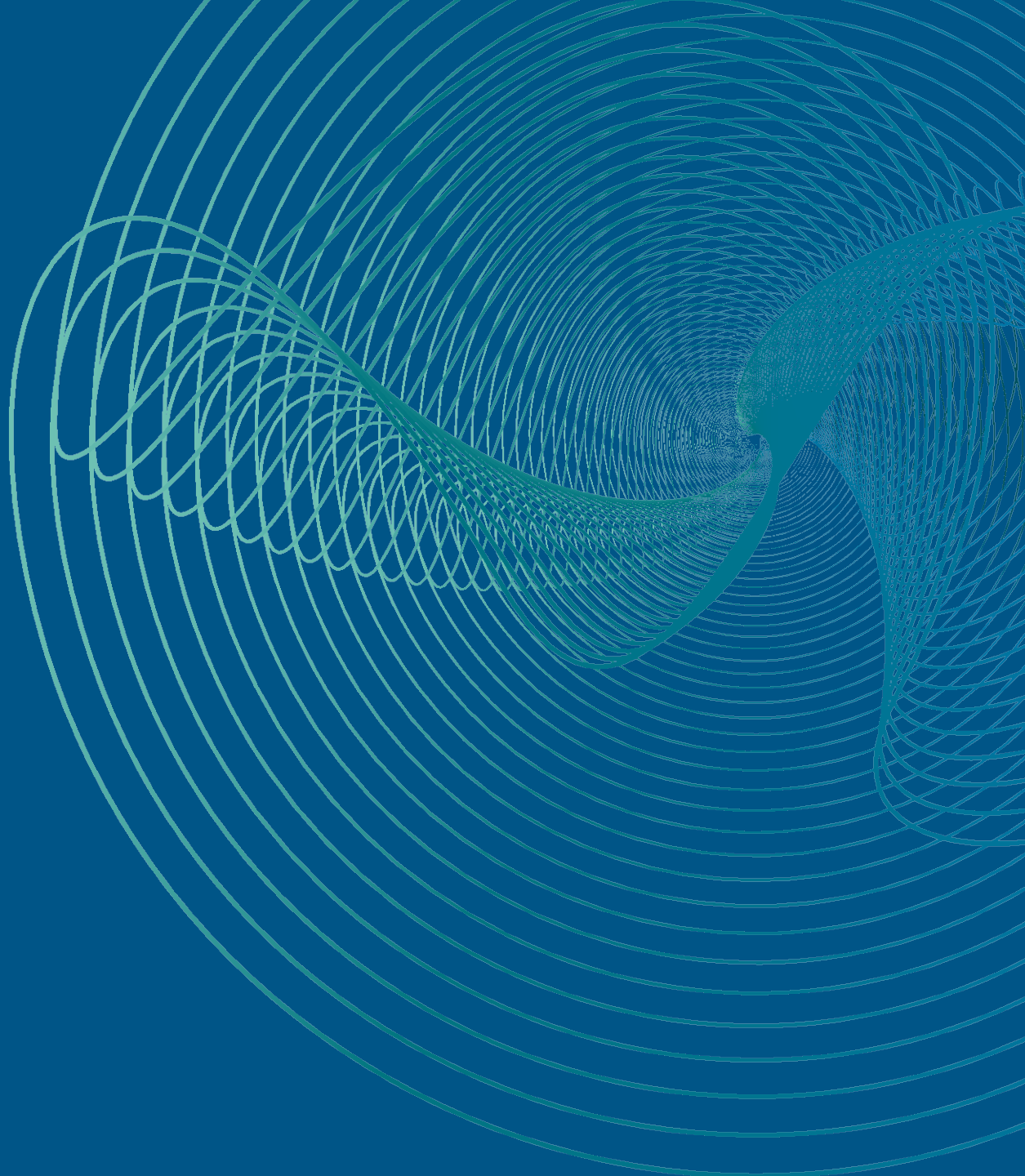

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Endnotes

Source referenced on all slides: *H.R.5376 - Inflation Reduction Act of 2022*

1. https://www.congress.gov/bill/117th-congress/house-bill/5376/text?q=%7B%22search%22%3A%5B%22inflation+reduction+act%22%2C%22inflation%22%2C%22reduction%22%2C%22act%22%5D%7D&r=1&s=4
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