

Drug Pricing Update

On June 22, 2021, Senate Finance Committee Chairman Ron Wyden (D-OR) released his comprehensive “Principles for Drug Pricing Reform” document that builds off of the legislation he introduced with Senator Chuck Grassley (R-IA) in the 116th Congress. His proposal is largely in response to H.R. 3, the comprehensive drug pricing reform package introduced in the House of Representatives earlier this year. Chair Wyden’s package, which does include things such as Medicare negotiated drug prices, capping out of pocket costs for Medicare beneficiaries, and limiting price increases to the rate of inflation does not reach as far as the House Democrats’ proposal in an effort to bring together the moderate and progressive wings of the Democratic party.

For Chair Wyden, it is necessary to propose legislation that can unite all wings of the Democratic Party because it is unlikely that any comprehensive drug pricing legislation that includes Medicare negotiated prices will get any Republican support. Additionally, Democrats will need to utilize a budget reconciliation bill to get the legislation passed, which will require all 50 Democratic votes in the Senate.

You can view Chair Wyden’s proposal [HERE](#).

While Congress has yet to come to an agreement as to what comprehensive drug pricing reform will look like, Americans and even those in the pharmaceutical industry believe something needs to be done to lower prices. PhRMA Chief Operating Officer Lori Reilly recently stated during a Milken Institute panel that “As long as we ensure that those costs go to patient ability to access their medicines, and keep the balanced ecosystem that we believe is in place today as it relates to innovation, we’re absolutely willing to partner with anyone to have those conversations.” This is a significant shift in traditional thinking as it was widely thought that the drug industry would fight any effort to lower drug prices.

PRG will continue to monitor the drug pricing conversation and provide updates as necessary.

ARPA-H Update

Inside and outside of government there is a growing concern about where ARPA-H will be housed as it is being widely reported that the new agency will be within the National Institutes of Health. Many are concerned about creating a duplicative bureaucratic process with some of the same problems that plague the current NIH research system. Should ARPA-H be bogged down by some of the same issues as NIH, it is unlikely that ARPA-H will have the freedom and

flexibility that was billed when the Biden administration proposed the new agency. On the other hand, the administration believes that ARPA-H being included in NIH will allow ARPA-H to have the foundation to hit the ground running to achieve its lofty mandate, similar to the Department of Defense's Defense Advanced Research Projects Agency.

Both Secretary of Health and Human Services Becerra and NIH Director Collins have come out in support of ARPA-H, stating that the new agency will have its own identity separate of other research opportunities within NIH.

All discussion on ARPA-H in recent HHS budget hearings is available in the Congressional hearings section below.

CURES 2.0 is Here

On June 22, 2021, Reps Diana DeGette (D-CO) and Fred Upton (R-MI), who led the first iteration of the 21st Century Cures Act, released draft legislation that would create a new federal advanced research agency to cure cancer, Alzheimer's and other diseases. In addition to realizing the President's dream of creating ARPA-H, the legislation would:

- Improve how Medicare covers innovative new health care technologies, making them more available to those who need them.
- Increase diversity in clinical trials to ensure new drugs and treatments are both safe and effective for a greater majority of patients throughout the country.
- Require FDA to expand the collection and use of Real World Evidence to aid in the development of new, patient-focused treatment approaches.
- Provide training and educational programs for caregivers – many of whom are often family members with no prior health care experience – to help improve the quality of care patients are provided at home, between clinical visits.
- Provide patients greater access to more health information to improve their understanding of the illness they face and make them a more integral part of the decision-making process when assessing which course of treatment is best for them.
- Increase access to telehealth services for patients covered under Medicare, Medicaid or the Children's Health Insurance Program (CHIP) to make these services more accessible to more Americans.

You can view a section-by-section summary of the legislation [HERE](#).

Surprise Billing Update

On July 1, 2021, the Biden administration released a rule that bans patients from receiving surprise medical bills from providers outside their insurance network. The rule is the first of several expected to be published by the administration as a result of the No Surprises Act passed by Congress last December. This legislation prohibits doctors and hospitals, and almost all healthcare providers from sending insured patients bills after they unknowingly receive care from out-of-network providers. However, ground ambulances were left out of the legislation and could remain a source of surprise billing. The reason this rule and subsequent rules will need to be published is that Congress left it up to the Biden administration to implement certain details of the law before it takes effect starting January 1, 2022.

The rule addresses three main issues. First, it defines a standard “fair” price for out-of-network care that arbitrators should use as a baseline when deciding how much an insurance plan should pay doctors and hospitals. Second, the rule mandates that hospitals must post rules banning surprise billing on their websites, and that healthcare providers must notify patients with a form if the health care provider is not a part of the patient’s insurance network. It reads, “If you sign this form, you may pay more because you are giving up your protections under federal law.” They must gain the consent of the patient before treating them. Third, the rule enacts a complaint system for those who believe their doctor or hospital billed them illegally under the new law, with no time limit set for when one can file a complaint.

Additionally, emergency services will be billed at in-network prices and patients cannot be charged out-of-network prices if treatment is provided in an in-network healthcare facility. The rule also states that any out-of-network cost sharing like deductibles or copayments cannot be higher than if the treatment was provided by an in-network provider.

The rule will be subject to 60 days of public comment.

Telehealth Update

Congress is working to ensure that telehealth policies for Medicare recipients adopted under the Trump administration at the start of the pandemic remain in effect after the health emergency ends. The Department of Health and Human Services told governors that the public health emergency declaration will likely remain through the end of 2021. Senate plan S. 1512, sponsored by Sen. Brian Schatz (D-HI), aims to permanently enact Trump Medicare coverage and payment rules for telehealth services. It would end all geographic-based restrictions on telehealth for Medicare patients, let rural health providers and clinics that provide care in underserved areas permanently use telehealth, and allow patients to begin care from home. The bill also would authorize the Secretary of Health and Human Services to permanently end telehealth restrictions and mandate a study on the use of telehealth during the pandemic. The bill currently has 59 cosponsors in the Senate, meaning it is likely to clear the 60 vote threshold needed to pass legislation in the Senate. An identical version of the bill has also been introduced in the House of Representatives by Rep. Mike Thompson (D-CA) and currently has 60 cosponsors.

On June 22, Representatives Liz Cheney (R-WY) and Debbie Dingell (D-MI) introduced H.R. 4040. The bill would make it easier for older Americans to access telehealth services by permanently enshrining telehealth flexibilities that were given to Medicare recipients during the pandemic. Providers would be authorized to provide telehealth services to patients no matter where they live in the country. The legislation would also allow Medicare to pay for doctors’ visits on audio-only phone calls instead of requiring a video component in order to receive coverage.

On June 9, Sen. Joe Manchin (D-WV), alongside Sens. Joni Ernst (R-IA), Jeanne Shaheen (D-NH), and Jerry Moran (R-KS) introduced the Protecting Rural Telehealth Access Act. The bill would allow payment-parity for audio-only health services for clinically appropriate appointments and for Critical Access Hospitals to bill directly for telehealth services. It would also permanently

allow rural health clinics and Federally Qualified Health Centers to serve as distance sites for providing telehealth services and Medicare recipients to be treated from their homes by waiving geographic restrictions. Additionally, the bill would allow store and forward technologies, which involve collecting clinical information and sending it to another site for examination. This practice is only currently allowed in Alaska and Hawaii.

President Biden Drops Health Goals From Bipartisan Infrastructure Package

On June 24, 2021, the Biden administration announced that they had reached a deal on an infrastructure framework with a bipartisan group of lawmakers. The \$1.2 trillion framework includes investments in clean transportation infrastructure, clean water infrastructure, clean power infrastructure, and resiliency to climate change. Notably missing from the framework is any sort of health provisions or the American Families Plan that President Biden had coined as “human infrastructure.” Republicans indicated that they would be unable to support any sort of human infrastructure in the bipartisan framework.

Instead, President Biden indicated that he would work to include his American Families Plan and many of his health goals in the next reconciliation bill that he stated would move on a dual track with the bipartisan infrastructure deal. He even went so far as to indicate that he could potentially veto the bipartisan traditional infrastructure plan should another budget reconciliation bill not move with it. However, President Biden has since backtracked on that position in an effort to appease Republicans.

Should a larger reconciliation package not accompany the bipartisan traditional infrastructure bill, Biden risks upsetting the progressive wing of the Democratic Party who believe the bipartisan framework does not go far enough to address climate change or human infrastructure.

PRG will continue to provide updates on the negotiations as necessary.

Recent Congressional Hearings

**Senate Appropriations Committee, Subcommittee on Labor, Health and Human Services,
Education and Related Agencies**

**[Hearing on the President’s Fiscal Year 2022 Budget Request for the United States
Department of Health and Human Services](#)**

June 9, 2021

Opening Statements

Chairwoman Patty Murray (D-WA)

Secretary Becerra, I am pleased to say this budget represents a world of change from the past few years on health care and a roadmap on progress for years to come. It proposes increasing

the Centers for Disease Control and Prevention (CDC) budget by nearly a quarter, which, as we discussed in our hearings with Director Walensky, will not only help see our nation through this pandemic, but help us rebuild our public health system and better prepare for the next one. It also proposes serious investments to tackle other on-going public health crises. Health care providers across my state have reported a sharp uptick in youth mental health emergencies during this pandemic and the national suicide rate has been climbing for years. This budget builds on the resources we've provided for mental health and substance use services in our COVID-19 bills with an additional \$9.7 billion for the Substance Abuse and Mental Health Services Administration and an increase of \$3.7 billion over fiscal year '21 levels. Washington state also saw drug overdoses increase by 38 percent over the first half of 2020 and our nation saw a record-breaking number of overdose deaths last year. President Biden is proposing a historic investment of \$10.7 billion across Health and Human Services (HHS) programs to end the opioid epidemic. And he is proposing we continue the progress we've seen towards ending another epidemic by investing \$670 million in the HIV/AIDS Elimination Initiative. And to aid the fight against cancer, Alzheimer's, long-term COVID-19, and countless other diseases, President Biden is calling for the largest budget increase for the National Institute of Health in the agency's history. In the fight against systemic racism, he has proposed new investments across the department to reduce health disparities. And after years of relentless attacks on women's health care and reproductive rights, President Biden is charting a clear path in a new direction, one that puts women's health first and puts patients, not politicians, in charge of their own health care decisions. I am pleased to see this budget call for \$340 million for the Title X Family Planning program, which helps so many patients-- particularly women of color - get birth control, cancer screening, STD screenings and other essential care. This funding will build on the administration's recent progress to restore the Title X Family Planning program with a proposed -- new proposed rule.

Ranking Member Roy Blunt (R-MO)

I support the National Institute of Health (NIH) increases. I think the research institute at NIH, ARPA-H is in the right place at the right time with the right focus, and I announced in our hearing last week, if you remember chair, that I intend to be supportive of that. And I believe we can make it work in a way we wouldn't have envisioned before the last couple of years and the new things we did to step up to the pandemic.

Secretary Xavier Becerra

"Now more than ever we must ensure that the department has the resources to achieve its mission and to build a strong public health system and a healthier America. For HHS the budget proposes 13 -- I'm sorry a \$131 billion in discretionary budget authority and \$1.5 trillion in mandatory funding. This budget underscores the administration's commitment to prepare the nation for the next public health crisis. To expand access to affordable healthcare, to address health disparities, to tackle the opioid and other drug crises and to invest in other priority areas like maternal health, tribal health, and early childhood education. We know the fight against COVID-19 is not yet over. But even as HHS works to beat the pandemic, we must also prepare for the next public health challenge. To start the budget makes significant investments in our preparedness and response capabilities including by investing in the strategic national stockpile and the public health workforce. It provides a new mandatory funding stream for the manufacturer of medical countermeasures here at home to protect Americans from future

pandemics and create U.S. jobs. The budget includes the largest fiscal year investment in the CDC in almost two decades. The budget reflects the President's commitment to expanding access to quality affordable healthcare for all Americans. It builds on the groundbreaking reforms introduced in the American Rescue Plan by permanently extending the enhanced premium subsidies that put affordable healthcare coverage within reach for millions more Americans. The budget also expands access to home and community-based services under Medicaid; critical services that allow older Americans and our loved ones with disabilities to live independently in their homes and communities. And the budget calls for Congress to take additional steps this year to lower the cost of prescription drugs and further expand and improve health coverage through additional benefits and public coverage options. Healthcare must be a right not a privilege, and I will work hard to ensure that families across the nation are able to secure the healthcare that they need. And as we work to expand access to affordable healthcare and address the challenges of COVID-19 and future pandemics, we need to address public crises that are already here like violence in our communities and climate change. The President's budget increases funding to support domestic violence survivors, it addresses gun violence by doubling funding for firearm violence prevention research, and allows HHS to play a major role in the administration's government wide effort to tackle the climate crisis by supporting research and programs identifying the human health impacts of the climate change and establishing an Office of Climate Change and Health Equity. To ensure that HHS is equably servicing all Americans, the budget invests in reducing maternal mortality and morbidity that disproportionately impacts women of color. It builds on the American Rescue Plan's state auction to extend Medicaid postpartum coverage. It funds a range of rural healthcare programs and expands the pipeline for rural health providers. It includes a dramatic funding increase and advanced appropriations for the Indian Health Services, and it invests in improving access to vital reproductive and preventative care services through Title 10. To support families and build the best possible future for our children, the budget makes major investments to ensure high quality childcare is affordable for low- and middle-income families and to provide high quality pre-K for all three and four-year-olds. We know our experiences as children shape the adults we become. Support in childhood leads to success in the future. To address COVID-19's unprecedented acceleration of substance use and mental health disorders, the budget makes historic investments in SAMHSA to support research, prevention, treatment and recovery services. To support innovation and research, the budget increases funding for NIH by \$9 billion, \$6.5 billion of which will go to establish the Advanced Research Project Agency for Health, ARPA-H, with an initial focus on cancer and other diseases, as diabetes, and Alzheimer's. This major investment in federal research and development will leverage ambitious ideas to build transformational innovation through health research and the application and implementation of health breakthroughs."

Q&A

Senator Joe Manchin (D-WV)

And then also, my final question -- the 340B program is essential for providing access to safer and affordable medications for low-income West Virginians and low-income people all over our country. Recently, you've determined -- HHS has determined that six pharmaceutical companies have violated the program by restricting access to contract pharmacies. The undermining of the 340B program by pharmaceutical companies and pharmacy benefit managers has taken its toll on my West Virginia hospitals, community health centers and their

contract pharmacy partners, and I'm sure in every state of every one of us have been hit with this. What are the next steps that you will take as the head of HHS to ensure the integrity of the 340B program?

Secretary Xavier Becerra: “Well Senator, as you just said, we just put out in writing, we didn't just say it verbally, we put out in writing a clear message to these six manufacturers that we believe that they're violating the law.

You violate the law you pay the consequences. And so -Has it been turned over to DOJ?

Secretary Xavier Becerra: We're waiting for responses. Some have responded, but we're waiting for full responses. By the way, our budget also does increase funding in this area. We -- I think we provide almost a doubling, not quite a doubling of the money that is available to make sure that we can do the grant rulemaking that we need. I hope what you'll do is you'll give us more authority to actually clear guidance on what can be done and can't be done on 340B.”

I hope -- and I really think we could do that in a bipartisan way, because I tell you we're all being affected.

Senate Finance Committee

[The President's FY 2022 HHS Budget](#)

June 10, 2021

Opening Statements

Chairman Ron Wyden (D-OR)

I'm going to begin with out-of-control prescription drug prices. Far too many Americans are getting clobbered with every trip to pick up their medications at the pharmacy window. The latest drug pricing news is the approval of Aducanumab, a new medication for Alzheimer's disease, one of the chronic diseases that now defines Medicare in the modern day. The drug's approval was controversial. There is little data showing it actually does what the company says it will do. Despite that, Aducanumab has an unconscionable list price of \$56,000 per year. Let us understand it is not a cure like some other recent breakthrough drugs have been. Patients could be on Aducanumab for years at a time after their diagnosis, multiplying the overall cost of treatment. Setting aside the lack of clear evidence that this new Alzheimer's drug actually works, medical science today is clearly capable of miracles. The speedy development of highly effective coronavirus vaccines is just one example. Every single member of the Finance Committee welcomes and cheers those advances. However, Americans are terrified by the status quo on prescription drug pricing. Not only are too many Americans' foregoing or rationing their prescriptions, but sky-high drug prices could bust America's health care budgets. I am working now to update the Finance Committee's prescription drug legislation from the last Congress, and I welcome the ideas of all members of the committee. I believe it is long past time to give Medicare the authority to negotiate better prices for prescription drugs on behalf of more than 50 million seniors. Overwhelmingly, the American people support this idea. President Biden during his speech in April called on Congress to get it done. We're all hungry for genuine medical breakthroughs. But Senators, I would simply say what does it mean if the vast majority of Americans can't afford them?

Ranking Member Mike Crapo (R-ID)

The budget request also suggests using Medicare dollars to expand Obamacare just as we saw with the original passage of the ACA more than a decade ago rather than champion the market-based reforms that have made Medicare Advantage in Part D such resounding success stories for our nation's seniors. The budget proposes a convoluted price control scheme for prescription drugs that would reduce access to life saving cures in the years ahead.

Secretary Xavier Becerra

The budget provides historic investments in SAMHSA to support research, prevention, treatment and recovery services to support innovation and research. The budget increases funding for NIH by \$9 billion, six and a half billion of which will go to establish the Advanced Research Projects Agency for Health (ARPA-H). With an initial focus on cancer and other diseases such as diabetes and Alzheimer's. This major investment in federal research and development will leverage ambitious ideas to build transformational innovation through health research and the application and implementation of health breakthroughs.

And the budget calls on Congress to take additional steps this year to lower the cost of prescription drugs and further expand and improve health coverage through additional benefits and public coverage options. Health care must be a right, not a privilege, and we'll work hard to ensure that families across the nation are able to secure the health care they need as we work to expand access to affordable health care and address the challenges of COVID-19 and future pandemics.

Q&A

Chairman Ron Wyden (D-OR)

If only a fraction of seniors suffering from Alzheimer's were prescribed additional Medicare, Part B spending would double overnight. Seniors taking the drug would be asked to pay more than \$11,000 and coinsurance each year. Now the President has called on the Congress to lower the cost of prescription drugs through negotiation, and you to your credit, I just learned this at the Ways and Means Committee, you basically said, just give me the authority. I want the authority. I want to go to work. Tell us, if you would, what kind of tools would be most useful to you in using that authority? For example, one that comes to my mind would be finding a way to get analysis of prescription drugs to determine which ones were the best and you can factor that into your decision making. But I'd be curious because people say all right, we hear from Senators Medicare should negotiate, tell us a little bit about what kind of tools you would use if you got the authority you were talking about yesterday in Ways and Means.

Secretary Xavier Becerra: I'll tell you that one of the things that is always helpful is oversight. The more we can have eyes on what's going on to make sure the industry is doing the right thing. The providers are handling these medications and medical supplies properly. The more we know that we're getting a good bang for the buck for the American people, but there are other ideas. You've had ideas in your legislation that I know you're trying to move forward again with maybe the negotiation of drug prices. You can talk about providing drug rebates in the event that a manufacturer tries

to increase the price of a prescription drug by more than inflation. There are a number of good ideas that are out there, as I said, give us the authority and we'll go to work.

Ranking Member Mike Crapo (R-ID)

The President's Health Care and Human Services budget before us does not include policy specifications or cost estimates regarding a number of the health care proposals such as lowering the Medicare age of eligibility to 60. Mr. Secretary, when will we see a policy outline and scoring estimates for these administration requests?

Secretary Xavier Becerra: And Senator there, I think the President has signaled very strongly we need to continue to try to extract as much value out of every dollar for health care. And certainly, as the chairman has said with regard to prescription drugs, I think everyone agrees that the prices are way too high. And so, there are any number of ideas rather than an outline of a specific approach. We have indicated, for example, negotiating Medicare drug prices would save us several hundred billions of dollars. We could do something similar to what Senator Wyden and Senator Grassley have proposed where you push on rebates so that if a drug company tries to increase prices too quickly, you get a rebate back from them. That saves tens of billions of dollars. The numbers are out there, whether from CBO or OMB, we're willing to sit down and come up with a solution. We know that you need to get the votes to pass something, but we are -- we're game and ready to go.

Senator Debbie Stabenow (D-MI)

Thank you. Let me also just ask, when we look at the new Alzheimer's drug cost, bipartisan efforts have been very involved over the years in putting a lot more into research, but if people can't afford the products that ultimately that come out of the research, we haven't done our job. And so, I was appalled that Biogen priced their Alzheimer's drug that was approved by the FDA at \$56,000 per year. I'm not going to debate whether or not this is effective or not, but I can just say this is more than double the median household income for Michiganders over 65, double the Social Security yearly income, and more than the average income. I'm extremely concerned about where this is going in terms of cost to seniors. So, as somebody who authored amendment to provide you the authority to negotiate under Medicare, I hope that you will continue to look for every possible way in order for us to bring prices down. \$56,000 a year is impossible for people.

Secretary Xavier Becerra: Senator innovation is effective only if patients can afford it, and so I look forward to working with you, so we have that ability.

Senator Bill Cassidy (R-LA)

What are the significant plans, for example, to decrease expenditures within the Medicare program?

Secretary Xavier Becerra: There are a number of solutions that are out there that have been out there for years. I remember when I was in Congress, many people had proposed a number of things like what we did with the Affordable Care Act, which added years to the life and solvency of the Medicare system. It could be reducing the cost of prescription drug medication.

Senator Ben Cardin (D-MD)

I want to start with prescription drugs. I know the chairman mentioned that it's the first thing off the bat today, the high cost of prescription drugs, and Senator Stabenow mentioned that, and I agree with that. But I want to go from a different perspective and that is drug shortages. We have high cost of prescription drugs and then we have drugs that are not terribly expensive that are not available because the profit motive is not there. And as a result, we have extremely important drugs, some used to deal with cancer treatment that are not available as they should be. I was happy to see the President's budget included \$22 million for a new resilient supply chain and shortage program. Could you just share with us how those funds, if appropriated by Congress, would be used to deal with this drug shortage issue?

Secretary Xavier Becerra: Senator what we're hoping to do is find that we have always a stockpile, that we are better prepared that we're telegraphing where things will go. In my opening statement, I mentioned how we're right now in the process of preparing for the next pandemic, the next health crises. And so, in addressing that, one of these will have to do is make sure we have the medicines necessary to address that. So, we're going to try to do what we can to try to boost the supply including, if possible, through domestic manufacture of that supply.

Senator Chuck Grassley (R-IA)

I know that President Biden has a big interest in reducing drug prices. There's a lot of Republicans in the United States Senate that want to do it and I would conclude that if President Biden and his staff feels it can be done by reconciliation, then I think that I would quit talking and not ask any questions. But if they would come to the conclusion that possibly some of the things that are being talked about on the Democratic side can't get 60 votes in the United States Senate, I think it would lead you to the work that Senator Wyden and I have done over the last two years on reducing prescription drugs and probably could easily get 65 to 70 votes in the United States Senate, maybe even more than that. We did have 10 House Democrats who wrote to Speaker Pelosi worried about getting something done on prescription drugs if it wasn't a bipartisan prescription drug bill. So, it kind of brings me to this dialogue with you. Can I infer from the fact that the President's budget does not assume passage of H.R. Three, that the administration accepts that there's no path forward on H.R. Three? Would you be willing - if that's something you might agree to, would you recommend to President Biden that he instead focus efforts towards supporting a bipartisan bill that can get 60 votes in the United States Senate and then get something really done and big time in this area? Because Big Pharma doesn't like what Grassley and Wyden have been working on for two years.

Secretary Xavier Becerra: Senator First, thank you for all the work that you have done with the chairman to try to get this solved. I think we're anxious to work with the two of you and members on both sides of the aisle and in both chambers to try to get something done. The President has said plainly that he wants to get behind some reforms to reduce drug prices. He has said he's open and supports negotiating prices. He has said he supports the idea of seeking rebates when prices are too high. And I think what the President has signaled in his budget is that we're open to make sure that what we end up doing is reducing the price of prescription drugs for Americans. And so, we look forward to working with you and all of your colleagues to get something done.

Senator Bob Mendez (D-NJ)

I didn't intend to talk about this, but I just want to make a point that when we talk about prescription drug reform, there are many ways to try to seek it. What I am concerned is I consistently see that we take revenue from the pharmaceutical industry, but we don't lower the cost of prescription drugs. So, I don't quite get it that if you keep taking revenue from the industry, but you don't lower the cost of prescription drugs, how does that help the consumer? So, for me, the bottom line is going to be show me how you are going to lower the costs for consumers on prescription drugs and doing so in such a way that as we just saw in the midst of this pandemic, how important this industry is to produce a lifesaving vaccine? So, I think we have to get our priorities right in that regard and that's going to be my bottom line.

Senator Tom Carper (D-DE)

A couple of years ago, Mr. Secretary, this committee led by Senators Wyden and Grassley passed bipartisan legislation to reduce prescription drug prices for Medicare beneficiaries. Lower drug prices for seniors and lower drug prices for Medicare and Medicaid also require drug companies to make price increases publicly available. You may recall, I spoke with you recently about your willingness to maybe explore whether or not that bipartisan agreement which enjoyed a lot of my Democrat support and quite a bit of Republican support might be pulled off the Bellotti shelf and dusted off in this Congress in the years to build on for future legislative efforts in its space. Have you had a chance to give out any thought in the Senate?

Secretary Xavier Becerra: Yes, I appreciate the question. Have given a great deal of thought and we're actually working right now to try to be supportive of the work that you're doing, and certainly the work that Senator Wyden and Senator Grassley have done so that we can try to see progress made. There are any number of proposals that are out there. The President has made it clear he is supportive of making progress in reducing the price of prescription drugs. He has been supportive of negotiating drug prices. He has been supportive of the efforts in the Wyden-Grassley legislation to try to deal with high prices through rebates. We are open, we're ready. We're waiting to see where you all wish to go as well, and we'll be good partners as we try to help Americans pay less for their prescription medication.

Senator Tom Carper (D-DE)

So that's encouraging. I would urge you to be proactive. There's a possibility we could do something again and build on what we agreed to two years ago. Second, a follow up question of this also with respect to prescription drug prices Mr. Secretary, the President's budget calls on Congress to pass legislation to lower prescription drug prices in part by allowing the of the Secretary of Health and Human Services to negotiate directly with pharmaceutical manufacturers. However, there's been debate among my colleagues on what negotiations would actually look like. And as the principal negotiator under this proposal, what approach would you take to share with us some insights as to what kind of approach approaches you would take to negotiating to lower drug prices? And what authorities you'd be looking to us in the Congress for to make this happen?

Secretary Xavier Becerra: Senator, the last point you made is where I think we should start, which is that we will look to Congress to see how we can get this done. We may have ideas and we certainly can provide technical assistance. But there are any number

of approaches when it comes to how you would negotiate those prices. H.R. Three legislation that passed in the House last year provides one means, others have other ideas. All I know is that the President is anxious for to work with Congress to reduce the cost of prescription medication.

Senator Elizabeth Warren (D-MA)

President Biden's budget proposes an historic investment in the American people when it comes to health care. The President has called on Congress to do more, especially for Medicare. Now Medicare is very popular, but it is not perfect, especially when it comes to covering the services that older Americans need. For example, 50 percent of people age 75 or older have a disabling hearing loss, but Medicare doesn't offer a comprehensive hearing benefit. It also doesn't cover full dental or vision services, even though 70 percent of seniors have no dental insurance and older Americans are at increased risk for severe eye problems. So that's why the President as part of his budget called on Congress to quote 'improve access to dental vision and hearing coverage in Medicare'. So, Secretary Becerra, let me ask you, how would expanding Medicare coverage to include vision, dental and hearing services, improve the health and well-being of Medicare beneficiaries, especially low-income beneficiaries and seniors in medically underserved groups.

Secretary Xavier Becerra: Well, Senator, I think as we've discussed in the past, and I think the President made very clear, we have ways that we can expand these services. And in fact, we must because we know it's to our own benefit to provide these preventative services as early as possible to our seniors. What I can tell you is that there are ways to pay for these additional services. We've discussed some of those as well in the past. If you were to save money on prescription drug medication by negotiating prices or providing that the industry must provide rebates when it increases prices too quickly, you start to develop the resources you need to pay for things like providing access to oral dental, health services, vision services, and hearing services. So, we're looking forward to working with you to make sure that we continue to make Medicare even better and where we go. I know that really would depend on Congress, but we're ready where we want to be.

Good, I like that. I strongly agree with President Biden. Congress should expand Medicare to include vision, hearing and dental coverage and it should lower the age of Medicare. In fact, I think we should go lower than the President proposed to age 55. Now President Biden also wants Congress to let Medicare negotiate payments for high-cost Part D drugs, something you referred to earlier Mr. Secretary. But Big Pharma is lobbying hard to maintain the status quo. So let me ask you, Mr. Secretary, as Congress crafts legislation to lower drug prices, the pharmaceutical lobbyists are out there. Fear mongering and pressing us to pass some watered-down bill that fails to tackle drug pricing head on. How do you think Congress should respond? Are we going to go with these half measures, or do you think we should pass a strong negotiation bill that implements the President's agenda?

Secretary Xavier Becerra: Senator I think COVID-19 has taught us so many different things. It continues to teach us, and we see what happens when we aren't prepared. I don't think anyone wants the American public to not be prepared to face down whether it's a pandemic or something as serious as making sure that all of us have access to the prescription medication we need. We will leave it to Congress, but we think this is an opportunity to make a generational change in how we do business when it comes to prescription medication.

Good, I'm glad to hear that Secretary Becerra. I agree the time for delays and half measures and equivocating and industry friendly legislating is over. It is time for Congress to step up and put President Biden's Medicare priorities into action. And I don't just mean some of the priorities, I mean all of them: authorizing drug price negotiation with real muscle, expanding Medicare benefits, and lowering the eligibility age. As you say, we have an opportunity here to dramatically improve the Medicare program and we shouldn't waste it by being afraid to take on interest groups that are profiting off our current system.

Chairman Ron Wyden (D-OR)

But you and I have worked together for a long time and enjoyed service in the Congress. And I think we know some practical steps forward in this committee. Senator Grassley and I were able to get Senators to say that when pharmaceutical companies are price gouging on drugs like insulin, which has gone up 12-fold in price in recent years and not gotten 12 times better, they're going to lose your subsidies. And we look forward to continuing our work with you and build on the positive news that you gave us today. And recognize we've got some very heavy lifting, particularly in terms of taking on some of the big, entrenched lobbies in health care, so that we can make real changes that help people like lowering drug prices.

House Ways and Means Committee

[Ways and Means Committee Hearing on the President's Proposed Fiscal Year 2022 Budget with the Department of Health and Human Services Secretary Becerra](#)

June 8, 2021

Opening Statements

Representative Kevin Brady (R-TX)

“Regrettably though this hearing reveals a budget that is truly partisan. After a massive pandemic, President Biden insists on putting Washington in charge of American's personal health decisions even when it means canceling their private health insurance through Medicare for all future cures for devastating diseases through H.R. 3, imposing costly new one size fits all mandates on Main Street businesses, ignoring the looming insolvency of Medicare, creating new entitlements that require dramatically higher payroll taxes on workers and puts the IRS in charge of your time off and doubling down on the fatally flawed Affordable Care Act. The fact is, Americans don't trust Washington with their life and death medical decisions. They oppose a socialist takeover of their health care and they know that good paying jobs and growing wages do far more for working families than one size fits all Washington mandates and permanently smaller paychecks. Americans also don't want lower drug prices at the expense of future cures for Alzheimer's, Parkinson's, ALS, diabetes and cancer. As Democrats rush through the House with H.R. 3, they want Congress to work together to deliver lower drug prices and more lifesaving cures as Republicans proposed in the bipartisan H.R. 19. President Biden's budget ignores the looming insolvency of Medicare without meaningful reforms to address the fact that this program is just five years away from going broke. Instead, Democrats make it worse by expanding the program beyond today's seniors, jeopardizing the Medicare guarantee that seniors paid a lifetime into. The possibility that telehealth benefits may soon be stripped from

those who relied on it to get to the Covid pandemic is another problem ignored in the Biden budget.”

Secretary Xavier Becerra

“The budget increases funding for NIH by nine billion dollars, six and a half billion of which will go to establishing the Advanced Research Projects Agency for Health (ARPA-H), with an initial focus on cancer and other diseases such as diabetes and Alzheimer's. This major investment in federal research and development will leverage ambitious ideas to build transformational innovation through health research and the application and implementation of health breakthroughs.”

Q&A

Representative Lloyd Doggett (D-TX)

And with regard to prescription drug pricing, is it important that our legislation not discriminate against the uninsured, that we provide benefits to them?

Secretary Xavier Becerra: Again, thank you for being dogged in this because you are right. Like you, I agree that we want to make sure everyone has a chance to participate and to benefit from lower prices.

Representative Tom Reed (R-NY)

Thank you, Mr. Chairman, and it's great to see you again Mr. Secretary here at the committee. Mr. Secretary, I just want to try to get two quick questions and one is a very heavy concern about the drug pricing takeover that H.R. 3 represents and what the President has supported in his budget and one of the things that I'm greatly concerned about is the incorporation of the quality adjusted life years in setting drug prices from foreign countries in American drug pricing policy. And I just wanted to see, Secretary, if you could commit today to us, to this committee, that HHS will not use quality adjusted life years to set drug prices in the U.S. either directly or by proxy during your tenure as Secretary.

Secretary Xavier Becerra: So first let me just say I look forward to working with you. You know President Biden has made it very clear. We're going to do everything we can to try to bring down the cost of prescription medicines. And so we're going to look at everything, but we will absolutely work with you and your colleagues to make sure that what we do is done right, that everyone feels that it's fair and it's accountable. So let me just make sure that we're in touch if you'd like, if you'd like to work on this issue.

I definitely look forward to working with you and I know you had a conversation with my colleague Cathy McMorris Rodgers on this issue. And I just want to make sure that that quality adjusted life years does not become the de facto or de jure policy of your office in setting drug prices here nationally, which would be, I think a very difficult or very problematic policy for America to establish. In regards to its drug pricing policy.

Representative Brad Wenstrup (R-OH)

We need to address the cost of drugs in the United States. It's important for our patients and I think there's bipartisan room here and I believe that foreign price controls will not leave room

for the next set of cures. And so we have that balance between innovation and then cost. At the end of the day, let's lead that, let's lead the world on both of those things. I know there's a lot of things we can work together on. I always talk about the health span of America, you just kind of touched on it there a little bit. We always take a look at life span, but what about the health span of Americans? Prevention and cures are often looked at as a cost and that's on the short term. But we don't often look at what we save in the long term when we do this. And it sounds like you're on board with that. I do want you to be aware that we have a rural and underserved health care task force that the Chairman put together and it includes Representative Arrington, Sewell, Davis, and me. And I look forward to working with you to address the health disparities in these communities. And you sound eager to want to engage in those. So I appreciate that. Substance abuse, we can't ignore that. It's a problem. If you've read the book Dreamland, that's my district on the cover. If you haven't read it, I recommend it to your attention. I'm proud of the work we've done on surprise billing. Let's make sure it gets done right. And I will say this to it as a physician, there's no part of me that doesn't want Americans to have access to health care. That's obviously extremely important. You know, we talk about Medicaid. I'm proud to live in a country that has a safety net like that, that is there for people so that we can maintain some health care for those that have trouble affording it and for other reasons. But the statistics have showed that that particular plan has the highest mortality and morbidity of any in the country. And I think we're better if we start to look at solutions to how fewer Americans need the Medicaid program because the fewer that are on it, then the better it is for those that are still in it, that's more of that. We want more of the best care for more Americans. So I'd like to continue to work with you on those issues. So I threw out a lot there, but I really do look forward to working with you and I -- I'm asking you one question. Will you commit to work with Congress and particularly members of Congress that have medical backgrounds?

Representative Carol Miller (R-WV)

Thank you Chairman Neal and Ranking Member Brady and thank you, Secretary Becerra for being here today. It's so nice to be able to meet you. You know, we all can agree that we want the best health care outcomes for America and access to care for all of those who need it the most at the most affordable price. However, we seem to have very different ways of accomplishing these goals and instead of a top down government centric approach outlined by the administration's budget, I think we should focus rather on the patients, the cures, and ensuring long term solvency for our health care system. Within this budget, the President has called on Congress to cut prescription drug prices. The plan, H.R. 3, would result in fewer cures, as many as one hundred I've heard from entering into the market. And this legislation would completely kill American innovation, actually raising prices on seniors and cost American lives. We cannot let such a disastrous piece of legislation reach the President's desk. The Republican solution of H.R. 19 would lower the costs of drugs, increase pricing transparency and further American innovation. The Covid-19 pandemic has forever changed our health care landscape within West Virginia, who I represent. We saw many patients with increased access to care through telehealth. Given the extremely rural nature of my state, patients sometimes had to travel hours just to see a doctor and through telehealth they were able to pick up their phone and meet with their provider. I've heard from those providers who love it too and they are able to see their patients more efficiently. I hope that we can take the lessons learned from telehealth during the pandemic and to continue funding telehealth. I think it's so important Mr. Secretary.

Secretary Xavier Becerra

Congressman Blumenauer, as you know, this administration is willing to look under every rock that any member of Congress puts before us to see if there's a better solution for health care. We want to continue to expand coverage. We want to continue to lower costs. So if you and your colleagues come up with some good ideas when it comes to prescription drugs on better access on innovation, on bending the curve, we're willing to listen.

Representative Terri Sewell (D-AL)

The pandemic has laid bare the historic racial inequities that exist in our health care system for so many Americans. My constituency, in the black belt of Alabama, is painfully aware of the pervasive systemic and institutional influence that have influenced and contributed to the disparities in health care. As it is true in so many areas of health care, there are a lot of problems centered around access to care and trust in the medical and scientific community. A specific area that I'd like to focus on today is cancer, a disease that takes over 600,000 American lives. Every year, minority and rural populations are especially burdened by cancer due to the higher rates of late stage diagnosis. Experts tell us that one of the most important ways to beat cancer is to catch it early before it spreads. If you or your loved one is diagnosed with cancer, the very next words that you want to hear are: but we've caught it early enough. I have sponsored last Congress and this Congress a bipartisan bill called the Medicare Multiple Cancer Early Detection Screening Coverage Act, a bill that I am pleased to be cosponsoring with colleagues Representative Arrington, Ruiz, and Hudson. This legislation seeks to modernize Medicare coverage to enable providers and seniors to have access to new tests that use a simple blood draw to screen for over 50 types of cancer, including pancreatic cancer and find them early when patients still have a fighting chance. But until now, our tools to do so have been limited. Secretary Becerra, we only have screening for five cancers that are covered by Medicare and for this reason, pancreatic cancer and so many other cancers are not being found early enough. And the impact on seniors and Medicare in terms of cost is staggering, catching cancer at its earliest stage in people without symptoms would be an amazing game changer. Currently unknown cancers continue to spread often becoming more static and lives are lost because of that. For example, pancreatic cancer, which is the third leading cause of cancer in my home state of Alabama, has a very low survival rate in part because it is not caught early enough. Only 80 percent of the cases of this disease have a survival rate. Only 15 percent of pancreatic cancers are found early enough and survival rates for pancreatic cancer are six times higher when it is found earlier versus late. In fact, this very committee, your colleague, our friend, Congressman John Lewis, passed away because of this cancer. Fortunately, new multiple cancer early detection screening tools are emerging for our seniors in pain and Medicare patients who are often most at risk. I ask for your commitment Secretary Becerra in addressing this horrible cancer, all of these cancers, by expanding the access to tools in the toolkit that will be paid for by Medicare that we can catch disease early on. In closing, I'd like to ask a question regarding that, sir. I know that you're committed to closing the equity gaps that exist in health care. Can you talk to us specifically about what your this administration is doing about that and how we can work with you in order to make sure we're saving lives?

Secretary Xavier Becerra: First, preventative care. That was the whole process behind the Affordable Care Act, is to get to people before they were too sick. We know for many communities, especially rural and regional communities. We're always at the end

of the end of the stage when it comes to getting the kind of care up front. Secondly, data, we need to get good data.

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

- [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](#)
This bill, introduced by Sen. Bill Cassidy on April 29, 2021, amends the Federal Food, Drug, and Cosmetic Act to modernize therapeutic equivalence rating determinations.
- [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 Rep. 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](#) (7/2/2021): **CMS bans surprise billing** - The rule will affect people with job-based coverage or individual health plans who unwittingly receive care from out-of-network providers.

[Axios](#) (7/2/2021): **Ads target moderate Dems, pharma allies** - One Democratic defector in the Senate could sink the party's effort to lower prescription drug prices, and a series of new ad campaigns are giving strong hints about who advocates are most worried about, Axios' Caitlin Owens writes.

[Politico](#) (7/2/2021): **THE BEGINNING OF THE END FOR 'SURPRISE' MEDICAL BILLS** — Biden's HHS is out with its first of several rules for enforcing a long-awaited ban on "surprise" bills — a complex undertaking that will have far-reaching consequences for health care in the U.S.

[Politico](#) (7/1/2021): **PROGRESSIVE GROUP HITS SENATE MODERATES WITH DRUG-PRICING ADS** — Patients For Affordable Drugs Now is out with a new six-figure ad campaign to pressure moderate Democrats in the Senate who haven't yet endorsed Finance Chair Ron Wyden's plan to empower Medicare to negotiate drug prices.

[Modern Healthcare](#) (6/30/2021): **Hospitals decry extending Medicare cuts to pay for infrastructure bill** - The American Hospital Association and other hospital groups are urging the Senate to abandon a plan to pay for a bipartisan infrastructure bill with cuts to Medicare providers.

[Axios](#) (6/30/2021): **Hospitals' warning shot on infrastructure plan** - The nation's largest hospital groups really don't want the Senate to pay for its infrastructure deal with funding that would otherwise go to them, Axios' Caitlin Owens writes.

[Politico](#) (6/30/2021): **HOSPITALS BLAST BIDEN'S INFRASTRUCTURE PAY-FORS** — Nine hospital organizations are criticizing the White House's plan to fund billions of dollars in new infrastructure spending as part of a bipartisan deal.

[Politico Pro](#) (6/29/2021): **Virtual care becomes a common cause in a divided Congress** - Congress appears poised to let millions of Medicare recipients continue to video chat with their doctors after the pandemic is over. A set of telemedicine policies the Trump administration adopted during lockdowns is emerging as an unexpected bipartisan rallying point as lawmakers begin to weigh life after Covid-19. The coverage policies are due to lapse once the health emergency ends, which could limit telehealth payments to rural providers and doctors with existing relationships with patients.

[Politico](#) (6/29/2021): **WATCHDOG RELEASES REPORT ON INDUSTRY INFLUENCE ON PATIENT GROUPS** — Patients for Affordable Drugs, one of the progressive groups pushing for legislation that would empower Medicare to negotiate pharmaceutical prices, released a new report today documenting the industry's financial ties and influence on patient advocacy groups and charitable groups like the American Cancer Society and the Patient Advocate Foundation.

[Modern Healthcare](#) (6/29/2021): **Biden wants to tweak Obamacare marketplaces to expand coverage** - A CMS proposed rule would expand the annual open enrollment period and allow low-income people to enroll in subsidized coverage every month.

[Politico](#) (6/29/2021): **DRUG PRICING GROUP REPORT ON INDUSTRY TIES TO PATIENT ADVOCACY GROUPS** — Patients for Affordable Drugs Now, a progressive group pushing for significant drug-pricing reforms, released a report today documenting the pharmaceutical industry's influence on patient advocacy groups and charitable groups like the American Cancer Society and the Patient Advocate Foundation.

[Politico Pro](#) (6/29/2021): **Biden pitches new plans for boosting ACA enrollment** - The Biden administration is looking to extend Obamacare's annual enrollment season and allow some of the poorest marketplace customers to buy coverage essentially whenever they want, under a new proposal aimed at bolstering the health care law.

[Axios](#) (6/28/2021): **Alzheimer's drug presents Democrats' new policy dilemma** - With a \$56,000-a-year price tag, Biogen's newly approved Alzheimer's drug Aduhelm is dovetailing into the debate on Capitol Hill over how to lower prescription drug prices.

[Politico](#) (6/28/2021): **BIDEN RUSHES TO REHAB INFRASTRUCTURE BILL** — The bipartisan group of Senate negotiators "did not want to go along with any of my Family Plan issues, the human infrastructure that I talk about," Biden said Thursday, in comments that set off a weekend firestorm. The president had to dial up members of Congress himself to patch things up, two people with knowledge of the calls told our Natasha Korecki and Christopher Cadelago, and on Saturday he issued a formal reversal of what Republicans had taken as a veto threat. That seems to have been good enough for GOP senators, who have since signaled their support, Burgess Everett reports.

[Politico Pro](#) (6/26/2021): **Georgia senators back federalized Medicaid expansion in infrastructure legislation** - Georgia's Democratic senators are urging lawmakers to use upcoming infrastructure legislation to provide health coverage to low-income adults in the states refusing Medicaid expansion, according to a letter provided to POLITICO.

[Axios](#) (6/25/2021): **Drug Price Negotiations' Staying Power**- What makes drug price negotiation a powerful idea — with bipartisan support from more than 80% of the public — is not the budgetary savings policymakers covet. It's the potential to lower costs for patients and businesses paying for health benefits, Kaiser Family Foundation's Drew Altman writes.

[Modern Healthcare](#) (6/25/2021): **Democrats Propose \$400 Billion Medicaid Boost for Home Care**- States would have to opt in to the program to receive a 10 percentage point increase in the federal Medicaid match that must go to expanding home- and community-based services.

[Modern Health Care](#) (6/23/2021): **ASCO: Cancer Patients Should Be Included In Vaccine Trials**- Cancer patients have largely been excluded from COVID-19 vaccine trials, and the American Society of Clinical Oncology is asking drug manufacturers to change that in an effort to deduce whether the safety and effectiveness extends to these often-immunocompromised patients.

[Politico](#) (6/23/2021): **Everyone wants drug pricing reforms to happen already — even the drug industry**- PhRMA Chief Operating Officer Lori Reilly acknowledged that the drug industry needs

to make concessions to lower drug costs for patients, but she defended Aduhelm's \$56,000 annual price tag.

[The Hill](#) (6/23/2021): **Biogen Opens the Door to Adjusting Price of Alzheimer's Drug Amid Outcry**- The company said in a statement that if more people end up taking the drug than it expects, it could adjust the price, which is currently set at \$56,000 per year, *The Hill's Peter Sullivan Reports*.

[Modern Health Care](#) (6/22/2021): **HHS Scraps Policy to Compel 340B Discounts for Contract Pharmacies**- HHS' battle with drug makers over 340B drug discounts for contract pharmacies may continue since the agency could still try to force the companies into compliance.

[Modern Health Care](#) (6/22/2021): **Supreme Court Rejects Review of Insurers' ACA Funding Lawsuit**- The U.S Supreme Court on Monday rejected the latest appeal by private insurance companies seeking reimbursement for losses over claims covered under the Affordable Care Act.

[The Hill](#) (6/22/2021): **Senate Finance Chair Releases Principles for Lowering Prescription Drug Prices**- Sen. Ron Wyden (D-OR) has been working behind the scenes to craft a bill to lower drug prices that can get all 50 Senate Democrats on board so that a measure can pass the chamber, as Republican support is not expected, *The Hill's Peter Sullivan Reports*.

[Politico](#) (6/22/2021): **NEW BILL AIMS TO MAKE PANDEMIC TELEHEALTH BENEFITS PERMANENT**- Reps. [Liz Cheney](#) (R-Wyo.) and [Debbie Dingell](#) (D-Mich.) are introducing [legislation](#) to make it easier for older adults to access telehealth services. The bill would codify new telehealth flexibilities for Medicare beneficiaries granted during the pandemic.

[Modern Health Care](#) (6/21/2021): **Congressional Democrats Hope to Expand Coverage in Medicare, Medicaid This Year**- Congressional Democrats have big plans to extend health coverage to more Americans by closing the Medicaid coverage gap and potentially adding dental, hearing and vision benefits to Medicare.

[Axios](#) (6/21/2021): **Health Care Spending is Picking Up**- Annualized health care spending hit almost \$4 trillion this past April, up 32.4% from April 2020, according to an analysis of federal data from the Altarum think tank.

[Axios](#) (6/21/2021): **Pricey Drugs Lack Cost Effectiveness Data**- Nearly \$50 billion, or a third of Medicare Part D costs in 2016, were for drugs that did not have cost-effectiveness analyses, according to a report from [JAMA Network Open](#).

[Politico](#) (6/21/2021): **WITH OBAMACARE SAFE, A NEW BATTLE BEGINS**- The Supreme Court's decision Thursday dealt the final blow to GOP dreams of repealing the Affordable Care Act; now, Democrats must [reckon with the future of their health care vision](#), *Politico's Susannah Luthi* writes.

[Politico](#) (6/21/2021): **MANCHIN SAYS WOODCOCK 'NOT RIGHT' FOR FDA**- Citing both the opioid epidemic — especially acute in his state — and FDA's recent approval of a controversial

Alzheimer's drug, Biogen's Aduhelm, the moderate West Virginia Democrat urged the White House to look elsewhere.

Axios (6/18/2021): **The Surprise Billing Fight Isn't Over**- Washington's latest health care brawl is over wonky questions about how last year's law banning surprise medical bills will now actually be implemented by the Biden administration. Billions of dollars are at stake — either for providers or for patients and employers, Axios' Caitlin Owens reports.

Axios (6/18/2021): **Dems' high-risk, high-reward health care push**- Democrats are considering including major health care reforms in a massive legislative package that could be passed without Republican votes, teeing up a grueling fight with the health care industry — and, potentially, each other, Axios' Caitlin Owens reports. A draft document of potential measures that could be in the package included allowing Medicare to negotiate prescription drug prices, a Senate Democratic aide confirmed to Axios.

Axios (6/17/2021): **Vermont, Massachusetts and Maryland are lifting their pandemic emergency orders, with more expected to follow suit**- In Massachusetts and Maryland, health industry leaders have raised concerns about telehealth coverage losses and are pushing for their legislatures to address the issue.

Modern Healthcare (6/17/2021): **U.S. drug spending to spike at least 8% by mid-2020s with new Alzheimer's drug**—The research group Altarum estimates spending on the drug Aduhelm will comprise more than 1% of all national health spending by the mid-2020s, despite limited proof of efficacy.

Politico (6/17/2021): **LABOR LAUNCHES NEW PUSH FOR DRUG PRICE BILL** — A coalition of more than 100 labor unions, religious groups and health policy advocates Wednesday warned congressional committee chairs and Democratic leaders not to leave Medicare drug price negotiation, Medicare-at-50, and an expansion of benefits out of its larger jobs and families plans.

Politico (6/17/2021): **DRUG MAKERS SCORE POINTS IN LATEST 340B ROUND** — AstraZeneca notched a small but potentially significant victory Wednesday in the pharmaceutical industry's tussle with hospitals over the 340B drug discount program. A federal judge in Delaware refused to dismiss the company's lawsuit against a Trump-era health agency advisory opinion, which said that manufacturers needed to pony up the program's generous drug discounts to contract pharmacies, Politico's Susannah Luthi reports.

Politico (6/17/2021): **MEDICAID GROUPS URGE CONGRESS TO AMEND REBATE MINIMUMS** — In what can only be described as uncanny timing (ahem, Aduhelm), the Medicaid and CHIP Payment and Access Commission recommended this week that lawmakers raise the minimum rebate percentage on drugs the FDA green-lights under the accelerated approval pathway. The increased percentage should apply until the drug receives traditional approval post-confirmatory trial, the group said.

[Axios](#) (6/16/2021): **Medicare drug spending soars**— The amount Medicare spent on drugs that are dispensed at pharmacies increased 26% from 2013 through 2018, members of the Medicare Advisory Payment Commission wrote in their [new annual report](#).

[Axios](#) (6/16/2021): **Anthem joins insurer-backed generics effort**— A new initiative aiming to create cheaper generic drugs for retail pharmacies signed on Anthem Blue Cross Blue Shield — one the largest insurers in the U.S. — as well as drug manufacturer Catalent as partners, officials announced this morning.

[Modern Healthcare](#) (6/16/2021): **HHS wants to kill Trump rule on community health center insulin, Epi-Pen discounts**— HHS wants to scrap a rule from the Trump administration that would require community health centers pass 340B discounts on insulin and Epi-Pens directly to low-income patients.

[Politico](#) (6/15/2021): **THE ADUHELM SAGA CONTINUES**— FDA's approval of Aduhelm, a drug from Biogen that targets the brain plaques characteristic of Alzheimer's disease, has increased pressure on insurers to cover the pricey drug plus related, and expensive, tests.

[Axios](#) (6/15/2021): **Hospitals skirt price transparency**— Most hospitals aren't fully complying with a new federal rule requiring them to make their prices available, per a new study in *JAMA Internal Medicine*, [Axios'](#) Caitlin Owens reports.

[Axios](#) (6/15/2021): **Mississippi became the first state** to jointly sue drug makers and PBMs over the cost of insulin, [STAT](#) reported.

[Modern Healthcare](#) (6/15/21): **Centene to pay \$143 million in Medicaid drug overcharging settlements**— Centene will reserve \$1.1 billion for future settlements related to its Envolve pharmacy benefit manager. The agreements comes as more states investigate the insurer's PBM operations.

[Politico](#) (6/14/21): **WHY CAPITOL HILL IS SILENT ON A PRICEY NEW ALZHEIMER'S DRUG** — The FDA's approval of aducanumab would seem like the [perfect candidate](#) for inflaming Washington's long-running debate over sky-high prescription drug prices. But lawmakers are wary of dashing desperate patients' hope for treatment — even one that may provide little or no benefit.

[Axios](#) (6/14/21): **America's biggest hospitals vs. their patients**— More than a quarter of the 100 U.S. hospitals with the highest revenue sued patients over unpaid medical bills between 2018 and mid-2020, according to [new research](#) by Johns Hopkins University provided exclusively to Axios.

[Politico](#) (6/11/2021): **BIDEN'S FDA DILEMMA DEEPENS** — Capitol Hill opposition to acting FDA Commissioner Janet Woodcock's candidacy for the permanent job is hardening in the wake of the agency's approval of a new Alzheimer's drug known as aducanumab, your hosts report with Lauren Gardner.

[Politico Pro](#) (6/10/2021): **AMID TENSIONS, FINANCE DEMOCRATS BEGIN REVAMPING 2019 DRUG PRICING BILL** — Senate Finance Chair Ron Wyden (D-Ore.) confirmed in a hearing this morning that he's begun updating the 2019 bill he co-authored with Sen. Chuck Grassley (R-Iowa)

that would have cut subsidies from drug companies that raised prices more than the cost of inflation, POLITICO's Alice Miranda Ollstein reports.

[Modern Healthcare](#) (6/10/2021): **Healthcare costs projected to increase 6.5% in 2022** - Deferred or forgone care, growing mental health issues, preparations for the next pandemic and investments in digital tools are expected to increase costs in 2022.

[Politico](#) (6/10/2021): **PATIENT, CONSUMER GROUPS PUSH BIDEN ON SURPRISE BILL REGULATIONS** — More than 20 organizations are urging the administration to adhere to a core set of principles when drafting regulations to prevent patients from receiving costly “surprise” medical bills, POLITICO’s Rachel Roubein reports.

[Modern Healthcare](#) (6/9/2021): **Biden administration pushes domestic pharmaceutical production** - The White House recommended federal agencies invest more in drug manufacturing technology, boost transparency policies and work with international allies to stabilize the healthcare supply chain.

[The Hill](#) (6/9/2021): **Senate crafts Pelosi alternative on drug prices** - Senate Democrats are crafting their own proposal to lower prescription drug prices, an alternative to Speaker Nancy Pelosi’s (D-Calif.) plan, amid doubts about whether the far-reaching House bill can get all 50 Senate Democrats on board.

[Wall Street Journal](#) (6/9/2021): **Amazon Has Signed Multiple Companies to Its Telehealth Service** - Amazon . com Inc. has signed multiple companies to its Amazon Care telehealth service and will need thousands of employees to scale the service, company executive Babak Parviz said Wednesday.

[Politico](#) (6/9/2021): **SENATE WADES THROUGH DRUG PRICING QUAGMIRE** — Finance Committee Chair Ron Wyden (D-Ore.) spent the Memorial Day recess lobbying his colleagues to back a bill to empower Medicare to negotiate prescription drug prices — but consensus remains elusive, POLITICO’s Alice Miranda Ollstein reports.

[Politico](#) (6/8/2021): **BECERRA TO TESTIFY ON BIDEN’S BUDGET** — President Joe Biden is proposing a more than 23 percent boost in HHS funding, including extra cash for the Centers for Disease Control and Prevention, as well as for the National Institutes of Health, where the president envisions a new institute aimed at cancer, Alzheimer’s disease and diabetes.

[Modern Healthcare](#) (6/7/2021): **CMS could pull Georgia's waiver to privatize its ACA marketplace** - CMS Administrator Chiquita Brooks-LaSure wants to know more about how Georgia's plan to privatize its Obamacare exchange could affect equity and access to coverage.

[Modern Healthcare](#) (6/7/2021): **Biden turns to Obama to help boost health care enrollment** - The White House effort to spotlight the expanded enrollment and claim strong numbers for the health law comes as the political world and the health care system await a Supreme Court ruling on the law's constitutionality.

[Politico](#) (6/4/2021): **WARREN WANTS GILEAD CEO TO TESTIFY ON DRUG PRICES** — Warren is inviting the drug company's chief executive, Daniel O'Day, to a June 16 hearing on competition in the pharmaceutical industry, POLITICO's Alice Miranda Ollstein reports.

[Modern Healthcare](#) (6/4/2021): **Healthcare employment saw modest uptick in May** - New federal data show a slight increase in healthcare jobs in May. The industry's employment recovery has been slow since its pandemic-driven nosedive about a year ago.

[Politico](#) (6/4/2021): **CMS STARTS REVIEWING GEORGIA'S OBAMACARE WAIVER** — In one of her earliest actions since being confirmed, CMS chief Chiquita Brooks-LaSure sent a letter Thursday to Republican Gov. Brian Kemp seeking more analysis of Georgia's plan to leave HealthCare.gov, POLITICO's Rachel Roubein reports.

[The Hill](#) (6/3/2021): **Biden health official 'taking a look' at Trump drug pricing proposal** - A key Biden administration health official said Thursday that she is "taking a look" at one of former President Trump's proposals to lower drug prices, but did not commit to pursuing the plan.

[The Hill](#) (6/3/2021): **Poll: Majority of Republicans support Medicare negotiations for prescription drug prices** - A majority of polled Republicans backed giving Medicare the authority to negotiate lower prescription drug prices, according to a survey released Thursday.

[Stat News](#) (6/3/2021): **Senate finance chair investigates AbbVie over its corporate tax strategy** - AbbVie, which is already being probed by congressional Democrats for its pricing practices, is now being investigated by Senate Finance Committee chair Ron Wyden, who accused the drug maker of shifting profits offshore and registering patents in low-tax jurisdictions to consistently avoid paying U.S. corporate income taxes.

[Modern Healthcare](#) (6/3/2021): **Expanding insurance coverage is top priority for new CMS administrator** - The new head of the federal agency that oversees health benefits for nearly 150 million Americans and \$1 trillion in federal spending said in one of her first interviews that her top priorities will be broadening insurance coverage and ensuring health equity.

[Politico](#) (6/2/2021): **ADVOCATES RELEASE POLLING IN SUPPORT OF DRUG PRICING REFORM** — Democratic-aligned health advocacy groups Protect Our Care and West Health are out with new polling today from Arizona, West Virginia, New Jersey and Delaware showing strong public support for passing a bill to empower Medicare to negotiate drug prices.

[Fierce Pharma](#) (6/1/2021): **Biden's 2022 budget re-ups prospect of Medicare drug pricing negotiations** - Attempts to rein in prescription drug prices over the past few years haven't amounted to much, but pricing is still on the agenda for President Joe Biden.



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