

# 2023 Healthcare Policy Outlook

## Policy Background and Landscape

The first year of the Biden Administration was dominated by the COVID-19 pandemic, as reflected by healthcare policy debates in 2021. President Biden's first major achievement was passage of the \$1.9 trillion *American Rescue Plan Act* (ARP), which included more than \$100 billion in healthcare funding for vaccines, research, testing, Affordable Care Act (ACA) subsidies, state health funding and money for rural providers.

After securing record funding to address COVID, Democrats in the White House and on the Hill turned their attention to the far-reaching "Build Back Better" (BBB) legislative proposal offered by President Biden. The initial BBB plan totaled \$4.2 trillion and proved too large to secure passage given the razor-thin margins in the Senate as introduced.

Then in August, Democrats passed the "Inflation Reduction Act" (IRA), a \$740 billion package that contained significant healthcare policy changes, including:

- Drug Pricing: What is arguably the most significant healthcare policy in the IRA will provide Medicare with the ability to set prices for several high-cost drugs in the Part D and Part B programs. The policy, which has long been a Democratic priority, will begin in 2023 when CMS will select ten Part D drugs for negotiation, with government prices taking effect in 2026.
- ACA Subsidies: Another major policy in the IRA was the extension of enhanced ACA exchange subsidies through 2025. Those subsidies were increased and made available to people above 400% of poverty for the first time as a provision of the ARP. These expanded subsidies will increase ACA funding by \$33 billion according to [CBO](#) which could boost exchange health insurance coverage.
- Rebate Rule Repeal: In 2019, President Trump issued a rule reforming how pharmacy benefit managers are reimbursed through rebates on negotiated drugs. Though intended to lower long-term drug costs, federal budgeters linked rebates with lower drug spending by Medicare. Thus, the rule was estimated to increase federal spending and repealing it saved an estimated [\\$122 billion](#). Viewed as a budget gimmick by some, this policy means lawmakers lost a potential offset for future healthcare spending. It also suggests any PBM reforms will have to be legislative.

## 2023 Healthcare Policy Tracker

The following is a living tracker of specific healthcare policy issues that will drive the legislative and rulemaking process over the next two years. This list will be regularly updated as events, elections and priorities in Washington shift the healthcare landscape.

### COVID & Monkeypox Funding

The White House [requested](#) \$22.4 billion for COVID funding for vaccines, testing and research in the FY 2023 Continuing Resolution. In addition, the Administration sought \$4.5 billion to address monkeypox via vaccinations, testing, treatment, and operational support. Republicans have balked at the funding which could be punted to later appropriations. The President's request may face headwinds in a Republican House and was further complicated by his recent assertion that "[the pandemic is over.](#)"

### Prescription Drug User Fee Act

The current regime of Food and Drug Administration (FDA) user fees, which pay the salaries of agency staff who review drug and medical device applications, is set to expire on October 1, 2022. Reports now indicate that lawmakers may take up a clean extension of current law in order to avert a lapse in funding. While the House has already passed a bill to extend the program ([H.R. 7667](#)), disagreements with the Senate threaten to push the debate into the lame duck or beyond.

House and Senate lawmakers agreed to a continuing resolution (CR) that would avert a government shutdown until Congress can work out a longer-term spending bill in mid-December. The bill includes reauthorization of FDA's prescription and generic drug, biosimilar and medical device user fee programs for another five years, which means the agency will not have to lay off user-fee funded staff. Although a victory to some, the stripped-down version of the user fee reauthorization bill does not include provisions such as riders that would reform FDA's accelerated approval program, as well as its oversight of cosmetics and dietary supplements. Nor does the bill include riders that would address change control plans for artificial intelligence/machine learning (AI/ML) medical devices, mandate the agency periodically update its medical device cybersecurity guidance and reduce the cost of generic drugs by easing their path to market.

### Medicare Physician Fees

In July 2022, CMS [issued rules](#) for 2023 Medicare physician fee schedule which include the expiration of a 3% physician pay increase as well as a proposed reduction to fee conversions. As a result, physicians are expected to see a 4.42% decrease in Medicare fees beginning in January 2023. Doctors and provider groups have [petitioned Congress](#) to act and avert these proposed reductions through legislation prior to the end of the year. Whether Congress will act again at a cost of roughly \$4 billion is yet to be determined.

## Drug Price Negotiation Implementation

HHS must publish the initial list of ten high-cost drugs subject to price negotiation by September 1, 2023. Once published, the negotiation period will begin on October 1, 2023, and manufacturers of these drugs must submit information to the government at appointed intervals. The government will determine a “maximum fair price” for covered drugs by February 1, 2024. Manufacturers will have 30 days to accept or make a counteroffer. Manufacturers that do not agree to the final price will be subject to a tax penalty. According to [CBO](#), the policy will result in a \$100 billion reduction in Medicare spending.

## Medicaid Expansion & Waivers

Despite strong federal inducements in the ARP, there are 12 states that have not expanded their Medicaid program under the ACA. Expanding government coverage in those states has been a major priority for President Biden. The BBB proposed to extend ACA subsidies to people under the poverty line in states that have not expanded. The Administration is also phasing out Section 1115 [waivers](#) that allowed flexible Medicaid spending in those states, including work requirements and fees. With Congress unlikely to act, expect more creative pressure from the White House for states to expand.

## Electronic Health Records & Interoperability

The rollout of electronic health record modernization (EHRM) plans within the Department of Veterans Affairs (VA) sparked widespread [interest](#) among Members of Congress. Though there is consensus that EHRM is an important goal, it brings with it concerns about technology gaps, privacy and security. Congress will watch the VA rollout closely and may consider legislation. Meanwhile, [CMS](#) will refine and update standards for EHRMs to meet Medicare interoperability requirements.

## Surprise Medical Billing Implementation

In August, the Departments of Health and Human Services, Labor, and Treasury released [final rules](#) related to the implementation of the “No Surprises Act” of 2020. The rules have been contentious since then and faced legal challenges on the grounds that the rules gave too much weight to benchmark prices. With the final rule now issued, the American Hospital Association and American Medical Association [reiterated](#) threats to sue which could further delay implementation.

## **Nursing Home Ownership**

The Biden Administration failed to secure \$150 billion in proposed home care and nursing funding sought in the President's "Build Back Better" plan. That does not mean, however, that the Administration has abandoned its interest in elderly care. The White House will now focus specifically on quality of care at nursing homes. Citing reports that private equity ownership of nursing homes correlates to [diminishing health outcomes](#), the Administration and HHS will focus on [nursing home ownership](#) structures and consider potential rulemaking at some point over the next two years.

## **House Republican "Personal Option"**

House Republicans recently released their "Commitment to America" legislative agenda. While healthcare policy details are lacking, the initial outline makes it clear that Republicans hope to rhetorically juxtapose Democrat calls for a public option with the GOP plan messaged to voters as the "personal option." The plan is a notable step away from the goal of repealing and replacing ACA and a move toward focusing on smaller goals like "transparency, choice and competition." Expect Republican legislation on telemedicine, electronic records, FDA drug approval times and insurance portability.

## **House Democrats "Personal Option"**

House Democrats are praising the recently passed Inflation Reduction Act (IRA). The legislation represents the largest investment in addressing climate change in U.S. history, allows Medicare to negotiate with pharmaceutical companies on the costliest prescription drugs and extends health care subsidies through the 2024 election. Provisions in the bill are currently being implemented and applied.

## **Hospital Funding**

COVID relief included funding through the PHE, while the ARP included \$8.5 billion for rural communities. Rural hospitals are facing a funding cliff, in danger of losing some \$600 million in Medicare funding unless Congress intervenes. Any relief measure would likely have to be included in a must-pass bill, like the anticipated stopgap funding measure to keep the government running into the new fiscal year or a year-end spending deal.

## **Cancer Moonshot**

Early in 2022, President Biden announced a reignition of the Cancer Moonshot, highlighting new goals: to reduce the cancer death rate by half within 25 years and improve the lives of people with cancer and cancer survivors. Biden announced he is signing a new executive order that launches a National Biotechnology and Biomanufacturing Initiative, to help ensure that the technology that will help end cancer is made in America. Biden also announced the creation of a Cancer Cabinet that incorporated different corners of the government to work toward goal.