



## Health Policy Briefing

September 5, 2023

### HHS Selects the First Drugs for Medicare Drug Price Negotiation

The Biden administration [released](#) the list of the first 10 Part D drugs subject to the price negotiation process established by the 2022 *Inflation Reduction Act*:

- Bristol-Pfizer’s Eliquis, used as a blood thinner;
- Eli Lilly’s Jardiance, used for diabetes and heart failure;
- Johnson & Johnson’s Xarelto, used as a blood thinner;
- Merck’s Januvia, used for diabetes;
- AstraZeneca’s Farxiga, used for diabetes and heart failure;
- Novartis’ Entresto, used for heart failure;
- Amgen’s Enbrel, used for autoimmune diseases;
- AbbVie-J&J’s Imbruvica, used for blood cancers;
- J&J’s Stelara, used for autoimmune diseases; and
- Novo Nordisk’s NovoLog, used for diabetes.

The Centers for Medicare and Medicaid Services plans to hold a public patient-focused listening session for each of the selected drugs between October 30, 2023, and November 15, 2023. The listening sessions will provide an opportunity for patients and other interested parties to share input on therapeutic alternatives to the selected drugs, how the selected drugs address unmet medical needs, and the impact of selected drugs on specific populations. Registration to apply to be a speaker opened on September 1, 2023, and will close on October 2, 2023. The public is also invited to submit data on selected drugs, therapeutic alternatives to the selected drugs, data related to unmet medical needs, and data on impacts on specific populations by October 2, 2023.

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## Medicare Drug Price Negotiation Timeline

Medicare can now negotiate prices for drugs it spends the most on. The negotiated prices for the first 10 drugs won't go into effect until 2026, but preparations are underway.

### 2023

Sept. 1, 2023

Medicare agency (CMS) deadline to announce 10 Part D drugs selected for negotiation.

Oct. 1, 2023

Deadline for drugmakers to sign agreements to negotiate.

Oct. 2, 2023

Deadline for companies to submit manufacturer-specific data.

### 2024

Feb. 1, 2024

CMS sends initial offers of maximum fair price with justification.

March 2, 2024

Deadline for drugmakers to accept offer or make counteroffer.

Aug. 1, 2024

Negotiation period ends.

Sept. 1, 2024

CMS publishes maximum fair prices for 10 selected drugs.

### 2025

March 1, 2025

CMS provides explanation of maximum fair price for each drug.

### 2026

Jan. 1, 2026

Maximum fair prices go into effect for selected drugs.

Source: Centers for Medicare & Medicaid Services

Bloomberg Law

## Majority Leader Steve Scalise Undergoing Treatment for Blood Cancer

House Majority Leader Steve Scalise (R-La.) has been diagnosed with multiple myeloma, “a very treatable blood cancer,” according to a statement released last week. Scalise has already begun treatment, which will last several months. He plans to return to Washington when the House of Representatives reconvenes later this month, and announced that he expects to continue his work as Majority Leader during this period.

## White House Calls on Congress to Pass Continuing Resolution

The Biden administration formally asked Congress to pass a short-term spending bill to prevent a government shutdown at the end of the fiscal year on September 30. The White House is also seeking \$40 billion in emergency spending as a part of the stopgap package. Conservatives in the House Freedom Caucus have already expressed opposition to any clean continuing resolution that does not include the **Secure the Border Act**, address the “unprecedented weaponization of the Justice Department and FBI,” and “end the Left’s cancerous woke policies in the Pentagon.” Both Democrat and Republican leaders of the Senate have signaled their support for a stopgap spending measure, and Senate Majority Leader Chuck Schumer (D-N.Y.) stated that the Senate’s focus will be on government funding when the chamber returns from August recess this week.

## Doc Caucus Members Ask Appropriators to Act on Abortion Training Programs

The GOP Doctors Caucus sent a [letter](#) to House Appropriations Labor-Health and Human Services-Education Subcommittee Chairman Robert Aderholt (R-Ala.) in support of a change to physician training requirements that would result in medical residents having to opt-in to learn about abortion services, rather than the current process of allowing them to opt-out of such lessons. Several Doc Caucus members and former practicing OB/GYN Rep. Michael Burgess (R-Texas) raised concerns that the current opt-out process “is fundamentally unjust and places undue pressure on [residents] to partake in training that may conflict with their beliefs.” The letter encourages appropriators to prohibit federal funds from being used to implement opt-out curricula.

## House Budget Panel Launches Health Care Task Force

House Budget Committee Chairman Jodey Arrington (R-Texas) recently [announced](#) the formation of a task force on health care. The task force will focus on bending the cost curve of health care, and will work to examine key drivers of health care costs and proposals to reduce health care spending. Rep. Michael Burgess (R-Texas) will serve as the chair of the task force, whose members include Reps. Drew Ferguson (R-Ga.), Buddy Carter (R-Ga.), Lloyd Smucker (R-Pa.), Blake Moore (R-Utah), and Rudy Yakym (R-Ind.). According to Arrington, the Task Force “will be guided by the principles that health care in America should be affordable, accessible, and personalized.” It plans to explore the Congressional Budget Office’s modeling and projection capabilities of health care policies “to ensure policymakers can access the best data when evaluating potential impacts on the federal budget and patients.” The task force issued a [request for information \(RFI\)](#) seeking comments by October 15 “on solutions to improve outcomes and reduce federal health care spending in the budget.”

## NIH Nominee Reaches Agreement with Warren on Ethics Demands

Sen. Elizabeth Warren (D-Mass.) will support the confirmation of Monica Bertagnolli to serve as the Director of the National Institutes of Health (NIH) after the Biden administration nominee agreed to a pair of ethics demands. Bertagnolli agreed to not seek employment or compensation from any pharmaceutical company with an annual revenue of \$10 billion or more for four years after leaving her government post. She also agreed to recuse herself from NIH decisions related to companies with which she has had a prior relationship for four years. The standard recusal period is two years. Bertagnolli’s path to confirmation is still complicated by Senate Health, Education, Labor, and Pensions Committee Chairman Bernie Sander’s (I-Vt.) refusal to schedule a hearing on her nomination. Sanders has pledged to oppose all administration health nominees until the White House takes unilateral action to cut drug prices. The NIH has been without a permanent leader since Dr. Francis Collins stepped down in December 2021.

## Warren, Jayapal Urge FDA to Address Orange Book-Related Problems

Sen. Elizabeth Warren (D-Mass.) and Rep. Pramila Jayapal (D-Wash.) sent a [letter](#) to the Food and Drug Administration (FDA) urging the agency to close alleged regulatory loopholes which they assert delay the entry of generic competition to the market and enable manufacturers of brand pharmaceuticals to keep high prices in place for longer periods of time. The lawmakers specifically recommend that the FDA narrow the patents allowed to be listed in the Orange Book, which is used by generic drug companies to determine when they can file a generic drug for approval. The letter also calls for increased information sharing between the FDA and the U.S. Patent and Trademark Office to help determine whether manufacturers are using the patent system in an anti-competitive manner.

## New HHS OIG Strategy on Medicare, Medicaid Managed Care

The U.S. Department of Health and Human Services Office of the Inspector General (OIG) published a coordinated oversight [plan](#) for managed care in the Medicare and Medicaid programs last week. The strategy will be used to align OIG’s audits, evaluations, investigations, and enforcement of managed care. It aims to promote access to care for people enrolled in managed care, provide comprehensive financial oversight, promote data accuracy, and encourage data driven decisions. OIG’s work will be guided by the following managed care life cycle and the unique risks and vulnerabilities associated with each stage: plan establishment and contracting, enrollment, payment, and the provision of services.

## Department of Labor Proposes to Extend Overtime Protections

The Biden administration has proposed to revive an Obama-era regulation to require employers to pay overtime to salaried workers earning less than \$55,000 a year. The regulation, which would increase the salary threshold for overtime from \$35,668, would impact a total of 3.6 million employees, including approximately 600,000 individuals working in the nation’s health care and social services sectors. The notice of proposed rulemaking will be open for public comment for 60 days.

H.R.5269 — To amend the Federal Food, Drug, and Cosmetic Act to provide for the establishment and maintenance of a Pediatric Research Site Network; Sponsor: Curtis, John R. [Rep.-R-UT-3]; Committees: House - Energy and Commerce

H.R.5287 — To direct the Secretary of Veterans Affairs to establish a pilot program to provide veteran health savings accounts to allow veterans to receive primary care furnished under non-Department direct primary care service arrangements, and for other purposes. Sponsor: Roy, Chip [Rep.-R-TX-21]; Committees: House - Veterans' Affairs

H.R.5299 — To amend title XVIII of the Social Security Act to establish a demonstration program for international coverage under the Medicare program; Sponsor: Espaillat, Adriano [Rep.-D-NY-13]; Committees: House - Ways and Means; Energy and Commerce

H.R.5308 — To reauthorize the Distance Learning and Telemedicine Program of the Department of Agriculture; Sponsor: Langworthy, Nicholas A. [Rep.-R-NY-23]; Committees: House - Agriculture

H.R.5312 — To amend the Child Nutrition Act of 1966 to support women, infants, and children impacted by substance use disorder, and for other purposes; Sponsor: Manning, Kathy E. [Rep.-D-NC-6]; Committees: House - Education and the Workforce

H.R.5317 — To amend the Internal Revenue Code of 1986 to allow distributions from a health flexible spending arrangement or health reimbursement arrangement directly to a health savings account in connection with establishing coverage under a high deductible health plan; Sponsor: Steel, Michelle [Rep.-R-CA-45]; Committees: House - Ways and Means