State of Infrastructure and Reconciliation Negotiations

Informal negotiations on a pared down reconciliation package picked back up last week after President Biden’s first official State of the Union (SOTU). President Biden used his speech to highlight domestic priorities that Senator Joe Manchin (D-WV) had previously ruled out in any sort of reconciliation package that could get his support, such as extending the Child Tax Credit. Manchin returned to the Capitol on March 2, 2022 and indicated that he is still open to a slimmed down reconciliation package that includes climate spending, drug pricing reform, and rolling back some of the 2017 tax cuts. He noted that while formal negotiations are not occurring at this time, conversations are still happening. While there is some hope that a deal could be reached before summer, Democrats in Congress and the President will have to address other pressing issues such as the international crisis in Ukraine and government funding before they can turn their full attention to accomplishing President Biden’s domestic agenda.

Additionally, Senate Majority Leader Chuck Schumer (D-NY) announced on Monday, March 7, 2022, that the Senate would use various Congressional hearings to jumpstart talks about a new reconciliation package. The Senate Finance Committee will kick this off next week with a new hearing on lowering the cost of prescription drugs, one of the most important issues to the American people.

Drug Pricing Update

After President Biden’s SOTU, Senator Joe Manchin (D-WV), the deciding vote on any reconciliation package in the Senate, stated that he would be open to a pared down reconciliation package that includes provisions on climate spending, drug pricing reform, and rolling back the 2017 tax cuts. Drug pricing has long been an issue that Senator Manchin has said he would support in a reconciliation package, specifically allowing Medicare to negotiate drug prices. Manchin has consistently reiterated his support for the Democrat’s drug pricing package, negotiated last fall and argued that the revenue generated from these drug pricing provisions and reforming the tax code would help reduce the deficit as well as help pay for the climate and social spending programs in any future reconciliation package. The Senate Finance Committee will be holding a hearing on lowering the cost of prescription drugs. PRG will monitor the hearing and provide a summary.

View Senate Majority Leader Schumer’s remarks on the agreement HERE. View Senate Finance Committee Chairman Ron Wyden’s remarks on the agreement HERE.

Appropriations Update
On February 17, 2022, the Senate and House passed another continuing resolution (CR) in order to temporarily fund the government through March 11. As this new deadline looms, negotiations on the FY2022 appropriations package continue behind closed doors between Senate Appropriations Chairman Patrick Leahy (D-VT), Vice Chair Richard Shelby (R-AL), House Appropriations Chair Rosa DeLauro (D-CT), and Ranking Member Kay Granger (R-TX). As negotiations are ongoing, it is likely that another CR will be needed in order for appropriations leadership to come to a deal.

There are two specific issues that are currently holding up a deal. The first is a $10 billion aid package requested by the Biden administration for Ukraine after Russia’s invasion in February. There is disagreement between Republicans and Democrats as to whether that funding should be voted on separately from an omnibus or included in any sort of funding package. The second issue is the Biden administration’s request for more Covid-19 relief funding. Republicans have shown apprehension to including more relief funding as they are generally looking to end the pandemic emergency and attempt to return to normal life. Republican votes are needed for the omnibus and attached Covid-19 relief funding to pass, therefore the Biden administration will have to convince some Republicans to vote for the relief package.

SNO, along with the National Brain Tumor Society, sent the below letters to House and Senate Appropriations Committee leadership in January of 2022, highlighting our appropriations priorities.

FY22 NIHNCI Senate Letter  
FY22 PRCRP Senate Letter  
FY22 NIHNCI House Letter  
FY22 PRCRP House Letter

**President Biden’s First Official State of the Union**

On March 1, 2022, President Biden delivered his first State of the Union address to a joint session of Congress.

The speech covered a range of topics, from the Russian invasion of Ukraine, the recovery from the COVID-19 pandemic, investments in American infrastructure and manufacturing, the Biden administration’s plans to combat inflation and lower the deficit, continued COVID relief efforts, gun violence, immigration, the opioid epidemic, the mental health crisis, support for veterans, ending cancer, and President Biden’s recent nomination of Ketanji Brown Jackson to serve as a Supreme Court Justice. While the President mentioned clean energy investments on occasion, energy and environment policy did not play an outsize role in his speech.

President Biden began his speech by speaking directly to the American people about his vision to build a better America, but then promptly turned to address the ongoing war in Ukraine. He condemned President Putin’s premeditated and unprovoked attack on Ukraine and spoke to how his administration has extensively shared intelligence with allies and the public in order to combat the Kremlin’s deception. After outlining the recent slate of sanctions imposed by the US and its allies, he indicated that the Department of Justice is assembling a dedicated task force to go after
the crimes of Russian oligarchs and to seize assets such as yachts and private apartments. He also announced that the US is cutting off air space access to all Russian flights and that the US and 30 other countries will release 60 million barrels of oil from global strategic reserves. He closed with a message that in the battle between democracies and autocracies, Putin will never weaken the resolve of the free world.

President Biden next addressed the state of the economic recovery as the country recovers from the COVID-19 pandemic. He touted the success of the American Rescue Plan that delivered immediate economic benefits to tens of millions of Americans. He also pointed to statistics indicating that the economy created more jobs last year than in any other year in American history and that the economy is growing at its fastest levels since 1962. He argued against trickle down economic theories, and instead emphasized the importance of educating Americans, building up the American workforce, and having an economy built from the bottom up.

President Biden then discussed the historic investments in infrastructure from the bipartisan Infrastructure Investment and Jobs Act. He announced that his administration is rolling out plans to repair 65,000 miles of road and 1,500 bridges in disrepair. He also emphasized the necessity of Buy American requirements to ensure these investments directly benefit the American people.

He then turned to American manufacturing, centered most of this discussion in terms of competitiveness with China. He mentioned an Intel semiconductor fabrication plant being built in Ohio and used that as a jumping off point to urge Congress to pass bipartisan legislation that would increase spending for technology manufacturing, particularly for semiconductors.

President Biden next addressed the ongoing inflation that has significantly impacted the American people. After addressing the roots of the inflation crisis, he argued that “one way to fight inflation is to drive down wages and make Americans poorer. I have a better plan to fight inflation. Lower your costs, not your wages.” He advocated for “Building a Better America,” a plan that he said has been endorsed by 17 Nobel Laureates in economics. First, he advocated for cutting the cost of prescription drugs, including to let Medicare negotiate drug prices. Second, he advocated to cut energy costs for every family by $500 a year by combatting climate change. He advocated for tax credits to weatherize homes, as well as incentives for clean energy production and electric vehicles that would reduce costs families pay at the gasoline pumps. Third, he advocated to cut the cost of childcare. He also called on the Senate to confirm his nomination of Sara Bloom Raskin to serve on the Federal Reserve.

He then addressed a variety of economic matters, including taxes, the deficit, economic competition, and fraud related to COVID relief efforts. He argued that the present tax system is unfair and urged Congress to adopt his proposed 15% minimum tax rate for corporations. President Biden also announced that the Department of Justice will appoint a new chief prosecutor for pandemic fraud. He then emphasized the importance of market competition to reduce prices and assist Americans, pointing to meat packing and shipping as two of the most egregious examples of corporations unfairly driving up prices for Americans. He closed by urging Congress to enact the Paycheck Fairness Act, paid leave, raise the minimum wage to $15 an hour, extend the child tax credit, increase Pell grants and support for HBCUs, invest in community colleges, and pass the PRO Act to allow workers the opportunity to unionize.
President Biden then addressed the COVID-19 pandemic, emphasizing the massive gains the country has made over the past year. He advocated for four commonsense steps to ensure the country remains on track to a steady recovery: staying protected with vaccines and treatments, preparing for new variants, ending the shutdown of schools and business, and to continue vaccinating the world.

President Biden next addressed the rise of gun violence and the potential for police reform. He emphasized that “The answer is not to defund the police, it is to fund the police with the resources and training they need to protect our communities.” He also urged Congress to pass universal background checks, to ban high-capacity assault weapons, and to replace the liability shield that protects gun manufacturers from being sued.

President Biden next addressed a variety of legal matters that will be faced by his Supreme Court Justice nominee Ketanji Brown Jackson. He called on the Senate to pass the Freedom to Vote Act and the John Lewis Voting Rights Act. He also emphasized the need to protect a woman’s right to choose given attacks on abortion access throughout the country. He also asked for Congress to pass the bipartisan Equality Act to assist LGBTQ individuals, particularly youth.

President Biden offered a short summary of his vision to fix the American immigration system. He first outlined steps that his administration has taken to better secure the border via new technologies, increased patrols, and support for Central and South American countries. He also urged Congress to provide a pathway to citizenship for DREAMers, farm workers, and other essential workers in order to help the American economy.

President Biden closed with a “Unity Agenda,” that called for Congressional action on four traditionally nonpartisan priorities. First, beating the opioid crisis. Second, taking on the mental health crisis, especially among children. Third, supporting veterans including expanding eligibility for medical relief for those that have been exposed to toxic smoke from burn pits. Fourth, ending cancer through the Cancer Moonshot initiative, which will be a central focus of the administration’s efforts over the next years.

Cancer Mentions in SOTU

“Veterans are the best of us.

I’ve always believed that we have a sacred obligation to equip all those we send to war and care for them and their families when they come home.

My administration is providing assistance with job training and housing, and now helping lower-income veterans get VA care debt-free.

Our troops in Iraq and Afghanistan faced many dangers.

One was stationed at bases and breathing in toxic smoke from “burn pits” that incinerated wastes of war—medical and hazard material, jet fuel, and more.

When they came home, many of the world’s fittest and best trained warriors were never the same.
A cancer that would put them in a flag-draped coffin.
I know.
One of those soldiers was my son Major Beau Biden.
We don’t know for sure if a burn pit was the cause of his brain cancer, or the diseases of so many of our troops.
But I’m committed to finding out everything we can.
Committed to military families like Danielle Robinson from Ohio.
The widow of Sergeant First Class Heath Robinson.
He was born a soldier. Army National Guard. Combat medic in Kosovo and Iraq.
Stationed near Baghdad, just yards from burn pits the size of football fields.
Heath’s widow Danielle is here with us tonight. They loved going to Ohio State football games. He loved building Legos with their daughter.
But cancer from prolonged exposure to burn pits ravaged Heath’s lungs and body.
Danielle says Heath was a fighter to the very end.
He didn’t know how to stop fighting, and neither did she.
Through her pain she found purpose to demand we do better.
Tonight, Danielle—we are.
The VA is pioneering new ways of linking toxic exposures to diseases, already helping more veterans get benefits.
And tonight, I’m announcing we’re expanding eligibility to veterans suffering from nine respiratory cancers.
I’m also calling on Congress: pass a law to make sure veterans devastated by toxic exposures in Iraq and Afghanistan finally get the benefits and comprehensive health care they deserve.
And fourth, let’s end cancer as we know it.
This is personal to me and Jill, to Kamala, and to so many of you.
Cancer is the #2 cause of death in America—second only to heart disease.

Last month, I announced our plan to supercharge the Cancer Moonshot that President Obama asked me to lead six years ago.

Our goal is to cut the cancer death rate by at least 50% over the next 25 years, turn more cancers from death sentences into treatable diseases.

More support for patients and families.

To get there, I call on Congress to fund ARPA-H, the Advanced Research Projects Agency for Health.

It’s based on DARPA—the Defense Department project that led to the Internet, GPS, and so much more.

ARPA-H will have a singular purpose—to drive breakthroughs in cancer, Alzheimer’s, diabetes, and more.

A unity agenda for the nation.

We can do this.”

View a full transcript of President Biden’s remarks HERE.

**Telehealth Update**

On Thursday, March 3, 2022, the Senate voted to end the pandemic emergency with Senate Republicans forcing a vote on the issue using a provision in the National Emergencies Act. Typically, a vote on legislation such as this would require 60 votes to pass, however, a technical process in the National Emergencies Act allows the bill to pass with a simple majority. While the emergency will likely not end due to Democrats having control of the House of Representatives, it signals that many in Congress are pushing for pandemic policies to come to an end.

Telehealth is one of the policies that could be impacted should the pandemic emergency declaration come to an end. Currently, there is not an agreement on telehealth flexibility extensions upon the declaration ending. Negotiations are currently taking place to include an extension in an omnibus bill to fund the government for FY2022, however little progress has been made with Democrats and Republicans blaming each other for dragging their feet on the issue.

**House Energy and Commerce Subcommittee on Health Hearing Summary**

House Energy and Commerce Committee Subcommittee on Health
ARPA-H: The Next Frontier of Biomedical Research
February 8, 2022

**Witnesses**
Summary

On February 8th, 2022, the Subcommittee on Health of the House Committee on Energy and Commerce held a hearing to discuss the Biden Administration’s proposal to establish the Advanced Research Projects Agency for Health (ARPA-H). ARPA-H is included in the President’s FY2022 budget as a component of the National Institute of Health (NIH). The proposed funding level is $6.5 billion available for three years. ARPA-H will be tasked with building high-risk, high reward platforms to drive biomedical breakthroughs. The hearing centered around the benefits of establishing the ARPA-H. There was debate as to whether such an agency would be necessary to facilitate the kinds of biomedical research discussed amongst the plethora of other government agencies set up to facilitate and fund medical research. The infrastructure of the agency and whether or not ARPA-H should be an independent organization was debated thoroughly.

In her opening statement Chairwoman Anna Eshoo (D-CA) described the unique opportunity ARPA-H presented to bridge the gap between basic research and applied research. She pointed to the many ideas that are lost due to being too high risk for private sector investment. She stated that too often, opportunities for development are lost in the private sector because of their focus on profitability and markets. She believes ARPA-H will manage this. She noted that the agency would be an independent agency with the U.S Department of Health and Human Services (HHS) and proposed that the program managers be made up of not career government employees, but a wide arrange of field experts, academics, and scientists. In his opening statement, Chairman of the Full Committee Frank Pallone (D-NJ) voiced excitement over the new model proposed by the Biden Administration. He listed barriers to making groundbreaking discoveries and translating them to market including cost and scalability, regulatory pathways, and the question of profit. He went on to explain what other agencies such as the Defense Advanced Research Projects Agency (DARPA) have done to alleviate these barriers. He stated that while the existing biomedical
research in the U.S. is the best in the world, there are still gaps that need to be addressed. He also mentioned the funding proposed in the House to support the proposal of ARPA-H and how this hearing will impact the decision to approve that funding for the establishment of the agency.

In his opening statement, Ranking Member Brett Guthrie (R-KY) noted that healthcare seems to be a place of common ground on the committee, nevertheless he does have questions of the National Institute of Health (NIH) itself and the role the new agency would have. He mentioned the issue of the Chinese masking themselves to steal biomedical funding and grants from the NIH and asked how the agencies are working to remove foreign influence. He pointed out that ARPA-H’s research will not remove the private sectors responsibility to bring breakthrough phenomena to the markets. He stated that we need to ask how ARPA-H will fit in with the private sector. In her opening statement Ranking Member of the Full Committee Cathy McMorris Rodgers (R-WA) questioned whether or not we need to create a new agency. She voiced her concerns over the NIH and their lack of cooperation in answering how tax dollars are being spent and allotted. She stated that she is unconvinced a new agency is the answer, when it has no clearly stated goals, or mission. Instead, she pointed to other scientific agencies and questioned whether these were not working and if committee oversight would be needed.

In their opening statements witnesses discussed the need for an environment in which innovation and high-risk initiatives can thrive and take place without the disincentive to fail, and without the slow peer-review process that tends to be conservative. Dr. Yamamoto stated that ARPA-H is starting at the ending point of the NIH, it’s sole purpose will be to seek application and not discovery, thus modeled after DARPA, ARPA-H will continue with the NIH rather than threaten it. Dr. Yamamoto also made it clear that he believes ARPA-H needs to operate as an independent agency in HHS rather than as a component of NIH due to their separate cultures. Krofah made the same assertions of ARPA-H about its ability to take risks and achieve breakthroughs. However, she stated that there is no reason that ARPA-H can not be a component of the NIH and still accomplish its mission. She stated that the leaders of ARPA-H will be critical in empowering the initiatives and suggested an external advisory committee. Dr. Ling in his statement praised the creation of an organization that will say yes to daunting tasks such as tackling autism and cancer. Dr. Ling also made it clear that an end-to-end solution is the goal, patients, doctors, and researchers need to be involved in the process from the beginning. He finished by emphasizing the importance of ARPA-H being an independent organization, held accountable by the managers and then to Congress. Dr. Giroir made note of two cultural foundations that will be crucial to the success of ARPA-H, it must nurture and foster interactive innovation. He went on to elaborate stating there can be no disincentive to fail, and the directors must motivate and be diverse, excelling across multiple disciplines. He finished by reiterating that being an independent agency would be crucial to its success. Dr. Miller expressed differing opinions from the rest of the witnesses, citing challenges with ARPA-H including its lack of structure, lack of mission, and the need for a strategic plan before he would feel comfortable spending funding the agency. Dr. Miller instead suggested that funding and principles of ARPA-H be applied to the NIH extramural grant program, stating that we should look to change the NIH to create more transparency and accountability instead of adding an additional burden on taxpayers.

Throughout the hearing, Democrats generally voiced support for the implementation of ARPA-H, citing the Covid-19 pandemic and the ability of operation Warp Speed to produce a rapid response with the vaccine rollouts. They argued that ARPA-H would be able to harness the power of both the government and private sector to build upon the work method implemented during
Covid-19. They also asked questions regarding hierarchy structuring and avoiding redundancy across other scientific agencies like the NIH.

Throughout the hearing, Republicans were generally skeptical of the need for a new agency to be established, and whether the established NIH agency needs to be reformed before creating a new apparatus. They were also concerned with the discipline and accountability of ARPA-H, asking questions of accountability, language used to ensure correct turnover, and tenure limits. They shared concerns with Democrats over duplicative action across agencies, both Rep. Dan Crenshaw (R-TX), and Rep. Kurt Schrader (D-OR) asked questions regarding how to ensure the same research is not being done in both the private and government sectors.

MRI imaging was mentioned, prompted by a question asked by Rep. Crenshaw (R-TX), Dr. Ling believes the establishment of ARPA-H will create innovation in imaging technology that will allow detection of cancers earlier as well as drive cost down for the imaging itself. Rep. Diana DeGette (D-CO) asked a question regarding how programs such as the Cancer Moonshot and operation Warp speed are critical to technological information. Rep. Bilirakis (R-FL) asked a question regarding ARPA-H’s ability to fill the gaps in research particularly for rare diseases.

**Question and Answer**

**Rep. Kim Schrier (D-WA)**

Dr. Yamamoto, I wanted to ask a few things. If you wouldn’t mind answering briefly, how ARPA-H could impact just everyday people in Washington state? In your opinion would ARPA-H be a catalyst for expanding CAR-T gene therapy maybe to see if it would work in solid tumors?

**Dr. Yamamoto:** CAR-T Therapy is in many ways powerful and amazing and important as it is really the tip of the sword for being able to do cell engineering and enables us to develop cell therapies that deliver needed therapeutics to the point of action. The exact cells that are responsible for the disease for example. So, I think there is every possibility that under an ARPA-H like management, that we’ll definitely be able to serve people throughout your state and the country, and world in fact, because they provide the kind of targeting that allows for early diagnosis for a highly effective therapy early in the state of the disease and that sort of detection and treatment is really what’s needed in order to really counter disease, early detection and targeted treatment.

Speed is of the essence right, 8 years to get CAR-T is remarkable in one sense, but with the force we put into operation Warp Speed imagine what we could do for say pediatric solid tumors, brain tumors.

**Dr. Yamamoto:** And may I just add there is a project at UCSF being taken right now to be able to use CAR-T therapies in Glioblastoma, a very important and devastating brain disease.

**Up to Date List of Drug Related Legislation for the 117th Congress**

- **H.R. 6875 – Right Drug Dose Now Act**
  This bill introduced on 02/28/2022 by Rep. Eric Swalwell [D-CA-15], is to update the National Action Plan for Adverse Drug Event Prevention to provide educational
information on adverse drug events and pharmacogenomic testing, to improve electronic health records for pharmacogenomic information, and for other purposes.

- **H.R. 6834 – Recall Unsafe Drugs Act of 2022**
  The bill, introduced on 02/25/2022 by Rep. Rosa L. DeLauro [D-CT-3], will provide the mandatory recall of drugs regulated by the Food and Drug Administration.

- **H.R. 6833 – Affordable Insulin Now Act and S.3700**

- **H.R. 6757 – Insulin Savings for Patients Act**
  The bill, introduced on 02/18/2022 by Rep. Michael C. Burgess [R-TX-26] will amend title XVIII of the Social Security Act to establish under the Medicare prescription drug program a minimum amount of price concessions for insulin to be passed through to beneficiaries at the point-of-sale.

- **H.R. 6710**
  Introduced by Rep. Yvette Herrell [R-NM-2] on 02/11/2022, the bill will direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to submit to Congress a report on barriers, including regulatory inefficiencies, to domestic manufacturing of active pharmaceutical ingredients, finished drug products, and devices.

- **S. 3615 – Cutting Medicare Prescription Drug Prices in Half Act**
  The bill, introduced by Sen. Bernard Sanders [I-VT] on 02/09/2022, will establish a cap on costs for covered prescription drugs under Medicare parts B and D.

- **S. 3493 - Drug Shortages Shelf Life Extension Act**
  This bill, introduced by Sen. Ben Cardin (D-MD) on January 12, 2022, requires guidance on extending expiration dates for certain drugs, and for other purposes.

- **H.R. 6483 - Improved Transparency of Foreign Drug Manufacturing Act of 2022**
  This bill, introduced by Rep. Anna Eshoo (D-CA) on January 25, 2022, amends the Federal Food, Drug, and Cosmetic Act to clarify reporting requirements for establishments within a foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of an active pharmaceutical ingredient, and for other purposes.

- **S. 3576**
  This bill, introduced by Sen. Mike Braun (R-IN) on February 3, 2022, allows sponsors of certain new drug applications to rely upon investigations conducted in certain foreign countries, and for other purposes.

- **H.R. 6584**
This bill, introduced by Rep. Anna Eshoo (D-CA) on February 3, 2022, directs the Commissioner of Food and Drugs to amend certain regulations to increase clinical trial diversity, and for other purposes.

- **S. 3449**
  This bill, introduced by Sen. Gary Peters (D-MI) on January 10, 2022, requires foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device to register with the Food and Drug Administration regardless of whether the drug or device undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported into the United States.

- **S. 3401 – ABC Safe Drug Act**
  This bill, introduced by Sen. Tom Cotton (R-AR) on December 15, 2021, requires the Secretary of Health and Human Services to maintain a list of the country of origin of all drugs marketed in the United States, to ban the use of Federal funds for the purchase of drugs manufactured in the People's Republic of China, and for other purposes.

- **S.3339 - Capping Prescription Costs Act of 2021**
  This bill, introduced by Sen. Raphael Warnock (D-GA) on December 8, 2021, limits cost sharing for prescription drugs, and for other purposes.

- **H.R.6101 - Drug Price Transparency in Medicaid Act of 2021**
  This bill, introduced by Rep. Buddy Carter on December 1, 2021, amends title XIX of the Social Security Act to improve transparency and prevent the use of abusive spread pricing and related practices in the Medicaid program.

- **H.R.5872**
  This bill, introduced by Rep. Sean Patrick Maloney (D-NY) on November 4th, 2021, amends the Federal Food, Drug and Cosmetic Act to treat as misbranded cosmetics with packaging or labeling using the term “natural” unless the cosmetic meets certain standards, and for other purposes.

- **S.3080**
  This bill, introduced by Senator Tina Smith (D-MN) on October 27, 2021, amends the Employee Retirement Income Security Act of 1974 to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide for cost-sharing for oral anticancer drugs on terms no less favorable than the cost-sharing provided for anticancer medications administered by a health care provider.

- **H.R.5632**
  This bill, introduced by Rep. Kurt Schrader (D-OR) on October 19, 2021, establishes a statutory definition for long-term care pharmacy under the Medicare prescription drug benefit.

- **H.R.5576**
This bill, introduced by Rep. Susan Wild (D-PA) on October 12, 2021, allows states to apply the requirements of the Medicaid Drug Rebate Program to covered outpatient drugs under the Children's Health Insurance Program (CHIP).

- **H.R. 5463**
  This bill, introduced by Rep. Matthew Rosendale (R-MT) on September 30, 2021, increases reporting requirements and transparency requirements in the 340B Drug Pricing Program, and for other purposes.

- **H.R. 5237**
  This bill, introduced by Rep. Scott Peters (D-CA) on September 10, 2021, amends titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients' out-of-pocket costs, and to ensure accountability to taxpayers, and for other purposes.

- **S. 2595 - Drug Shortages Prevention and Quality Improvement Act**
  This bill, introduced by Senator Ben Cardin (D-MD) on August 4, 2021, addresses prescription drug shortages and improve the quality of prescription drugs, and for other purposes.

- **H.R. 4991 - Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2021**
  This bill, introduced by Rep. Peter DeFazio (D-OR) on August 10, 2021, requires persons who undertake federally funded research and development of a biomedical product or service to enter into reasonable pricing agreements with the Secretary of Health and Human Services, and for other purposes.

- **H.R. 5099 - Lowering Medicare Premiums and Prescription Drug Costs Act**
  This bill, introduced by Rep. Bradley Schneider (D-IL) on August 24, 2021, amends title XVIII of the Social Security Act to move Medicare cost-sharing benefits from Medicaid to Medicare, and for other purposes.

- **H.R. 3662**
  This bill, introduced by Rep. Morgan Griffith (R-VA) on June 1, 2021, amends the Federal Food, Drug, and Cosmetic Act to ensure patients have access to certain urgent-use compounded medications, and for other purposes.

- **H.R. 3761**
  This bill, introduced by Rep. Mike Gallagher (R-WI) on June 8, 2021, amends the Federal Food, Drug, and Cosmetic Act to establish a time-limited provisional approval pathway, subject to specific obligations, for certain drugs and biological products, and for other purposes.

- **H.R. 3927 and S. 2082**
  This bill, introduced by Rep. Buddy Carter (R-GA) and Sen. Tim Scott (R-SC) on June 16, 2021, mitigates drug shortages and provide incentives for maintaining, expanding, and relocating the manufacturing of active pharmaceutical ingredients, excipients, medical
diagnostic devices, pharmaceuticals, and personal protective equipment in the United States, and for other purposes.

• **S. 2257**
  This bill, introduced by Sen. Jacky Rosen (D-NV) on June 24, 2021, provides Federal support for nonprofit generic and essential medicine and device manufacturers to increase the availability of drugs and devices in order to reduce drug or device shortages and drug and device costs.

• **S. 2304**
  This bill, introduced by Sen. Dick Durbin (D-IL) on June 24, 2021, amends title XI of the Social Security Act to require that direct-to-consumer advertisements for prescription drugs and biological products include an appropriate disclosure of pricing information.

• **H.R. 4121**
  This bill, introduced by Rep. Jody Arrington (R-TX) on June 24, 2021, codifies a final rule issued by the Secretary of Health and Human Services relating to fraud and abuse and the removal of safe harbor protection for certain drug rebates, and for other purposes.

• **H.R. 4158**
  This bill, introduced by Rep. Bobby Rush (D-IL) on June 24, 2021, amends titles XVIII and XIX of the Social Security Act to eliminate cost sharing with respect to coverage of insulin as a covered part D drug under the Medicare program or as a covered outpatient drug under the Medicaid program.

• **H.R. 4287**
  This bill, introduced by Rep. Greg Murphy (R-NC) on June 30, 2021, directs the Comptroller General of the United States to conduct a study on how direct-to-consumer pharmaceutical advertising negatively impacts drug costs to consumers, and for other purposes.

• **S. 1644**
  This bill, introduced by Sen. Mike Braun (R-IN) on May 13, 2021, amends the Federal Food, Drug, and Cosmetic Act to establish a time-limited provisional approval pathway, subject to specific obligations, for certain drugs and biological products, and for other purposes.

• **S. 1645**
  This bill, introduced by Sen. Mike Braun (R-IN) on May 13, 2021, provides for an accelerated approval pathway for certain drugs that are authorized to be lawfully marketed in other countries.

• **H.R. 3203**
  This bill, introduced by Rep. Doris Matsui (D-CA) on May 13, 2021, enables certain hospitals that were participating in or applied for the drug discount program under section 340B of the Public Health Service Act prior to the COVID-19 public health emergency to temporarily maintain eligibility for such program, and for other purposes.
• **S. 1773**
This bill, introduced by Sen. Bob Casey (D-PA) on May 20, 2021, amends title XI of the Social Security Act to establish internet website-based dashboards to allow the public to review information on spending for, and utilization of, prescription drugs and biologicals covered under the Medicare and Medicaid programs.

• **H.R. 3437**
This bill, introduced by Rep. Bobby Rush (D-IL) on May 20, 2021, requires the Secretary of Health and Human Services to guarantee BioBonds in order to provide funding for loans to eligible biomedical companies and universities to carry out clinical trials approved by the Food and Drug Administration, and for other purposes.

• **H.R. 2344**
This bill, introduced by Rep. Tim Ryan (D-OH) on April 1, 2021, requires the use of prescription drug monitoring programs.

• **H.R. 2484**
This bill, introduced by Rep. Katie Porter (D-CA) on April 13, 2021, amends title XXVII of the Public Health Service Act and title XVIII of the Social Security Act to require pharmacies to disclose any differential between the cost of a prescription drug based on whether certain individuals use prescription drug coverage to acquire such drug, and for other purposes.

• **S. 1124**
This bill, introduced by Sen. Marsha Blackburn on April 14, 2021, preserves non-interference under the Medicare part D Prescription Drug Benefit program.

• **H.R. 2608**
This bill, introduced by Rep. Peter Welch (D-VT) on April 15, 2021, amends title XVIII of the Social Security Act to ensure equal access of Medicare beneficiaries to community pharmacies in underserved areas as network pharmacies under Medicare prescription drug coverage, and for other purposes.

• **H.R. 2623**
This bill, introduced by Rep. Josh Gottheimer (D-NJ) on April 16, 2021, amends the Internal Revenue Code of 1986 to restore the amount of the orphan drug tax credit, and for other purposes.

• **H.R. 2706**
This bill, introduced by Rep. Katie Porter (D-CA) on April 20, 2021, amends title XVIII of the Social Security Act to require drug manufacturers to pay a Medicare part B rebate for certain drugs if the price of such drugs increases faster than inflation.

• **H.R. 2829 and S. 1323**
This bill, introduced by Rep. Peter Welch (D-VT) and Sen. Jeff Merkley (D-OR) on April 22, 2021, requires the Secretary of Health and Human Services to establish reference prices for prescription drugs for purposes of Federal health programs, and for other purposes.
• **S. 1366**
  This bill, introduced by Sen. Elizabeth Warren (D-MA) on April 26, 2021, secures the supply of drugs in the United States, and for other purposes.

• **H.R. 2846**
  This bill, introduced by Rep. David McKinley (R-WV) on April 27, 2021, amends title XVIII of the Social Security Act to require PDP sponsors of a prescription drug plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes.

• **H.R. 2853**
  This bill, introduced by Rep. Kurt Schrader (D-OR) on April 27, 2021, amends the Federal Food, Drug, and Cosmetic Act, with respect to eligibility for approval of a subsequent generic drug, to remove the barrier to that approval posed by the 180-day exclusivity period afforded to a first generic applicant that has not yet received final approval, and for other purposes.

• **S. 1425**
  This bill, introduced by Sen. Amy Klobuchar (D-MN) on April 28, 2021, enables the Federal Trade Commission 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, and for other purposes.

• **S. 1428**
  This bill, introduced by Sen. Amy Klobuchar (D-MN) on April 28, 2021, prohibits 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.

• **H.R. 2868**
  This bill, introduced by Rep. G.K. Butterfield (D-NC) on April 28, 2021, amends title XIX of the Social Security Act to prohibit additional rebates under the Medicaid program for certain noninnovator multiple source drugs.

• **H.R. 2870**
  This bill, introduced by Rep. Buddy Carter (R-GA) on April 28, 2021, amends the Public Health Service Act to provide for stockpiles to ensure that all Americans have access to generic drugs at risk of shortage, and for other purposes.

• **H.R. 2883**
  This bill, introduced by Rep. Hakeem Jeffries (D-NY) on April 28, 2021, enables the Federal Trade Commission 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, and for other purposes.

- **H.R. 2891**
  This bill, introduced by Rep. Jerry Nadler (D-NY) on April 28, 2021, prohibits prescription drug companies from compensating other prescription drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product into the market.

- **S. 1462**
  This bill, introduced by Sen. Bill Cassidy on April 29, 2021, amends the Federal Food, Drug, and Cosmetic Act to simplify the generic drug application process.

- **S. 1463**

- **S. 1508**
  This bill, introduced by Sen. Roger Marshall (R-KS) on April 29, 2021, provides for the use of emergency use authorization data and real world evidence gathered during an emergency to support premarket applications for drugs, biological products, and devices, and for other purposes.

- **S. 1523**
  This bill, introduced by Sen. Mike Braun (R-IN) on April 29, 2021, amends title XI of the Social security Act and title XXVII of the Public Health Service Act to establish requirements with respect to prescription drug benefits.

- **H.R. 2148**
  This bill, introduced by Rep. Ro Khanna (D-CA) on March 23, 2021, aims to significantly lower prescription drug prices for patients in the United States by ending government-granted monopolies for manufacturers who charge drug prices that are higher than the median prices at which the drugs are available in other countries.

- **S. 909**
  This bill, introduced by Sen. Bernie Sanders (I-VT) on March 23, 2021, aims to significantly lower prescription drug prices for patients in the United States by ending government-granted monopolies for manufacturers who charge drug prices that are higher than the median prices at which the drugs are available in other countries.

- **S. 898**
  This bill, introduced by Sen. Tammy Baldwin (D-WI) on March 23, 2021, requires reporting regarding certain drug price increases, and for other purposes.

- **S. 833**
This bill, introduced by Sen. Amy Klobuchar (D-MN) on March 18, 2021, amends XVII of the Social Security Act to allow the Secretary of Health and Human Services to negotiate fair prescription drug prices under part D of the Medicare program.

- **H.R. 597**
  This bill, introduced by Re. Jan Schakowsky (D-IL) on January 28, 2021, requires any COVID-19 drug developed in whole or in part with Federal support to be affordable and accessible by prohibiting monopolies and price gouging, and for other purposes.

- **S. 141**
  This bill, introduced by Sen. Jeanne Shaheen (D-NH) on January 28, 2021, amends the Internal Revenue Code of 1986 to deny the deduction for advertising and promotional expenses for prescription drugs.

- **H.R. 153**
  This bill, introduced by Rep. Bobby Rush (D-IL) on January 4, 2021, prohibits brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products, and for other purposes.

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**In The News**

**Modern Healthcare** (2/25/2022): **CMS redesigns Direct Contracting into an ACO model** - The new ACO model will incorporate health equity requirements, make changes to risk adjustment policies and more.

**Politico** (2/24/2022): **TELEHEALTH FOREVER FOR MEDICARE?** The LIBRE Initiative, a Hispanic advocacy group, is urging lawmakers to enact legislation so Medicare continues to cover telehealth services for older Hispanics, regardless of whether a public health emergency is established — as it has been doing since the pandemic’s early days.

**Bloomberg** (2/24/2022): **FDA Plans Interstate Drug Shipment Rules**: The FDA will write regulations around interstate shipments of drugs between pharmacies after suspending a standard agreement that’s been caught up in litigation since its release. The agency intends to use the notice-and-comment rulemaking process to “codify provisions” of a memorandum of understanding with states involving shipments of compounded medications, according to a Tuesday filing with the U.S. District Court for the District of Columbia. Compounded drugs are those mixed by a pharmacist for a specific patient based on a doctor’s prescription.

**Politico Pro** (2/23/2022): **DEMS, GOP SPAR OVER ARPA-H PROPOSAL** — Bipartisan support for one of President Joe Biden’s top health priorities is splintering over concerns about costs and structure, a reflection of a widening fissure between the parties on funding medical research, POLITICO’s Sarah Owermohle reports.
The Hill (2/23/2022): **Judge strikes down part of Biden surprise billing rules in win for doctors** - A federal judge in Texas on Wednesday struck down part of the Biden administration’s regulations protecting patients from getting stuck with “surprise” medical bills when they see the doctor, in a win for doctors who sued to block part of the rules.

Politico Pro (2/22/2022): **NEW HEALTH AGENCY ENSNARED IN POLITICAL DIVIDES** — Emerging resistance to Biden’s idea of a new multibillion-dollar agency to tackle some of health care’s biggest challenges reflects a widening gap over what used to be a cross-party island in a divisive sea — funding medical research.

Bloomberg (2/22/2022): **Warren Urges U.S. to Seize Patents on Pfizer’s Cancer Drug**: Pfizer’s prostate cancer medicine Xtandi is in the crosshairs of a growing campaign for the government to seize patent rights to bolster competition. Sen. Elizabeth Warren (D-Mass.) and two other lawmakers—Sen. Angus King (I-Maine) and Rep. Lloyd Doggett (D-Texas)—are pushing the Biden administration to take unilateral action to lower the price of the drug, pointing to a decades-old law that lets the federal government leverage “march-in rights” to license patents on certain medicines to outside manufacturers.

Politico (2/18/2022): **CALIFF FDA PRIORITIES** — New FDA commissioner Robert Califf was sworn in Thursday to lead the agency where he’ll face a number of challenges.

Bloomberg (2/17/2022): **Biden Taps OSTP Temporary Leadership**: Biden yesterday tapped Dr. Alondra Nelson to perform the duties of director of the White House Office of Science and Technology Policy and former NIH director Dr. Francis Collins to perform the duties of science advisor to the president until permanent leadership is confirmed.

Politico (2/17/2022): **COLLINS IS BACK** — We hardly had time to miss former National Institutes of Health Director Francis Collins, who will become President Joe Biden’s science adviser, the White House said late Wednesday, while Alondra Nelson will become its acting director of the Office of Science and Technology Policy. Both will split the role left vacant by Eric Lander’s resignation.

Modern Healthcare (2/17/2022): **Certain specialty pharmacy drugs double in price at hospitals, study finds** - While the cost differences between pharmacies and hospitals seem clear cut, some experts say the data doesn't highlight the complexities of hospital drug pricing.

Bloomberg (2/17/2022): **Drug Price Reporting Rules Foiled by Loopholes in Supply Chain**: U.S. transparency rules for drug and health costs are being stymied by interlocking business deals between insurers, pharmacy liaisons, and other companies, including some that are overseas. Those are observations gleaned from industry comments about a multi-agency rule (RIN 0938 AU66) designed to give employers and insurers a window into how the care they’re paying for is priced. Entities at every stage of the supply chain say they need more information on what the other companies in the system are paying. The reporting requirements went into effect in December, and regulators are seeking input into how to clarify the rules.

Politico (2/16/2022): **HHS ASKS CONGRESS FOR $30B FOR COVID RESPONSE** — Health and Human Services Secretary Xavier Becerra told congressional appropriators in charge of crafting a
supplemental pandemic funding package on Tuesday that his agency needs at least $30 billion to keep its wide-ranging Covid-19 response work going.

**Axios** (2/16/2022): **Lawmakers wary of Biden's $30B COVID request** - The Biden administration has requested $30 billion more to fuel the COVID response, sources familiar with the matter told Axios' Caitlin Owens and Sarah Mucha.

**Modern Healthcare** (2/16/2022): **HHS gives $55M to community health centers for virtual care access** - The number of community health centers offering virtual visits has risen 130% since 2019.

**Modern Healthcare** (2/16/2022): **Senate confirms Biden’s FDA pick despite political divisions** - The FDA hasn’t had a permanent leader in more than a year despite playing a central role in the COVID-19 response effort, reviewing the vaccines, drugs and tests used to fight the pandemic.

**Politico** (2/15/2022): **THE PUBLIC HEALTH EMERGENCY QUESTION** — Today marks the 60-day countdown for the current public health emergency declaration to expire. That might seem like a random milestone, but the Health and Human Services Department has promised to provide states and health groups with 60 days’ notice of any possible termination of the emergency.

**Bloomberg** (2/14/2022): **Republicans Call On Biden to End Emergency**: The House Energy and Commerce Committee’s top Republican Cathy McMorris Rodgers (R-Wash.) and over 70 House Republicans pressed Biden and the Department of Health and Human Services “to accept that COVID-19 has become endemic, recognize that current heavy-handed government interventions are doing more harm than good, and immediately begin the process to unwind the Public Health Emergency.” Doing so may present significant ramifications, such as loosening federal authority on vaccine mandates.

**Bloomberg** (2/14/2022): **White House Shifts to Deficit Reduction to Get Manchin’s Vote**: The White House is considering reworking Biden’s economic and social spending plan to emphasize deficit reduction in a bid to secure support from Sen. Joe Manchin (D-W.Va.) a person familiar with the administration’s discussions said. Top congressional Democrats have also in recent days discussed adding deficit reduction measures. While Biden’s administration has insisted that the president’s agenda would be fully paid for, Manchin has stalled the $2 trillion package of climate, tax and social spending initiatives, citing his concern about the effect on federal debt as well as inflation.

**Politico** (2/11/2022): **DEMS SET UP CALIFF VOTE FOR NEXT WEEK** — Senate Majority Leader Chuck Schumer filed a motion Thursday to limit debate on Robert Califf’s nomination, setting up a vote as early as Tuesday on his confirmation to lead FDA, your morning co-hosts and Adam Cancryn report. Interviews with more than 50 senators this week indicated that, while many have not yet publicly stated how they’d vote, some key Republicans haven’t ruled out supporting him as the agency heads into its third year of managing a hefty portion of the U.S. pandemic response.

**Bloomberg** (2/11/2022): **Biden Urges Passage of Drug Pricing Plan** - President Joe Biden called on lawmakers to pass his plan to lower prescription drugs prices, saying he’s seeking to cut down surging costs faced by families at a time when inflation is spiking. “Bringing down the cost of healthcare, bringing down the cost of prescription drugs is an easy thing for us to do,” Biden said. “It can be done legally with the stroke of a pen.”
Politico (2/11/2022): BIDEN LOOKS TO REVIVE HEALTH AGENDA — President Joe Biden went to Virginia Thursday to restart a popular health priority that stalled amid pandemic challenges and congressional deadlock: drug price reform.

Politico (2/11/2022): BIDEN: DRUGMAKERS ‘SHOULD BE TREATED MORE LIKE A UTILITY’ — President Joe Biden stumped Thursday for several prescription drug pricing policies he wants Congress to take up, including Medicare negotiation and taxes on firms that raise drug prices faster than the inflation rate. Doing so, he argued, would help families already dealing with higher food and gas prices.

Politico (2/11/2022): ADVISORY COMMITTEE VOTES AGAINST APPROVING CANCER DRUG TESTED IN CHINA — FDA’s external advisory committee on oncology drugs voted 14-1 against approval of a therapy from Eli Lilly and Innovent Biologics on Thursday, citing the need for another clinical trial with more diversity, Katherine reports.

Associated Press (2/10/2022): Biden Puts Focus on Drug Prices as He Tries to Revive Agenda - President Joe Biden is trying to jump-start progress on his stalled domestic agenda by refocusing attention on one of his most popular proposals, limiting the cost of prescription drugs.

Politico (2/10/2022): WYDEN BACKS CALIFF AFTER FDA NOMINEE PROMISES MORE PHARMA OVERSIGHT — Senate Finance Chair Ron Wyden (D-Ore.) pledged his support for Biden’s FDA nominee Robert Califf on Thursday after the former agency commissioner agreed to more oversight of drug companies that win accelerated approval for new medicines, Alice reports.

The Hill (2/9/2022): Sanders calls on Democrats to bring up drug pricing bill in Senate - Sanders calls on Democrats to bring up drug pricing bill in Senate Sen. Bernie Sanders (I-Vt.) on Wednesday called on Senate Democrats to vote on legislation to lower the cost of prescription drugs.

Politico Pro (2/8/2022): THE ARPA HEARING GETS … INTERESTING — A congressional panel convenes this morning to discuss funding one of President Joe Biden’s top priorities: A new, multibillion-dollar health agency focused on preventing, diagnosing and developing new treatments for conditions like cancer and Alzheimer’s disease. But the president’s top witness became a liability — and resigned late Monday, pulling out of defending one of the president’s biggest initiatives.

Politico Pro (2/8/2022): 90+ GROUPS PUSH SENATE DEMS TO REVIVE BBB’S DRUG PRICE REFORMS — A coalition of some of the country’s biggest unions, corporations, physicians’ and disease advocacy groups wrote to every Senate Democrat today to demand the revival of Democrats’ stalled social spending bill and, particularly, the inclusion of provisions to lower drug prices.

Bloomberg (2/8/2022): Lawmakers Seek Telehealth Expansion in Stopgap: A bipartisan, bicameral group of lawmakers are calling for the permanent extension of expanded coverage of telehealth services to be included in the stopgap legislation. “Throughout this pandemic we have seen how telecommunications systems can help triage and assess ill patients remotely,” and reduce exposure to Covid-19 “for our most vulnerable,” the 44 lawmakers including Sen. Marsha Blackburn (R-Tenn.) and Brian Schatz (D-Hawaii) said in a letter to congressional leaders.
**Bloomberg** (2/8/2022): **Testimony Yanked as Embattled White House Science Aide Resigns:** Embattled White House science adviser Eric Lander will resign from his post effective by Feb. 18, and will no longer testify before a House panel today. Rep. Anna Eshoo (D-Calif.), chairwoman of the House Energy and Commerce health subcommittee, confirmed the hearing will proceed with the second panel of witnesses.

**Politico** (2/7/2022): **THE LAST BATTLE OF GIANTS** — Retiring Sens. Patrick Leahy (D-Vt.) and Richard Shelby (R-Ala.) are laying 35 years of experience working together on the line, hoping to cut a massive deal on government spending to avoid the string of stopgap funding patches and shutdown threats that have plagued Congress for months.

**Bloomberg** (2/7/2022): **Biden Cancer Plan Called Bold, Achievable** - President Joe Biden's goal of cutting the cancer death rate in half will require strides in population-level research and weeding out disparities in care, the head of the National Cancer Institute said.