



## Health Policy Briefing

February 13, 2023

### President Delivers 2023 SOTU Address

President Joe Biden delivered his State of the Union (SOTU) address on Tuesday; the speech highlighted his administration’s accomplishments on infrastructure, the climate, and consumer protections over the past two years. The President promised to not allow the nation to default on its debt, calling on Congress to pass a clean increase of the debt-ceiling and criticizing Republicans seeking to use debt-ceiling negotiations to force spending cuts. Biden’s speech also commended the work done by his administration to reach a point in which “COVID no longer controls our lives,” while acknowledging the need for Congress to fund ongoing efforts to support the development of new vaccines and treatments in response to emerging COVID-19 variants. Other health care priorities covered in the President’s address include:

- Drug pricing: The President touted provisions contained in last year’s Inflation Reduction Act to cap out-of-pocket (OOP) drug costs for Medicare beneficiaries at \$2,000 per year, allow drug price negotiations for the first time under the Medicare program, and to cap the OOP cost of insulin at \$35 per month for Medicare beneficiaries. He also called for a universal \$35 insulin price cap for all Americans.
- Medicaid expansion: Biden called on the 11 states that have yet to expand their Medicaid programs to fill the coverage gap for the two million uninsured individuals who earn too much to qualify for Medicaid but too little to receive subsidies through their health insurance exchange.
- Abortion: The President called on Congress to codify Roe v. Wade and stated that he would veto any national abortion ban passed by Congress.
- Cancer Moonshot: Biden recommitted his support for the Cancer Moonshot initiative and called on Congress to do the same. The initiative aims to reduce the nation’s cancer death rate by 50% over the next 25 years.
- Medicare: The President stated his plans to extend the Medicare Trust Fund by at least two decades and pledged to veto any attempts to cut the Medicare program.

The President’s full remarks, as prepared for delivery, can be found [here](#). The Republican responses to the SOTU were delivered by Governor Sarah Huckabee Sanders (Ark.) and newly-elected Rep. Juan Ciscomani (Ariz.-06).

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## Senate Judiciary Advances Five Bipartisan Drug Pricing Bills

The Senate Judiciary Committee advanced five bipartisan bills aimed at reforming the drug patent system and increasing competition in the pharmaceutical marketplace. Each of the bills were reported favorably by voice vote. The following legislation was considered:

- S. 79, Interagency Patent Coordination and Improvement Act of 2023, to establish an interagency task force between the United States Patent and Trademark Office and the Food and Drug Administration for purposes of sharing information and providing technical assistance with respect to patents.
- S. 113, Prescription Pricing for the People Act of 2023, to require the Federal Trade Commission (FTC) to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with appropriate policy recommendations.
- S. 142, Preserve Access to Affordable Generics and Biosimilars Act, to prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products.
- S. 148, Stop STALLING Act, to enable the FTC to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition, and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns.
- S. 150, Affordable Prescriptions for Patients Act of 2023, to amend the Federal Trade Commission Act to prohibit product hopping. During consideration of this bill, Sen. Mazie Hirono (D-Hawaii) expressed concerns about potential unintended consequences, such as companies avoiding follow-on research out of fear of litigation. Sen. Mike Lee (R-Utah) also argued that the FTC already has the authority necessary to address such anticompetitive behavior.

While lawmakers appeared optimistic about the bills' chances of passing the Senate, it remains unclear whether they would be taken up by the Republican-controlled House of Representatives.

## Finance, HELP Leadership Consider Common Ground for 118th Congress

With congressional committees convening for their first organizational meetings of the 118th Congress in recent weeks, panel leadership have begun to shed light on their agendas for the next two years. In the Senate Finance Committee, Ranking Member Mike Crapo (R-Idaho) outlined health care priorities that largely align with those of Chair Ron Wyden (D-Ore.). While Crapo has highlighted the need for oversight of the Biden administration's implementation of the Inflation Reduction Act's drug pricing provisions, both leaders are aiming to target rising health care costs, health care workforce shortages, and access to telehealth during the 118th Congress. Sen. Ben Cardin (D-Md.) will serve as the new chair of the Senate Finance Health Care Subcommittee, replacing Sen. Debbie Stabenow (D-Mich.) who will remain a member of the subcommittee. Sen. Steve Daines (R-Mont.) will continue to serve as the subcommittee's ranking member. Cardin has said that he will focus on behavioral health and care for those with substance use disorders, expanding Medicaid and Medicare coverage for dental health, and maintaining telehealth access as subcommittee chair. Senate Health, Education, Labor, and Pensions (HELP) Committee Chair Bernie Sanders (I-Vt.) and Ranking Member Bill Cassidy (R-La.) also previewed their common ground priorities during the panel's first meeting of the 118th Congress last week. These focus areas include the opioid crisis, oral health care, mental health care, and prescription drug costs, with Ranking Member Cassidy specifically acknowledging the need to balance concerns around affordability and medical innovation in drug pricing.

## HHS Prepares States, Stakeholders For End of PHE

U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra set a [letter](#) to governors last week discussing his decision to renew the COVID-19 public health emergency (PHE) for the final time, effective February 11, and to terminate the PHE on May 11. HHS also released a [fact sheet](#) providing a transition roadmap describing the impact of the PHE expiration. Those PHE-linked flexibilities and policies that will be affected by the end of the emergency declaration include:

- Medicare beneficiaries who are enrolled in Part B will continue to have coverage without cost sharing for laboratory-conducted COVID-19 tests when ordered by a provider, but their current access to free over the counter (OTC) COVID-19 tests will end.
- The requirement for private insurance companies to cover COVID-19 tests without cost sharing, both for OTC and laboratory tests, will end.
- State Medicaid programs must provide coverage without cost sharing for COVID-19 testing until the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE. That means that mandatory coverage will end on September 30, 2024.
- Reporting of COVID-19 laboratory results and immunization data to CDC will change. HHS will no longer have the express authority to require lab test reporting for COVID-19. Hospital data reporting will continue as required by the Centers for Medicare and Medicaid Services conditions of participation through April 30, 2024, but reporting may be reduced from the current daily reporting to a lesser frequency.
- Certain Food and Drug Administration COVID-19-related guidance documents for industry that affect clinical practice and supply chains will end or be temporarily extended. FDA is in the process of addressing which policies are no longer needed and which should be continued, and the agency will announce plans for each guidance prior to the end of the PHE.
- During the PHE, manufacturers of certain devices related to the diagnosis and treatment of COVID-19 have been required to notify the FDA “of a permanent discontinuance in the manufacture of the device” or “an interruption in the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States.” This requirement will end when the PHE ends.
- Public Readiness and Emergency Preparedness (PREP) Act liability protections for countermeasure activities that are not related to any USG agreement (e.g., products entirely in the commercial sector or solely a state or local activity) will end unless another federal, state, or local emergency declaration is in place for the area where countermeasures are administered.
- The ability of health care providers to safely dispense controlled substances via telemedicine without an in-person interaction is affected; however, there will be rulemaking that will propose to extend these flexibilities.

The Department will host a briefing on Monday, February 13 at 3:00 p.m. ET to discuss the end of the PHE. Registration information is available [here](#).

## BCBSA Proposes Policies to Reduce Health Care Costs

The Blue Cross Blue Shield Association (BCBSA) released a proposed [plan](#) last week to lower health care costs which it estimates would reduce federal deficits by \$337 billion over the next decade and reduce overall national health expenditures by \$767 billion. Their proposal focuses on lowering the prices paid for health care in Medicare and the commercial insurance market through six policies: adopting site-neutral payment policies in Medicare, expanding antitrust funding and enforcement, prohibiting anti-competitive provisions in provider contracts, facilitating generic drug and biosimilar entry, limiting the exclusivity period for biologicals, and repealing the tax deduction for drug advertising. BCBSA also proposes two additional policies which it argues will protect against increases in health care costs: preserving the ability of health insurers to use step therapy and pharmacy networks and to continue allowing health insurers to utilize prior authorization.

## Upcoming Congressional Hearings and Markups

House Energy and Commerce Subcommittee on Oversight and Investigations and Subcommittee on Health field hearing “President Biden’s Border Crisis is a Public Health Crisis;” 6:00 p.m.; February 15

Senate Health, Education, Labor, and Pensions Committee hearing “Examining Health Care Workforce Shortages: Where Do We Go From Here?” 10:00 a.m.; February 16

Senate Committee on Commerce, Science, and Transportation hearing to examine bringing transparency and accountability to pharmacy benefit managers; 10:00 a.m.; February 16

## Recently Introduced Health Legislation

H.R.830 — To amend title XXVII of the Public Health Service Act to apply additional payments, discounts, and other financial assistance towards the cost-sharing requirements of health insurance plans, and for other purposes; Sponsor: Carter, Earl L. “Buddy” [Rep.-R-GA-1]; Committees: House - Energy and Commerce

H.R.831 — To amend title XVIII of the Social Security Act to provide for coverage under part B of the Medicare program for medically necessary dental procedures; Sponsor: Cohen, Steve [Rep.-D-TN-9]; Committees: House - Energy and Commerce; Ways and Means

H.R.833 — To amend titles XVIII and XIX of the Social Security Act to provide for enhanced payments to rural health care providers under the Medicare and Medicaid programs, and for other purposes; Sponsor: Graves, Sam [Rep.-R-MO-6]; Committees: House - Energy and Commerce; Ways and Means; Budget

H.R.834 — To amend title XVIII of the Social Security Act to support rural residency training funding that is equitable for all States, and for other purposes; Sponsor: Harshbarger, Diana [Rep.-R-TN-1]; Committees: House - Ways and Means; Energy and Commerce

H.R.849 — To require the Department of Defense to share best practices with, and offers training to, State and local first responders regarding how to most effectively aid victims who experience trauma-related injuries; Sponsor: Torres, Ritchie [Rep.-D-NY-15]; Committees: House - Armed Services

H.R.853 — To amend titles II and XVIII of the Social Security Act to establish a Social Security Surplus Protection Account in the Federal Old-Age and Survivors Insurance Trust Fund to hold the Social Security surplus and a Medicare Surplus Protection Account in the Federal Hospital Insurance Trust Fund to hold the Medicare surplus, to provide for suspension of investment of amounts held in such Accounts until enactment of legislation providing for investment of the Trust Funds in investment vehicles other than obligations of the United States, and to establish a Social Security and Medicare Part A Investment Commission to make recommendations for alternative forms of investment of the Social Security and Medicare surpluses; Sponsor: Walberg, Tim [Rep.-R-MI-5]; Committees: House - Ways and Means

S.J.Res.10 — A joint resolution providing for congressional disapproval under chapter 8 of title 5, United States Code, of the rule submitted by the Department of Veterans Affairs relating to “Reproductive Health Services”; Sponsor: Tuberville, Tommy [Sen.-R-AL]; Committees: Senate - Veterans’ Affairs

S.280 — A bill to ensure that only licensed health care professionals furnish disability examinations under a certain Department of Veterans Affairs pilot program for use of contract physicians for disability examinations, and for other purposes; Sponsor: Rubio, Marco [Sen.-R-FL]; Committees: Senate - Veterans’ Affairs

S.288 — A bill to prevent, treat, and cure tuberculosis globally; Sponsor: Menendez, Robert [Sen.-D-NJ]; Committees: Senate - Foreign Relations

S.289 — A bill to improve national security at the National Institutes of Health, to address national security issues in the licensure of biological products, to address national security considerations in research at the Department of Health and Human Services, and for other purposes; Sponsor: Rubio, Marco [Sen.-R-FL]; Committees: Senate - Health, Education, Labor, and Pensions

S.302 — A bill to amend title 10, United States Code, to direct the Secretary of Defense to provide colorectal cancer screening for members of the uniformed services who served in locations associated with toxic exposure, and for other purposes; Sponsor: Klobuchar, Amy [Sen.-D-MN]; Committees: Senate - Armed Services

H.Res.99 — Supporting the goals and ideals of “National Black HIV/AIDS Awareness Day”; Sponsor: Lee, Barbara [Rep.-D-CA-12]; Committees: House - Energy and Commerce

H.J.Res.31 — Providing for congressional disapproval under chapter 8 of title 5, United States Code, of the rule submitted by the Department of Veterans Affairs relating to “Reproductive Health Services”; Sponsor: Cloud, Michael [Rep.-R-TX-27]; Committees: House - Veterans’ Affairs

H.R.875 — To authorize the Secretary of the Treasury to issue obligations to make Medicare and Social Security payments, despite the debt limit being reached; Sponsor: James, John [Rep.-R-MI-10]; Committees: House - Ways and Means

H.R.880 — To establish a program to provide for women’s heart health continuing medical education, and for other purposes; Sponsor: Sherrill, Mikie [Rep.-D-NJ-11]; Committees: House - Energy and Commerce

S.312 — A bill to amend title XVIII of the Social Security Act to modernize payments for ambulatory surgical centers under the Medicare program, and for other purposes; Sponsor: Blumenthal, Richard [Sen.-D-CT]; Committees: Senate – Finance

S.315 — A bill to direct the Secretary of Health and Human Services and other Federal officials to compile into a searchable database information relating to Federal support for biomedical research and development, and for other purposes; Sponsor: Merkley, Jeff [Sen.-D-OR]; Committees: Senate - Health, Education, Labor, and Pensions

S.323 — A bill to ensure the privacy of pregnancy termination or loss information under the HIPAA privacy regulations and the HITECH Act; Sponsor: Hirono, Mazie K. [Sen.-D-HI]; Committees: Senate - Health, Education, Labor, and Pensions

S.324 — A bill to authorize the Secretary of Health and Human Services to carry out activities relating to neglected diseases of poverty; Sponsor: Booker, Cory A. [Sen.-D-NJ]; Committees: Senate - Health, Education, Labor, and Pensions

S.326 — A bill to direct the Secretary of Veterans Affairs to carry out a study and clinical trials on the effects of cannabis on certain health outcomes of veterans with chronic pain and post-traumatic stress disorder, and for other purposes; Sponsor: Tester, Jon [Sen.-D-MT]; Committees: Senate - Veterans’ Affairs

H.Res.118 — Maintaining Medicare; Sponsor: Van Duyne, Beth [Rep.-R-TX-24]; Committees: House - Ways and Means; Energy and Commerce

H.R.885 — To direct the Secretary of Health and Human Services and other Federal officials to compile into a searchable database information relating to Federal support for biomedical research and development, and for other purposes; Sponsor: Doggett, Lloyd [Rep.-D-TX-37]; Committees: House - Energy and Commerce; Armed Services; Veterans’ Affairs; Judiciary; Ways and Means; Science, Space, and Technology

H.R.894 — To amend title 38, United States Code, to provide for limitations on copayments for contraception furnished by the Department of Veterans Affairs, and for other purposes; Sponsor: Brownley, Julia [Rep.-D-CA-26]; Committees: House - Veterans' Affairs

H.R.896 — To ensure that patients receive accurate health care information by prohibiting misleading and deceptive advertising or representation in the provision of health care services, to require the identification of the license of health care professionals, and for other purposes; Sponsor: Bucshon, Larry [Rep.-R-IN-8]; Committees: House - Energy and Commerce

H.R.901 — To require the Food and Drug Administration to prioritize enforcement of disposable electronic nicotine delivery system products; Sponsor: Cherfilus-McCormick, Sheila [Rep.-D-FL-20]; Committees: House - Energy and Commerce

H.R.902 — To provide for further comprehensive research at the National Institute of Neurological Disorders and Stroke on unruptured intracranial aneurysms; Sponsor: Clarke, Yvette D. [Rep.-D-NY-9]; Committees: House - Energy and Commerce

H.R.949 — To amend title XI of the Social Security Act to eliminate the general Medicaid funding limitations for territories of the United States, and for other purposes; Sponsor: Sablan, Gregorio Kilili Camacho [Del.-D-MP-At Large]; Committees: House - Energy and Commerce

H.R.952 — To amend title XIX of the Social Security Act to renew the application of the Medicare payment rate floor to primary care services furnished under the Medicaid program, and for other purposes; Sponsor: Schrier, Kim [Rep.-D-WA-8]; Committees: House - Energy and Commerce

H.R.955 — To amend title XVIII of the Social Security Act to allow payments under the Medicare program for certain items and services furnished by off-campus outpatient departments of a provider to be determined under the prospective payment system for hospital outpatient department services, and for other purposes; Sponsor: Smith, Adrian [Rep.-R-NE-3]; Committees: House - Energy and Commerce; Ways and Means

H.R.960 — To amend title XVIII of the Social Security Act to prohibit the use of an inpatient-only list in designating hospital outpatient services under the Medicare program; Sponsor: Steube, W. Gregory [Rep.-R-FL-17]; Committees: House - Energy and Commerce; Ways and Means

H.R.972 — To amend title XVIII of the Social Security Act to modernize payments for ambulatory surgical centers under the Medicare program, and for other purposes; Sponsor: Wenstrup, Brad R. [Rep.-R-OH-2]; Committees: House - Energy and Commerce; Ways and Means