Garden City Hotel, which today continues to serve thousands of visitors attending thoroughbred races at Belmont race track.

On a more personal note, Garden City is also a community that welcomed my family with open arms. It was in Garden City where my father, the eldest son of an Irish immigrant, ran a successful construction company, where my parents raised me and my nine brothers and sisters, and where I first learned about the importance of public service and civic engagement.

Garden City is a wonderful community filled with wonderful people. I am proud to join my friends, family, and neighbors in celebrating its 150th anniversary.

LOWER DRUG COSTS NOW ACT OF 2019

The SPEAKER pro tempore (Ms. DELBENE). Pursuant to House Resolution 758 and rule XVIII, the Chair declares the House in the Committee of the Whole House on the state of the Union for the further consideration of the bill, H.R. 3.

Will the gentlewoman from Texas (Mrs. FLETCHER) kindly take the chair.

□ 0915

IN THE COMMITTEE OF THE WHOLE

Accordingly, the House resolved itself into the Committee of the Whole House on the state of the Union for the further consideration of the bill (H.R. 3) to establish a fair price negotiation program, protect the Medicare program from excessive price increases, and establish an out-of-pocket maximum for Medicare part D enrollees, and for other purposes, with Mrs. FLETCHER (Acting Chair) in the chair.

The Clerk read the title of the bill.

The Acting CHAIR. When the Committee of the Whole rose on Wednesday, December 11, 2019, 60 minutes remained in general debate.

The gentleman from Maryland (Mr. HOYER) and the gentleman from Oregon (Mr. WALDEN) each have 30 minutes remaining.

The Chair recognizes the gentleman from Maryland.

Mr. HOYER. Madam Chair, I yield myself 1 minute.

Madam Chair, with this legislation, Democrats are fulfilling our pledge to the American people in passing legislation that will bring down prescription drug costs for the people. That is one of the three central pillars of our For the People Agenda.

With H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, we are delivering for the people. This legislation, named in memory of my dear friend and our colleague, Elijah Cummings, who fought so hard to lower the cost of prescription drugs, will give Medicare the power to negotiate directly with drug companies, which will help bring drug prices down, as we do now, Madam Chair, for our veterans.

It will make those lower drug prices available to Americans with private insurance as well—not just Medicare, but with private insurance—and it will create a new out-of-pocket limit of $2,000, a cap on out-of-pocket expenses for prescription drugs for those on Medicare part D.

According to the nonpartisan Congressional Budget Office, H.R. 3 will save American taxpayers approximately half a trillion dollars over the next 10 years.

Now, H.R. 3 reinvests those savings, Madam Chair, in key initiatives, including expanding Medicare benefits to cover dental, vision, and hearing services; investing in new research, treatment, and cures; and combating the opioid crisis—all three objectives that the American public overwhelmingly support.

President Trump, Madam Chair, promised in 2016, before his election, that he would work to negotiate lower drug prices, something this bill would give his administration the authority to do. For that reason, he ought to support it.

He said in 2016: ''When it comes time to negotiate the cost of drugs, we are going to negotiate like crazy.'' He said that in a campaign setting. Hopefully, he still believes that today.

I hope he will join in encouraging the Senate to take up H.R. 3, because in 2018, he said this: ''One common cancer drug is nearly seven times as expensive for Medicare as it is for other countries. . . . This happens because the government pays whatever price the drug companies set without any negotiation whatsoever.'' So said President Trump on October 25, 2018.

He went on to say just 2 months ago, in October: ''. . . we want to bring our prices down to what other countries are paying, or at least close. . . .''

Madam Chair, that is what this legislation does.

President Trump went on to say: ''. . . and let the other countries pay more. Because they're setting such low prices that we're actually subsidizing other countries, and that's just not going to happen anymore.''

Those were remarks before the Cabinet meeting on October 16, 2019, just a few weeks ago.

That is what this legislation does. That is why the Senate ought to pass this legislation and the President ought to sign it. I hope he will join us in encouraging the Senate to take up H.R. 3 without delay and pass it. And I urge the President to reverse his opposition to this bill and sign it, his opposition being totally inconsistent with those three quotes that I just articulated.

Too many Americans, Madam Chair, are struggling to pay for their prescription drugs. I have heard awful stories from constituents in my district, as I know every one of us has, about families rationing insulin and having to forego rent or food or other necessities in order to pay for their prescription drugs. That is not an option. Without them, their health will deteriorate, and, yes, they may die.

One senior from Clinton, Maryland, in my district, wrote to tell me that one of her prescription drugs more than doubled in price, and she left the pharmacy empty-handed because she couldn't afford it.

With H.R. 3, we can bring relief to people like her.

With H.R. 3, we can lower the cost of prescription drugs so that Americans can live healthy lives and pursue their American Dream.

Madam Chair, I want to thank Chairman PALLONE, Chairman NEAL, Chairman SCOTT, and their committees for working hard on this bill to help Americans lower their prescription drug costs and live longer and healthier lives.

Madam Chair, this should not be a partisan issue. The President articulated the desire to achieve the objective of bringing prices down. That is what this bill does. That is what CBO says it does. So I urge my colleagues to support this.

Now, Madam Chair, I know you could do this, but I want to do it because I am so proud not only of HALEY STEVENS herself, who is an extraordinary Member of the Congress of the United States, a wonderful member of the previous administration, and somebody who has worked in the private sector and the public sector and who has been elected president of your class, Madam Chair, the freshman class, an extraordinary group of 63 people, 64 if we count our friend CONOR LAMB who was elected in a special election just before you—and he, of course, lords it over you that he is a senior member of the freshman class; I understand that.

But HALEY STEVENS leads an extraordinary group of 64 people who have contributed so much to our society already in their lives, in their productive, constructive lives, and now have come to the Congress. And they came with a promise to do three things, at least:

Number one, to help with wages and jobs and opportunities;

Number two, to bring prescription costs down; and

Number three, to invest in infrastructure.

In this bill, we meet one-third of those promises, and they have made it possible.

Madam Chair, I yield the balance of my time to the gentlewoman from Michigan (Ms. STEVENS), the president of the freshman class, so she may manage the remainder of the time.

Ms. STEVENS. Madam Chair, I reserve the balance of my time.

Mr. WALDEN. Madam Chair, I yield myself such time as I may consume.

I appreciate the distinguished majority leader's comments about President Trump.

I have been around Congress for 21 years, and I have never seen a President of either party lean more forward in trying to get down the cost of prescription drugs, to give taxpayers more of their hard-earned income, to get an

economy up and running like we have never seen it before, to tackle the issue of unemployment and get unemployment numbers down to the lowest level in 50 years in every category all across the country, and to reduce the burdens of overregulation. President Trump has done all those things.

He also has called for getting down the price of prescription drugs. I have been in several meetings where he has done that, and I share his passion for that, and I know he wants a bipartisan bill that can become law and be put on his desk.

Everything you heard from the distinguished majority leader about President Trump's views are accurate, but he actually read H.R. 3. And if you read the Statement of Administration Policy, he recognizes that this goes too far and he would have to veto it, that it is a partisan-only bill—partisan only.

And here is part of the problem with H.R. 3: It hands the government a club. There is no negotiation in here. If you don't agree to what the government says the price should be, the government in Washington comes after your revenues, and up to 95 percent of your revenues for selling that drug they can just come and take.

By the way, when you throw in the cost of taxation and everything else, it is well over 100 percent that a drug manufacturer who is innovating some new drug and has the patent for that great American innovation, the government says: If you don't sell it for what we want within a band, we are taking it. We are not taking your patent—well, they might come back and do that in another iteration, but: What we are doing is taking all the revenues. We will bankrupt you.

That is why 138 different small innovative startup innovators in this space wrote to the Speaker and the Republican leader. And I want to quote from their letter, Madam Chair. It says: ''We represent the community of emerging biotechnology companies whose researchers and scientists strive daily to develop innovative life-changing therapies and cures for patients. We take pride that we are providing hope to patients and their families and changing the world through medical breakthroughs. These dreams will be shattered if H.R. 3, the Lower Drug Costs Now Act, is passed.''

They went on to say: ''Unfortunately, H.R. 3 is an unprecedented and aggressive government intervention in the U.S. market of drug development and delivery that will limit patient access to these extraordinary advancements in healthcare.''

Look, we all agree drug costs are too high, and we want to work together to stop the gaming and bring down the prices.

Our alternative, which we will debate in a few minutes, does that, but it doesn't do it at the expense of completely upending the ecosystem that allows American innovators to do what no one else in the world does as well, and that is come up with new cures for diseases and make them available.

Madam Chair, I enter into the RECORD the letter from 138 startup innovators in its full context.

DECEMBER 5, 2019.

Hon. NANCY PELOSI,
Speaker of the House,
Washington, DC.
Hon. KEVIN MCCARTHY,
House Republican Leader,
Washington, DC.

DEAR SPEAKER PELOSI AND REPUBLICAN LEADER MCCARTHY: We represent the community of emerging biotechnology companies whose researchers and scientists strive daily to develop innovative life-changing therapies and cures for patients. We take pride that we are providing hope to patients and their families and changing the world through medical breakthroughs. These dreams will be shattered if H.R. 3, the Lower Drug Costs Now Act, is passed.

We are at an incredible inflection point in science and technology that is bringing forth transformative treatments and even cures for cancer, infectious diseases, and a myriad of other serious and rare diseases. These advancements are benefiting lives of millions of patients and alleviating human suffering, while helping to reduce other more expensive parts of our health care system, such as hospital spending. Our continued success depends on maintaining an environment that supports investment in tomorrow's discoveries.

Unfortunately, H.R. 3 is an unprecedented and aggressive government intervention in the U.S. market of drug development and delivery that will limit patient access to these extraordinary advancements in health care. This extreme proposal will upend the ecosystem of U.S. biomedical innovation, destroying our ability to attract private investment dollars that allow us to develop new treatments and change the course of healthcare delivery for so many patients.

We strongly urge you to abandon H.R. 3. Further, in order to keep pace with this biomedical revolution and ensure America remains the world leader in innovation, we hope that you will pursue bipartisan, holistic policies that modernize our health care payment system and lower drug costs for patients.

Sincerely,

Adelene Perkins, Chair & CEO, Infinity Pharmaceuticals, Inc.; Adrian Gottschalk, President & CEO, Foghorn Therapeutics; Alden Pritchard, CEO, Kaio Therapy, Inc.; Alex Nichols, PhD, President & CEO, Mythic Therapeutics; Amit Munshi, President & CEO, Arena Pharmaceuticals, Inc.; Andre Turenne, President & CEO, Voyager Therapeutics, Inc.; Aprile Pilon, PhD, President & CEO, Trove Therapeutics, Inc.; Armando Anido, Chairman & CEO, Zynerba Pharmaceuticals; Axel Bolte, Co-Founder, President & CEO, Inozyme Pharma; Barry Quart, President & CEO, Heron Therapeutics.

Bassil Dahiyat, President & CEO, Xencor, Inc.; Bill Enright, CEO, Vaccitech, Ltd.; Bill Newell, CEO, Sutro Biopharma; Blake Wise, CEO, Achaogen, Inc.; Bonnie Anderson, Chairman & CEO, Veracyte, Inc.; Bradford Zakes, President & CEO, Cerevast Therapeutics; Brandi Simpson, CEO, Navigen, Inc.; Brian Windsor, CEO, Lung Therapeutics, Inc.; Briggs W. Morrison, MD, CEO, Syndax Pharmaceuticals; Bruce Clark, PhD, President & CEO, Medicago, Inc.

Casey Lynch, CEO, Cortexyme; Cedric Francois, Co-Founder, CEO & President; Apellis Pharmaceuticals; Chris Gibson, Co-Founder & CEO, Recursion; Christopher Barden, CEO, Treventis Corporation; Christopher Burns, PhD, President & CEO, VenatoRx Pharmaceuticals, Inc.; Christopher Schaber, President & CEO, Soligenix, Inc.; Ciara Kennedy, PhD, CEO, Amplyx Pharmaceuticals; Clay Seigall, President, CEO & Chairman, Seattle Genetics, Inc.; Craig Chambliss, President & CEO, Neurelis; David Baker, President & CEO, Vallon Pharmaceuticals.

David Bears, Founder & CEO, Tolero Pharmaceuticals; David de Graaf, PhD, President & CEO, Comet Therapeutics, Inc.; David Donabedian, PhD, Co-Founder & CEO, Axial Biotherapeutics; David Lucchino, President & CEO, Frequency Therapeutics, Inc.; David Mazzo, President & CEO, Caladrius Biosciences; David Meeker, CEO, KSQ Therapeutics; Doug Kahn, Chairman & CEO, TetraGenetics, Inc.; Douglas Doerfler, President & CEO, MaxCyte, Inc.; Dr. Elizabeth Poscillico, President & CEO, EluSys Therapeutics, Inc.; Eric Dube, PhD, CEO, Retrophin, Inc.

Eric Schuur, President & CEO, HepaTx Corporation; Erika Smith, CEO, ReNetX Bio; Franciso LePort, Founder & CEO, Gordian Biotechnology; Gail Maderis, President & CEO, Antiva Biosciences; Gary Phillips, President & CEO, Orphomed, Inc.; Geno Germano, President & CEO, Elucida Oncology, Inc.; George Scangos, CEO, VIR Biotechnology; Gil Van Bokkelen, Founder, Chairman & CEO, Athersys, Inc.; Greg Verdine, President & CEO, LifeMine Therapeutics, Inc., FOG Pharmaceuticals, Inc.; Imran Alibhai, CEO, Tvardi Therapeutics.

James Breitmeyer, President & CEO, Octernal Therapeutics, Inc.; James Flanigon, CEO, Honeycomb Biotechnologies; James Sapirstein, President & CEO, AzurRx BioPharma; Jay Evans, President & CEO, Inimmune Corporation; Jeb Keiper, CEO, Nimbus Therapeutics; Jeff Cleland, PhD, Executive Chair, Orpheris, Inc.; Jeff Jonker, President & CEO, Ambys Medicines; Jeff Kindler, CEO, Centrexion Therapeutics; Jeremy Levin, Chairman & CEO, Ovid Therapeutics, Inc.; Joe Payne, President & CEO, Arcturus Therapeutics, Inc..

John Crowley, Chairman & CEO, Amicus Therapeutics, Inc.; John Jacobs, President & CEO, Harmony Biosciences; John Maraganore, CEO, Alnylam Pharmaceuticals; Julia Owens, President & CEO, Millendo Therapeutics, Inc.; Justin Gover, CEO & Executive Director, Greenwich Biosciences; Keith Dionne, CEO, Casma Therapeutics; Keith Murphy, Founder, CEO & President, Viscient Biosciences; Ken Mills, CEO, REGENXBIO, Inc.; Ken Moch, President & CEO, Cognition Therapeutics; Kent Savage, CEO, PhotoPharmics, Inc.

Kevin Gorman, CEO, Neurocrine Biosciences; Kiran Reddy, MD, CEO, Praxis Medicines; Lawrence Brown, CEO, Galactica Pharmaceuticals; Lorenzo Pellegrini, Founder, Palladio Biosciences; Marc De Garidel, Chairman & CEO, Corvidia Therapeutics; Marilyn Bruno, PhD, CEO, Aequor, Inc.; Mark Leuchtenberger, Executive Chairman, Aleta Biotherapeutics; Mark Pruzanski, MD, President & CEO, Intercept Pharmaceuticals, Inc.; Mark Timney, CEO, The Medicines Company; Markus Renschler, MD, President & CEO, Cyteir Therapeutics.

Martin Babier, CEO, Principia Biopharma; Melissa Bradford-Klug, CEO, Mayfield Pharmaceuticals; Michael Clayman, MD, CEO, Flexion Therapeutics; Michael J. Karlin, Co-CEO, Ibex Biosciences, LLC; Michael Raab, CEO, Ardelyx, Inc.; Mike Narachi, President & CEO, Coda Biotherapeutics; Ming Wang, PhD, President & CEO, Phanestra Therapeutics, Inc.; Morgan Brown, Executive VP & CFO, Lipocine; Nancy Simonian, CEO, Syros Pharmaceuticals; Olin Beck, CEO, Bastion Biologics.

Pam Randhawa, President & CEO, Empiriko Corporation; Pat McEnany, President & CEO, Catalyst Pharmaceuticals, Inc.; Paul Bolno, MD, CEO, Wave Life Sciences; Paul Boucher, President & CEO, Parion Sciences, Inc.; Paul Hastings, CEO, Nkarta Therapeutics; Paul Laikind, President & CEO, Viacyte; Peter Savas, CEO & Chairman, LikeMinds, Inc.; Rachel King, Founder & CEO, GlycoMimetics, Inc.; Randy Milby, Founder & CEO, Hillstream BioPharma, Inc.; Rashida Karmali, PhD, President & CEO, Tactical Therapeutics, Inc.

Richard Markus, CEO, Dantari Pharmaceuticals; Richard Pascoe, Chairman & CEO, Histogen, Inc.; Richard Samulski, President, Asklepios BioPharmaceutical, Inc.; Rick Russell, President, Minverva Neurosciences; Rick Winningham, Chairman & CEO, Theravance Biopharma; Rob Etherington, President & CEO, Clene Nanomedicine; Robert Goodwin, PhD, CEO, Vibliome Therapeutics, Inc.; Robert Gould, PhD, President & CEO, Fulcrom Therapeutics; Robert M. Bernard, President & CEO, Ichor Medical Systems; Robert Wills, Chairman, CymaBay Therapeutics, Inc.

Roger Tung, President & CEO, CoNCERT Pharmaceuticals; Ron Cohen, Founder, President & CEO, Acorda Therapeutics, Inc.; Russ Teichert, PhD, CEO, Scintillant Bioscience; Russell Herndon, President & CEO, Hydra Biosciences, LLC; Samantha S. Truex, CEO, Quench Bio; Sandy Macrae, President & CEO, Sangamo Therapeutics, Inc.; Scott Koenig, President & CEO, MacroGenics, Inc.; Sean McCarthy, President, CEO & Chairman, CytomX; Sharon Mates, Founder, Chairman & CEO, Intra-Cellular Therapies; Shawn K. Singh, CEO, VistaGen Therapeutics, Inc.

Stan Abel, President & CEO, SiteOne Therapeutics, Inc.; Stanley Erck, President & CEO, Novavak; Stephen Farr, PhD, President & CEO, Zogenix, Inc.; Stephen R. Davis, CEO, ACADIA Pharmaceuticals; Stephen Yoder, CEO & President, Pieries Pharmaceuticals; Sue Washer, President & CEO, AGTC; Sujal Shah, President & CEO, CymaBay Therapeutics, Inc.; Ted Love, CEO, Global Blood Therapeutics; Terry Tormey, CEO, Kibow Biotech.

Thomas Wiggans, Founder, President & CEO, Dermira, Inc.; Tia Lyles-Williams, Founder & CEO, LucasPye BIO; Tim Bertram, CEO, inRegen & TC Bio; Timothy Walbert, President & CEO, Horizon Therapeutics; Todd Brady, CEO, Aldeyra Therapeutics; Vipin Garg, PhD, CEO, Altimmune; Wendye Robbins, MD, President & CEO, Blade Therapeutics; Will DeLoache, CEO, Novome Biotechnologies; Zandy Forbes, CEO, MeiraGTx.

Mr. WALDEN. Madam Chair, I know the Democrats yesterday said: We don't care. It is worth it. We don't need all those cures.

That is, in effect, what they said.

And then they said: Oh, those are just somebody's talking points.

No. This is the Congressional Budget Office's independent analysis that said we will lose 38 cures right out of the gate in the next two decades because of H.R. 3, and that for every year thereafter in the 2030s, we will lose 10 percent of what we otherwise would have.

Is that the cure for Alzheimer's? rheumatoid arthritis? ALS? Parkinson's?

That is what Democrats are saying they don't care about, that it is worth it to let those go in order to force the government price in this market.

We don't think that has to be the case. I don't think it is an either/or choice. They are making it that with H.R. 3.

I think we can have innovation without the heavy-handed club mugging innovation by taking the revenues of companies when they don't agree with what the government sets as the price.

And we know in foreign countries that they want to model America after, upwards of 40 percent of cancer drugs are not available in those countries, and they are available here in the United States.

You can go across every one of the six indicator countries, look at how they control drug costs, and, yes, they do have lower drug costs—and that is why we have a trade negotiator, so we can get lower drug costs in these trade agreements and stop getting ripped off—but what they do to really control is they control access.

There was a lot talked about in terms of death panels when ObamaCare was considered. This bill actually represents that.

We are told that by the people who innovate in this space that they will not be able to continue to innovate as they have in the past and that drugs that save lives will not be available because they won't be invented.

That is not just my words. That is the Congressional Budget Office; that is the Council of Economic Advisers.

There isn't a think tank out there yet that I have seen, no independent analysis that says H.R. 3 is going to do anything but that.

Innovation goes up on the rocks with H.R. 3. Lives will be lost; cures will never be found; and Americans won't be better off.

It doesn't have to be that way. We have bipartisan legislation in our substitute that will bring down prices, bring down drug costs, bring about transparency, put a cap on what seniors spend on Medicare, address the insulin cost issue, and it can become law.

Madam Chair, I reserve the balance of my time.

□ 0930

Ms. STEVENS. Madam Chair, I yield myself as much time as I may consume.

Madam Chair, I want to thank our majority leader for designating his time in managing the floor on the heels of the passage of today's historic vote.

Today is a beacon of hope for so many families who have been burdened by the outrageous costs of prescription drugs in this country.

Lower Drug Costs Now Act lowers drug costs now for the families who are counting on us, the families who are burdened with exorbitant costs of prescription drugs that they cannot afford. Lower prescription drugs for the parents of a child with a rare disability who are wondering how they can afford to pay that bill. Lower prescription drugs for the retired American who worked all of their life and now cannot afford to pay for that medication. Lower prescription drugs now for the senior who is afraid to go to the pharmacy to pick up that prescription drug because of what it might cost. Lower prescription drugs for a third of Americans who do not get their prescription drugs because they cannot afford them. That is what we are here today to do.

Some have chosen to listen to the drug companies. Some have chosen to take their cues. Take it from somebody who worked in an innovation research lab about the plight of research and development in this country and the investments that go into funding basic innovation research and how that gets done through public-private partnership. But do not put the American people at the expense of that plight because we know that our basic research dollars rest within the National Institutes of Health, that they rest within the work that we are doing in the Science, Space, and Technology Committee.

This legislation today, my friends, this legislation appropriately named after our beloved colleague, Elijah E. Cummings, someone who was never afraid to stand up for what was right and who led by true and pure example, we were so blessed to have stood in his light. And while serving as the Chair of the Oversight Committee, he showed us the way by uncovering many of these corrupt practices that have caused drug prices to be out of reach for so many.

I am also especially pleased to highlight provisions in this bill that were long championed by one of my great friends and mentors, former Congressman Sander Levin. These provisions for the first time will allow our Nation's older adults to receive coverage for dental, vision, and hearing under Medicare. I hope Mr. LEVIN is proudly watching as the House in which he served for 36 years, this very body, delivers on this effort.

I can speak for members of the freshman class, who have stood on the shoulders of the Members who have come before us to say that we were sent to Washington with a mandate to bring down the cost of prescription drugs and to deliver for the American people.

H.R. 3 is a long overdue change to the way we do business around here. This will untie the hands of the Federal Government to negotiate prices for the oldest and most expensive drugs in Medicare part D and apply those prices to all Americans.

In my district, in Michigan's 11th District, southeastern Michigan, H.R. 3, the Lower Prescription Drugs Now Act stands to benefit over 100,000 people enrolled in Medicare part D alone, as well as over 600,000 people who are enrolled in private health insurance.

We all know someone who has had their life impacted by cancer, whether it be a parent, a cousin, a relative, a dear friend. For the 9,000 women diagnosed with breast cancer in Michigan this year, H.R. 3 will lower their medication by 65 percent from $69,000 to $23,000 per year. For the 4,500 Michiganians diagnosed with prostate cancer this year, H.R. 3, the Lower Prescription Drugs Now Act will lower the cost of their medication from over $100,000 to $37,000 per year. And the list goes on.

Many of these patients live as close as a 10-minute drive from Canada in Michigan where Canadians are paying cents on the dollar for the exact same drugs. We ask why should that be in a country as wealthy, as prosperous, as innovative, as creative, and successful as ours? Drugs like insulin. H.R. 3 will finally level the global playing field for Americans.

The tremendous savings generated from H.R. 3, the Lower Prescription Drugs Now Act, will go right back into the research to develop new drugs with some of the savings also bringing us one step closer to stemming the devastating tide of the opioid epidemic.

I ask my friends to join me in commandeering this opioid epidemic that is ravaging far too many communities across this beautiful country. Far too many communities. Where recent graduates from high school say we go to our high school reunions in graveyards, in cemeteries because of this opioid epidemic.

I am proud that this historic piece of legislation also includes a bill that I had the privilege of authoring to lower prescription drug costs for lower-income, older adults, who are enrolled in the lowest cost part D plan that covers their medication needs.

The time is now, and I urge my colleagues, I implore them, to follow the will of their constituents and pass H.R. 3, the Lower Drug Costs Now Act of 2019.

Madam Chair, I reserve the balance of my time.

Mr. WALDEN. Madam Chair, I yield myself such time as I may consume.

It is important to know that in our substitute we cut the costs of cancer treatment for seniors in half, as well. There is bipartisan agreement on this. In fact, everything in our substitute is bipartisan.

It is also important to note that in Canada it takes 14 months longer to get access to miracle new medicines compared to what we have in America. They have 52 percent of the medicines there that we have here. They have 60 percent of the cancer medicines. That means 40 percent of the cancer medicines, the latest cutting-edge ones, the ones we read about and see on ''60 Minutes'' that are curing cancer here in America, you can't get in Canada. I don't want to import that here.

And when it comes to reducing access to drugs, basic research is essential. Nobody has done more to deal with that than the gentleman from Michigan, former chairman of the committee, FRED UPTON, who led the effort with Cures to get more research in the National Institutes of Health.

Madam Chair, I yield 3 minutes to the gentleman from Michigan (Mr. UPTON).

Mr. UPTON. Madam Chair, I thank the gentleman for yielding.

I thank the Democratic leadership for, I think the first time this year, allowing our side to actually have a substitute to a major piece of legislation. And I thank our leadership, because that substitute is not a partisan substitute but, rather, a bipartisan substitute. In fact, every single provision in this bill has got strong bipartisan support, which was packaged together.

Tomorrow will mark the third anniversary of President Obama's signing of 21st Century Cures, a bill that DIANA DEGETTE and I helped shepherd through our committee on a unanimous vote, and we passed here in the House 392–26.

21st Century Cures increased NIH funding by some $45 billion over a 10-year span. It sped up the approval of drugs and devices, and just after 3 years we have seen the number of cell, gene, and nucleoid therapies have more than doubled. In fact, research this last year will actually exceed $13 billion. The FDA is predicted to approve as many as 20 gene therapy drugs by the year 2025. That is wonderful news.

We all want to do something about drug prices, and that is what a vote for our substitute, H.R. 19, will do. The President will sign that bill, but he is not going to sign this bill, H.R. 3, because it is going to slow down the ability to find the cures that we want to find for these awful diseases.

Now, those aren't my words. That is the CBO, a nonpartisan group, it is the CEA, the Council of Economic Advisers.

But in today's ''Wall Street Journal,'' the former director of the FDA, Scott Gottlieb, writes, ''This week the House will vote on legislation known as H.R. 3. The price-control approach would increase uncertainty and reduce returns from biotech investment, raising the cost of capital for these invaluable endeavors.'' He is right on. We want to find new cures. We want to find new technologies and to use those. We want precision medicine.

Madam Chair, I include the ''Price Controls Would Stifle Biotech Innovation'' in the RECORD.

PRICE CONTROLS WOULD STIFLE BIOTECH INNOVATION

A House price-control bill would do the most damage to transformative and life-saving medications.

(By Scott Gottlieb, Dec. 11, 2019)

Victoria Gray of Mississippi recently became the first U.S. patient with a genetic disorder to be treated using the Crispr gene-editing technique. Doctors used a novel drug to overwrite the function of a faulty gene that gave rise to her sickle-cell disease. Advances in life science can define this century, but policy makers must resist the urge to adopt policies that impose price controls and punish drugmakers for taking risks.

The convergence of information technology and biology allows scientists to translate the human genome into digital data that can accelerate diagnoses and cures. Over the next decade, it is a near certainty that we will have gene-therapy cures for deadly inherited disorders such as muscular dystrophy. Cell-based and regenerative medicine can restore human functions lost to disease, including returning some sight to the blind. Gene editing will be used to alter DNA to erase the origins of a range of debilitating inherited disorders.

These are only some of the opportunities at hand. Yet bad policies could sap the risk-taking that brings forth the most important innovations. For instance, the Lower Drug Costs Now Act would expose the 250 costliest drugs to government price controls. The high-cost drugs lawmakers target are often the most innovative and potentially transformative new medications. This week the House will vote on the legislation, known as H.R. 3.

The price-control approach would increase uncertainty and reduce returns from biotech investment, raising the cost of capital for these invaluable endeavors. It would alter incentives and shift money from the most speculative but highest-value science, including regenerative medicine and gene editing. Money would flow instead to known disease areas and well-characterized targets, using proven approaches such as pill-form drugs.

New and high-risk drug platforms like gene therapies are often targeted first to treat rare and serious conditions; after they are proven to work safely, they will be used to treat morecommon maladies, such as heart disease. This is how medicine advances. But if investors knew their returns would be capped, they would direct their investments toward safer projects with lesser payoffs. We would still get new drugs, but the treatments would be very different.

Fifteen years ago, the standard refrain from drug-industry critics was that all the big drugmakers did was develop ''me too'' medicines—the seventh version of a blood-pressure pill or a cholesterol-lowering statin. In response, the federal government took steps, some of which shaped Medicare Part D, to encourage investment in ''specialty'' drugs that were more novel.

Since then, investment capital has shifted sharply. Cancer and rare diseases receive substantially more attention and resources. The number of cell, gene and nucleotide therapies in development has more than doubled over the past three years, while total investment in cell and gene therapies eclipsed $13 billion last year.

The Food and Drug Administration approved four gene therapies in only the past three years, with 800 similar kinds of products in various stages of development. An assessment of the current pipeline and historical rates of success in clinical trials suggests that by 2025 the FDA will be approving 10 to 20 gene-therapy drugs a year. Progress

is especially strong in oncology. The number of cancer drugs in development has quadrupled since 1996.

These specialty drugs often aren't cheap. They target narrow conditions for which the cost of risk-taking and drug development is amortized over a smaller number of eligible patients. Highly novel drug platforms can also cost more initially to perfect. Based on my informal survey of companies, enrolling a single patient in a clinical trial for a gene-altering drug often costs between $500,000 and $700,000 and can reach as high as $1 million.

To support this innovation, total spending on research and development by the 15 biggest drugmakers topped $100 billion in 2018, up 32 percent in the past five years. A cancer cure, or a gene-therapy remedy, can sharply reduce the lifetime cost of treating a debilitating disease. It can dramatically alter the length and productivity of people's lives. But high-cost treatments are pricing out a growing number of underinsured patients, keeping them from using medications that could alter their providence. This is unacceptable.

There are ways to make specialty drugs more affordable without eroding the incentives that drive capital into the riskiest but most promising endeavors. One is to help second-to-market drugs get through the regulatory process.

Once an effective drug is approved to treat a deadly condition, introducing a second drug to treat the same disease can be hard. It's tough to recruit patients with a debilitating disease for a clinical trial when a proven medicine is already available. Moreover, the smaller pool of patients who will be newly diagnosed each year with the same disease isn't always large enough to support the cost of developing a second drug, reducing competition that can lower pnces.

We offer first-to-market breakthrough drugs an efficient route through FDA review. We could give second-to-market competing medicines the same regulatory benefits. Further, when the biology of a drug target is very well understood, and the basis for how it interacts with a disease firmly established, we can create a new regulatory designation to streamline development of a competing drug and shift data collection to real-world, post-approval settings.

Many drugs targeted by H.R. 3 for government price controls are examples of the innovation we should try to encourage. In fact, they are the investments that critics who griped about me-too medicines said they wanted. Now the same crowd is crafting policies that would shift investment back into the more mundane endeavors they once lamented.

Mr. UPTON. Madam Chair, I have served on the Health Subcommittee for all my days on the Energy and Commerce Committee, and we have seen firsthand the different families impacted by these awful diseases, whether it be Alzheimer's or sickle cell, cystic fibrosis.

Just this last week, we witnessed real advancements, we think, in pancreatic cancer stage III, stage IV. SMA, spinal muscular atrophy, a disease that is often fatal by the year 9 or 10; we saw a woman who had been on a new drug for 15 days, and for the first time she could actually move her neck after more than 10 years literally trapped in a wheelchair.

If we want to find the advancements and cures for these diseases, we need to pass H.R. 19.

I urge my colleagues to vote for that substitute and get a bill to the President that he will actually sign, and we can get something done.

Ms. STEVENS. Madam Chair, I yield 1½ minutes to the gentlewoman from Washington (Ms. DELBENE).

Ms. DELBENE. Madam Chair, I thank the gentlewoman for yielding.

I rise today in support of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act.

The rising costs of prescription drugs is one of the top issues I hear about from my constituents, and it has been getting worse.

This year alone, I have received nearly four times as many calls and letters about prescription drug prices than all of last year. And there are many, many stories, but I would like to share one today to remind us why this legislation is so necessary.

A constituent of mine, Dana from Kenmore, Washington, has lived with type 1 diabetes for nearly 14 years. When Dana was first diagnosed, insulin cost her $50 each month. Today that same insulin costs over $600 per month. That is an 1,100 percent increase for the exact same product.

We talked about innovation, but there have been virtually no changes to insulin since Dana's diagnosis, so the price spike is inexplicable.

Dana is not only a diabetes patient, but she is also a nurse practitioner and a diabetes educator. And she has told me about her patients that go to Canada where they can get insulin for just $40 a month. She has also shared stories of her own patients who can't afford their medications, who ration their insulin, which we know can lead to poorer health, vision loss, kidney failure, and even death.

H.R. 3 will finally give the Health and Human Services secretary the power to negotiate a fair price for insulin, which will dramatically help patients like Dana and all the patients that she serves.

Madam Chair, I urge my colleagues to support this legislation.

Mr. WALDEN. Madam Speaker, I yield 1½ minute to the gentleman from Georgia (Mr. CARTER), Congress' only pharmacist.

Mr. CARTER of Georgia. Madam Chair, I thank the gentleman for yielding.

We have a situation here where we all want the same thing. We all want to bring down prescription drug prices. We want the same thing. We need the same thing. We can achieve the same thing. We can achieve the same thing without taking the risk of drugs not coming to the market.

Physicians take an oath when they graduate from medical school, it is called the Hippocratic Oath. It says, ''first, do no harm.'' Now, whether you believe the Congressional Budget Office that it will be eight to 15 drugs, or whether you believe the Council of Economic Advisers that it will be over 100 drugs, even if it is one drug, that is one drug too many.

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It is simply a chance we cannot afford to take. Every one of us in this body knows a story, knows someone who has suffered from that awful disease Alzheimer's. It is an awful disease.

Barbara Lutz tells the story about her husband, Richard, who suffered from that disease. She tells the story about how she and her family suffered through that with him. Oftentimes, it is the caregivers who suffer so much.

Finally, Richard has succumbed to that disease after a 7-year fight. Now, people who are diagnosed or who have family and loved ones who are diagnosed with Alzheimer's come up to Barbara and ask her: ''What do I do? What do I do?'' Barbara simply told me: ''All I can tell them is to pray for a cure.''

This is not a Republican-Democratic issue. This is our issue. This is America's issue. We have to solve it together, and we can do that.

Ms. STEVENS. Madam Chair, I think we are all here to make sure that every Alzheimer's patient and every family affected by Alzheimer's has access to the lowest, most affordable prescription drugs possible, which is why we are so pleased to be ushering in today's piece of legislation.

Madam Chair, I yield 3 minutes to the gentleman from Nevada (Mr. HORSFORD).

Mr. HORSFORD. Madam Chair, I thank my colleague from Michigan for her leadership and for guiding this debate on the floor today.

Madam Chair, I rise to speak in support of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, named after a man who I have great respect for, who was a mentor of mine, and who fought so hard to hold Big Pharma accountable.

Today is a big day for the American people because we are finally putting their health over the interests of Big Pharma's profits. I am speaking in support of this legislation for the hundreds, if not thousands, of constituents who have shared their stories with me throughout this year. This issue is the single most important issue in my district. I am speaking in support of people like my constituent Mario.

About a year ago, Mario was diagnosed with diabetes and recently sought care for a lesion on his foot that wouldn't heal. Because he couldn't afford the proper medications, Mario ended up losing his toe and had to leave his job. His daughter had to drop out of college to work full time to help pay for Mario's medications.

This is an issue that not only impacts the lives of the patients who are in desperate need of lifesaving medications to stay healthy, but it is also impacting those who love and care for them. It is altering the future of their families.

As Chairman Cummings would say: ''We are better than this.'' We are better than this as a nation, to put the interests of Big Pharma and their profits

over the interests of the American people and their health.

For far too long, American families have been forced to pay 4, 5, or even 10 times more for their prescriptions than patients in other countries.

Do my colleagues on the other side think that that is right, that your constituents are subsidizing the healthcare for people across the world when you have people in your own neighborhood who are rationing their medications, making false choices to pay their rent, buy food, or take the necessary medication as prescribed by their doctors? Well, I don't. I don't think that that is a choice the American people should have to make.

Today, we are taking the necessary action to move this legislation forward, and I hope that my colleagues on the other side will work with us and that the President will work with us.

What my constituents tell me is not that they are Democrats, not that they are Republicans, not that they are Democrats, not that they are independents. They tell me that they have diabetes, that they have cancer, that they have heart disease, that they have asthma, that they have HIV and AIDS, that they are dying, and that they need the healthcare that they demand.

Madam Chair, I ask us to pass H.R. 3.

Mr. WALDEN. Madam Chair, may I inquire as to how much time each side has remaining.

The Acting CHAIR. The gentleman from Oregon has 18 minutes remaining. The gentlewoman from Michigan has 17½ minutes remaining.

Mr. WALDEN. Madam Chair, I yield 1½ minutes to the gentleman from North Carolina (Mr. HOLDING).

Mr. HOLDING. Madam Chair, H.R. 3 is a shortsighted proposal and a bad deal for our constituents.

It will compromise the strong legacy of innovation that our Nation is proud of. It will be a grave mistake to fundamentally change the market structure that makes America a viable market for cutting-edge innovation in biopharmaceuticals.

Government price setting will kill innovation in clinical areas where it is most needed. The pricing scheme outlined in H.R. 3 would disincentivize research and development for drugs that are first in their class, such as the future cure for Alzheimer's or ASL.

Government price controls will not only kill innovation but will also fundamentally change the doctor-patient relationship in this country. This bill would allow bureaucrats to make the most personal of choices about the course of treatment for our constituents. Treatment decisions in this country should be made between a patient and their physician and should not be based on the rationing of treatments by bureaucrats in foreign nations.

In North Carolina, H.R. 3's pricing scheme would shatter the biopharmaceutical ecosystem that supports 40,000 jobs directly, 200,000 jobs indirectly, and generates $13 billion in economic output annually. That is just in North Carolina.

H.R. 3 would put small and midsized biotech firms out of business and threaten hundreds of thousands of our constituents' jobs. We should reject H.R. 3 and, instead, advance meaningful legislation that lowers patients' out-of-pocket costs, that protects innovation, and that would actually be signed into law.

Ms. STEVENS. Madam Chair, I yield 3 minutes to the gentleman from Colorado (Mr. CROW).

Mr. CROW. Madam Chair, I rise today to speak in favor of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, and I am eager to vote for this landmark piece of legislation today.

I am proud that we are here boldly taking a stand against the influence of special interests in Congress and a stand for the American people, to help them afford critical lifesaving medications.

Back home in Colorado's Sixth Congressional District, when I am hosting townhalls or roundtables with families, college students, or seniors, I hear the same thing: Prescription drugs are too expensive, and Congress needs to act now.

Currently, as we stand here, one in three Coloradans can't afford to pay for their basic medications and are having to either ration their medication or stop taking it altogether. This needs to stop now.

Thousands of Coloradans are diagnosed with cancer every year, and the treatments for these patients cost $100,000 or more. Instead of working to increase access and lower costs, the pharmaceutical companies are price gouging these patients, our constituents, across the country. This needs to stop now.

I am proud to have worked with my freshman colleague, Representative PORTER, to introduce H.R. 4663, the Freedom from Price Gouging Act, which has been included as a provision in H.R. 3. Our provision would hold these bad actors accountable and prevent them from raising the cost of prescription drugs past the rate of inflation. The CBO recently found that this measure would save American taxpayers $38 billion over the next decade.

Importantly, H.R. 3 gives the Federal Government authority to negotiate prices for insulin and other lifesaving drugs. As I stand here today, 300,000 Coloradans with diabetes will save up to 75 percent on their insulin under H.R. 3. It also caps the exorbitant amount that seniors have to pay for drugs that simply improve the quality of their life.

As I stand here today, hundreds of thousands of Coloradans with heart disease, asthma, arthritis, and cancer will directly benefit from H.R. 3.

On top of the drug pricing provisions, this bill invests billions in savings back into our healthcare system. $10 billion would go to our Nation's community health centers, which serve over 29 million Americans from underserved communities.

It also invests $10 billion into the NIH and $2 billion into the FDA to promote research and drug safety. It invests another $10 billion to respond to our Nation's opioid epidemic, which has destroyed far too many American families.

We cannot wait any longer while our neighbors' and family members' lives are at risk and while pharmaceutical companies continue to fill their pockets, making tens of billions of dollars, historic profits.

Americans rightly expect us to deliver on our promise to fight and reduce the cost of prescription drugs. That is why I will cast my vote as a ''yes'' today to deliver relief for my constituents and the American people.

Ms. STEVENS. Madam Chair, I yield myself 30 seconds.

As a subtle point of clarification, today, as we embark on a historic moment, we are looking to pass the Elijah E. Cummings Lower Drug Costs Now legislation, not the invest in R&D act. Embracing the status quo for the millions of Americans who are counting on us is certainly fully and wholly unacceptable.

Madam Chair, I reserve the balance of my time.

Mr. WALDEN. Madam Chair, I yield myself 1½ minutes.

Madam Chair, I want to make clear that I am always willing to come to the other side of the aisle to work these things out.

All of us came here with similar cause and calling, to lower the price of prescription drugs, to stop the abuse and bad behavior of pharmaceutical companies when they keep generics from coming to market. But I don't think anybody came here to take away cures for patients who come to our offices every year begging for a cure for Alzheimer's, pancreatic cancer, or ASL, you name the disease.

My mother died of ovarian cancer. My father had bladder cancer. My sister-in-law died of brain cancer. We lost a son to a heart defect. We all want cures.

We know by independent analysis that H.R. 3 denies access to cures. That is a fact. It is a fact that the Council of Economic Advisers says up to 100 cures will be lost. The Congressional Budget Office says in the next two decades, 38 cures would be lost. It doesn't have to be that way.

We can lower drug costs. We can incent innovation. My friend from Michigan talked about being involved in the innovation world. This is a letter from 138 leaders of these incredible American innovators who beg us not to shatter the dreams of Americans, which they say H.R. 3 will do by completely upending the process.

That is why President Trump said he cannot sign this. No President has ever leaned further than President Trump.

The Acting CHAIR. The time of the gentleman has expired.

Mr. WALDEN. Madam Chair, I yield myself 15 additional seconds.

We have an alternative. Everything in our substitute bill is bipartisan. Even if you feel like you have to vote for H.R. 3, there is no reason you should have to vote against the proposals in here. There is not a poison pill. They are all bipartisan. They will all bring meaningful relief to our folks at home, and nothing in here will reduce innovation.

Ms. STEVENS. Madam Chair, I yield 2 minutes to the gentlewoman from Arizona (Mrs. KIRKPATRICK).

Mrs. KIRKPATRICK. Madam Chair, I thank the Congresswoman for yielding.

I want to echo what I hear from my constituents: Do I put gas in my car, or do I buy my medication? Do I put food on the table for my family, or do I pay for my prescription drugs? Do I buy a generic drug here in the United States that costs $900, or do I drive to Mexico where I can buy it for $9?

These are real, lifesaving, life-or-death issues that we are dealing with.

I want you to know this is personal to me because, when I was a 19-year-old waitress, I came home one night to my family, and my parents weren't home. They said, ''Your mom took your dad to the hospital,'' and I drove to the hospital.

I said: ''Okay, I will go check on him.''

As I was walking in the door, the doctor walked out, and he said: ''Your dad is dead.''

That was due to a lack of healthcare, including prescription drugs.

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He had an undiagnosed heart disease that could have been treated, and in this day and age it would not have been an issue. So I fully support H.R. 3. This is something that is critical to American families and they are dealing with every day.

A mother shouldn't have to decide if she is going to drive to Mexico, where she is not exactly sure if the drug she is purchasing for her child has the same standards and quality that she would get here in the United States.

So, Madam Chair, I urge my colleagues to support H.R. 3. This is life or death.

Mr. BRADY. Madam Chair, I yield 2 minutes to the gentleman from Ohio (Mr. WENSTRUP), who is a key leader on healthcare on the Ways and Means Committee.

Mr. WENSTRUP. Madam Chair, 26 years ago, my sister had two forms of leukemia that most people die from immediately; but because of earlier clinical trials and innovative treatments, there was a way to get some leukemia patients into remission.

Then we developed bone marrow transplants, and I matched her for that.

Five years later, they called her a cure.

Today, my sister is alive, working, raising a family, and we have treatments for leukemia that lead to a cure without even needing bone marrow transplants.

These treatments are just steps in finding cures; and, as we work to lower prescription drug prices, I want to make sure that we are looking at it from all angles. We need to be aware of the impacts on the quality of and access to care when considering effective solutions to lower drug prices.

H.R. 3 threatens and, actually, puts a knife in the heart of the pillars of research and development that have helped make America the leader in health innovation.

Relying on foreign countries to set our prices is misguided. I don't want to see the U.S. be controlled or manipulated by an arrangement some other cabal of countries makes to affect our markets and our patients. Other countries do not always share the same priorities we do on access to quality care and saving lives.

What do we sacrifice with this bill? The best care? Cutting-edge research? A lifesaving drug?

Unfortunately, the approach before us today is a dangerous one. Government price controls and a looming threat of a 95 percent tax will dramatically hurt our country's ability to research and innovate new cures. Estimates show that the bill would lead to the loss of dozens of new drugs. That means fewer lifesaving drugs and fewer American lives saved.

As a physician, I can attest that every doctor's goal is to get the best treatment for their patients. We can do more without going and having this stop development and innovation.

The Republican alternative to this bill, H.R. 19, is bipartisan, and it is an effort to lower prescription drug prices while also protecting patients' access to new medicines and cures.

Americans deserve to have a healthcare system that delivers treatments when they need it most and makes care more affordable.

Ms. STEVENS. Madam Chair, I yield 1 minute to the gentleman from California (Mr. ROUDA).

Mr. ROUDA. Madam Chair, I thank the gentlewoman from Michigan for yielding 1 minute.

Madam Chair, I rise today in support of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act.

Earlier this year, Chairman Cummings convened our first Oversight and Reform Committee hearing to examine the impact of soaring prescription drug costs on our constituents. It is fitting we named this legislation to honor our friend who used his gavel to highlight the stories of Americans who are suffering and dying because they couldn't afford astronomical drug prices while living in the greatest and richest country in the world.

This bill would institute negotiation for fair drug prices, lower out-of-pocket costs for seniors, improve coverage for Medicare beneficiaries, and invest in innovative new treatment in our fight against the addiction crisis.

Madam Chair, I support this legislation because it would improve access to affordable prescription drugs for more than 600,000 of my constituents, and I urge my colleagues to support this legislation and ensure our constituents have access to lifesaving medication.

Mr. BRADY. Madam Chair, I yield myself 2 minutes.

So we have heard today that we should pass H.R. 3 because you can go to Canada and get medicines for pennies on the dollar. Here is what they don't tell you:

There are lots of medicines you can get for zero in Canada because they are not available. Canadians have access to about half of the lifesaving cures available here in America.

Guess where they come when they need that cure and that recent medical breakthrough? They come to America.

What happens when we start acting and behaving like Canada? Who is going to be our safety net?

Why should patients in America have to choose between affordable medicines and a lifesaving cure for Alzheimer's, ALS, Parkinson's, or cancer?

Why should parents with sick children in America be forced to wait longer for the newest drug breakthrough that could save their life?

Why should Americans face a shorter life?

Because the costliest and most painful drug to me is the one that was never created.

At the depths of NANCY PELOSI's drug bill is a dangerous trade-off: lower drug prices in the short term, but fewer lifesaving cures in the future.

This is a cruel and false choice, which is why this bill will quickly die with no bipartisan support in the Senate.

As Republicans, we believe we need to do both: lower drug prices and accelerate new lifesaving cures.

Mr. Chairman, I reserve the balance of my time.

Ms. STEVENS. Mr. Chairman, I yield myself 30 seconds.

Mr. Chairman, it is a fact that pharmaceutical drug companies spend more on marketing than they do on R&D.

It is a fact that life expectancy in this country is going down, and it has gone down for the third year in a row.

It is a fact that we are in a moment of crisis, and now is the time for us to pass the Lower Drug Costs Now Act.

Mr. Chairman, I yield 2 minutes to the gentlewoman from Nevada (Mrs. LEE), who is my good friend.

Mrs. LEE of Nevada. Mr. Chairman, I thank the gentlewoman for yielding.

Mr. Chairman, I am here to speak in support of the Elijah E. Cummings Lower Drug Costs Now Act, and, in particular, I want to speak in support of my bill which is included in the act, the Enhancing Retirement Security for Medicare Beneficiaries Act, which would guarantee that the disbursements of retirement savings are not counted when determining if someone qualifies for Medicare part D's low-income subsidy program.

As a young girl, I learned the importance of saving money. My first job was running a paper route in my neighborhood in Canton, Ohio, at the age of 8. At the end of every week, I would put aside a quarter or two just to save up for a candy bar. It wasn't much, but it taught me the importance that saving money is worth it.

Americans and our seniors should not be punished for saving for their retirement, but when retirement savings are counted towards eligibility for prescription drug assistance, we are punishing the very seniors who have been working hard and saving money.

The fact is that no group of Nevadans relies more on prescription drugs than our seniors, and the rising cost of living is hard enough on older Americans. We should be making it easier for them to retire in dignity, and that means not forcing them to choose between buying groceries or lifesaving medication.

Mr. Chairman, I am pleased that my bill was included in the underlying text of H.R. 3, and it is time that we lower prescription drug costs not just for seniors on Medicare, but for all Americans.

Mr. BRADY. Mr. Chairman, I yield myself 30 seconds.

It is a fact that drug companies in America spend three times as much on R&D than on marketing and advertising.

It is a fact that the dangerous Pelosi drug bill robs up to $1 trillion of research and development costs that will not be used for lifesaving cures in America.

It is a fact, from the Congressional Budget Office, that we will lose at least 38 new cures as a result of this bill; the Council of Economic Advisers, 100 new cures; and the California Life Sciences Association says 9 out of 10 cures that they would be working on will never happen in America.

Mr. Chairman, I yield 2 minutes to the gentleman from Texas (Mr. ARRINGTON), who is a key leader on the Ways and Means Committee.

Mr. ARRINGTON. Mr. Chairman, I thank my friend and ranking Republican on Ways and Means for the opportunity, and I thank him for his leadership on this important issue.

Mr. Chairman, we all agree that the prices of drugs are too high. We agree that something needs to be done to fix this for all Americans, not just our seniors.

The problem I have—and it is a big problem—is the way we go about doing this. It is like a rerun of ObamaCare. It is this government knows best, this top-down, government-controlled, let's tax, regulate, and mandate our way to a better system. It doesn't work.

So we are doubling down on a failed philosophy on how to deliver affordable quality products to the American people.

The approach should be more choices, more competition, a healthier market, and greater transparency.

By the way, we have worked on those issues in a bipartisan fashion. I have introduced two pieces of legislation with my Democrat friends that would do just that.

The problem here is not just this top-down, heavy-handed government knows best, let's fix the crisis and assume nothing bad will happen. It is that nothing is going to come of this H.R. 3. It is a messaging bill. It is purely political, and it won't help the people whom we all intend to help.

I do not judge the motives of my colleagues. I think they want to help our seniors just as I do. But we can't do it with partisan messaging bills. We have to do it by working together.

In a former life, I was vice chancellor at Texas Tech, and I was responsible for bringing new drug technologies, therapies, and biologics to market.

Ms. STEVENS. Mr. Chairman, I yield 3 minutes to the gentlewoman from Michigan (Ms. SLOTKIN), who is my dear friend.

Ms. SLOTKIN. Mr. Chair, for the last 2 years, the single most common issue that Michiganders raise with me is the price of prescription drugs. Michiganders, regardless of party, are demanding that Congress do something about it. People literally clutch my arm at the grocery store to tell me how their son is rationing his insulin or their daughter couldn't go to summer camp because she couldn't afford the inhalers.

That is why shortly after being sworn in in January, I started working in earnest on the issue. I am very proud to stand behind my colleagues and support H.R. 3, the Lower Drug Costs Now Act. This important legislation will drive down the cost of the country's most expensive drugs by allowing our government to negotiate for the very best prices.

To be clear, the VA does the exact same thing. I am on military insurance, and the VA can negotiate for drug prices. Why not allow Medicare to do the very same thing?

To put this in perspective, there are over 800,000 Michiganders living with diabetes, and common insulin medications can cost somewhere between $1,200 and $20,000 a year. This includes Sarah, a woman who lives in Holly, Michigan, where I live, who literally says she is being priced out of her life. Her insulin costs are higher than her rent per month.

This bill, if passed, would allow the government to negotiate, bringing the price down to as little as $400 a year. Once the price is negotiated, all Americans, including Medicare recipients, benefit from that price. The bill would also improve Medicare coverage for seniors and lower their out-of-pocket costs.

Two months ago, I cointroduced a bill that included vision coverage in Medicare. That means Medicare recipients, once every 2 years, will get an eye exam and one set of either glasses or contacts.

I am very pleased that this was incorporated into this bigger bill along with other measures that would include hearing coverage and dental coverage for the first time. So, finally, preventive care will be part of the routine coverage for Medicare.

To be clear, the bill pays for itself. Negotiation saves us, according to the CBO, $450 billion, which covers the additions to Medicare and still gives $10 billion for research and development to the National Institutes of Health.

Mr. Chairman, you will hear my colleagues and Big Pharma say that you have to make a choice between research and lifesaving cures and the price of prescription drugs. That is a false choice, and anyone who watches TV and sees those annoying ads knows that the drug companies have plenty of places to cut their funding.

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Members from both parties in the House and Senate, and indeed the President, have said the right things when it comes to lowering drug prices. Now it is time to walk the walk.

Mr. BRADY. Mr. Chairman, I yield such time as he may consume to the gentleman from California (Mr. MCCARTHY), the Republican leader of the House.

Mr. MCCARTHY. Mr. Chairman, I thank the gentleman for yielding, but more importantly, I thank him for his work on this bill, and all the others, as well, in their committees.

There is an urgent need to address the soaring cost of prescription drugs that burden too many American families. It is well past time that we offer a practical solution that actually lowers costs while ensuring new cures can reach Americans fighting disease and illness.

This Congress in the past has spent a great deal of time making sure that we have cures for the future. That is why Republicans introduced this bill, Lower Costs, More Cures Act, and I urge all my colleagues to support it.

The bill was written with a rule: each policy must be bipartisan. I know in this town and in this climate, that is not achieved very often, but for an issue as crucial as lowering the cost of prescription drugs for Americans, partisanship should be set aside.

Later today, we will see which side and which bill is bipartisan. By drawing on the very best ideas, H.R. 19 makes crucial reforms that will lower out-of-pocket costs for Americans at drugstore counters. For seniors, it makes medication more affordable by capping their out-of-pocket costs. It increases the availability of generics and biosimilar drugs by prohibiting drug companies from delaying the start of their exclusivity period. It speeds up the FDA approval process. It provides greater price transparency by requiring insurance companies to make information about drug costs available in the doctor's office before a prescription is written. And for diabetics who have

high deductibles in their plans, it allows insurance companies to cover the cost of insulin before meeting the plan's deductibility.

While Republicans offer practical solutions, Democrats are catering to their progressive base by opening a door to a government takeover of our prescription drug market.

Mr. Chairman, Speaker PELOSI's partisan plan, H.R. 3, will make our broken system worse by placing more barriers between Americans and their medication, including by reducing the number of new drugs on the market instead of helping them reach the patients. According to estimates from the Council of Economic Advisers, the Speaker's radical proposal could kill upwards of 100 new drugs over the next decade.

Pause for one moment and think about that: 100 new drugs over the next decade will be killed by passing H.R. 3. That is one-third of the total number of new drugs expected to enter the market during that time.

Moreover, the Council estimates that H.R. 3 would reduce America's average life expectancy by 4 months. Nearly a quarter of the projected gains in life expectancies over the next decade, simply because you want to appease the progressive base and have a partisan bill that denies us more cures and shortens our lifespan.

But you will achieve one goal today: You will have one party vote for a bill that will not become law, but you will appease a base with this and impeachment.

And it is not just the Council. The CBO reports that fewer drugs will be available because of the provisions in H.R. 3. The Democrat's plan is yet another example of how unnecessary government control harms the very people it claims to help.

All of us have or know someone with a loved one who has fought a disease or an illness for which no cure has been found. Imagine how demoralizing it will be to cut off hope for a future cure. All of us have gone through this. My father never got to see the day I was elected because he lost his life to cancer. He battled it for 3 years. I would give anything to have found a cure for my father's cancer. But it is not just his.

If we delay one cure, that is one cure too many. The best way to lower costs is not to lose the cures, even the loss of one.

Mr. Chairman, Americans want their government to put the best available ideas into action. They deserve solutions, not political posturing filled with empty promises. The saddest part of today, we could have had prescription drug prices lowered on this floor even earlier in this year. There was a window of opportunity, a moment in time where you did not see the partisanship that we see today, a moment in the Committee on Energy and Commerce where every single Democrat and every single Republican voted on three bills to lower the price of prescription drugs.

But as I learned as a child on ''Schoolhouse Rock,'' ''I am just a bill on Capitol Hill,'' at the time it goes from a committee and before it gets to the floor, it goes through leadership. And unfortunately for the Americans across this country, leadership changed that bill, not the Members in the House. They changed that bill so when it came to the floor it became partisan.

And you know what? Our drugs were not lowered, the bill did not become law, and we are impeding the exact same thing today.

You will have two choices: You will have a choice of H.R. 3, that, yes, had to be negotiated even this week with progressives on the other side to appease them to make sure this was as partisan as can be. It won't become law. It will be another talking point, a moment of time to try to explain why you wasted a majority on just investigations.

But you will have another opportunity, a substitute. If you want to lower drug prices in 2019, vote for H.R. 19. You know why? Because every single provision in that bill is bipartisan.

Can we not, with one issue, at one moment in one time put partisanship aside? Can we put people before politics? Can we expand our life expectancy? Can we find 100 more cures? Can we do that?

I know you might upset a few in your party, but think about how many more lives we will save. There is always a moment in time that I have hope that this Congress will rise and keep the promises that I heard before an election took place, that we would be different, that we would govern together, that we would find bipartisanship.

Today, on the floor, you will have that window. You will have a bill that has every single provision. You will have a report that says, No, we won't stop 100 new cures in the next decade. No, they will give hope to the American public that there will be opportunity to cure disease that you have today and live a long and full life.

And you know what? It is the only bill on the floor today that could become law. So if you want to make a real change, you have a voting card to do it.

Ms. STEVENS. Mr. Chairman, I yield 1 minute to the gentleman from New York (Mr. ROSE), my friend.

Mr. ROSE of New York. Mr. Chair, before I came to Congress, my job was to make sure that those without healthcare and those who could barely afford it, could have access.

Every day, we would see doctors and nurses do the impossible in the worst system. And without fail, we all would wonder why no one would do anything to change it. Well, today we are. This bill does not cater to a base. This bill does not cater to Big Pharma, but this bill does cater to that family tonight who is going to have to choose between paying for prescription drugs or putting food on the table. This bill caters to the American people.

Today, Big Pharma loses, and the American people win. Because what we are doing today is giving Medicare the power to negotiate skyrocketing costs of prescription drugs. This historic legislation also creates new out-of-pocket limits on prescription drug costs for Medicare beneficiaries. It reinvests savings so that we can create new breakthrough treatments and cures at NIH, and it provides $10 billion in funding to combat the opioid epidemic.

For decades, Big Pharma and corporate PACs could count on their lobbyists and politicians to keep them safe at the expense of the American people. Not anymore. Today, the American people win. I urge all my colleagues to vote ''yes.''

Mr. BRADY. Mr. Chairman, I yield 1 minute to the gentleman from Nebraska (Mr. FORTENBERRY), one of the leaders in healthcare.

Mr. FORTENBERRY. Mr. Chair, I thank both leaders, first of all, for this debate. This is absolutely critical, and here is why:

The other day, I went to the doctor—a kind of a common ailment. The doctor prescribed an antibiotic.

I said, ''Doc, let's check the price before we use the credit card.''

He said, ''Don't worry about it. It is going to be about $6. It is commonly used.''

But guess what? The list price was about $430. It used to be $6 in 2011; now, it is $430.

We have a problem. We have a big problem in America. A very big Democrat, a very big Republican problem. I want to commend my Democratic colleagues for raising the issue, for putting this on the agenda, for making an attempt to propose something. There is strong disagreement with the nature of the policy proposal, but there ought to be unification around the idea that we have to do something.

I commend my Republican colleagues for putting together a bill of all the bipartisan initiatives that are around here that we can agree on.

So what is going to happen is we are going to get stuck again, really, really quickly. This bill now has a chance of going into law, the bipartisan bill. There is some opposition to it, and it could be fleshed out further.

The President has called for negotiations. This is an important part of all of us. So let's get back to work after we get past this moment.

Mr. Chair, I thank everyone for a spirited and good debate.

Ms. STEVENS. Mr. Chairman, I yield 1 minute to the gentlewoman from California (Ms. PELOSI), the Speaker of the House.

Ms. PELOSI. Mr. Chairman, I thank the gentlewoman from Michigan, a leader in the freshman class, for yielding time and for her extraordinary leadership in so many ways.

It is just so invigorating to see the freshmen Members of this class taking

the lead on this important legislation. Many of us just came in from the steps of the Capitol where, again, the freshmen Members took the lead.

Following up on a promise made last year during the election, For the People, we will lower the cost of healthcare in America by lowering the cost of prescription drugs. H.R. 3 does just that, named for our great and departed—may he rest in peace—Elijah E. Cummings Lower Drug Costs Now Drug Act.

This is very, very important. And it may come as news to some of our Republican friends who were saying things to the contrary, but this is a product of the work of three committees in Congress.

I thank Chairman PALLONE of the Committee on Energy and Commerce, Chairman RICHIE NEAL of the Committee on Ways and Means, and BOBBY SCOTT, chair of the Committee on Education and Labor, for their relentless and persistent work on this lifesaving legislation where many freshmen are speaking now, controlling the time.

But in the course of the debate of yesterday, under the aegis of the committees of jurisdiction, many of them spoke at that time as well, demonstrating their leadership on this issue, making it a reality on the floor of the House. Again, I thank them for their bold urgency to lower the cost of drugs.

The crushing burden of prescription drugs is an issue that impacts every family in America. Much talk is given around here about having a seat at the table. The most important seat at the most important table is the kitchen table of America's working families where they enjoy family, but also address challenges that face them, whether it is in their health or in their financial health and how that is related.

□ 1030

This legislation today speaks to that important table of concerns.

In my travels across the country, I have seen grown men cry about how they cannot meet the needs of their families when it comes to prescription drug costs, a spouse with a long-term illness, children with chronic diseases, and the rest.

Prescription drug prices are out of control. The price of insulin invented nearly a century ago—when people say we have to cover our research costs—doubled from 2012 to 2016 because of Big Pharma.

Many people use it. A lot of people buy it. Let's increase our profits, they say.

Americans are paying four times or more for what Big Pharma charges for the exact drugs in other countries.

While Big Pharma companies reap record-breaking profits and multibillion-dollar windfalls from the GOP tax scam, 58 million Americans couldn't afford to fill a prescription they needed to stay healthy in the past year—58 million Americans.

Thirty-four million Americans know a loved one who died from not being able to afford a treatment that they needed.

We face medical, economic, and moral crises that demand that we act and that we act boldly.

Yes, they have a motion to recommit. I think it was appropriate that the Republicans have the opportunity to put an alternative on the floor, incremental pieces, not going to the heart of the matter. How dare they ever think of enabling the Secretary to negotiate for lower prices, which is the heart of the matter.

We have been trying to do this for a number of years. Today, we will.

Last year, again, we made the promise For the People, that we would lower the cost of prescription drugs. We are finally giving Medicare the power to negotiate lower drug prices.

Some Republicans say it is un-American for the Secretary to be able to negotiate for lower prices—un-American—then making those lower prices available to the hundreds of millions of Americans with private insurance, too.

We are insisting that American seniors and families shouldn't have to pay more for our medicines than what Big Pharma charges for the same drug overseas. I say that again. H.R. 3 means lowering the cost of medication for Americans with leukemia by more than 70 percent. It means lowering the cost of medication for arthritis, which more than 50 million Americans have, by almost 75 percent. It means lowering the cost of asthma medication for 25 million Americans with this condition from $1,500 to $270.

Yesterday, we had Mr. Riordan testify at our press conference. The cost of his medication for asthma, in his case, was over $60,000 a month. Eighty percent of it was covered by Medicare, but he had to pay over $4,000 a month.

Can you absorb that? $4,000 a month for a drug that you are supposed to take four times a month? He was taking it twice a month, once a month, or not at all, not a healthy thing to do, but reaping big profits for Big Pharma.

Under H.R. 3, some commonly used insulins could cost as little as $400 a year.

With the Elijah E. Cummings Lower Drug Costs Now Act of 2019, we put more money back into the pockets of seniors and hardworking families. We drive down insurance premiums, making it easier to afford coverage.

When we lift the immense burden of drug costs on employers, the CBO says American businesses can expect bigger paychecks and salaries for their workers.

H.R. 3 also represents the most transformative expansion of Medicare since its inception.

Now, many people on the other side of the aisle did not support Medicare at its inception, but this is a vast improvement because we are investing more than a half-trillion dollars—that is with a T-R—a half-trillion dollars that we are saving by lowering out-of-control prices and investing in historic new benefits for vision, dental, and hearing for Medicare beneficiaries for the first time.

With these huge savings, we are also investing in new research for new treatments and cures and fighting the opioid epidemic, as the gentleman from New York (Mr. ROSE) pointed out, and in the community health centers that deliver quality healthcare to so many Americans.

Advocacy groups representing tens of millions of Americans, seniors, retirees, patients, providers, faith leaders, businesses, and the men and women of labor, and more, support H.R. 3.

AARP wrote to Members of Congress this week and said: ''This important legislation is a bold step toward lowering prescription drug prices and improving Medicare for seniors and families across the country. . . . H.R. 3 will help more Americans afford their prescription drugs and get the care they need to stay healthy.'' They said that in their support of the legislation.

There is every reason in the world for Republicans to join us in passing this bill. The bill delivers on President Trump's promise to the American people. In his words, he said: ''When it comes time to negotiate the cost of drugs, we are going to negotiate like crazy.''

Negotiation is what this bill is about. The Republican substitute is what this bill is not about, and that negotiation is the heart of the matter.

The President also said: ''It's unacceptable that Americans pay vastly more than people in other countries for the exact same drugs, often made in the exact same place. This is wrong; this is unfair; and together, we will stop it.''

Actually, in creating this bill, and working with the committees to do so, we were working with the interests of the White House, the administration, on all of this.

I don't know where it happened, but somewhere along the way, negotiation and the rest fell by the by, and that, again, could be attributed to I don't know what.

Democrats named H.R. 3, as I mentioned, in honor of Chairman Elijah Cummings, our North Star who worked across the aisle and down Pennsylvania Avenue—he met with the President—to lower prescription drug prices.

In honor of Chairman Cummings, and for the sake of the millions of Americans struggling with high prescription drug costs, I urge a strong vote on H.R. 3 to lower drug costs now for all Americans, for the people. I urge an ''aye'' vote.

Mr. BRADY. Mr. Chairman, I yield myself 30 seconds.

When the Republican Congress, in 2003, joined with President Bush to create the affordable drug plan for seniors, then-Leader NANCY PELOSI and Democrats tried to kill it. She famously predicted that creating the part D program for seniors would end ''Medicare as we know it.''

Can you imagine how many seniors' lives would have been lost if Democrats had succeeded in stopping the affordable Medicare drug program that 43 million seniors have come to depend upon? They were dangerously wrong then, and they are dangerously wrong again.

Mr. Chair, I yield 2 minutes to the gentleman from California (Mr. NUNES), the leader of the Health Subcommittee for the Ways and Means Committee.

Mr. NUNES. Mr. Chair, I thank the gentleman from Texas for yielding to me. I want to speak in opposition to H.R. 3.

Saying that drug costs are too high for many Americans, Republicans and Democrats can agree on that. That is why we spent the better part of a year working toward a bipartisan solution to lower out-of-pocket prescription drug costs and crack down on overpriced drugs.

Sadly, Democrats abandoned that effort in favor of the socialist policies in H.R. 3. For Democrats, the answer is always more government, and H.R. 3 is no exception.

The bill gives the government sweeping new powers to allow government bureaucrats to arbitrarily set drug prices. Democrats keep calling it negotiation.

Here is how negotiation works under H.R. 3. The Federal Government will tell a drug company what the drug price is going to be. If the drug company doesn't like it, they have two options: pay a 95 percent tax on their revenue or leave the U.S. market. That doesn't sound like negotiation to me.

The Congressional Budget Office claims this will result in such low drug prices that some of the lifesaving cures won't even come to market. Under this arrangement, there is very little incentive for drug companies to invest the time and money it takes to create new cures and treatments. We know it takes $2.6 billion and 10 to 15 years, on average, to bring one drug to market.

This bill's arbitrary action against drug companies carries a steep cost to the American people in the form of fewer future cures. What cures will those be? Alzheimer's? Cancer? Schizophrenia?

Killing drug innovation and ending the development of lifesaving cures is unacceptable. We can't take that risk. We have to do better for sick Americans hoping and praying for a cure for themselves or their loved ones.

We can solve this problem, but not with the Democrats' fewer cures act. We have to do this in a bipartisan way.

Fortunately, there is an alternative to the Democrats' proposal. This week, Republicans have introduced H.R. 19.

The Acting CHAIR (Mr. ROUDA). The time of the gentleman has expired.

Mr. BRADY. I yield the gentleman from California an additional 15 seconds.

Mr. NUNES. I have introduced H.R. 19, the Lower Cost, More Cures Act. This bill contains effective bipartisan policies that could become law right now.

It cracks down on overpriced drugs and lowers costs for patients without crushing the hope of future lifesaving medicines.

It is time to stop playing political games and start working toward solutions for the American people.

H.R. 3 is a terrible idea that will drive drugs out of the U.S. market.

Ms. STEVENS. Mr. Chairman, if the gentleman from Texas is prepared to close, I am prepared to close.

I reserve the balance of my time.

Mr. BRADY. Mr. Chairman, I yield myself the balance of my time.

Imagine life under H.R. 3, the Democrats' fewer cures bill. There will be lower costs for some medicines, no doubt. Both bills do that. But if you have a rare disease, or your loved one does, whether it is ALS you are struggling with or dementia or Alzheimer's, if you were a dynamic person who now is struggling with Parkinson's, cancer, diabetes, pulmonary hypertension, the hope for your cure may never come. The waiting for your cure may be years, decades, or never.

The truth of the matter is—and it is undeniable—H.R. 3, the Democrats' bill, will cause fewer cures here in America.

Don't take my word for it. The Congressional Budget Office estimates 38 cures lost over the next two decades, the Council of Economic Advisers, 100 cures lost over the next several decades.

California Life Sciences Association said, if we do what NANCY PELOSI's bill does, nearly 9 out of 10 drugs we would have created will never exist. There will be fewer cures for Americans when we need it most.

I will tell you, drug prices are too high in many cases. There is no excuse for these price spikes, none at all.

But I will tell you what, the costliest drug ever is the one that is never created, that leaves the ravages of these diseases to these loved ones who are struggling with them.

We already know this is the case because in Canada, France, these other countries that H.R. 3 wants to make us look like, they have about half the medicines we do. When they do get a medicine, they will wait a year or 2 longer to even get it.

Well, if you have got ALS, if you have got a glioblastoma, you are done at that point. That is what that bill brings about.

We know, fewer drugs in America, because today, we have created, over the last several years, 111 new drugs in America. France, this is the France drug pricing scheme, 11. 111 in America. Eleven in France.

That is their vision of a day in the life of someone with a rare, deadly disease in America.

Our bill, the Lower Cost, More Cures Act, lowers out-of-pocket costs for Americans because we crack down on overpriced drugs. We give seniors, for example, the power and the information to choose the right place for their medicines, which can lower their chemotherapy by half.

We pull back the curtain on everyone involved in this drug pricing process. We force drug companies to pay more and shoulder more burden in the part D prescription plan. We force them to justify their increases. We force them to list their prices in the ad so we know.

We accelerate; we don't kill lifesaving medical cures. We go further, further than H.R. 3. We permanently make it easier for Americans to deduct high medical expenses from their taxes, allowing them to use their HSAs for over-the-counter medicines, including feminine hygiene products. We save seniors over $300 a year in the popular Medicare prescription drug program.

□ 1045

All these ideas are bipartisan. All these can be passed by Congress. All can be signed by President Trump this year if Democrats abandon their partisan game and continue what was really good bipartisan work that got shelved for this bill that dies.

When this is done, let's come back together. Let's work together. Everyone knows, in good faith, we have to tackle these drug prices. Let's prove to America that we can actually work together not for impeachment, not for the junk we are wasting our time on, but for things that really matter to families back home.

Mr. Chair, I yield back the balance of my time.

Ms. STEVENS. Mr. Speaker, I yield myself the balance of my time.

Mr. Chairman, we have heard compelling argument today. We have heard compelling argument around the need and the reason to lower the costs of prescription drugs now. We are taking bold and reasonable steps today to bring down the costs of prescription drugs in this country. It is a significant and historic day that ushers in a beacon of hope for so many.

The answer from our Democratic majority today is solutions, solutions based on fact, solutions based on the guiding principle of the people, who we represent, to deliver for them.

The question is, when will we do something? Today, our legislation, the Elijah E. Cummings Lower Drug Costs Now Act, that is what we are going to be passing, lowering drug costs now for the people who cannot wait, for the child of parents who are pushed to the brink, for the older American who is afraid to go to the pharmacy to pick up their prescription drug because of what it might cost, for the senior who is afraid to go to the doctor just to get that prescription, for the one-third of Americans who forgo their prescription drugs because of their costs.

President Truman said that America is not built on fear. America is built on imagination. America is built on courage. And America is built on the willingness to do the job at hand.

That, my friends, is what our majority is doing here today, tackling a solution for the millions of people, the countless number of people, whose voices only make their way into this Chamber by those who represent them, not the large multinational company that has more money than it knows what to do with. It is for the individual, hardworking American, which is why, today, I ask my colleagues to join me in passing the Elijah E. Cummings Lower Drug Costs Now Act for every American, for the people, by the people.

This is a historic and proud day, Mr. Chairman, and this is what we came here for.

Mr. Chairman, I yield back the balance of my time.

Mr. DEFAZIO. Mr. Chair, today, I will vote in support of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act.

Because of pharmaceutical companies' price gouging, Americans pay more out-of-pocket for prescription drugs than individuals in any other country. Americans need lower drug prices now, and Congress has the ability to enact important reforms to deliver immediate relief.

I believe H.R. 3 takes some important first steps towards delivering that relief and towards improving the health and financial security of American seniors and families.

In particular, I am strongly supportive of provisions that will lower out-of-pocket prescription drug costs for Medicare Part D beneficiaries. The legislation also limits price increases under Medicare Part Band D by creating an inflation rebate. Specifically, if a drug company raises the price of a drug in Part B or D above the 2016 rate of inflation, the company must lower the price or be required to pay the entire price above inflation in the form of a rebate back to the Treasury.

After strong pushback from myself and other progressive members, I am pleased that House leadership restored language designed to prevent pharmaceutical price-gouging for upwards of 150 million Americans with private health care plans and increased the minimum number of drugs that must be negotiated per year from 25 to 50.

While I believe these provisions will ultimately deliver relief to millions of Americans, I believe Congress can and must do more to combat rising drug prices and price-gouging pharmaceutical companies.

Currently, pharmaceutical companies charge outrageous prices because there is no adequate law to prevent drug companies from reaping massive profits with drugs developed on the taxpayer's dime.

To combat this ridiculous practice, I introduced H.R. 4640, the Affordable Drug Pricing for Taxpayer-Funded Prescription Drugs Act, which would end price gouging on prescription drugs developed with taxpayer-funded research by requiring federal agencies and federally-funded non-profits to secure affordable pricing agreements from drug manufacturers before granting them exclusive rights to develop drugs or other health care products. Americans should not pay to develop a drug only to see it put on the shelves in the U.S. at a much higher price than other nations.

I partnered with Rep. DOGGETT to offer an amendment to H.R. 3 that is similar to my legislation. While the amendment was not made in order, I will continue to push House leadership for full consideration of H.R. 4640.

Beyond this, I am a strong supporter of the Prescription Drug Price Relief Act, which would require the Secretary of Health and Human Services (HHS) to make sure that Americans don't pay more for prescription drugs than the median price of: Canada, the United Kingdom, France, Germany, and Japan. If pharmaceutical manufacturers refuse to negotiate, HHS would be required to approve cheaper generic versions of those drugs, regardless of any prior patents or market exclusivities. If Congress were to enact this legislation, prices of most brand name drugs would be significantly reduced.

Furthermore, uninsured patients should have access to negotiated prices under H.R. 3. That's why I supported an amendment that would have guaranteed that any negotiated price savings could have been accessed by the most vulnerable in our country, those who lack health insurance. Unfortunately, this amendment was not included in the final bill, meaning uninsured patients will continue to face the highest price at the pharmacy counter—pharmaceutical companies' list price.

I am also disappointed that an amendment I supported to allow the federal government to negotiate prescription drug prices for Medicare Part D was not made in order.

In 2003, the House Republican majority passed Medicare Part D. While I have consistently been a leader in the fight to lower drug prices for seniors, I opposed this legislation because it included a provision that prevents the federal government from negotiating better prescription drug prices for Medicare recipients. This means that drug companies are free to charge Medicare recipients higher prices, more than anyone else in the world. This is unacceptable.

The amendment offered to H.R. 3 would have authorized the federal government to negotiate prescription drug prices for Medicare Part D, and if drug companies refuse to negotiate, this legislation would enable the federal government to issue a competitive license to another company to produce the medication as a generic. The bottom line is that seniors shouldn't have to ration their pills or limit their dosage because they can't afford to pay for prescriptions each month.

Mr. LARSON of Connecticut. Mr. Chair, I rise in support of H.R. 3, the ''Elijah E. Cummings Lower Drugs Costs Now Act,'' named after my dear friend and colleague Elijah Cummings who passed away earlier this year. I commend the Speaker, Chairman NEAL, Chairman PALLONE and Chairman SCOTT for their efforts to bring this historic legislation to the floor today.

For too long Americans have seen prices for prescription drugs rise out of control, to the point where many must make the decision about whether they will spend limited income on their necessary prescriptions, or food, housing and transportation. How is it in the wealthiest country in the world this is happening?

I've heard from many constituents who are indeed facing this very choice.

Patricia, an 88 year old woman in Connecticut said, ''Do I have to lose my rent or stop eating in order to continue breathing? I don't want to end up in a nursing home on oxygen. I am not an ex-smoker. I am the proud daughter of a West Virginia coal miner. Please help me and other poor frail elderly.''

Rosemary from Wethersfield wrote, ''The cost of the Epi-Pen is outrageous. Even with my insurance it is so expensive I couldn't get the prescription filled and took my chances. When I had an allergic reaction I called 911 instead.''

Kevin from Manchester, a young man in his mid-30s who has a job and health insurance, also wrote, ''The annual cost of my medications is about $8,000 . . . I stop taking my medication. My asthma is noticeably worse. I worry that it's only a matter of time until I have a flare up and end up in the hospital.''

H.R. 3 will allow the Secretary of Health and Human Services to negotiate for better prices on prescription drugs in Medicare, lowering prices for patients in Medicare and the private market.

I have long advocated for negotiation of drug prices and have included it in the Medicare Buy In and Health Stabilization Act introduced with my colleague from New York, Rep. BRIAN HIGGINS, and with my colleague from Connecticut, Rep. JOE COURTNEY.

The bill also caps Medicare beneficiaries' out-of-pocket spending on prescription drugs at $2,000. And for the first time, with the savings from Medicare reimbursement for drugs, we are able to expand Medicare to cover dental, hearing and vision services as a benefit to traditional Medicare. In my district alone, more than 100,000 people will benefit from adding these new services.

It's time we implement these much-needed changes and make prescription drugs more affordable. It's time to pass the Lower Drug Costs Now Act.

Ms. LEE of California. Mr. Chair, I rise today in strong support of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act.

This bill takes on Big Pharma to help lower the cost of prescription drugs for everyday families. It is beyond outrageous that the U.S. government is not currently allowed to negotiate drug prices through Medicare. And it is shocking that Big Pharma is charging people in the United States, hundreds of times more than what they charge in other countries.

But H.R. 3 will help fix that. It allows the government to negotiate drug pricing through Medicare, and expands Medicare to cover vision, dental and hearing for the first time, while also investing in community health centers and critical research.

I'm especially pleased that this bill incorporates key provisions championed by our Progressive Caucus Co-Chairs PRAMILA JAYAPAL and MARK POCAN that increase the number of drugs that Medicare is able to negotiate and protect 150 million Americans with private health care plans from being price gouged by Big Pharma.

I urge a YES vote on this important bill named for our beloved, departed colleague Elijah Cummings who fought day in and out for the people. We miss him.

Ms. JOHNSON of Texas. Mr. Chair, today I rise in recognition of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. This legislation will serve as a critical improvement towards ensuring that essential medications are finally affordable and accessible.

As the first registered nurse elected to Congress, I know how the exorbitantly high prices of critical medications burden individuals and their families. Americans should not have to

pay more for their medicines, when compared to the same ones sold by pharmaceutical companies, for drastically lower prices in other countries. It is why I rise today in support of this bill, which provides the authority, mandate, and tools for the Secretary of Health and Human Services to negotiate lower drug prices and caps annual out-of-pocket costs in Medicare Part D.

The Congressional Budget Office has scored the Elijah E. Cummings Lower Drug Costs Now Act to save our country $456 billion in the next ten years. With these savings generated from lowering drug costs, significant reinvestments will be made to reduce out-of-pocket costs, close coverage gaps for Medicare beneficiaries, invest in critical funding in innovative new treatments, and fight against our nation's opioid crisis.

Specifically, I was very pleased to support the inclusion of Medicare Part B coverage for dental, vision, and hearing benefits. For the thousands of seniors in my district and throughout the state of Texas, it is undeniable that this expansion of coverage will be lifechanging, especially as our constituents encounter additional health challenges associated with aging.

As a member of the Congressional Black Caucus, I am especially vigilant in ensuring that minority communities which face higher rates of diabetes can access life-saving medications and are not forced to resort to rationing their insulin out of desperation. People living with diabetes will be heartened to learn that the Lower Drug Costs Now Act could potentially save them more than $700 on an annual supply of certain types of insulin.

The benefits of the Lower Drug Costs Now Act will even extend to the medical facilities we know and trust throughout our states. Our community health centers and nonprofit hospitals will be able to access the lowered negotiated drug prices because they qualify as providers of services, suppliers, and employers.

This bill moves our nation forward in addressing the need for accessible and affordable medications. However, it is prudent to note that there remains much to be done. We must continue to advocate for the inclusion of the uninsured population in these savings. Texas has the highest rate of uninsured individuals in the nation. Therefore, the lowered drug costs achieved in this bill will have limited impact in my state for the uninsured.

As members of this body, we should all stand in support to lower drug costs. I would like to especially honor the memory of my dear colleague, the Honorable Elijah E. Cummings. It is altogether very fitting that we recognize his long fight against high drug prices by passing H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, in his memory.

Ms. SÁNCHEZ. Mr. Chair, I rise in support of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act.

I would like to thank Chairmen NEAL, PALLONE, and SCOTT for their tireless efforts to get this legislation passed.

Prescriptions are not recommendations, Doctors have written them for a reason. Patients, our constituents, our friends, our family members, need these medications. They cannot afford to skip their medications.

However, I have heard so many heartbreaking stories from individuals in my district. Alice in Whittier has to rely on her doctors for insulin samples because she cannot afford insulin. Adrian in Norwalk is choosing to pay his bills rather than his eight different medications. David in La Mirada is considering cutting his dosage because he cannot afford to refill his full dosage as often as he should. They, and so many others, are just making do. Frankly, that's not good enough for me.

With H.R. 3, we are giving power back to the people in my district and to millions of Americans. The savings from this bill will also be given back to the public with reinvestments in innovation and the search for new cures and treatments.

I look forward to this bill's passage today. It is time to act and lower the cost of prescription drugs now.

The Acting CHAIR. All time for general debate has expired.

In lieu of the amendments in the nature of a substitute recommended by the Committee on Education and Labor, Committee on Energy and Commerce, and the Committee on Ways and Means, printed in the bill, an amendment in the nature of a substitute consisting of the text of Rules Committee Print 116–41, modified by the amendment printed in part A of House Report 116–334, shall be considered as adopted and shall be considered as an original bill for purpose of further amendment under the 5-minute rule. The bill, as amended, shall be considered as read.

The text of the bill, as amended, is as follows:

H.R. 3

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Elijah E. Cummings Lower Drug Costs Now Act''.

(b) TABLE OF CONTENTS.—The table of contents is as follows:

TITLE I—LOWERING PRICES THROUGH FAIR DRUG PRICE NEGOTIATION

SEC. 101. PROVIDING FOR LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS

U.S.C. 1301 et seq.) is amended by adding at the end the following new part:

"PART E—FAIR PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS

''SEC. 1191. ESTABLISHMENT OF PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish a Fair Price Negotiation Program (in this part referred to as the 'program'). Under the program, with respect to each price applicability period, the Secretary shall—

''(1) publish a list of selected drugs in accordance with section 1192;

''(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1193;

''(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1194; and

''(4) carry out the administrative duties described in section 1196.

''(b) DEFINITIONS RELATING TO TIMING.—For purposes of this part:

''(1) INITIAL PRICE APPLICABILITY YEAR.—The term 'initial price applicability year' means a plan year (beginning with plan year 2023) or, if agreed to in an agreement under section 1193 by the Secretary and manufacturer involved, a period of more than one plan year (beginning on or after January 1, 2023).

''(2) PRICE APPLICABILITY PERIOD.—The term 'price applicability period' means, with respect to a drug, the period beginning with the initial price applicability year with respect to which such drug is a selected drug and ending with the last plan year during which the drug is a selected drug.

''(3) SELECTED DRUG PUBLICATION DATE.—The term 'selected drug publication date' means, with respect to each initial price applicability year, April 15 of the plan year that begins 2 years prior to such year.

''(4) VOLUNTARY NEGOTIATION PERIOD.—The term 'voluntary negotiation period' means, with respect to an initial price applicability year with respect to a selected drug, the period—

''(A) beginning on the sooner of—

''(i) the date on which the manufacturer of the drug and the Secretary enter into an agreement under section 1193 with respect to such drug; or

''(ii) June 15 following the selected drug publication date with respect to such selected drug; and

''(B) ending on March 31 of the year that begins one year prior to the initial price applicability year.

''(c) OTHER DEFINITIONS.—For purposes of this part:

''(1) FAIR PRICE ELIGIBLE INDIVIDUAL.—The term 'fair price eligible individual' means, with respect to a selected drug—

''(A) in the case such drug is furnished or dispensed to the individual at a pharmacy or by a mail order service—

''(i) an individual who is enrolled under a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title if coverage is provided under such plan for such selected drug; and

''(ii) an individual who is enrolled under a group health plan or health insurance coverage offered in the group or individual market (as such terms are defined in section 2791 of the Public Health Service Act) with respect to which there is in effect an agreement with the Secretary under section 1197 with respect to such selected drug as so furnished or dispensed; and

''(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier—

''(i) an individual who is entitled to benefits under part A of title XVIII or enrolled under part B of such title if such selected drug is covered under the respective part; and

''(ii) an individual who is enrolled under a group health plan or health insurance coverage offered in the group or individual market (as such terms are defined in section 2791 of the Public Health Service Act) with respect to which there is in effect an agreement with the Secretary under section 1197 with respect to such selected drug as so furnished or administered.

''(2) MAXIMUM FAIR PRICE.—The term 'maximum fair price' means, with respect to a plan year during a price applicability period and with respect to a selected drug (as defined in section 1192(c)) with respect to such period, the price published pursuant to section 1195 in the Federal Register for such drug and year.

''(3) AVERAGE INTERNATIONAL MARKET PRICE DEFINED.—

''(A) IN GENERAL.—The terms 'average international market price' and 'AIM price' mean, with respect to a drug, the average price (which shall be the net average price, if practicable, and volume-weighted, if practicable) for a unit (as defined in paragraph (4)) of the drug for sales of such drug (calculated across different dosage forms and strengths of the drug and not based on the specific formulation or package size or package type), as computed (as of the date of publication of such drug as a selected drug under section 1192(a)) in all countries described in clause (ii) of subparagraph (B) that are applicable countries (as described in clause (i) of such subparagraph) with respect to such drug.

''(B) APPLICABLE COUNTRIES.—

''(i) IN GENERAL.—For purposes of subparagraph (A), a country described in clause (ii) is an applicable country described in this clause with respect to a drug if there is available an average price for any unit for the drug for sales of such drug in such country.

''(ii) COUNTRIES DESCRIBED.—For purposes of this paragraph, the following are countries described in this clause:

''(I) Australia.
''(II) Canada.
''(III) France.
''(IV) Germany.
''(V) Japan.
''(VI) The United Kingdom.

''(4) UNIT.—The term 'unit' means, with respect to a drug, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug that is dispensed.

"SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS AS SELECTED DRUGS.

''(a) IN GENERAL.—Not later than the selected drug publication date with respect to an initial price applicability year, the Secretary shall select and publish in the Federal Register a list of—

''(1)(A) with respect to an initial price applicability year during 2023, at least 25 negotiation-eligible drugs described in subparagraphs (A) and (B), but not subparagraph (C), of subsection (d)(1) (or, with respect to an initial price applicability year during such period beginning after 2023, the maximum number (if such number is less than 25) of such negotiation-eligible drugs for the year) with respect to such year; and

''(B) with respect to an initial price applicability year during 2024 or a subsequent year, at least 50 negotiation-eligible drugs described in subparagraphs (A) and (B), but not subparagraph (C), of subsection (d)(1) (or, with respect to an initial price applicability year during such period, the maximum number (if such number is less than 50) of such negotiation-eligible drugs for the year) with respect to such year;

''(2) all negotiation-eligible drugs described in subparagraph (C) of such subsection with respect to such year; and

''(3) all new-entrant negotiation-eligible drugs (as defined in subsection (g)(1)) with respect to such year.

Each drug published on the list pursuant to the previous sentence shall be subject to the negotiation process under section 1194 for the voluntary negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for any subsequent year during the applicable price applicability period). In applying this subsection, any negotiation-eligible drug that is selected under this subsection for an initial price applicability year shall not count toward the required minimum amount of drugs to be selected under paragraph (1) for any subsequent year, including such a drug so selected that is subject to renegotiation under section 1194.

''(b) SELECTION OF DRUGS.—In carrying out subsection (a)(1) the Secretary shall select for inclusion on the published list described in subsection (a) with respect to a price applicability period, the negotiation-eligible drugs that the Secretary projects will result in the greatest savings to the Federal Government or fair price eligible individuals during the price applicability period. In making this projection of savings for drugs for which there is an AIM price for a price applicability period, the savings shall be projected across different dosage forms and strengths of the drugs and not based on the specific formulation or package size or package type of the drugs, taking into consideration both the volume of drugs for which payment is made, to the extent such data is available, and the amount by which the net price for the drugs exceeds the AIM price for the drugs.

''(c) SELECTED DRUG.—For purposes of this part, each drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a 'selected drug' with respect to such year and each subsequent plan year beginning before the first plan year beginning after the date on which the Secretary determines two or more drug products—

''(1) are approved or licensed (as applicable)—

''(A) under section 505(j) of the Federal Food, Drug, and Cosmetic Act using such drug as the listed drug; or

''(B) under section 351(k) of the Public Health Service Act using such drug as the reference product; and

''(2) continue to be marketed.

''(d) NEGOTIATION-ELIGIBLE DRUG.—

''(1) IN GENERAL.—For purposes of this part, the term 'negotiation-eligible drug' means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that meets any of the following criteria:

''(A) COVERED PART D DRUGS.—The drug is among the 125 covered part D drugs (as defined in section 1860D–2(e)) for which there was an estimated greatest net spending under parts C and D of title XVIII, as determined by the Secretary, during the most recent plan year prior to such drug publication date for which data are available.

''(B) OTHER DRUGS.—The drug is among the 125 drugs for which there was an estimated greatest net spending in the United States (including the 50 States, the District of Columbia, and the territories of the United States), as determined by the Secretary, during the most recent plan year prior to such drug publication date for which data are available.

''(C) INSULIN.—The drug is a qualifying single source drug described in subsection (e)(3).

''(2) CLARIFICATION.—In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1), the Secretary shall, to the extent practicable, use data that is aggregated across dosage forms and strengths of the drug and not based on the specific formulation or package size or package type of the drug.

''(3) PUBLICATION.—Not later than the selected drug publication date with respect to an initial price applicability year, the Secretary

shall publish in the Federal Register a list of negotiation-eligible drugs with respect to such selected drug publication date.

''(e) QUALIFYING SINGLE SOURCE DRUG.—For purposes of this part, the term 'qualifying single source drug' means any of the following:

''(1) DRUG PRODUCTS.—A drug that—

''(A) is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and continues to be marketed pursuant to such approval; and

''(B) is not the listed drug for any drug that is approved and continues to be marketed under section 505(j) of such Act.

''(2) BIOLOGICAL PRODUCTS.—A biological product that—

''(A) is licensed under section 351(a) of the Public Health Service Act, including any product that has been deemed to be licensed under section 351 of such Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009, and continues to be marketed under section 351 of such Act; and

''(B) is not the reference product for any biological product that is licensed and continues to be marketed under section 351(k) of such Act.

''(3) INSULIN PRODUCT.—Notwithstanding paragraphs (1) and (2), any insulin product that is approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act and continues to be marketed under such section 505 or 351, including any insulin product that has been deemed to be licensed under section 351(a) of the Public Health Service Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and continues to be marketed pursuant to such licensure.

For purposes of applying paragraphs (1) and (2), a drug or biological product that is marketed by the same sponsor or manufacturer (or an affiliate thereof or a cross-licensed producer or distributor) as the listed drug or reference product described in such respective paragraph shall not be taken into consideration.

''(f) INFORMATION ON INTERNATIONAL DRUG PRICES.—For purposes of determining which negotiation-eligible drugs to select under subsection (a) and, in the case of such drugs that are selected drugs, to determine the maximum fair price for such a drug and whether such maximum fair price should be renegotiated under section 1194, the Secretary shall use data relating to the AIM price with respect to such drug as available or provided to the Secretary and shall on an ongoing basis request from manufacturers of selected drugs information on the AIM price of such a drug.

''(g) NEW-ENTRANT NEGOTIATION-ELIGIBLE DRUGS.—

''(1) IN GENERAL.—For purposes of this part, the term 'new-entrant negotiation-eligible drug' means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug—

''(A) that is first approved or licensed, as described in paragraph (1), (2), or (3) of subsection (e), as applicable, during the year preceding such selected drug publication date; and

''(B) that the Secretary determines under paragraph (2) is likely to be included as a negotiation-eligible drug with respect to the subsequent selected drug publication date.

''(2) DETERMINATION.—In the case of a qualifying single source drug that meets the criteria described in subparagraph (A) of paragraph (1), with respect to an initial price applicability year, if the wholesale acquisition cost at which such drug is first marketed in the United States is equal to or greater than the median household income (as determined according to the most recent data collected by the United States Census Bureau), the Secretary shall determine before the selected drug publication date with respect to the initial price applicability year, if the drug is likely to be included as a negotiation-eligible drug with respect to the subsequent selected drug publication date, based on the projected spending under title XVIII or in the United States on such drug. For purposes of this paragraph the term 'United States' includes the 50 States, the District of Columbia, and the territories of the United States.

''SEC. 1193. MANUFACTURER AGREEMENTS.

''(a) IN GENERAL.—For purposes of section 1191(a)(2), the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than June 15 following the selected drug publication date with respect to such selected drug, under which—

''(1) during the voluntary negotiation period for the initial price applicability year for the selected drug, the Secretary and manufacturer, in accordance with section 1194, negotiate to determine (and, by not later than the last date of such period and in accordance with subsection (c), agree to) a maximum fair price for such selected drug of the manufacturer in order to provide access to such price—

''(A) to fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(1) and are furnished or dispensed such drug during, subject to subparagraph (2), the price applicability period; and

''(B) to hospitals, physicians, and other providers of services and suppliers with respect to fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to subparagraph (2), the price applicability period;

''(2) the Secretary and the manufacturer shall, in accordance with a process and during a period specified by the Secretary pursuant to rulemaking, renegotiate (and, by not later than the last date of such period and in accordance with subsection (c), agree to) the maximum fair price for such drug if the Secretary determines that there is a material change in any of the factors described in section 1194(d) relating to the drug, including changes in the AIM price for such drug, in order to provide access to such maximum fair price (as so renegotiated)—

''(A) to fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(1) and are furnished or dispensed such drug during any year during the price applicability period (beginning after such renegotiation) with respect to such selected drug; and

''(B) to hospitals, physicians, and other providers of services and suppliers with respect to fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during any year described in subparagraph (A);

''(3) the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided to fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1191(c)(1), at the pharmacy or by a mail order service at the point-of-sale of such drug;

''(4) the manufacturer, subject to subsection (d), submits to the Secretary, in a form and manner specified by the Secretary—

''(A) for the voluntary negotiation period for the price applicability period (and, if applicable, before any period of renegotiation specified pursuant to paragraph (2)) with respect to such drug all information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part, including information described in section 1192(f) and section 1194(d)(1); and

''(B) on an ongoing basis, information on changes in prices for such drug that would affect the AIM price for such drug or otherwise provide a basis for renegotiation of the maximum fair price for such drug pursuant to paragraph (2);

''(5) the manufacturer agrees that in the case the selected drug of a manufacturer is a drug described in subsection (c), the manufacturer will, in accordance with such subsection, make any payment required under such subsection with respect to such drug; and

''(6) the manufacturer complies with requirements imposed by the Secretary for purposes of administering the program, including with respect to the duties described in section 1196.

''(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO LONGER A SELECTED DRUG.—An agreement entered into under this section shall be effective, with respect to a drug, until such drug is no longer considered a selected drug under section 1192(c).

''(c) SPECIAL RULE FOR CERTAIN SELECTED DRUGS WITHOUT AIM PRICE.—

''(1) IN GENERAL.—In the case of a selected drug for which there is no AIM price available with respect to the initial price applicability year for such drug and for which an AIM price becomes available beginning with respect to a subsequent plan year during the price applicability period for such drug, if the Secretary determines that the amount described in paragraph (2)(A) for a unit of such drug is greater than the amount described in paragraph (2)(B) for a unit of such drug, then by not later than one year after the date of such determination, the manufacturer of such selected drug shall pay to the Treasury an amount equal to the product of—

''(A) the difference between such amount described in paragraph (2)(A) for a unit of such drug and such amount described in paragraph (2)(B) for a unit of such drug; and

''(B) the number of units of such drug sold in the United States, including the 50 States, the District of Columbia, and the territories of the United States, during the period described in paragraph (2)(B).

''(2) AMOUNTS DESCRIBED.—

''(A) WEIGHTED AVERAGE PRICE BEFORE AIM PRICE AVAILABLE.—For purposes of paragraph (1), the amount described in this subparagraph for a selected drug described in such paragraph, is the amount equal to the weighted average manufacturer price (as defined in section 1927(k)(1)) for such dosage strength and form for the drug during the period beginning with the first plan year for which the drug is included on the list of negotiation-eligible drugs published under section 1192(d) and ending with the last plan year during the price applicability period for such drug with respect to which there is no AIM price available for such drug.

''(B) AMOUNT MULTIPLIER AFTER AIM PRICE AVAILABLE.—For purposes of paragraph (1), the amount described in this subparagraph for a selected drug described in such paragraph, is the amount equal to 200 percent of the AIM price for such drug with respect to the first plan year during the price applicability period for such drug with respect to which there is an AIM price available for such drug.

''(d) CONFIDENTIALITY OF INFORMATION.—Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) may be used only by the Secretary or disclosed to and used by the Comptroller General of the United States or the Medicare Payment Advisory Commission for purposes of carrying out this part.

''(e) REGULATIONS.—

''(1) IN GENERAL.—The Secretary shall, pursuant to rulemaking, specify, in accordance with paragraph (2), the information that must be submitted under subsection (a)(4).

''(2) INFORMATION SPECIFIED.—Information described in paragraph (1), with respect to a selected drug, shall include information on sales of the drug (by the manufacturer of the drug or by another entity under license or other agreement with the manufacturer, with respect to the sales of such drug, regardless of the name under which the drug is sold) in any foreign country

that is part of the AIM price. The Secretary shall verify, to the extent practicable, such sales from appropriate officials of the government of the foreign country involved.

''(f) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under section 1196(c)(1), as applicable, for purposes of administering the program.

''SEC. 1194. NEGOTIATION AND RENEGOTIATION PROCESS.

''(a) IN GENERAL.—For purposes of this part, under an agreement under section 1193 between the Secretary and a manufacturer of a selected drug, with respect to the period for which such agreement is in effect and in accordance with subsections (b) and (c), the Secretary and the manufacturer—

''(1) shall during the voluntary negotiation period with respect to the initial price applicability year for such drug, in accordance with this section, negotiate a maximum fair price for such drug for the purpose described in section 1193(a)(1); and

''(2) as applicable pursuant to section 1193(a)(2) and in accordance with the process specified pursuant to such section, renegotiate such maximum fair price for such drug for the purpose described in such section.

''(b) NEGOTIATING METHODOLOGY AND OBJECTIVE.—

''(1) IN GENERAL.—The Secretary shall develop and use a consistent methodology for negotiations under subsection (a) that, in accordance with paragraph (2) and subject to paragraph (3), achieves the lowest maximum fair price for each selected drug while appropriately rewarding innovation.

''(2) PRIORITIZING FACTORS.—In considering the factors described in subsection (d) in negotiating (and, as applicable, renegotiating) the maximum fair price for a selected drug, the Secretary shall, to the extent practicable, consider all of the available factors listed but shall prioritize the following factors:

''(A) RESEARCH AND DEVELOPMENT COSTS.—The factor described in paragraph (1)(A) of subsection (d).

''(B) MARKET DATA.—The factor described in paragraph (1)(B) of such subsection.

''(C) UNIT COSTS OF PRODUCTION AND DISTRIBUTION.—The factor described in paragraph (1)(C) of such subsection.

''(D) COMPARISON TO EXISTING THERAPEUTIC ALTERNATIVES.—The factor described in paragraph (2)(A) of such subsection.

''(3) REQUIREMENT.—

''(A) IN GENERAL.—In negotiating the maximum fair price of a selected drug, with respect to an initial price applicability year for the selected drug, and, as applicable, in renegotiating the maximum fair price for such drug, with respect to a subsequent year during the price applicability period for such drug, in the case that the manufacturer of the selected drug offers under the negotiation or renegotiation, as applicable, a price for such drug that is not more than the target price described in subparagraph (B) for such drug for the respective year, the Secretary shall agree under such negotiation or renegotiation, respectively, to such offered price as the maximum fair price.

''(B) TARGET PRICE.—

''(i) IN GENERAL.—Subject to clause (ii), the target price described in this subparagraph for a selected drug with respect to a year, is the average price (which shall be the net average price, if practicable, and volume-weighted, if practicable) for a unit of such drug for sales of such drug, as computed (across different dosage forms and strengths of the drug and not based on the specific formulation or package size or package type of the drug) in the applicable country described in section 1191(c)(3)(B) with respect to such drug that, with respect to such year, has the lowest average price for such drug as compared to the average prices (as so computed) of such drug with respect to such year in the other applicable countries described in such section with respect to such drug.

''(ii) SELECTED DRUGS WITHOUT AIM PRICE.—In applying this paragraph in the case of negotiating the maximum fair price of a selected drug for which there is no AIM price available with respect to the initial price applicability year for such drug, or, as applicable, renegotiating the maximum fair price for such drug with respect to a subsequent year during the price applicability period for such drug before the first plan year for which there is an AIM price available for such drug, the target price described in this subparagraph for such drug and respective year is the amount that is 80 percent of the average manufacturer price (as defined in section 1927(k)(1)) for such drug and year.

''(4) ANNUAL REPORT.—After the completion of each voluntary negotiation period, the Secretary shall submit to Congress a report on the maximum fair prices negotiated (or, as applicable, renegotiated) for such period. Such report shall include information on how such prices so negotiated (or renegotiated) meet the requirements of this part, including the requirements of this subsection.

''(c) LIMITATION.—

''(1) IN GENERAL.—Subject to paragraph (2), the maximum fair price negotiated (including as renegotiated) under this section for a selected drug, with respect to each plan year during a price applicability period for such drug, shall not exceed 120 percent of the AIM price applicable to such drug with respect to such year.

''(2) SELECTED DRUGS WITHOUT AIM PRICE.—In the case of a selected drug for which there is no AIM price available with respect to the initial price applicability year for such drug, for each plan year during the price applicability period before the first plan year for which there is an AIM price available for such drug, the maximum fair price negotiated (including as renegotiated) under this section for the selected drug shall not exceed the amount equal to 85 percent of the average manufacturer price for the drug with respect to such year.

''(d) CONSIDERATIONS.—For purposes of negotiating and, as applicable, renegotiating (including for purposes of determining whether to renegotiate) the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary, consistent with subsection (b)(2), shall take into consideration the factors described in paragraphs (1), (2), (3), and (5), and may take into consideration the factor described in paragraph (4):

''(1) MANUFACTURER-SPECIFIC INFORMATION.—The following information, including as submitted by the manufacturer:

''(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.

''(B) Market data for the drug, including the distribution of sales across different programs and purchasers and projected future revenues for the drug.

''(C) Unit costs of production and distribution of the drug.

''(D) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.

''(E) Data on patents and on existing and pending exclusivity for the drug.

''(F) National sales data for the drug.

''(G) Information on clinical trials for the drug in the United States or in applicable countries described in section 1191(c)(3)(B).

''(2) INFORMATION ON ALTERNATIVE PRODUCTS.—The following information:

''(A) The extent to which the drug represents a therapeutic advance as compared to existing therapeutic alternatives and, to the extent such information is available, the costs of such existing therapeutic alternatives.

''(B) Information on approval by the Food and Drug Administration of alternative drug products.

''(C) Information on comparative effectiveness analysis for such products, taking into consideration the effects of such products on specific populations, such as individuals with disabilities, the elderly, terminally ill, children, and other patient populations.

In considering information described in subparagraph (C), the Secretary shall not use evidence or findings from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Nothing in the previous sentence shall affect the application or consideration of an AIM price for a selected drug.

''(3) FOREIGN SALES INFORMATION.—To the extent available on a timely basis, including as provided by a manufacturer of the selected drug or otherwise, information on sales of the selected drug in each of the countries described in section 1191(c)(3)(B).

''(4) VA DRUG PRICING INFORMATION.—Information disclosed to the Secretary pursuant to subsection (f).

''(5) ADDITIONAL INFORMATION.—Information submitted to the Secretary, in accordance with a process specified by the Secretary, by other parties that are affected by the establishment of a maximum fair price for the selected drug.

''(e) REQUEST FOR INFORMATION.—For purposes of negotiating and, as applicable, renegotiating (including for purposes of determining whether to renegotiate) the maximum fair price of a selected drug under this part with the manufacturer of the drug, with respect to a price applicability period, and other relevant data for purposes of this section—

''(1) the Secretary shall, not later than the selected drug publication date with respect to the initial price applicability year of such period, request drug pricing information from the manufacturer of such selected drug, including information described in subsection (d)(1); and

''(2) by not later than October 1 following the selected drug publication date, the manufacturer of such selected drug shall submit to the Secretary such requested information in such form and manner as the Secretary may require. The Secretary shall request, from the manufacturer or others, such additional information as may be needed to carry out the negotiation and renegotiation process under this section.

''(f) DISCLOSURE OF INFORMATION.—For purposes of this part, the Secretary of Veterans Affairs may disclose to the Secretary of Health and Human Services the price of any negotiation-eligible drug that is purchased pursuant to section 8126 of title 38, United States Code.

''SEC. 1195. PUBLICATION OF MAXIMUM FAIR PRICES.

''(a) IN GENERAL.—With respect to an initial price applicability year and selected drug with respect to such year, not later than April 1 of the plan year prior to such initial price applicability year, the Secretary shall publish in the Federal Register the maximum fair price for such drug negotiated under this part with the manufacturer of such drug.

''(b) UPDATES.—

''(1) SUBSEQUENT YEAR MAXIMUM FAIR PRICES.—For a selected drug, for each plan year subsequent to the initial price applicability year for such drug with respect to which an agreement for such drug is in effect under section 1193, the Secretary shall publish in the Federal Register—

''(A) subject to subparagraph (B), the amount equal to the maximum fair price published for such drug for the previous year, increased by the annual percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) as of September of such previous year; or

''(B) in the case the maximum fair price for such drug was renegotiated, for the first year for which such price as so renegotiated applies, such renegotiated maximum fair price.

''(2) PRICES NEGOTIATED AFTER DEADLINE.—In the case of a selected drug with respect to an initial price applicability year for which the maximum fair price is determined under this part after the date of publication under this section, the Secretary shall publish such maximum fair price in the Federal Register by not later than 30 days after the date such maximum price is so determined.

''SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PROVISIONS.

''(a) ADMINISTRATIVE DUTIES.—

''(1) IN GENERAL.—For purposes of section 1191, the administrative duties described in this section are the following:

''(A) The establishment of procedures (including through agreements with manufacturers under this part, contracts with prescription drug plans under part D of title XVIII and MA–PD plans under part C of such title, and agreements under section 1197 with group health plans and health insurance issuers of health insurance coverage offered in the individual or group market) under which the maximum fair price for a selected drug is provided to fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1191(c)(1), at pharmacies or by mail order service at the point-of-sale of the drug for the applicable price period for such drug and providing that such maximum fair price is used for determining cost-sharing under such plans or coverage for the selected drug.

''(B) The establishment of procedures (including through agreements with manufacturers under this part and contracts with hospitals, physicians, and other providers of services and suppliers and agreements under section 1197 with group health plans and health insurance issuers of health insurance coverage offered in the individual or group market) under which, in the case of a selected drug furnished or administered by such a hospital, physician, or other provider of services or supplier to fair price eligible individuals (who with respect to such drug are described in subparagraph (B) of section 1191(c)(1)), the maximum fair price for the selected drug is provided to such hospitals, physicians, and other providers of services and suppliers (as applicable) with respect to such individuals and providing that such maximum fair price is used for determining cost-sharing under the respective part, plan, or coverage for the selected drug.

''(C) The establishment of procedures (including through agreements and contracts described in subparagraphs (A) and (B)) to ensure that, not later than 90 days after the dispensing of a selected drug to a fair price eligible individual by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

''(i) the lesser of—

''(I) the wholesale acquisition cost of the drug;

''(II) the national average drug acquisition cost of the drug; and

''(III) any other similar determination of pharmacy acquisition costs of the drug, as determined by the Secretary; and

''(ii) the maximum fair price for the drug.

''(D) The establishment of procedures to ensure that the maximum fair price for a selected drug is applied before—

''(i) any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of fair price eligible individuals as the Secretary may specify; and

''(ii) any other discounts.

''(E) The establishment of procedures to enter into appropriate agreements and protocols for the ongoing computation of AIM prices for selected drugs, including, to the extent possible, to compute the AIM price for selected drugs and including by providing that the manufacturer of such a selected drug should provide information for such computation not later than 3 months after the first date of the voluntary negotiation period for such selected drug.

''(F) The establishment of procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of the drug.

''(G) The establishment of procedures to negotiate and apply the maximum fair price in a manner that does not include any dispensing or similar fee.

''(H) The establishment of procedures to carry out the provisions of this part, as applicable, with respect to—

''(i) fair price eligible individuals who are enrolled under a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title;

''(ii) fair price eligible individuals who are enrolled under a group health plan or health insurance coverage offered by a health insurance issuer in the individual or group market with respect to which there is an agreement in effect under section 1197; and

''(iii) fair price eligible individuals who are entitled to benefits under part A of title XVIII or enrolled under part B of such title.

''(I) The establishment of a negotiation process and renegotiation process in accordance with section 1194, including a process for acquiring information described in subsection (d) of such section and determining amounts described in subsection (b) of such section.

''(J) The provision of a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, fair price eligible individuals, and the third party with a contract under subsection (c)(1).

''(2) MONITORING COMPLIANCE.—

''(A) IN GENERAL.—The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under section 1193, including by establishing a mechanism through which violations of such terms may be reported.

''(B) NOTIFICATION.—If a third party with a contract under subsection (c)(1) determines that the manufacturer is not in compliance with such agreement, the third party shall notify the Secretary of such noncompliance for appropriate enforcement under section 4192 of the Internal Revenue Code of 1986 or section 1198, as applicable.

''(b) COLLECTION OF DATA.—

''(1) FROM PRESCRIPTION DRUG PLANS AND MA–PD PLANS.—The Secretary may collect appropriate data from prescription drug plans under part D of title XVIII and MA–PD plans under part C of such title in a timeframe that allows for maximum fair prices to be provided under this part for selected drugs.

''(2) FROM HEALTH PLANS.—The Secretary may collect appropriate data from group health plans or health insurance issuers offering group or individual health insurance coverage in a timeframe that allows for maximum fair prices to be provided under this part for selected drugs.

''(3) COORDINATION OF DATA COLLECTION.—To the extent feasible, as determined by the Secretary, the Secretary shall ensure that data collected pursuant to this subsection is coordinated with, and not duplicative of, other Federal data collection efforts.

''(c) CONTRACT WITH THIRD PARTIES.—

''(1) IN GENERAL.—The Secretary may enter into a contract with 1 or more third parties to administer the requirements established by the Secretary in order to carry out this part. At a minimum, the contract with a third party under the preceding sentence shall require that the third party—

''(A) receive and transmit information between the Secretary, manufacturers, and other individuals or entities the Secretary determines appropriate;

''(B) receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under agreements under this part;

''(C) provide adequate and timely information to manufacturers, consistent with the agreement with the manufacturer under this part, as necessary for the manufacturer to fulfill its obligations under this part; and

''(D) permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the third party to determine discounts for applicable drugs of the manufacturer under the program.

''(2) PERFORMANCE REQUIREMENTS.—The Secretary shall establish performance requirements for a third party with a contract under paragraph (1) and safeguards to protect the independence and integrity of the activities carried out by the third party under the program under this part.

''SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER HEALTH PLANS.

''(a) AGREEMENT TO PARTICIPATE UNDER PROGRAM.—

''(1) IN GENERAL.—Subject to paragraph (2), under the program under this part the Secretary shall be treated as having in effect an agreement with a group health plan or health insurance issuer offering group or individual health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), with respect to a price applicability period and a selected drug with respect to such period—

''(A) with respect to such selected drug furnished or dispensed at a pharmacy or by mail order service if coverage is provided under such plan or coverage during such period for such selected drug as so furnished or dispensed; and

''(B) with respect to such selected drug furnished or administered by a hospital, physician, or other provider of services or supplier if coverage is provided under such plan or coverage during such period for such selected drug as so furnished or administered.

''(2) OPTING OUT OF AGREEMENT.—The Secretary shall not be treated as having in effect an agreement under the program under this part with a group health plan or health insurance issuer offering group or individual health insurance coverage with respect to a price applicability period and a selected drug with respect to such period if such a plan or issuer affirmatively elects, through a process specified by the Secretary, not to participate under the program with respect to such period and drug.

''(b) PUBLICATION OF ELECTION.—With respect to each price applicability period and each selected drug with respect to such period, the Secretary and the Secretary of Labor and the Secretary of the Treasury, as applicable, shall make public a list of each group health plan and each health insurance issuer offering group or individual health insurance coverage, with respect to which coverage is provided under such plan or coverage for such drug, that has elected under subsection (a) not to participate under the program with respect to such period and drug.

''SEC. 1198. CIVIL MONETARY PENALTY.

''(a) VIOLATIONS RELATING TO OFFERING OF MAXIMUM FAIR PRICE.—Any manufacturer of a selected drug that has entered into an agreement under section 1193, with respect to a plan year during the price applicability period for such drug, that does not provide access to a price that is not more than the maximum fair price (or a lesser price) for such drug for such year—

''(1) to a fair price eligible individual who with respect to such drug is described in subparagraph (A) of section 1191(c)(1) and who is furnished or dispensed such drug during such year; or

''(2) to a hospital, physician, or other provider of services or supplier with respect to fair price eligible individuals who with respect to such drug is described in subparagraph (B) of such section and is furnished or administered such drug by such hospital, physician, or provider or supplier during such year;

shall be subject to a civil monetary penalty equal to ten times the amount equal to the difference between the price for such drug made available for such year by such manufacturer with respect to such individual or hospital, physician, provider, or supplier and the maximum fair price for such drug for such year.

''(b) VIOLATIONS OF CERTAIN TERMS OF AGREEMENT.—Any manufacturer of a selected drug that has entered into an agreement under section 1193, with respect to a plan year during the price applicability period for such drug, that is in violation of a requirement imposed pursuant to section 1193(a)(6) shall be subject to a civil monetary penalty of not more than $1,000,000 for each such violation.

''(c) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this section in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''SEC. 1199. MISCELLANEOUS PROVISIONS.

''(a) PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to data collected under this part.

''(b) NATIONAL ACADEMY OF MEDICINE STUDY.—Not later than December 31, 2025, the National Academy of Medicine shall conduct a study, and submit to Congress a report, on recommendations for improvements to the program under this part, including the determination of the limits applied under section 1194(c).

''(c) MEDPAC STUDY.—Not later than December 31, 2025, the Medicare Payment Advisory Commission shall conduct a study, and submit to Congress a report, on the program under this part with respect to the Medicare program under title XVIII, including with respect to the effect of the program on individuals entitled to benefits or enrolled under such title.

''(d) LIMITATION ON JUDICIAL REVIEW.—The following shall not be subject to judicial review:

''(1) The selection of drugs for publication under section 1192(a).

''(2) The determination of whether a drug is a negotiation-eligible drug under section 1192(d).

''(3) The determination of the maximum fair price of a selected drug under section 1194.

''(4) The determination of units of a drug for purposes of section 1191(c)(3).

''(e) COORDINATION.—In carrying out this part with respect to group health plans or health insurance coverage offered in the group market that are subject to oversight by the Secretary of Labor or the Secretary of the Treasury, the Secretary of Health and Human Services shall coordinate with such respective Secretary.

''(f) DATA SHARING.—The Secretary shall share with the Secretary of the Treasury such information as is necessary to determine the tax imposed by section 4192 of the Internal Revenue Code of 1986.

''(g) GAO STUDY.—Not later than December 31, 2025, the Comptroller General of the United States shall conduct a study of, and submit to Congress a report on, the implementation of the Fair Price Negotiation Program under this part.''.

(b) APPLICATION OF MAXIMUM FAIR PRICES AND CONFORMING AMENDMENTS.—

(1) UNDER MEDICARE.—

(A) APPLICATION TO PAYMENTS UNDER PART B.—Section 1847A(b)(1)(B) of the Social Security Act (42 U.S.C. 1395w–3a(b)(1)(B)) is amended by inserting ''or in the case of such a drug or biological that is a selected drug (as defined in section 1192(c)), with respect to a price applicability period (as defined in section 1191(b)(2)), 106 percent of the maximum fair price (as defined in section 1191(c)(2) applicable for such drug and a plan year during such period'' after ''paragraph (4)''.

(B) EXCEPTION TO PART D NON-INTERFERENCE.—Section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)) is amended by inserting '', except as provided under part E of title XI'' after ''the Secretary''.

(C) APPLICATION AS NEGOTIATED PRICE UNDER PART D.—Section 1860D–2(d)(1) of the Social Security Act (42 U.S.C. 1395w–102(d)(1)) is amended—

(i) in subparagraph (B), by inserting '', subject to subparagraph (D),'' after ''negotiated prices''; and

(ii) by adding at the end the following new subparagraph:

''(D) APPLICATION OF MAXIMUM FAIR PRICE FOR SELECTED DRUGS.—In applying this section, in the case of a covered part D drug that is a selected drug (as defined in section 1192(c)), with respect to a price applicability period (as defined in section 1191(b)(2)), the negotiated prices used for payment (as described in this subsection) shall be the maximum fair price (as defined in section 1191(c)(2)) for such drug and for each plan year during such period.''.

(D) INFORMATION FROM PRESCRIPTION DRUG PLANS AND MA–PD PLANS REQUIRED.—

(i) PRESCRIPTION DRUG PLANS.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraph:

''(8) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall require the sponsor to provide information to the Secretary as requested by the Secretary in accordance with section 1196(b).''.

(ii) MA–PD PLANS.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)) is amended by adding at the end the following new subparagraph:

''(E) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Section 1860D–12(b)(8).''.

(2) UNDER GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE.—

(A) PHSA.—Part A of title XXVII of the Public Health Service Act is amended by inserting after section 2729 the following new section:

''SEC. 2729A. FAIR PRICE NEGOTIATION PROGRAM AND APPLICATION OF MAXIMUM FAIR PRICES.

''(a) IN GENERAL.—In the case of a group health plan or health insurance issuer offering group or individual health insurance coverage that is treated under section 1197 of the Social Security Act as having in effect an agreement with the Secretary under the Fair Price Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period with respect to which coverage is provided under such plan or coverage—

''(1) the provisions of such part shall apply—

''(A) if coverage of such selected drug is provided under such plan or coverage if the drug is furnished or dispensed at a pharmacy or by a mail order service, to the plans or coverage offered by such plan or issuer, and to the individuals enrolled under such plans or coverage, during such period, with respect to such selected drug, in the same manner as such provisions apply to prescription drug plans and MA–PD plans, and to individuals enrolled under such prescription drug plans and MA–PD plans during such period; and

''(B) if coverage of such selected drug is provided under such plan or coverage if the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the plans or coverage offered by such plan or issuers, to the individuals enrolled under such plans or coverage, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary, to individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, and to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period;

''(2) the plan or issuer shall apply any cost-sharing responsibilities under such plan or coverage, with respect to such selected drug, by substituting an amount not more than the maximum fair price negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-sharing would have otherwise applied, and such cost-sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and

''(3) the Secretary shall apply the provisions of such part E to such plan, issuer, and coverage, such individuals so enrolled in such plans and coverage, and such hospitals, physicians, and other providers and suppliers participating in such plans and coverage.

''(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR PRICE NEGOTIATION PROGRAM.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan or issuer to not participate in the Fair Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan or coverage before the beginning of the plan year for which such election was made.''.

(B) ERISA.—

(i) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181 et. seq.) is amended by adding at the end the following new section:

''SEC. 716. FAIR PRICE NEGOTIATION PROGRAM AND APPLICATION OF MAXIMUM FAIR PRICES.

''(a) IN GENERAL.—In the case of a group health plan or health insurance issuer offering group health insurance coverage that is treated under section 1197 of the Social Security Act as having in effect an agreement with the Secretary under the Fair Price Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period with respect to which coverage is provided under such plan or coverage—

''(1) the provisions of such part shall apply, as applicable—

''(A) if coverage of such selected drug is provided under such plan or coverage if the drug is furnished or dispensed at a pharmacy or by a mail order service, to the plans or coverage offered by such plan or issuer, and to the individuals enrolled under such plans or coverage, during such period, with respect to such selected drug, in the same manner as such provisions apply to prescription drug plans and MA–PD plans, and to individuals enrolled under such prescription drug plans and MA–PD plans during such period; and

''(B) if coverage of such selected drug is provided under such plan or coverage if the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the plans or coverage offered by such plan or issuers, to the individuals enrolled under such plans or coverage, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary, to individuals entitled to benefits under part A of title XVIII or enrolled under

part B of such title, and to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period;

''(2) the plan or issuer shall apply any cost-sharing responsibilities under such plan or coverage, with respect to such selected drug, by substituting an amount not more than the maximum fair price negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-sharing would have otherwise applied, and such cost-sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and

''(3) the Secretary shall apply the provisions of such part E to such plan, issuer, and coverage, and such individuals so enrolled in such plans.

''(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR PRICE NEGOTIATION PROGRAM.—A group health plan or a health insurance issuer offering group health insurance coverage shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan or issuer to not participate in the Fair Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan or coverage before the beginning of the plan year for which such election was made.''.

(ii) APPLICATION TO RETIREE AND CERTAIN SMALL GROUP HEALTH PLANS.—Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 716''.

(iii) CLERICAL AMENDMENT.—The table of sections for subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following:

''Sec. 716. Fair Price Negotiation Program and application of maximum fair prices.''.

(C) IRC.—

(i) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

''SEC. 9816. FAIR PRICE NEGOTIATION PROGRAM AND APPLICATION OF MAXIMUM FAIR PRICES.

''(a) IN GENERAL.—In the case of a group health plan that is treated under section 1197 of the Social Security Act as having in effect an agreement with the Secretary under the Fair Price Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period with respect to which coverage is provided under such plan—

''(1) the provisions of such part shall apply, as applicable—

''(A) if coverage of such selected drug is provided under such plan if the drug is furnished or dispensed at a pharmacy or by a mail order service, to the plan, and to the individuals enrolled under such plan during such period, with respect to such selected drug, in the same manner as such provisions apply to prescription drug plans and MA–PD plans, and to individuals enrolled under such prescription drug plans and MA–PD plans during such period; and

''(B) if coverage of such selected drug is provided under such plan if the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the plan, to the individuals enrolled under such plan, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary, to individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, and to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period;

''(2) the plan shall apply any cost-sharing responsibilities under such plan, with respect to such selected drug, by substituting an amount not more than the maximum fair price negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-sharing would have otherwise applied, and such cost-sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and

''(3) the Secretary shall apply the provisions of such part E to such plan and such individuals so enrolled in such plan.

''(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR PRICE NEGOTIATION PROGRAM.—A group health plan shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan to not participate in the Fair Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan before the beginning of the plan year for which such election was made.''.

(ii) APPLICATION TO RETIREE AND CERTAIN SMALL GROUP HEALTH PLANS.—Section 9831(a)(2) of the Internal Revenue Code of 1986 is amended by inserting ''other than with respect to section 9816,'' before ''any group health plan''.

(iii) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of such Code is amended by adding at the end the following new item:

''Sec. 9816. Fair Price Negotiation Program and application of maximum fair prices.''.

(3) FAIR PRICE NEGOTIATION PROGRAM PRICES INCLUDED IN BEST PRICE AND AMP.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(A) in subsection (c)(1)(C)(ii)—

(i) in subclause (III), by striking at the end ''; and'';

(ii) in subclause (IV), by striking at the end the period and inserting ''; and''; and

(iii) by adding at the end the following new subclause:

''(V) in the case of a rebate period and a covered outpatient drug that is a selected drug (as defined in section 1192(c)) during such rebate period, shall be inclusive of the price for such drug made available from the manufacturer during the rebate period by reason of application of part E of title XI to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States.''; and

(B) in subsection (k)(1)(B), by adding at the end the following new clause:

''(iii) CLARIFICATION.—Notwithstanding clause (i), in the case of a rebate period and a covered outpatient drug that is a selected drug (as defined in section 1192(c)) during such rebate period, any reduction in price paid during the rebate period to the manufacturer for the drug by a wholesaler or retail community pharmacy described in subparagraph (A) by reason of application of part E of title XI shall be included in the average manufacturer price for the covered outpatient drug.''.

SEC. 102. SELECTED DRUG MANUFACTURER EXCISE TAX IMPOSED DURING NONCOMPLIANCE PERIODS.

(a) IN GENERAL.—Subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

''SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE PERIODS.

''(a) IN GENERAL.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any selected drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of—

''(1) such tax, divided by

''(2) the sum of such tax and the price for which so sold.

''(b) NONCOMPLIANCE PERIODS.—A day is described in this subsection with respect to a selected drug if it is a day during one of the following periods:

''(1) The period beginning on the June 16th immediately following the selected drug publication date and ending on the first date during which the manufacturer of the drug has in place an agreement described in subsection (a) of section 1193 of the Social Security Act with respect to such drug.

''(2) The period beginning on the April 1st immediately following the June 16th described in paragraph (1) and ending on the first date during which the manufacturer of the drug has agreed to a maximum fair price under such agreement.

''(3) In the case of a selected drug with respect to which the Secretary of Health and Human Services has specified a renegotiation period under such agreement, the period beginning on the first date after the last date of such renegotiation period and ending on the first date during which the manufacturer of the drug has agreed to a renegotiated maximum fair price under such agreement.

''(4) With respect to information that is required to be submitted to the Secretary of Health and Human Services under such agreement, the period beginning on the date on which such Secretary certifies that such information is overdue and ending on the date that such information is so submitted.

''(5) In the case of a selected drug with respect to which a payment is due under subsection (c) of such section 1193, the period beginning on the date on which the Secretary of Health and Human Services certifies that such payment is overdue and ending on the date that such payment is made in full.

''(c) APPLICABLE PERCENTAGE.—For purposes of this section, the term 'applicable percentage' means—

''(1) in the case of sales of a selected drug during the first 90 days described in subsection (b) with respect to such drug, 65 percent,

''(2) in the case of sales of such drug during the 91st day through the 180th day described in subsection (b) with respect to such drug, 75 percent,

''(3) in the case of sales of such drug during the 181st day through the 270th day described in subsection (b) with respect to such drug, 85 percent, and

''(4) in the case of sales of such drug during any subsequent day, 95 percent.

''(d) SELECTED DRUG.—For purposes of this section—

''(1) IN GENERAL.—The term 'selected drug' means any selected drug (within the meaning of section 1192 of the Social Security Act) which is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing.

''(2) UNITED STATES.—The term 'United States' has the meaning given such term by section 4612(a)(4).

''(3) COORDINATION WITH RULES FOR POSSESSIONS OF THE UNITED STATES.—Rules similar to the rules of paragraphs (2) and (4) of section 4132(c) shall apply for purposes of this section.

''(e) OTHER DEFINITIONS.—For purposes of this section, the terms 'selected drug publication date' and 'maximum fair price' have the meaning given such terms in section 1191 of the Social Security Act.

''(f) ANTI-ABUSE RULE.—In the case of a sale which was timed for the purpose of avoiding the tax imposed by this section, the Secretary may treat such sale as occurring during a day described in subsection (b).''.

(b) NO DEDUCTION FOR EXCISE TAX PAYMENTS.—Section 275 of the Internal Revenue Code of 1986 is amended by adding ''or by section 4192'' before the period at the end of subsection (a)(6).

(c) CONFORMING AMENDMENTS.—

(1) Section 4221(a) of the Internal Revenue Code of 1986 is amended by inserting ''or 4192'' after ''section 4191''.

(2) Section 6416(b)(2) of such Code is amended by inserting ''or 4192'' after ''section 4191''.

(d) CLERICAL AMENDMENTS.—

(1) The heading of subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by striking ''**Medical Devices**'' and inserting ''**Other Medical Products**''.

(2) The table of subchapters for chapter 32 of such Code is amended by striking the item relating to subchapter E and inserting the following new item:

''SUBCHAPTER E. OTHER MEDICAL PRODUCTS''.

(3) The table of sections for subchapter E of chapter 32 of such Code is amended by adding at the end the following new item:

''Sec. 4192. Selected drugs during noncompliance periods.''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to sales after the date of the enactment of this Act.

SEC. 103. FAIR PRICE NEGOTIATION IMPLEMENTATION FUND.

(a) IN GENERAL.—There is hereby established a Fair Price Negotiation Implementation Fund (referred to in this section as the ''Fund''). The Secretary of Health and Human Services may obligate and expend amounts in the Fund to carry out this title and titles II and III (and the amendments made by such titles).

(b) FUNDING.—There is authorized to be appropriated, and there is hereby appropriated, out of any monies in the Treasury not otherwise appropriated, to the Fund $3,000,000,000, to remain available until expended, of which—

(1) $600,000,000 shall become available on the date of the enactment of this Act;

(2) $600,000,000 shall become available on October 1, 2020;

(3) $600,000,000 shall become available on October 1, 2021;

(4) $600,000,000 shall become available on October 1, 2022; and

(5) $600,000,000 shall become available on October 1, 2023.

(c) SUPPLEMENT NOT SUPPLANT.—Any amounts appropriated pursuant to this section shall be in addition to any other amounts otherwise appropriated pursuant to any other provision of law.

TITLE II—MEDICARE PARTS B AND D PRESCRIPTION DRUG INFLATION REBATES

SEC. 201. MEDICARE PART B REBATE BY MANUFACTURERS.

(a) IN GENERAL.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

''(x) REBATE BY MANUFACTURERS FOR SINGLE SOURCE DRUGS WITH PRICES INCREASING FASTER THAN INFLATION.—

''(1) REQUIREMENTS.—

''(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 6 months after the end of each calendar quarter beginning on or after July 1, 2021, the Secretary shall, for each part B rebatable drug, report to each manufacturer of such part B rebatable drug the following for such calendar quarter:

''(i) Information on the total number of units of the billing and payment code described in subparagraph (A)(i) of paragraph (3) with respect to such drug and calendar quarter.

''(ii) Information on the amount (if any) of the excess average sales price increase described in subparagraph (A)(ii) of such paragraph for such drug and calendar quarter.

''(iii) The rebate amount specified under such paragraph for such part B rebatable drug and calendar quarter.

''(B) MANUFACTURER REQUIREMENT.—For each calendar quarter beginning on or after July 1, 2021, the manufacturer of a part B rebatable drug shall, for such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such calendar quarter, provide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such calendar quarter.

''(2) PART B REBATABLE DRUG DEFINED.—

''(A) IN GENERAL.—In this subsection, the term 'part B rebatable drug' means a single source drug or biological (as defined in subparagraph (D) of section 1847A(c)(6)), including a biosimilar biological product (as defined in subparagraph (H) of such section), paid for under this part, except such term shall not include such a drug or biological—

''(i) if the average total allowed charges for a year per individual that uses such a drug or biological, as determined by the Secretary, are less than, subject to subparagraph (B), $100; or

''(ii) that is a vaccine described in subparagraph (A) or (B) of section 1861(s)(10).

''(B) INCREASE.—The dollar amount applied under subparagraph (A)(i)—

''(i) for 2022, shall be the dollar amount specified under such subparagraph for 2021, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12 month period ending with June of the previous year; and

''(ii) for a subsequent year, shall be the dollar amount specified in this clause (or clause (i)) for the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12 month period ending with June of the previous year.

Any dollar amount specified under this subparagraph that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(3) REBATE AMOUNT.—

''(A) IN GENERAL.—For purposes of paragraph (1), the amount specified in this paragraph for a part B rebatable drug assigned to a billing and payment code for a calendar quarter is, subject to paragraph (4), the amount equal to the product of—

''(i) subject to subparagraphs (B) and (G), the total number of units of the billing and payment code for such part B rebatable drug furnished under this part during the calendar quarter; and

''(ii) the amount (if any) by which—

''(I) the payment amount under subparagraph (B) or (C) of section 1847A(b)(1), as applicable, for such part B rebatable drug during the calendar quarter; exceeds

''(II) the inflation-adjusted payment amount determined under subparagraph (C) for such part B rebatable drug during the calendar quarter.

''(B) EXCLUDED UNITS.—For purposes of subparagraph (A)(i), the total number of units of the billing and payment code for each part B rebatable drug furnished during a calendar quarter shall not include—

''(i) units packaged into the payment for a procedure or service under section 1833(t) or under section 1833(i) (instead of separately payable under such respective section);

''(ii) units included under the single payment system for renal dialysis services under section 1881(b)(14); or

''(iii) units of a part B rebatable drug of a manufacturer furnished to an individual, if such manufacturer, with respect to the furnishing of such units of such drug, provides for discounts under section 340B of the Public Health Service Act or for rebates under section 1927.

''(C) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this subparagraph for a part B rebatable drug for a calendar quarter is—

''(i) the payment amount for the billing and payment code for such drug in the payment amount benchmark quarter (as defined in subparagraph (D)); increased by

''(ii) the percentage by which the rebate period CPI–U (as defined in subparagraph (F)) for the calendar quarter exceeds the benchmark period CPI–U (as defined in subparagraph (E)).

''(D) PAYMENT AMOUNT BENCHMARK QUARTER.—The term 'payment amount benchmark quarter' means the calendar quarter beginning January 1, 2016.

''(E) BENCHMARK PERIOD CPI–U.—The term 'benchmark period CPI–U' means the consumer price index for all urban consumers (United States city average) for July 2015.

''(F) REBATE PERIOD CPI–U.—The term 'rebate period CPI–U' means, with respect to a calendar quarter described in subparagraph (C), the greater of the benchmark period CPI–U and the consumer price index for all urban consumers (United States city average) for the first month of the calendar quarter that is two calendar quarters prior to such described calendar quarter.

''(G) COUNTING UNITS.—

''(i) CUT-OFF PERIOD TO COUNT UNITS.—For purposes of subparagraph (A)(i), subject to clause (ii), to count the total number of billing units for a part B rebatable drug for a quarter, the Secretary may use a cut-off period in order to exclude from such total number of billing units for such quarter claims for services furnished during such quarter that were not processed at an appropriate time prior to the end of the cut-off period.

''(ii) COUNTING UNITS FOR CLAIMS PROCESSED AFTER CUT-OFF PERIOD.—If the Secretary uses a cut-off period pursuant to clause (i), in the case of units of a part B rebatable drug furnished during a quarter but pursuant to application of such cut-off period excluded for purposes of subparagraph (A)(i) from the total number of billing units for the drug for such quarter, the Secretary shall count such units of such drug so furnished in the total number of billing units for such drug for a subsequent quarter, as the Secretary determines appropriate.

''(4) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

''(A) SUBSEQUENTLY APPROVED DRUGS.—Subject to subparagraph (B), in the case of a part B rebatable drug first approved or licensed by the Food and Drug Administration after July 1, 2015, clause (i) of paragraph (3)(C) shall be applied as if the term 'payment amount benchmark quarter' were defined under paragraph (3)(D) as the third full calendar quarter after the day on which the drug was first marketed and clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (3)(E) as if the reference to 'July 2015' under such paragraph were a reference to 'the first month of the first full calendar quarter after the day on which the drug was first marketed'.

''(B) TIMELINE FOR PROVISION OF REBATES FOR SUBSEQUENTLY APPROVED DRUGS.—In the case of a part B rebatable drug first approved or licensed by the Food and Drug Administration after July 1, 2015, paragraph (1)(B) shall be applied as if the reference to 'July 1, 2021' under such paragraph were a reference to the later of the 6th full calendar quarter after the day on which the drug was first marketed or July 1, 2021.

''(C) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate amount under paragraph (1)(B) with respect to a part B rebatable drug that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act or in the case of other exigent circumstances, as determined by the Secretary.

''(D) SELECTED DRUGS.—In the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c)) for a price applicability period (as defined in section 1191(b)(2))—

''(i) for calendar quarters during such period for which a maximum fair price (as defined in section 1191(c)(2)) for such drug has been determined and is applied under part E of title XI,

the rebate amount under paragraph (1)(B) shall be waived; and

''(ii) in the case such drug is determined (pursuant to such section 1192(c)) to no longer be a selected drug, for each applicable year beginning after the price applicability period with respect to such drug, clause (i) of paragraph (3)(C) shall be applied as if the term 'payment amount benchmark quarter' were defined under paragraph (3)(D) as the calendar quarter beginning January 1 of the last year beginning during such price applicability period with respect to such selected drug and clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (3)(E) as if the reference to 'July 2015' under such paragraph were a reference to the July of the year preceding such last year.

''(5) APPLICATION TO BENEFICIARY COINSURANCE.—In the case of a part B rebatable drug, if the payment amount for a quarter exceeds the inflation adjusted payment for such quarter—

''(A) in computing the amount of any coinsurance applicable under this title to an individual with respect to such drug, the computation of such coinsurance shall be based on the inflation-adjusted payment amount determined under paragraph (3)(C) for such part B rebatable drug; and

''(B) the amount of such coinsurance is equal to 20 percent of such inflation-adjusted payment amount so determined.

''(6) REBATE DEPOSITS.—Amounts paid as rebates under paragraph (1)(B) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(7) CIVIL MONEY PENALTY.—If a manufacturer of a part B rebatable drug has failed to comply with the requirements under paragraph (1)(B) for such drug for a calendar quarter, the manufacturer shall be subject to, in accordance with a process established by the Secretary pursuant to regulations, a civil money penalty in an amount equal to at least 125 percent of the amount specified in paragraph (3) for such drug for such calendar quarter. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(8) STUDY AND REPORT.—

''(A) STUDY.—The Secretary shall conduct a study of the feasibility of and operational issues involved with the following:

''(i) Including multiple source drugs (as defined in section 1847A(c)(6)(C)) in the rebate system under this subsection.

''(ii) Including drugs and biologicals paid for under MA plans under part C in the rebate system under this subsection.

''(iii) Including drugs excluded under paragraph (2)(A) and units of the billing and payment code of the drugs excluded under paragraph (3)(B) in the rebate system under this subsection.

''(B) REPORT.—Not later than 3 years after the date of the enactment of this subsection, the Secretary shall submit to Congress a report on the study conducted under subparagraph (A).

''(9) APPLICATION TO MULTIPLE SOURCE DRUGS.—The Secretary may, based on the report submitted under paragraph (8) and pursuant to rulemaking, apply the provisions of this subsection to multiple source drugs (as defined in section 1847A(c)(6)(C)), including, for purposes of determining the rebate amount under paragraph (3), by calculating manufacturer-specific average sales prices for the benchmark period and the rebate period.''.

(b) AMOUNTS PAYABLE; COST-SHARING.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (S), by striking ''with respect to'' and inserting ''subject to subparagraph (DD), with respect to'';

(ii) by striking ''and (CC)'' and inserting ''(CC)''; and

(iii) by inserting before the semicolon at the end the following: '', and (DD) with respect to a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) for which the payment amount for a calendar quarter under paragraph (3)(A)(ii)(I) of such section for such quarter exceeds the inflation-adjusted payment under paragraph (3)(A)(ii)(II) of such section for such quarter, the amounts paid shall be the difference between (i) the payment amount under paragraph (3)(A)(ii)(I) of such section for such drug, and (ii) 20 percent of the inflation-adjusted payment amount under paragraph (3)(A)(ii)(II) of such section for such drug'';

(B) by adding at the end of the flush left matter following paragraph (9), the following: ''For purposes of applying paragraph (1)(DD), subsections (i)(9) and (t)(8)(F), and section 1834(x)(5), the Secretary shall make such estimates and use such data as the Secretary determines appropriate, and notwithstanding any other provision of law, may do so by program instruction or otherwise.'';

(2) in subsection (i), by adding at the end the following new paragraph:

''(9) In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) for which payment under this subsection is not packaged into a payment for a covered OPD service (as defined in subsection (t)(1)(B)) (or group of services) furnished on or after July 1, 2021, under the system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1834(x)(5), paragraph (1)(DD) of subsection (a), and the flush left matter following paragraph (9) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1834(x)(5) and subsection (a) apply under such section and subsection.''; and

(3) in subsection (t)(8), by adding at the end the following new subparagraph:

''(F) PART B REBATABLE DRUGS.—In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) for which payment under this part is not packaged into a payment for a service furnished on or after July 1, 2021, under the system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1834(x)(5), paragraph (1)(DD) of subsection (a), and the flush left matter following paragraph (9) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1834(x)(5) and subsection (a) apply under such section and subsection.''.

(c) CONFORMING AMENDMENTS.—

(1) TO PART B ASP CALCULATION.—Section 1847A(c)(3) of the Social Security Act (42 U.S.C. 1395w–3a(c)(3)) is amended by inserting ''or section 1834(x)'' after ''section 1927''.

(2) EXCLUDING PARTS B DRUG INFLATION REBATE FROM BEST PRICE.—Section 1927(c)(1)(C)(ii)(I) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by inserting ''or section 1834(x)'' after ''this section''.

(3) COORDINATION WITH MEDICAID REBATE INFORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)(i)) is amended by striking ''or to carry out section 1847B'' and inserting ''to carry out section 1847B or section 1834(x)''.

SEC. 202. MEDICARE PART D REBATE BY MANUFACTURERS.

(a) IN GENERAL.—Part D of title XVIII of the Social Security Act is amended by inserting after section 1860D–14A (42 U.S.C. 1395w–114a) the following new section:

''SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN DRUGS WITH PRICES INCREASING FASTER THAN INFLATION.

''(a) IN GENERAL.—

''(1) IN GENERAL.—Subject to the provisions of this section, in order for coverage to be available under this part for a part D rebatable drug (as defined in subsection (h)(1)) of a manufacturer (as defined in section 1927(k)(5)) dispensed during an applicable year, the manufacturer must have entered into and have in effect an agreement described in subsection (b).

''(2) AUTHORIZING COVERAGE FOR DRUGS NOT COVERED UNDER AGREEMENTS.—Paragraph (1) shall not apply to the dispensing of a covered part D drug if—

''(A) the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries under this part; or

''(B) the Secretary determines that in the period beginning on January 1, 2022, and ending on December 31, 2022, there were extenuating circumstances.

''(3) APPLICABLE YEAR.—For purposes of this section the term 'applicable year' means a year beginning with 2022.

''(b) AGREEMENTS.—

''(1) TERMS OF AGREEMENT.—An agreement described in this subsection, with respect to a manufacturer of a part D rebatable drug, is an agreement under which the following shall apply:

''(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 9 months after the end of each applicable year with respect to which the agreement is in effect, the Secretary, for each part D rebatable drug of the manufacturer, shall report to the manufacturer the following for such year:

''(i) Information on the total number of units (as defined in subsection (h)(2)) for each dosage form and strength with respect to such part D rebatable drug and year.

''(ii) Information on the amount (if any) of the excess average manufacturer price increase described in subsection (c)(1)(B) for each dosage form and strength with respect to such drug and year.

''(iii) The rebate amount specified under subsection (c) for each dosage form and strength with respect to such drug and year.

''(B) MANUFACTURER REQUIREMENTS.—For each applicable year with respect to which the agreement is in effect, the manufacturer of the part D rebatable drug, for each dosage form and strength with respect to such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such year, shall provide to the Secretary a rebate that is equal to the amount specified in subsection (c) for such dosage form and strength with respect to such drug for such year.

''(2) LENGTH OF AGREEMENT.—

''(A) IN GENERAL.—An agreement under this section, with respect to a part D rebatable drug, shall be effective for an initial period of not less than one year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

''(B) TERMINATION.—

''(i) BY SECRETARY.—The Secretary may provide for termination of an agreement under this section for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

''(ii) BY A MANUFACTURER.—A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

''(I) if the termination occurs before January 30 of the plan year, as of the day after the end of the plan year; and

''(II) if the termination occurs on or after January 30 of the plan year, as of the day after the end of the succeeding plan year.

''(C) EFFECTIVENESS OF TERMINATION.—Any termination under this paragraph shall not affect rebates due under the agreement under this section before the effective date of its termination.

''(D) DELAY BEFORE REENTRY.—In the case of any agreement under this section with a manufacturer that is terminated in a plan year, the Secretary may not enter into another such agreement with the manufacturer (or a successor manufacturer) before the subsequent plan year, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

''(c) REBATE AMOUNT.—

''(1) IN GENERAL.—For purposes of this section, the amount specified in this subsection for a dosage form and strength with respect to a part D rebatable drug and applicable year is, subject to subparagraphs (B) and (C) of paragraph (5), the amount equal to the product of—

''(A) the total number of units of such dosage form and strength with respect to such part D rebatable drug and year; and

''(B) the amount (if any) by which—

''(i) the annual manufacturer price (as determined in paragraph (2)) paid for such dosage form and strength with respect to such part D rebatable drug for the year; exceeds

''(ii) the inflation-adjusted payment amount determined under paragraph (3) for such dosage form and strength with respect to such part D rebatable drug for the year.

''(2) DETERMINATION OF ANNUAL MANUFACTURER PRICE.—The annual manufacturer price determined under this paragraph for a dosage form and strength, with respect to a part D rebatable drug and an applicable year, is the sum of the products of—

''(A) the average manufacturer price (as defined in subsection (h)(6)) of such dosage form and strength, as calculated for a unit of such drug, with respect to each of the calendar quarters of such year; and

''(B) the ratio of—

''(i) the total number of units of such dosage form and strength dispensed during each such calendar quarter of such year; to

''(ii) the total number of units of such dosage form and strength dispensed during such year.

''(3) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this paragraph for a dosage form and strength with respect to a part D rebatable drug for an applicable year, subject to subparagraphs (A) and (D) of paragraph (5), is—

''(A) the benchmark year manufacturer price determined under paragraph (4) for such dosage form and strength with respect to such drug and an applicable year; increased by

''(B) the percentage by which the applicable year CPI–U (as defined in subsection (h)(5)) for the applicable year exceeds the benchmark period CPI–U (as defined in subsection (h)(4)).

''(4) DETERMINATION OF BENCHMARK YEAR MANUFACTURER PRICE.—The benchmark year manufacturer price determined under this paragraph for a dosage form and strength, with respect to a part D rebatable drug and an applicable year, is the sum of the products of—

''(A) the average manufacturer price (as defined in subsection (h)(6)) of such dosage form and strength, as calculated for a unit of such drug, with respect to each of the calendar quarters of the payment amount benchmark year (as defined in subsection (h)(3)); and

''(B) the ratio of—

''(i) the total number of units of such dosage form and strength dispensed during each such calendar quarter of such payment amount benchmark year; to

''(ii) the total number of units of such dosage form and strength dispensed during such payment amount benchmark year.

''(5) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

''(A) SUBSEQUENTLY APPROVED DRUGS.—In the case of a part D rebatable drug first approved or licensed by the Food and Drug Administration after January 1, 2016, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term 'payment amount benchmark year' were defined under subsection (h)(3) as the first calendar year beginning after the day on which the drug was first marketed by any manufacturer and subparagraph (B) of paragraph (3) shall be applied as if the term 'benchmark period CPI–U' were defined under subsection (h)(4) as if the reference to 'January 2016' under such subsection were a reference to 'January of the first year beginning after the date on which the drug was first marketed by any manufacturer'.

''(B) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate under paragraph (1) with respect to a part D rebatable drug that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act or in the case of other exigent circumstances, as determined by the Secretary.

''(C) TREATMENT OF NEW FORMULATIONS.—

''(i) IN GENERAL.—In the case of a part D rebatable drug that is a line extension of a part D rebatable drug that is an oral solid dosage form, the Secretary shall establish a formula for determining the amount specified in this subsection with respect to such part D rebatable drug and an applicable year with consideration of the original part D rebatable drug.

''(ii) LINE EXTENSION DEFINED.—In this subparagraph, the term 'line extension' means, with respect to a part D rebatable drug, a new formulation of the drug (as determined by the Secretary), such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.

''(D) SELECTED DRUGS.—In the case of a part D rebatable drug that is a selected drug (as defined in section 1192(c)) for a price applicability period (as defined in section 1191(b)(2))—

''(i) for plan years during such period for which a maximum fair price (as defined in section 1191(c)(2)) for such drug has been determined and is applied under part E of title XI, the rebate under subsection (b)(1)(B) shall be waived; and

''(ii) in the case such drug is determined (pursuant to such section 1192(c)) to no longer be a selected drug, for each applicable year beginning after the price applicability period with respect to such drug, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term 'payment amount benchmark year' were defined under subsection (h)(3) as the last year beginning during such price applicability period with respect to such selected drug and subparagraph (B) of paragraph (3) shall be applied as if the term 'benchmark period CPI–U' were defined under subsection (h)(4) as if the reference to 'January 2016' under such subsection were a reference to January of the last year beginning during such price applicability period with respect to such drug.

''(d) REBATE DEPOSITS.—Amounts paid as rebates under subsection (c) shall be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(e) INFORMATION.—For purposes of carrying out this section, the Secretary shall use information submitted by manufacturers under section 1927(b)(3).

''(f) CIVIL MONEY PENALTY.—In the case of a manufacturer of a part D rebatable drug with an agreement in effect under this section who has failed to comply with the terms of the agreement under subsection (b)(1)(B) with respect to such drug for an applicable year, the Secretary may impose a civil money penalty on such manufacturer in an amount equal to 125 percent of the amount specified in subsection (c) for such drug for such year. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(g) JUDICIAL REVIEW.—There shall be no judicial review of the following:

''(1) The determination of units under this section.

''(2) The determination of whether a drug is a part D rebatable drug under this section.

''(3) The calculation of the rebate amount under this section.

''(h) DEFINITIONS.—In this section:

''(1) PART D REBATABLE DRUG DEFINED.—

''(A) IN GENERAL.—The term 'part D rebatable drug' means a drug or biological that would (without application of this section) be a covered part D drug, except such term shall, with respect to an applicable year, not include such a drug or biological if the average annual total cost under this part for such year per individual who uses such a drug or biological, as determined by the Secretary, is less than, subject to subparagraph (B), $100, as determined by the Secretary using the most recent data available or, if data is not available, as estimated by the Secretary.

''(B) INCREASE.—The dollar amount applied under subparagraph (A)—

''(i) for 2023, shall be the dollar amount specified under such subparagraph for 2022, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period beginning with January of 2022; and

''(ii) for a subsequent year, shall be the dollar amount specified in this subparagraph for the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period beginning with January of the previous year.

Any dollar amount specified under this subparagraph that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(2) UNIT DEFINED.—The term 'unit' means, with respect to a part D rebatable drug, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the part D rebatable drug that is dispensed to individuals under this part.

''(3) PAYMENT AMOUNT BENCHMARK YEAR.—The term 'payment amount benchmark year' means the year beginning January 1, 2016.

''(4) BENCHMARK PERIOD CPI–U.—The term 'benchmark period CPI–U' means the consumer price index for all urban consumers (United States city average) for January 2016.

''(5) APPLICABLE YEAR CPI–U.—The term 'applicable year CPI–U' means, with respect to an applicable year, the consumer price index for all urban consumers (United States city average) for January of such year.

''(6) AVERAGE MANUFACTURER PRICE.—The term 'average manufacturer price' has the meaning, with respect to a part D rebatable drug of a manufacturer, given such term in section 1927(k)(1), with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927.''.

(b) CONFORMING AMENDMENTS.—

(1) TO PART B ASP CALCULATION.—Section 1847A(c)(3) of the Social Security Act (42 U.S.C. 1395w–3a(c)(3)), as amended by section 201(c)(1), is further amended by striking ''section 1927 or section 1834(x)'' and inserting ''section 1927, section 1834(x), or section 1860D–14B''.

(2) EXCLUDING PART D DRUG INFLATION REBATE FROM BEST PRICE.—Section 1927(c)(1)(C)(ii)(I) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by section 201(c)(2), is further amended by striking ''or section 1834(x)'' and inserting '', section 1834(x), or section 1860D–14B''.

(3) COORDINATION WITH MEDICAID REBATE INFORMATION DISCLOSURE.—Section

1927(b)(3)(D)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)(i)), as amended by section 201(c)(3), is further amended by striking ''or section 1834(x)'' and inserting '', section 1834(x), or section 1860D–14B''.

SEC. 203. PROVISION REGARDING INFLATION REBATES FOR GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.

(a) IN GENERAL.—Not later than December 31, 2021, the Secretary of Labor, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, shall submit to Congress a report on—

(1) potential models for an agreement process with manufacturers of prescription drugs under which such manufacturers provide for inflation rebates with respect to such drugs that are furnished or dispensed to participants and beneficiaries of group health plans and health insurance coverage offered in the group market in a manner similar to how manufacturers provide for rebates under section 1834(x) of the Social Security Act, as added by section 201, and section 1860D–14B of such Act, as added by section 202, with respect to prescription drugs that are furnished or dispensed under part B of title XVIII of such Act and part D of such title, respectively; and

(2) potential models for enforcement mechanisms with respect to such an agreement process that ensure that such inflation rebates are proportionally distributed, with respect to costs, to group health plans and health insurance issuers offering health insurance coverage in the group market, to participants and beneficiaries of such plans and coverage, or to both.

(b) REGULATIONS.—Not later than December 31, 2022, the Secretary of Labor shall, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, promulgate regulations to implement a model described in subsection (a)(1) and a model described in subsection (a)(2), if the Secretary determines that—

(1) the process of a sufficient number (as determined by the Secretary) of drugs described in subsection (a)(1) have increased over a period of time (as determined by the Secretary) at a percentage that exceeds the percentage by which the consumer price index for all urban consumers (United States city average) has increased over such period; and

(2) such model described in subsection (a)(1) and such model described in subsection (a)(2) are feasible.

SEC. 204. ANNUAL REPORT ON DRUG COSTS IN GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.

(a) INITIAL REPORT.—Not later than December 31, 2021, the Secretary of Labor shall, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, submit to Congress a report, with respect to a period (as determined by the Secretary of Labor), on—

(1) whether the prices of prescription drugs that are furnished or dispensed to participants and beneficiaries of group health plans and health insurance coverage offered in the group market during such period have increased at a percentage that exceeds the percentage by which the consumer price index for all urban consumers (United States city average) increased for such period; and

(2) whether there are mechanisms by which manufacturers of prescription drugs have attempted to recover rebate payments required of such manufacturers under section 1834(x) of the Social Security Act, as added by section 201, and section 1860D–14B of such Act, as added by section 202, with respect to prescription drugs that are furnished or dispensed under part B of title XVIII of such Act and part D of such title, respectively, through increased prices charged with respect to drugs that are furnished or dispensed to participants and beneficiaries of group health plans and health insurance coverage offered in the group market during such period.

(b) ANNUAL REPORT.—Not later than December 31 of each year following 2021, the Secretary of Labor shall, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, submit to Congress a report updating the information and analysis included in the report required under subsection (a), reflecting, in part, new price and cost information and data for the 12-month period after the period on which the prior year's report was based.

SEC. 205. COLLECTION OF DATA.

(a) MANUFACTURERS OF PRESCRIPTION DRUGS.—Manufacturers of prescription drugs shall submit to the Secretary of Health and Human Services, Secretary of Labor, and the Secretary of the Treasury appropriate data as necessary for the Secretaries to obtain information needed to provide the reports under sections 203 and 204.

(b) GROUP HEALTH PLANS AND HEALTH INSURANCE ISSUERS OFFERING HEALTH INSURANCE COVERAGE IN THE GROUP MARKET.—Group health plans and health insurance issuers offering health insurance coverage in the group market shall submit to the Secretary of Health and Human Services, Secretary of Labor, and the Secretary of the Treasury appropriate data as necessary for the Secretaries to obtain information needed to provide the reports under sections 203 and 204.

TITLE III—PART D IMPROVEMENTS AND MAXIMUM OUT-OF-POCKET CAP FOR MEDICARE BENEFICIARIES

SEC. 301. MEDICARE PART D BENEFIT REDESIGN.

(a) BENEFIT STRUCTURE REDESIGN.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–102(b)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A), in the matter preceding clause (i), by inserting ''for a year preceding 2022 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2022 and each subsequent year'' after ''paragraph (3)'';

(B) in subparagraph (C)—

(i) in clause (i), in the matter preceding subclause (I), by inserting ''for a year preceding 2022,'' after ''paragraph (4),''; and

(ii) in clause (ii)(III), by striking ''and each subsequent year'' and inserting ''and 2021''; and

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by inserting ''for a year preceding 2022,'' after ''paragraph (4),''; and

(II) in subclause (I)(bb), by striking ''a year after 2018'' and inserting ''each of years 2018 through 2021''; and

(ii) in clause (ii)(V), by striking ''2019 and each subsequent year'' and inserting ''each of years 2019 through 2021'';

(2) in paragraph (3)(A)—

(A) in the matter preceding clause (i), by inserting ''for a year preceding 2022,'' after ''and (4),''; and

(B) in clause (ii), by striking ''for a subsequent year'' and inserting ''for each of years 2007 through 2021''; and

(3) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i)—

(I) by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively, and moving the margin of each such redesignated item 2 ems to the right;

(II) in the matter preceding item (aa), as redesignated by subclause (I), by striking ''is equal to the greater of—'' and inserting ''is equal to—

''(I) for a year preceding 2022, the greater of—'';

(III) by striking the period at the end of item (bb), as redesignated by subclause (I), and inserting ''; and''; and

(IV) by adding at the end the following:

''(II) for 2022 and each succeeding year, $0.''; and

(ii) in clause (ii), by striking ''clause (i)(I)'' and inserting ''clause (i)(I)(aa)'';

(B) in subparagraph (B)—

(i) in clause (i)—

(I) in subclause (V), by striking ''or'' at the end;

(II) in subclause (VI)—

(aa) by striking ''for a subsequent year'' and inserting ''for 2021''; and

(bb) by striking the period at the end and inserting a semicolon; and

(III) by adding at the end the following new subclauses:

''(VII) for 2022, is equal to $2,000; or

''(VIII) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.''; and

(ii) in clause (ii), by striking ''clause (i)(II)'' and inserting ''clause (i)'';

(C) in subparagraph (C)(i), by striking ''and for amounts'' and inserting ''and, for a year preceding 2022, for amounts''; and

(D) in subparagraph (E), by striking ''In applying'' and inserting ''For each of years 2011 through 2021, in applying''.

(b) DECREASING REINSURANCE PAYMENT AMOUNT.—Section 1860D–15(b)(1) of the Social Security Act (42 U.S.C. 1395w–115(b)(1)) is amended by inserting after ''80 percent'' the following: ''(or, with respect to a coverage year after 2021, 20 percent)''.

(c) MANUFACTURER DISCOUNT PROGRAM.—

(1) IN GENERAL.—Part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–101 et seq.), as amended by section 202, is further amended by inserting after section 1860D–14B the following new section:

''SEC. 1860D–14C. MANUFACTURER DISCOUNT PROGRAM.

''(a) ESTABLISHMENT.—The Secretary shall establish a manufacturer discount program (in this section referred to as the 'program'). Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c). The Secretary shall establish a model agreement for use under the program by not later than January 1, 2021, in consultation with manufacturers, and allow for comment on such model agreement.

''(b) TERMS OF AGREEMENT.—

''(1) IN GENERAL.—

''(A) AGREEMENT.—An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer that are dispensed on or after January 1, 2022.

''(B) PROVISION OF DISCOUNTED PRICES AT THE POINT-OF-SALE.—The discounted prices described in subparagraph (A) shall be provided to the applicable beneficiary at the pharmacy or by the mail order service at the point-of-sale of an applicable drug.

''(C) TIMING OF AGREEMENT.—

''(i) SPECIAL RULE FOR 2022.—In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2022, and ending on December 31, 2022, the manufacturer shall enter into such agreement not later than 30 days after the date of the establishment of a model agreement under subsection (a).

''(ii) 2023 AND SUBSEQUENT YEARS.—In order for an agreement with a manufacturer to be in effect under this section with respect to plan year 2023 or a subsequent plan year, the manufacturer shall enter into such agreement (or such agreement shall be renewed under paragraph (4)(A)) not later than January 30 of the preceding year.

''(2) PROVISION OF APPROPRIATE DATA.—Each manufacturer with an agreement in effect under

this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.

''(3) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination under subparagraph (A) of subsection (c)(1) or procedures established under such subsection (c)(1).

''(4) LENGTH OF AGREEMENT.—

''(A) IN GENERAL.—An agreement under this section shall be effective for an initial period of not less than 12 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

''(B) TERMINATION.—

''(i) BY THE SECRETARY.—The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

''(ii) BY A MANUFACTURER.—A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

''(I) if the termination occurs before January 30 of a plan year, as of the day after the end of the plan year; and

''(II) if the termination occurs on or after January 30 of a plan year, as of the day after the end of the succeeding plan year.

''(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.

''(iv) NOTICE TO THIRD PARTY.—The Secretary shall provide notice of such termination to a third party with a contract under subsection (d)(3) within not less than 30 days before the effective date of such termination.

''(c) DUTIES DESCRIBED.—The duties described in this subsection are the following:

''(1) ADMINISTRATION OF PROGRAM.—Administering the program, including—

''(A) the determination of the amount of the discounted price of an applicable drug of a manufacturer;

''(B) the establishment of procedures under which discounted prices are provided to applicable beneficiaries at pharmacies or by mail order service at the point-of-sale of an applicable drug;

''(C) the establishment of procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

''(i) the negotiated price of the applicable drug; and

''(ii) the discounted price of the applicable drug;

''(D) the establishment of procedures to ensure that the discounted price for an applicable drug under this section is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as the Secretary may specify; and

''(E) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the third party with a contract under subsection (d)(3).

''(2) MONITORING COMPLIANCE.—

''(A) IN GENERAL.—The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under this section.

''(B) NOTIFICATION.—If a third party with a contract under subsection (d)(3) determines that the manufacturer is not in compliance with such agreement, the third party shall notify the Secretary of such noncompliance for appropriate enforcement under subsection (e).

''(3) COLLECTION OF DATA FROM PRESCRIPTION DRUG PLANS AND MA–PD PLANS.—The Secretary may collect appropriate data from prescription drug plans and MA–PD plans in a timeframe that allows for discounted prices to be provided for applicable drugs under this section.

''(d) ADMINISTRATION.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall provide for the implementation of this section, including the performance of the duties described in subsection (c).

''(2) LIMITATION.—In providing for the implementation of this section, the Secretary shall not receive or distribute any funds of a manufacturer under the program.

''(3) CONTRACT WITH THIRD PARTIES.—The Secretary shall enter into a contract with 1 or more third parties to administer the requirements established by the Secretary in order to carry out this section. At a minimum, the contract with a third party under the preceding sentence shall require that the third party—

''(A) receive and transmit information between the Secretary, manufacturers, and other individuals or entities the Secretary determines appropriate;

''(B) receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under agreements under this section;

''(C) provide adequate and timely information to manufacturers, consistent with the agreement with the manufacturer under this section, as necessary for the manufacturer to fulfill its obligations under this section; and

''(D) permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the third party to determine discounts for applicable drugs of the manufacturer under the program.

''(4) PERFORMANCE REQUIREMENTS.—The Secretary shall establish performance requirements for a third party with a contract under paragraph (3) and safeguards to protect the independence and integrity of the activities carried out by the third party under the program under this section.

''(5) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement the program under this section by program instruction or otherwise.

''(6) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the program under this section.

''(e) ENFORCEMENT.—

''(1) AUDITS.—Each manufacturer with an agreement in effect under this section shall be subject to periodic audit by the Secretary.

''(2) CIVIL MONEY PENALTY.—

''(A) IN GENERAL.—The Secretary may impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with such agreement for each such failure in an amount the Secretary determines is equal to the sum of—

''(i) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and

''(ii) 25 percent of such amount.

''(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(f) CLARIFICATION REGARDING AVAILABILITY OF OTHER COVERED PART D DRUGS.—Nothing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not an applicable drug (including a generic drug or a drug that is not on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in).

''(g) DEFINITIONS.—In this section:

''(1) APPLICABLE BENEFICIARY.—The term 'applicable beneficiary' means an individual who, on the date of dispensing a covered part D drug—

''(A) is enrolled in a prescription drug plan or an MA–PD plan;

''(B) is not enrolled in a qualified retiree prescription drug plan; and

''(C) has incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that exceed the annual deductible with respect to such individual for such year, as specified in section 1860D–2(b)(1), section 1860D–14(a)(1)(B), or section 1860D–14(a)(2)(B), as applicable.

''(2) APPLICABLE DRUG.—The term 'applicable drug', with respect to an applicable beneficiary—

''(A) means a covered part D drug—

''(i) approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act; and

''(ii)(I) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

''(II) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

''(III) is provided through an exception or appeal; and

''(B) does not include a selected drug (as defined in section 1192(c)) during a price applicability period (as defined in section 1191(b)(2)) with respect to such drug.

''(3) APPLICABLE NUMBER OF CALENDAR DAYS.—The term 'applicable number of calendar days' means—

''(A) with respect to claims for reimbursement submitted electronically, 14 days; and

''(B) with respect to claims for reimbursement submitted otherwise, 30 days.

''(4) DISCOUNTED PRICE.—

''(A) IN GENERAL.—The term 'discounted price' means, with respect to an applicable drug of a manufacturer dispensed during a year to an applicable beneficiary—

''(i) who has not incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year, 90 percent of the negotiated price of such drug; and

''(ii) who has incurred such costs, as so determined, in the year that are equal to or exceed such threshold for the year, 70 percent of the negotiated price of such drug.

''(B) CLARIFICATION.—Nothing in this section shall be construed as affecting the responsibility of an applicable beneficiary for payment of a dispensing fee for an applicable drug.

''(C) SPECIAL CASE FOR CERTAIN CLAIMS.—

''(i) CLAIMS SPANNING DEDUCTIBLE.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary

does not fall above the annual deductible specified in section 1860D–2(b)(1) for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls above such annual deductible.

''(ii) CLAIMS SPANNING OUT-OF-POCKET THRESHOLD.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall entirely below or entirely above the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year, the manufacturer of the applicable drug shall provide the discounted price—

''(I) in accordance with subparagraph (A)(i) on the portion of the negotiated price of the applicable drug that falls below such threshold; and

''(II) in accordance with subparagraph (A)(ii) on the portion of such price of such drug that falls at or above such threshold.

''(5) MANUFACTURER.—The term 'manufacturer' means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

''(6) NEGOTIATED PRICE.—The term 'negotiated price' has the meaning given such term in section 423.100 of title 42, Code of Federal Regulations (or any successor regulation), except that, with respect to an applicable drug, such negotiated price shall not include any dispensing fee for the applicable drug.

''(7) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—The term 'qualified retiree prescription drug plan' has the meaning given such term in section 1860D–22(a)(2).''.

(2) SUNSET OF MEDICARE COVERAGE GAP DISCOUNT PROGRAM.—Section 1860D–14A of the Social Security Act (42 U.S.C. 1395–114a) is amended—

(A) in subsection (a), in the first sentence, by striking ''The Secretary'' and inserting ''Subject to subsection (h), the Secretary''; and

(B) by adding at the end the following new subsection:

''(h) SUNSET OF PROGRAM.—

''(1) IN GENERAL.—The program shall not apply with respect to applicable drugs dispensed on or after January 1, 2022, and, subject to paragraph (2), agreements under this section shall be terminated as of such date.

''(2) CONTINUED APPLICATION FOR APPLICABLE DRUGS DISPENSED PRIOR TO SUNSET.—The provisions of this section (including all responsibilities and duties) shall continue to apply after January 1, 2022, with respect to applicable drugs dispensed prior to such date.''.

(3) INCLUSION OF ACTUARIAL VALUE OF MANUFACTURER DISCOUNTS IN BIDS.—Section 1860D–11 of the Social Security Act (42 U.S.C. 1395w–111) is amended—

(A) in subsection (b)(2)(C)(iii)—

(i) by striking ''assumptions regarding the reinsurance'' and inserting ''assumptions regarding—

''(I) the reinsurance''; and

(ii) by adding at the end the following:

''(II) for 2022 and each subsequent year, the manufacturer discounts provided under section 1860D–14C subtracted from the actuarial value to produce such bid; and''; and

(B) in subsection (c)(1)(C)—

(i) by striking ''an actuarial valuation of the reinsurance'' and inserting ''an actuarial valuation of—

''(i) the reinsurance'';

(ii) in clause (i), as inserted by clause (i) of this subparagraph, by adding ''and'' at the end; and

(iii) by adding at the end the following:

''(ii) for 2022 and each subsequent year, the manufacturer discounts provided under section 1860D–14C;''.

(d) CONFORMING AMENDMENTS.—

(1) Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102) is amended—

(A) in subsection (a)(2)(A)(i)(I), by striking '', or an increase in the initial'' and inserting ''or, for a year preceding 2022, an increase in the initial'';

(B) in subsection (c)(1)(C)—

(i) in the subparagraph heading, by striking ''AT INITIAL COVERAGE LIMIT''; and

(ii) by inserting ''for a year preceding 2022 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2022 and each subsequent year'' after ''subsection (b)(3) for the year'' each place it appears; and

(C) in subsection (d)(1)(A), by striking ''or an initial'' and inserting ''or, for a year preceding 2022, an initial''.

(2) Section 1860D–4(a)(4)(B)(i) of the Social Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is amended by striking ''the initial'' and inserting ''for a year preceding 2022, the initial''.

(3) Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (C), by striking ''The continuation'' and inserting ''For a year preceding 2022, the continuation'';

(ii) in subparagraph (D)(iii), by striking ''1860D–2(b)(4)(A)(i)(I)'' and inserting ''1860D–2(b)(4)(A)(i)(I)(aa)''; and

(iii) in subparagraph (E), by striking ''The elimination'' and inserting ''For a year preceding 2022, the elimination''; and

(B) in paragraph (2)—

(i) in subparagraph (C), by striking ''The continuation'' and inserting ''For a year preceding 2022, the continuation''; and

(ii) in subparagraph (E), by striking ''1860D–2(b)(4)(A)(i)(I)'' and inserting ''1860D–2(b)(4)(A)(i)(I)(aa)''.

(4) Section 1860D–21(d)(7) of the Social Security Act (42 U.S.C. 1395w–131(d)(7)) is amended by striking ''section 1860D–2(b)(4)(B)(i)'' and inserting ''section 1860D–2(b)(4)(C)(i)''.

(5) Section 1860D–22(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w–132(a)(2)(A)) is amended—

(A) by striking ''the value of any discount'' and inserting the following: ''the value of—

''(i) for years prior to 2022, any discount'';

(B) in clause (i), as inserted by subparagraph (A) of this paragraph, by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following new clause:

''(ii) for 2022 and each subsequent year, any discount provided pursuant to section 1860D–14C.''.

(6) Section 1860D–41(a)(6) of the Social Security Act (42 U.S.C. 1395w–151(a)(6)) is amended—

(A) by inserting ''for a year before 2022'' after ''1860D–2(b)(3)''; and

(B) by inserting ''for such year'' before the period.

(7) Section 1860D–43 of the Social Security Act (42 U.S.C. 1395w–153) is amended—

(A) in subsection (a)—

(i) by striking paragraph (1) and inserting the following:

''(1) participate in—

''(A) for 2011 through 2021, the Medicare coverage gap discount program under section 1860D–14A; and

''(B) for 2022 and each subsequent year, the manufacturer discount program under section 1860D–14C;'';

(ii) by striking paragraph (2) and inserting the following:

''(2) have entered into and have in effect—

''(A) for 2011 through 2021, an agreement described in subsection (b) of section 1860D–14A with the Secretary; and

''(B) for 2022 and each subsequent year, an agreement described in subsection (b) of section 1860D–14C with the Secretary; and''; and

(iii) by striking paragraph (3) and inserting the following:

''(3) have entered into and have in effect, under terms and conditions specified by the Secretary—

''(A) for 2011 through 2021, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of section 1860D–14A; and

''(B) for 2022 and each subsequent year, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of section 1860D–14C.''; and

(B) by striking subsection (b) and inserting the following:

''(b) EFFECTIVE DATE.—Paragraphs (1)(A), (2)(A), and (3)(A) of subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011, and before January 1, 2022, and paragraphs (1)(B), (2)(B), and (3)(B) of such subsection shall apply to covered part D drugs dispensed under this part on or after January 1, 2022.''.

(8) Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(A) in subsection (c)(1)(C)(i)(VI), by inserting before the period at the end the following: ''or under the manufacturer discount program under section 1860D–14C''; and

(B) in subsection (k)(1)(B)(i)(V), by inserting before the period at the end the following: ''or under section 1860D–14C''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan year 2022 and subsequent plan years.

SEC. 302. ALLOWING CERTAIN ENROLLEES OF PRESCRIPTION DRUGS PLANS AND MA–PD PLANS UNDER MEDICARE PROGRAM TO SPREAD OUT COST-SHARING UNDER CERTAIN CIRCUMSTANCES.

Section 1860D–2(b)(2) of the Social Security Act (42 U.S.C. 1395w–102(b)(2)), as amended by section 301, is further amended—

(1) in subparagraph (A), by striking ''Subject to subparagraphs (C) and (D)'' and inserting ''Subject to subparagraphs (C), (D), and (E)''; and

(2) by adding at the end the following new subparagraph:

''(E) ENROLLEE OPTION REGARDING SPREADING COST-SHARING.—The Secretary shall establish by regulation a process under which, with respect to plan year 2022 and subsequent plan years, a prescription drug plan or an MA–PD plan shall, in the case of a part D eligible individual enrolled with such plan for such plan year who is not a subsidy eligible individual (as defined in section 1860D–14(a)(3)) and with respect to whom the plan projects that the dispensing of the first fill of a covered part D drug to such individual will result in the individual incurring costs that are equal to or above the annual out-of-pocket threshold specified in paragraph (4)(B) for such plan year, provide such individual with the option to make the coinsurance payment required under subparagraph (A) (for the portion of such costs that are not above such annual out-of-pocket threshold) in the form of periodic installments over the remainder of such plan year.''.

SEC. 303. ESTABLISHMENT OF PHARMACY QUALITY MEASURES UNDER MEDICARE PART D.

Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended—

(1) by redesignating the paragraph (6), as added by section 50354 of division E of the Bipartisan Budget Act of 2018 (Public Law 115–123), as paragraph (7); and

(2) by adding at the end the following new paragraph:

''(8) APPLICATION OF PHARMACY QUALITY MEASURES.—

''(A) IN GENERAL.—A PDP sponsor that implements incentive payments to a pharmacy or

price concessions paid by a pharmacy based on quality measures shall use measures established or approved by the Secretary under subparagraph (B) with respect to payment for covered part D drugs dispensed by such pharmacy.

''(B) STANDARD PHARMACY QUALITY MEASURES.—The Secretary shall establish or approve standard quality measures from a consensus and evidence-based organization for payments described in subparagraph (A). Such measures shall focus on patient health outcomes and be based on proven criteria measuring pharmacy performance.

''(C) EFFECTIVE DATE.—The requirement under subparagraph (A) shall take effect for plan years beginning on or after January 1, 2021, or such earlier date specified by the Secretary if the Secretary determines there are sufficient measures established or approved under subparagraph (B) to meet the requirement under subparagraph (A).''.

TITLE IV—DRUG PRICE TRANSPARENCY

SEC. 401. DRUG PRICE TRANSPARENCY.

Part A of title XI of the Social Security Act is amended by adding at the end the following new sections:

''SEC. 1150C. REPORTING ON DRUG PRICES.

''(a) DEFINITIONS.—In this section:

''(1) MANUFACTURER.—The term 'manufacturer' means the person—

''(A) that holds the application for a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act; or

''(B) who is responsible for setting the wholesale acquisition cost for the drug.

''(2) QUALIFYING DRUG.—The term 'qualifying drug' means any drug that is approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act—

''(A) that has a wholesale acquisition cost of $100 or more, adjusted for inflation occurring after the date of enactment of this section, for a month's supply or a typical course of treatment that lasts less than a month, and is—

''(i) subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act; and

''(ii) not a preventative vaccine; and

''(B) for which, during the previous calendar year, at least 1 dollar of the total amount of sales were for individuals enrolled under the Medicare program under title XVIII or under a State Medicaid plan under title XIX or under a waiver of such plan.

''(3) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given that term in section 1847A(c)(6)(B).

''(b) REPORT.—

''(1) REPORT REQUIRED.—The manufacturer of a qualifying drug shall submit a report to the Secretary if, with respect to the qualifying drug—

''(A) there is an increase in the price of the qualifying drug that results in an increase in the wholesale acquisition cost of that drug that is equal to—

''(i) 10 percent or more within a 12-month period beginning on or after January 1, 2019; or

''(ii) 25 percent or more within a 36-month period beginning on or after January 1, 2019;

''(B) the estimated price of the qualifying drug or spending per individual or per user of such drug (as estimated by the Secretary) for the applicable year (or per course of treatment in such applicable year as determined by the Secretary) is at least $26,000 beginning on or after January 1, 2021; or

''(C) there was an increase in the price of the qualifying drug that resulted in an increase in the wholesale acquisition cost of that drug that is equal to—

''(i) 10 percent or more within a 12-month period that begins and ends during the 5-year period preceding January 1, 2021; or

''(ii) 25 percent or more within a 36-month period that begins and ends during the 5-year period preceding January 1, 2021.

''(2) REPORT DEADLINE.—Each report described in paragraph (1) shall be submitted to the Secretary—

''(A) in the case of a report with respect to an increase in the price of a qualifying drug that occurs during the period beginning on January 1, 2019, and ending on the day that is 60 days after the date of the enactment of this section, not later than 90 days after such date of enactment;

''(B) in the case of a report with respect to an increase in the price of a qualifying drug that occurs after the period described in subparagraph (A), not later than 30 days prior to the planned effective date of such price increase for such qualifying drug;

''(C) in the case of a report with respect to a qualifying drug that meets the criteria under paragraph (1)(B), not later than 30 days after such drug meets such criteria; and

''(D) in the case of a report with respect to an increase in the price of a qualifying drug that occurs during a 12-month or 36-month period described in paragraph (1)(C), not later than April 1, 2021.

''(c) CONTENTS.—A report under subsection (b), consistent with the standard for disclosures described in section 213.3(d) of title 12, Code of Federal Regulations (as in effect on the date of enactment of this section), shall, at a minimum, include—

''(1) with respect to the qualifying drug—

''(A) the percentage by which the manufacturer will raise the wholesale acquisition cost of the drug within the 12-month period or 36-month period as described in subsection (b)(1)(A)(i), (b)(1)(A)(ii), (b)(1)(C)(i), or (b)(1)(C)(ii), as applicable, and the effective date of such price increase or the cost associated with a qualifying drug if such drug meets the criteria under subsection (b)(1)(B) and the effective date at which such drug meets such criteria;

''(B) an explanation for, and description of, each price increase for such drug that will occur during the 12-month period or the 36-month period described in subsection (b)(1)(A)(i), (b)(1)(A)(ii), (b)(1)(C)(i), or (b)(1)(C)(ii), as applicable;

''(C) an explanation for, and description of, the cost associated with a qualifying drug if such drug meets the criteria under subsection (b)(1)(B), as applicable;

''(D) if known and different from the manufacturer of the qualifying drug, the identity of—

''(i) the sponsor or sponsors of any investigational new drug applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act for clinical investigations with respect to such drug, for which the full reports are submitted as part of the application—

''(I) for approval of the drug under section 505 of such Act; or

''(II) for licensure of the drug under section 351 of the Pubic Health Service Act; and

''(ii) the sponsor of an application for the drug approved under such section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act;

''(E) a description of the history of the manufacturer's price increases for the drug since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351 of the Public Health Service Act, or since the manufacturer acquired such approved application or license, if applicable;

''(F) the current wholesale acquisition cost of the drug;

''(G) the total expenditures of the manufacturer on—

''(i) materials and manufacturing for such drug;

''(ii) acquiring patents and licensing for such drug; and

''(iii) purchasing or acquiring such drug from another manufacturer, if applicable;

''(H) the percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds;

''(I) the total expenditures of the manufacturer on research and development for such drug that is necessary to demonstrate that it meets applicable statutory standards for approval under section 505 of the Federal Food, Drug, and Cosmetic Act or licensure under section 351 of the Public Health Service Act, as applicable;

''(J) the total expenditures of the manufacturer on pursuing new or expanded indications or dosage changes for such drug under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;

''(K) the total expenditures of the manufacturer on carrying out postmarket requirements related to such drug, including under section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act;

''(L) the total revenue and the net profit generated from the qualifying drug for each calendar year since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351 of the Public Health Service Act, or since the manufacturer acquired such approved application or license; and

''(M) the total costs associated with marketing and advertising for the qualifying drug;

''(2) with respect to the manufacturer—

''(A) the total revenue and the net profit of the manufacturer for each of the 12-month period described in subsection (b)(1)(A)(i) or (b)(1)(C)(i) or the 36-month period described in subsection (b)(1)(A)(ii) or (b)(1)(C)(ii), as applicable;

''(B) all stock-based performance metrics used by the manufacturer to determine executive compensation for each of the 12-month periods described in subsection (b)(1)(A)(i) or (b)(1)(C)(i) or the 36-month periods described in subsection (b)(1)(A)(ii) or (b)(1)(C)(ii), as applicable; and

''(C) any additional information the manufacturer chooses to provide related to drug pricing decisions, such as total expenditures on—

''(i) drug research and development; or

''(ii) clinical trials, including on drugs that failed to receive approval by the Food and Drug Administration; and

''(3) such other related information as the Secretary considers appropriate and as specified by the Secretary.

''(d) INFORMATION PROVIDED.—The manufacturer of a qualifying drug that is required to submit a report under subsection (b), shall ensure that such report and any explanation for, and description of, each price increase described in subsection (c)(1) shall be truthful, not misleading, and accurate.

''(e) CIVIL MONETARY PENALTY.—Any manufacturer of a qualifying drug that fails to submit a report for the drug as required by this section, following notification by the Secretary to the manufacturer that the manufacturer is not in compliance with this section, shall be subject to a civil monetary penalty of $75,000 for each day on which the violation continues.

''(f) FALSE INFORMATION.—Any manufacturer that submits a report for a drug as required by this section that knowingly provides false information in such report is subject to a civil monetary penalty in an amount not to exceed $100,000 for each item of false information.

''(g) PUBLIC POSTING.—

''(1) IN GENERAL.—Subject to paragraph (4), the Secretary shall post each report submitted under subsection (b) on the public website of the Department of Health and Human Services the day the price increase of a qualifying drug is scheduled to go into effect.

''(2) FORMAT.—In developing the format in which reports will be publicly posted under paragraph (1), the Secretary shall consult with stakeholders, including beneficiary groups, and

shall seek feedback from consumer advocates and readability experts on the format and presentation of the content of such reports to ensure that such reports are—

''(A) user-friendly to the public; and

''(B) written in plain language that consumers can readily understand.

''(3) LIST.—In addition to the reports submitted under subsection (b), the Secretary shall also post a list of each qualifying drug with respect to which the manufacturer was required to submit such a report in the preceding year and whether such manufacturer was required to submit such report based on a qualifying price increase or whether such drug meets the criteria under subsection (b)(1)(B).

''(4) PROTECTED INFORMATION.—In carrying out this section, the Secretary shall enforce applicable law concerning the protection of confidential commercial information and trade secrets.

''SEC. 1150D. ANNUAL REPORT TO CONGRESS.

''(a) IN GENERAL.—Subject to subsection (b), the Secretary shall submit to the Committees on Energy and Commerce and Ways and Means of the House of Representatives and the Committees on Health, Education, Labor, and Pensions and Finance of the Senate, and post on the public website of the Department of Health and Human Services in a way that is user-friendly to the public and written in plain language that consumers can readily understand, an annual report—

''(1) summarizing the information reported pursuant to section 1150C;

''(2) including copies of the reports and supporting detailed economic analyses submitted pursuant to such section;

''(3) detailing the costs and expenditures incurred by the Department of Health and Human Services in carrying out section 1150C; and

''(4) explaining how the Department of Health and Human Services is improving consumer and provider information about drug value and drug price transparency.

''(b) PROTECTED INFORMATION.—In carrying out this section, the Secretary shall enforce applicable law concerning the protection of confidential commercial information and trade secrets.''.

TITLE V—PROGRAM IMPROVEMENTS FOR MEDICARE LOW-INCOME BENEFICIARIES

SEC. 501. DISSEMINATION TO MEDICARE PART D SUBSIDY ELIGIBLE INDIVIDUALS OF INFORMATION COMPARING PREMIUMS OF CERTAIN PRESCRIPTION DRUG PLANS.

Section 1860D–1(c)(3) of the Social Security Act (42 U.S.C. 1395w–101(c)(3)) is amended by adding at the end the following new subparagraph:

''(C) INFORMATION ON PREMIUMS FOR SUBSIDY ELIGIBLE INDIVIDUALS.—

''(i) IN GENERAL.—For plan year 2022 and each subsequent plan year, the Secretary shall disseminate to each subsidy eligible individual (as defined in section 1860D–14(a)(3)) information under this paragraph comparing premiums that would apply to such individual for prescription drug coverage under LIS benchmark plans, including, in the case of an individual enrolled in a prescription drug plan under this part, information that compares the premium that would apply if such individual were to remain enrolled in such plan to premiums that would apply if the individual were to enroll in other LIS benchmark plans.

''(ii) LIS BENCHMARK PLAN.—For purposes of clause (i), the term 'LIS benchmark plan' means, with respect to an individual, a prescription drug plan under this part that is offered in the region in which the individual resides and—

''(I) that provides for a premium that is not more than the low-income benchmark premium amount (as defined in section 1860D–14(b)(2)) for such region; or

''(II) with respect to which the premium would be waived as de minimis pursuant to section 1860D–14(a)(5) for such individual.''.

SEC. 502. PROVIDING FOR INTELLIGENT ASSIGNMENT OF CERTAIN SUBSIDY ELIGIBLE INDIVIDUALS AUTO-ENROLLED UNDER MEDICARE PRESCRIPTION DRUG PLANS AND MA–PD PLANS.

(a) IN GENERAL.—Section 1860D–1(b)(1) of the Social Security Act (42 U.S.C. 1395w–101(b)(1)) is amended—

(1) in subparagraph (C)—

(A) by inserting after ''PDP region'' the following: ''or through use of an intelligent assignment process that is designed to maximize the access of such individual to necessary prescription drugs while minimizing costs to such individual and to the program under this part to the greatest extent possible. In the case the Secretary enrolls such individuals through use of an intelligent assignment process, such process shall take into account the extent to which prescription drugs necessary for the individual are covered in the case of a PDP sponsor of a prescription drug plan that uses a formulary, the use of prior authorization or other restrictions on access to coverage of such prescription drugs by such a sponsor, and the overall quality of a prescription drug plan as measured by quality ratings established by the Secretary''; and

(B) by striking ''Nothing in the previous sentence'' and inserting ''Nothing in this subparagraph''; and

(2) in subparagraph (D)—

(A) by inserting after ''PDP region'' the following: ''or through use of an intelligent assignment process that is designed to maximize the access of such individual to necessary prescription drugs while minimizing costs to such individual and to the program under this part to the greatest extent possible. In the case the Secretary enrolls such individuals through use of an intelligent assignment process, such process shall take into account the extent to which prescription drugs necessary for the individual are covered in the case of a PDP sponsor of a prescription drug plan that uses a formulary, the use of prior authorization or other restrictions on access to coverage of such prescription drugs by such a sponsor, and the overall quality of a prescription drug plan as measured by quality ratings established by the Secretary''; and

(B) by striking ''Nothing in the previous sentence'' and inserting ''Nothing in this subparagraph''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply with respect to plan years beginning with plan year 2022.

SEC. 503. EXPANDING ELIGIBILITY FOR LOW-INCOME SUBSIDIES UNDER PART D OF THE MEDICARE PROGRAM.

Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)), as amended by section 301(d), is further amended—

(1) in the subsection heading, by striking ''INDIVIDUALS'' and all that follows through ''LINE'' and inserting ''CERTAIN INDIVIDUALS'';

(2) in paragraph (1)—

(A) by striking the paragraph heading and inserting ''INDIVIDUALS WITH CERTAIN LOW INCOMES''; and

(B) in the matter preceding subparagraph (A), by inserting ''(or, with respect to a plan year beginning on or after January 1, 2022, 150 percent)'' after ''135 percent''; and

(3) in paragraph (2)—

(A) by striking the paragraph heading and inserting ''OTHER LOW-INCOME INDIVIDUALS''; and

(B) in the matter preceding subparagraph (A), by striking ''In the case of a subsidy'' and inserting ''With respect to a plan year beginning before January 1, 2022, in the case of a subsidy''.

SEC. 504. AUTOMATIC ELIGIBILITY OF CERTAIN LOW-INCOME TERRITORIAL RESIDENTS FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER THE MEDICARE PROGRAM; SUNSET OF ENHANCED ALLOTMENT PROGRAM.

(a) AUTOMATIC ELIGIBILITY OF CERTAIN LOW-INCOME TERRITORIAL RESIDENTS FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER THE MEDICARE PROGRAM.—

(1) IN GENERAL.—Section 1860D–14(a)(3) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)) is amended—

(A) in subparagraph (B)(v)—

(i) in subclause (I), by striking ''and'' at the end;

(ii) in subclause (II), by striking the period and inserting ''; and''; and

(iii) by inserting after subclause (II) the following new subclause:

''(III) with respect to plan years beginning on or after January 1, 2024, shall provide that any part D eligible individual who is enrolled for medical assistance under the State Medicaid plan of a territory (as defined in section 1935(f)) under title XIX (or a waiver of such a plan) shall be treated as a subsidy eligible individual described in paragraph (1).''; and

(B) in subparagraph (F), by adding at the end the following new sentence: ''The previous sentence shall not apply with respect to eligibility determinations for premium and cost-sharing subsidies under this section made on or after January 1, 2024.''.

(2) CONFORMING AMENDMENT.—Section 1860D–31(j)(2)(D) of the Social Security Act (42 U.S.C. 1395w–141(j)(2)(D)) is amended by adding at the end the following new sentence: ''The previous sentence shall not apply with respect to amounts made available to a State under this paragraph on or after January 1, 2024.''.

(b) SUNSET OF ENHANCED ALLOTMENT PROGRAM.—

(1) IN GENERAL.—Section 1935(e) of the Social Security Act (42 U.S.C. 1396u–5(e)) is amended—

(A) in paragraph (1)(A), by inserting after ''such State'' the following: ''before January 1, 2021''; and

(B) in paragraph (3)—

(i) in subparagraph (A), in the matter preceding clause (i), by inserting after ''a year'' the following: ''(before 2024)''; and

(ii) in subparagraph (B)(iii), by striking ''a subsequent year'' and inserting ''each of fiscal years 2008 through 2023''.

(2) TERRITORY DEFINED.—Section 1935 of the Social Security Act (42 U.S.C. 1396u–5) is amended by adding at the end the following new subsection:

''(f) TERRITORY DEFINED.—In this section, the term 'territory' means Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.''.

SEC. 505. AUTOMATIC QUALIFICATION OF CERTAIN MEDICAID BENEFICIARIES FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER PART D OF THE MEDICARE PROGRAM.

Clause (v) of section 1860D–14(a)(3)(B) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)(B)), as amended by section 504, is further amended—

(1) in subclause (II), by striking ''and'' at the end;

(2) in subclause (III), by striking the period and inserting ''; and''; and

(3) by inserting after subclause (III) the following new subclause:

''(IV) with respect to plan years beginning on or after January 1, 2024, shall, notwithstanding the preceding clauses of this subparagraph, provide that any part D eligible individual not described in subclause (I), (II), or (III) who is enrolled, as of the day before the date on which such individual attains the age of 65, for medical assistance under a State plan under title XIX (or a waiver of such plan) pursuant to clause (i)(VIII) or (ii)(XX) of section 1902(a)(10)(A), and who has income below 200 percent of the poverty line applicable to a family of the size involved, shall be treated as a subsidy eligible individual described in paragraph (1) for a limited period of time, as specified by the Secretary.''.

SEC. 506. PROVIDING FOR CERTAIN RULES REGARDING THE TREATMENT OF ELIGIBLE RETIREMENT PLANS IN DETERMINING THE ELIGIBILITY OF INDIVIDUALS FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER PART D OF THE MEDICARE PROGRAM.

Section 1860D–14(a)(3)(C)(i) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)(C)(i)) is amended, by striking ''except that support and maintenance furnished in kind shall not be counted as income; and'' and inserting ''except that—

''(I) support and maintenance furnished in kind shall not be counted as income; and

''(II) for plan years beginning on or after January 1, 2024, any distribution or withdrawal from an eligible retirement plan (as defined in subparagraph (B) of section 402(c)(8) of the Internal Revenue Code of 1986, but excluding any defined benefit plan described in clause (iv) or (v) of such subparagraph and any qualified trust (as defined in subparagraph (A) of such section) which is part of such a defined benefit plan) shall be counted as income; and''.

SEC. 507. REDUCING COST-SHARING AND OTHER PROGRAM IMPROVEMENTS FOR LOW-INCOME BENEFICIARIES.

(a) INCREASE IN INCOME ELIGIBILITY TO 150 PERCENT OF FPL FOR QUALIFIED MEDICARE BENEFICIARIES.—

(1) IN GENERAL.—Section 1905(p)(2)(A) of the Social Security Act (42 U.S.C. 1396d(p)(2)(A)) is amended by striking ''shall be at least the percent provided under subparagraph (B) (but not more than 100 percent) of the official poverty line'' and all that follows through the period at the end and inserting the following: ''shall be—

''(i) before January 1, 2022, at least the percent provided under subparagraph (B) (but not more than 100 percent) of the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved; and

''(ii) on or after January 1, 2022, equal to 150 percent of the official poverty line (as so defined and revised) applicable to a family of the size involved.''.

(2) NOT COUNTING IN-KIND SUPPORT AND MAINTENANCE AS INCOME.—Section 1905(p)(2)(D) of the Social Security Act (42 U.S.C. 1396d(p)(2)(D)) is amended by adding at the end the following new clause:

''(iii) In determining income under this subsection, support and maintenance furnished in kind, as described in section 1612(a)(2)(A), shall not be counted as income.''.

(3) CONFORMING AMENDMENTS.—

(A) Section 1902(a)(10)(E) of the Social Security Act (42 U.S.C. 1396a(a)(10)(E)) is amended—

(i) in clause (iii), by striking ''for making medical'' and inserting ''before January 1, 2022, for making medical''; and

(ii) in clause (iv), by striking ''subject to sections'' and inserting ''before January 1, 2022, subject to sections''.

(B) Section 1933 of the Social Security Act (42 U.S.C. 1396u–3) is amended—

(i) in subsection (a), by striking ''A State plan'' and inserting ''Subject to subsection (h), a State plan''; and

(ii) by adding at the end the following new subsection:

''(h) SUNSET.—The provisions of this section shall have no force or effect after December 31, 2021.''.

(b) 100 PERCENT FMAP.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended by adding at the end the following new subsection:

''(gg) INCREASED FMAP FOR EXPANDED MEDICARE COST-SHARING POPULATIONS.—

''(1) IN GENERAL.—Notwithstanding subsection (b), with respect to expenditures described in paragraph (2) the Federal medical assistance percentage shall be equal to 100 percent.

''(2) EXPENDITURES DESCRIBED.—The expenditures described in this paragraph are expenditures made on or after January 1, 2022, for medical assistance for medicare cost-sharing provided to any individual under clause (i) or (ii) of section 1902(a)(10)(E) who would not have been eligible for medicare cost-sharing under any such clause under the income or resource eligibility standards in effect on October 1, 2018.''.

TITLE VI—PROVIDING FOR DENTAL, VISION, AND HEARING COVERAGE UNDER THE MEDICARE PROGRAM

SEC. 601. DENTAL AND ORAL HEALTH CARE.

(a) COVERAGE.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—

(1) in subparagraph (GG), by striking ''and'' after the semicolon at the end;

(2) in subparagraph (HH), by striking the period at the end and adding ''; and''; and

(3) by adding at the end the following new subparagraph:

''(II) dental and oral health services (as defined in subsection (kkk));''.

(b) DENTAL AND ORAL HEALTH SERVICES DEFINED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''(kkk) DENTAL AND ORAL HEALTH SERVICES.—

''(1) IN GENERAL.—The term 'dental and oral health services' means items and services (other than such items and services for which payment may be made under part A as inpatient hospital services) that are furnished during 2025 or a subsequent year, for which coverage was not provided under part B as of the date of the enactment of this subsection, and that are—

''(A) the preventive and screening services described in paragraph (2) furnished by a doctor of dental surgery or of dental medicine (as described in subsection (r)(2)) or an oral health professional (as defined in paragraph (4)); or

''(B) the basic treatments specified for such year by the Secretary pursuant to paragraph (3)(A) and the major treatments specified for such year by the Secretary pursuant to paragraph (3)(B) furnished by such a doctor or such a professional.

''(2) PREVENTIVE AND SCREENING SERVICES.—The preventive and screening services described in this paragraph are the following:

''(A) Oral exams.

''(B) Dental cleanings.

''(C) Dental x-rays performed in the office of a doctor or professional described in paragraph (1)(A).

''(D) Fluoride treatments.

''(3) BASIC AND MAJOR TREATMENTS.—For 2025 and each subsequent year, the Secretary shall specify—

''(A) basic treatments (which may include basic tooth restorations, basic periodontic services, tooth extractions, and oral disease management services); and

''(B) major treatments (which may include major tooth restorations, major periodontic services, bridges, crowns, and root canals);

that shall be included as dental and oral health services for such year.

''(4) ORAL HEALTH PROFESSIONAL.—The term 'oral health professional' means, with respect to dental and oral health services, a health professional who is licensed to furnish such services, acting within the scope of such license, by the State in which such services are furnished.''.

(c) PAYMENT; COINSURANCE; AND LIMITATIONS.—

(1) IN GENERAL.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—

(A) in subparagraph (N), by inserting ''and dental and oral health services (as defined in section 1861(kkk))'' after ''section 1861(hhh)(1))'';

(B) by striking ''and'' before ''(CC)''; and

(C) by inserting before the semicolon at the end the following: '', and (DD) with respect to dental and oral health services (as defined in section 1861(kkk)), the amount paid shall be the payment amount specified under section 1834(x)''.

(2) PAYMENT AND LIMITS SPECIFIED.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

''(x) PAYMENT AND LIMITS FOR DENTAL AND ORAL HEALTH SERVICES.—

''(1) IN GENERAL.—The payment amount under this part for dental and oral health services (as defined in section 1861(kkk)) shall be, subject to paragraph (3), the applicable percent (specified in paragraph (2)) of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1848. In determining such amounts determined under such payment basis, the Secretary shall consider payment rates paid to dentists for comparable services under State plans under title XIX, under the TRICARE program under chapter 55 of title 10 of the United States Code, and by other health care payers, such as Medicare Advantage plans under part C.

''(2) APPLICABLE PERCENT.—For purposes of paragraph (1), the applicable percent specified in this paragraph is, with respect to dental and oral health services (as defined in section 1861(kkk)) furnished in a year—

''(A) that are preventive and screening services described in paragraph (2) or basic treatments specified for such year pursuant to paragraph (3)(A) of such section, 80 percent; and

''(B) that are major treatments specified for such year pursuant to paragraph (3)(B) of such section—

''(i) in the case such services are furnished during 2025, 10 percent;

''(ii) in the case such services are furnished during 2026 or a subsequent year before 2029, the applicable percent specified under this subparagraph for the previous year, increased by 10 percentage points; and

''(iii) in the case such services are furnished during 2029 or a subsequent year, 50 percent.

''(3) LIMITATIONS.—With respect to dental and oral health services that are—

''(A) preventive and screening oral exams, payment may be made under this part for not more than two such exams during a 12-month period;

''(B) dental cleanings, payment may be made under this part for not more than two such cleanings during a 12-month period; and

''(C) not described in subparagraph (A) or (B), payment may be made under this part only at such frequencies and under such circumstances determined appropriate by the Secretary.''.

(d) PAYMENT UNDER PHYSICIAN FEE SCHEDULE.—

(1) IN GENERAL.—Section 1848(j)(3) of the Social Security Act (42 U.S.C. 1395w–4(j)(3)) is amended by inserting ''(2)(II),'' before ''(3)''.

(2) EXCLUSION FROM MIPS.—Section 1848(q)(1)(C)(ii) of the Social Security Act (42 U.S.C. 1395w–4(q)(1)(C)(ii)) is amended—

(A) in subclause (II), by striking ''or'' at the end;

(B) in subclause (III), by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following new subclause:

''(IV) with respect to 2025 and each subsequent year, is a doctor of dental surgery or of dental medicine (as described in section 1861(r)(2)) or is an oral health professional (as defined in section 1861(kkk)(4)).''.

(3) INCLUSION OF ORAL HEALTH PROFESSIONALS AS CERTAIN PRACTITIONERS.—Section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C)) is amended by adding at the end the following new clause:

''(vii) With respect to 2025 and each subsequent year, an oral health professional (as defined in section 1861(kkk)(4)).''.

(e) DENTURES.—

(1) IN GENERAL.—Section 1861(s)(8) of the Social Security Act (42 U.S.C. 1395x(s)(8)) is amended—

(A) by striking ''(other than dental)''; and

(B) by inserting ''and excluding dental, except for a full or partial set of dentures furnished on or after January 1, 2025'' after ''colostomy care''.

(2) SPECIAL PAYMENT RULES.—

(A) LIMITATIONS.—Section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)) is amended by adding at the end the following new paragraph:

''(6) SPECIAL PAYMENT RULE FOR DENTURES.—Payment may be made under this part with respect to an individual for dentures—

''(A) not more than once during any 5-year period (except in the case that a doctor or professional described in section 1861(kkk)(1)(A) determines such dentures do not fit the individual); and

''(B) only to the extent that such dentures are furnished pursuant to a written order of such a doctor or professional.''.

(B) APPLICATION OF COMPETITIVE ACQUISITION.—

(i) IN GENERAL.—Section 1834(h)(1)(H) of the Social Security Act (42 U.S.C. 1395m(h)(1)(H)) is amended—

(I) in the subparagraph heading, by inserting '', DENTURES'' after ''ORTHOTICS'';

(II) by inserting '', of dentures described in paragraph (2)(D) of such section,'' after ''2011,''; and

(III) in clause (i), by inserting '', such dentures'' after ''orthotics''.

(ii) CONFORMING AMENDMENT.—Section 1847(a)(2) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)) is amended by adding at the end the following new subparagraph:

''(D) DENTURES.—Dentures described in section 1861(s)(8) for which payment would otherwise be made under section 1834(h).''.

(iii) EXEMPTION OF CERTAIN ITEMS FROM COMPETITIVE ACQUISITION.—Section 1847(a)(7) of the Social Security Act (42 U.S.C. 1395w–3(a)(7)) is amended by adding at the end the following new subparagraph:

''(C) CERTAIN DENTURES.—Those items and services described in paragraph (2)(D) if furnished by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service.''.

(f) EXCLUSION MODIFICATIONS.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (O), by striking ''and'' at the end;

(B) in subparagraph (P), by striking the semicolon at the end and inserting '', and''; and

(C) by adding at the end the following new subparagraph:

''(Q) in the case of dental and oral health services (as defined in section 1861(kkk)) that are preventive and screening services described in paragraph (2) of such section, which are furnished more frequently than provided under section 1834(x)(3) and under circumstances other than circumstances determined appropriate under such section;''; and

(2) in paragraph (12), by inserting before the semicolon at the end the following: ''and except that payment may be made under part B for dental and oral health services that are covered under section 1861(s)(2)(II)''.

(g) CERTAIN NON-APPLICATION.—

(1) IN GENERAL.—Paragraphs (1) and (4) of section 1839(a) of the Social Security Act (42 U.S.C. 1395r(a)) are amended by adding at the end of each such paragraphs the following: ''In applying this paragraph there shall not be taken into account benefits and administrative costs attributable to the amendments made by section 601 (other than subsection (g)) of the Elijah E. Cummings Lower Drug Costs Now Act and the Government contribution under section 1844(a)(4)''.

(2) PAYMENT.—Section 1844(a) of such Act (42 U.S.C. 1395w(a)) is amended—

(A) in paragraph (3), by striking the period at the end and inserting ''; plus''; and

(B) by adding at the end the following new paragraph:

''(4) a Government contribution equal to the amount that is estimated to be payable for benefits and related administrative costs incurred that are attributable to the amendments made by section 601 (other than subsection (g)) of the Elijah E. Cummings Lower Drug Costs Now Act.''.

(h) IMPLEMENTATION FUNDING.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the ''Secretary'') shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) to the Centers for Medicare & Medicaid Services Program Management Account of—

(A) $20,000,000 for each of fiscal years 2020 through 2025 for purposes of implementing the amendments made by this section; and

(B) such sums as determined appropriate by the Secretary for each subsequent fiscal year for purposes of administering the provisions of such amendments.

(2) AVAILABILITY AND ADDITIONAL USE OF FUNDS.—Funds transferred pursuant to paragraph (1) shall remain available until expended and may be used, in addition to the purpose specified in paragraph (1)(A), to implement the amendments made by sections 602 and 603.

SEC. 602. PROVIDING COVERAGE FOR HEARING CARE UNDER THE MEDICARE PROGRAM.

(a) PROVISION OF AURAL REHABILITATION AND TREATMENT SERVICES BY QUALIFIED AUDIOLOGISTS.—Section 1861(ll)(3) of the Social Security Act (42 U.S.C. 1395x(ll)(3)) is amended by inserting ''(and, beginning January 1, 2023, such aural rehabilitation and treatment services)'' after ''assessment services''.

(b) COVERAGE OF HEARING AIDS.—

(1) INCLUSION OF HEARING AIDS AS PROSTHETIC DEVICES.—Section 1861(s)(8) of the Social Security Act (42 U.S.C. 1395x(s)(8)) is amended by inserting '', and including hearing aids furnished on or after January 1, 2023, to individuals diagnosed with profound or severe hearing loss'' before the semicolon at the end.

(2) PAYMENT LIMITATIONS FOR HEARING AIDS.—Section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)), as amended by section 601(e)(2)(A), is further amended by adding at the end the following new paragraph:

''(7) LIMITATIONS FOR HEARING AIDS.—Payment may be made under this part with respect to an individual, with respect to hearing aids furnished on or after January 1, 2023—

''(A) not more than once during a 5-year period;

''(B) only for types of such hearing aids that are not over-the-counter hearing aids (as defined in section 520(q)(1) of the Federal Food, Drug, and Cosmetic Act) and that are determined appropriate by the Secretary; and

''(C) only if furnished pursuant to a written order of a physician or qualified audiologist (as defined in section 1861(ll)(4)(B)).''.

(3) APPLICATION OF COMPETITIVE ACQUISITION.—

(A) IN GENERAL.—Section 1834(h)(1)(H) of the Social Security Act (42 U.S.C. 1395m(h)(1)(H)), as amended by section 601(e)(2)(B)(i), is further amended—

(i) in the header, by inserting '', HEARING AIDS'' after ''DENTURES'';

(ii) by inserting '', of hearing aids described in paragraph (2)(E) of such section,'' after ''paragraph (2)(D) of such section''; and

(iii) in clause (i), by inserting '', such hearing aids'' after ''such dentures''.

(B) CONFORMING AMENDMENT.—

(i) IN GENERAL.—Section 1847(a)(2) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)), as amended by section 601(e)(2)(B)(ii), is further amended by adding at the end the following new subparagraph:

''(E) HEARING AIDS.—Hearing aids described in section 1861(s)(8) for which payment would otherwise be made under section 1834(h).''.

(ii) EXEMPTION OF CERTAIN ITEMS FROM COMPETITIVE ACQUISITION.—Section 1847(a)(7) of the Social Security Act (42 U.S.C. 1395w–3(a)(7)), as amended by section 601(e)(2)(B)(iii), is further amended by adding at the end the following new subparagraph:

''(D) CERTAIN HEARING AIDS.—Those items and services described in paragraph (2)(E) if furnished by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service.''.

(4) INCLUSION OF AUDIOLOGISTS AS CERTAIN PRACTITIONERS TO RECEIVE PAYMENT ON AN ASSIGNMENT-RELATED BASIS.—Section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C)), as amended by section 601(d)(4), is further amended by adding at the end the following new clause:

''(viii) With respect to 2023 and each subsequent year, a qualified audiologist (as defined in section 1861(ll)(4)(B)).''.

(c) EXCLUSION MODIFICATION.—Section 1862(a)(7) of the Social Security Act (42 U.S.C. 1395y(a)(7)) is amended by inserting ''(except such hearing aids or examinations therefor as described in and otherwise allowed under section 1861(s)(8))'' after ''hearing aids or examinations therefor''.

(d) CERTAIN NON-APPLICATION.—

(1) IN GENERAL.—The last sentence of section 1839(a)(1) of the Social Security Act (42 U.S.C. 1395r(a)(1)), as added by section 601(g)(1), is amended by striking ''section 601 (other than subsection (g))'' and inserting ''sections 601 (other than subsection (g)), 602 (other than subsection (d))''.

(2) PAYMENT.—Paragraph (4) of section 1844(a) of such Act (42 U.S.C. 1395w(a)), as added by section 601(g)(2), is amended by striking ''section 601 (other than subsection (g))'' and inserting ''sections 601 (other than subsection (g)), 602 (other than subsection (d))''.

(e) REPORT; REGULATIONS.—

(1) REPORT.—Not later than the date that is 3 years after the date of the enactment of this Act, the Inspector General of the Department of Health and Human Services shall conduct a study to assess (and submit to the Secretary of Health and Human Services a report on) any program integrity or overutilization risks with respect to allowing qualified audiologists (as defined in paragraph (4)(B) of 1861(ll) of the Social Security Act (42 U.S.C. 1395x(ll))) to furnish audiology services (as defined in paragraph (3) of such section) to individuals entitled to benefits under part A of title XVIII of such Act (42 U.S.C. 1395c et seq.) and enrolled for benefits under part B of such title (42 U.S.C.1395j et seq.) without such individuals being referred by a physician (as defined in section 1861(r) of such Act (42 U.S.C. 1395x(r))) or practitioner (as described in section 602.32 of title 42, Code of Federal Regulations) to such qualified audiologists. In conducting such study, the Inspector General may take into account experiences with audiologists furnishing audiology services to enrollees in other Federal programs, including in a health benefit plan under chapter 89 of title 5, United States Code or in health care benefits under the TRICARE program under chapter 55 of title 10 of the United States Code or under chapter 17 of title 38 of such Code.

(2) REGULATIONS.—The Secretary of Health and Human Services may promulgate regulations to allow qualified audiologists (as so defined) to furnish audiology services (as so defined) without a referral from a physician or practitioner, consistent with the findings submitted to the Secretary pursuant to paragraph (1)(B).

(f) IMPLEMENTATION FUNDING.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the ''Secretary'') shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) to the Centers for Medicare & Medicaid Services Program Management Account of—

(A) $20,000,000 for each of fiscal years 2020 through 2024 for purposes of implementing the amendments made by this section; and

(B) such sums as determined appropriate by the Secretary for each subsequent fiscal year for purposes of administering the provisions of such amendments.

(2) AVAILABILITY AND ADDITIONAL USE OF FUNDS.—Funds transferred pursuant to paragraph (1) shall remain available until expended and may be used, in addition to the purpose specified in paragraph (1)(A), to implement the amendments made by sections 601 and 603.

SEC. 603. PROVIDING COVERAGE FOR VISION CARE UNDER THE MEDICARE PROGRAM.

(a) COVERAGE.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)), as amended by section 601(a), is further amended—

(1) in subparagraph (HH), by striking ''and'' after the semicolon at the end;

(2) in subparagraph (II), by striking the period at the end and adding ''; and''; and

(3) by adding at the end the following new subparagraph:

''(JJ) vision services (as defined in subsection (lll));''.

(b) VISION SERVICES DEFINED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by section 601(b), is further amended by adding at the end the following new subsection:

''(lll) VISION SERVICES.—The term 'vision services' means—

''(1) routine eye examinations to determine the refractive state of the eyes, including procedures performed during the course of such examination; and

''(2) contact lens fitting services;

furnished on or after January 1, 2023, by or under the direct supervision of an optometrist or ophthalmologist who is legally authorized to furnish such examinations, procedures, or fitting services (as applicable) under State law (or the State regulatory mechanism provided by State law) of the State in which the examinations, procedures, or fitting services are furnished.''.

(c) PAYMENT LIMITATIONS.—Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by section 601(c)(2), is further amended by adding at the end the following new subsection:

''(y) LIMITATION FOR VISION SERVICES.—With respect to vision services (as defined in section 1861(lll)) and an individual, payment may be made under this part for only 1 routine eye examination described in paragraph (1) of such section and 1 contact lens fitting service described in paragraph (2) of such section during a 2-year period.''.

(d) PAYMENT UNDER PHYSICIAN FEE SCHEDULE.—Section 1848(j)(3) of the Social Security Act (42 U.S.C. 1395w–4(j)(3)), as amended by section 601(d)(1), is further amended by inserting ''(2)(JJ),'' before ''(3)''.

(e) COVERAGE OF CONVENTIONAL EYEGLASSES AND CONTACT LENSES.—Section 1861(s)(8) of the Social Security Act (42 U.S.C. 1395x(s)(8)), as amended by section 602(b)(1), is further amended by striking '', and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens'' and inserting '', including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens, if furnished before January 1, 2023, including conventional eyeglasses or contact lenses, whether or not furnished subsequent to such a surgery, if furnished on or after January 1, 2024''.

(f) SPECIAL PAYMENT RULES FOR EYEGLASSES AND CONTACT LENSES.—

(1) LIMITATIONS.—Section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)), as amended by section 601(e)(2)(A) and section 602(b)(2), is further amended by adding at the end the following new paragraph:

''(8) PAYMENT LIMITATIONS FOR EYEGLASSES AND CONTACT LENSES.—

''(A) IN GENERAL.—With respect to eyeglasses and contact lenses furnished to an individual on or after January 1, 2023, subject to subparagraph (B), payment may be made under this part only—

''(i) during a 2-year period, for either 1 pair of eyeglasses (including lenses and frames) or not more than a 2-year supply of contact lenses that is provided in not more than 180-day increments;

''(ii) with respect to amounts attributable to the lenses and frames of such a pair of eyeglasses or amounts attributable to such a 2-year supply of contact lenses, in an amount not greater than—

''(I) for a pair of eyeglasses furnished in, or a 2-year supply of contact lenses beginning in, 2023—

''(aa) $85 for the lenses of such pair of eyeglasses and $85 for the frames of such pair of eyeglasses; or

''(bb) $85 for such 2-year supply of contact lenses; and

''(II) for the lenses and frames of a pair of eyeglasses furnished in, or a 2-year supply of contact lenses beginning in, a subsequent year, the dollar amounts specified under this subparagraph for the previous year, increased by the percentage change in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

''(iii) for types of eyeglass lenses, and for types of contact lenses, as determined appropriate by the Secretary;

''(iv) if furnished pursuant to a written order of a physician described in section 1861(lll); and

''(v) if during the 2-year period described in clause (i), the individual did not already receive (as described in subparagraph (B)) one pair of conventional eyeglasses or contact lenses subsequent to a cataract surgery with insertion of an intraocular lens furnished during such period.

''(B) EXCEPTION.—With respect to a 2-year period described in subparagraph (A)(i), in the case of an individual who receives cataract surgery with insertion of an intraocular lens, notwithstanding subparagraph (A), payment may be made under this part for one pair of conventional eyeglasses or contact lenses furnished subsequent to such cataract surgery during such period.''.

(2) APPLICATION OF COMPETITIVE ACQUISITION.—

(A) IN GENERAL.—Section 1834(h)(1)(H) of the Social Security Act (42 U.S.C. 1395m(h)(1)(H)), as amended by section 601(e)(2)(B)(i) and section 602(b)(3)(A), is further amended—

(i) in the header by inserting '', EYEGLASSES, AND CONTACT LENSES'' after ''HEARING AIDS'';

(ii) by inserting ''and of eyeglasses and contact lenses described in paragraph (2)(F) of such section,'' after ''paragraph (2)(E) of such section,''; and

(iii) in clause (i), by inserting '', or such eyeglasses and contact lenses'' after ''such hearing aids''.

(B) CONFORMING AMENDMENT.—

(i) IN GENERAL.—Section 1847(a)(2) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)), as amended by section 601(e)(2)(B)(ii) and section 602(b)(3)(B)(i), is further amended by adding at the end the following new subparagraph:

''(F) EYEGLASSES AND CONTACT LENSES.—Eyeglasses and contact lenses described in section 1861(s)(8) for which payment would otherwise be made under section 1834(h).''.

(ii) EXEMPTION OF CERTAIN ITEMS FROM COMPETITIVE ACQUISITION.—Section 1847(a)(7) of the Social Security Act (42 U.S.C. 1395w–3(a)(7)), as amended by section 601(e)(2)(B)(iii) and section 602(b)(3)(B)(ii), is further amended by adding at the end the following new subparagraph:

''(E) CERTAIN EYEGLASSES AND CONTACT LENSES.—Those items and services described in paragraph (2)(F) if furnished by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service.''.

(g) EXCLUSION MODIFICATIONS.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)), as amended by section 601(f), is further amended—

(1) in paragraph (1)—

(A) in subparagraph (P), by striking ''and'' at the end;

(B) in subparagraph (Q), by striking the semicolon at the end and inserting '', and''; and

(C) by adding at the end the following new subparagraph:

''(R) in the case of vision services (as defined in section 1861(lll)) that are routine eye examinations and contact lens fitting services (as described in paragraph (1) or (2), respectively, of such section), which are furnished more frequently than once during a 2-year period;''; and

(2) in paragraph (7)—

(A) by inserting ''(other than such an examination that is a vision service that is covered under section 1861(s)(2)(JJ))'' after ''eye examinations''; and

(B) by inserting ''(other than such a procedure that is a vision service that is covered under section 1861(s)(2)(JJ))'' after ''refractive state of the eyes''.

(h) CERTAIN NON-APPLICATION.—

(1) IN GENERAL.—The last sentence of section 1839(a)(1) of the Social Security Act (42 U.S.C. 1395r(a)(1)), as added by section 601(g)(1) and amended by section 602(d)(1), is further amended by inserting '', and 603 (other than subsection (h))'' after ''602 (other than subsection (d))''.

(2) PAYMENT.—Paragraph (4) of section 1844(a) of such Act (42 U.S.C. 1395w(a)), as added by section 601(g)(2) and amended by section 602(d)(2), is further amended by inserting '', and 603 (other than subsection (h))'' after ''602 (other than subsection (d))''.

(i) IMPLEMENTATION FUNDING.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the ''Secretary'') shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) to the Centers for Medicare & Medicaid Services Program Management Account of—

(A) $20,000,000 for each of fiscal years 2020 through 2024 for purposes of implementing the amendments made by this section; and

(B) such sums as determined appropriate by the Secretary for each subsequent fiscal year for purposes of administering the provisions of such amendments.

(2) AVAILABILITY AND ADDITIONAL USE OF FUNDS.—Funds transferred pursuant to paragraph (1) shall remain available until expended and may be used, in addition to the purpose specified in paragraph (1)(A), to implement the amendments made by sections 601 and 602.

TITLE VII—NIH, FDA, AND OPIOIDS FUNDING

Subtitle A—Biomedical Innovation Expansion

SEC. 701. NIH INNOVATION INITIATIVES.

(a) NIH INNOVATION ACCOUNT.—

(1) IN GENERAL.—Section 1001(b) of the 21st Century Cures Act (Public Law 114–255) is amended by adding at the end the following:

''(5) SUPPLEMENTAL FUNDING AND ADDITIONAL ACTIVITIES.—

''(A) IN GENERAL.—In addition to the funds made available under paragraph (2), there are authorized to be appropriated, and are hereby appropriated, to the Account, out of any monies in the Treasury not otherwise appropriated, to be available until expended without further appropriation, the following:

''(i) For fiscal year 2021, $255,400,000.

''(ii) For fiscal year 2022, $260,400,000.

''(iii) For fiscal year 2023, $163,400,000.

''(iv) For fiscal year 2024, $547,000,000.

''(v) For fiscal year 2025, $848,000,000.

''(vi) For fiscal year 2026, $842,400,000.

''(vii) For fiscal year 2027, $1,089,600,000.

''(viii) For fiscal year 2028, $1,115,600,000.

''(ix) For fiscal year 2029, $1,170,600,000.

''(x) For fiscal year 2030, $1,207,600,000.

''(B) SUPPLEMENTAL FUNDING FOR CERTAIN PROJECTS.—Of the total amounts made available under subparagraph (A) for each of fiscal years 2021 through 2030, a total amount not to exceed the following shall be made available for the following categories of NIH Innovation Projects:

''(i) For projects described in paragraph (4)(A), an amount not to exceed a total of $2,070,600,000 as follows:

''(I) For each of fiscal years 2021 and 2022, $50,000,000.

''(II) For fiscal year 2024, $100,000,000.

''(III) For each of fiscal years 2025 and 2026, $300,000,000.

''(IV) For each of fiscal years 2027 through 2029, $317,000,000.

''(V) For fiscal year 2030, $319,600,000.

''(ii) For projects described in paragraph (4)(B), an amount not to exceed a total of $2,041,900,000 as follows:

''(I) For each of fiscal years 2021 and 2022, $50,000,000.

''(II) For fiscal year 2024, $128,000,000.

''(III) For fiscal year 2025, $209,000,000.

''(IV) For fiscal year 2026, $100,000,000.

''(V) For fiscal year 2027, $325,000,000.

''(VI) For fiscal year 2028, $350,000,000.

''(VII) For fiscal year 2029, $400,000,000.

''(VIII) For fiscal year 2030, $429,900,000.

''(iii) For projects described in paragraph (4)(C), an amount not to exceed a total of $1,558,400,000 as follows:

''(I) For each of fiscal years 2024 and 2025, $151,200,000.

''(II) For each of fiscal years 2026 through 2030, $251,200,000.

''(iv) For projects described in paragraph (4)(D), an amount not to exceed $15,400,000 for each of fiscal years 2021 through 2030.

''(C) ADDITIONAL NIH INNOVATION PROJECTS.—In addition to funding NIH Innovation Projects pursuant to subparagraph (B), of the total amounts made available under subparagraph (A), a total amount not to exceed the following shall be made available for the following categories of NIH Innovation Projects:

''(i) To support research related to combating antimicrobial resistance and antibiotic resistant bacteria, including research into new treatments, diagnostics, and vaccines, research, in consultation with the Centers for Disease Control and Prevention, into stewardship, and the development of strategies, in coordination with the Biomedical Advanced Research and Development Authority under section 319L of the Public Health Service Act, to support commercialization of new antibiotics, not to exceed a total of 1,144,500,000, as follows:

''(I) For each of fiscal years 2021 through 2024, $100,000,000.

''(II) For each of fiscal years 2025 and 2026, $120,000,000.

''(III) For each of fiscal years 2027 through 2029, $125,000,000.

''(IV) For fiscal year 2030, $129,500,000.

''(ii) To support research and research activities related to rare diseases or conditions, including studies or analyses that help to better understand the natural history of a rare disease or condition and translational studies related to rare diseases or conditions, not to exceed a total of $530,600,000, as follows:

''(I) For fiscal year 2021, $40,000,000.

''(II) For fiscal year 2022, $45,000,000.

''(III) For fiscal year 2023, $48,000,000.

''(IV) For each of fiscal years 2024 and 2025, $52,400,000.

''(V) For fiscal year 2026, $55,800,000.

''(VI) For fiscal year 2027, $56,000,000.

''(VII) For fiscal year 2028, $57,000,000.

''(VIII) For each of fiscal years 2029 and 2030, $62,000,000.''.

(2) CONFORMING AMENDMENTS.—Section 1001 of the 21st Century Cures Act (Public Law 114–255) is amended—

(A) in subsection (a), by striking ''subsection (b)(4)'' and inserting ''subsections (b)(4) and (b)(5)'';

(B) in subsection (b)(1), by striking ''paragraph (4)'' and inserting ''paragraphs (4) and (5)''; and

(C) in subsection (c)(2)(A)(ii), by inserting ''or pursuant to subsection (b)(5)'' after ''subsection (b)(3)''; and

(D) in subsection (d), by inserting ''or pursuant to subsection (b)(5)'' after ''subsection (b)(3)''.

(b) WORKPLAN.—Section 1001(c)(1) of the 21st Century Cures Act (Public Law 114–255) is amended by adding at the end the following:

''(D) UPDATES.—The Director of NIH shall , after seeking recommendations in accordance with the process described in subparagraph (C), update the work plan submitted under this subsection for each of fiscal years 2021 through 2030 to reflect the amendments made to this section by the Elijah E. Cummings Lower Drug Costs Now Act.''.

(c) ANNUAL REPORTS.—Section 1001(c)(2)(A) of the 21st Century Cures Act (Public Law 114–255) is amended by striking ''2027'' and inserting ''2030''.

(d) SUNSET.—Section 1001(e) of the 21st Century Cures Act (Public Law 114–255) is amended by striking ''September 30, 2026'' and inserting ''September 30, 2030''.

SEC. 702. NIH CLINICAL TRIAL.

Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

''SEC. 404O. CLINICAL TRIAL ACCELERATION PILOT INITIATIVE.

''(a) ESTABLISHMENT OF PILOT PROGRAM.—The Secretary, acting through the Director of the National Institutes of Health, shall, not later than 2 years after the date of enactment of this Act, establish and implement a pilot program to award multi-year contracts to eligible entities to support phase II clinical trials and phase III clinical trials—

''(1) to promote innovation in treatments and technologies supporting the advanced research and development and production of high need cures; and

''(2) to provide support for the development of medical products and therapies.

''(b) ELIGIBLE ENTITIES.—To be eligible to receive assistance under the pilot program established under subsection (a), an entity shall—

''(1) be seeking to market a medical product or therapy that is the subject of clinical trial or trials to be supported using such assistance;

''(2) be a public or private entity, which may include a private or public research institution, a contract research organization, an institution of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)), a medical center, a biotechnology company, or an academic research institution; and

''(3) comply with requirements of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product.

''(c) DUTIES.—The Secretary, acting through the Director of National Institutes of Health, shall—

''(1) in establishing the pilot program under subsection (a), consult with—

''(A) the Director of the National Center for Advancing Translational Sciences and the other national research institutes in considering their requests for new or expanded clinical trial support efforts; and

''(B) the Commissioner of Food and Drugs and any other head of a Federal agency as the Secretary determines to be appropriate to ensure coordination and efficiently advance clinical trial activities;

''(2) in implementing the pilot program under subsection (a), consider consulting with patients and patient advocates; and

''(3) in awarding contracts under the pilot program under subsection (a), consider—

''(A) the expected health impacts of the clinical trial or trials to be supported under the contract; and

''(B) the the degree to which the medical product or therapy that is the subject of such clinical trial or trials is a high need cure.

''(d) EXCLUSION.—A contract may not be awarded under the pilot program under subsection (a) if the drug that is the subject of the clinical trial or trials to be supported under the contract is a drug designated under section 526 of the Federal Food, Drug, and Cosmetic Act as a drug for a rare disease or condition.

''(e) NIH CLINICAL TRIAL ACCELERATOR ACCOUNT.—

''(1) ESTABLISHMENT.—There is established in the Treasury an account, to be known as the 'NIH Clinical Trial Accelerator Account' (referred to in this section as the 'Account'), for purposes of carrying out this section.

''(2) TRANSFER OF DIRECT SPENDING SAVINGS.—There shall be transferred to the Account from the general fund of the Treasury, $500,000,000 for each of fiscal years 2021 through 2025, to be available until expended without further appropriation.

''(3) WORK PLAN.—Not later than 180 days after the date of enactment of this Act, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a work plan that includes the proposed implementation of this section and the proposed allocation of funds in the Account.

''(f) REPORTS TO CONGRESS.—Not later than October 1 of each fiscal year, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on—

''(1) the implementation of this section;

''(2) any available results on phase II clinical trials and phase III clinical trials supported under this section during such fiscal year; and

''(3) the extent to which Federal funds are obligated to support such clinical trials, including the specific amount of such support and awards pursuant to an allocation from the Account under subsection (e).

''(g) DEFINITIONS.—In this section:

''(1) PHASE II CLINICAL TRIAL.—The term 'phase II clinical trial' means a phase II clinical investigation, as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

''(2) PHASE III CLINICAL TRIALS.—The term 'phase III clinical trial' means a phase III clinical investigation, as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

''(3) HIGH NEED CURE.—The term 'high need cure' has the meaning given such term in section 480(a)(3).''.

Subtitle B—Investing in Safety and Innovation

SEC. 711. FOOD AND DRUG ADMINISTRATION.

(a) FDA INNOVATION ACCOUNT.—

(1) IN GENERAL.—Section 1002(b) of the 21st Century Cures Act (Public Law 114–255) is amended—

(A) in paragraph (1), by striking ''paragraph (4)'' and inserting ''paragraphs (4) and (5)''; and

(B) by adding at the end the following new paragraph:

''(5) SUPPLEMENTAL FUNDING AND ADDITIONAL ACTIVITIES.—

''(A) IN GENERAL.—In addition to the funds made available under paragraph (2), there are authorized to be appropriated, and are hereby appropriated, to the Account, out of any monies in the Treasury not otherwise appropriated, to be available until expended without further appropriation, the following:

''(i) For fiscal year 2020, $417,500,000.

''(ii) For each of fiscal years 2021 and 2022, $157,500,000.

''(iii) For each of fiscal years 2023 through 2025, $152,500,000.

''(iv) For each of fiscal years 2026 through 2029, $202,500,000.

''(B) SUPPLEMENTAL FUNDING FOR CERTAIN ACTIVITIES.—Of the total amounts made available under subparagraph (A) for each of fiscal years 2026 through 2029, a total amount not to exceed $50,000,000 for each such fiscal year, shall be made available for the activities under subtitles A through F (including the amendments made by such subtitles) of title III of this Act and section 1014 of the Federal Food, Drug, and Cosmetic Act, as added by section 3073 of this Act.

''(C) ADDITIONAL FDA ACTIVITIES.—In addition to funding activities pursuant to subparagraph (B), of the total amounts made available under subparagraph (A), a total amount not to exceed the following shall be made available for the following categories of activities:

''(i) For modernization of the technical infrastructure of the Food and Drug Administration, including enhancements such as interoperability across the agency, and additional capabilities to develop an advanced information technology infrastructure to support the agency's regulatory mission:

''(I) For fiscal year 2020, $180,000,000.

''(II) For each of fiscal years 2021 through 2029, $60,000.

''(ii) For support for continuous manufacturing of drugs and biological products, including complex biological products such as regenerative medicine therapies, through grants to institutions of higher education and nonprofit organizations and other appropriate mechanisms, for each of fiscal years 2020 through 2029, $20,000,000.

''(iii) For support for the Commissioner of Food and Drugs to engage experts, such as through the formation and operation of public-private partnerships or other appropriate collaborative efforts, to advance the development and delivery of individualized human gene therapy products:

''(I) For fiscal year 2020, $50,000,000.

''(II) For each of fiscal years 2021 through 2029, $10,000,000.

''(iv) For support for inspections, enforcement, and quality surveillance activities across the Food and Drug Administration, including foreign and domestic inspections across products, for each of fiscal years 2020 through 2029, $20,000,000.

''(v) For support for activities of the Food and Drug Administration related to customs and border protection to provide improvements to technologies, inspection capacity, and sites of import (including international mail facilities) in which the Food and Drug Administration operates, for each of fiscal years 2020 through 2029, $10,000,000.

''(vi) To further advance the development of a coordinated postmarket surveillance system for all medical products, including drugs, biological products, and devices, linked to electronic health records in furtherance of the Food and Drug Administration's postmarket surveillance capabilities:

''(I) For fiscal year 2020, $112,500,000.

''(II) For each of fiscal years 2021 through 2029, $12,500,000.

''(vii) For support for Food and Drug Administration activities to keep pace with the projected product development of regenerative therapies, including cellular and somatic cell gene therapy products:

''(I) For each of fiscal years 2020 through 2022, $10,000,000.

''(II) For each of fiscal years 2023 through 2029, $5,000,000.

''(viii) For carrying out section 714A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d–3a; relating to hiring authority for scientific, technical, and professional personnel), for each of fiscal years 2020 through 2029, $2,500,000.

''(ix) For the Food and Drug Administration to support improvements to the technological infrastructure for reporting and analysis of adverse events associated with the use of drugs and biological products, for each of fiscal years 2020 through 2029, $12,500,000.''.

(2) CONFORMING AMENDMENTS.—Section 1002 of the 21st Century Cures Act (Public Law 114–255) is amended—

(A) in subsection (a), by inserting before the period at the end the following: ''or pursuant to subparagraph (A) of subsection (b)(5) to carry out the activities described in subparagraphs (B) and (C) of such subsection''; and

(B) in subsection (d)—

(i) by inserting ''or pursuant to subparagraph (A) of subsection (b)(5)'' after ''subsection (b)(3)''; and

(ii) by striking ''subsection (b)(4)'' and inserting ''subsections (b)(4) and (b)(5)''.

(b) ANNUAL REPORT.—Section 1002(c)(2)(A) of the 21st Century Cures Act (Public Law 114–255) is amended, in the matter preceding clause (i), by striking ''2026'' and inserting ''2030''.

(c) SUNSET.—Section 1002(e) of the 21st Century Cures Act (Public Law 114–255) is amended by striking ''September 30, 2025'' and inserting ''September 30, 2030''.

Subtitle C—Opioid Epidemic Response

SEC. 721. OPIOID EPIDEMIC RESPONSE FUND.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall use any funds made available pursuant to subsection (b) to carry out the programs and activities described in subsection (c) to address the opioid and substance use disorder epidemic. Such funds shall be in addition to any funds which are otherwise available to carry out such programs and activities.

(b) OPIOID EPIDEMIC RESPONSE FUND.—

(1) ESTABLISHMENT OF ACCOUNT.—There is established in the Treasury an account, to be known as the Opioid Epidemic Response Fund (referred to in this section as the ''Fund''), for purposes of funding the programs and activities described in subsection (c).

(2) FUNDING.—There is authorized to be appropriated, and there is appropriated, to the Fund, out of any monies in the Treasury not otherwise appropriated $1,980,000,000 for each of fiscal years 2021 through 2025.

(3) AVAILABILITY.—Amounts made available by paragraph (2) shall be made available to the agencies specified in subsection (c) in accordance with such subsection. Amounts made available to an agency pursuant to the preceding sentence for a fiscal year shall remain available until expended.

(c) PROGRAMS AND ACTIVITIES.—Of the total amount in the Fund for each of fiscal years 2021 through 2025, such amount shall be allocated as follows:

(1) SAMHSA.—For the Substance Abuse and Mental Health Services Administration to carry out programs and activities pursuant to section 722, $1,500,000,000 for each of fiscal years 2021 through 2025.

(2) CDC.—For the Centers for Disease Control and Prevention to carry out programs and activities pursuant to section 723, $120,000,000 for each of fiscal years 2021 through 2025.

(3) FDA.—For the Food and Drug Administration to carry out programs and activities pursuant to section 724, $10,000,000 for each of fiscal years 2021 through 2025.

(4) NIH.—For the National Institutes of Health to carry out programs and activities pursuant to section 725, $240,000,000 for each of fiscal years 2021 through 2025.

(5) HRSA.—For the Health Resources and Services Administration to carry out programs and activities pursuant to section 726, $90,000,000 for each of fiscal years 2021 through 2025.

(6) ACF.—For the Administration for Children and Families to carry out programs and activities pursuant to section 727, $20,000,000 for each of fiscal years 2021 through 2025.

(d) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce, the Committee on Appropriations, and the Committee on Education and Labor of the House of Representatives, a work plan including the proposed allocation of funds made available pursuant to subsection (b) for each of fiscal years 2021 through 2025 and the contents described in subparagraph (B).

(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—

(i) the amount of money to be obligated or expended out of the Fund in each fiscal year for each program and activity described in subsection (c); and

(ii) a description and justification of each such program and activity.

(2) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2022 through 2026, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce, the Committee on Appropriations, and the Committee on Education and Labor of the House of Representatives, a report including—

(A) the amount of money obligated or expended out of the Fund in the prior fiscal year for each program and activity described in subsection (c);

(B) a description of all programs and activities using funds made available pursuant to subsection (b); and

(C) how the programs and activities are responding to the opioid and substance use disorder epidemic.

(e) LIMITATIONS.—Notwithstanding any authority in this subtitle or any appropriations Act, any funds made available pursuant to subsection (b) may not be used for any purpose other than the programs and activities described in subsection (c).

SEC. 722. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.

(a) IN GENERAL.—The entirety of the funds made available pursuant to section 721(c)(1) shall be for the Assistant Secretary for Mental Health and Substance Use to continue to award the State Opioid Response Grants funded by the heading ''Substance Abuse And Mental Health Services Administration—Substance Abuse Treatment'' in title II of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2018 (Public Law 115–141). Subject to subsections (b) and (c), such grants shall be awarded in the same manner and subject to the same conditions as were applicable to such grants for fiscal year 2018.

(b) REQUIREMENT THAT TREATMENT BE EVIDENCE-BASED.—As a condition on receipt of a grant pursuant to subsection (a), a grantee shall agree that—

(1) treatments, practices, or interventions funded through the grant will be evidence-based; and

(2) such treatments, practices, and interventions will include medication-assisted treatment for individuals diagnosed with opioid use disorder, using drugs only if the drugs have been approved or licensed by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(c) RESERVATIONS.—Of the amount made available pursuant to section 731(c)(1) for a fiscal year—

(1) not less than $75,000,000 shall be reserved to make grants under subsection (a) to Indian Tribes or Tribal organizations; and

(2) not less than $50,000,000 shall be reserved to make grants under subsection (a) to political subdivisions of States, such as counties, cities, or towns.

SEC. 723. CENTERS FOR DISEASE CONTROL AND PREVENTION.

(a) ADDRESSING OPIOID USE DISORDER.—The entirety of the funds made available pursuant to section 721(c)(2) shall be for the Director of the Centers for Disease Control and Prevention, pursuant to applicable authorities in the Public Health Service Act (42 U.S.C. 201 et seq.), to continue and expand programs of the Centers for Disease Control and Prevention to address opioid and substance use disorder, including by—

(1) improving the timeliness and quality of data on the opioid use disorder epidemic, including improvement of—

(A) data on fatal and nonfatal overdoses;

(B) syndromic surveillance;

(C) data on long-term sequelae (including neonatal abstinence syndrome); and

(D) cause of death reporting related to substance abuse or opioid overdose;

(2) expanding and strengthening evidence-based prevention and education strategies;

(3) supporting responsible prescribing practices, including through development and dissemination of prescriber guidelines;

(4) improving access to and use of effective prevention, treatment, and recovery support, including through grants and the provision of technical assistance to States and localities;

(5) strengthening partnerships with first responders, including to protect their safety;

(6) considering the needs of vulnerable populations;

(7) addressing infectious diseases linked to the opioid crisis;

(8) strengthening prescription drug monitoring programs; and

(9) providing financial and technical assistance to State and local health department efforts to treat and prevent substance use disorder.

(b) LIMITATION.—Of the funds made available pursuant to section 721(c)(2) for carrying out this section, not more than 20 percent may be used for intramural purposes.

SEC. 724. FOOD AND DRUG ADMINISTRATION.

The entirety of the funds made available pursuant to section 721(c)(3) shall be for the Commissioner of Food and Drugs, pursuant to applicable authorities in the Public Health Service Act (42 U.S.C. 201 et seq.) or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and other applicable law, to support widespread innovation in non-opioid and non-addictive medical products for pain treatment, access to opioid addiction treatments, appropriate use of approved opioids, and efforts to reduce illicit importation of opioids. Such support may include the following:

(1) Facilitating the development of non-opioid and non-addictive pain treatments.

(2) Advancing guidance documents for sponsors of non-opioid pain products.

(3) Developing evidence to inform the potential for nonprescription overdose therapies.

(4) Examining expanded labeling indications for medication-assisted treatment.

(5) Conducting public education and outreach, including public workshops or public meetings, regarding the benefits of medication-assisted treatment, including all drugs approved by the Food and Drug Administration, and device treatment options approved or cleared by the Food and Drug Administration.

(6) Exploring the expansion and possible mandatory nature of prescriber education regarding pain management and appropriate opioid prescribing through authorities under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1).

(7) Examining options to limit the duration of opioid prescriptions for acute pain, including through packaging options.

(8) Increasing staff and infrastructure capacity to inspect and analyze packages at international mail facilities and pursue criminal investigations.

SEC. 725. NATIONAL INSTITUTES OF HEALTH.

The entirety of the funds made available pursuant to section 721(c)(4) shall be for the Director of the National Institutes of Health, pursuant to applicable authorities in the Public Health Service Act (42 U.S.C. 201 et seq.), to carry out activities related to—

(1) accelerating research for addressing the opioid use disorder epidemic, including developing non-opioid medications and interventions, including non-addictive medications, to manage pain, as well as developing medications and interventions to treat and to prevent substance use disorders;

(2) conducting and supporting research on which treatments (in terms of pain management as well as treating and preventing substance use disorders) are optimal for which patients; and

(3) conducting and supporting research on creating longer-lasting or faster-acting antidotes for opioid overdose, particularly in response to the prevalence of fentanyl and carfentanyl overdoses.

SEC. 726. HEALTH RESOURCES AND SERVICES ADMINISTRATION.

The entirety of the funds made available pursuant to section 721(c)(5) shall be for the Administrator of the Health Resources and Services Administration, pursuant to applicable authorities in titles III, VII, and VIII of the Public Health Service Act (42 U.S.C. 241 et seq.), to carry out activities that increase the availability and capacity of the behavioral health workforce. Such activities shall include providing loan repayment assistance for substance use disorder treatment providers.

SEC. 727. ADMINISTRATION FOR CHILDREN AND FAMILIES.

Of the funds made available pursuant to section 721(c)(6) for each of fiscal years 2021 through 2025, $20,000,000 for each such fiscal year shall be for the Secretary of Health and Human Services to carry out title I of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101 et seq.).

TITLE VIII—MISCELLANEOUS

SEC. 801. GUARANTEED ISSUE OF CERTAIN MEDIGAP POLICIES.

(a) GUARANTEED ISSUE OF MEDIGAP POLICIES TO ALL MEDIGAP-ELIGIBLE MEDICARE BENEFICIARIES.—

(1) IN GENERAL.—Section 1882(s) of the Social Security Act (42 U.S.C. 1395ss(s)) is amended—

(A) in paragraph (2)(A), by striking ''65 years of age or older and is enrolled for benefits under part B'' and inserting ''entitled to, or enrolled for, benefits under part A and enrolled for benefits under part B'';

(B) in paragraph (2)(D), by striking ''who is 65 years of age or older as of the date of issuance and'';

(C) in paragraph (3)(B)(ii), by striking ''is 65 years of age or older and''; and

(D) in paragraph (3)(B)(vi), by striking ''at age 65''.

(2) ADDITIONAL ENROLLMENT PERIOD FOR CERTAIN INDIVIDUALS.—

(A) ONE-TIME ENROLLMENT PERIOD.—

(i) IN GENERAL.—In the case of a specified individual, the Secretary shall establish a one-time enrollment period described in clause (iii) during which such an individual may enroll in any medicare supplemental policy of the individual's choosing.

(ii) APPLICATION.—The provisions of—

(I) paragraph (2) of section 1882(s) of the Social Security Act (42 U.S.C. 1395ss(s)) shall apply with respect to a specified individual who is described in subclause (I) of subparagraph (B)(iii) as if references in such paragraph (2) to the 6 month period described in subparagraph (A) of such paragraph were references to the one-time enrollment period established under clause (i); and

(II) paragraph (3) of such section shall apply with respect to a specified individual who is described in subclause (II) of subparagraph (B)(iii) as if references in such paragraph (3) to the period specified in subparagraph (E) of such paragraph were references to the one-time enrollment period established under clause (i).

(iii) PERIOD.—The enrollment period established under clause (i) shall be the 6-month period beginning on January 1, 2024.

(B) SPECIFIED INDIVIDUAL.—For purposes of this paragraph, the term ''specified individual'' means an individual who—

(i) is entitled to hospital insurance benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.) pursuant to section 226(b) or section 226A of such Act (42 U.S.C. 426(b); 426–1);

(ii) is enrolled for benefits under part B of such Act (42 U.S.C. 1395j et seq.); and

(iii)(I) would not, but for the amendments made by subparagraphs (A) and (B) of paragraph (1) and the provisions of this paragraph (if such provisions applied to such individual), be eligible for the guaranteed issue of a medicare supplemental policy under paragraph (2) of section 1882(s) of such Act (42 U.S.C. 1395ss(s)); or

(II) would not, but for the amendments made by subparagraphs (C) and (D) of paragraph (1) and the provisions of this paragraph (if such provisions applied to such individual), be eligible for the guaranteed issue of a medicare supplemental policy under paragraph (3) of such section.

(C) OUTREACH PLAN.—

(i) IN GENERAL.—The Secretary shall develop an outreach plan to notify specified individuals of the one-time enrollment period established under subparagraph (A).

(ii) CONSULTATION.—In implementing the outreach plan developed under clause (i), the Secretary shall consult with consumer advocates, brokers, insurers, the National Association of Insurance Commissioners, and State Health Insurance Assistance Programs.

(3) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to medicare supplemental policies effective on or after January 1, 2024.

(b) GUARANTEED ISSUE OF MEDIGAP POLICIES FOR MEDICARE ADVANTAGE ENROLLEES.—

(1) IN GENERAL.—Section 1882(s)(3) of the Social Security Act (42 U.S.C. 1395ss(s)(3)), as amended by subsection (a), is further amended—

(A) in subparagraph (B), by adding at the end the following new clause:

''(vii) The individual—

''(I) was enrolled in a Medicare Advantage plan under part C for not less than 12 months;

''(II) subsequently disenrolled from such plan;

''(III) elects to receive benefits under this title through the original Medicare fee-for-service program under parts A and B; and

''(IV) has not previously elected to receive benefits under this title through the original Medicare fee-for-service program pursuant to disenrollment from a Medicare Advantage plan under part C.'';

(B) by striking subparagraph (C)(iii) and inserting the following:

''(iii) Subject to subsection (v)(1), for purposes of an individual described in clause (vi) or (vii) of subparagraph (B), a medicare supplemental policy described in this subparagraph shall include any medicare supplemental policy.''; and

(C) in subparagraph (E)—

(i) in clause (iv), by striking ''and'' at the end;

(ii) in clause (v), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following new clause—

''(vi) in the case of an individual described in subparagraph (B)(vii), the annual, coordinated election period (as defined in section 1851(e)(3)(B)) or a continuous open enrollment period (as defined in section 1851(e)(2)) during which the individual disenrolls from a Medicare Advantage plan under part C.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to medicare supplemental policies effective on or after January 1, 2024.

SEC. 802. REPORTING REQUIREMENTS FOR PDP SPONSORS REGARDING POINT-OF-SALE REJECTIONS UNDER MEDICARE PART D.

Section 1860D–4(g) of the Social Security Act (42 U.S.C. 1395w–104(g)) is amended by adding at the end the following new paragraph:

''(3) REPORTING REQUIREMENTS REGARDING POINT-OF-SALE REJECTIONS.—

''(A) IN GENERAL.—With respect to a plan year beginning on or after January 1, 2020, a PDP sponsor offering a prescription drug plan shall submit to the Secretary, in a form and manner specified by the Secretary, information on point-of-sale rejections made during a period of time occurring in such plan year (as specified by the Secretary), including each of the following:

''(i) The reason for each point-of-sale rejection.

''(ii) Identifying information for each drug with respect to which a point-of-sale rejection was made.

''(iii) With respect to applicable types of point-of-sale rejections (as specified by the Secretary), each of the following:

''(I) Whether such a rejection was consistent with the formulary of the plan (as approved by the Secretary).

''(II) Whether a coverage determination or appeal of a coverage determination was requested for the drug with respect to which such a rejection was made.

''(III) The outcome of any such coverage determination or appeal of a coverage determination.

''(IV) The length of time between when such a rejection was made and when the drug with respect to which such rejection was made is dispensed, as applicable.

''(B) PUBLIC AVAILABILITY OF INFORMATION.—The Secretary shall make publicly available on the public website of the Centers for Medicare & Medicaid Services information submitted under subparagraph (A).

''(C) USE OF INFORMATION.—The Secretary may use information submitted under subparagraph (A), as determined appropriate, in developing measures for the 5-star rating system under section 1853(o)(4).

''(D) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph through program instruction or otherwise.

''(E) FUNDING.—The are authorized to be appropriated to the Secretary from the Federal Supplementary Medical Insurance Trust Fund under section 1841 such sums as may be necessary to implement this paragraph.''.

SEC. 803. PROVIDING ACCESS TO ANNUAL MEDICARE NOTIFICATIONS IN MULTIPLE LANGUAGES.

(a) IN GENERAL.—Section 1804 of the Social Security Act (42 U.S.C. 1395b–2) is amended by adding at the end the following new subsection:

''(e) The notice provided under subsection (a) shall be translated into languages in addition to English and Spanish. In carrying out the previous sentence, the Secretary shall prioritize translation of the notice into languages in which documents provided by the Commissioner of Social Security are translated and language that are the most frequently requested for translation for purposes of applying for old-age insurance benefits under title II.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to notices distributed prior to each Medicare open enrollment period beginning after January 1, 2020.

SEC. 804. TEMPORARY INCREASE IN MEDICARE PART B PAYMENT FOR CERTAIN BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 1847A(b)(8) of the Social Security Act (42 U.S.C. 1395w–3a(b)(8)) is amended—

(1) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and moving the margin of each such redesignated clause 2 ems to the right;

(2) by striking ''PRODUCT.—The amount'' and inserting the following: ''PRODUCT.—

''(A) IN GENERAL.—Subject to subparagraph (B), the amount''; and

(3) by adding at the end the following new subparagraph:

''(B) TEMPORARY PAYMENT INCREASE.—

''(i) IN GENERAL.—In the case of a qualifying biosimilar biological product that is furnished during the applicable 5-year period for such product, the amount specified in this paragraph for such product with respect to such period is the sum determined under subparagraph (A), except that clause (ii) of such subparagraph shall be applied by substituting '8 percent' for '6 percent'.

''(ii) APPLICABLE 5-YEAR PERIOD.—For purposes of clause (i), the applicable 5-year period for a biosimilar biological product is—

''(I) in the case of such a product for which payment was made under this paragraph as of December 31, 2019, the 5-year period beginning on January 1, 2020; and

''(II) in the case of such a product for which payment is first made under this paragraph during a calendar quarter during the period beginning January 1, 2020, and ending December 31, 2024, the 5-year period beginning on the first day of such calendar quarter during which such payment is first made.

''(iii) QUALIFYING BIOSIMILAR BIOLOGICAL PRODUCT DEFINED.—For purposes of this subparagraph, the term 'qualifying biosimilar biological product' means a biosimilar biological product described in paragraph (1)(C) with respect to which—

''(I) in the case of a product described in clause (ii)(I), the average sales price is not more than the average sales price for the reference biological product; and

''(II) in the case of a product described in clause (ii)(II), the wholesale acquisition cost is not more than the wholesale acquisition cost for the reference biological product.''.

SEC. 805. WAIVING MEDICARE COINSURANCE FOR COLORECTAL CANCER SCREENING TESTS.

Section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) is amended—

(1) in the second sentence, by striking ''section 1834(0)'' and inserting ''section 1834(o)'';

(2) by moving such second sentence 2 ems to the left; and

(3) by inserting the following third sentence following such second sentence: ''For services furnished on or after January 1, 2021, paragraph (1)(Y) shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.''.

SEC. 806. MEDICARE COVERAGE OF CERTAIN LYMPHEDEMA COMPRESSION TREATMENT ITEMS.

(a) COVERAGE.—

(1) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by section 601 and section 603, is further amended—

(A) in subsection (s)(2)—

(i) in subparagraph (II), by striking ''and'' after the semicolon at the end;

(ii) in subparagraph (JJ), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following new subparagraph:

''(KK) lymphedema compression treatment items (as defined in subsection (mmm));''; and

(B) by adding at the end the following new subsection:

''(mmm) LYMPHEDEMA COMPRESSION TREATMENT ITEMS.—The term 'lymphedema compression treatment items' means compression garments, devices, bandaging systems, components, and supplies, including multilayer compression bandaging systems, standard fit gradient compression garments, and other compression garments, devices, bandaging systems, components, or supplies (as determined by the Secretary), that are—

''(1) furnished on or after January 1, 2022, to an individual with a diagnosis of lymphedema for the treatment of such condition;

''(2) primarily and customarily used in the medical treatment of lymphedema, as determined by the Secretary; and

''(3) prescribed by a physician (or a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) to the extent authorized under State law).''.

(2) PAYMENT.—

(A) IN GENERAL.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)), as amended by section 601(c)(1), is further amended—

(i) by striking ''and'' before ''(DD)''; and

(ii) by inserting before the semicolon at the end the following: '', and (EE) with respect to lymphedema compression treatment items (as defined in section 1861(mmm)), the amount paid shall be equal to 80 percent of the lesser of the actual charge or the amount determined under the payment basis determined under section 1834(z)''.

(B) PAYMENT BASIS AND LIMITATIONS.—Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by sections 601(c)(2) and 603(c), is further amended by adding at the end the following new subsection:

''(z) PAYMENT FOR LYMPHEDEMA COMPRESSION TREATMENT ITEMS.—

''(1) IN GENERAL.—The Secretary shall determine an appropriate payment basis for lymphedema compression treatment items (as defined in section 1861(mmm)). In making such a determination, the Secretary may take into account payment rates for such items under State plans (or waivers of such plans) under title XIX, the Veterans Health Administration, and group health plans and health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), and such other information as the Secretary determines appropriate.

''(2) FREQUENCY LIMITATION.—No payment may be made under this part for lymphedema compression treatment items furnished other than at such frequency as the Secretary may establish.

''(3) APPLICATION OF COMPETITIVE ACQUISITION.—In the case of lymphedema compression treatment items that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

''(A) the payment basis under this subsection for such items furnished in such area shall be the payment basis determined under such competitive acquisition program; and

''(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise determined under this subsection for an area that is not a competitive acquisition area under section 1847, and in the

case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.''.

(3) CONFORMING AMENDMENTS.—

(A) EXCLUSIONS.—Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)), as amended by section 601(f) and section 603(g), is further amended—

(i) in subparagraph (Q), by striking ''and'' at the end;

(ii) in subparagraph (R), by striking the semicolon and inserting '', and''; and

(iii) by adding at the end the following new subparagraph:

''(S) in the case of lymphedema compression treatment items (as defined in section 1861(mmm)), which are furnished more frequently than is established pursuant to section 1834(z)(2);''.

(B) APPLICATION OF COMPETITIVE ACQUISITION.—

(i) IN GENERAL.—Section 1847(a)(2) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)), as amended by sections 601(e)(2)(B)(ii), 602(b)(3)(B)(i), and 603(f)(2)(B), is further amended by adding at the end the following new subparagraph:

''(G) LYMPHEDEMA COMPRESSION TREATMENT ITEMS.—Lymphedema compression treatment items (as defined in section 1861(mmm)) for which payment would otherwise be made under section 1834(z).''.

(b) INCLUSION IN REQUIREMENTS FOR SUPPLIERS OF MEDICAL EQUIPMENT AND SUPPLIES.—Section 1834(j)(5) of the Social Security Act (42 U.S.C. 1395m(j)(5)) is amended—

(1) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively; and

(2) by inserting after subparagraph (D) the following new subparagraph:

''(E) lymphedema compression treatment items (as defined in section 1861(mmm));''.

(c) STUDY AND REPORT ON IMPLEMENTATION.—

(1) STUDY.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall conduct a study on the implementation of Medicare coverage of certain lymphedema compression treatment items under the amendments made by this Act. Such study shall include an evaluation of the following:

(A) Medicare beneficiary utilization of items and services under parts A and B of title XVIII of the Social Security Act as a result of the implementation of such amendments.

(B) Whether the Secretary has determined, pursuant to section 1861(mmm) of the Social Security Act, as added by subsection (a)(1), that lymphedema compression treatment items other than compression bandaging systems and standard fit gradient compression garments are covered under such section.

(2) REPORT.—Not later than January 1, 2024, the Secretary shall submit to Congress and make available to the public a report on the study conducted under paragraph (1).

SEC. 807. PHYSICIAN FEE UPDATE.

Section 1848(d)(19) of the Social Security Act (42 U.S.C. 1395w–4(d)(19)) is amended to read as follows:

''(19) UPDATE FOR 2020 THROUGH 2025.—The update to the single conversion factor established in paragraph (1)(C)—

''(A) for each of 2020 through 2022 shall be 0.5 percent; and

''(B) for each of 2023 through 2025 shall be 0.0 percent.''.

SEC. 808. ADDITIONAL COMMUNITY HEALTH CENTER FUNDING.

Section 10503 of the Patient Protection and Affordable Care Act (42 U.S.C. 254b–2) is amended by striking subsection (c) and inserting the following:

''(c) ADDITIONAL ENHANCED FUNDING; CAPITAL PROJECTS.—There is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, to the CHC Fund—

''(1) to be transferred to the Secretary of Health and Human Services to provide additional enhanced funding for the community health center program under section 330 of the Public Health Service Act, $1,000,000,000 for each of fiscal years 2021 through 2025; and

''(2) to be transferred to the Secretary of Health and Human Services for capital projects of the community health center program under section 330 of the Public Health Service Act, $5,000,000,000 for the period of fiscal years 2021 through 2025.''.

SEC. 809. GRANTS TO IMPROVE TRAUMA SUPPORT SERVICES AND MENTAL HEALTH CARE FOR CHILDREN AND YOUTH IN EDUCATIONAL SETTINGS.

(a) GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS AUTHORIZED.—The Secretary, in coordination with the Assistant Secretary for Mental Health and Substance Use, is authorized to award grants to, or enter into contracts or cooperative agreements with, State educational agencies, local educational agencies, Indian Tribes (as defined in section 4 of the Indian Self-Determination and Education Assistance Act) or their tribal educational agencies, a school operated by the Bureau of Indian Education, a Regional Corporation, or a Native Hawaiian educational organization, for the purpose of increasing student access to evidence-based trauma support services and mental health care by developing innovative initiatives, activities, or programs to link local school systems with local trauma-informed support and mental health systems, including those under the Indian Health Service.

(b) DURATION.—With respect to a grant, contract, or cooperative agreement awarded or entered into under this section, the period during which payments under such grant, contract, or agreement are made to the recipient may not exceed 4 years.

(c) USE OF FUNDS.—An entity that receives a grant, contract, or cooperative agreement under this section shall use amounts made available through such grant, contract, or cooperative agreement for evidence-based activities, which shall include any of the following:

(1) Collaborative efforts between school-based service systems and trauma-informed support and mental health service systems to provide, develop, or improve prevention, screening, referral, and treatment and support services to students, such as providing trauma screenings to identify students in need of specialized support.

(2) To implement schoolwide positive behavioral interventions and supports, or other trauma-informed models of support.

(3) To provide professional development to teachers, teacher assistants, school leaders, specialized instructional support personnel, and mental health professionals that—

(A) fosters safe and stable learning environments that prevent and mitigate the effects of trauma, including through social and emotional learning;

(B) improves school capacity to identify, refer, and provide services to students in need of trauma support or behavioral health services; or

(C) reflects the best practices for trauma-informed identification, referral, and support developed by the Interagency Task Force on Trauma-Informed Care.

(4) Services at a full-service community school that focuses on trauma-informed supports, which may include a full-time site coordinator, or other activities consistent with section 4625 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7275).

(5) Engaging families and communities in efforts to increase awareness of child and youth trauma, which may include sharing best practices with law enforcement regarding trauma-informed care and working with mental health professionals to provide interventions, as well as longer term coordinated care within the community for children and youth who have experienced trauma and their families.

(6) To provide technical assistance to school systems and mental health agencies.

(7) To evaluate the effectiveness of the program carried out under this section in increasing student access to evidence-based trauma support services and mental health care.

(8) To establish partnerships with or provide subgrants to Head Start agencies (including Early Head Start agencies), public and private preschool programs, child care programs (including home-based providers), or other entities described in subsection (a), to include such entities described in this paragraph in the evidence-based trauma initiatives, activities, support services, and mental health systems established under this section in order to provide, develop, or improve prevention, screening, referral, and treatment and support services to young children and their families.

(d) APPLICATIONS.—To be eligible to receive a grant, contract, or cooperative agreement under this section, an entity described in subsection (a) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, which shall include the following:

(1) A description of the innovative initiatives, activities, or programs to be funded under the grant, contract, or cooperative agreement, including how such program will increase access to evidence-based trauma support services and mental health care for students, and, as applicable, the families of such students.

(2) A description of how the program will provide linguistically appropriate and culturally competent services.

(3) A description of how the program will support students and the school in improving the school climate in order to support an environment conducive to learning.

(4) An assurance that—

(A) persons providing services under the grant, contract, or cooperative agreement are adequately trained to provide such services; and

(B) teachers, school leaders, administrators, specialized instructional support personnel, representatives of local Indian Tribes or tribal organizations as appropriate, other school personnel, and parents or guardians of students participating in services under this section will be engaged and involved in the design and implementation of the services.

(5) A description of how the applicant will support and integrate existing school-based services with the program in order to provide mental health services for students, as appropriate.

(6) A description of the entities in the community with which the applicant will partner or to which the applicant will provide subgrants in accordance with subsection (c)(8).

(e) INTERAGENCY AGREEMENTS.—

(1) LOCAL INTERAGENCY AGREEMENTS.—To ensure the provision of the services described in subsection (c), a recipient of a grant, contract, or cooperative agreement under this section, or their designee, shall establish a local interagency agreement among local educational agencies, agencies responsible for early childhood education programs, Head Start agencies (including Early Head Start agencies), juvenile justice authorities, mental health agencies, child welfare agencies, and other relevant agencies, authorities, or entities in the community that will be involved in the provision of such services.

(2) CONTENTS.—In ensuring the provision of the services described in subsection (c), the local interagency agreement shall specify with respect to each agency, authority, or entity that is a party to such agreement—

(A) the financial responsibility for the services;

(B) the conditions and terms of responsibility for the services, including quality, accountability, and coordination of the services; and

(C) the conditions and terms of reimbursement among such agencies, authorities, or entities, including procedures for dispute resolution.

(f) EVALUATION.—The Secretary shall reserve not more than 3 percent of the funds made available under subsection (l) for each fiscal year to—

(1) conduct a rigorous, independent evaluation of the activities funded under this section; and

(2) disseminate and promote the utilization of evidence-based practices regarding trauma support services and mental health care.

(g) DISTRIBUTION OF AWARDS.—The Secretary shall ensure that grants, contracts, and cooperative agreements awarded or entered into under this section are equitably distributed among the geographical regions of the United States and among tribal, urban, suburban, and rural populations.

(h) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to prohibit an entity involved with a program carried out under this section from reporting a crime that is committed by a student to appropriate authorities; or

(2) to prevent Federal, State, and tribal law enforcement and judicial authorities from exercising their responsibilities with regard to the application of Federal, tribal, and State law to crimes committed by a student.

(i) SUPPLEMENT, NOT SUPPLANT.—Any services provided through programs carried out under this section shall supplement, and not supplant, existing mental health services, including any special education and related services provided under the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

(j) CONSULTATION WITH INDIAN TRIBES.—In carrying out subsection (a), the Secretary shall, in a timely manner, meaningfully consult with Indian Tribes and their representatives to ensure notice of eligibility.

(k) DEFINITIONS.—In this section:

(1) ELEMENTARY SCHOOL.—The term ''elementary school'' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(2) EVIDENCE-BASED.—The term ''evidence-based'' has the meaning given such term in section 8101(21)(A)(i) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801(21)(A)(i)).

(3) NATIVE HAWAIIAN EDUCATIONAL ORGANIZATION.—The term ''Native Hawaiian educational organization'' has the meaning given such term in section 6207 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7517).

(4) LOCAL EDUCATIONAL AGENCY.—The term ''local educational agency'' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(5) REGIONAL CORPORATION.—The term ''Regional Corporation'' has the meaning given the term in section 3 of the Alaska Native Claims Settlement Act (43 U.S.C. 1602).

(6) SCHOOL.—The term ''school'' means a public elementary school or public secondary school.

(7) SCHOOL LEADER.—The term ''school leader'' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(8) SECONDARY SCHOOL.—The term ''secondary school'' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Education.

(10) SPECIALIZED INSTRUCTIONAL SUPPORT PERSONNEL.—The term ''specialized instructional support personnel'' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(11) STATE EDUCATIONAL AGENCY.—The term ''State educational agency'' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(l) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, and there is appropriated, out of any money in the Treasury not otherwise appropriated, to carry out this section, $20,000,000 for each of fiscal years 2021 through 2025.

SEC. 810. PATHWAY TO HEALTH CAREERS ACT.

(a) SHORT TITLE.—This section may be cited as the ''Pathways to Health Careers Act''.

(b) EXTENSION THROUGH FISCAL YEAR 2020 OF FUNDING FOR DEMONSTRATION PROJECTS TO ADDRESS HEALTH PROFESSIONS WORKFORCE NEEDS.—

(1) IN GENERAL.—Section 2008(c)(1) of the Social Security Act (42 U.S.C. 1397g(c)(1)) is amended by striking ''2019.'' and inserting ''2020, and to provide technical assistance and cover administrative costs associated with implementing the successor to this section $15,000,000 for fiscal year 2020.''.

(2) AVAILABILITY OF OTHER FUNDS.—Upon the date of the enactment of this section—

(A) amounts expended pursuant to section 1501 of division B of Public Law 116–59, or any other prior law making amounts available for fiscal year 2020 for activities authorized by section 2008 of the Social Security Act, shall be charged to the appropriation made by subsection (c)(1) of such section 2008 for fiscal year 2020 (not including the amount for technical assistance and administrative costs); and

(B) if such enactment occurs on or before November 21, 2019, the availability of funds appropriated in, and the authority provided under, such section 1501 shall terminate.

(c) CAREER PATHWAYS THROUGH HEALTH PROFESSION OPPORTUNITY GRANTS.—Effective October 1, 2020, section 2008 of the Social Security Act (42 U.S.C. 1397g) is amended to read as follows:

''SEC. 2008. CAREER PATHWAYS THROUGH HEALTH PROFESSION OPPORTUNITY GRANTS.

''(a) APPLICATION REQUIREMENTS.—An eligible entity desiring a grant under this section for a project shall submit to the Secretary an application for the grant, that includes the following:

''(1) A description of how the applicant will use a career pathways approach to train eligible individuals for health professions that pay well or will put eligible individuals on a career path to an occupation that pays well, under the project.

''(2) A description of the adult basic education and literacy activities, work readiness activities, training activities, and case management and career coaching services that the applicant will use to assist eligible individuals to gain work experience, connection to employers, and job placement, and a description of the plan for recruiting, hiring, and training staff to provide the case management, mentoring, and career coaching services, under the project directly or through local governmental, apprenticeship, educational, or charitable institutions.

''(3) In the case of an application for a grant under this section for a demonstration project described in subsection (c)(2)(B)(i)(I)—

''(A) a demonstration that the State in which the demonstration project is to be conducted has in effect policies or laws that permit certain allied health and behavioral health care credentials to be awarded to people with certain arrest or conviction records (which policies or laws shall include appeals processes, waivers, certificates, and other opportunities to demonstrate rehabilitation to obtain credentials, licensure, and approval to work in the proposed health careers), and a plan described in the application that will use a career pathway to assist participants with such a record in acquiring credentials, licensing, and employment in the specified careers;

''(B) a discussion of how the project or future strategic hiring decisions will demonstrate the experience and expertise of the project in working with job seekers who have arrest or conviction records or employers with experience working with people with arrest or conviction records;

''(C) an identification of promising innovations or best practices that can be used to provide the training;

''(D) a proof of concept or demonstration that the applicant has done sufficient research on workforce shortage or in-demand jobs for which people with certain types of arrest or conviction records can be hired;

''(E) a plan for recruiting students who are eligible individuals into the project; and

''(F) a plan for providing post-employment support and ongoing training as part of a career pathway under the project.

''(4) In the case of an application for a grant under this section for a demonstration project described in subsection (c)(2)(B)(i)(II)—

''(A) a description of the partnerships, strategic staff hiring decisions, tailored program activities, or other programmatic elements of the project, such as training plans for doulas and other community health workers and training plans for midwives and other allied health professions, that are designed to support a career pathway in pregnancy, birth, or post-partum services; and

''(B) a demonstration that the State in which the demonstration project is to be conducted recognizes doulas or midwives, as the case may be.

''(5) A demonstration that the applicant has experience working with low-income populations, or a description of the plan of the applicant to work with a partner organization that has the experience.

''(6) A plan for providing post-employment support and ongoing training as part of a career pathway under the project.

''(7) A description of the support services that the applicant will provide under the project, including a plan for how child care and transportation support services will be guaranteed and, if the applicant will provide a cash stipend or wage supplement, how the stipend or supplement would be calculated and distributed.

''(8) A certification by the applicant that the project development included—

''(A) consultation with a local workforce development board established under section 107 of the Workforce Innovation and Opportunity Act;

''(B) consideration of apprenticeship and pre-apprenticeship models registered under the Act of August 16, 1937 (also known as the 'National Apprenticeship Act');

''(C) consideration of career pathway programs in the State in which the project is to be conducted; and

''(D) a review of the State plan under section 102 or 103 of the Workforce Innovation and Opportunity Act.

''(9) A description of the availability and relevance of recent labor market information and other pertinent evidence of in-demand jobs or worker shortages.

''(10) A certification that the applicant will directly provide or contract for the training services described in the application.

''(11) A commitment by the applicant that, if the grant is made to the applicant, the applicant will—

''(A) during the planning period for the project, provide the Secretary with any information needed by the Secretary to establish adequate data reporting and administrative structure for the project;

''(B) hire a person to direct the project not later than the end of the planning period applicable to the project;

''(C) accept all technical assistance offered by the Secretary with respect to the grant;

''(D) participate in such in-person grantee conferences as are regularly scheduled by the Secretary;

''(E) provide all data required by the Secretary under subsection (g); and

''(F) notify the local disabled veterans' outreach program specialists under section 4103A of title 38, United States Code, and the local veterans' employment representatives under section 4104 of such title, of the grantee's outreach plan

for advertising training opportunities to potential participants in the project.

''(b) PREFERENCES IN CONSIDERING APPLICATIONS.—In considering applications for a grant under this section, the Secretary shall give preference to—

''(1) applications submitted by applicants to whom a grant was made under this section or any predecessor to this section;

''(2) applications submitted by applicants who have business and community partners in each of the following categories:

''(A) State and local government agencies and social service providers, including a State or local entity that administers a State program funded under part A of this title;

''(B) institutions of higher education, apprenticeship programs, and local workforce development boards established under section 107 of the Workforce Innovation and Opportunity Act; and

''(C) health care employers, health care industry or sector partnerships, labor unions, and labor-management partnerships;

''(3) applications that include opportunities for mentoring or peer support, and make career coaching available, as part of the case management plan;

''(4) applications which describe a project that will serve a rural area in which—

''(A) the community in which the individuals to be enrolled in the project reside is located;

''(B) the project will be conducted; or

''(C) an employer partnership that has committed to hiring individuals who successfully complete all activities under the project is located;

''(5) applications that include a commitment to providing project participants with a cash stipend or wage supplement; and

''(6) applications which have an emergency cash fund to assist project participants financially in emergency situations.

''(c) GRANTS.—

''(1) COMPETITIVE GRANTS.—

''(A) GRANT AUTHORITY.—

''(i) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of Education, may make a grant in accordance with this paragraph to an eligible entity whose application for the grant is approved by the Secretary, to conduct a project designed to train low-income individuals for allied health professions, health information technology, physicians assistants, nursing assistants, registered nurse, advanced practice nurse, and other professions considered part of a health care career pathway model.

''(ii) GUARANTEE OF GRANTEES IN EACH STATE AND THE DISTRICT OF COLUMBIA.—For each grant cycle, the Secretary shall award a grant under this paragraph to at least 2 eligible entities in each State that is not a territory, to the extent there are a sufficient number of applications submitted by the entities that meet the requirements applicable with respect to such a grant. If, for a grant cycle, there are fewer than 2 such eligible entities in a State, the Secretary shall include that information in the report required by subsection (g)(2) that covers the fiscal year.

''(B) GUARANTEE OF GRANTS FOR INDIAN POPULATIONS.—From the amount reserved under subsection (i)(2)(B) for each fiscal year, the Secretary shall award a grant under this paragraph to at least 10 eligible entities that are an Indian tribe, a tribal organization, or a tribal college or university, to the extent there are a sufficient number of applications submitted by the entities that meet the requirements applicable with respect to such a grant.

''(C) GUARANTEE OF GRANTEES IN THE TERRITORIES.—From the amount reserved under subsection (i)(2)(C) for each fiscal year, the Secretary shall award a grant under this paragraph to at least 2 eligible entities that are located in a territory, to the extent there are a sufficient number of applications submitted by the entities that meet the requirements applicable with respect to such a grant.

''(2) GRANTS FOR DEMONSTRATION PROJECTS.—

''(A) GRANT AUTHORITY.—The Secretary, in consultation with the Secretary of Labor and the Secretary of Education (and, with respect to demonstration projects of the type described in subparagraph (B)(i)(I), the Attorney General) shall make a grant in accordance with this subsection to an eligible entity whose application for the grant is approved by the Secretary, to conduct a demonstration project that meets the requirements of subparagraph (B).

''(B) REQUIREMENTS.—The requirements of this subparagraph are the following:

''(i) TYPE OF PROJECT.—The demonstration project shall be of 1 of the following types:

''(I) INDIVIDUALS WITH ARREST OR CONVICTION RECORDS DEMONSTRATION.—The demonstration project shall be of a type designed to provide education and training for eligible individuals with arrest or conviction records to enter and follow a career pathway in the health professions through occupations that pay well and are expected to experience a labor shortage or be in high demand.

''(II) PREGNANCY AND CHILDBIRTH CAREER PATHWAY DEMONSTRATION.—The demonstration project shall be of a type designed to provide education and training for eligible individuals to enter and follow a career pathway in the field of pregnancy, childbirth, or post-partum, in a State that recognizes doulas or midwives and that provides payment for services provided by doulas or midwives, as the case may be, under private or public health insurance plans.

''(ii) DURATION.—The demonstration project shall be conducted for not less than 5 years.

''(C) MINIMUM ALLOCATION OF FUNDS FOR EACH TYPE OF DEMONSTRATION PROJECT.—

''(i) INDIVIDUALS WITH ARREST OR CONVICTION RECORDS DEMONSTRATIONS.—Not less than 25 percent of the amounts made available for grants under this paragraph shall be used to make grants for demonstration projects of the type described in subparagraph (B)(i)(I).

''(ii) PREGNANCY AND CHILDBIRTH CAREER PATHWAY DEMONSTRATIONS.—Not less than 25 percent of the amounts made available for grants under this paragraph shall be used to make grants for demonstration projects of the type described in subparagraph (B)(i)(II).

''(3) GRANT CYCLE.—The grant cycle under this section shall be not less than 5 years, with a planning period of not more than the 1st 12 months of the grant cycle. During the planning period, the amount of the grant shall be in such lesser amount as the Secretary determines appropriate.

''(d) USE OF GRANT.—

''(1) IN GENERAL.—An entity to which a grant is made under this section shall use the grant in accordance with the approved application for the grant.

''(2) SUPPORT TO BE PROVIDED.—

''(A) REQUIRED SUPPORT.—A project for which a grant is made under this section shall include the following:

''(i) An assessment for adult basic skill competency, and provision of adult basic skills education if necessary for lower-skilled eligible individuals to enroll in the project and go on to enter and complete post-secondary training, through means including the following:

''(I) Establishing a network of partners that offer pre-training activities for project participants who need to improve basic academic skills or English language proficiency before entering a health occupational training career pathway program.

''(II) Offering resources to enable project participants to continue advancing adult basic skill proficiency while enrolled in a career pathway program.

''(III) Embedding adult basic skill maintenance as part of ongoing post-graduation career coaching and mentoring.

''(ii) A guarantee that child care is an available and affordable support service for project participants through means such as the following;

''(I) Referral to, and assistance with, enrollment in a subsidized child care program.

''(II) Direct payment to a child care provider if a slot in a subsidized child care program is not available or reasonably accessible.

''(III) Payment of co-payments or associated fees for child care.

''(iii) Case management plans that include career coaching (with the option to offer appropriate peer support and mentoring opportunities to help develop soft skills and social capital), which may be offered on an ongoing basis before, during, and after initial training as part of a career pathway model.

''(iv) A plan to provide project participants with transportation through means such as the following:

''(I) Referral to, and assistance with enrollment in, a subsidized transportation program.

''(II) If a subsidized transportation program is not reasonably available, direct payments to subsidize transportation costs.

For purposes of this clause, the term 'transportation' includes public transit, or gasoline for a personal vehicle if public transit is not reasonably accessible or available.

''(v) In the case of a demonstration project of the type described in subsection (c)(2)(B)(i)(I), access to legal assistance for project participants for the purpose of addressing arrest or conviction records and associated workforce barriers.

''(B) ALLOWED SUPPORT.—The goods and services provided under a project for which a grant is made under this section may include the following:

''(i) A cash stipend that is at least monthly.

''(ii) A reserve fund for financial assistance to project participants in emergency situations.

''(iii) Tuition, and training materials such as books, software, uniforms, shoes, and hair nets.

''(iv) In-kind resource donations such as interview clothing and conference attendance fees.

''(v) Assistance with accessing and completing high school equivalency or adult basic education courses as necessary to achieve success in the project and make progress toward career goals.

''(vi) Assistance with programs and activities, including legal assistance, deemed necessary to address arrest or conviction records as an employment barrier.

''(vii) Other support services as deemed necessary for family well-being, success in the project, and progress toward career goals.

''(C) TREATMENT OF SUPPORT FOR PURPOSES OF MEANS-TESTED PROGRAMS.—Any goods or services provided to an eligible individual participating in a project for which a grant is made under this section shall not be considered income, and shall not be taken into account for purposes of determining the eligibility of the individual for, or amount of benefits to be provided to the individual, under any means-tested program.

''(3) TRAINING.—The number of hours of training provided to an eligible individual under a project for which a grant is made under this section, for a recognized postsecondary credential, including an industry-recognized credential, which is awarded in recognition of attainment of measurable technical or occupational skills necessary to gain employment or advance within an occupation (including a certificate awarded by a local workforce development board established under section 107 of the Workforce Innovation and Opportunity Act), shall be—

''(A) not less than the number of hours of training required for certification in that level of skill by the State in which the project is conducted; or

''(B) if there is no such requirement, such number of hours of training as the Secretary finds is necessary to achieve that skill level.

''(4) INCOME LIMITATION.—An entity to which a grant is made under this section shall not use

the grant to provide support to a person who is not an eligible individual.

''(5) INCLUSION OF TANF RECIPIENTS.—In the case of a project for which a grant is made under this section that is conducted in a State that has a program funded under part A of title IV, at least 10 percent of the eligible individuals to whom support is provided under the project shall meet the income eligibility requirements under that State program, without regard to whether the individuals receive benefits or services directly under that State program.

''(6) PROHIBITION.—An entity to which a grant is made under this section shall not use the grant for purposes of entertainment, except that case management and career coaching services may include celebrations of specific career-based milestones such as completing a semester, graduation, or job placement.

''(e) TECHNICAL ASSISTANCE.—

''(1) IN GENERAL.—The Secretary shall provide technical assistance—

''(A) to assist eligible entities in applying for grants under this section;

''(B) that is tailored to meet the needs of grantees at each stage of the administration of projects for which grants are made under this section;

''(C) that is tailored to meet the specific needs of Indian tribes, tribal organizations, and tribal colleges and universities;

''(D) that is tailored to meet the specific needs of the territories;

''(E) that is tailored to meet the specific needs of eligible entities in carrying out demonstration projects for which a grant is made under this section; and

''(F) to facilitate the exchange of information among eligible entities regarding best practices and promising practices used in the projects.

''(2) CONTINUATION OF PEER TECHNICAL ASSISTANCE CONFERENCES.—The Secretary shall continue to hold peer technical assistance conferences for entities to which a grant is made under this section or was made under the immediate predecessor of this section.

''(f) EVALUATION OF DEMONSTRATION PROJECTS.—

''(1) IN GENERAL.—The Secretary shall, by grant, contract, or interagency agreement, conduct rigorous and well-designed evaluations of the demonstration projects for which a grant is made under this section.

''(2) REQUIREMENT APPLICABLE TO INDIVIDUALS WITH ARREST OR CONVICTION RECORDS DEMONSTRATION.—In the case of a project of the type described in subsection (c)(2)(B)(i)(I), the evaluation shall include identification of successful activities for creating opportunities for developing and sustaining, particularly with respect to low-income individuals with arrest or conviction records, a health professions workforce that has accessible entry points, that meets high standards for education, training, certification, and professional development, and that provides increased wages and affordable benefits, including health care coverage, that are responsive to the needs of the workforce.

''(3) REQUIREMENT APPLICABLE TO PREGNANCY AND CHILDBIRTH CAREER PATHWAY DEMONSTRATION.—In the case of a project of the type described in subsection (c)(2)(B)(i)(II), the evaluation shall include identification of successful activities for creating opportunities for developing and sustaining, particularly with respect to low-income individuals and other entry-level workers, a career pathway that has accessible entry points, that meets high standards for education, training, certification, and professional development, and that provides increased wages and affordable benefits, including health care coverage, that are responsive to the needs of the birth, pregnancy, and post-partum workforce.

''(4) RULE OF INTERPRETATION.—Evaluations conducted pursuant to this subsection may include a randomized controlled trial, but this subsection shall not be interpreted to require an evaluation to include such a trial.

''(g) REPORTS.—

''(1) TO THE SECRETARY.—An eligible entity awarded a grant to conduct a project under this section shall submit interim reports to the Secretary on the activities carried out under the project, and, on the conclusion of the project, a final report on the activities. Each such report shall include data on participant outcomes related to earnings, employment in health professions, graduation rate, graduation timeliness, credential attainment, participant demographics, and other data specified by the Secretary.

''(2) TO THE CONGRESS.—During each Congress, the Secretary shall submit to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate a report—

''(A) on the demographics of the participants in the projects for which a grant is made under this section;

''(B) on the rate of which project participants completed all activities under the projects;

''(C) on the employment credentials acquired by project participants;

''(D) on the employment of project participants on completion of activities under the projects, and the earnings of project participants at entry into employment;

''(E) on best practices and promising practices used in the projects;

''(F) on the nature of any technical assistance provided to grantees under this section;

''(G) on, with respect to the period since the period covered in the most recent prior report submitted under this paragraph—

''(i) the number of applications submitted under this section, with a separate statement of the number of applications referred to in subsection (b)(5);

''(ii) the number of applications that were approved, with a separate statement of the number of such applications referred to in subsection (b)(5); and

''(iii) a description of how grants were made in any case described in the last sentence of subsection (c)(1)(A)(ii); and

''(H) that includes an assessment of the effectiveness of the projects with respect to addressing health professions workforce shortages or in-demand jobs.

''(h) DEFINITIONS.—In this section:

''(1) ALLIED HEALTH PROFESSION.—The term 'allied health profession' has the meaning given in section 799B(5) of the Public Health Service Act.

''(2) CAREER PATHWAY.—The term 'career pathway' has the meaning given that term in section 3(7) of the Workforce Innovation and Opportunity Act.

''(3) DOULA.—The term 'doula' means an individual who—

''(A) is certified by an organization that has been established for not less than 5 years and that requires the completion of continuing education to maintain the certification, to provide non-medical advice, information, emotional support, and physical comfort to an individual during the individual's pregnancy, childbirth, and post-partum period; and

''(B) maintains the certification by completing the required continuing education.

''(4) ELIGIBLE ENTITY.—The term 'eligible entity' means any of the following entities that demonstrates in an application submitted under this section that the entity has the capacity to fully develop and administer the project described in the application:

''(A) A local workforce development board established under section 107 of the Workforce Innovation and Opportunity Act.

''(B) A State or territory, a political subdivision of a State or territory, or an agency of a State, territory, or such a political subdivision, including a State or local entity that administers a State program funded under part A of this title.

''(C) An Indian tribe, a tribal organization, or a tribal college or university.

''(D) An institution of higher education (as defined in the Higher Education Act of 1965).

''(E) A hospital (as defined in section 1861(e)).

''(F) A high-quality skilled nursing facility.

''(G) A Federally qualified health center (as defined in section 1861(aa)(4)).

''(H) A nonprofit organization described in section 501(c)(3) of the Internal Revenue Code of 1986, a labor organization, or an entity with shared labor-management oversight, that has a demonstrated history of providing health profession training to eligible individuals.

''(I) In the case of a demonstration project of the type provided for in subsection (c)(2)(B)(i)(II) of this section, an entity recognized by a State, Indian tribe, or tribal organization as qualified to train doulas or midwives, if midwives or doulas, as the case may be, are permitted to practice in the State involved.

''(J) An opioid treatment program (as defined in section 1861(jjj)(2)), and other high quality comprehensive addiction care providers.

''(5) ELIGIBLE INDIVIDUAL.—The term 'eligible individual' means an individual whose family income does not exceed 200 percent of the Federal poverty level.

''(6) FEDERAL POVERTY LEVEL.—The term 'Federal poverty level' means the poverty line (as defined in section 673(2) of the Omnibus Budget Reconciliation Act of 1981, including any revision required by such section applicable to a family of the size involved).

''(7) INDIAN TRIBE; TRIBAL ORGANIZATION.—The terms 'Indian tribe' and 'tribal organization' have the meaning given the terms in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).

''(8) INSTITUTION OF HIGHER EDUCATION.—The term 'institution of higher education' has the meaning given the term in section 101 or 102(a)(1)(B) of the Higher Education Act of 1965.

''(9) TERRITORY.—The term 'territory' means the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.

''(10) TRIBAL COLLEGE OR UNIVERSITY.—The term 'tribal college or university' has the meaning given the term in section 316(b) of the Higher Education Act of 1965.

''(i) FUNDING.—

''(1) IN GENERAL.—Out of any funds in the Treasury of the United States not otherwise appropriated, there are appropriated to the Secretary to carry out this section $425,000,000 for each of fiscal years 2021 through 2025.

''(2) ALLOCATION OF FUNDS.—Of the amount appropriated for a fiscal year under paragraph (1) of this subsection—

''(A) 75 percent shall be available for grants under subsection (c)(1)(A);

''(B) 4 percent shall be reserved for grants under subsection (c)(1)(B);

''(C) 5 percent shall be reserved for grants under subsection (c)(1)(C);

''(D) 6 percent shall be available for demonstration project grants under subsection (c)(2);

''(E) 6 percent, plus all amounts referred to in subparagraphs (A) through (D) of this paragraph that remain unused after all grant awards are made for the fiscal year, shall be available for the provision of technical assistance and associated staffing; and

''(F) 4 percent shall be available for studying the effects of the demonstration and non-demonstration projects for which a grant is made under this section, and for associated staffing, for the purpose of supporting the rigorous evaluation of the demonstration projects, and supporting the continued study of the short-, medium-, and long-term effects of all such projects, including the effectiveness of new or added elements of the non-demonstration projects.

''(j) NONAPPLICABILITY OF PRECEDING SECTIONS OF THIS SUBTITLE.—

''(1) IN GENERAL.—Except as provided in paragraph (2), the preceding sections of this subtitle shall not apply to a grant awarded under this section.

''(2) EXCEPTION FOR CERTAIN LIMITATIONS ON USE OF GRANTS.—Section 2005(a) (other than paragraphs (2), (3), (5), (6), and (8)) shall apply to a grant awarded under this section to the same extent and in the same manner as such section applies to payments to States under this subtitle.''.

SEC. 811. HOME VISITING TO REDUCE MATERNAL MORTALITY AND MORBIDITY ACT.

(a) SHORT TITLE.—This section may be cited as the ''Home Visiting to Reduce Maternal Mortality and Morbidity Act''.

(b) INCREASE IN TRIBAL SET-ASIDE PERCENTAGE.—

(1) IN GENERAL.—Section 511(j)(2)(A) of the Social Security Act (42 U.S.C. 711(j)(2)(A)) is amended by striking ''3'' and inserting ''6''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2020.

(c) INCREASE IN FUNDING.—Section 511(j)(1) of such Act (42 U.S.C. 711(j)(1)) is amended—

(1) by striking ''and'' at the end of subparagraph (G); and

(2) by striking subparagraph (H) and inserting the following:

''(H) $400,000,000 for each of fiscal years 2017 through 2020;

''(I) $600,000,000 for fiscal year 2021; and

''(J) $800,000,000 for fiscal year 2022.''.

(d) USE OF ADDITIONAL FUNDS.—Section 511(c) of such Act (42 U.S.C. 711(c)) is amended by adding at the end the following:

''(6) USE OF CERTAIN FUNDS TO PROVIDE ADDITIONAL RESOURCES TO ADDRESS HIGH RATES OF MATERNAL MORTALITY AND MORBIDITY, SUPPORT UNMET NEEDS IDENTIFIED BY THE NEEDS ASSESSMENT, OR INCREASE ALLOCATIONS TO STATES AND TERRITORIES BASED ON RELATIVE POPULATION OR POVERTY.—The Secretary shall ensure that any amounts exceeding $400,000,000 that are used for grants under this subsection for a fiscal year are used to—

''(A) provide additional funding priority to States, tribes, and territories to address high rates of maternal mortality and morbidity;

''(B) address unmet needs identified by a needs assessment conducted under subsection (b); or

''(C) increase the amounts allocated under this section to States and to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, and American Samoa, based on the proportion of children who have not attained 5 years of age and are living in poverty.''.

The Acting CHAIR. No further amendment to the bill, as amended, shall be in order except those printed in part B of House Report 116–334. Each such further amendment may be offered only in the order printed in the report, by a Member designated in the report, shall be considered read, shall be debatable for the time specified in the report, equally divided and controlled by the proponent and an opponent, shall not be subject to amendment, and shall not be subject to a demand for division of the question.

AMENDMENT NO. 1 OFFERED BY MR. WALDEN

The Acting CHAIR. It is now in order to consider amendment No. 1 printed in part B of House Report 116–334.

Mr. WALDEN. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Strike all after the enactment clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Lower Costs, More Cures Act of 2019''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—MEDICARE PARTS B AND D

Subtitle A—Medicare Part B Provisions

SEC. 101. IMPROVEMENTS TO MEDICARE SITE-OF-SERVICE TRANSPARENCY.

Section 1834(t) of the Social Security Act (42 U.S.C. 1395m(t)) is amended—

(1) in paragraph (1)—

(A) in the heading, by striking ''IN GENERAL'' and inserting ''SITE PAYMENT'';

(B) in the matter preceding subparagraph (A)—

(i) by striking ''or to'' and inserting '', to'';

(ii) by inserting '', or to a physician for services furnished in a physician's office'' and ''surgical center''; and

(iii) by inserting ''(or 2021 with respect to a physician for services furnished in a physician's office)'' after ''2018''; and

(C) in subparagraph (A)—

(i) by striking ''and the'' and inserting '', the''; and

(ii) by inserting '', and the physician fee schedule under section 1848 (with respect to the practice expense component of such payment amount)'' after ''such section'';

(2) by redesignating paragraphs (2) through (4) as paragraphs (3) through (5), respectively; and

(3) by inserting after paragraph (1) the following new paragraph:

''(2) PHYSICIAN PAYMENT.—Beginning in 2021, the Secretary shall expand the information included on the Internet website described in paragraph (1) to include—

''(A) the amount paid to a physician under section 1848 for an item or service for the settings described in paragraph (1); and

''(B) the estimated amount of beneficiary liability applicable to the item or service.''.

SEC. 102. REQUIRING MANUFACTURERS OF CERTAIN SINGLE-DOSE CONTAINER OR SINGLE-USE PACKAGE DRUGS PAYABLE UNDER PART B OF THE MEDICARE PROGRAM TO PROVIDE REFUNDS WITH RESPECT TO DISCARDED AMOUNTS OF SUCH DRUGS.

Section 1847A of the Social Security Act (42 U.S.C. 1395–3a) is amended by adding at the end the following new subsection:

''(h) REFUND FOR CERTAIN DISCARDED SINGLE-DOSE CONTAINER OR SINGLE-USE PACKAGE DRUGS.—

''(1) SECRETARIAL PROVISION OF INFORMATION.—

''(A) IN GENERAL.—For each calendar quarter beginning on or after July 1, 2021, the Secretary shall, with respect to a refundable single-dose container or single-use package drug (as defined in paragraph (8)), report to each manufacturer (as defined in subsection (c)(6)(A)) of such refundable single-dose container or single-use package drug the following for the calendar quarter:

''(i) Subject to subparagraph (C), information on the total number of units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined using a mechanism such as the JW modifier used as of the date of enactment of this subsection (or any such successor modifier that includes such data as determined appropriate by the Secretary).

''(ii) The refund amount that the manufacturer is liable for pursuant to paragraph (3).

''(B) DETERMINATION OF DISCARDED AMOUNTS.—For purposes of subparagraph (A)(i), with respect to a refundable single-dose container or single-use package drug furnished during a quarter, the amount of such drug that was discarded shall be determined based on the amount of such drug that was unused and discarded for each drug on the date of service.

''(C) EXCLUSION OF UNITS OF PACKAGED DRUGS.—The total number of units of the billing and payment code of a refundable single-dose container or single-use package drug of a manufacturer furnished during a calendar quarter for purposes of subparagraph (A)(i), and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (3)(A)(ii), shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

''(2) MANUFACTURER REQUIREMENT.—For each calendar quarter beginning on or after July 1, 2021, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, provide to the Secretary a refund that is equal to the amount specified in paragraph (3) for such drug for such quarter.

''(3) REFUND AMOUNT.—

''(A) IN GENERAL.—The amount of the refund specified in this paragraph is, with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after July 1, 2021, an amount equal to the estimated amount (if any) by which—

''(i) the product of—

''(I) the total number of units of the billing and payment code for such drug that were discarded during such quarter (as determined under paragraph (1)); and

''(II)(aa) in the case of a refundable single-dose container or single-use package drug that is a single source drug or biological, the amount determined for such drug under subsection (b)(4); or

''(bb) in the case of a refundable single-dose container or single-use package drug that is a biosimilar biological product, the average sales price determined under subsection (b)(8)(A); exceeds

''(ii) an amount equal to the applicable percentage (as defined in subparagraph (B)) of the estimated total allowed charges for such drug during the quarter.

''(B) APPLICABLE PERCENTAGE DEFINED.—

''(i) IN GENERAL.—For purposes of subparagraph (A)(ii), the term 'applicable percentage' means—

''(I) subject to subclause (II), 10 percent; and

''(II) if applicable, in the case of a refundable single-dose container or single-use package drug described in clause (ii), a percentage specified by the Secretary pursuant to such clause.

''(ii) TREATMENT OF DRUGS THAT HAVE UNIQUE CIRCUMSTANCES.—In the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in paragraph (8)(B), the Secretary, through notice and comment rulemaking, may increase the applicable percentage otherwise applicable under clause (i)(I) as determined appropriate by the Secretary.

''(4) FREQUENCY.—Amounts required to be refunded pursuant to paragraph (2) shall be paid in regular intervals (as determined appropriate by the Secretary).

''(5) REFUND DEPOSITS.—Amounts paid as refunds pursuant to paragraph (2) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(6) ENFORCEMENT.—

''(A) AUDITS.—

''(i) MANUFACTURER AUDITS.—Each manufacturer of a refundable single-dose container or single-use package drug that is required to provide a refund under this subsection shall be subject to periodic audit with respect to such drug and such refunds by the Secretary.

''(ii) PROVIDER AUDITS.—The Secretary shall conduct periodic audits of claims submitted under this part with respect to refundable single-dose container or single-use package drugs in accordance with the authority under section 1833(e) to ensure compliance with the requirements applicable under this subsection.

''(B) CIVIL MONEY PENALTY.—

''(i) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who has failed to comply with the requirement under paragraph (2) for such drug for a calendar quarter in an amount equal to the sum of—

''(I) the amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and

''(II) 25 percent of such amount.

''(ii) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(7) IMPLEMENTATION.—The Secretary shall implement this subsection through notice and comment rulemaking.

''(8) DEFINITION OF REFUNDABLE SINGLE-DOSE CONTAINER OR SINGLE-USE PACKAGE DRUG.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), in this subsection, the term 'refundable single-dose container or single-use package drug' means a single source drug or biological (as defined in section 1847A(c)(6)(D)) or a biosimilar biological product (as defined in section 1847A(c)(6)(H)) for which payment is established under this part and that is furnished from a single-dose container or single-use package.

''(B) EXCLUSIONS.—The term 'refundable single-dose container or single-use package drug' does not include—

''(i) a drug or biological that is either a radiopharmaceutical or an imaging agent;

''(ii) a drug or biological for which dosage and administration instructions approved by the Commissioner of Food and Drugs require filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process; or

''(iii) a drug or biological approved by the Food and Drug Administration on or after the date of enactment of this subsection and with respect to which payment has been made under this part for less than 18 months.''.

SEC. 103. PROVIDING FOR VARIATION IN PAYMENT FOR CERTAIN DRUGS COVERED UNDER PART B OF THE MEDICARE PROGRAM.

(a) IN GENERAL.—Section 1847A(b) of the Social Security Act (42 U.S.C. 1395w–3a(b)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A), by inserting after ''or 106 percent'' the following: ''(or, for a multiple source drug (other than autologous cellular immunotherapy) furnished on or after January 1, 2021, the applicable percent specified in paragraph (9)(A) for the drug and quarter involved)''; and

(B) in subparagraph (B) of paragraph (1), by inserting after ''106 percent'' the following: ''(or, for a single source drug or biological (other than autologous cellular immunotherapy) furnished on or after January 1, 2021, the applicable percent specified in paragraph (9)(A) for the drug or biological and quarter involved)''; and

(2) by adding at the end the following new paragraph:

''(9) APPLICATION OF VARIABLE PERCENTAGES BASED ON PERCENTILE RANKING OF PER BENEFICIARY ALLOWED CHARGES.—

''(A) APPLICABLE PERCENT TO BE APPLIED.—

''(i) IN GENERAL.—Subject to clauses (ii), with respect to a drug or biological furnished in a calendar quarter beginning on or after January 1, 2021, if the Secretary determines that the percentile rank of a drug or biological under subparagraph (B)(i)(III), with respect to per beneficiary allowed charges for all such drugs or biologicals, is—

''(I) at least equal to the 85th percentile, the applicable percent for the drug for such quarter under this subparagraph is 104 percent;

''(II) at least equal to the 70th percentile, but less than the 85th percentile, such applicable percent is 106 percent;

''(III) at least equal to the 50th percentile, but less than the 70th percentile, such applicable percent is 108 percent; or

''(IV) less than the 50th percentile, such applicable percent is 110 percent.

''(ii) CASES WHERE DATA NOT SUFFICIENTLY AVAILABLE TO COMPUTE PER BENEFICIARY ALLOWED CHARGES.—Subject to clause (iii), in the case of a drug or biological furnished for which the amount of payment is determined under subparagraph (A) or (B) of paragraph (1) and not under subsection (c)(4), for calendar quarters during a period in which data are not sufficiently available to compute a per beneficiary allowed charges for the drug or biological, the applicable percent is 106 percent.

''(B) DETERMINATION OF PERCENTILE RANK OF PER BENEFICIARY ALLOWED CHARGES OF DRUGS.—

''(i) IN GENERAL.—With respect to a calendar quarter beginning on or after January 1, 2021, for drugs and biologicals for which the amount of payment is determined under subparagraph (A) or (B) of paragraph (1), except for drugs or biologicals for which data are not sufficiently available, the Secretary shall—

''(I) compute the per beneficiary allowed charges (as defined in subparagraph (C)) for each such drug or biological;

''(II) adjust such per beneficiary allowed charges for the quarter, to the extent provided under subparagraph (D); and

''(III) array such adjusted per beneficiary allowed charges for all such drugs or biologicals from high to low and rank such drugs or biologicals by percentile of such arrayed per beneficiary allowed charges.

''(ii) FREQUENCY.—The Secretary shall make the computations under clause (i)(I) every 6 months (or, if necessary, as determined by the Secretary, every 9 or 12 months) and such computations shall apply to succeeding calendar quarters until a new computation has been made.

''(iii) APPLICABLE DATA PERIOD.—For purposes of this paragraph, the term 'applicable data period' means the most recent period for which the data necessary for making the computations under clause (i) are available, as determined by the Secretary.

''(C) PER BENEFICIARY ALLOWED CHARGES DEFINED.—In this paragraph, the term 'per beneficiary allowed charges' means, with respect to a drug or biological for which the amount of payment is determined under subparagraph (A) or (B) of paragraph (1)—

''(i) the allowed charges for the drug or biological for which payment is so made for the applicable data period, as estimated by the Secretary; divided by

''(ii) the number of individuals for whom any payment for the drug or biological was made under paragraph (1) for the applicable data period, as estimated by the Secretary.

''(D) ADJUSTMENT TO REFLECT CHANGES IN AVERAGE SALES PRICE.—In applying this paragraph for a particular calendar quarter, the Secretary shall adjust the per beneficiary allowed charges for a drug or biological by multiplying such per beneficiary allowed charges under subparagraph (C) for the applicable data period by the ratio of—

''(i) the average sales price for the drug or biological for the most recent calendar quarter used under subsection (c)(5)(B); to

''(ii) the average sales price for the drug or biological for the calendar quarter (or the weighted average for the quarters involved) included in the applicable data period.''.

(b) APPLICATION OF JUDICIAL REVIEW PROVISIONS.—Section 1847A(g) of the Social Security Act is amended—

(1) by striking ''and'' at the end of paragraph (4);

(2) by striking the period at the end of paragraph (5) and inserting ''; and''; and

(3) by adding at the end the following new paragraph:

''(6) the determination of per beneficiary allowed charges of drugs or biologicals and ranking of such charges under subsection (b)(9).''.

SEC. 104. ESTABLISHMENT OF MAXIMUM ADD-ON PAYMENT FOR DRUGS AND BIOLOGICALS.

(a) IN GENERAL.—Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a), as amended by section 103, is further amended—

(1) in subsection (b)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking ''paragraph (7)'' and inserting ''paragraphs (7) and (10)''; and

(B) by adding at the end the following new paragraph:

''(10) MAXIMUM ADD-ON PAYMENT AMOUNT.—

''(A) IN GENERAL.—In determining the payment amount under the provisions of subparagraph (A), (B), or (C) of paragraph (1) of this subsection, subsection (c)(4)(A)(ii), or subsection (d)(3)(C) for a drug or biological furnished on or after January 1, 2021, if the applicable add-on payment (as defined in subparagraph (B)) for each drug or biological on a claim for a date of service exceeds the maximum add-on payment amount specified under subparagraph (C) for the drug or biological, then the payment amount otherwise determined for the drug or biological under those provisions, as applicable, shall be reduced by the amount of such excess.

''(B) APPLICABLE ADD-ON PAYMENT DEFINED.—In this paragraph, the term 'applicable add-on payment' means the following amounts, determined without regard to the application of subparagraph (A):

''(i) In the case of a multiple source drug, an amount equal to the difference between—

''(I) the amount that would otherwise be applied under paragraph (1)(A); and

''(II) the amount that would be applied under such paragraph if '100 percent' were substituted for the applicable percent (as defined in paragraph (9)) for such drug.

''(ii) In the case of a single source drug or biological, an amount equal to the difference between—

''(I) the amount that would otherwise be applied under paragraph (1)(B); and

''(II) the amount that would be applied under such paragraph if '100 percent' were substituted for the applicable percent (as defined in paragraph (9)) for such drug or biological.

''(iii) In the case of a biosimilar biological product, the amount otherwise determined under paragraph (8)(B).

''(iv) In the case of a drug or biological during the initial period described in subsection (c)(4)(A), an amount equal to the difference between—

''(I) the amount that would otherwise be applied under subsection (c)(4)(A)(ii); and

''(II) the amount that would be applied under such subsection if '100 percent' were substituted, as applicable, for—

''(aa) '103 percent' in subclause (I) of such subsection; or

''(bb) any percent in excess of 100 percent applied under subclause (II) of such subsection.

''(v) In the case of a drug or biological to which subsection (d)(3)(C) applies, an amount equal to the difference between—

''(I) the amount that would otherwise be applied under such subsection; and

''(II) the amount that would be applied under such subsection if '100 percent' were substituted, as applicable, for—

''(aa) any percent in excess of 100 percent applied under clause (i) of such subsection; or

''(bb) '103 percent' in clause (ii) of such subsection.

''(C) MAXIMUM ADD-ON PAYMENT AMOUNT SPECIFIED.—For purposes of subparagraph (A), the maximum add-on payment amount specified in this subparagraph is—

''(i) with respect to a drug or biological (other than autologous cellular immunotherapy)—

''(I) for each of 2021 through 2028, $1,000; and

''(II) for a subsequent year, the amount specified in this subparagraph for the preceding year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States

city average) for the 12-month period ending with June of the previous year; or

''(ii) with respect to a drug or biological consisting of autologous cellular immunotherapy—

''(I) for each of 2021 through 2028, $2,000; and

''(II) for a subsequent year, the amount specified in this subparagraph for the preceding year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year.

Any amount determined under this subparagraph that is not a multiple of $10 shall be rounded to the nearest multiple of $10.''

(2) in subsection (c)(4)(A)(ii), by striking ''in the case'' and inserting ''subject to subsection (b)(10), in the case''.

(b) CONFORMING AMENDMENTS RELATING TO SEPARATELY PAYABLE DRUGS.—

(1) OPPS.—Section 1833(t)(14) of the Social Security Act (42 U.S.C. 1395l(t)(14)) is amended—

(A) in subparagraph (A)(iii)(II), by inserting '', subject to subparagraph (I)'' after ''are not available''; and

(B) by adding at the end the following new subparagraph:

''(I) APPLICATION OF MAXIMUM ADD-ON PAYMENT FOR SEPARATELY PAYABLE DRUGS AND BIOLOGICALS.—In establishing the amount of payment under subparagraph (A) for a specified covered outpatient drug that is furnished as part of a covered OPD service (or group of services) on or after January 1, 2021, if such payment is determined based on the average price for the year established under section 1847A pursuant to clause (iii)(II) of such subparagraph, the provisions of subsection (b)(10) of section 1847A shall apply to the amount of payment so established in the same manner as such provisions apply to the amount of payment under section 1847A.''.

(2) ASC.—Section 1833(i)(2)(D) of the Social Security Act (42 U.S.C. 1395l(i)(2)(D)) is amended—

(A) by moving clause (v) 6 ems to the left;

(B) by redesignating clause (vi) as clause (vii); and

(C) by inserting after clause (v) the following new clause:

''(vi) If there is a separate payment under the system described in clause (i) for a drug or biological furnished on or after January 1, 2021, the provisions of subsection (t)(14)(I) shall apply to the establishment of the amount of payment for the drug or biological under such system in the same manner in which such provisions apply to the establishment of the amount of payment under subsection (t)(14)(A).''.

SEC. 105. TREATMENT OF DRUG ADMINISTRATION SERVICES FURNISHED BY CERTAIN EXCEPTED OFF-CAMPUS OUTPATIENT DEPARTMENTS OF A PROVIDER.

Section 1833(t)(16) of the Social Security Act (42 12 U.S.C. 1395l(t)(16)) is amended by adding at the end the following new subparagraph:

''(G) SPECIAL PAYMENT RULE FOR DRUG ADMINISTRATION SERVICES FURNISHED BY AN EXCEPTED DEPARTMENT OF A PROVIDER.—

''(i) IN GENERAL.—In the case of a covered OPD service that is a drug administration service (as defined by the Secretary) furnished by a department of a provider described in clause (ii) or (iv) of paragraph (21)(B), the payment amount for such service furnished on or after January 1, 2021, shall be the same payment amount (as determined in paragraph (21)(C)) that would apply if the drug administration service was furnished by an off-campus outpatient department of a provider (as defined in paragraph (21)(B)).

''(ii) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The reductions made under this subparagraph—

''(I) shall not be considered an adjustment under paragraph (2)(E); and

''(II) shall not be implemented in a budget neutral manner.''.

Subtitle B—Drug Price Transparency

SEC. 111. REPORTING ON EXPLANATION FOR DRUG PRICE INCREASES.

(a) IN GENERAL.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

''PART W—DRUG PRICE REPORTING; DRUG VALUE FUND

''SEC. 399OO. REPORTING ON EXPLANATION FOR DRUG PRICE INCREASES.

''(a) DEFINITIONS.—In this section:

''(1) MANUFACTURER.—The term 'manufacturer' means the person—

''(A) that holds the application for a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; or

''(B) who is responsible for setting the wholesale acquisition cost for the drug.

''(2) QUALIFYING DRUG.—The term 'qualifying drug' means any drug that is approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under subsection (a) or (k) of section 351 of this Act—

''(A) that has a wholesale acquisition cost of $100 or more, adjusted for inflation occurring after the date of enactment of this section, for a month's supply or a typical course of treatment that lasts less than a month, and is—

''(i) subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act;

''(ii) administered or otherwise dispensed to treat a disease or condition affecting more than 200,000 persons in the United States; and

''(iii) not a vaccine; and

''(B) for which, during the previous calendar year, at least 1 dollar of the total amount of sales were for individuals enrolled under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or under a State Medicaid plan under title XIX of such Act (42 U.S.C. 1396 et seq.) or under a waiver of such plan.

''(3) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given that term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).

''(b) REPORT.—

''(1) REPORT REQUIRED.—The manufacturer of a qualifying drug shall submit a report to the Secretary—

''(A) for each increase in the price of a qualifying drug that results in an increase in the wholesale acquisition cost of that drug that is equal to—

''(i) 10 percent or more within a single calendar year beginning on or after January 1, 2019; or

''(ii) 25 percent or more within three consecutive calendar years for which the first such calendar year begins on or after January 1, 2019; and

''(B) in the case that the qualifying drug is first covered under title XVIII with respect to an applicable year, if the estimated cost or spending under such title per individual or per user of such drug (as estimated by the Secretary) for such applicable year (or per course of treatment in such applicable year, as defined by the Secretary) is at least $26,000.

''(2) REPORT DEADLINE.—Each report described in paragraph (1) shall be submitted to the Secretary—

''(A) in the case of a report with respect to an increase in the price of a qualifying drug that occurs during the period beginning on January 1, 2019, and ending on the day that is 60 days after the date of enactment of this section, not later than 90 days after such date of enactment;

''(B) in the case of a report with respect to an increase in the price of a qualifying drug that occurs after the period described in subparagraph (A), not later than 30 days prior to the planned effective date of such price increase for such qualifying drug; and

''(C) in the case of a report with respect to a qualifying drug that meets the criteria described in paragraph (1)(B), not later than 30 days after such drug meets such criteria.

''(c) CONTENTS.—A report under subsection (b), consistent with the standard for disclosures described in section 213.3(d) of title 12, Code of Federal Regulations (as in effect on the date of enactment of this section), shall, at a minimum, include—

''(1) with respect to the qualifying drug—

''(A) the percentage by which the manufacturer will raise the wholesale acquisition cost of the drug within the calendar year or three consecutive calendar years as described in subsection (b)(1)(A) or (b)(1)(B), if applicable, and the effective date of such price increase;

''(B) an explanation for, and description of, each price increase for such drug that will occur during the calendar year period described in subsection (b)(1)(A) or the three consecutive calendar year period described in subsection (b)(1)(B), as applicable;

''(C) if known and different from the manufacturer of the qualifying drug, the identity of—

''(i) the sponsor or sponsors of any investigational new drug applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act for clinical investigations with respect to such drug, for which the full reports are submitted as part of the application—

''(I) for approval of the drug under section 505 of such Act; or

''(II) for licensure of the drug under section 351 of this Act; and

''(ii) the sponsor of an application for the drug approved under such section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act;

''(D) a description of the history of the manufacturer's price increases for the drug since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351 of this Act, or since the manufacturer acquired such approved application or license, if applicable;

''(E) the current wholesale acquisition cost of the drug;

''(F) the total expenditures of the manufacturer on—

''(i) materials and manufacturing for such drug; and

''(ii) acquiring patents and licensing for such drug;

''(G) the percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds;

''(H) the total expenditures of the manufacturer on research and development for such drug that is necessary to demonstrate that it meets applicable statutory standards for approval under section 505 of the Federal Food, Drug, and Cosmetic Act or licensure under section 351 of this Act, as applicable;

''(I) the total expenditures of the manufacturer on pursuing new or expanded indications or dosage changes for such drug under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act;

''(J) the total expenditures of the manufacturer on carrying out postmarket requirements related to such drug, including under section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act;

''(K) the total revenue and the net profit generated from the qualifying drug for each calendar year since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351, or since the manufacturer acquired such approved application or license; and

''(L) the total costs associated with marketing and advertising for the qualifying drug;

''(2) with respect to the manufacturer—

''(A) the total revenue and the net profit of the manufacturer for each of the 1-year period described in subsection (b)(1)(A) or the 3-year period described in subsection (b)(1)(B), as applicable;

''(B) all stock-based performance metrics used by the manufacturer to determine executive compensation for each of the 1-year period described in subsection (b)(1)(A) or the 3-year period described in subsection (b)(1)(B), as applicable; and

''(C) any additional information the manufacturer chooses to provide related to drug pricing decisions, such as total expenditures on—

''(i) drug research and development; or

''(ii) clinical trials, including on drugs that failed to receive approval by the Food and Drug Administration; and

''(3) such other related information as the Secretary considers appropriate and as specified by the Secretary through notice-and-comment rulemaking.

''(d) INFORMATION PROVIDED.—The manufacturer of a qualifying drug that is required to submit a report under subsection (b), shall ensure that such report and any explanation for, and description of, each price increase described in subsection (c)(1)(B) shall be truthful, not misleading, and accurate.

''(e) CIVIL MONETARY PENALTY.—Any manufacturer of a qualifying drug that fails to submit a report for the drug as required by this section, following notification by the Secretary to the manufacturer that the manufacturer is not in compliance with this section, shall be subject to a civil monetary penalty of $75,000 for each day on which the violation continues.

''(f) FALSE INFORMATION.—Any manufacturer that submits a report for a drug as required by this section that knowingly provides false information in such report is subject to a civil monetary penalty in an amount not to exceed $75,000 for each item of false information.

''(g) PUBLIC POSTING.—

''(1) IN GENERAL.—Subject to paragraph (3), the Secretary shall post each report submitted under subsection (b) on the public website of the Department of Health and Human Services the day the price increase of a qualifying drug is scheduled to go into effect.

''(2) FORMAT.—In developing the format in which reports will be publicly posted under paragraph (1), the Secretary shall consult with stakeholders, including beneficiary groups, and shall seek feedback from consumer advocates and readability experts on the format and presentation of the content of such reports to ensure that such reports are—

''(A) user-friendly to the public; and

''(B) written in plain language that consumers can readily understand.

''(3) PROTECTED INFORMATION.—Nothing in this section shall be construed to authorize the public disclosure of information submitted by a manufacturer that is prohibited from disclosure by applicable laws concerning the protection of trade secrets, commercial information, and other information covered under such laws.

''SEC. 399OO–1. ANNUAL REPORT TO CONGRESS.

''(a) IN GENERAL.—Subject to subsection (b), the Secretary shall submit to Congress, and post on the public website of the Department of Health and Human Services in a way that is user-friendly to the public and written in plain language that consumers can readily understand, an annual report—

''(1) summarizing the information reported pursuant to section 399OO;

''(2) including copies of the reports and supporting detailed economic analyses submitted pursuant to such section;

''(3) detailing the costs and expenditures incurred by the Department of Health and Human Services in carrying out section 399OO; and

''(4) explaining how the Department of Health and Human Services is improving consumer and provider information about drug value and drug price transparency.

''(b) PROTECTED INFORMATION.—Nothing in this section shall be construed to authorize the public disclosure of information submitted by a manufacturer that is prohibited from disclosure by applicable laws concerning the protection of trade secrets, commercial information, and other information covered under such laws.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) takes effect on the date of enactment of this Act.

SEC. 112. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.

Section 1150A of the Social Security Act (42 U.S.C. 1320b–23) is amended—

(1) in subsection (c), in the matter preceding paragraph (1), by inserting ''(other than as permitted under subsection (e))'' after ''disclosed by the Secretary''; and

(2) by adding at the end the following new subsection:

''(e) PUBLIC AVAILABILITY OF CERTAIN INFORMATION.—

''(1) IN GENERAL.—In order to allow the comparison of PBMs' ability to negotiate rebates, discounts, direct and indirect remuneration fees, administrative fees, and price concessions and the amount of such rebates, discounts, direct and indirect remuneration fees, administrative fees, and price concessions that are passed through to plan sponsors, beginning January 1, 2020, the Secretary shall make available on the Internet website of the Department of Health and Human Services the information with respect to the second preceding calendar year provided to the Secretary on generic dispensing rates (as described in paragraph (1) of subsection (b)) and information provided to the Secretary under paragraphs (2) and (3) of such subsection that, as determined by the Secretary, is with respect to each PBM.

''(2) AVAILABILITY OF DATA.—In carrying out paragraph (1), the Secretary shall ensure the following:

''(A) CONFIDENTIALITY.—The information described in such paragraph is displayed in a manner that prevents the disclosure of information, with respect to an individual drug or an individual plan, on rebates, discounts, direct and indirect remuneration fees, administrative fees, and price concessions.

''(B) CLASS OF DRUG.—The information described in such paragraph is made available by class of drug, using an existing classification system, but only if the class contains such number of drugs, as specified by the Secretary (but not fewer than three drugs), to ensure confidentiality of proprietary information or other information that is prevented to be disclosed under subparagraph (A).''.

SEC. 113. STUDY OF PHARMACEUTICAL SUPPLY CHAIN INTERMEDIARIES AND MERGER ACTIVITY.

(a) INITIAL REPORT.—Not later than 1 year after the date of enactment of this Act, the Commission shall submit to the appropriate committees of Congress a report that—

(1) addresses at minimum—

(A) whether pharmacy benefit managers—

(i) charge payers a higher price than the reimbursement rate at which the pharmacy benefit managers reimburse competing pharmacies;

(ii) steer patients for anticompetitive purposes to any pharmacies, including retail, mail-order, or any other type of pharmacy, in which the pharmacy benefit manager has an ownership interest;

(iii) audit or review proprietary data, including acquisition costs, patient information, or dispensing information, of competing pharmacies that can be used for anticompetitive purposes; or

(iv) use formulary designs to increase the market share of higher cost prescription drugs and depress the market share of lower cost prescription drugs (each net of rebates and discounts);

(B) how companies and payers assess the benefits, costs, and risks of contracting with intermediaries, including pharmacy services administrative organizations, and whether more information about the roles of intermediaries should be available to consumers and payers; and

(C) whether there are any specific legal or regulatory obstacles the Commission currently faces in ensuring a competitive and transparent marketplace in the pharmaceutical supply chain, including the pharmacy benefit manager marketplace and pharmacy services administrative organizations; and

(2) provides—

(A) observations or conclusions drawn from the November 2017 roundtable entitled ''Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics'', and any similar efforts;

(B) specific actions the Commission intends to take as a result of the November 2017 roundtable, and any similar efforts, including a detailed description of relevant forthcoming actions, additional research or roundtable discussions, consumer education efforts, or enforcement actions; and

(C) policy or legislative recommendations to—

(i) improve transparency and competition in the pharmaceutical supply chain;

(ii) prevent and deter anticompetitive behavior in the pharmaceutical supply chain; and

(iii) best ensure that consumers benefit from any cost savings or efficiencies that may result from mergers and consolidations.

(b) INTERIM REPORT.—Not later than 180 days after the date of enactment of this Act, the Commission shall submit to the appropriate committees of Congress an interim report on the progress of the report required by subsection (a), along with preliminary findings and conclusions based on information collected to that date.

(c) DEFINITIONS.—In this section:

(1) APPROPRIATE COMMITTEES OF CONGRESS.—The term ''appropriate committees of Congress'' means—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on the Judiciary of the Senate; and

(C) the Committee on the Judiciary of the House of Representatives.

(2) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

SEC. 114. REQUIRING CERTAIN MANUFACTURERS TO REPORT DRUG PRICING INFORMATION WITH RESPECT TO DRUGS UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a) is amended—

(1) in subsection (b)—

(A) in paragraph (2)(A), by inserting ''or subsection (f)(2), as applicable'' before the period at the end;

(B) in paragraph (3), in the matter preceding subparagraph (A), by inserting ''or subsection (f)(2), as applicable,'' before ''determined by''; and

(C) in paragraph (6)(A), in the matter preceding clause (i), by inserting ''or subsection (f)(2), as applicable,'' before ''determined by''; and

(2) in subsection (f)—

(A) by striking ''For requirements'' and inserting the following:

''(1) IN GENERAL.—For requirements''; and

(B) by adding at the end the following new paragraph:

''(2) MANUFACTURERS WITHOUT A REBATE AGREEMENT UNDER TITLE XIX.—

''(A) IN GENERAL.—If the manufacturer of a drug or biological described in subparagraph (C), (E), or (G) of section 1842(o)(1) or in section 1881(b)(14)(B) that is payable under this part has not entered into and does not have in effect a rebate agreement described in subsection (b) of section 1927, for calendar quarters beginning on or after January 1, 2020, such manufacturer shall report to the Secretary the information described in subsection (b)(3)(A)(iii) of such section 1927 with respect to such drug or biological in a time and manner specified by the Secretary. For purposes of applying this paragraph, a drug or biological described in the previous sentence includes items, services, supplies, and products that are payable under this part as a drug or biological.

''(B) AUDIT.—Information reported under subparagraph (A) is subject to audit by the Inspector General of the Department of Health and Human Services.

''(C) VERIFICATION.—The Secretary may survey wholesalers and manufacturers that directly distribute drugs described in subparagraph (A), when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of such a drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(D) CONFIDENTIALITY.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph (other than the wholesale acquisition cost for purposes of carrying out this section) is confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler, except—

''(i) as the Secretary determines to be necessary to carry out this section (including the determination and implementation of the payment amount), or to carry out section 1847B;

''(ii) to permit the Comptroller General of the United States to review the information provided; and

''(iii) to permit the Director of the Congressional Budget Office to review the information provided.''.

(b) ENFORCEMENT.—Section 1847A of such Act (42 U.S.C. 1395w–3a) is further amended—

(1) in subsection (d)(4)—

(A) in subparagraph (A), by striking ''IN GENERAL'' and inserting ''MISREPRESENTATION'';

(B) in subparagraph (B), by striking ''subparagraph (B)'' and inserting ''subparagraph (A), (B), or (C)'';

(C) by redesignating subparagraph (B) as subparagraph (D); and

(D) by inserting after subparagraph (A) the following new subparagraphs:

''(B) FAILURE TO PROVIDE TIMELY INFORMATION.—If the Secretary determines that a manufacturer described in subsection (f)(2) has failed to report on information described in section 1927(b)(3)(A)(iii) with respect to a drug or biological in accordance with such subsection, the Secretary shall apply a civil money penalty in an amount of $10,000 for each day the manufacturer has failed to report such information and such amount shall be paid to the Treasury.

''(C) FALSE INFORMATION.—Any manufacturer required to submit information under subsection (f)(2) that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law.''; and

(2) in subsection (c)(6)(A), by striking the period at the end and inserting '', except that, for purposes of subsection (f)(2), the Secretary may, if the Secretary determines appropriate, exclude repackagers of a drug or biological from such term.''.

(c) MANUFACTURERS WITH A REBATE AGREEMENT.—

(1) IN GENERAL.—Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(A)) is amended by adding at the end the following new sentence: ''For purposes of applying clause (iii), a drug or biological described in the flush matter following such clause includes items, services, supplies, and products that are payable under this part as a drug or biological.''.

(2) TECHNICAL AMENDMENT.—Section 1927(b)(3)(A)(iii) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(A)(iii)) is amended by striking ''section 1881(b)(13)(A)(ii)'' and inserting ''section 1881(b)(14)(B)''.

(d) REPORT.—Not later than January 1, 2021, the Inspector General of the Department of Health and Human Services shall assess and submit to Congress a report on the accuracy of average sales price information submitted by manufacturers under section 1847A of the Social Security Act (42 U.S.C. 1395w–3a). Such report shall include any recommendations on how to improve the accuracy of such information.

SEC. 115. MAKING PRESCRIPTION DRUG MARKETING SAMPLE INFORMATION REPORTED BY MANUFACTURERS AVAILABLE TO CERTAIN INDIVIDUALS AND ENTITIES.

(a) IN GENERAL.—Section 1128H of the Social Security Act (42 U.S.C. 1320a–7i) is amended—

(1) by redesignating subsection (b) as subsection (e); and

(2) by inserting after subsection (a) the following new subsections:

''(b) DATA SHARING AGREEMENTS.—

''(1) IN GENERAL.—The Secretary shall enter into agreements with the specified data sharing individuals and entities described in paragraph (2) under which—

''(A) upon request of such an individual or entity, as applicable, the Secretary makes available to such individual or entity the information submitted under subsection (a) by manufacturers and authorized distributors of record; and

''(B) such individual or entity agrees to not disclose publicly or to another individual or entity any information that identifies a particular practitioner or health care facility.

''(2) SPECIFIED DATA SHARING INDIVIDUALS AND ENTITIES.—For purposes of paragraph (1), the specified data sharing individuals and entities described in this paragraph are the following:

''(A) OVERSIGHT AGENCIES.—Health oversight agencies (as defined in section 164.501 of title 45, Code of Federal Regulations), including the Centers for Medicare & Medicaid Services, the Office of the Inspector General of the Department of Health and Human Services, the Government Accountability Office, the Congressional Budget Office, the Medicare Payment Advisory Commission, and the Medicaid and CHIP Payment and Access Commission.

''(B) RESEARCHERS.—Individuals who conduct scientific research (as defined in section 164.501 of title 45, Code of Federal Regulations) in relevant areas as determined by the Secretary.

''(C) PAYERS.—Private and public health care payers, including group health plans, health insurance coverage offered by health insurance issuers, Federal health programs, and State health programs.

''(3) EXEMPTION FROM FREEDOM OF INFORMATION ACT.—Except as described in paragraph (1), the Secretary may not be compelled to disclose the information submitted under subsection (a) to any individual or entity. For purposes of section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act), this paragraph shall be considered a statute described in subsection (b)(3)(B) of such section.

''(c) PENALTIES.—

''(1) DATA SHARING AGREEMENTS.—Subject to paragraph (3), any specified data sharing individual or entity described in subsection (b)(2) that violates the terms of a data sharing agreement the individual or entity has with the Secretary under subsection (b)(1) shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each such violation. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

''(2) FAILURE TO REPORT.—Subject to paragraph (3), any manufacturer or authorized distributor of record of an applicable drug under subsection (a) that fails to submit information required under such subsection in a timely manner in accordance with rules or regulations promulgated to carry out such subsection shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each such failure. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

''(3) LIMITATION.—The total amount of civil money penalties imposed under paragraph (1) or (2) with respect to a year and an individual or entity described in paragraph (1) or a manufacturer or distributor described in paragraph (2), respectively, shall not exceed $150,000.

''(d) DRUG SAMPLE DISTRIBUTION INFORMATION.—

''(1) IN GENERAL.—Not later than January 1 of each year (beginning with 2021), the Secretary shall maintain a list containing information related to the distribution of samples of applicable drugs. Such list shall provide

the following information with respect to the preceding year:

''(A) The name of the manufacturer or authorized distributor of record of an applicable drug for which samples were requested or distributed under this section.

''(B) The quantity and class of drug samples requested.

''(C) The quantity and class of drug samples distributed.

''(2) PUBLIC AVAILABILITY.—The Secretary shall make the information in such list available to the public on the Internet website of the Food and Drug Administration.''.

(b) FDA MAINTENANCE OF INFORMATION.—The Food and Drug Administration shall maintain information available to affected reporting companies to ensure their ability to fully comply with the requirements of section 1128H of the Social Security Act.

(c) PROHIBITION ON DISTRIBUTION OF SAMPLES OF OPIOIDS.—Section 503(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)) is amended—

(1) by moving the margin of paragraph (4) 2 ems to the left; and

(2) by adding at the end the following:

''(5) No person may distribute a drug sample of a drug that is—

''(A) an applicable drug (as defined in section 1128H(e) of the Social Security Act);

''(B) a controlled substance (as defined in section 102 of the Controlled Substances Act) for which the findings required under section 202(b)(2) of such Act have been made; and

''(C) approved under section 505 for use in the management or treatment of pain (other than for the management or treatment of a substance use disorder).''.

(d) MEDPAC REPORT.—Not later than 3 years after the date of the enactment of this Act, the Medicare Payment Advisory Commission shall conduct a study on the impact of drug samples on provider prescribing practices and health care costs and may, as the Commission deems appropriate, make recommendations on such study.

SEC. 116. REQUIRING PRESCRIPTION DRUG PLAN SPONSORS TO INCLUDE REAL-TIME BENEFIT INFORMATION AS PART OF SUCH SPONSOR'S ELECTRONIC PRESCRIPTION PROGRAM UNDER THE MEDICARE PROGRAM.

Section 1860D–4(e)(2) of the Social Security Act (42 U.S.C. 1395w–104(e)(2)) is amended—

(1) in subparagraph (D), by striking ''To the extent'' and inserting ''Except as provided in subparagraph (F), to the extent''; and

(2) by adding at the end the following new subparagraph:

''(F) REAL-TIME BENEFIT INFORMATION.—

''(i) IN GENERAL.—Not later than January 1, 2021, the program shall implement real-time benefit tools that are capable of integrating with a prescribing health care professional's electronic prescribing or electronic health record system for the transmission of formulary and benefit information in real time to prescribing health care professionals. With respect to a covered part D drug, such tools shall be capable of transmitting such information specific to an individual enrolled in a prescription drug plan. Such information shall include the following:

''(I) A list of any clinically-appropriate alternatives to such drug included in the formulary of such plan.

''(II) Cost-sharing information for such drug and such alternatives, including a description of any variance in cost-sharing based on the pharmacy dispensing such drug or such alternatives.

''(III) Information relating to whether such drug is included in the formulary of such plan and any prior authorization or other utilization management requirements applicable to such drug and such alternatives so included.

''(ii) ELECTRONIC TRANSMISSION.—The provisions of subclauses (I) and (II) of clause (ii) of subparagraph (E) shall apply to an electronic transmission described in clause (i) in the same manner as such provisions apply with respect to an electronic transmission described in clause (i) of such subparagraph.

''(iii) SPECIAL RULE FOR 2021.—The program shall be deemed to be in compliance with clause (i) for 2021 if the program complies with the provisions of section 423.160(b)(7) of title 42, Code of Federal Regulations (or a successor regulation), for such year.

''(iv) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed as to allow a real-time benefits tool to steer an individual, without the consent of the individual, to a particular pharmacy or pharmacy setting over their preferred pharmacy setting nor prohibit the designation of a preferred pharmacy under such tool.''.

SEC. 117. SENSE OF CONGRESS REGARDING THE NEED TO EXPAND COMMERCIALLY AVAILABLE DRUG PRICING COMPARISON PLATFORMS.

It is the sense of Congress that—

(1) commercially available drug pricing comparison platforms can, at no cost, help patients find the lowest price for their medications at their local pharmacy;

(2) such platforms should be integrated, to the maximum extent possible, in the health care delivery ecosystem; and

(3) pharmacy benefit managers should work to disclose generic and brand name drug prices to such platforms to ensure that—

(A) patients can benefit from the lowest possible price available to them; and

(B) overall drug prices can be reduced as more educated purchasing decisions are made based on price transparency.

SEC. 118. TECHNICAL CORRECTIONS.

(a) IN GENERAL.—Section 3022(b) of the Public Health Service Act (42 U.S.C. 300jj–52(b)) is amended by adding at the end the following new paragraph:

''(4) APPLICATION OF AUTHORITIES UNDER INSPECTOR GENERAL ACT OF 1978.—In carrying out this subsection, the Inspector General shall have the same authorities as provided under section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if included in the enactment of the 21st Century Cures Act (Public Law 114–255).

Subtitle C—Medicare Part D Benefit Redesign

SEC. 121. MEDICARE PART D BENEFIT REDESIGN.

(a) BENEFIT STRUCTURE REDESIGN.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w– 102(b)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by inserting ''for a year preceding 2022 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2022 and each subsequent year'' after ''paragraph (3)''; and

(ii) in clause (i), by inserting after ''25 percent'' the following: ''(or, for 2022 and each subsequent year, 15 percent)'';

(B) in subparagraph (C)—

(i) in clause (i), in the matter preceding subclause (I), by inserting ''for a year preceding 2022,'' after ''paragraph (4),''; and

(ii) in clause (ii)(III), by striking ''and each subsequent year'' and inserting ''and 2021''; and

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by inserting ''for a year preceding 2022,'' after ''paragraph (4),''; and

(II) in subclause (I)(bb), by striking ''a year after 2018'' and inserting ''each of years 2018 through 2021''; and

(ii) in clause (ii)(V), by striking ''2019 and each subsequent year'' and inserting ''each of years 2019 through 2021'';

(2) in paragraph (3)(A)—

(A) in the matter preceding clause (i), by inserting ''for a year preceding 2022,'' after ''and (4),''; and

(B) in clause (ii), by striking ''for a subsequent year'' and inserting ''for each of years 2007 through 2021'';

(3) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i)—

(I) by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively, and indenting appropriately;

(II) in the matter preceding item (aa), as redesignated by subclause (I), by striking ''is equal to the greater of—'' and inserting ''is equal to—

''(I) for a year preceding 2022, the greater of—''.

(III) by striking the period at the end of item (bb), as redesignated by subclause (I), and inserting ''; and''; and

(IV) by adding at the end the following:

''(II) for 2022 and each succeeding year, $0.''; and

(ii) in clause (ii)—

(I) by striking ''clause (i)(I)'' and inserting ''clause (i)(I)(aa)''; and

(II) by adding at the end the following new sentence: ''The Secretary shall continue to calculate the dollar amounts specified in clause (i)(I)(aa), including with the adjustment under this clause, after 2021 for purposes of section 1860D–14(a)(1)(D)(iii).'';

(B) in subparagraph (B)—

(i) in clause (i)—

(I) in subclause (V), by striking ''or'' at the end;

(II) in subclause (VI)—

(aa) by striking ''for a subsequent year'' and inserting ''for 2021''; and

(bb) by striking the period at the end and inserting a semicolon; and

(III) by adding at the end the following new subclauses:

''(VII) for 2022, is equal to $3,100; or

''(VIII) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.''; and

(ii) in clause (ii), by striking ''clause (i)(II)'' and inserting ''clause (i)'';

(C) in subparagraph (C)(i), by striking ''and for amounts'' and inserting ''and for a year preceding 2022 for amounts''; and

(D) in subparagraph (E), by striking ''In applying'' and inserting ''For each of 2011 through 2021, in applying''.

(b) DECREASING REINSURANCE PAYMENT AMOUNT.—Section 1860D–15(b)(1) of the Social Security Act (42 U.S.C. 1395w–115(b)(1)) is amended—

(1) by striking ''equal to 80 percent'' and inserting ''equal to–

''(A) for a year preceding 2022, 80 percent'';

(2) in subparagraph (A), as added by paragraph (1), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(B) for 2022 and each subsequent year, the sum of—

''(i) an amount equal to 20 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred

costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) with respect to applicable drugs (as defined in section 1860D–14B(g)(2)); and

''(ii) an amount equal to 30 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) with respect to covered part D drugs that are not applicable drugs (as so defined).''.

(c) MANUFACTURER DISCOUNT PROGRAM.—

(1) IN GENERAL.—Part D of title XVIII of the Social Security Act is amended by inserting after section 1860D–14A (42 U.S.C. 1495w–114) the following new section:

''SEC. 1860D–14B. MANUFACTURER DISCOUNT PROGRAM.

''(a) ESTABLISHMENT.—The Secretary shall establish a manufacturer discount program (in this section referred to as the 'program'). Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c). The Secretary shall establish a model agreement for use under the program by not later than January 1, 2021, in consultation with manufacturers, and allow for comment on such model agreement.

''(b) TERMS OF AGREEMENT.—

''(1) IN GENERAL.—

''(A) AGREEMENT.—An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer that are dispensed on or after January 1, 2022.

''(B) PROVISION OF DISCOUNTED PRICES AT THE POINT-OF-SALE.—The discounted prices described in subparagraph (A) shall be provided to the applicable beneficiary at the pharmacy or by the mail order service at the point-of-sale of an applicable drug.

''(2) PROVISION OF APPROPRIATE DATA.—Each manufacturer with an agreement in effect under this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.

''(3) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination under subparagraph (A) of subsection (c)(1) or procedures established under such subsection (c)(1).

''(4) LENGTH OF AGREEMENT.—

''(A) IN GENERAL.—An agreement under this section shall be effective for an initial period of not less than 12 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

''(B) TERMINATION.—

''(i) BY THE SECRETARY.—The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

''(ii) BY A MANUFACTURER.—A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

''(I) if the termination occurs before January 30 of a plan year, as of the day after the end of the plan year; and

''(II) if the termination occurs on or after January 30 of a plan year, as of the day after the end of the succeeding plan year.

''(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.

''(iv) NOTICE TO THIRD PARTY.—The Secretary shall provide notice of such termination to a third party with a contract under subsection (d)(3) within not less than 30 days before the effective date of such termination.

''(5) EFFECTIVE DATE OF AGREEMENT.—An agreement under this section shall take effect on a date determined appropriate by the Secretary, which may be at the start of a calendar quarter.

''(c) DUTIES DESCRIBED.—The duties described in this subsection are the following:

''(1) ADMINISTRATION OF PROGRAM.—Administering the program, including—

''(A) the determination of the amount of the discounted price of an applicable drug of a manufacturer;

''(B) the establishment of procedures under which discounted prices are provided to applicable beneficiaries at pharmacies or by mail order service at the point-of-sale of an applicable drug;

''(C) the establishment of procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

''(i) the negotiated price of the applicable drug; and

''(ii) the discounted price of the applicable drug;

''(D) the establishment of procedures to ensure that the discounted price for an applicable drug under this section is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as the Secretary may specify; and

''(E) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the third party with a contract under subsection (d)(3).

''(2) MONITORING COMPLIANCE.—

''(A) IN GENERAL.—The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under this section.

''(B) NOTIFICATION.—If a third party with a contract under subsection (d)(3) determines that the manufacturer is not in compliance with such agreement, the third party shall notify the Secretary of such noncompliance for appropriate enforcement under subsection (e).

''(3) COLLECTION OF DATA FROM PRESCRIPTION DRUG PLANS AND MA–PD PLANS.—The Secretary may collect appropriate data from prescription drug plans and MA–PD plans in a timeframe that allows for discounted prices to be provided for applicable drugs under this section.

''(d) ADMINISTRATION.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall provide for the implementation of this section, including the performance of the duties described in subsection (c).

''(2) LIMITATION.—In providing for the implementation of this section, the Secretary shall not receive or distribute any funds of a manufacturer under the program.

''(3) CONTRACT WITH THIRD PARTIES.—The Secretary shall enter into a contract with 1 or more third parties to administer the requirements established by the Secretary in order to carry out this section. At a minimum, the contract with a third party under the preceding sentence shall require that the third party—

''(A) receive and transmit information between the Secretary, manufacturers, and other individuals or entities the Secretary determines appropriate;

''(B) receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under agreements under this section;

''(C) provide adequate and timely information to manufacturers, consistent with the agreement with the manufacturer under this section, as necessary for the manufacturer to fulfill its obligations under this section; and

''(D) permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the third party to determine discounts for applicable drugs of the manufacturer under the program.

''(4) PERFORMANCE REQUIREMENTS.—The Secretary shall establish performance requirements for a third party with a contract under paragraph (3) and safeguards to protect the independence and integrity of the activities carried out by the third party under the program under this section.

''(5) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the program under this section.

''(e) ENFORCEMENT.—

''(1) AUDITS.—Each manufacturer with an agreement in effect under this section shall be subject to periodic audit by the Secretary.

''(2) CIVIL MONEY PENALTY.—

''(A) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with such agreement for each such failure in an amount the Secretary determines is commensurate with the sum of—

''(i) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and

''(ii) 25 percent of such amount.

''(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(f) CLARIFICATION REGARDING AVAILABILITY OF OTHER COVERED PART D DRUGS.—Nothing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in.

''(g) DEFINITIONS.—In this section:

''(1) APPLICABLE BENEFICIARY.—The term 'applicable beneficiary' means an individual who, on the date of dispensing a covered part D drug—

''(A) is enrolled in a prescription drug plan or an MA–PD plan;

''(B) is not enrolled in a qualified retiree prescription drug plan; and

''(C) has incurred costs for covered part D drugs in the year that are equal to or exceed

the annual deductible specified in section 1860D–2(b)(1) for such year.

''(2) APPLICABLE DRUG.—The term 'applicable drug' means, with respect to an applicable beneficiary, a covered part D drug—

''(A) approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (including a product licensed under subsection (k) of such section); and

''(B)(i) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

''(ii) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

''(iii) is provided through an exception or appeal.

''(3) APPLICABLE NUMBER OF CALENDAR DAYS.—The term 'applicable number of calendar days' means—

''(A) with respect to claims for reimbursement submitted electronically, 14 days; and

''(B) with respect to claims for reimbursement submitted otherwise, 30 days.

''(4) DISCOUNTED PRICE.—

''(A) IN GENERAL.—The term 'discounted price' means, with respect to an applicable drug of a manufacturer furnished during a year to an applicable beneficiary, 90 percent of the negotiated price of such drug.

''(B) CLARIFICATION.—Nothing in this section shall be construed as affecting the responsibility of an applicable beneficiary for payment of a dispensing fee for an applicable drug.

''(C) SPECIAL CASE FOR CLAIMS SPANNING DEDUCTIBLE.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall at or above the annual deductible specified in section 1860D–2(b)(1) for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls at or above such annual deductible.

''(5) MANUFACTURER.—The term 'manufacturer' means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

''(6) NEGOTIATED PRICE.—The term 'negotiated price' has the meaning given such term in section 1860D–2(d)(1)(B), except that such negotiated price shall not include any dispensing fee for an applicable drug.

''(7) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—The term 'qualified retiree prescription drug plan' has the meaning given such term in section 11860D–22(a)(2).''.

(2) SUNSET OF MEDICARE COVERAGE GAP DISCOUNT PROGRAM.—Section 1860D–14A of the Social Security Act (42 U.S.C. 1395–114a) is amended—

(A) in subsection (a), in the first sentence, by striking ''The Secretary'' and inserting ''Subject to subsection (h), the Secretary''; and

(B) by adding at the end the following new subsection:

''(h) SUNSET OF PROGRAM.—

''(1) IN GENERAL.—The program shall not apply to applicable drugs dispensed on or after January 1, 2022, and, subject to paragraph (2), agreements under this section shall be terminated as of such date.

''(2) CONTINUED APPLICATION FOR APPLICABLE DRUGS DISPENSED PRIOR TO SUNSET.—The provisions of this section (including all responsibilities and duties) shall continue to apply after January 1, 2022, with respect to applicable drugs dispensed prior to such date.''.

(3) INCLUSION OF ACTUARIAL VALUE OF MANUFACTURER DISCOUNTS IN BIDS.—Section 1860D–11 of the Social Security Act (42 U.S.C. 1395w–111) is amended—

(A) in subsection (b)(2)(C)(iii)—

(i) by striking ''assumptions regarding the reinsurance'' and inserting ''assumptions regarding—

''(I) the reinsurance''; and

(ii) by adding at the end the following:

''(II) for 2022 and each subsequent year, the manufacturer discounts provided under section 1860D–14B subtracted from the actuarial value to produce such bid; and''; and

(B) in subsection (c)(1)(C)—

(i) by striking ''an actuarial valuation of the reinsurance'' and inserting ''an actuarial valuation of—

''(i) the reinsurance'';

(ii) in clause (i), as added by clause (i) of this subparagraph, by adding ''and'' at the end; and

(iii) by adding at the end the following:

''(ii) for 2022 and each subsequent year, the manufacturer discounts provided under section 1860D–14B;''.

(d) DETERMINATION OF ALLOWABLE REINSURANCE COSTS.—Section 1860D–15(b) of the Social Security Act (42 U.S.C. 1395w–115(b)) is amended—

(1) in paragraph (2)—

(A) by striking ''COSTS.—For purposes'' and inserting ''COSTS.—

''(A) IN GENERAL.—Subject to subparagraph (B), for purposes''.

(B) by adding at the end the following new subparagraph:

''(B) INCLUSION OF MANUFACTURER DISCOUNTS ON APPLICABLE DRUGS.—For purposes of applying subparagraph (A), the term 'allowable reinsurance costs' shall include the portion of the negotiated price (as defined in section 1860D–14B(g)(6)) of an applicable drug (as defined in section 1860D–14(g)(2)) that was paid by a manufacturer under the manufacturer discount program under section 1860D–14B.''; and

(2) in paragraph (3)—

(A) in the first sentence, by striking ''For purposes'' and inserting ''Subject to paragraph (2)(B), for purposes''; and

(B) in the second sentence, by inserting ''or, in the case of an applicable drug, by a manufacturer'' after ''by the individual or under the plan''.

(e) UPDATING RISK ADJUSTMENT METHODOLOGIES TO ACCOUNT FOR PART D MODERNIZATION REDESIGN.—Section 1860D–15(c) of the Social Security Act (42 U.S.C. 1395w–115(c)) is amended by adding at the end the following new paragraph:

''(3) UPDATING RISK ADJUSTMENT METHODOLOGIES TO ACCOUNT FOR PART D MODERNIZATION REDESIGN.—The Secretary shall update the risk adjustment model used to adjust bid amounts pursuant to this subsection as appropriate to take into account changes in benefits under this part pursuant to the amendments made by section 121 of the Lower Costs, More Cures Act of 2019.''.

(f) CONDITIONS FOR COVERAGE OF DRUGS UNDER THIS PART.—Section 1860D–43 of the Social Security Act (42 U.S.C. 1395w–153) is amended—

(1) in subsection (a)—

(A) in paragraph (2), by striking ''and'' at the end;

(B) in paragraph (3), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following new paragraphs:

''(4) participate in the manufacturer discount program under section 1860D–14B;

''(5) have entered into and have in effect an agreement described in subsection (b) of such section 1860D–14B with the Secretary; and

''(6) have entered into and have in effect, under terms and conditions specified by the Secretary, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of such section 1860D–14B.'';

(2) by striking subsection (b) and inserting the following:

''(b) EFFECTIVE DATE.—Paragraphs (1) through (3) of subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011, and before January 1, 2022, and paragraphs (4) through (6) of such subsection shall apply to covered part D drugs dispensed on or after January 1, 2022.''; and

(3) in subsection (c), by striking paragraph (2) and inserting the following:

''(2) the Secretary determines that in the period beginning on January 1, 2011, and ending on December 31, 2011 (with respect to paragraphs (1) through (3) of subsection (a)) or the period beginning on January 1, 2022, and ending December 31, 2022 (with respect to paragraphs (4) through (6) of such subsection), there were extenuating circumstances.''.

(g) CONFORMING AMENDMENTS.—

(1) Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102) is amended—

(A) in subsection (a)(2)(A)(i)(I), by striking '', or an increase in the initial'' and inserting ''or for a year preceding 2022 an increase in the initial'';

(B) in subsection (c)(1)(C)—

(i) in the subparagraph heading, by striking ''AT INITIAL COVERAGE LIMIT''; and

(ii) by inserting ''for a year preceding 2022 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2022 and each subsequent year'' after ''subsection (b)(3) for the year'' each place it appears; and

(C) in subsection (d)(1)(A), by striking ''or an initial'' and inserting ''or for a year preceding 2022, an initial''.

(2) Section 1860D–4(a)(4)(B)(i) of the Social Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is amended by striking ''the initial'' and inserting ''for a year preceding 2022, the initial''.

(3) Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (C), by striking ''The continuation'' and inserting ''For a year preceding 2022, the continuation'';

(ii) in subparagraph (D)(iii), by striking ''1860D–2(b)(4)(A)(i)(I)'' and inserting ''1860D–2(b)(4)(A)(i)(I)(aa)''; and

(iii) in subparagraph (E), by striking ''The elimination'' and inserting ''For a year preceding 2022, the elimination''; and

(B) in paragraph (2)—

(i) in subparagraph (C), by striking ''The continuation'' and inserting ''For a year preceding 2022, the continuation''; and

(ii) in subparagraph (E)—

(I) by inserting ''for a year preceding 2022,'' after ''subsection (c)''; and

(II) by striking ''1860D– 2(b)(4)(A)(i)(I)'' and inserting ''1860D–2(b)(4)(A)(i)(I)(aa)''.

(4) Section 1860D–21(d)(7) of the Social Security Act (42 U.S.C. 1395w–131(d)(7)) is amended by striking ''section 1860D–2(b)(4)(B)(i)'' and inserting ''section 1860D–2(b)(4)(C)(i)''.

(5) Section 1860D–22(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w–132(a)(2)(A)) is amended—

(A) by striking ''the value of any discount'' and inserting the following: ''the value of—

''(i) for years prior to 2022, any discount'';

(B) in clause (i), as inserted by subparagraph (A) of this paragraph, by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following new clause:

''(ii) for 2022 and each subsequent year, any discount provided pursuant to section 1860D–14B.''.

(6) Section 1860D–41(a)(6) of the Social Security Act (42 U.S.C. 1395w–151(a)(6)) is amended—

(A) by inserting ''for a year before 2022'' after ''1860D–2(b)(3)''; and

(B) by inserting ''for such year'' before the period.

(h) EFFECTIVE DATE.—The amendments made by this section shall apply to plan year 2022 and subsequent plan years.

Subtitle D—Other Medicare Part D Provisions

SEC. 131. TRANSITIONAL COVERAGE AND RETROACTIVE MEDICARE PART D COVERAGE FOR CERTAIN LOW-INCOME BENEFICIARIES.

Section 1860D–14 of the Social Security Act (42 U.S.C. 1395w–114) is amended—

(1) by redesignating subsection (e) as subsection (f); and

(2) by adding after subsection (d) the following new subsection:

''(e) LIMITED INCOME NEWLY ELIGIBLE TRANSITION PROGRAM.—

''(1) IN GENERAL.—Beginning not later than January 1, 2021, the Secretary shall carry out a program to provide transitional coverage for covered part D drugs for LI NET eligible individuals in accordance with this subsection.

''(2) LI NET ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this subsection, the term 'LI NET eligible individual' means a part D eligible individual who—

''(A) meets the requirements of clauses (ii) and (iii) of subsection (a)(3)(A); and

''(B) has not yet enrolled in a prescription drug plan or an MA–PD plan, or, who has so enrolled, but with respect to whom coverage under such plan has not yet taken effect.

''(3) TRANSITIONAL COVERAGE.—For purposes of this subsection, the term 'transitional coverage' means, with respect to an LI NET eligible individual—

''(A) immediate access to covered part D drugs at the point-of-sale during the period that begins on the first day of the month such individual is determined to meet the requirements of clauses (ii) and (iii) of subsection (a)(3)(A) and ends on the date that coverage under a prescription drug plan or MA–PD plan takes effect with respect to such individual; and

''(B) in the case of an LI NET eligible individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) or a recipient of supplemental security income benefits under title XVI, retroactive coverage (in the form of reimbursement of the amounts that would have been paid under this part had such individual been enrolled in a prescription drug plan or MA–PD plan) of covered part D drugs purchased by such individual during the period that begins on the date that is the later of—

''(i) the date that such individual was first eligible for a low-income subsidy under this part; or

''(ii) the date that is 36 months prior to the date such individual enrolls in a prescription drug plan or MA–PD plan, and ends on the date that coverage under such plan takes effect.

''(4) PROGRAM ADMINISTRATION.—

''(A) SINGLE POINT OF CONTACT.—The Secretary shall, to the extent feasible, administer the program under this subsection through a contract with a single program administrator.

''(B) BENEFIT DESIGN.—The Secretary shall ensure that the transitional coverage provided to LI NET eligible individuals under this subsection—

''(i) provides access to all covered part D drugs under an open formulary;

''(ii) permits all pharmacies determined by the Secretary to be in good standing to process claims under the program;

''(iii) is consistent with such requirements as the Secretary considers necessary to improve patient safety and ensure appropriate dispensing of medication; and

''(iv) meets such other requirements as the Secretary may establish.

''(5) RELATIONSHIP TO OTHER PROVISIONS OF THIS TITLE; WAIVER AUTHORITY.—

''(A) IN GENERAL.—The following provisions shall not apply with respect to the program under this subsection:

''(i) Paragraphs (1) and (3)(B) of section 1860D–4(a) (relating to dissemination of general information; availability of information on changes in formulary through the internet).

''(ii) Subparagraphs (A) and (B) of section 1860D–4(b)(3) (relating to requirements on development and application of formularies; formulary development).

''(iii) Paragraphs (1)(C) and (2) of section 1860D–4(c) (relating to medication therapy management program).

''(B) WAIVER AUTHORITY.—The Secretary may waive such other requirements of title XI and this title as may be necessary to carry out the purposes of the program established under this subsection.''.

SEC. 132. ALLOWING THE OFFERING OF ADDITIONAL PRESCRIPTION DRUG PLANS UNDER MEDICARE PART D.

(a) RESCINDING AND ISSUANCE OF NEW GUIDANCE.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall—

(1) rescind sections of any sub-regulatory guidance that limit the number of prescription drug plans in each PDP region that may be offered by a PDP sponsor under part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–101 et seq.); and

(2) issue new guidance specifying that a PDP sponsor may offer up to 4 (or a greater number if determined appropriate by the Secretary) prescription drug plans in each PDP region, except in cases where the PDP sponsor may offer up to 2 additional plans in a PDP region pursuant to section 1860D–11(d)(4) of the Social Security Act (42 U.S.C. 1395w–111(d)(4)), as added by subsection (b).

(b) OFFERING OF ADDITIONAL PLANS.—Section 1860D–11(d) of the Social Security Act (42 U.S.C. 1395w–111(d)) is amended by adding at the end the following new paragraph:

''(4) OFFERING OF ADDITIONAL PLANS.—

''(A) IN GENERAL.—For plan year 2022 and each subsequent plan year, a PDP sponsor may offer up to 2 additional prescription drug plans in a PDP region (in addition to any limit established by the Secretary under this part) provided that the PDP sponsor complies with subparagraph (B) with respect to at least one such prescription drug plan.

''(B) REQUIREMENTS.—In order to be eligible to offer up to 2 additional plans in a PDP region pursuant to subparagraph (A), a PDP sponsor must ensure that, with respect to at least one such prescription drug plan, the sponsor or any entity that provides pharmacy benefits management services under a contract with any such sponsor or plan does not receive direct or indirect remuneration, as defined in section 423.308 of title 42, Code of Federal Regulations (or any successor regulation), unless at least 25 percent of the aggregate reductions in price or other remuneration received by the PDP sponsor or entity from drug manufacturers with respect to the plan and plan year—

''(i) are reflected at the point-of-sale to the enrollee; or

''(ii) are used to reduce total beneficiary cost-sharing estimated by the PDP sponsor for prescription drug coverage under the plan in the annual bid submitted by the PDP sponsor under section 1860D–11(b).

''(C) DEFINITION OF REDUCTIONS IN PRICE.—For purposes of subparagraph (B), the term 'reductions in price' refers only to collectible amounts, as determined by the Secretary, which excludes amounts which after adjudication and reconciliation with pharmacies and manufacturers are duplicate in nature, contrary to other contractual clauses, or otherwise ineligible (such as due to beneficiary disenrollment or coordination of benefits).''.

(c) RULE OF CONSTRUCTION.—Nothing in the provisions of, or amendments made by, this section shall be construed as limiting the ability of the Secretary to increase any limit otherwise applicable on the number of prescription drug plans that a PDP sponsor may offer, at the discretion of the PDP sponsor, in a PDP region under part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–101 et seq.).

SEC. 133. ALLOWING CERTAIN ENROLLEES OF PRESCRIPTION DRUGS PLANS AND MA–PD PLANS UNDER MEDICARE PROGRAM TO SPREAD OUT COST-SHARING UNDER CERTAIN CIRCUMSTANCES.

(a) STANDARD PRESCRIPTION DRUG COVERAGE.—Section 1860D–2(b)(2) of the Social Security Act (42 U.S.C. 1395w–102(b)(2)), as amended by section 121, is further amended—

(1) in subparagraph (A), by striking ''Subject to subparagraphs (C) and (D)'' and inserting ''Subject to subparagraphs (C), (D), and (E)''; and

(2) by adding at the end the following new subparagraph:

''(E) ENROLLEE OPTION REGARDING SPREADING COST-SHARING.—

''(i) IN GENERAL.—The Secretary shall establish by regulation a process under which, with respect to plan year 2022 and subsequent plan years, a prescription drug plan or an MA–PD plan shall, in the case of a part D eligible individual enrolled with such plan for such plan year with respect to whom the plan projects that the dispensing of a covered part D drug to such individual will result in the individual incurring costs within a 30-day period that are equal to a significant percentage (as specified by the Secretary pursuant to such regulation) of the annual out-of-pocket threshold specified in paragraph (4)(B) for such plan year, provide such individual with the option to make the coinsurance payment required under subparagraph (A) for such costs in the form of equal monthly installments over the remainder of such plan year.

''(ii) SIGNIFICANT PERCENTAGE LIMITATIONS.—In specifying a significant percentage pursuant to the regulation established by the Secretary under clause (i), the Secretary may not specify a percentage that is less than 30 percent or greater than 100 percent.''.

(b) ALTERNATIVE PRESCRIPTION DRUG COVERAGE.—Section 1860D–2(c) of the Social Security Act (42 U.S.C. 1395w–102(c)) is amended by adding at the end the following new paragraph:

''(4) SAME ENROLLEE OPTION REGARDING SPREADING COST-SHARING.—For plan year 2022 and subsequent plan years, the coverage provides the enrollee option regarding spreading

cost-sharing described in and required under subsection (b)(2)(E).''.

SEC. 134. ESTABLISHING A MONTHLY CAP ON BENEFICIARY INCURRED COSTS FOR INSULIN PRODUCTS AND SUPPLIES UNDER A PRESCRIPTION DRUG PLAN OR MA–PD PLAN.

(a) IN GENERAL.—Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102), as amended by sections 121 and 133, is further amended—

(1) in subsection (b)(2)—

(A) in subparagraph (A), by striking ''and (E)'' and inserting ''(E), and (F)'';

(B) in subparagraph (B), by striking ''and (D)'' and inserting ''(D), and (F)''; and

(C) by adding at the end the following new subparagraph:

''(F) CAP ON INCURRED COSTS FOR INSULIN PRODUCTS AND SUPPLIES.—

''(i) IN GENERAL.—The coverage provides benefits, for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold described in paragraph (4)(B) and with respect to a month (beginning with January of 2022), with cost sharing that is equal to $0 for a specified covered part D drug (as defined in clause (iii)) furnished to an individual who has incurred costs during such month with respect to specified covered part D drugs equal to—

''(I) for months occurring in 2022, $50; or

''(II) for months occurring in a subsequent year, the amount applicable under this clause for months occurring in the year preceding such subsequent year, increased by the annual percentage increase specified in paragraph (6) for such subsequent year and rounded to the nearest dollar.

''(ii) APPLICATION.—The provisions of clauses (i) through (iii) of paragraph (4)(C) shall apply with respect to the determination of the incurred costs for specified covered part D drugs for purposes of clause (i) in the same manner as such provisions apply with respect to the determination of incurred costs for covered part D drugs for purposes of paragraph (4)(A).

''(iii) SPECIFIED COVERED PART D DRUG.—For purposes of this subparagraph, the term 'specified covered part D drug' means a covered part D drug that is—

''(I) insulin; or

''(II) a medical supply associated with the injection of insulin (as defined in regulations of the Secretary promulgated pursuant to subsection (e)(1)(B)).''; and

(2) in subsection (c), by adding at the end the following new paragraph:

''(5) SAME PROTECTION WITH RESPECT TO EXPENDITURES FOR INSULIN AND CERTAIN MEDICAL SUPPLIES.—The coverage provides the coverage required under subsection (b)(2)(F).''.

(b) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Section 1860D–14(a)(1)(D) of the Social Security Act (42 U.S.C. 1395w–114(a)(1)(D)), as amended by section 121, is further amended—

(A) in clause (ii), by striking ''section 1860D–2(b)(2)'' and inserting ''section 1860D–2(b)(2)(A)''; and

(B) in clause (iii), by striking ''section 1860D–2(b)(2)'' and inserting ''section 1860D–2(b)(2)(A)''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply with respect to plan year 2022 and each subsequent plan year.

SEC. 135. GROWTH RATE OF MEDICARE PART D OUT-OF-POCKET COST THRESHOLD.

(a) PROVIDING MEDICARE PART D BENEFICIARIES WITH CERTAIN 2020 OFFSET PAYMENTS.—Section 1860D–2(b)(4) of the Social Security Act (42 U.S.C. 1395w–102(b)(4)) is amended by adding at the end the following new subparagraph:

''(F) 2020 OFFSET PAYMENTS.—

''(i) IN GENERAL.—Subject to clause (iv), the Secretary shall provide for payment from the Medicare Prescription Drug Account as follows:

''(I) In the case of a specified individual (as defined in clause (ii)(I)) who as of the last day of a calendar quarter in 2020 has incurred costs for covered part D drugs so that the individual has exceeded the annual out-of-pocket threshold applied under subparagraph (B)(i)(V) for 2020, payment to the individual by not later than 15th day of the third month following the end of such quarter of the amount by which such threshold so applied exceeded the target threshold for 2020.

''(II) In the case of a specified individual who is not described in subclause (I) and who as of the last day of 2020 has incurred costs for covered part D drugs so that the individual has exceeded the target threshold for 2020, payment to the individual by not later than December 31, 2021 of the amount by which such incurred costs exceeded the target threshold for 2020.

''(ii) DEFINITIONS.—For purposes of this subparagraph:

''(I) SPECIFIED INDIVIDUAL.—The term 'specified individual' means an individual who—

''(aa) is enrolled in a prescription drug plan or an MA–PD plan;

''(bb) is not enrolled in a qualified retiree prescription drug plan; and

''(cc) is not entitled to an income-related subsidy under section 1860D–14(a).

''(II) TARGET THRESHOLD FOR 2020.—the term 'target threshold for 2020' means the annual out-of-pocket threshold that would have been applied under subparagraph (B)(i) for 2020 if such threshold had been determined in accordance with subclause (IV) of such subparagraph instead of subclause (V) of such subparagraph.

''(iii) NOTIFICATION.—In the case of any specified individual who during 2020 has incurred costs for covered part D drugs so that the individual has exceeded the target threshold for 2020, the Secretary shall, not later than September 30, 2021, provide to such individual a notification informing such individual of such individual's right to a payment described in clause (i) and the estimated timing of such payment.

''(iv) CLARIFICATION.—The Secretary shall provide only 1 payment under this subparagraph with respect to any individual.

''(v) IMPLEMENTATION.—The Secretary may implement this subparagraph by program instruction or otherwise.''.

(b) REDUCED GROWTH RATE FOR 2021 OF MEDICARE PART D OUT-OF-POCKET COST THRESHOLD.—Section 1860D–2(b)(4)(B)(i) of the Social Security Act (42 U.S.C. 1395w–102(b)(4)(B)(i)) is amended—

(1) in subclause (V), by striking at the end ''or'';

(2) by redesignating subclause (VI) as subclause (VIII); and

(3) by inserting after subclause (V) the following new subclauses:

''(VI) for 2021, is equal to the amount that would have been applied under this subparagraph for 2020 if such amount had been determined in accordance with subclause (IV) instead of subclause (V), increased by the lesser of—

''(aa) the annual percentage increase described in paragraph (7) for 2021, plus 2 percentage points; or

''(bb) the annual percentage increase described in paragraph (6) for 2021;

''(VII) for 2022, is equal to the amount that would have been applied under this subparagraph for 2022 if the amendments made by section 1101(d)(1) of the Health Care and Education Reconciliation Act of 2010 and by section 135 of the Lower Costs, More Cures Act of 2019 had not been enacted; or''.

Subtitle E—MedPAC

SEC. 141. PROVIDING THE MEDICARE PAYMENT ADVISORY COMMISSION AND MEDICAID AND CHIP PAYMENT AND ACCESS COMMISSION WITH ACCESS TO CERTAIN DRUG PAYMENT INFORMATION, INCLUDING CERTAIN REBATE INFORMATION.

(a) ACCESS TO CERTAIN PART D PAYMENT DATA.—Section 1860D–15(f) of the Social Security Act (42 U.S.C. 1395w–115(f)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A)(ii), by striking ''and'' at the end;

(B) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

(C) by inserting at the end the following new subparagraph:

''(C) by the Executive Director of the Medicare Payment Advisory Commission for purposes of monitoring, making recommendations, and analysis of the program under this title and by the Executive Director of the Medicaid and CHIP Payment and Access Commission for purposes of monitoring, making recommendations, and analysis of the Medicaid program established under title XIX and the Children's Health Insurance Program under title XXI.''; and

(2) by adding at the end the following new paragraph:

''(3) ADDITIONAL RESTRICTIONS ON DISCLOSURE OF INFORMATION.—The Executive Directors described in paragraph (2)(C) shall not disclose any of the following information disclosed to such Executive Directors or obtained by such Executive Directors pursuant to such paragraph, with respect to a prescription drug plan offered by a PDP sponsor:

''(A) The specific amounts or the identity of the source of any rebates, price concessions, or other forms of direct or indirect remuneration under such prescription drug plan.

''(B) Information submitted with the bid submitted under section 1860D–11 by such PDP sponsor.

''(C) In the case of such information from prescription drug event records, in a form that would not be permitted under section 423.505(m) of title 42, Code of Federal Regulations, or any successor regulation, if made by the Centers for Medicare & Medicaid Services.''.

(b) ACCESS TO CERTAIN REBATE AND PAYMENT DATA UNDER MEDICARE AND MEDICAID.—Section 1927(b)(3)(D) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)) is amended—

(1) in the matter before clause (i), by striking ''subsection (a)(6)(A)(ii)'' and inserting ''subsection (a)(6)(A)'';

(2) in clause (v), by striking ''and'' at the end;

(3) in clause (vi), by striking the period at the end and inserting '', and'';

(4) by inserting after clause (vi) the following new clause:

''(vii) to permit the Executive Director of the Medicare Payment Advisory Commission and the Executive Director of the Medicaid and CHIP Payment and Access Commission to review the information provided.'';

(5) in the matter at the end, by striking ''1860D–4(c)(2)(E)'' and inserting ''1860D–4(c)(2)(G)''; and

(6) by adding at the end the following new sentence: ''Any information disclosed to the Executive Director of the Medicare Payment Advisory Commission or the Executive Director of the Medicaid and CHIP Payment and Access Commission pursuant to this subparagraph shall not be disclosed by either such Executive Director in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler.''.

TITLE II—MEDICAID

SEC. 201. SUNSET OF LIMIT ON MAXIMUM REBATE AMOUNT FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.

Section 1927(c)(2)(D) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)(D)) is amended by inserting after ''December 31, 2009,'' the following: ''and before January 1, 2023,''.

SEC. 202. MEDICAID PHARMACY AND THERAPEUTICS COMMITTEE IMPROVEMENTS.

(a) IN GENERAL.—Subparagraph (A) of section 1927(d)(4) of the Social Security Act (42 U.S.C. 1396r–8(d)(4)) is amended to read as follows:

''(A)(i) The formulary is developed and reviewed by a pharmacy and therapeutics committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State.

''(ii) Subject to clause (vi), the State establishes and implements a conflict of interest policy for the pharmacy and therapeutics committee that—

''(I) is publicly accessible;

''(II) requires all committee members to complete, on at least an annual basis, a disclosure of relationships, associations, and financial dealings that may affect their independence of judgement in committee matters; and

''(III) contains clear processes, such as recusal from voting or discussion, for those members who report a conflict of interest, along with appropriate processes to address any instance where a member fails to report a conflict of interest.

''(iii) The membership of the pharmacy and therapeutics committee—

''(I) includes at least 1 actively practicing physician and at least 1 actively practicing pharmacist, each of whom—

''(aa) is independent and free of conflict with respect to manufacturers and Medicaid participating plans or subcontractors, including pharmacy benefit managers; and

''(bb) has expertise in the care of 1 or more Medicaid-specific populations such as elderly or disabled individuals, children with complex medical needs, or low-income individuals with chronic illnesses; and

''(II) is made publicly available.

''(iv) At the option of the State, the State's drug use review board established under subsection (g)(3) may serve as the pharmacy and therapeutics committee provided the State ensures that such board meets the requirements of clauses (ii) and (iii).

''(v) The State reviews and has final approval of the formulary established by the pharmacy and therapeutics committee.

''(vi) If the Secretary determines it appropriate or necessary based on the findings and recommendations of the Comptroller General of the United States in the report submitted to Congress under section 203 of the Lower Costs, More Cures Act of 2019, the Secretary shall issue guidance that States must follow for establishing conflict of interest policies for the pharmacy and therapeutics committee in accordance with the requirements of clause (ii), including appropriate standards and requirements for identifying, addressing, and reporting on conflicts of interest.''.

(b) APPLICATION TO MEDICAID MANAGED CARE ORGANIZATIONS.—Clause (xiii) of section 1903(m)(2)(A) of the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is amended—

(1) by striking ''and (III)'' and inserting ''(III)'';

(2) by striking the period at the end and inserting '', and (IV) any formulary used by the entity for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity is developed and reviewed by a pharmacy and therapeutics committee that meets the requirements of clauses (ii) and (iii) of section 1927(d)(4)(A).''; and

(3) by moving the left margin 2 ems to the left.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 1 year after the date of enactment of this Act.

SEC. 203. GAO REPORT ON CONFLICTS OF INTEREST IN STATE MEDICAID PROGRAM DRUG USE REVIEW BOARDS AND PHARMACY AND THERAPEUTICS (P&T) COMMITTEES.

(a) INVESTIGATION.—The Comptroller General of the United States shall conduct an investigation of potential or existing conflicts of interest among members of State Medicaid program State drug use review boards (in this section referred to as ''DUR Boards'') and pharmacy and therapeutics committees (in this section referred to as ''P&T Committees'').

(b) REPORT.—Not later than 24 months after the date of enactment of this Act, the Comptroller General shall submit to Congress a report on the investigation conducted under subsection (a) that includes the following:

(1) A description outlining how DUR Boards and P&T Committees operate in States, including details with respect to—

(A) the structure and operation of DUR Boards and statewide P&T Committees;

(B) States that operate separate P&T Committees for their fee-for-service Medicaid program and their Medicaid managed care organizations or other Medicaid managed care arrangements (collectively referred to in this section as ''Medicaid MCOs)''; and

(C) States that allow Medicaid MCOs to have their own P&T Committees and the extent to which pharmacy benefit managers administer or participate in such P&T Committees.

(2) A description outlining the differences between DUR Boards established in accordance with section 1927(g)(3) of the Social Security Act (42 U.S.C. 1396r(g)(3)) and P&T Committees.

(3) A description outlining the tools P&T Committees may use to determine Medicaid drug coverage and utilization management policies.

(4) An analysis of whether and how States or P&T Committees establish participation and independence requirements for DUR Boards and P&T Committees, including with respect to entities with connections with drug manufacturers, State Medicaid programs, managed care organizations, and other entities or individuals in the pharmaceutical industry.

(5) A description outlining how States, DUR Boards, or P&T Committees define conflicts of interest.

(6) A description of how DUR Boards and P&T Committees address conflicts of interest, including who is responsible for implementing such policies.

(7) A description of the tools, if any, States use to ensure that there are no conflicts of interest on DUR Boards and P&T Committees.

(8) An analysis of the effectiveness of tools States use to ensure that there are no conflicts of interest on DUR Boards and P&T Committees and, if applicable, recommendations as to how such tools could be improved.

(9) A review of strategies States may use to guard against conflicts of interest on DUR Boards and P&T Committees and to ensure compliance with the requirements of titles XI and XIX of the Social Security Act (42 U.S.C. 1301 et seq., 1396 et seq.) and access to effective, clinically appropriate, and medically necessary drug treatments for Medicaid beneficiaries, including recommendations for such legislative and administrative actions as the Comptroller General determines appropriate.

SEC. 204. ENSURING THE ACCURACY OF MANUFACTURER PRICE AND DRUG PRODUCT INFORMATION UNDER THE MEDICAID DRUG REBATE PROGRAM.

(a) AUDIT OF MANUFACTURER PRICE AND DRUG PRODUCT INFORMATION.—

(1) IN GENERAL.—Subparagraph (B) of section 1927(b)(3) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)) is amended to read as follows:

''(B) AUDITS AND SURVEYS OF MANUFACTURER PRICE AND DRUG PRODUCT INFORMATION.—

''(i) AUDITS.—The Secretary shall conduct ongoing audits of the price and drug product information reported by manufacturers under subparagraph (A) for the most recently ended rebate period to ensure the accuracy and timeliness of such information. In conducting such audits, the Secretary may employ evaluations, surveys, statistical sampling, predictive analytics and other relevant tools and methods.

''(ii) VERIFICATIONS SURVEYS OF AVERAGE MANUFACTURER PRICE AND MANUFACTURER'S AVERAGE SALES PRICE.—In addition to the audits required under clause (i), the Secretary may survey wholesalers and manufacturers (including manufacturers that directly distribute their covered outpatient drugs (in this subparagraph referred to as 'direct sellers')), when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) to make payment reported under subparagraph (A).

''(iii) PENALTIES.—In addition to other penalties as may be prescribed by law, including under subparagraph (C) of this paragraph, the Secretary may impose a civil monetary penalty in an amount not to exceed $185,000 on an annual basis on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with an audit or survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(iv) REPORTS.—

''(I) REPORT TO CONGRESS.—The Secretary shall, not later than 18 months after date of enactment of this subparagraph, submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate regarding additional regulatory or statutory changes that may be required in order to ensure accurate and timely reporting and oversight of manufacturer price and drug product information, including whether changes should be made to reasonable assumption requirements to ensure such assumptions are reasonable and accurate or whether another methodology for ensuring accurate and timely reporting of price and drug product information should be considered to ensure the integrity of the drug rebate program under this section.

''(II) ANNUAL REPORTS.—The Secretary shall, on at least an annual basis, submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate summarizing the results of the audits and surveys conducted under this subparagraph

during the period that is the subject of the report.

''(III) CONTENT.—Each report submitted under subclause (II) shall, with respect to the period that is the subject of the report, include summaries of—

''(aa) error rates in the price, drug product, and other relevant information supplied by manufacturers under subparagraph (A);

''(bb) the timeliness with which manufacturers, wholesalers, and direct sellers provide information required under subparagraph (A) or under clause (i) or (ii) of this subparagraph;

''(cc) the number of manufacturers, wholesalers, and direct sellers and drug products audited under this subparagraph;

''(dd) the types of price and drug product information reviewed under the audits conducted under this subparagraph;

''(ee) the tools and methodologies employed in such audits;

''(ff) the findings of such audits, including which manufacturers, if any, were penalized under this subparagraph; and

''(gg) such other relevant information as the Secretary shall deem appropriate.

''(IV) PROTECTION OF INFORMATION.—In preparing a report required under subclause (II), the Secretary shall redact such proprietary information as the Secretary determines appropriate to prevent disclosure of, and to safeguard, such information.

''(v) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this subparagraph, there is authorized to be appropriated $2,000,000 for fiscal year 2020 and each fiscal year thereafter.''.

(2) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the first day of the first fiscal quarter that begins after the date of enactment of this Act.

(b) INCREASED PENALTIES FOR NONCOMPLIANCE WITH REPORTING REQUIREMENTS.—

(1) INCREASED PENALTY FOR LATE REPORTING OF INFORMATION.—Section 1927(b)(3)(C)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(i)) is amended by striking ''increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury'' and inserting '', for each covered outpatient drug with respect to which such information is not provided, $50,000 for the first day that such information is not provided on a timely basis and $19,000 for each subsequent day that such information is not provided''.

(2) INCREASED PENALTY FOR KNOWINGLY REPORTING FALSE INFORMATION.—Section 1927(b)(3)(C)(ii) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking ''$100,000'' and inserting ''$500,000''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the first day of the first fiscal quarter that begins after the date of enactment of this Act.

SEC. 205. IMPROVING TRANSPARENCY AND PREVENTING THE USE OF ABUSIVE SPREAD PRICING AND RELATED PRACTICES IN MEDICAID.

(a) PASS-THROUGH PRICING REQUIRED.—

(1) IN GENERAL.—Section 1927(e) of the Social Security Act (42 U.S.C. 1396r–8(e)) is amended by adding at the end the following:

''(6) PASS-THROUGH PRICING REQUIRED.—A contract between the State and a pharmacy benefit manager (referred to in this paragraph as a 'PBM'), or a contract between the State and a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D)) that includes provisions making the entity responsible for coverage of covered outpatient drugs dispensed to individuals enrolled with the entity, shall require that payment for such drugs and related administrative services (as applicable), including payments made by a PBM on behalf of the State or entity, is based on a pass-through pricing model under which—

''(A) any payment made by the entity of the PBM (as applicable) for such a drug—

''(i) is limited to—

''(I) ingredient cost; and

''(II) a professional dispensing fee that is not less than the professional dispensing fee that the State plan or waiver would pay if the plan or waiver was making the payment directly;

''(ii) is passed through in its entirety by the entity or PBM to the pharmacy that dispenses the drug; and

''(iii) is made in a manner that is consistent with section 1902(a)(30)(A) and sections 447.512, 447.514, and 447.518 of title 42, Code of Federal Regulations (or any successor regulation) as if such requirements applied directly to the entity or the PBM;

''(B) payment to the entity or the PBM (as applicable) for administrative services performed by the entity or PBM is limited to a reasonable administrative fee that covers the reasonable cost of providing such services;

''(C) the entity or the PBM (as applicable) shall make available to the State, and the Secretary upon request, all costs and payments related to covered outpatient drugs and accompanying administrative services incurred, received, or made by the entity or the PBM, including ingredient costs, professional dispensing fees, administrative fees, post-sale and post-in-voice fees. Discounts, or related adjustments such as direct and indirect remuneration fees, and any and all remuneration; and

''(D) any form of spread pricing whereby any amount charged or claimed by the entity or the PBM (as applicable) is in excess of the amount paid to the pharmacies on behalf of the entity, including any post-sale or post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees or assessments (after allowing for a reasonable administrative fee as described in subparagraph (B)) is not allowable for purposes of claiming Federal matching payments under this title.''.

(2) CONFORMING AMENDMENT.—Clause (xiii) of section 1903(m)(2)(A) of such Act (42 U.S.C. 1396b(m)(2)(A)), as amended by section 202, is further amended—

(A) by striking ''and (IV)'' and inserting ''(IV)''; and

(B) by inserting before the period at the end the following: '', and (V) pharmacy benefit management services provided by the entity, or provided by a pharmacy benefit manager on behalf of the entity under a contract or other arrangement between the entity and the pharmacy benefit manager, shall comply with the requirements of section 1927(e)(6)''.

(3) EFFECTIVE DATE.—The amendments made by this subsection apply to contracts between States and managed care entities, other specified entities, or pharmacy benefits managers that are entered into or renewed on or after the date that is 18 months after the date of enactment of this Act.

(b) SURVEY OF RETAIL PRICES.—

(1) IN GENERAL.—Section 1927(f) of the Social Security Act (42 U.S.C. 1396r–8(f)) is amended—

(A) by striking ''and'' after the semicolon at the end of paragraph (1)(A)(i) and all that precedes it through ''(1)'' and inserting the following:

''(1) SURVEY OF RETAIL PRICES.—The Secretary shall conduct a survey of retail community drug prices, to include at least the national average drug acquisition cost, as follows:

''(A) USE OF VENDOR.—The Secretary may contract services for—

''(i) with respect to retail community pharmacies, the determination on a monthly basis of retail survey prices of the national average drug acquisition cost for covered outpatient drugs for such pharmacies, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available), the average reimbursement received for such drugs by such pharmacies from all sources of payment, including third parties, and, to the extent available, the usual and customary charges to consumers for such drugs; and'';

(B) by adding at the end of paragraph (1) the following:

''(F) SURVEY REPORTING.—In order to meet the requirement of section 1902(a)(54), a State shall require that any retail community pharmacy in the State that receives any payment, administrative fee, discount, or rebate related to the dispensing of covered outpatient drugs to individuals receiving benefits under this title, regardless of whether such payment, fee, discount, or rebate is received from the State or a managed care entity directly or from a pharmacy benefit manager or another entity that has a contract with the State or a managed care entity, shall respond to surveys of retail prices conducted under this subsection.

''(G) SURVEY INFORMATION.—Information on retail community prices obtained under this paragraph shall be made publicly available and shall include at least the following:

''(i) The monthly response rate of the survey including a list of pharmacies not in compliance with subparagraph (F).

''(ii) The sampling frame and number of pharmacies sampled monthly.

''(iii) Characteristics of reporting pharmacies, including type (such as independent or chain), geographic or regional location, and dispensing volume.

''(iv) Reporting of a separate national average drug acquisition cost for each drug for independent retail pharmacies and chain operated pharmacies.

''(v) Information on price concessions including on and off invoice discounts, rebates, and other price concessions.

''(vi) Information on average professional dispensing fees paid.

''(H) PENALTIES.—

''(i) FAILURE TO PROVIDE TIMELY INFORMATION.—A retail community pharmacy that fails to respond to a survey conducted under this subsection on a timely basis may be subject to a civil monetary penalty in the amount of $10,000 for each day in which such information has not been provided.

''(ii) FALSE INFORMATION.—A retail community pharmacy that knowingly provides false information in response to a survey conducted under this subsection may be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information.

''(iii) OTHER PENALTIES.—Any civil money penalties imposed under this subparagraph shall be in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceedings under section 1128A(a).

''(I) REPORT ON SPECIALTY PHARMACIES.—

''(i) IN GENERAL.—Not later than 1 year after the effective date of this subparagraph, the Secretary shall submit a report to Congress examining specialty drug coverage and reimbursement under this title.

''(ii) CONTENT OF REPORT.—Such report shall include a description of how State Medicaid programs define specialty drugs, how much State Medicaid programs pay for specialty drugs, how States and managed care plans determine payment for specialty drugs,

the settings in which specialty drugs are dispensed (such as retail community pharmacies or specialty pharmacies), whether acquisition costs for specialty drugs are captured in the national average drug acquisition cost survey, and recommendations as to whether specialty pharmacies should be included in the survey of retail prices to ensure national average drug acquisition costs capture drugs sold at specialty pharmacies and how such specialty pharmacies should be defined.'';

(C) in paragraph (2)—

(i) in subparagraph (A), by inserting '', including payments rates under Medicaid managed care plans,'' after ''under this title''; and

(ii) in subparagraph (B), by inserting ''and the basis for such dispensing fees'' before the semicolon; and

(D) in paragraph (4), by inserting '', and $5,000,000 for fiscal year 2020 and each fiscal year thereafter,'' after ''2010''.

(2) EFFECTIVE DATE.—The amendments made by this subsection take effect on the 1st day of the 1st quarter that begins on or after the date that is 18 months after the date of enactment of this Act.

(c) MANUFACTURER REPORTING OF WHOLESALE ACQUISITION COST.—Section 1927(b)(3) of such Act (42 U.S.C. 1396r–8(b)(3)), as amended by section 141, is further amended—

(1) in subparagraph (A)(i)—

(A) in subclause (I), by striking ''and'' after the semicolon;

(B) in subclause (II), by adding ''and'' after the semicolon;

(C) by moving the left margins of subclause (I) and (II) 2 ems to the right; and

(D) by adding at the end the following:

''(III) in the case of rebate periods that begin on or after the date of enactment of this subclause, on the wholesale acquisition cost (as defined in section 1847A(c)(6)(B)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act);''; and

(2) in subparagraph (D)—

(A) in the matter preceding clause (i), by inserting ''and clause (vii) of this subparagraph'' after ''1847A'';

(B) in clause (vi), by striking ''and'' after the comma;

(C) in clause (vii), by striking the period and inserting '', and''; and

(D) by inserting after clause (vii) the following:

''(viii) to the Secretary to disclose (through a website accessible to the public) the most recently reported wholesale acquisition cost (as defined in section 1847A(c)(6)(B)) for each covered outpatient drug (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), as reported under subparagraph (A)(i)(III).''.

SEC. 206. T–MSIS DRUG DATA ANALYTICS REPORTS.

(a) IN GENERAL.—Not later than May 1 of each calendar year beginning with calendar year 2021, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall publish on a website of the Centers for Medicare & Medicaid Services that is accessible to the public a report of the most recently available data on provider prescribing patterns under the Medicaid program.

(b) CONTENT OF REPORT.—

(1) REQUIRED CONTENT.—Each report required under subsection (a) for a calendar year shall include the following information with respect to each State (and, to the extent available, with respect to Puerto Rico, the United States Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa):

(A) A comparison of covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act (42 U.S.C. 1396r–8(k)(2))) prescribing patterns under the State Medicaid plan or waiver of such plan (including drugs prescribed on a fee-for-service basis and drugs prescribed under managed care arrangements under such plan or waiver)—

(i) across all forms or models of reimbursement used under the plan or waiver;

(ii) within specialties and subspecialties, as defined by the Secretary;

(iii) by episodes of care for—

(I) each chronic disease category, as defined by the Secretary, that is represented in the 10 conditions that accounted for the greatest share of total spending under the plan or waiver during the year that is the subject of the report;

(II) procedural groupings; and

(III) rare disease diagnosis codes;

(iv) by patient demographic characteristics, including race (to the extent that the Secretary determines that there is sufficient data available with respect to such characteristic in a majority of States), gender, and age;

(v) by patient high-utilizer or risk status; and

(vi) by high and low resource settings by facility and place of service categories, as determined by the Secretary.

(B) In the case of medical assistance for covered outpatient drugs (as so defined) provided under a State Medicaid plan or waiver of such plan in a managed care setting, an analysis of the differences in managed care prescribing patterns when a covered outpatient drug is prescribed in a managed care setting as compared to when the drug is prescribed in a fee-for-service setting.

(2) ADDITIONAL CONTENT.—A report required under subsection (a) for a calendar year may include State-specific information about prescription utilization management tools under State Medicaid plans or waivers of such plans, including—

(A) a description of prescription utilization management tools under State programs to provide long-term services and supports under a State Medicaid plan or a waiver of such plan;

(B) a comparison of prescription utilization management tools applicable to populations covered under a State Medicaid plan waiver under section 1115 of the Social Security Act (42 U.S.C. 1315) and the models applicable to populations that are not covered under the waiver;

(C) a comparison of the prescription utilization management tools employed by different Medicaid managed care organizations, pharmacy benefit managers, and related entities within the State;

(D) a comparison of the prescription utilization management tools applicable to each enrollment category under a State Medicaid plan or waiver; and

(E) a comparison of the prescription utilization management tools applicable under the State Medicaid plan or waiver by patient high-utilizer or risk status.

(3) ADDITIONAL ANALYSIS.—To the extent practicable, the Secretary shall include in each report published under subsection (a)—

(A) analyses of national, State, and local patterns of Medicaid population-based prescribing behaviors; and

(B) recommendations for administrative or legislative action to improve the effectiveness of, and reduce costs for, covered outpatient drugs under Medicaid while ensuring timely beneficiary access to medically necessary covered outpatient drugs.

(c) USE OF T–MSIS DATA.—Each report required under subsection (a) shall—

(1) be prepared using data and definitions from the Transformed Medicaid Statistical Information System (T–MSIS) data set (or a successor data set) that is not more than 24 months old on the date that the report is published; and

(2) as appropriate, include a description with respect to each State of the quality and completeness of the data, as well as any necessary caveats describing the limitations of the data reported to the Secretary by the State that are sufficient to communicate the appropriate uses for the information.

(d) PREPARATION OF REPORT.—Each report required under subsection (a) shall be prepared by the Administrator for the Centers for Medicare & Medicaid Services.

(e) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there is authorized to be appropriated $2,000,000 for fiscal year 2020 and each fiscal year thereafter.

SEC. 207. RISK-SHARING VALUE-BASED PAYMENT AGREEMENTS FOR COVERED OUTPATIENT DRUGS UNDER MEDICAID.

(a) IN GENERAL.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended by adding at the end the following new subsection:

''(l) STATE OPTION TO PAY FOR COVERED OUTPATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED AGREEMENTS.—

''(1) IN GENERAL.—Beginning January 1, 2022, a State shall have the option to pay (whether on a fee-for-service or managed care basis) for covered outpatient drugs that are potentially curative treatments intended for one-time use that are administered to individuals under this title by entering into a risk-sharing value-based payment agreement with the manufacturer of the drug in accordance with the requirements of this subsection.

''(2) SECRETARIAL APPROVAL.—

''(A) IN GENERAL.—A State shall submit a request to the Secretary to enter into a risk-sharing value based payment agreement, and the Secretary shall not approve a proposed risk-sharing value-based payment agreement between a State and a manufacturer for payment for a covered outpatient drug of the manufacturer unless the following requirements are met:

''(i) MANUFACTURER IS PARTY TO REBATE AGREEMENT AND IN COMPLIANCE WITH REQUIREMENTS.—The manufacturer has a rebate agreement in effect as required under subsection (a) and (b) of this section and is in compliance with all applicable requirements under this title.

''(ii) NO INCREASE TO PROJECTED NET FEDERAL SPENDING.—

''(I) IN GENERAL.—The Chief Actuary certifies that the projected payments for each covered outpatient drug under such proposed agreement would not result in greater estimated Federal spending under this title than the net Federal spending that would result in the absence of the agreement.

''(II) NET FEDERAL SPENDING DEFINED.—For purposes of this subsection, the term 'net Federal spending' means the amount of Federal payments the Chief Actuary estimates would be made under this title for administering a covered outpatient drug to an individual eligible for medical assistance under a State plan or a waiver of such plan, reduced by the amount of all rebates the Chief Actuary estimates would be paid with respect to the administering of such drug, including all rebates under this title and any supplemental or other additional rebates, in the absence of such an agreement.

''(III) INFORMATION.—The Chief Actuary shall make the certifications required under

this clause based on the most recently available and reliable drug pricing and product information. The State and manufacturer shall provide the Secretary and the Chief Actuary with all necessary information required to make the estimates needed for such certifications.

''(iii) LAUNCH AND LIST PRICE JUSTIFICATIONS.—The manufacturer submits all relevant information and supporting documentation necessary for pricing decisions as deemed appropriate by the Secretary, which shall be truthful and non-misleading, including manufacturer information and supporting documentation for launch price or list price increases, and any applicable justification required under section 1128L.

''(iv) CONFIDENTIALITY OF INFORMATION; PENALTIES.—The provisions of subparagraphs (C) and (D) of subsection (b)(3) shall apply to a manufacturer that fails to submit the information and documentation required under clauses (ii) and (iii) on a timely basis, or that knowingly provides false or misleading information, in the same manner as such provisions apply to a manufacturer with a rebate agreement under this section.

''(B) CONSIDERATION OF STATE REQUEST FOR APPROVAL.—

''(i) IN GENERAL.—The Secretary shall treat a State request for approval of a risk-sharing value-based payment agreement in the same manner that the Secretary treats a State plan amendment, and subpart B of part 430 of title 42, Code of Federal Regulations, including, subject to clause (ii), the timing requirements of section 430.16 of such title (as in effect on the date of enactment of this subsection), shall apply to a request for approval of a risk-sharing value-based payment agreement in the same manner as such subpart applies to a State plan amendment.

''(ii) TIMING.—The Secretary shall consult with the Commissioner of Food and Drugs as required under subparagraph (C) and make a determination on whether to approve a request from a State for approval of a proposed risk-sharing value-based payment agreement (or request additional information necessary to allow the Secretary to make a determination with respect to such request for approval) within the time period, to the extent practicable, specified in section 430.16 of title 42, Code of Federal Regulations (as in effect on the date of enactment of this subsection), but in no case shall the Secretary take more than 180 days after the receipt of such request for approval or response to such request for additional information to make such a determination (or request additional information).

''(C) CONSULTATION WITH THE COMMISSIONER OF FOOD AND DRUGS.—In considering whether to approve a risk-sharing value-based payment agreement, the Secretary, to the extent necessary, shall consult with the Commissioner of Food and Drugs to determine whether the relevant clinical parameters specified in such agreement are appropriate.

''(3) INSTALLMENT-BASED PAYMENT STRUCTURE.—

''(A) IN GENERAL.—A risk-sharing value-based payment agreement shall provide for a payment structure under which, for every installment year of the agreement (subject to subparagraph (B)), the State shall pay the total installment year amount in equal installments to be paid at regular intervals over a period of time that shall be specified in the agreement.

''(B) REQUIREMENTS FOR INSTALLMENT PAYMENTS.—

''(i) TIMING OF FIRST PAYMENT.—The State shall make the first of the installment payments described in subparagraph (A) for an installment year not later than 30 days after the end of such year.

''(ii) LENGTH OF INSTALLMENT PERIOD.—The period of time over which the State shall make the installment payments described in subparagraph (A) for an installment year shall not be longer than 5 years.

''(iii) NONPAYMENT OR REDUCED PAYMENT OF INSTALLMENTS FOLLOWING A FAILURE TO MEET CLINICAL PARAMETER.—If, prior to the payment date (as specified in the agreement) of any installment payment described in subparagraph (A) or any other alternative date or time frame (as otherwise specified in the agreement), the covered outpatient drug which is subject to the agreement fails to meet a relevant clinical parameter of the agreement, the agreement shall provide that—

''(I) the installment payment shall not be made; or

''(II) the installment payment shall be reduced by a percentage specified in the agreement that is based on the outcome achieved by the drug relative to the relevant clinical parameter.

''(4) NOTICE OF INTENT.—

''(A) IN GENERAL.—Subject to subparagraph (B), a manufacturer of a covered outpatient drug shall not be eligible to enter into a risk-sharing value-based payment agreement under this subsection with respect to such drug unless the manufacturer notifies the Secretary that the manufacturer is interested in entering into such an agreement with respect to such drug. The decision to submit and timing of a request to enter into a proposed risk-sharing value-based payment agreement shall remain solely within the discretion of the State and shall only be effective upon Secretarial approval as required under this subsection.

''(B) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—

''(i) IN GENERAL.—In the case of a manufacturer of a covered outpatient drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act after the date of enactment of this subsection, not more than 90 days after meeting with the Food and Drug Administration following phase II clinical trials for such drug (or, in the case of a drug described in clause (ii), not later than March 31, 2022), the manufacturer must notify the Secretary of the manufacturer's intent to enter into a risk-sharing value-based payment agreement under this subsection with respect to such drug. If no such meeting has occurred, the Secretary may use discretion as to whether a potentially curative treatment intended for one-time use may qualify for a risk-sharing value-based payment agreement under this section. A manufacturer notification of interest shall not have any influence on a decision for approval by the Food and Drug Administration.

''(ii) APPLICATION TO CERTAIN SUBSEQUENTLY APPROVED DRUGS.—A drug described in this clause is a covered outpatient drug of a manufacturer—

''(I) that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act after the date of enactment of this subsection; and

''(II) with respect to which, as of January 1, 2022, more than 90 days have passed after the manufacturer's meeting with the Food and Drug Administration following phase II clinical trials for such drug.

''(iii) PARALLEL APPROVAL.—The Secretary, in coordination with the Administrator of the Centers for Medicare & Medicaid Services and the Commissioner of Food and Drugs, shall, to the extent practicable, approve a State's request to enter into a proposed risk-sharing value-based payment agreement that otherwise meets the requirements of this subsection at the time that such a drug is approved by the Food and Drug Administration to help provide that no State that wishes to enter into such an agreement is required to pay for the drug in full at one time if the State is seeking to pay over a period of time as outlined in the proposed agreement.

''(iv) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be applied or construed to modify or affect the timeframes or factors involved in the Secretary's determination of whether to approve or license a drug under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.

''(5) SPECIAL PAYMENT RULES.—

''(A) IN GENERAL.—Except as otherwise provided in this paragraph, with respect to an individual who is administered a unit of a covered outpatient drug that is purchased under a State plan by a State Medicaid agency under a risk-sharing value-based payment agreement in an installment year, the State shall remain liable to the manufacturer of such drug for payment for such unit without regard to whether the individual remains enrolled in the State plan under this title (or a waiver of such plan) for each installment year for which the State is to make installment payments for covered outpatient drugs purchased under the agreement in such year.

''(B) DEATH.—In the case of an individual described in subparagraph (A) who dies during the period described in such subparagraph, the State plan shall not be liable for any remaining payment for the unit of the covered outpatient drug administered to the individual which is owed under the agreement described in such subparagraph.

''(C) WITHDRAWAL OF APPROVAL.—In the case of a covered outpatient drug that is the subject of a risk-sharing value-based agreement between a State and a manufacturer under this subsection, including a drug approved in accordance with section 506(c) of the Federal Food, Drug, and Cosmetic Act, and such drug is the subject of an application that has been withdrawn by the Secretary, the State plan shall not be liable for any remaining payment that is owed under the agreement.

''(D) ALTERNATIVE ARRANGEMENT UNDER AGREEMENT.—Subject to approval by the Secretary, the terms of a proposed risk-sharing value-based payment agreement submitted for approval by a State may provide that subparagraph (A) shall not apply.

''(E) GUIDANCE.—Not later than January 1, 2022, the Secretary shall issue guidance to States establishing a process for States to notify the Secretary when an individual who is administered a unit of a covered outpatient drug that is purchased by a State plan under a risk-sharing value-based payment agreement ceases to be enrolled under the State plan under this title (or a waiver of such plan) or dies before the end of the installment period applicable to such unit under the agreement.

''(6) TREATMENT OF PAYMENTS UNDER RISK-SHARING VALUE-BASED AGREEMENTS FOR PURPOSES OF AVERAGE MANUFACTURER PRICE; BEST PRICE.—The Secretary shall treat any payments made to the manufacturer of a covered outpatient drug under a risk-sharing value-based payment agreement under this subsection during a rebate period in the same manner that the Secretary treats payments made under a State supplemental rebate agreement under sections 447.504(c)(19) and 447.505(c)(7) of title 42, Code of Federal Regulations (or any successor regulations) for purposes of determining average manufacturer price and best price under this section with respect to the covered outpatient drug and a rebate period and for purposes of offsets required under subsection (b)(1)(B).

''(7) ASSESSMENTS AND REPORT TO CONGRESS.—

''(A) ASSESSMENTS.—

''(i) IN GENERAL.—Not later than 180 days after the end of each assessment period of any risk-sharing value-based payment agreement for a State approved under this subsection, the Secretary shall conduct an evaluation of such agreement which shall include an evaluation by the Chief Actuary to determine whether program spending under the risk-sharing value-based payment agreement aligned with the projections for the agreement made under paragraph (2)(A)(ii), including an assessment of whether actual Federal spending under this title under the agreement was less or more than net Federal spending would have been in the absence of the agreement.

''(ii) ASSESSMENT PERIOD.—For purposes of clause (i)—

''(I) the first assessment period for a risk-sharing value-based payment agreement shall be the period of time over which payments are scheduled to be made under the agreement for the first 10 individuals who are administered covered outpatient drugs under the agreement except that such period shall not exceed the 5-year period after the date on which the Secretary approves the agreement; and

''(II) each subsequent assessment period for a risk-sharing value-based payment agreement shall be the 5-year period following the end of the previous assessment period.

''(B) RESULTS OF ASSESSMENTS.—

''(i) TERMINATION OPTION.—If the Secretary determines as a result of the assessment by the Chief Actuary under subparagraph (A) that the actual Federal spending under this title for any covered outpatient drug that was the subject of the State's risk-sharing value-based payment agreement was greater than the net Federal spending that would have resulted in the absence of the agreement, the Secretary may terminate approval of such agreement and shall immediately conduct an assessment under this paragraph of any other ongoing risk-sharing value-based payment agreement to which the same manufacturer is a party.

''(ii) REPAYMENT REQUIRED.—

''(I) IN GENERAL.—If the Secretary determines as a result of the assessment by the Chief Actuary under subparagraph (A) that the Federal spending under the risk-sharing value-based agreement for a covered outpatient drug that was subject to such agreement was greater than the net Federal spending that would have resulted in the absence of the agreement, the manufacturer shall repay the difference to the State and Federal governments in a timely manner as determined by the Secretary.

''(II) TERMINATION FOR FAILURE TO PAY.—The failure of a manufacturer to make repayments required under subclause (I) in a timely manner shall result in immediate termination of all risk-sharing value-based agreements to which the manufacturer is a party.

''(III) ADDITIONAL PENALTIES.—In the case of a manufacturer that fails to make repayments required under subclause (I), the Secretary may treat such manufacturer in the same manner as a manufacturer that fails to pay required rebates under this section, and the Secretary may—

''(aa) suspend or terminate the manufacturer's rebate agreement under this section; and

''(bb) pursue any other remedy that would be available if the manufacturer had failed to pay required rebates under this section.

''(C) REPORT TO CONGRESS.—Not later than 5 years after the first risk-sharing value-based payment agreement is approved under this subsection, the Secretary shall submit to Congress and make available to the public a report that includes—

''(i) an assessment of the impact of risk-sharing value-based payment agreements on access for individuals who are eligible for benefits under a State plan or waiver under this title to medically necessary covered outpatient drugs and related treatments;

''(ii) an analysis of the impact of such agreements on overall State and Federal spending under this title;

''(iii) an assessment of the impact of such agreements on drug prices, including launch price and price increases; and

''(iv) such recommendations to Congress as the Secretary deems appropriate.

''(8) GUIDANCE AND REGULATIONS.—

''(A) IN GENERAL.—Not later than January 1, 2022, the Secretary shall issue guidance to States seeking to enter into risk-sharing value-based payment agreements under this subsection that includes a model template for such agreements. The Secretary may issue any additional guidance or promulgate regulations as necessary to implement and enforce the provisions of this subsection.

''(B) MODEL AGREEMENTS.—

''(i) IN GENERAL.—If a State expresses an interest in pursuing a risk-sharing value-based payment agreement under this subsection with a manufacturer for the purchase of a covered outpatient drug, the Secretary may share with such State any risk-sharing value-based agreement between a State and the manufacturer for the purchase of such drug that has been approved under this subsection. While such shared agreement may serve as a template for a State that wishes to propose, the use of a previously approved agreement shall not affect the submission and approval process for approval of a proposed risk-sharing value-based payment agreement under this subsection, including the requirements under paragraph (2)(A).

''(ii) CONFIDENTIALITY.—In the case of a risk-sharing value-based payment agreement that is disclosed to a State by the Secretary under this subparagraph and that is only in effect with respect to a single State, the confidentiality of information provisions described in subsection (b)(3)(D) shall apply to such information.

''(C) OIG CONSULTATION.—

''(i) IN GENERAL.—The Secretary shall consult with the Office of the Inspector General of the Department of Health and Human Services to determine whether there are potential program integrity concerns with agreement approvals or templates and address accordingly.

''(ii) OIG POLICY UPDATES AS NECESSARY.—The Inspector General of the Department of Health and Human Services shall review and update, as necessary, any policies or guidelines of the Office of the Inspector General of the Department of Human Services (including policies related to the enforcement of section 1128B) to accommodate the use of risk-sharing value-based payment agreements in accordance with this section.

''(9) RULES OF CONSTRUCTION.—

''(A) MODIFICATIONS.—Nothing in this subsection or any regulations promulgated under this subsection shall prohibit a State from requesting a modification from the Secretary to the terms of a risk-sharing value-based payment agreement. A modification that is expected to result in any increase to projected net State or Federal spending under the agreement shall be subject to recertification by the Chief Actuary as described in paragraph (2)(A)(ii) before the modification may be approved.

''(B) REBATE AGREEMENTS.—Nothing in this subsection shall be construed as requiring a State to enter into a risk-sharing value-based payment agreement or as limiting or superseding the ability of a State to enter into a supplemental rebate agreement for a covered outpatient drug.

''(C) FFP FOR PAYMENTS UNDER RISK-SHARING VALUE-BASED PAYMENT AGREEMENTS.—Federal financial participation shall be available under this title for any payment made by a State to a manufacturer for a covered outpatient drug under a risk-sharing value-based payment agreement in accordance with this subsection, except that no Federal financial participation shall be available for any payment made by a State to a manufacturer under such an agreement on and after the effective date of a disapproval of such agreement by the Secretary.

''(D) CONTINUED APPLICATION OF OTHER PROVISIONS.—Except as expressly provided in this subsection, nothing in this subsection or in any regulations promulgated under this subsection shall affect the application of any other provision of this Act.

''(10) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this subsection, there is authorized to be appropriated $5,000,000 for fiscal year 2020 and each fiscal year thereafter.

''(11) DEFINITIONS.—In this subsection:

''(A) CHIEF ACTUARY.—The term 'Chief Actuary' means the Chief Actuary of the Centers for Medicare & Medicaid Services.

''(B) INSTALLMENT YEAR.—The term 'installment year' means, with respect to a risk-sharing value-based payment agreement, a 12-month period during which a covered outpatient drug is administered under the agreement.

''(C) POTENTIALLY CURATIVE TREATMENT INTENDED FOR ONE-TIME USE.—The term 'potentially curative treatment intended for one-time use' means a treatment that consists of the administration of a covered outpatient drug that—

''(i) is a form of gene therapy for a rare disease, as defined by the Commissioner of Food and Drugs, designated under section 526 of the Federal Food, Drug, and Cosmetics Act, and approved under section 505 of such Act or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act to treat a serious or life-threatening disease or condition;

''(ii) if administered in accordance with the labeling of such drug, is expected to result in either—

''(I) the cure of such disease or condition; or

''(II) a reduction in the symptoms of such disease or condition to the extent that such disease or condition is not expected to lead to early mortality; and

''(iii) is expected to achieve a result described in clause (ii), which may be achieved over an extended period of time, after not more than 3 administrations.

''(D) RELEVANT CLINICAL PARAMETER.—The term 'relevant clinical parameter' means, with respect to a covered outpatient drug that is the subject of a risk-sharing value-based payment agreement—

''(i) a clinical endpoint specified in the drug's labeling or supported by one or more of the compendia described in section 1861(t)(2)(B)(ii)(I) that—

''(I) is able to be measured or evaluated on an annual basis for each year of the agreement on an independent basis by a provider or other entity; and

''(II) is required to be achieved (based on observed metrics in patient populations) under the terms of the agreement; or

''(ii) a surrogate endpoint (as defined in section 507(e)(9) of the Federal Food, Drug, and Cosmetic Act), including those developed by patient-focused drug development tools, that—

''(I) is able to be measured or evaluated on an annual basis for each year of the agreement on an independent basis by a provider or other entity; and

''(II) has been qualified by the Food and Drug Administration.

''(E) RISK-SHARING VALUE-BASED PAYMENT AGREEMENT.—The term 'risk-sharing value-based payment agreement' means an agreement between a State plan and a manufacturer—

''(i) for the purchase of a covered outpatient drug of the manufacturer that is a potentially curative treatment intended for one-time use;

''(ii) under which payment for such drug shall be made pursuant to an installment-based payment structure that meets the requirements of paragraph (3);

''(iii) which conditions payment on the achievement of at least 2 relevant clinical parameters (as defined in subparagraph (C));

''(iv) which provides that—

''(I) the State plan will directly reimburse the manufacturer for the drug; or

''(II) a third party will reimburse the manufacture in a manner approved by the Secretary; and

''(v) is approved by the Secretary in accordance with paragraph (2).

''(F) TOTAL INSTALLMENT YEAR AMOUNT.—The term 'total installment year amount' means, with respect to a risk-sharing value-based payment agreement for the purchase of a covered outpatient drug and an installment year, an amount equal to the product of—

''(i) the unit price of the drug charged under the agreement; and

''(ii) the number of units of such drug administered under the agreement during such installment year.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 1903(i)(10)(A) of the Social Security Act (42 U.S.C. 1396b(i)(10)(A)) is amended by striking ''or unless section 1927(a)(3) applies'' and inserting '', section 1927(a)(3) applies with respect to such drugs, or such drugs are the subject of a risk-sharing value-based payment agreement under section 1927(l)''.

(2) Section 1927(b) of the Social Security Act (42 U.S.C. 1396r–8(b)) is amended—

(A) in paragraph (1)(A), by inserting ''(except for drugs for which payment is made by a State under a risk-sharing value-based payment agreement under subsection (l))'' after ''under the State plan for such period''; and

(B) in paragraph (3)—

(i) in subparagraph (C)(i), by inserting ''or subsection (l)(2)(A)'' after ''subparagraph (A)''; and

(ii) in subparagraph (D), in the matter preceding clause (i), by inserting '', under subsection (l)(2)(A),'' after ''under this paragraph''.

SEC. 208. APPLYING MEDICAID DRUG REBATE REQUIREMENT TO DRUGS PROVIDED AS PART OF OUTPATIENT HOSPITAL SERVICES.

(a) IN GENERAL.—Section 1927(k)(3) of the Social Security Act (42 U.S.C. 1396r–8(k)(3)) is amended to read as follows:

''(3) LIMITING DEFINITION.—

''(A) IN GENERAL.—The term 'covered outpatient drug' does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

''(i) Inpatient hospital services.

''(ii) Hospice services.

''(iii) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

''(iv) Physicians' services.

''(v) Outpatient hospital services.

''(vi) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

''(vii) Other laboratory and x-ray services.

''(viii) Renal dialysis.

''(B) OTHER EXCLUSIONS.—Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication.

''(C) STATE OPTION.—At the option of a State, such term may include any drug, biological product, or insulin for which the State is the primary payer under this title or a demonstration project concerning this title, and that is provided on an outpatient basis as part of, or as incident to and in the same setting as, described in clause (iv) or (v) of subparagraph (A) and for which payment is made as part of payment for such services.

''(D) NO EFFECT ON BEST PRICE.—Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.''.

(b) EFFECTIVE DATE; IMPLEMENTATION GUIDANCE.—

(1) IN GENERAL.—The amendment made by subsection (a) shall take effect on the date that is 1 year after the date of enactment of this Act.

(2) IMPLEMENTATION AND GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance and relevant informational bulletins for States, manufacturers (as defined in section 1927(k)(5) of the Social Security Act (42 U.S.C. 1396r–8(k)(5)), and other relevant stakeholders, including health care providers, regarding implementation of the amendment made by subsection (a).

TITLE III—FOOD AND DRUG ADMINISTRATION

Subtitle A—CREATES Act

SEC. 301. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—In this section—

(1) the term ''commercially reasonable, market-based terms'' means—

(A) a nondiscriminatory price for the sale of the covered product at or below, but not greater than, the most recent wholesale acquisition cost for the drug, as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B));

(B) a schedule for delivery that results in the transfer of the covered product to the eligible product developer consistent with the timing under subsection (b)(2)(A)(iv); and

(C) no additional conditions are imposed on the sale of the covered product;

(2) the term ''covered product''—

(A) means—

(i) any drug approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to support approval of an application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, or otherwise meet the requirements for approval under either such section, any product, including any device, that is marketed or intended for use with such a drug or biological product; and

(B) does not include any drug or biological product that appears on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), unless—

(i) the drug or biological product has been on the drug shortage list in effect under such section 506E continuously for more than 6 months; or

(ii) the Secretary determines that inclusion of the drug or biological product as a covered product is likely to contribute to alleviating or preventing a shortage;

(3) the term ''device'' has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(4) the term ''eligible product developer'' means a person that seeks to develop a product for approval pursuant to an application for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for licensing pursuant to an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k));

(5) the term ''license holder'' means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the holder of a license under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a covered product;

(6) the term ''REMS'' means a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(7) the term ''REMS with ETASU'' means a REMS that contains elements to assure safe use under section 505–1(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f));

(8) the term ''Secretary'' means the Secretary of Health and Human Services;

(9) the term ''single, shared system of elements to assure safe use'' means a single, shared system of elements to assure safe use under section 505–1(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)); and

(10) the term ''sufficient quantities'' means an amount of a covered product that the eligible product developer determines allows it to—

(A) conduct testing to support an application under—

(i) subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

(ii) section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(B) fulfill any regulatory requirements relating to approval of such an application.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

(1) IN GENERAL.—An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

(2) ELEMENTS.—

(A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

(I) the covered product is not subject to a REMS with ETASU; or

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of the covered product authorization to the license holder;

(ii) that, as of the date on which the civil action is filed, the product developer has not obtained sufficient quantities of the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has submitted a written request to purchase sufficient quantities of the covered product to the license holder and such request—

(I) was sent to a named corporate officer of the license holder;

(II) was made by certified or registered mail with return receipt requested;

(III) specified an individual as the point of contact for the license holder to direct communications related to the sale of the covered product to the eligible product developer and a means for electronic and written communications with that individual; and

(IV) specified an address to which the covered product was to be shipped upon reaching an agreement to transfer the covered product; and

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms—

(I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product; and

(II) for a covered product that is subject to a REMS with ETASU, by 31 days after the later of—

(aa) the date on which the license holder received the request for the covered product; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU.

(ii) AUTHORIZATION.—Not later than 120 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—

(I) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

(II) development and testing that involves human clinical trials, if the eligible product developer has—

(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those provided by the REMS for the covered product; or

(BB) otherwise satisfied the Secretary that such protections will be provided; and

(bb) met any other requirements the Secretary may establish.

(iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

(3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—

(A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors was engaged in the manufacturing or commercial marketing of the covered product; and

(ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms;

(B) that—

(i) the license holder sells the covered product through agents, distributors, or wholesalers;

(ii) the license holder has placed no restrictions, explicit or implicit, on its agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder; or

(C) that the license holder made an offer to the individual specified pursuant to paragraph (2)(A)(iii)(III), by a means of communication (electronic, written, or both) specified pursuant to such paragraph, to sell sufficient quantities of the covered product to the eligible product developer at commercially reasonable market-based terms—

(i) for a covered product that is not subject to a REMS with ETASU, by the date that is 14 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 7 days after the date on which the eligible product developer received such offer from the license holder; or

(ii) for a covered product that is subject to a REMS with ETASU, by the date that is 20 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 10 days after the date on which the eligible product developer received such offer from the license holder.

(4) REMEDIES.—

(A) IN GENERAL.—If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—

(i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney's fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

(II) that the license holder failed to comply with an order issued under clause (i).

(B) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue that the license holder earned on the covered product during the period—

(i) beginning on—

(I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(II) for a covered product that is subject to a REMS with ETASU, the date that is 31 days after the later of—

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

(C) AVOIDANCE OF DELAY.—The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of any such award.

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim under Federal, State, or local law arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

(d) NO VIOLATION OF REMS.—Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) is amended by adding at the end the following new subsection:

''(l) PROVISION OF SAMPLES NOT A VIOLATION OF STRATEGY.—The provision of samples of a covered product to an eligible product developer (as those terms are defined in section 301(a) of the Lower Costs, More Cures Act of 2019) shall not be considered a violation of the requirements of any risk evaluation and mitigation strategy that may be in place under this section for such drug.''.

(e) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term ''antitrust laws''—

(A) has the meaning given the term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12); and

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

SEC. 302. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), as amended by section 301, is further amended—

(1) in subsection (g)(4)(B)—

(A) in clause (i) by striking ''or'' after the semicolon;

(B) in clause (ii) by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) accommodate different, comparable aspects of the elements to assure safe use for a drug that is the subject of an application under section 505(j), and the applicable listed drug.'';

(2) in subsection (i)(1), by striking subparagraph (C) and inserting the following:

''(C)(i) Elements to assure safe use, if required under subsection (f) for the listed drug, which, subject to clause (ii), for a drug that is the subject of an application under section 505(j) may use—

''(I) a single, shared system with the listed drug under subsection (f); or

''(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

''(ii) The Secretary may require a drug that is the subject of an application under section 505(j) and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f).'';

(3) in subsection (i), by adding at the end the following:

''(3) SHARED REMS.—If the Secretary approves, in accordance with paragraph (1)(C)(i)(II), a different, comparable aspect of the elements to assure safe use under subsection (f) for a drug that is the subject of an abbreviated new drug application under section 505(j), the Secretary may require that such different comparable aspect of the elements to assure safe use can be used with respect to any other drug that is the subject of an application under section 505(j) or 505(b) that references the same listed drug.''; and

(4) by adding at the end the following:

''(m) SEPARATE REMS.—When used in this section, the terms 'different, comparable aspect of the elements to assure safe use' or 'different, comparable approved risk evaluation and mitigation strategies' means a risk evaluation and mitigation strategy for a drug that is the subject of an application under section 505(j) that uses different methods or operational means than the strategy required under subsection (a) for the applicable listed drug, or other application under section 505(j) with the same such listed drug, but achieves the same level of safety as such strategy.''.

SEC. 303. RULE OF CONSTRUCTION.

(a) IN GENERAL.—Nothing in this subtitle, the amendments made by this subtitle, or in section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), shall be construed as—

(1) prohibiting a license holder from providing an eligible product developer access to a covered product in the absence of an authorization under this subtitle; or

(2) in any way negating the applicability of a REMS with ETASU, as otherwise required under such section 505–1, with respect to such covered product.

(b) DEFINITIONS.—In this section, the terms ''covered product'', ''eligible product developer'', ''license holder'', and ''REMS with ETASU'' have the meanings given such terms in section 301(a).

Subtitle B—Pay-for-Delay

SEC. 311. UNLAWFUL AGREEMENTS.

(a) AGREEMENTS PROHIBITED.—Subject to subsections (b) and (c), it shall be unlawful for an NDA or BLA holder and a subsequent filer (or for two subsequent filers) to enter into, or carry out, an agreement resolving or settling a covered patent infringement claim on a final or interim basis if under such agreement—

(1) a subsequent filer directly or indirectly receives from such holder (or in the case of such an agreement between two subsequent filers, the other subsequent filer) anything of value, including a license; and

(2) the subsequent filer agrees to limit or forego research on, or development, manufacturing, marketing, or sales, for any period of time, of the covered product that is the subject of the application described in subparagraph (A) or (B) of subsection (g)(8).

(b) EXCLUSION.—It shall not be unlawful under subsection (a) if a party to an agreement described in such subsection demonstrates by clear and convincing evidence that the value described in subsection (a)(1) is compensation solely for other goods or services that the subsequent filer has promised to provide.

(c) LIMITATION.—Nothing in this section shall prohibit an agreement resolving or settling a covered patent infringement claim in which the consideration granted by the NDA or BLA holder to the subsequent filer (or from one subsequent filer to another) as part of the resolution or settlement includes only one or more of the following:

(1) The right to market the covered product that is the subject of the application described in subparagraph (A) or (B) of subsection (g)(8) in the United States before the expiration of—

(A) any patent that is the basis of the covered patent infringement claim; or

(B) any patent right or other statutory exclusivity that would prevent the marketing of such covered product.

(2) A payment for reasonable litigation expenses not to exceed $7,500,000 in the aggregate.

(3) A covenant not to sue on any claim that such covered product infringes a patent.

(d) ENFORCEMENT BY FEDERAL TRADE COMMISSION.—

(1) GENERAL APPLICATION.—The requirements of this section apply, according to their terms, to an NDA or BLA holder or subsequent filer that is—

(A) a person, partnership, or corporation over which the Commission has authority pursuant to section 5(a)(2) of the Federal Trade Commission Act (15 U.S.C. 45(a)(2)); or

(B) a person, partnership, or corporation over which the Commission would have authority pursuant to such section but for the fact that such person, partnership, or corporation is not organized to carry on business for its own profit or that of its members.

(2) UNFAIR OR DECEPTIVE ACTS OR PRACTICES ENFORCEMENT AUTHORITY.—

(A) IN GENERAL.—A violation of this section shall be treated as an unfair or deceptive act or practice in violation of section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

(B) POWERS OF COMMISSION.—Except as provided in subparagraph (C) and paragraphs (1)(B) and (3)—

(i) the Commission shall enforce this section in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section; and

(ii) any NDA or BLA holder or subsequent filer that violates this section shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act.

(C) JUDICIAL REVIEW.—In the case of a cease and desist order issued by the Commission under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of this section, a party to such order may obtain judicial review of such order as provided in such section 5, except that—

(i) such review may only be obtained in—

(I) the United States Court of Appeals for the District of Columbia Circuit;

(II) the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined in section 801.1(a)(3) of title 16, Code of Federal Regulations, or any successor thereto, of the NDA or BLA holder (if any such holder is a party to such order) is incorporated as of the date that the application described in subparagraph (A) or (B) of subsection (g)(8) or an approved application that is deemed to be a license for a biological product under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148; 124 Stat. 817) is submitted to the Commissioner of Food and Drugs; or

(III) the United States Court of Appeals for the circuit in which the ultimate parent entity, as so defined, of any subsequent filer that is a party to such order is incorporated as of the date that the application described in subparagraph (A) or (B) of subsection (g)(8) is submitted to the Commissioner of Food and Drugs; and

(ii) the petition for review shall be filed in the court not later than 30 days after such order is served on the party seeking review.

(3) ADDITIONAL ENFORCEMENT AUTHORITY.—

(A) CIVIL PENALTY.—The Commission may commence a civil action to recover a civil penalty in a district court of the United States against any NDA or BLA holder or subsequent filer that violates this section.

(B) SPECIAL RULE FOR RECOVERY OF PENALTY IF CEASE AND DESIST ORDER ISSUED.—

(i) IN GENERAL.—If the Commission has issued a cease and desist order in a proceeding under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of this section—

(I) the Commission may commence a civil action under subparagraph (A) to recover a civil penalty against any party to such order at any time before the expiration of the 1-year period beginning on the date on which such order becomes final under section 5(g) of such Act (15 U.S.C. 45(g)); and

(II) in such civil action, the findings of the Commission as to the material facts in such proceeding shall be conclusive, unless—

(aa) the terms of such order expressly provide that the Commission's findings shall not be conclusive; or

(bb) such order became final by reason of section 5(g)(1) of such Act (15 U.S.C. 45(g)(1)), in which case such findings shall be conclusive if supported by evidence.

(ii) RELATIONSHIP TO PENALTY FOR VIOLATION OF AN ORDER.—The penalty provided in clause (i) for violation of this section is separate from and in addition to any penalty that may be incurred for violation of an order of the Commission under section 5(l) of the Federal Trade Commission Act (15 U.S.C. 45(l)).

(C) AMOUNT OF PENALTY.—

(i) IN GENERAL.—The amount of a civil penalty imposed in a civil action under subparagraph (A) on a party to an agreement described in subsection (a) shall be sufficient to deter violations of this section, but in no event greater than—

(I) if such party is the NDA or BLA holder (or, in the case of an agreement between two subsequent filers, the subsequent filer who gave the value described in subsection (a)(1)), the greater of—

(aa) 3 times the value received by such NDA or BLA holder (or by such subsequent filer) that is reasonably attributable to the violation of this section; or

(bb) 3 times the value given to the subsequent filer (or to the other subsequent filer) reasonably attributable to the violation of this section; and

(II) if such party is the subsequent filer (or, in the case of an agreement between two subsequent filers, the subsequent filer who received the value described in subsection (a)(1)), 3 times the value received by such subsequent filer that is reasonably attributable to the violation of this section.

(ii) FACTORS FOR CONSIDERATION.—In determining such amount, the court shall take into account—

(I) the nature, circumstances, extent, and gravity of the violation;

(II) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA or BLA holder (or, in the case of an agreement between two subsequent filers, the subsequent filer who gave the value described in subsection (a)(1)), compensation received by the subsequent filer (or, in the case of an agreement between two subsequent filers, the subsequent filer who received the value described in subsection (a)(1)), and the amount of commerce affected; and

(III) other matters that justice requires.

(D) INJUNCTIONS AND OTHER EQUITABLE RELIEF.—In a civil action under subparagraph (A), the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law.

(5) PRESERVATION OF AUTHORITY OF COMMISSION.—Nothing in this section shall be construed to affect any authority of the Commission under any other provision of law.

(e) FEDERAL TRADE COMMISSION RULEMAKING.—The Commission may, in its discretion, by rule promulgated under section 553 of title 5, United States Code, exempt from this section certain agreements described in subsection (a) if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers.

(f) ANTITRUST LAWS.—Nothing in this section shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), and of section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit, or supersede the right of a subsequent filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

(g) DEFINITIONS.—In this section:

(1) AGREEMENT RESOLVING OR SETTLING A COVERED PATENT INFRINGEMENT CLAIM.—The term ''agreement resolving or settling a covered patent infringement claim'' means any agreement that—

(A) resolves or settles a covered patent infringement claim; or

(B) is contingent upon, provides for a contingent condition for, or is otherwise related to the resolution or settlement of a covered patent infringement claim.

(2) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(3) COVERED PATENT INFRINGEMENT CLAIM.—The term ''covered patent infringement claim'' means an allegation made by the NDA or BLA holder to a subsequent filer (or, in the case of an agreement between two subsequent filers, by one subsequent filer to another), whether or not included in a complaint filed with a court of law, that—

(A) the submission of the application described in subparagraph (A) or (B) of paragraph (9), or the manufacture, use, offering for sale, sale, or importation into the United States of a covered product that is the subject of such an application—

(i) in the case of an agreement between an NDA or BLA holder and a subsequent filer, infringes any patent owned by, or exclusively licensed to, the NDA or BLA holder of the covered product; or

(ii) in the case of an agreement between two subsequent filers, infringes any patent owned by the subsequent filer; or

(B) in the case of an agreement between an NDA or BLA holder and a subsequent filer, the covered product to be manufactured under such application uses a covered product as claimed in a published patent application.

(4) COVERED PRODUCT.—The term ''covered product'' means a drug (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))), including a biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(5) NDA OR BLA HOLDER.—The term ''NDA or BLA holder'' means—

(A) the holder of—

(i) an approved new drug application filed under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) for a covered product; or

(ii) a biologics license application filed under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product;

(B) a person owning or controlling enforcement of the patent on—

(i) the list published under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) in connection with the application described in subparagraph (A)(i); or

(ii) any list published under section 351 of the Public Health Service Act (42 U.S.C. 262) comprised of patents associated with biologics license applications filed under section 351(a) of such Act (42 U.S.C. 262(a)); or

(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any entity described in subparagraph (A) or (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

(6) PATENT.—The term ''patent'' means a patent issued by the United States Patent and Trademark Office.

(7) STATUTORY EXCLUSIVITY.—The term ''statutory exclusivity'' means those prohibitions on the submission or approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii) through (iv) of section 505(j)(5)(F) (5-year and 3-year exclusivity), section 505(j)(5)(B)(iv) (180-day exclusivity), section 527 (orphan drug exclusivity), section 505A (pediatric exclusivity), or section 505E (qualified infectious disease product exclusivity) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F), 360cc, 355a, 355f), or prohibitions on the submission or licensing of biologics license applications under section 351(k)(6) (interchangeable biological product exclusivity) or section 351(k)(7) (biological product reference product exclusivity) of the Public Health Service Act (42 U.S.C. 262(k)(6), (7)).

(8) SUBSEQUENT FILER.—The term ''subsequent filer'' means—

(A) in the case of a drug, a party that owns or controls an abbreviated new drug application submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) or a new drug application submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21U.S.C. 355(b)(2)) and filed under section 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or has the exclusive rights to distribute the covered product that is the subject of such application; or

(B) in the case of a biological product, a party that owns or controls an application filed with the Food and Drug Administration under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) or has the exclusive rights to distribute the biological product that is the subject of such application.

(h) EFFECTIVE DATE.—This section applies with respect to agreements described in subsection (a) entered into on or after the date of the enactment of this Act.

SEC. 312. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1111(7) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by inserting ''or the owner of a patent for which a claim of infringement could reasonably be asserted against any person for making, using, offering to sell, selling, or importing into the United States a biological product that is the subject of a biosimilar biological product application'' before the period at the end.

(b) CERTIFICATION OF AGREEMENTS.—Section 1112 of such Act (21 U.S.C. 355 note) is amended by adding at the end the following:

''(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement under subsection (a) or (b) that is required to be filed under subsection (c) shall, within 30 days of such filing, execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification—

'''(1) represent the complete, final, and exclusive agreement between the parties;

'''(2) include any ancillary agreements that are contingent upon, provide a contingent condition for, were entered into within 30 days of, or are otherwise related to, the referenced agreement; and

'''(3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.''.

SEC. 313. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting ''section 311 of the Lower Costs, More Cures Act of 2019 or'' after ''that the agreement has violated''.

SEC. 314. COMMISSION LITIGATION AUTHORITY.

Section 16(a)(2) of the Federal Trade Commission Act (15 U.S.C. 56(a)(2)) is amended—

(1) in subparagraph (D), by striking ''or'' after the semicolon;

(2) in subparagraph (E), by inserting ''or'' after the semicolon; and

(3) by inserting after subparagraph (E) the following:

''(F) under section 311(d)(3)(A) of the Lower Costs, More Cures Act of 2019;''.

SEC. 315. STATUTE OF LIMITATIONS.

(a) IN GENERAL.—Except as provided in subsection (b), the Commission shall commence any administrative proceeding or civil action to enforce section 311 of this Act not later than 6 years after the date on which the parties to the agreement file the Notice of Agreement as provided by section 1112(c)(2) and (d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note).

(b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND DESIST ORDER.—If the Commission has issued a cease and desist order under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of section 311 of this Act and the proceeding for the issuance of such order was commenced within the period required by subsection (a) of this section, such subsection does not prohibit the commencement, after such period, of a civil action under section 311(d)(3)(A) against a party to such order or a civil action under subsection (l) of such section 5 for violation of such order.

Subtitle C—BLOCKING Act

SEC. 321. CHANGE CONDITIONS OF FIRST GENERIC EXCLUSIVITY TO SPUR ACCESS AND COMPETITION.

(a) IN GENERAL.—Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended—

(1) in subclause (I), by striking ''180 days after'' and all that follows through the period at the end and inserting the following: ''180 days after the earlier of—

''(aa) the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant; or

''(bb) the applicable date specified in subclause (III).''; and

(2) by adding at the end the following new subclause:

''(III) APPLICABLE DATE.—The applicable date specified in this subclause, with respect to an application for a drug described in subclause (I), is the date on which each of the following conditions is first met:

''(aa) The approval of such an application could be made effective, but for the eligibility of a first applicant for 180-day exclusivity under this clause.

''(bb) At least 30 months have passed since the date of submission of an application for the drug by at least one first applicant.

''(cc) Approval of an application for the drug submitted by at least one first applicant is not precluded under clause (iii).

''(dd) No application for the drug submitted by any first applicant is approved at the time the conditions under items (aa), (bb), and (cc) are all met, regardless of whether such an application is subsequently approved.''.

(b) INFORMATION.—The Secretary of Health and Human Services shall—

(1) not later than 120 days after the date of enactment of this Act, publish, as appropriate and available, information sufficient to allow applicants to assess whether the conditions described in section 505(j)(5)(B)(iv)(III) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) are satisfied for all applications where the exclusivity period under clause (iv)(I) of section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (as amended by such subsection) has not expired; and

(2) publish updates to such information to reflect the most recent information available to the Secretary.

Subtitle D—Purple Book

SEC. 331. PUBLIC LISTING.

Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is amended by adding at the end the following:

''(9) PUBLIC LISTING.—

''(A) IN GENERAL.—

''(i) INITIAL PUBLICATION.—Not later than 180 days after the date of enactment of the Lower Costs, More Cures Act of 2019, the Secretary shall publish and make available to the public in a searchable, electronic format—

''(I) a list in alphabetical order of the nonproprietary or proper name of each biological product for which a biologics license under subsection (a) or this subsection is in effect, or that has been deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009, as of such date of enactment;

''(II) the date of approval of the marketing application and the application number; and

''(III) the marketing or licensure status of the biological product for which a biologics license under subsection (a) or this subsection is in effect or that has been deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

''(ii) REVISIONS.—Every 30 days after the publication of the first list under clause (i), the Secretary shall revise the list to include each biological product which has been licensed under subsection (a) or this subsection during the 30-day period.

''(iii) PATENT INFORMATION.—Not later than 30 days after a list of patents under subsection (l)(3)(A), or a supplement to such list under subsection (l)(7), has been provided by the reference product sponsor to the subsection (k) applicant respecting a biological product included on the list published under this subparagraph, the reference product sponsor shall provide such list of patents (or supplement thereto) and their corresponding expiry dates to the Secretary, and the Secretary shall, in revisions made under clause (ii), include such information for such biological product. Within 30 days of providing any subsequent or supplemental list of patents to any subsequent subsection (k) applicant under subsection (l)(3)(A) or (l)(7), the reference product sponsor shall update the information provided to the Secretary under this clause with any additional patents from such subsequent or supplemental list and their corresponding expiry dates.

''(iv) LISTING OF EXCLUSIVITIES.—For each biological product included on the list published under this subparagraph, the Secretary shall specify each exclusivity period that is applicable and has not concluded under paragraph (6) or paragraph (7).

''(B) WITHDRAWAL OR SUSPENSION OF LICENSURE.—If the licensing of a biological product was withdrawn or suspended for safety, purity, or potency reasons, it may not be published in the list under subparagraph (A). If the withdrawal or suspension occurred after its publication in such list, the reference product sponsor shall notify the Secretary that—

''(i) the biological product shall be immediately removed from such list—

''(I) for the same period as the withdrawal or suspension; or

''(II) if the biological product has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety, purity, or potency reasons; and

''(ii) a notice of the removal shall be published in the Federal Register.''.

SEC. 332. REVIEW AND REPORT ON TYPES OF INFORMATION TO BE LISTED.

Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) solicit public comment regarding the type of information, if any, that should be added to or removed from the list required by paragraph (9) of section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as added by section 331; and

(2) transmit to Congress an evaluation of such comments, including any recommendations about the types of information that should be added to or removed from the list.

Subtitle E—Orange Book

SEC. 341. ORANGE BOOK.

(a) SUBMISSION OF PATENT INFORMATION FOR BRAND NAME DRUGS.—Paragraph (1) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended to read as follows:

''(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

''(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;

''(B) a full list of the articles used as components of such drug;

''(C) a full statement of the composition of such drug;

''(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

''(E) such samples of such drug and of the articles used as components thereof as the Secretary may require;

''(F) specimens of the labeling proposed to be used for such drug;

''(G) any assessments required under section 505B; and

''(H) patent information, with respect to each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, and consistent with the following requirements:

''(i) The applicant shall file with the application the patent number and the expiration date of—

''(I) any patent which claims the drug for which the applicant submitted the application and is a drug substance (including active ingredient) patent or a drug product (including formulation and composition) patent; and

''(II) any patent which claims the method of using such drug.

''(ii) If an application is filed under this subsection for a drug and a patent of the type described in clause (i) which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include such patent information.

Upon approval of the application, the Secretary shall publish the information submitted under subparagraph (H). The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by subparagraph (A).''.

(b) CONFORMING CHANGES TO REQUIREMENTS FOR SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—Section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended—

(1) by inserting after ''the patent number and the expiration date of any patent which'' the following: ''fulfills the criteria in subsection (b) and'';

(2) by inserting after the first sentence the following: ''Patent information that is not the type of patent information required by subsection (b) shall not be submitted.''; and

(3) by inserting after ''could not file patent information under subsection (b) because no patent'' the following: ''of the type required to be submitted in subsection (b)''.

(c) LISTING OF EXCLUSIVITIES.—Subparagraph (A) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

355(j)(7)) is amended by adding at the end the following:

''(iv) For each drug included on the list, the Secretary shall specify each exclusivity period that is applicable and has not concluded under—

''(I) clause (ii), (iii), or (iv) of subsection (c)(3)(E) of this section;

''(II) clause (iv) or (v) of paragraph (5)(B) of this subsection;

''(III) clause (ii), (iii), or (iv) of paragraph (5)(F) of this subsection;

''(IV) section 505A;

''(V) section 505E; or

''(VI) section 527(a).''.

(d) REMOVAL OF INVALID PATENTS.—

(1) IN GENERAL.—Section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

''(D)(i) The holder of an application approved under subsection (c) for a drug on the list shall notify within 14 days the Secretary in writing if either of the following occurs:

''(I) The Patent Trial and Appeals Board issues a decision from which no appeal has been or can be taken that a patent for such drug is invalid.

''(II) A court issues a decision from which no appeal has been or can be taken that a patent for such drug is invalid.

''(ii) The holder of an approved application shall include in any notification under clause (i) a copy of the decision described in subclause (I) or (II) of clause (i).

''(iii) The Secretary shall remove from the list any patent that is determined to be invalid in a decision described in subclause (I) or (II) of clause (i)—

''(I) promptly; but

''(II) not before the expiration of any 180-day exclusivity period under paragraph (5)(B)(iv) that relies on a certification described in paragraph (2)(A)(vii)(IV) that such patent was invalid.''.

(2) APPLICABILITY.—Subparagraph (D) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), as added by paragraph (1), applies only with respect to a decision described in such subparagraph that is issued on or after the date of enactment of this Act.

(e) REVIEW AND REPORT.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) solicit public comment regarding the types of patent information that should be included on the list under section 507(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

(2) transmit to the Congress an evaluation of such comments, including any recommendations about the types of patent information that should be included on or removed from such list.

SEC. 342. GAO REPORT TO CONGRESS.

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Comptroller General of the United States (referred to in this section as the ''Comptroller General'') shall submit to the Committee on Energy and Commerce of the House of Representatives a report on the patents included in the list published under section 505(j)(7) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(7)), including an analysis and evaluation of the types of patents included in such list and the claims such patents make about the products they claim.

(b) CONTENTS.—The Comptroller General shall include in the report under subsection (a)—

(1) data on the number of—

(A) patents included in the list published under paragraph (7) of section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)), that claim the active ingredient or formulation of a drug in combination with a device that is used for delivery of the drug, together comprising the finished dosage form of the drug; and

(B) claims in each patent that claim a device that is used for the delivery of the drug, but do not claim such device in combination with an active ingredient or formulation of a drug;

(2) data on the date of inclusion in the list under paragraph (7) of such section 505(j) for all patents under such list, as compared to patents that claim a method of using the drug in combination with a device;

(3) an analysis regarding the impact of including on the list under paragraph (7) of such section 505(j) certain types of patent information for drug product applicants and approved application holders, including an analysis of whether—

(A) the listing of the patents described in paragraph (1)(A) delayed the market entry of one or more drugs approved under such section 505(j); and

(B) not listing the patents described in paragraph (1)(A) would delay the market entry of one or more such drugs; and

(4) recommendations about which kinds of patents relating to devices described in paragraph (1)(A) should be submitted to the Secretary of Health and Human Services for inclusion on the list under paragraph (7) of such section 505(j) and which patents should not be required to be so submitted.

Subtitle F—Advancing Education on Biosimilars

SEC. 351. EDUCATION ON BIOLOGICAL PRODUCTS.

(a) WEBSITE; CONTINUING EDUCATION.—Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end the following:

''SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.

''(a) INTERNET WEBSITE.—

''(1) IN GENERAL.—The Secretary shall maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

''(2) CONTENT.—Educational materials provided under paragraph (1) may include—

''(A) explanations of key statutory and regulatory terms, including 'biosimilar' and 'interchangeable', and clarification regarding the use of interchangeable biosimilar biological products;

''(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

''(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

''(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 351(k) and reference products (as defined in section 351(i)), including the standards for review and licensing of each such type of biological product.

''(3) FORMAT.—The educational materials provided under paragraph (1) may be—

''(A) in formats such as webinars, continuing medical education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

''(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

''(4) OTHER INFORMATION.—In addition to the information described in paragraph (2), the Secretary shall continue to publish the following information:

''(A) The action package of each biological product licensed under subsection (a) or (k).

''(B) The summary review of each biological product licensed under subsection (a) or (k).

''(5) CONFIDENTIAL AND TRADE SECRET INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

''(b) CONTINUING EDUCATION.—The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.''.

(b) APPLICATION UNDER THE MEDICARE MERIT-BASED INCENTIVE PAYMENT SYSTEM.—Section 1848(q)(5)(C) of the Social Security Act (42 U.S.C. 1395w–4(q)(5)(C)) is amended by adding at the end the following new clause:

''(iv) CLINICAL MEDICAL EDUCATION PROGRAM ON BIOSIMILAR BIOLOGICAL PRODUCTS.—Completion of a clinical medical education program developed or improved under section 352A(b) of the Public Health Service Act by a MIPS eligible professional during a performance period shall earn such eligible professional one-half of the highest potential score for the performance category described in paragraph (2)(A)(iii) for such performance period. A MIPS eligible professional may only count the completion of such a program for purposes of such category one time during the eligible professional's lifetime.''.

Subtitle G—Streamlining Transition of Biological Products

SEC. 361. STREAMLINING THE TRANSITION OF BIOLOGICAL PRODUCTS.

Section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148) is amended—

(1) by striking ''An approved application'' and inserting the following:

''(A) IN GENERAL.—An approved application'';

(2) by adding at the end the following:

''(B) TREATMENT OF CERTAIN APPLICATIONS.—

''(i) IN GENERAL.—With respect to an application for a biological product submitted under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is filed not later than March 23, 2019, the Secretary shall continue to review such application under such section 505, even if such review continues after March 23, 2020.

''(ii) EFFECT ON LISTED DRUGS.—Only for purposes of carrying out clause (i), with respect to any applicable listed drug with respect to such application, the following shall apply:

''(I) Any drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and

that is referenced in an application described in clause (i), shall continue to be identified as a listed drug on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and the information for such drug on such list shall not be revised after March 20, 2020, until—

''(aa) such drug is removed from such list in accordance with subclause (III) or subparagraph (C) of such section 505(j)(7); or

''(bb) this subparagraph no longer has force or effect.

''(II) Any drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and that is referenced in an application described in clause (i) shall be subject only to requirements applicable to biological products licensed under such section.

''(III) Upon approval under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act of an application described in clause (i), the Secretary shall remove from the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act any listed drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act pursuant to subparagraph (A) and that is referenced in such approved application, unless such listed drug is referenced in one or more additional applications described in clause (i).

''(iii) DEEMED LICENSURE.—Upon approval of an application described in clause (i), such approved application shall be deemed to be a license for the biological product under section 351 of the Public Health Service Act, pursuant to subparagraph (A), and any period of exclusivity, as applicable, shall be determined in accordance with such section.

''(iv) RULE OF CONSTRUCTION.—

''(I) APPLICATION OF CERTAIN PROVISIONS.—

''(aa) PATENT CERTIFICATION OR STATEMENT.—An application described in clause (i) shall contain a patent certification or statement described in, as applicable, section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act or clauses (vii) and (viii) of section 505(j)(2)(A) of such Act and, with respect to any listed drug referenced in such application, comply with related requirements concerning any timely filed patent information listed pursuant to section 505(j)(7).

''(bb) DATE OF APPROVAL.—The earliest possible date on which any pending application described in clause (i) may be approved shall be determined based on—

''(AA) the last expiration date of any applicable period of exclusivity that would prevent such approval and that is described in section 505(c)(3)(E), 505(j)(5)(B)(iv), 505(j)(5)(F), 505A, 505E, or 527 of the Federal Food, Drug, and Cosmetic Act; and

''(BB) if the application was submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act and references any listed drug, the last applicable date determined under subparagraph (A), (B), or (C) of section 505(c)(3) of such Act, or, if the application was submitted under section 505(j) of such Act, the last applicable date determined under clause (i), (ii), or (iii) of section 505(j)(5)(B).

''(II) RULE OF CONSTRUCTION WITH RESPECT TO EXCLUSIVITY.—Nothing in this subparagraph shall be construed to affect section 351(k)(7)(D) of the Public Health Service Act.

''(v) AUTHORIZED DISCLOSURE.—The Secretary may continue to review an application after March 23, 2020, pursuant to clause (i), and continue to identify any applicable listed drug pursuant to clause (ii) on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, even if such review or listing may reveal the existence of such application and the identity of any listed drug for which the investigations described in section 505(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act are relied upon by the applicant for approval of the pending application. Nothing in this subparagraph shall be construed as authorizing the Secretary to disclose any other information that is a trade secret or confidential information described in section 552(b)(4) of title 5, United States Code.

''(vi) SUNSET.—Beginning on October 1, 2022, this subparagraph shall have no force or effect and any applications described in clause (i) that have not been approved shall be deemed withdrawn.''.

Subtitle H—Over-the-Counter Monograph Safety, Innovation, and Reform

SEC. 370. SHORT TITLE; REFERENCES IN SUBTITLE.

(a) SHORT TITLE.—This subtitle may be cited as the ''Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019''.

(b) REFERENCES.—Except as otherwise specified, any reference to ''this Act'' contained in this subtitle shall be treated as referring only to the provisions of this subtitle.

PART 1—OTC DRUG REVIEW

SEC. 371. REGULATION OF CERTAIN NONPRESCRIPTION DRUGS THAT ARE MARKETED WITHOUT AN APPROVED DRUG APPLICATION.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505F of such Act (21 U.S.C. 355g) the following:

''SEC. 505G. REGULATION OF CERTAIN NONPRESCRIPTION DRUGS THAT ARE MARKETED WITHOUT AN APPROVED DRUG APPLICATION.

''(a) NONPRESCRIPTION DRUGS MARKETED WITHOUT AN APPROVED APPLICATION.—Nonprescription drugs marketed without an approved drug application under section 505, as of the date of the enactment of this section, shall be treated in accordance with this subsection.

''(1) DRUGS SUBJECT TO A FINAL MONOGRAPH; CATEGORY I DRUGS SUBJECT TO A TENTATIVE FINAL MONOGRAPH.—A drug is deemed to be generally recognized as safe and effective under section 201(p)(1), not a new drug under section 201(p), and not subject to section 503(b)(1), if—

''(A) the drug is—

''(i) in conformity with the requirements for nonprescription use of a final monograph issued under part 330 of title 21, Code of Federal Regulations (except as provided in paragraph (2)), the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

''(ii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material extent and for a material time under section 201(p)(2); or

''(B) the drug is—

''(i) classified in category I for safety and effectiveness under a tentative final monograph that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations;

''(ii) in conformity with the proposed requirements for nonprescription use of such tentative final monograph, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

''(iii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material extent and for a material time under section 201(p)(2).

''(2) TREATMENT OF SUNSCREEN DRUGS.—With respect to sunscreen drugs subject to this section, the applicable requirements in terms of conformity with a final monograph, for purposes of paragraph (1)(A)(i), shall be the requirements specified in part 352 of title 21, Code of Federal Regulations, as published on May 21, 1999, beginning on page 27687 of volume 64 of the Federal Register, except that the applicable requirements governing effectiveness and labeling shall be those specified in section 201.327 of title 21, Code of Federal Regulations.

''(3) CATEGORY III DRUGS SUBJECT TO A TENTATIVE FINAL MONOGRAPH; CATEGORY I DRUGS SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE NOTICE OF PROPOSED RULEMAKING.—A drug that is not described in paragraph (1), (2), or (4) is not required to be the subject of an application approved under section 505, and is not subject to section 503(b)(1), if—

''(A) the drug is—

''(i) classified in category III for safety or effectiveness in the preamble of a proposed rule establishing a tentative final monograph that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

''(ii) in conformity with—

''(I) the conditions of use, including indication and dosage strength, if any, described for such category III drug in such preamble or in an applicable subsequent proposed rule;

''(II) the proposed requirements for drugs classified in such tentative final monograph in category I in the most recently proposed rule establishing requirements related to such tentative final monograph and in any final rule establishing requirements that are applicable to the drug; and

''(III) the general requirements for nonprescription drugs and conditions or requirements under subsection (b) or (k); and

''(iii) in a dosage form that, immediately prior to the date of the enactment of this section, had been used to a material extent and for a material time under section 201(p)(2); or

''(B) the drug is—

''(i) classified in category I for safety and effectiveness under a proposed monograph or advance notice of proposed rulemaking that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

''(ii) in conformity with the requirements for nonprescription use of such proposed monograph or advance notice of proposed rulemaking, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsection (b) or (k); and

''(iii) in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material extent and for a material time under section 201(p)(2).

''(4) CATEGORY II DRUGS DEEMED NEW DRUGS.—A drug that is classified in category II for safety or effectiveness under a tentative final monograph or that is subject to a determination to be not generally recognized as safe and effective in a proposed rule that is the most recently applicable proposal issued under part 330 of title 21, Code of Federal Regulations, shall be deemed to be a new drug under section 201(p), misbranded under section 502(ee), and subject to the requirement for an approved new drug application under section 505 beginning on the day

that is 180 calendar days after the date of the enactment of this section, unless, before such day, the Secretary determines that it is in the interest of public health to extend the period during which the drug may be marketed without such an approved new drug application.

''(5) DRUGS NOT GRASE DEEMED NEW DRUGS.—A drug that the Secretary has determined not to be generally recognized as safe and effective under section 201(p)(1) under a final determination issued under part 330 of title 21, Code of Federal Regulations, shall be deemed to be a new drug under section 201(p), misbranded under section 502(ee), and subject to the requirement for an approved new drug application under section 505.

''(6) OTHER DRUGS DEEMED NEW DRUGS.—Except as provided in subsection (m), a drug is deemed to be a new drug under section 201(p) and misbranded under section 502(ee) if the drug—

''(A) is not subject to section 503(b)(1); and

''(B) is not described in paragraph (1), (2), (3), (4), or (5), or subsection (b)(1)(B).

''(b) ADMINISTRATIVE ORDERS.—

''(1) IN GENERAL.—

''(A) DETERMINATION.—The Secretary may, on the initiative of the Secretary or at the request of one or more requestors, issue an administrative order determining whether there are conditions under which a specific drug, a class of drugs, or a combination of drugs, is determined to be—

''(i) not subject to section 503(b)(1); and

''(ii) generally recognized as safe and effective under section 201(p)(1).

''(B) EFFECT.—A drug or combination of drugs shall be deemed to not require approval under section 505 if such drug or combination of drugs—

''(i) is determined by the Secretary to meet the conditions specified in clauses (i) and (ii) of subparagraph (A);

''(ii) is marketed in conformity with an administrative order under this subsection;

''(iii) meets the general requirements for nonprescription drugs; and

''(iv) meets the requirements under subsections (c) and (k).

''(C) STANDARD.—The Secretary shall find that a drug is not generally recognized as safe and effective under section 201(p)(1) if—

''(i) the evidence shows that the drug is not generally recognized as safe and effective under section 201(p)(1); or

''(ii) the evidence is inadequate to show that the drug is generally recognized as safe and effective under section 201(p)(1).

''(2) ADMINISTRATIVE ORDERS INITIATED BY THE SECRETARY.—

''(A) IN GENERAL.—In issuing an administrative order under paragraph (1) upon the Secretary's initiative, the Secretary shall—

''(i) make reasonable efforts to notify informally, not later than 2 business days before the issuance of the proposed order, the sponsors of drugs who have a listing in effect under section 510(j) for the drugs or combination of drugs that will be subject to the administrative order;

''(ii) after any such reasonable efforts of notification—

''(I) issue a proposed administrative order by publishing it on the website of the Food and Drug Administration and include in such order the reasons for the issuance of such order; and

''(II) publish a notice of availability of such proposed order in the Federal Register;

''(iii) except as provided in subparagraph (B), provide for a public comment period with respect to such proposed order of not less than 45 calendar days; and

''(iv) if, after completion of the proceedings specified in clauses (i) through (iii), the Secretary determines that it is appropriate to issue a final administrative order—

''(I) issue the final administrative order, together with a detailed statement of reasons, which order shall not take effect until the time for requesting judicial review under paragraph (3)(D)(ii) has expired;

''(II) publish a notice of such final administrative order in the Federal Register;

''(III) afford requestors of drugs that will be subject to such order the opportunity for formal dispute resolution up to the level of the Director of the Center for Drug Evaluation and Research, which initially must be requested within 45 calendar days of the issuance of the order, and, for subsequent levels of appeal, within 30 calendar days of the prior decision; and

''(IV) except with respect to drugs described in paragraph (3)(B), upon completion of the formal dispute resolution procedure, inform the persons which sought such dispute resolution of their right to request a hearing.

''(B) EXCEPTIONS.—When issuing an administrative order under paragraph (1) on the Secretary's initiative proposing to determine that a drug described in subsection (a)(3) is not generally recognized as safe and effective under section 201(p)(1), the Secretary shall follow the procedures in subparagraph (A), except that—

''(i) the proposed order shall include notice of—

''(I) the general categories of data the Secretary has determined necessary to establish that the drug is generally recognized as safe and effective under section 201(p)(1); and

''(II) the format for submissions by interested persons;

''(ii) the Secretary shall provide for a public comment period of no less than 180 calendar days with respect to such proposed order, except when the Secretary determines, for good cause, that a shorter period is in the interest of public health; and

''(iii) any person who submits data in such comment period shall include a certification that the person has submitted all evidence created, obtained, or received by that person that is both within the categories of data identified in the proposed order and relevant to a determination as to whether the drug is generally recognized as safe and effective under section 201(p)(1).

''(3) HEARINGS; JUDICIAL REVIEW.—

''(A) IN GENERAL.—Only a person who participated in each stage of formal dispute resolution under subclause (III) of paragraph (2)(A)(iv) of an administrative order with respect to a drug may request a hearing concerning a final administrative order issued under such paragraph with respect to such drug. If a hearing is sought, such person must submit a request for a hearing, which shall be based solely on information in the administrative record, to the Secretary not later than 30 calendar days after receiving notice of the final decision of the formal dispute resolution procedure.

''(B) NO HEARING REQUIRED WITH RESPECT TO ORDERS RELATING TO CERTAIN DRUGS.—

''(i) IN GENERAL.—The Secretary shall not be required to provide notice and an opportunity for a hearing pursuant to paragraph (2)(A)(iv) if the final administrative order involved relates to a drug—

''(I) that is described in subsection (a)(3)(A); and

''(II) with respect to which no human or non-human data studies relevant to the safety or effectiveness of such drug have been submitted to the administrative record since the issuance of the most recent tentative final monograph relating to such drug.

''(ii) HUMAN DATA STUDIES AND NON-HUMAN DATA DEFINED.—In this subparagraph:

''(I) The term 'human data studies' means clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics studies, or bioavailability studies.

''(II) The term 'non-human data' means data from testing other than with human subjects which provides information concerning safety or effectiveness.

''(C) HEARING PROCEDURES.—

''(i) DENIAL OF REQUEST FOR HEARING.—If the Secretary determines that information submitted in a request for a hearing under subparagraph (A) with respect to a final administrative order issued under paragraph (2)(A)(iv) does not identify the existence of a genuine and substantial question of material fact, the Secretary may deny such request. In making such a determination, the Secretary may consider only information and data that are based on relevant and reliable scientific principles and methodologies.

''(ii) SINGLE HEARING FOR MULTIPLE RELATED REQUESTS.—If more than one request for a hearing is submitted with respect to the same administrative order under subparagraph (A), the Secretary may direct that a single hearing be conducted in which all persons whose hearing requests were granted may participate.

''(iii) PRESIDING OFFICER.—The presiding officer of a hearing requested under subparagraph (A) shall—

''(I) be designated by the Secretary;

''(II) not be an employee of the Center for Drug Evaluation and Research; and

''(III) not have been previously involved in the development of the administrative order involved or proceedings relating to that administrative order.

''(iv) RIGHTS OF PARTIES TO HEARING.—The parties to a hearing requested under subparagraph (A) shall have the right to present testimony, including testimony of expert witnesses, and to cross-examine witnesses presented by other parties. Where appropriate, the presiding officer may require that cross-examination by parties representing substantially the same interests be consolidated to promote efficiency and avoid duplication.

''(v) FINAL DECISION.—

''(I) At the conclusion of a hearing requested under subparagraph (A), the presiding officer of the hearing shall issue a decision containing findings of fact and conclusions of law. The decision of the presiding officer shall be final.

''(II) The final decision may not take effect until the period under subparagraph (D)(ii) for submitting a request for judicial review of such decision expires.

''(D) JUDICIAL REVIEW OF FINAL ADMINISTRATIVE ORDER.—

''(i) IN GENERAL.—The procedures described in section 505(h) shall apply with respect to judicial review of final administrative orders issued under this subsection in the same manner and to the same extent as such section applies to an order described in such section except that the judicial review shall be taken by filing in an appropriate district court of the United States in lieu of the appellate courts specified in such section.

''(ii) PERIOD TO SUBMIT A REQUEST FOR JUDICIAL REVIEW.—A person eligible to request a hearing under this paragraph and seeking judicial review of a final administrative order issued under this subsection shall file such request for judicial review not later than 60 calendar days after the latest of—

''(I) the date on which notice of such order is published;

''(II) the date on which a hearing with respect to such order is denied under subparagraph (B) or (C)(i);

''(III) the date on which a final decision is made following a hearing under subparagraph (C)(v); or

''(IV) if no hearing is requested, the date on which the time for requesting a hearing expires.

''(4) EXPEDITED PROCEDURE WITH RESPECT TO ADMINISTRATIVE ORDERS INITIATED BY THE SECRETARY.—

''(A) IMMINENT HAZARD TO THE PUBLIC HEALTH.—

''(i) IN GENERAL.—In the case of a determination by the Secretary that a drug, class of drugs, or combination of drugs subject to this section poses an imminent hazard to the public health, the Secretary, after first making reasonable efforts to notify, not later than 48 hours before issuance of such order under this subparagraph, sponsors who have a listing in effect under section 510(j) for such drug or combination of drugs—

''(I) may issue an interim final administrative order for such drug, class of drugs, or combination of drugs under paragraph (1), together with a detailed statement of the reasons for such order;

''(II) shall publish in the Federal Register a notice of availability of any such order; and

''(III) shall provide for a public comment period of at least 45 calendar days with respect to such interim final order.

''(ii) NONDELEGATION.—The Secretary may not delegate the authority to issue an interim final administrative order under this subparagraph.

''(B) SAFETY LABELING CHANGES.—

''(i) IN GENERAL.—In the case of a determination by the Secretary that a change in the labeling of a drug, class of drugs, or combination of drugs subject to this section is reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event associated with use of the drug, the Secretary may—

''(I) make reasonable efforts to notify informally, not later than 48 hours before the issuance of the interim final order, the sponsors of drugs who have a listing in effect under section 510(j) for such drug or combination of drugs;

''(II) after reasonable efforts of notification, issue an interim final administrative order in accordance with paragraph (1) to require such change, together with a detailed statement of the reasons for such order;

''(III) publish in the Federal Register a notice of availability of such order; and

''(IV) provide for a public comment period of at least 45 calendar days with respect to such interim final order.

''(ii) CONTENT OF ORDER.—An interim final order issued under this subparagraph with respect to the labeling of a drug may provide for new warnings and other information required for safe use of the drug.

''(C) EFFECTIVE DATE.—An order under subparagraph (A) or (B) shall take effect on a date specified by the Secretary.

''(D) FINAL ORDER.—After the completion of the proceedings in subparagraph (A) or (B), the Secretary shall—

''(i) issue a final order in accordance with paragraph (1);

''(ii) publish a notice of availability of such final administrative order in the Federal Register; and

''(iii) afford sponsors of such drugs that will be subject to such an order the opportunity for formal dispute resolution up to the level of the Director of the Center for Drug Evaluation and Research, which must initially be within 45 calendar days of the issuance of the order, and for subsequent levels of appeal, within 30 calendar days of the prior decision.

''(E) HEARINGS.—A sponsor of a drug subject to a final order issued under subparagraph (D) and that participated in each stage of formal dispute resolution under clause (iii) of such subparagraph may request a hearing on such order. The provisions of subparagraphs (A), (B), and (C) of paragraph (3), other than paragraph (3)(C)(v)(II), shall apply with respect to a hearing on such order in the same manner and to the same extent as such provisions apply with respect to a hearing on an administrative order issued under paragraph (2)(A)(iv).

''(F) TIMING.—

''(i) FINAL ORDER AND HEARING.—The Secretary shall—

''(I) not later than 6 months after the date on which the comment period closes under subparagraph (A) or (B), issue a final order in accordance with paragraph (1); and

''(II) not later than 12 months after the date on which such final order is issued, complete any hearing under subparagraph (E).

''(ii) DISPUTE RESOLUTION REQUEST.—The Secretary shall specify in an interim final order issued under subparagraph (A) or (B) such shorter periods for requesting dispute resolution under subparagraph (D)(iii) as are necessary to meet the requirements of this subparagraph.

''(G) JUDICIAL REVIEW.—A final order issued pursuant to subparagraph (F) shall be subject to judicial review in accordance with paragraph (3)(D).

''(5) ADMINISTRATIVE ORDER INITIATED AT THE REQUEST OF A REQUESTOR.—

''(A) IN GENERAL.—In issuing an administrative order under paragraph (1) at the request of a requestor with respect to certain drugs, classes of drugs, or combinations of drugs—

''(i) the Secretary shall, after receiving a request under this subparagraph, determine whether the request is sufficiently complete and formatted to permit a substantive review;

''(ii) if the Secretary determines that the request is sufficiently complete and formatted to permit a substantive review, the Secretary shall—

''(I) file the request; and

''(II) initiate proceedings with respect to issuing an administrative order in accordance with paragraphs (2) and (3); and

''(iii) except as provided in paragraph (6), if the Secretary determines that a request does not meet the requirements for filing or is not sufficiently complete and formatted to permit a substantive review, the requestor may demand that the request be filed over protest, and the Secretary shall initiate proceedings to review the request in accordance with paragraph (2)(A).

''(B) REQUEST TO INITIATE PROCEEDINGS.—

''(i) IN GENERAL.—A requestor seeking an administrative order under paragraph (1) with respect to certain drugs, classes of drugs, or combinations of drugs, shall submit to the Secretary a request to initiate proceedings for such order in the form and manner as specified by the Secretary. Such requestor may submit a request under this subparagraph for the issuance of an administrative order—

''(I) determining whether a drug is generally recognized as safe and effective under section 201(p)(1), exempt from section 503(b)(1), and not required to be the subject of an approved application under section 505; or

''(II) determining whether a change to a condition of use of a drug is generally recognized as safe and effective under section 201(p)(1), exempt from section 503(b)(1), and not required to be the subject of an approved application under section 505, if, absent such a changed condition of use, such drug is—

''(aa) generally recognized as safe and effective under section 201(p)(1) in accordance with subsection (a)(1), (a)(2), or an order under this subsection; or

''(bb) subject to subsection (a)(3), but only if such requestor initiates such request in conjunction with a request for the Secretary to determine whether such drug is generally recognized as safe and effective under section 201(p)(1), which is filed by the Secretary under subparagraph (A)(ii).

''(ii) EXCEPTION.—The Secretary is not required to complete review of a request for a change described in clause (i)(II) if the Secretary determines that there is an inadequate basis to find the drug is generally recognized as safe and effective under section 201(p)(1) under paragraph (1) and issues a final order announcing that determination.

''(iii) WITHDRAWAL.—The requestor may withdraw a request under this paragraph, according to the procedures set forth pursuant to subsection (d)(2)(B). Notwithstanding any other provision of this section, if such request is withdrawn, the Secretary may cease proceedings under this subparagraph.

''(C) EXCLUSIVITY.—

''(i) IN GENERAL.—A final administrative order issued in response to a request under this section shall have the effect of authorizing solely the order requestor (or the licensees, assignees, or successors in interest of such requestor with respect to the subject of such order), for a period of 18 months following the effective date of such final order and beginning on the date the requestor may lawfully market such drugs pursuant to the order, to market drugs—

''(I) incorporating changes described in clause (ii); and

''(II) subject to the limitations under clause (iv).

''(ii) CHANGES DESCRIBED.—A change described in this clause is a change subject to an order specified in clause (i), which—

''(I) provides for a drug to contain an active ingredient (including any ester or salt of the active ingredient) not previously incorporated in a drug described in clause (iii); or

''(II) provides for a change in the conditions of use of a drug, for which new human data studies conducted or sponsored by the requestor (or for which the requestor has an exclusive right of reference) were essential to the issuance of such order.

''(iii) DRUGS DESCRIBED.—The drugs described in this clause are drugs—

''(I) specified in subsection (a)(1), (a)(2), or (a)(3);

''(II) subject to a final order issued under this section;

''(III) subject to a final sunscreen order (as defined in section 586(2)(A)); or

''(IV) described in subsection (m)(1), other than drugs subject to an active enforcement action under chapter III of this Act.

''(iv) LIMITATIONS ON EXCLUSIVITY.—

''(I) IN GENERAL.—Only one 18-month period under this subparagraph shall be granted, under each order described in clause (i), with respect to changes (to the drug subject to such order) which are either—

''(aa) changes described in clause (ii)(I), relating to active ingredients; or

''(bb) changes described in clause (ii)(II), relating to conditions of use.

''(II) NO EXCLUSIVITY ALLOWED.—No exclusivity shall apply to changes to a drug which are—

''(aa) the subject of a Tier 2 OTC monograph order request (as defined in section 744L);

''(bb) safety-related changes, as defined by the Secretary, or any other changes the Secretary considers necessary to assure safe use; or

''(cc) changes related to methods of testing safety or efficacy.

''(v) NEW HUMAN DATA STUDIES DEFINED.—In this subparagraph, the term 'new human data studies' means clinical trials of safety

or effectiveness (including actual use studies), pharmacokinetics studies, or bioavailability studies, the results of which—

''(I) have not been relied on by the Secretary to support—

''(aa) a proposed or final determination that a drug described in subclause (I), (II), or (III) of clause (iii) is generally recognized as safe and effective under section 201(p)(1); or

''(bb) approval of a drug that was approved under section 505; and

''(II) do not duplicate the results of another study that was relied on by the Secretary to support—

''(aa) a proposed or final determination that a drug described in subclause (I), (II), or (III) of clause (iii) is generally recognized as safe and effective under section 201(p)(1); or

''(bb) approval of a drug that was approved under section 505.

''(6) INFORMATION REGARDING SAFE NONPRESCRIPTION MARKETING AND USE AS CONDITION FOR FILING A GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE REQUEST.—

''(A) IN GENERAL.—In response to a request under this section that a drug described in subparagraph (B) be generally recognized as safe and effective, the Secretary—

''(i) may file such request, if the request includes information specified under subparagraph (C) with respect to safe nonprescription marketing and use of such drug; or

''(ii) if the request fails to include information specified under subparagraph (C), shall refuse to file such request and require that nonprescription marketing of the drug be pursuant to a new drug application as described in subparagraph (D).

''(B) DRUG DESCRIBED.—A drug described in this subparagraph is a nonprescription drug which contains an active ingredient not previously incorporated in a drug—

''(i) specified in subsection (a)(1), (a)(2), or (a)(3);

''(ii) subject to a final order under this section; or

''(iii) subject to a final sunscreen order (as defined in section 586(2)(A)).

''(C) INFORMATION DEMONSTRATING PRIMA FACIE SAFE NONPRESCRIPTION MARKETING AND USE.—Information specified in this subparagraph, with respect to a request described in subparagraph (A)(i), is—

''(i) information sufficient for a prima facie demonstration that the drug subject to such request has a verifiable history of being marketed and safely used by consumers in the United States as a nonprescription drug under comparable conditions of use;

''(ii) if the drug has not been previously marketed in the United States as a nonprescription drug, information sufficient for a prima facie demonstration that the drug was marketed and safely used under comparable conditions of marketing and use in a country listed in section 802(b)(1)(A) or designated by the Secretary in accordance with section 802(b)(1)(B)—

''(I) for such period as needed to provide reasonable assurances concerning the safe nonprescription use of the drug; and

''(II) during such time was subject to sufficient monitoring by a regulatory body considered acceptable by the Secretary for such monitoring purposes, including for adverse events associated with nonprescription use of the drug; or

''(iii) if the Secretary determines that information described in clause (i) or (ii) is not needed to provide a prima facie demonstration that the drug can be safely marketed and used as a nonprescription drug, such other information the Secretary determines is sufficient for such purposes.

''(D) MARKETING PURSUANT TO NEW DRUG APPLICATION.—In the case of a request described in subparagraph (A)(ii), the drug subject to such request may be resubmitted for filing only if—

''(i) the drug is marketed as a nonprescription drug, under conditions of use comparable to the conditions specified in the request, for such period as the Secretary determines appropriate (not to exceed 5 consecutive years) pursuant to an application approved under section 505; and

''(ii) during such period, 1,000,000 retail packages of the drug, or an equivalent quantity as determined by the Secretary, were distributed for retail sale, as determined in such manner as the Secretary finds appropriate.

''(E) RULE OF APPLICATION.—Except in the case of a request involving a drug described in section 586(9), as in effect on January 1, 2017, if the Secretary refuses to file a request under this paragraph, the requestor may not file such request over protest under paragraph (5)(A)(iii).

''(7) PACKAGING.—An administrative order issued under paragraph (2), (4)(A), or (5) may include requirements for the packaging of a drug to encourage use in accordance with labeling. Such requirements may include unit dose packaging, requirements for products intended for use by pediatric populations, requirements to reduce risk of harm from unsupervised ingestion, and other appropriate requirements. This paragraph does not authorize the Food and Drug Administration to require standards or testing procedures as described in part 1700 of title 16, Code of Federal Regulations.

''(8) FINAL AND TENTATIVE FINAL MONOGRAPHS FOR CATEGORY I DRUGS DEEMED FINAL ADMINISTRATIVE ORDERS.—

''(A) IN GENERAL.—A final monograph or tentative final monograph described in subparagraph (B) shall be deemed to be a final administrative order under this subsection and may be amended, revoked, or otherwise modified in accordance with the procedures of this subsection.

''(B) MONOGRAPHS DESCRIBED.—For purposes of subparagraph (A), a final monograph or tentative final monograph is described in this subparagraph if it—

''(i) establishes conditions of use for a drug described in paragraph (1) or (2) of subsection (a); and

''(ii) represents the most recently promulgated version of such conditions, including as modified, in whole or in part, by any proposed or final rule.

''(C) DEEMED ORDERS INCLUDE HARMONIZING TECHNICAL AMENDMENTS.—The deemed establishment of a final administrative order under subparagraph (A) shall be construed to include any technical amendments to such order as the Secretary determines necessary to ensure that such order is appropriately harmonized, in terms of terminology or cross-references, with the applicable provisions of this Act (and regulations thereunder) and any other orders issued under this section.

''(c) PROCEDURE FOR MINOR CHANGES.—

''(1) IN GENERAL.—Minor changes in the dosage form of a drug that is described in paragraph (1) or (2) of subsection (a) or the subject of an order issued under subsection (b) may be made by a requestor without the issuance of an order under subsection (b) if—

''(A) the requestor maintains such information as is necessary to demonstrate that the change—

''(i) will not affect the safety or effectiveness of the drug; and

''(ii) will not materially affect the extent of absorption or other exposure to the active ingredient in comparison to a suitable reference product; and

''(B) the change is in conformity with the requirements of an applicable administrative order issued by the Secretary under paragraph (3).

''(2) ADDITIONAL INFORMATION.—

''(A) ACCESS TO RECORDS.—A sponsor shall submit records requested by the Secretary relating to such a minor change under section 704(a)(4), within 15 business days of receiving such a request, or such longer period as the Secretary may provide.

''(B) INSUFFICIENT INFORMATION.—If the Secretary determines that the information contained in such records is not sufficient to demonstrate that the change does not affect the safety or effectiveness of the drug or materially affect the extent of absorption or other exposure to the active ingredient, the Secretary—

''(i) may so inform the sponsor of the drug in writing; and

''(ii) if the Secretary so informs the sponsor, shall provide the sponsor of the drug with a reasonable opportunity to provide additional information.

''(C) FAILURE TO SUBMIT SUFFICIENT INFORMATION.—If the sponsor fails to provide such additional information within a time prescribed by the Secretary, or if the Secretary determines that such additional information does not demonstrate that the change does not—

''(i) affect the safety or effectiveness of the drug; or

''(ii) materially affect the extent of absorption or other exposure to the active ingredient in comparison to a suitable reference product,

the drug as modified is a new drug under section 201(p) and shall be deemed to be misbranded under section 502(ee).

''(3) DETERMINING WHETHER A CHANGE WILL AFFECT SAFETY OR EFFECTIVENESS.—

''(A) IN GENERAL.—The Secretary shall issue one or more administrative orders specifying requirements for determining whether a minor change made by a sponsor pursuant to this subsection will affect the safety or effectiveness of a drug or materially affect the extent of absorption or other exposure to an active ingredient in the drug in comparison to a suitable reference product, together with guidance for applying those orders to specific dosage forms.

''(B) STANDARD PRACTICES.—The orders and guidance issued by the Secretary under subparagraph (A) shall take into account relevant public standards and standard practices for evaluating the quality of drugs, and may take into account the special needs of populations, including children.

''(d) CONFIDENTIALITY OF INFORMATION SUBMITTED TO THE SECRETARY.—

''(1) IN GENERAL.—Subject to paragraph (2), any information, including reports of testing conducted on the drug or drugs involved, that is submitted by a requestor in connection with proceedings on an order under this section (including any minor change under subsection (c)) and is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, shall not be disclosed to the public unless the requestor consents to that disclosure.

''(2) PUBLIC AVAILABILITY.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall—

''(i) make any information submitted by a requestor in support of a request under subsection (b)(5)(A) available to the public not later than the date on which the proposed order is issued; and

''(ii) make any information submitted by any other person with respect to an order requested (or initiated by the Secretary) under subsection (b), available to the public upon such submission.

''(B) LIMITATIONS ON PUBLIC AVAILABILITY.—Information described in subparagraph (A) shall not be made public if—

''(i) the information pertains to pharmaceutical quality information, unless such information is necessary to establish standards under which a drug is generally recognized as safe and effective under section 201(p)(1);

''(ii) the information is submitted in a requestor-initiated request, but the requestor withdraws such request, in accordance with withdrawal procedures established by the Secretary, before the Secretary issues the proposed order;

''(iii) the Secretary requests and obtains the information under subsection (c) and such information is not submitted in relation to an order under subsection (b); or

''(iv) the information is of the type contained in raw datasets.

''(e) UPDATES TO DRUG LISTING INFORMATION.—A sponsor who makes a change to a drug subject to this section shall submit updated drug listing information for the drug in accordance with section 510(j) within 30 calendar days of the date when the drug is first commercially marketed, except that a sponsor who was the order requestor with respect to an order subject to subsection (b)(5)(C) (or a licensee, assignee, or successor in interest of such requestor) shall submit updated drug listing information on or before the date when the drug is first commercially marketed.

''(f) APPROVALS UNDER SECTION 505.—The provisions of this section shall not be construed to preclude a person from seeking or maintaining the approval of an application for a drug under sections 505(b)(1), 505(b)(2), and 505(j). A determination under this section that a drug is not subject to section 503(b)(1), is generally recognized as safe and effective under section 201(p)(1), and is not a new drug under section 201(p) shall constitute a finding that the drug is safe and effective that may be relied upon for purposes of an application under section 505(b)(2), so that the applicant shall be required to submit for purposes of such application only information needed to support any modification of the drug that is not covered by such determination under this section.

''(g) PUBLIC AVAILABILITY OF ADMINISTRATIVE ORDERS.—The Secretary shall establish, maintain, update (as determined necessary by the Secretary but no less frequently than annually), and make publicly available, with respect to orders issued under this section—

''(1) a repository of each final order and interim final order in effect, including the complete text of the order; and

''(2) a listing of all orders proposed and under development under subsection (b)(2), including—

''(A) a brief description of each such order; and

''(B) the Secretary's expectations, if resources permit, for issuance of proposed orders over a 3-year period.

''(h) DEVELOPMENT ADVICE TO SPONSORS OR REQUESTORS.—The Secretary shall establish procedures under which sponsors or requestors may meet with appropriate officials of the Food and Drug Administration to obtain advice on the studies and other information necessary to support submissions under this section and other matters relevant to the regulation of nonprescription drugs and the development of new nonprescription drugs under this section.

''(i) PARTICIPATION OF MULTIPLE SPONSORS OR REQUESTORS.—The Secretary shall establish procedures to facilitate efficient participation by multiple sponsors or requestors in proceedings under this section, including provision for joint meetings with multiple sponsors or requestors or with organizations nominated by sponsors or requestors to represent their interests in a proceeding.

''(j) ELECTRONIC FORMAT.—All submissions under this section shall be in electronic format.

''(k) EFFECT ON EXISTING REGULATIONS GOVERNING NONPRESCRIPTION DRUGS.—

''(1) REGULATIONS OF GENERAL APPLICABILITY TO NONPRESCRIPTION DRUGS.—Except as provided in this subsection, nothing in this section supersedes regulations establishing general requirements for nonprescription drugs, including regulations of general applicability contained in parts 201, 250, and 330 of title 21, Code of Federal Regulations, or any successor regulations. The Secretary shall establish or modify such regulations by means of rulemaking in accordance with section 553 of title 5, United States Code.

''(2) REGULATIONS ESTABLISHING REQUIREMENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

''(A) The provisions of section 310.545 of title 21, Code of Federal Regulations, as in effect on the day before the date of the enactment of this section, shall be deemed to be a final order under subsection (b).

''(B) Regulations in effect on the day before the date of the enactment of this section, establishing requirements for specific nonprescription drugs marketed pursuant to this section (including such requirements in parts 201 and 250 of title 21, Code of Federal Regulations), shall be deemed to be final orders under subsection (b), only as they apply to drugs—

''(i) subject to paragraph (1), (2), (3), or (4) of subsection (a); or

''(ii) otherwise subject to an order under this section.

''(3) WITHDRAWAL OF REGULATIONS.—The Secretary shall withdraw regulations establishing final monographs and the procedures governing the over-the-counter drug review under part 330 and other relevant parts of title 21, Code of Federal Regulations (as in effect on the day before the date of the enactment of this section), or make technical changes to such regulations to ensure conformity with appropriate terminology and cross references. Notwithstanding subchapter II of chapter 5 of title 5, United States Code, any such withdrawal or technical changes shall be made without public notice and comment and shall be effective upon publication through notice in the Federal Register (or upon such date as specified in such notice).

''(l) GUIDANCE.—The Secretary shall issue guidance that specifies—

''(1) the procedures and principles for formal meetings between the Secretary and sponsors or requestors for drugs subject to this section;

''(2) the format and content of data submissions to the Secretary under this section;

''(3) the format of electronic submissions to the Secretary under this section;

''(4) consolidated proceedings for appeal and the procedures for such proceedings where appropriate; and

''(5) for minor changes in drugs, recommendations on how to comply with the requirements in orders issued under subsection (c)(3).

''(m) RULE OF CONSTRUCTION.—

''(1) IN GENERAL.—This section shall not affect the treatment or status of a nonprescription drug—

''(A) that is marketed without an application approved under section 505 as of the date of the enactment of this section;

''(B) that is not subject to an order issued under this section; and

''(C) to which paragraphs (1), (2), (3), (4), or (5) of subsection (a) do not apply.

''(2) TREATMENT OF PRODUCTS PREVIOUSLY FOUND TO BE SUBJECT TO TIME AND EXTENT REQUIREMENTS.—

''(A) Notwithstanding subsection (a), a drug described in subparagraph (B) may only be lawfully marketed, without an application approved under section 505, pursuant to an order issued under this section.

''(B) A drug described in this subparagraph is a drug which, prior to the date of the enactment of this section, the Secretary determined in a proposed or final rule to be ineligible for review under the OTC drug review (as such phrase 'OTC drug review' was used in section 330.14 of title 21, Code of Federal Regulations, as in effect on the day before the date of the enactment of this section).

''(3) PRESERVATION OF AUTHORITY.—

''(A) Nothing in paragraph (1) shall be construed to preclude or limit the applicability of any provision of this Act other than this section.

''(B) Nothing in subsection (a) shall be construed to prohibit the Secretary from issuing an order under this section finding a drug to be not generally recognized as safe and effective under section 201(p)(1), as the Secretary determines appropriate.

''(n) INVESTIGATIONAL NEW DRUGS.—A drug is not subject to this section if an exemption for investigational use under section 505(i) is in effect for such drug.

''(o) INAPPLICABILITY OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to collections of information made under this section.

''(p) INAPPLICABILITY OF NOTICE AND COMMENT RULEMAKING AND OTHER REQUIREMENTS.—The requirements of subsection (b) shall apply with respect to orders issued under this section instead of the requirements of subchapter II of chapter 5 of title 5, United States Code.

''(q) DEFINITIONS.—In this section:

''(1) The term 'nonprescription drug' refers to a drug not subject to the requirements of section 503(b)(1).

''(2) The term 'sponsor' refers to any person marketing, manufacturing, or processing a drug that—

''(A) is listed pursuant to section 510(j); and

''(B) is or will be subject to an administrative order under this section of the Food and Drug Administration.

''(3) The term 'requestor' refers to any person or group of persons marketing, manufacturing, processing, or developing a drug.''.

(b) GAO STUDY.—Not later than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall submit a study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate addressing the effectiveness and overall impact of exclusivity under section 505G of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and section 586C of such Act (21 U.S.C. 360fff–3), including the impact of such exclusivity on consumer access. Such study shall include—

(1) an analysis of the impact of exclusivity under such section 505G for nonprescription drug products, including—

(A) the number of nonprescription drug products that were granted exclusivity and the indication for which the nonprescription drug products were determined to be generally recognized as safe and effective;

(B) whether the exclusivity for such drug products was granted for—

(i) a new active ingredient (including any ester or salt of the active ingredient); or

(ii) changes in the conditions of use of a drug, for which new human data studies conducted or sponsored by the requestor were essential;

(C) whether, and to what extent, the exclusivity impacted the requestor's or sponsor's decision to develop the drug product;

(D) an analysis of the implementation of the exclusivity provision in such section 505G, including—

(i) the resources used by the Food and Drug Administration;

(ii) the impact of such provision on innovation, as well as research and development in the nonprescription drug market;

(iii) the impact of such provision on competition in the nonprescription drug market;

(iv) the impact of such provision on consumer access to nonprescription drug products;

(v) the impact of such provision on the prices of nonprescription drug products; and

(vi) whether the administrative orders initiated by requestors under such section 505G have been sufficient to encourage the development of nonprescription drug products that would likely not be otherwise developed, or developed in as timely a manner; and

(E) whether the administrative orders initiated by requestors under such section 505G have been sufficient incentive to encourage innovation in the nonprescription drug market; and

(2) an analysis of the impact of exclusivity under such section 586C for sunscreen ingredients, including—

(A) the number of sunscreen ingredients that were granted exclusivity and the specific ingredient that was determined to be generally recognized as safe and effective;

(B) whether, and to what extent, the exclusivity impacted the requestor's or sponsor's decision to develop the sunscreen ingredient;

(C) whether, and to what extent, the sunscreen ingredient granted exclusivity had previously been available outside of the United States;

(D) an analysis of the implementation of the exclusivity provision in such section 586C, including—

(i) the resources used by the Food and Drug Administration;

(ii) the impact of such provision on innovation, as well as research and development in the sunscreen market;

(iii) the impact of such provision on competition in the sunscreen market;

(iv) the impact of such provision on consumer access to sunscreen products;

(v) the impact of such provision on the prices of sunscreen products; and

(vi) whether the administrative orders initiated by requestors under such section 505G have been utilized by sunscreen ingredient sponsors and whether such process has been sufficient to encourage the development of sunscreen ingredients that would likely not be otherwise developed, or developed in as timely a manner; and

(E) whether the administrative orders initiated by requestors under such section 586C have been sufficient incentive to encourage innovation in the sunscreen market.

(c) CONFORMING AMENDMENT.—Section 751(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379r(d)(1)) is amended—

(1) in the matter preceding subparagraph (A)—

(A) by striking ''final regulation promulgated'' and inserting ''final order under section 505G''; and

(B) by striking ''and not misbranded''; and

(2) in subparagraph (A), by striking ''regulation in effect'' and inserting ''regulation or order in effect''.

SEC. 372. MISBRANDING.

Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(ee) If it is a nonprescription drug that is subject to section 505G, is not the subject of an application approved under section 505, and does not comply with the requirements under section 505G.

''(ff) If it is a drug and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744M.''.

SEC. 373. DRUGS EXCLUDED FROM THE OVER-THE-COUNTER DRUG REVIEW.

(a) IN GENERAL.—Nothing in this Act (or the amendments made by this Act) shall apply to any nonprescription drug (as defined in section 505G(q) of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act) which was excluded by the Food and Drug Administration from the Over-the-Counter Drug Review in accordance with the paragraph numbered 25 on page 9466 of volume 37 of the Federal Register, published on May 11, 1972.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to preclude or limit the applicability of any other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 374. TREATMENT OF SUNSCREEN INNOVATION ACT.

(a) REVIEW OF NONPRESCRIPTION SUNSCREEN ACTIVE INGREDIENTS.—

(1) APPLICABILITY OF SECTION 505G FOR PENDING SUBMISSIONS.—

(A) IN GENERAL.—A sponsor of a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that, as of the date of enactment of this Act, is subject to a proposed sunscreen order under section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3) may elect, by means of giving written notification to the Secretary of Health and Human Services within 180 calendar days of the enactment of this Act, to transition into the review of such ingredient or combination of ingredients pursuant to the process set out in section 505G of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act.

(B) ELECTION EXERCISED.—Upon receipt by the Secretary of Health and Human Services of a timely notification under subparagraph (A)—

(i) the proposed sunscreen order involved is deemed to be a request for an order under subsection (b) of section 505G of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act; and

(ii) such order is deemed to have been accepted for filing under subsection (b)(6)(A)(i) of such section 505G.

(C) ELECTION NOT EXERCISED.—If a notification under subparagraph (A) is not received by the Secretary of Health and Human Services within 180 calendar days of the date of enactment of this Act, the review of the proposed sunscreen order described in subparagraph (A)—

(i) shall continue under section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3); and

(ii) shall not be eligible for review under section 505G, added by section 1001 of this Act.

(2) DEFINITIONS.—In this subsection, the terms ''sponsor'', ''nonprescription'', ''sunscreen active ingredient'', and ''proposed sunscreen order'' have the meanings given to those terms in section 586 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff).

(b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

(1) FINAL SUNSCREEN ORDERS.—Paragraph (3) of section 586C(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3(e)) is amended to read as follows:

''(3) RELATIONSHIP TO ORDERS UNDER SECTION 505G.—A final sunscreen order shall be deemed to be a final order under section 505G.''.

(2) MEETINGS.—Paragraph (7) of section 586C(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3(b)) is amended—

(A) by striking ''A sponsor may request'' and inserting the following:

''(A) IN GENERAL.—A sponsor may request''; and

(B) by adding at the end the following:

''(B) CONFIDENTIAL MEETINGS.—A sponsor may request one or more confidential meetings with respect to a proposed sunscreen order, including a letter deemed to be a proposed sunscreen order under paragraph (3), to discuss matters relating to data requirements to support a general recognition of safety and effectiveness involving confidential information and public information related to such proposed sunscreen order, as appropriate. The Secretary shall convene a confidential meeting with such sponsor in a reasonable time period. If a sponsor requests more than one confidential meeting for the same proposed sunscreen order, the Secretary may refuse to grant an additional confidential meeting request if the Secretary determines that such additional confidential meeting is not reasonably necessary for the sponsor to advance its proposed sunscreen order, or if the request for a confidential meeting fails to include sufficient information upon which to base a substantive discussion. The Secretary shall publish a post-meeting summary of each confidential meeting under this subparagraph that does not disclose confidential commercial information or trade secrets. This subparagraph does not authorize the disclosure of confidential commercial information or trade secrets subject to 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.''.

(3) EXCLUSIVITY.—Section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3) is amended by adding at the end the following:

''(f) EXCLUSIVITY.—

''(1) IN GENERAL.—A final sunscreen order shall have the effect of authorizing solely the order requestor (or the licensees, assignees, or successors in interest of such requestor with respect to the subject of such request and listed under paragraph (5)) for a period of 18 months, to market a sunscreen ingredient under this section incorporating changes described in paragraph (2) subject to the limitations under paragraph (4), beginning on the date the requestor (or any licensees, assignees, or successors in interest of such requestor with respect to the subject of such request and listed under paragraph (5)) may lawfully market such sunscreen ingredient pursuant to the order.

''(2) CHANGES DESCRIBED.—A change described in this paragraph is a change subject to an order specified in paragraph (1) that permits a sunscreen to contain an active sunscreen ingredient not previously incorporated in a marketed sunscreen listed in paragraph (3).

''(3) MARKETED SUNSCREEN.—The marketed sunscreen ingredients described in this paragraph are sunscreen ingredients—

''(A) marketed in accordance with a final monograph for sunscreen drug products set forth at part 352 of title 21, Code of Federal Regulations (as published at 64 Fed. Reg. 27687); or

''(B) marketed in accordance with a final order issued under this section.

''(4) LIMITATIONS ON EXCLUSIVITY.—Only one 18-month period may be granted per ingredient under paragraph (1).

''(5) LISTING OF LICENSEES, ASSIGNEES, OR SUCCESSORS IN INTEREST.—Requestors shall submit to the Secretary at the time when a drug subject to such request is introduced or delivered for introduction into interstate

commerce, a list of licensees, assignees, or successors in interest under paragraph (1).''.

(4) SUNSET PROVISION.—Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff et seq.) is amended by adding at the end the following:

''SEC. 586H. SUNSET.

''This subchapter shall cease to be effective at the end of fiscal year 2022.''.

(5) TREATMENT OF FINAL SUNSCREEN ORDER.—The Federal Food, Drug, and Cosmetic Act is amended by striking section 586E of such Act (21 U.S.C. 360fff–5).

(c) TREATMENT OF AUTHORITY REGARDING FINALIZATION OF SUNSCREEN MONOGRAPH.—

(1) IN GENERAL.—

(A) REVISION OF FINAL SUNSCREEN ORDER.—Not later than November 26, 2019, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall amend and revise the final administrative order concerning nonprescription sunscreen (referred to in this subsection as the ''sunscreen order'') for which the content, prior to the date of enactment of this Act, was represented by the final monograph for sunscreen drug products set forth in part 352 of title 21, Code of Federal Regulations (as in effect on May 21, 1999).

(B) ISSUANCE OF REVISED SUNSCREEN ORDER; EFFECTIVE DATE.—A revised sunscreen order described in subparagraph (A) shall be—

(i) issued in accordance with the procedures described in section 505G(c)(2) of the Federal Food, Drug, and Cosmetic Act;

(ii) issued in proposed form not later than May 28, 2019;

(iii) effective not later than November 26, 2020; and

(iv) issued by the Secretary at least 1 year prior to the effective date of the revised order.

(2) REPORTS.—If a revised sunscreen order issued under paragraph (1) does not include provisions related to the effectiveness of various sun protection factor levels, and does not address all dosage forms known to the Secretary to be used in sunscreens marketed in the United States without a new drug application approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), the Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the rationale for omission of such provisions from such order, and a plan and timeline to compile any information necessary to address such provisions through such order.

(d) TREATMENT OF NON-SUNSCREEN TIME AND EXTENT APPLICATIONS.—

(1) IN GENERAL.—Any application described in section 586F of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–6) that was submitted to the Secretary pursuant to section 330.14 of title 21, Code of Federal Regulations, as such provisions were in effect immediately prior to the date of enactment date of this Act, shall be extinguished as of such date of enactment, subject to paragraph (2).

(2) ORDER REQUEST.—Nothing in paragraph (1) precludes the submission of an order request under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act, with respect to a drug that was the subject of an application extinguished under paragraph (1).

SEC. 375. ANNUAL UPDATE TO CONGRESS ON APPROPRIATE PEDIATRIC INDICATION FOR CERTAIN OTC COUGH AND COLD DRUGS.

(a) IN GENERAL.—Subject to subsection (c), the Secretary of Health and Human Services shall, beginning not later than 1 year after the date of enactment of this Act, annually submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a letter describing the progress of the Food and Drug Administration—

(1) in evaluating the cough and cold monograph described in subsection (b) with respect to children under age 6; and

(2) as appropriate, revising such cough and cold monograph to address such children through the order process under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act.

(b) COUGH AND COLD MONOGRAPH DESCRIBED.—The cough and cold monograph described in this subsection consists of the conditions under which nonprescription drugs containing antitussive, expectorant, nasal decongestant, or antihistamine active ingredients (or combinations thereof) are generally recognized as safe and effective, as specified in part 341 of title 21, Code of Federal Regulations (as in effect immediately prior to the date of enactment of this Act), and included in an order deemed to be established under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act.

(c) DURATION OF AUTHORITY.—The requirement under subsection (a) shall terminate as of the date of a letter submitted by the Secretary of Health and Human Services pursuant to such subsection in which the Secretary indicates that the Food and Drug Administration has completed its evaluation and revised, in a final order, as applicable, the cough and cold monograph as described in subsection (a)(2).

SEC. 376. TECHNICAL CORRECTIONS.

(a) IMPORTS AND EXPORTS.—Section 801(e)(4)(E)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)(E)(iii)) is amended by striking ''subparagraph'' each place such term appears and inserting ''paragraph''.

(b) FDA REAUTHORIZATION ACT OF 2017.—

(1) IN GENERAL.—Section 905(b)(4) of the FDA Reauthorization Act of 2017 (Public Law115–52) is amended by striking ''Section 744H(e)(2)(B)'' and inserting ''Section 744H(f)(2)(B)''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect as of the enactment of the FDA Reauthorization Act of 2017 (Public Law 115–52).

PART 2—USER FEES

SEC. 381. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This part may be cited as the ''Over-the-Counter Monograph User Fee Act of 2019''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this part will be dedicated to OTC monograph drug activities, as set forth in the goals identified for purposes of part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 382. FEES RELATING TO OVER-THE-COUNTER DRUGS.

Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by inserting after part 9 the following:

''PART 10—FEES RELATING TO OVER-THE-COUNTER DRUGS

''SEC. 744L. DEFINITIONS.

''In this part:

''(1) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control, both of the business entities.

''(2) The term 'contract manufacturing organization facility' means an OTC monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.

''(3) The term 'costs of resources allocated for OTC monograph drug activities' means the expenses in connection with OTC monograph drug activities for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and costs related to contracts with such contractors;

''(B) management of information, and the acquisition, maintenance, and repair of computer resources;

''(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

''(D) collecting fees under section 744M and accounting for resources allocated for OTC monograph drug activities.

''(4) The term 'FDA establishment identifier' is the unique number automatically generated by Food and Drug Administration's Field Accomplishments and Compliance Tracking System (FACTS) (or any successor system).

''(5) The term 'OTC monograph drug' means a nonprescription drug without an approved new drug application which is governed by the provisions of section 505G.

''(6) The term 'OTC monograph drug activities' means activities of the Secretary associated with OTC monograph drugs and inspection of facilities associated with such products, including the following activities:

''(A) The activities necessary for review and evaluation of OTC monographs and OTC monograph order requests, including—

''(i) orders proposing or finalizing applicable conditions of use for OTC monograph drugs;

''(ii) orders affecting status regarding general recognition of safety and effectiveness of an OTC monograph ingredient or combination of ingredients under specified conditions of use;

''(iii) all OTC monograph drug development and review activities, including intra-agency collaboration;

''(iv) regulation and policy development activities related to OTC monograph drugs;

''(v) development of product standards for products subject to review and evaluation;

''(vi) meetings referred to in section 505G(i);

''(vii) review of labeling prior to issuance of orders related to OTC monograph drugs or conditions of use; and

''(viii) regulatory science activities related to OTC monograph drugs.

''(B) Inspections related to OTC monograph drugs.

''(C) Monitoring of clinical and other research conducted in connection with OTC monograph drugs.

''(D) Safety activities with respect to OTC monograph drugs, including—

''(i) collecting, developing, and reviewing safety information on OTC monograph drugs, including adverse event reports;

''(ii) developing and using improved adverse event data-collection systems, including information technology systems; and

''(iii) developing and using improved analytical tools to assess potential safety risks, including access to external databases.

''(E) Other activities necessary for implementation of section 505G.

''(7) The term 'OTC monograph order request' means a request for an order submitted under section 505G(b)(5).

''(8) The term 'Tier 1 OTC monograph order request' means any OTC monograph order request not determined to be a Tier 2 OTC monograph order request.

''(9)(A) The term 'Tier 2 OTC monograph order request' means, subject to subparagraph (B), an OTC monograph order request for—

''(i) the reordering of existing information in the drug facts label of an OTC monograph drug;

''(ii) the addition of information to the other information section of the drug facts label of an OTC monograph drug, as limited by section 201.66(c)(7) of title 21, Code of Federal Regulations (or any successor regulations);

''(iii) modification to the directions for use section of the drug facts label of an OTC monograph drug, if such changes conform to changes made pursuant to section 505G(c)(3)(A);

''(iv) the standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph;

''(v) a change to ingredient nomenclature to align with nomenclature of a standards-setting organization; or

''(vi) addition of an interchangeable term in accordance with section 330.1 of title 21, Code of Federal Regulations (or any successor regulations).

''(B) The Secretary may, based on program implementation experience or other factors found appropriate by the Secretary, characterize any OTC monograph order request as a Tier 2 OTC monograph order request (including recharacterizing a request from Tier 1 to Tier 2) and publish such determination in a proposed order issued pursuant to section 505G.

''(10)(A) The term 'OTC monograph drug facility' means a foreign or domestic business or other entity that—

''(i) is—

''(I) under one management, either direct or indirect; and

''(II) at one geographic location or address engaged in manufacturing or processing the finished dosage form of an OTC monograph drug;

''(ii) includes a finished dosage form manufacturer facility in a contractual relationship with the sponsor of one or more OTC monograph drugs to manufacture or process such drugs; and

''(iii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: production of clinical research supplies, testing, or placement of outer packaging on packages containing multiple products, for such purposes as creating multipacks, when each monograph drug product contained within the overpackaging is already in a final packaged form prior to placement in the outer overpackaging.

''(B) For purposes of subparagraph (A)(i)(II), separate buildings or locations within close proximity are considered to be at one geographic location or address if the activities conducted in such buildings or locations are—

''(i) closely related to the same business enterprise;

''(ii) under the supervision of the same local management; and

''(iii) under a single FDA establishment identifier and capable of being inspected by the Food and Drug Administration during a single inspection.

''(C) If a business or other entity would meet criteria specified in subparagraph (A), but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

''(11) The term 'OTC monograph drug meeting' means any meeting regarding the content of a proposed OTC monograph order request.

''(12) The term 'person' includes an affiliate of a person.

''(13) The terms 'requestor' and 'sponsor' have the meanings given such terms in section 505G.

''SEC. 744M. AUTHORITY TO ASSESS AND USE OTC MONOGRAPH FEES.

''(a) TYPES OF FEES.—Beginning with fiscal year 2019, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) FACILITY FEE.—

''(A) IN GENERAL.—Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility as determined under subsection (c).

''(B) EXCEPTIONS.—

''(i) A fee shall not be assessed under subparagraph (A) if the identified OTC monograph drug facility—

''(I) has ceased all activities related to OTC monograph drugs prior to January 31, 2019, for the first program year, and December 31 of the fiscal year for subsequent fiscal years; and

''(II) has updated its registration to reflect such change under the requirements for drug establishment registration set forth in section 510.

''(ii) The amount of the fee for a contract manufacturing organization facility shall be equal to two-thirds of the amount of the fee for an OTC monograph drug facility that is not a contract manufacturing organization facility.

''(C) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (c).

''(D) DUE DATE.—

''(i) FOR FIRST PROGRAM YEAR.—For fiscal year 2019, the facility fees required under subparagraph (A) shall be due 45 calendar days after publication of the Federal Register notice provided for under subsection (c)(4)(A).

''(ii) SUBSEQUENT FISCAL YEARS.—For each fiscal year after fiscal year 2019, the facility fees required under subparagraph (A) shall be due on the later of—

''(I) the first business day of June of such year; or

''(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

''(2) OTC MONOGRAPH ORDER REQUEST FEE.—

''(A) IN GENERAL.—Each person that submits an OTC monograph order request shall be subject to a fee for an OTC monograph order request. The amount of such fee shall be—

''(i) for a Tier 1 OTC monograph order request, $500,000, adjusted for inflation for the fiscal year (as determined under subsection (c)(1)(B)); and

''(ii) for a Tier 2 OTC monograph order request, $100,000 adjusted for inflation for the fiscal year (as determined under subsection (c)(1)(B)).

''(B) DUE DATE.—The OTC monograph order request fees required under subparagraph (A) shall be due on the date of submission of the OTC monograph order request.

''(C) EXCEPTION FOR CERTAIN SAFETY CHANGES.—A person who is named as the requestor in an OTC monograph order shall not be subject to a fee under subparagraph (A) if the Secretary finds that the OTC monograph order request seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen—

''(i) a contraindication, warning, or precaution;

''(ii) a statement about risk associated with misuse or abuse; or

''(iii) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug.

''(D) REFUND OF FEE IF ORDER REQUEST IS RECATEGORIZED AS A TIER 2 OTC MONOGRAPH ORDER REQUEST.—If the Secretary determines that an OTC monograph request initially characterized as Tier 1 shall be re-characterized as a Tier 2 OTC monograph order request, and the requestor has paid a Tier 1 fee in accordance with subparagraph (A)(i), the Secretary shall refund the requestor the difference between the Tier 1 and Tier 2 fees determined under subparagraphs (A)(i) and (A)(ii), respectively.

''(E) REFUND OF FEE IF ORDER REQUEST REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any order request which is refused for filing or was withdrawn before being accepted or refused for filing.

''(F) FEES FOR ORDER REQUESTS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—An OTC monograph order request that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest.

''(G) REFUND OF FEE IF ORDER REQUEST WITHDRAWN.—If an order request is withdrawn after the order request was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the order request after the application was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

''(3) REFUNDS.—

''(A) IN GENERAL.—Other than refunds provided pursuant to any of subparagraphs (D) through (G) of paragraph (2), the Secretary shall not refund any fee paid under paragraph (1) except as provided in subparagraph (B).

''(B) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under paragraph (1) or (2), a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

''(4) NOTICE.—Within the timeframe specified in subsection (c), the Secretary shall publish in the Federal Register the amount of the fees under paragraph (1) for such fiscal year.

''(b) FEE REVENUE AMOUNTS.—

''(1) FISCAL YEAR 2019.—For fiscal year 2019, fees under subsection (a)(1) shall be established to generate a total facility fee revenue amount equal to the sum of—

''(A) the annual base revenue for fiscal year 2019 (as determined under paragraph (3));

''(B) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(2)); and

''(C) additional direct cost adjustments (as determined under subsection (c)(3)).

''(2) SUBSEQUENT FISCAL YEARS.—For each of the fiscal years 2020 through 2023, fees under subsection (a)(1) shall be established to generate a total facility fee revenue amount equal to the sum of—

''(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

''(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

''(C) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(2));

''(D) additional direct cost adjustments (as determined under subsection (c)(3)); and

''(E) additional dollar amounts for each fiscal year as follows:

''(i) $7,000,000 for fiscal year 2020.

''(ii) $6,000,000 for fiscal year 2021.

''(iii) $7,000,000 for fiscal year 2022.

''(iv) $3,000,000 for fiscal year 2023.

''(3) ANNUAL BASE REVENUE.—For purposes of paragraphs (1)(A) and (2)(A), the dollar amount of the annual base revenue for a fiscal year shall be—

''(A) for fiscal year 2019, $8,000,000; and

''(B) for fiscal years 2020 through 2023, the dollar amount of the total revenue amount established under this subsection for the previous fiscal year, not including any adjustments made under subsection (c)(2) or (c)(3).

''(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

''(1) INFLATION ADJUSTMENT.—

''(A) IN GENERAL.—For purposes of subsection (b)(2)(B), the dollar amount of the inflation adjustment to the annual base revenue for fiscal year 2020 and each subsequent fiscal year shall be equal to the product of—

''(i) such annual base revenue for the fiscal year under subsection (b)(2); and

''(ii) the inflation adjustment percentage under subparagraph (C).

''(B) OTC MONOGRAPH ORDER REQUEST FEES.—For purposes of subsection (a)(2), the dollar amount of the inflation adjustment to the fee for OTC monograph order requests for fiscal year 2020 and each subsequent fiscal year shall be equal to the product of—

''(i) the applicable fee under subsection (a)(2) for the preceding fiscal year; and

''(ii) the inflation adjustment percentage under subparagraph (C).

''(C) INFLATION ADJUSTMENT PERCENTAGE.—The inflation adjustment percentage under this subparagraph for a fiscal year is equal to—

''(i) for each of fiscal years 2020 and 2021, the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data; and

''(ii) for each of fiscal years 2022 and 2023, the sum of—

''(I) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years; and

''(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years.

''(2) OPERATING RESERVE ADJUSTMENT.—

''(A) IN GENERAL.—For fiscal year 2019 and subsequent fiscal years, for purposes of subsections (b)(1)(B) and (b)(2)(C), the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenue and fees if such an adjustment is necessary to provide operating reserves of carryover user fees for OTC monograph drug activities for not more than the number of weeks specified in subparagraph (B).

''(B) NUMBER OF WEEKS.—The number of weeks specified in this subparagraph is—

''(i) 3 weeks for fiscal year 2019;

''(ii) 7 weeks for fiscal year 2020;

''(iii) 10 weeks for fiscal year 2021;

''(iv) 10 weeks for fiscal year 2022; and

''(v) 10 weeks for fiscal year 2023.

''(C) DECREASE.—If the Secretary has carryover balances for such process in excess of 10 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in such subparagraph to provide for not more than 10 weeks of such operating reserves.

''(D) RATIONALE FOR ADJUSTMENT.—If an adjustment under this paragraph is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (4) establishing fee revenue and fees for the fiscal year involved.

''(3) ADDITIONAL DIRECT COST ADJUSTMENT.—The Secretary shall, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees for purposes of subsection (b)(2)(D) by an amount equal to—

''(A) $14,000,000 for fiscal year 2019;

''(B) $7,000,000 for fiscal year 2020;

''(C) $4,000,000 for fiscal year 2021;

''(D) $3,000,000 for fiscal year 2022; and

''(E) $3,000,000 for fiscal year 2023.

''(4) ANNUAL FEE SETTING.—

''(A) FISCAL YEAR 2019.—The Secretary shall, not later than the second Monday in March of 2019—

''(i) establish OTC monograph drug facility fees for fiscal year 2019 under subsection (a), based on the revenue amount for such year under subsection (b) and the adjustments provided under this subsection; and

''(ii) publish fee revenue, facility fees, and OTC monograph order requests in the Federal Register.

''(B) SUBSEQUENT FISCAL YEARS.—The Secretary shall, not later than the second Monday in March of each fiscal year that begins after September 30, 2019—

''(i) establish for each such fiscal year, based on the revenue amounts under subsection (b) and the adjustments provided under this subsection—

''(I) OTC monograph drug facility fees under subsection (a)(1); and

''(II) OTC monograph order request fees under subsection (a)(2); and

''(ii) publish such fee revenue amounts, facility fees, and OTC monograph order request fees in the Federal Register.

''(d) IDENTIFICATION OF FACILITIES.—Each person that owns an OTC monograph drug facility shall submit to the Secretary the information required under this subsection each year. Such information shall, for each fiscal year—

''(1) be submitted as part of the requirements for drug establishment registration set forth in section 510; and

''(2) include for each such facility, at a minimum, identification of the facility's business operation as that of an OTC monograph drug facility.

''(e) EFFECT OF FAILURE TO PAY FEES.—

''(1) OTC MONOGRAPH DRUG FACILITY FEE.—

''(A) IN GENERAL.—Failure to pay the fee under subsection (a)(1) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

''(i) The Secretary shall place the facility on a publicly available arrears list.

''(ii) All OTC monograph drugs manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(ff).

''(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(1) is paid.

''(2) ORDER REQUESTS.—An OTC monograph order request submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person under this section have been paid.

''(3) MEETINGS.—A person subject to fees under this section shall be considered ineligible for OTC monograph drug meetings until all such fees owed by such person have been paid.

''(f) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—Subject to subparagraph (C), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year.

''(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be available to defray increases in the costs of the resources allocated for OTC monograph drug activities (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $12,000,000, multiplied by the adjustment factor applicable to the fiscal year involved under subsection (c)(1).

''(C) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (B) in any fiscal year if the costs funded by appropriations and allocated for OTC monograph drug activities are not more than 15 percent below the level specified in such subparagraph.

''(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2019), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2019 through 2023, there is authorized to be appropriated for fees under this section an amount equal to the total amount of fees assessed for such fiscal year under this section.

''(g) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(h) CONSTRUCTION.—This section may not be construed to require that the number of

full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in OTC monograph drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

"SEC. 744N. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2019, and not later than 120 calendar days after the end of each fiscal year thereafter for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 2001(b) of the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019 during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals.

''(b) FISCAL REPORT.—Not later than 120 calendar days after the end of fiscal year 2019 and each subsequent fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the internet website of the Food and Drug Administration.

''(d) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for OTC monograph drug activities for the first 5 fiscal years after fiscal year 2023, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

''(B) publish such recommendations in the Federal Register;

''(C) provide for a period of 30 calendar days for the public to provide written comments on such recommendations;

''(D) hold a meeting at which the public may present its views on such recommendations; and

''(E) after consideration of such public views and comments, revise such recommendations as necessary.

''(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2023, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.''.

Subtitle I—Other Provisions

SEC. 391. PROTECTING ACCESS TO BIOLOGICAL PRODUCTS.

Section 351(k)(7) of the Public Health Service Act (42 U.S.C. 262(k)(7)) is amended by adding at the end the following:

''(D) DEEMED LICENSES.—

''(i) NO ADDITIONAL EXCLUSIVITY THROUGH DEEMING.—An approved application that is deemed to be a license for a biological product under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 shall not be treated as having been first licensed under subsection (a) for purposes of subparagraphs (A) and (B).

''(ii) APPLICATION OF LIMITATIONS ON EXCLUSIVITY.—Subparagraph (C) shall apply with respect to a reference product referred to in such subparagraph that was the subject of an approved application that was deemed to be a license pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

''(iii) APPLICABILITY.—The exclusivity periods described in section 527, section 505A(b)(1)(A)(ii), and section 505A(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act shall continue to apply to a biological product after an approved application for the biological product is deemed to be a license for the biological product under subsection (a) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.''.

SEC. 392. ORPHAN DRUG CLARIFICATION.

Section 527(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(c)) is amended by adding at the end the following:

''(3) APPLICABILITY.—This subsection applies to any drug designated under section 526 for which an application was approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act after the date of enactment of the FDA Reauthorization Act of 2017, regardless of the date on which such drug was designated under section 526.''.

SEC. 393. CONDITIONS OF USE FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 351(k)(2)(A)(iii) of the Public Health Service Act (42 U.S.C. 262(k)(2)(A)(iii) is amended—

(1) in subclause (I), by striking ''; and'' and inserting a semicolon;

(2) in subclause (II), by striking the period and inserting ''; and'' ; and

(3) by adding at the end the following:

''(III) may include information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product.''.

SEC. 394. CLARIFYING THE MEANING OF NEW CHEMICAL ENTITY.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E)—

(i) in clause (ii), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(ii) in clause (iii), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(B) in subsection (j)(5)(F)—

(i) in clause (ii), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(ii) in clause (iii), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(C) in subsection (l)(2)(A)(i), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(D) in subsection (s), in the matter preceding paragraph (1), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(E) in subsection (u)(1), in the matter preceding subparagraph (A)—

(i) by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(ii) by striking ''same active ingredient'' and inserting ''same active moiety'';

(2) in section 512(c)(2)(F) (21 U.S.C. 360b(c)(2)(F))—

(A) in clause (i), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(B) in clause (ii), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(C) in clause (v), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(3) in section 524(a)(4)(C) (21 U.S.C. 360n(a)(4)(C)), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(4) in section 529(a)(4)(A)(ii) (21 U.S.C. 360ff(a)(4)(A)(ii)), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(5) in section 565A(a)(4)(D) (21 U.S.C. 360bbb–4a(a)(4)(D)), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''.

TITLE IV—REVENUE PROVISIONS

SEC. 401. PERMANENT EXTENSION OF REDUCTION IN MEDICAL EXPENSE DEDUCTION FLOOR.

(a) IN GENERAL.—Section 213(a) of the Internal Revenue Code of 1986 is amended by striking ''10 percent'' and inserting ''7.5 percent''.

(b) CONFORMING AMENDMENTS.—

(1) Section 213 of such Code is amended by striking subsection (f).

(2) Section 56(b)(1) of such Code is amended by striking subparagraph (B) and by redesignating subparagraphs (C), (D), (E), and (F), as subparagraphs (B), (C), (D), and (E), respectively.

(c) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years ending after December 31, 2018.

SEC. 402. SAFE HARBOR FOR HIGH DEDUCTIBLE HEALTH PLANS WITHOUT DEDUCTIBLE FOR INSULIN.

(a) IN GENERAL.—Section 223(c)(2)(C) of the Internal Revenue Code of 1986 is amended by inserting ''or for insulin or any device for the delivery of insulin'' before the period at the end.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to months beginning after the date of the enactment of this Act.

SEC. 403. INCLUSION OF CERTAIN OVER-THE-COUNTER MEDICAL PRODUCTS AS QUALIFIED MEDICAL EXPENSES.

(a) HSAs.—Section 223(d)(2) of the Internal Revenue Code of 1986 is amended—

(1) by striking the last sentence of subparagraph (A) and inserting the following: ''For purposes of this subparagraph, amounts paid for menstrual care products shall be treated as paid for medical care.''; and

(2) by adding at the end the following new subparagraph:

''(D) MENSTRUAL CARE PRODUCT.—For purposes of this paragraph, the term 'menstrual care product' means a tampon, pad, liner, cup, sponge, or similar product used by individuals with respect to menstruation or other genital-tract secretions.''.

(b) ARCHER MSAs.—Section 220(d)(2)(A) of such Code is amended by striking the last sentence and inserting the following: ''For purposes of this subparagraph, amounts paid for menstrual care products (as defined in section 223(d)(2)(D)) shall be treated as paid for medical care.''.

(c) HEALTH FLEXIBLE SPENDING ARRANGEMENTS AND HEALTH REIMBURSEMENT ARRANGEMENTS.—Section 106 of such Code is amended by striking subsection (f) and inserting the following new subsection:

''(f) REIMBURSEMENTS FOR MENSTRUAL CARE PRODUCTS.—For purposes of this section and section 105, expenses incurred for menstrual care products (as defined in section 223(d)(2)(D)) shall be treated as incurred for medical care.''.

(d) EFFECTIVE DATES.—

(1) DISTRIBUTIONS FROM SAVINGS ACCOUNTS.—The amendment made by subsections (a) and (b) shall apply to amounts paid after December 31, 2019.

(2) REIMBURSEMENTS.—The amendment made by subsection (c) shall apply to expenses incurred after December 31, 2019.

TITLE V—MISCELLANEOUS

SEC. 501. PAYMENT FOR BIOSIMILAR BIOLOGICAL PRODUCTS DURING INITIAL PERIOD.

Section 1847A(c)(4) of the Social Security Act (42 U.S.C. 1395w–3a(c)(4)) is amended—

(1) in each of subparagraphs (A) and (B), by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively, and moving such subclauses 2 ems to the right;

(2) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii) and moving such clauses 2 ems to the right;

(3) by striking ''UNAVAILABLE.—In the case'' and inserting ''UNAVAILABLE.—

''(A) IN GENERAL.—Subject to subparagraph (B), in the case''; and

(4) by adding at the end the following new subparagraph:

''(B) LIMITATION ON PAYMENT AMOUNT FOR BIOSIMILAR BIOLOGICAL PRODUCTS DURING INITIAL PERIOD.—In the case of a biosimilar biological product furnished on or after July 1, 2020, in lieu of applying subparagraph (A) during the initial period described in such subparagraph with respect to the biosimilar biological product, the amount payable under this section for the biosimilar biological product is the lesser of the following:

''(i) The amount determined under clause (ii) of such subparagraph for the biosimilar biological product.

''(ii) The amount determined under subsection (b)(1)(B) for the reference biological product.''.

SEC. 502. GAO STUDY AND REPORT ON AVERAGE SALES PRICE.

(a) STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States (in this section referred to as the ''Comptroller General'') shall conduct a study on spending for applicable drugs under part B of title XVIII of the Social Security Act.

(2) APPLICABLE DRUGS DEFINED.—In this section, the term ''applicable drugs'' means drugs and biologicals—

(A) for which reimbursement under such part B is based on the average sales price of the drug or biological; and

(B) that account for the largest percentage of total spending on drugs and biologicals under such part B (as determined by the Comptroller General, but in no case less that 25 drugs or biologicals).

(3) REQUIREMENTS.—The study under paragraph (1) shall include an analysis of the following:

(A) The extent to which each applicable drug is paid for—

(i) under such part B for Medicare beneficiaries; or

(ii) by private payers in the commercial market.

(B) Any change in Medicare spending or Medicare beneficiary cost-sharing that would occur if the average sales price of an applicable drug was based solely on payments by private payers in the commercial market.

(C) The extent to which drug manufacturers provide rebates, discounts, or other price concessions to private payers in the commercial market for applicable drugs, which the manufacturer includes in its average sales price calculation, for—

(i) formulary placement;

(ii) utilization management considerations; or

(iii) other purposes.

(D) Barriers to drug manufacturers providing such price concessions for applicable drugs.

(E) Other areas determined appropriate by the Comptroller General.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

SEC. 503. REQUIRING PRESCRIPTION DRUG PLANS AND MA–PD PLANS TO REPORT POTENTIAL FRAUD, WASTE, AND ABUSE TO THE SECRETARY OF HHS.

Section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104) is amended by adding at the end the following new subsection:

''(p) REPORTING POTENTIAL FRAUD, WASTE, AND ABUSE.—Beginning January 1, 2021, the PDP sponsor of a prescription drug plan shall report to the Secretary, as specified by the Secretary—

''(1) any substantiated or suspicious activities (as defined by the Secretary) with respect to the program under this part as it relates to fraud, waste, and abuse; and

''(2) any steps made by the PDP sponsor after identifying such activities to take corrective actions.''.

SEC. 504. ESTABLISHMENT OF PHARMACY QUALITY MEASURES UNDER MEDICARE PART D.

Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended by adding at the end the following new paragraph:

''(8) APPLICATION OF PHARMACY QUALITY MEASURES.—

''(A) IN GENERAL.—A PDP sponsor that implements incentive payments to a pharmacy or price concessions paid by a pharmacy based on quality measures shall use measures established or approved by the Secretary under subparagraph (B) with respect to payment for covered part D drugs dispensed by such pharmacy.

''(B) STANDARD PHARMACY QUALITY MEASURES.—The Secretary shall establish or approve standard quality measures from a consensus and evidence-based organization for payments described in subparagraph (A). Such measures shall focus on patient health outcomes and be based on proven criteria measuring pharmacy performance.

''(C) EFFECTIVE DATE.—The requirement under subparagraph (A) shall take effect for plan years beginning on or after January 1, 2023, or such earlier date specified by the Secretary if the Secretary determines there are sufficient measures established or approved under subparagraph (B) to meet the requirement under subparagraph (A).''.

SEC. 505. IMPROVING COORDINATION BETWEEN THE FOOD AND DRUG ADMINISTRATION AND THE CENTERS FOR MEDICARE & MEDICAID SERVICES.

(a) IN GENERAL.—

(1) PUBLIC MEETING.—

(A) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall convene a public meeting for the purposes of discussing and providing input on improvements to coordination between the Food and Drug Administration and the Centers for Medicare & Medicaid Services in preparing for the availability of novel medical products described in subsection (c) on the market in the United States.

(B) ATTENDEES.—The public meeting shall include—

(i) representatives of relevant Federal agencies, including representatives from each of the medical product centers within the Food and Drug Administration and representatives from the coding, coverage, and payment offices within the Centers for Medicare & Medicaid Services;

(ii) stakeholders with expertise in the research and development of novel medical products, including manufacturers of such products;

(iii) representatives of commercial health insurance payers;

(iv) stakeholders with expertise in the administration and use of novel medical products, including physicians; and

(v) stakeholders representing patients and with expertise in the utilization of patient experience data in medical product development.

(C) TOPICS.—The public meeting shall include a discussion of—

(i) the status of the drug and medical device development pipeline related to the availability of novel medical products;

(ii) the anticipated expertise necessary to review the safety and effectiveness of such products at the Food and Drug Administration and current gaps in such expertise, if any;

(iii) the expertise necessary to make coding, coverage, and payment decisions with respect to such products within the Centers for Medicare & Medicaid Services, and current gaps in such expertise, if any;

(iv) trends in the differences in the data necessary to determine the safety and effectiveness of a novel medical product and the data necessary to determine whether a novel

medical product meets the reasonable and necessary requirements for coverage and payment under title XVIII of the Social Security Act pursuant to section 1862(a)(1)(A) of such Act (42 U.S.C. 1395y(a)(1)(A));

(v) the availability of information for sponsors of such novel medical products to meet each of those requirements; and

(vi) the coordination of information related to significant clinical improvement over existing therapies for patients between the Food and Drug Administration and the Centers for Medicare & Medicaid Services with respect to novel medical products.

(D) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—No information discussed as a part of the public meeting under this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

(2) IMPROVING TRANSPARENCY OF CRITERIA FOR MEDICARE COVERAGE.—

(A) DRAFT GUIDANCE.—Not later than 18 months after the public meeting under paragraph (1), the Secretary shall update the final guidance titled ''National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development'' to address any opportunities to improve the availability and coordination of information as described in clauses (iv) through (vi) of paragraph (1)(C).

(B) FINAL GUIDANCE.—Not later than 12 months after issuing draft guidance under subparagraph (A), the Secretary shall finalize the updated guidance to address any such opportunities.

(b) REPORT ON CODING, COVERAGE, AND PAYMENT PROCESSES UNDER MEDICARE FOR NOVEL MEDICAL PRODUCTS.—Not later than 12 months after the date of the enactment of this Act, the Secretary shall publish a report on the Internet website of the Department of Health and Human Services regarding processes under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) with respect to the coding, coverage, and payment of novel medical products described in subsection (c). Such report shall include the following:

(1) A description of challenges in the coding, coverage, and payment processes under the Medicare program for novel medical products.

(2) Recommendations to—

(A) incorporate patient experience data (such as the impact of a disease or condition on the lives of patients and patient treatment preferences) into the coverage and payment processes within the Centers for Medicare & Medicaid Services;

(B) decrease the length of time to make national and local coverage determinations under the Medicare program (as those terms are defined in subparagraph (A) and (B), respectively, of section 1862(l)(6) of the Social Security Act (42 U.S.C. 1395y(l)(6));

(C) streamline the coverage process under the Medicare program and incorporate input from relevant stakeholders into such coverage determinations; and

(D) identify potential mechanisms to incorporate novel payment designs similar to those in development in commercial insurance plans and State plans under title XIX of such Act (42 U.S.C. 1396 et seq.) into the Medicare program.

(c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For purposes of this section, a novel medical product described in this subsection is a medical product, including a drug, biological (including gene and cell therapy), or medical device, that has been designated as a breakthrough therapy under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)), a breakthrough device under section 515B of such Act (21 U.S.C. 360e–3), or a regenerative advanced therapy under section 506(g) of such Act (21 U.S.C. 356(g)).

SEC. 506. PATIENT CONSULTATION IN MEDICARE NATIONAL AND LOCAL COVERAGE DETERMINATIONS IN ORDER TO MITIGATE BARRIERS TO INCLUSION OF SUCH PERSPECTIVES.

Section 1862(l) of the Social Security Act (42 U.S.C. 1395y(l)) is amended by adding at the end the following new paragraph:

''(7) PATIENT CONSULTATION IN NATIONAL AND LOCAL COVERAGE DETERMINATIONS.—The Secretary may consult with patients and organizations representing patients in making national and local coverage determinations.''.

SEC. 507. MEDPAC REPORT ON SHIFTING COVERAGE OF CERTAIN MEDICARE PART B DRUGS TO MEDICARE PART D.

(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the ''Commission'') shall conduct a study on shifting coverage of certain drugs and biologicals for which payment is currently made under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) to part D of such title (42 U.S.C. 1395w–21 et seq.). Such study shall include an analysis of—

(1) differences in program structures and payment methods for drugs and biologicals covered under such parts B and D, including effects of such a shift on program spending, beneficiary cost-sharing liability, and utilization management techniques for such drugs and biologicals; and

(2) the feasibility and policy implications of shifting coverage of drugs and biologicals for which payment is currently made under such part B to such part D.

(b) REPORT.—

(1) IN GENERAL.—Not later than June 30, 2021, the Commission shall submit to Congress a report containing the results of the study conducted under subsection (a).

(2) CONTENTS.—The report under paragraph (1) shall include information, and recommendations as the Commission deems appropriate, regarding—

(A) formulary design under such part D;

(B) the ability of the benefit structure under such part D to control total spending on drugs and biologicals for which payment is currently made under such part B;

(C) changes to the bid process under such part D, if any, that may be necessary to integrate coverage of such drugs and biologicals into such part D; and

(D) any other changes to the program that Congress should consider in determining whether to shift coverage of such drugs and biologicals from such part B to such part D.

(E) the feasibility and policy implications of creating a methodology to preserve the healthcare provider's ability to take title of the drug, including a methodology under which—

(i) prescription drug plans negotiate reimbursement rates and other arrangements with drug manufacturers on behalf of a wholesaler;

(ii) wholesalers purchase the drugs from the manufacturers at the negotiated rate and ship them through distributors to physicians to administer to patients;

(iii) physicians and hospitals purchase the drug from the wholesaler via the distributor;

(iv) after administering the drug, the physician submits a claim to the MAC for their drug administration fee;

(v) to be reimbursed for the purchase of the drug from the distributor, the physician furnishes the claim for the drug itself to the wholesaler and the wholesaler would refund the cost of the drug to the physician; and

(vi) the wholesaler passes this claim to the PDP to receive reimbursement.

SEC. 508. REQUIREMENT THAT DIRECT-TO-CONSUMER ADVERTISEMENTS FOR PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS INCLUDE TRUTHFUL AND NON-MISLEADING PRICING INFORMATION.

Part A of title XI of the Social Security Act is amended by adding at the end the following new section:

''SEC. 1150C. REQUIREMENT THAT DIRECT-TO-CONSUMER ADVERTISEMENTS FOR PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS INCLUDE TRUTHFUL AND NON-MISLEADING PRICING INFORMATION.

''(a) IN GENERAL.—The Secretary shall require that each direct-to-consumer advertisement for a prescription drug or biological product for which payment is available under title XVIII or XIX includes an appropriate disclosure of truthful and non-misleading pricing information with respect to the drug or product.

''(b) DETERMINATION BY CMS.—The Secretary, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall determine the components of the requirement under subsection (a), such as the forms of advertising, the manner of disclosure, the price point listing, and the price information for disclosure.''.

SEC. 509. CHIEF PHARMACEUTICAL NEGOTIATOR AT THE OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE.

(a) IN GENERAL.—Section 141 of the Trade Act of 1974 (19 U.S.C. 2171) is amended—

(1) in subsection (b)(2)—

(A) by striking ''and one Chief Innovation and Intellectual Property Negotiator'' and inserting ''one Chief Innovation and Intellectual Property Negotiator, and one Chief Pharmaceutical Negotiator'';

(B) by striking ''or the Chief Innovation and Intellectual Property Negotiator'' and inserting ''the Chief Innovation and Intellectual Property Negotiator, or the Chief Pharmaceutical Negotiator''; and

(C) by striking ''and the Chief Innovation and Intellectual Property Negotiator'' and inserting ''the Chief Innovation and Intellectual Property Negotiator, and the Chief Pharmaceutical Negotiator''; and

(2) in subsection (c), by adding at the end the following new paragraph:

''(7) The principal function of the Chief Pharmaceutical Negotiator shall be to conduct trade negotiations and to enforce trade agreements relating to United States pharmaceutical products and services. The Chief Pharmaceutical Negotiator shall be a vigorous advocate on behalf of United States pharmaceutical interests. The Chief Pharmaceutical Negotiator shall perform such other functions as the United States Trade Representative may direct.''.

(b) COMPENSATION.—Section 5314 of title 5, United States Code, is amended by striking ''Chief Innovation and Intellectual Property Negotiator, Office of the United States Trade Representative.'' and inserting the following:

''Chief Innovation and Intellectual Property Negotiator, Office of the United States Trade Representative.

''Chief Pharmaceutical Negotiator, Office of the United States Trade Representative.''.

(c) REPORT REQUIRED.—Not later than the date that is one year after the appointment of the first Chief Pharmaceutical Negotiator pursuant to paragraph (2) of section 141(b) of the Trade Act of 1974, as amended by subsection (a), and annually thereafter, the United States Trade Representative shall submit to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives a report describing in detail—

(1) enforcement actions taken by the United States Trade Representative during the one-year period preceding the submission

of the report to ensure the protection of United States pharmaceutical products and services; and

(2) other actions taken by the United States Trade Representative to advance United States pharmaceutical products and services.

SEC. 510. WAIVING MEDICARE COINSURANCE FOR COLORECTAL CANCER SCREENING TESTS.

Section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) is amended—

(1) by moving the flush text following paragraph (9) 2 ems to the left; and

(2) by adding at the end of such flush text the following new sentence: ''For items and services furnished on or after January 1, 2021, paragraph (1)(Y) shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.''.

The Acting CHAIR. Pursuant to House Resolution 758, the gentleman from Oregon (Mr. WALDEN) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Oregon.

Mr. WALDEN. Mr. Chairman, I yield myself 2 minutes.

I rise in support of the substitute amendment, H.R. 19, the Lower Costs, More Cures Act.

There is a better way, ladies and gentlemen. We can reduce the high costs of drugs. We can improve health and lower long-term costs without stifling innovation and restricting patients' access to new, lifesaving medications.

H.R. 19, the Lower Costs, More Cures Act, is the bipartisan solution that can be signed into law this year and immediately begin to provide relief to patients and seniors from high prescription costs.

This bill lowers out-of-pocket spending. It protects access to new medicines and cures. It strengthens transparency and accountability and champions competition.

Every single proposal in this substitute is bipartisan, Democrats and Republicans coming together.

First, H.R. 19 encourages innovation of groundbreaking new cures and promotes the introduction of more low-cost generic and biosimilar competition to the marketplace faster, through inclusion of the CREATES Act, which streamlines the regulation of over-the-counter products, stopping the pay-for-delay agreements and patent system gamesmanship.

These policies unanimously passed the Energy and Commerce Committee earlier this year. They would have unanimously passed on this House floor, had a poison pill not been put in up in the Rules Committee.

H.R. 19 also has a critical provision to make insulin more affordable by requiring insurance companies to cap the costs of insulin for seniors at $50 a month.

H.R. 19 increases transparency and removes uncertainty at the pharmacy counter by requiring insurance companies to make information about drug costs available in the doctor's office before a prescription is written.

It reduces the cost of drug administration, including for cancer treatment. We can cut that in half. We will pay for quality, not sites.

H.R. 19, for the first time, places a cap on seniors' out-of-pocket costs for the year.

Critically, it stops the U.S. from subsidizing other freeloader foreign countries by having a strong trade rep to negotiate better deals for Americans.

This will lower costs, and it will bring about cures.

Mr. Chairman, I urge bipartisan support, and I reserve the balance of my time.

Ms. PORTER. Mr. Chair, I rise in opposition to the amendment.

The Acting CHAIR (Mr. PHILLIPS). The gentlewoman from California is recognized for 5 minutes.

Ms. PORTER. Mr. Chairman, I yield myself such time as I may consume.

I made a promise to my constituents when I was elected that I would lower drug prices, and that requires a strong, robust plan for negotiating fair prices for Americans.

Our constituents are demanding lower drug prices, and this amendment fails to deliver. It does nothing to address the root causes of high drug prices and would let pharma companies continue to raise prices unreasonably for the same drug year after year.

I have a bill to stop that, which is included in H.R. 3. The Freedom from Price Gouging Act recovers taxpayer dollars from pharmaceutical companies when they try to hike their prices not just once per year but multiple times every year in order to boost their profits.

This legislation has bipartisan support. It is included in Republican Senator GRASSLEY's drug pricing package in the Senate.

Without a way to hold drug price increases to at most the rate of inflation, drug companies can just counter your amendment's required discounts by jacking up drug prices and setting sky-high launch prices. They can continue to raise those prices year after year, and the American people will have no choice but to pay those prices because without a way to truly hold drug companies accountable, nothing will change.

I believe we need real, substantive reforms, and for a while, so did our President. Though he has recently walked back this commitment, he once promised the American people that he would authorize the HHS Secretary to negotiate a fair deal on drugs. Do you know why he did that? Because drug price negotiation only upsets Big Pharma's CEOs. Everybody else—in fact, 90 percent of Americans—support giving the Secretary the power to negotiate prices for drugs, Democrats, Republicans, independents alike.

H.R. 3 does just that. It pairs real reforms on drug pricing with a Medicare part D redesign that caps out-of-pocket expenses for seniors and more equitably shares the responsibility to determine prices among the Federal Government part D plans and drug manufacturers.

The Walden amendment fails to achieve that goal. This amendment doesn't help the 150 million Americans with employer insurance, and many of those Americans even with good insurance still can't afford their medications. This amendment will gut protections in H.R. 3 and leave us with legislation that doesn't do nearly enough to rein in the costs of prescription drugs.

It is time for all of us to take real action to lower drug prices for our constituents.

Mr. Chair, I reserve the balance of my time.

Mr. WALDEN. Mr. Chairman, I yield 1½ minutes to the gentleman from Texas (Mr. BRADY), the leading Republican on the powerful House Ways and Means Committee.

Mr. BRADY. Mr. Chairman, I thank the gentleman for yielding and for his strong leadership on this. It has been invaluable.

Like impeachment, Speaker PELOSI's fewer cures bill was written in secret, highly partisan, and is dead when it goes to the Senate. The President won't sign it. The Senate won't take it up. It is losing support every day.

Here is an idea. Let's pass a bill. Let's come together. The only bill that has bipartisan provisions, bicameral provisions, a bill that lowers prices, deserves to become law, a bill you can be proud of, the Lower Costs, More Cures Act, our Republican bill.

It doesn't kill cures; it accelerates them. It makes it easier for patients to use their personal healthcare plans to lower costs for medicines, holds pharma accountable by insisting they pay more of the drug costs for seniors. It pulls back the curtain on drug pricing. It forces these companies to justify their prices. It can help seniors lower their medicine costs by $300 a year.

Every Member of Congress who pledged to deliver lower costs for families and seniors and who truly wants more cures for diseases will fulfill that promise with H.R. 19. I urge support.

Ms. PORTER. Mr. Chairman, I agree with my Republican colleagues that we do need bipartisan action on drug pricing. Negotiating drug prices is not partisan to the American people; it is common sense.

But let's be clear. The amendment to this bill is not bipartisan. Only Republicans have cosponsored this amendment.

Mr. WALDEN. Will the gentlewoman yield?

Ms. PORTER. I yield to the gentleman from Oregon.

Mr. WALDEN. That is true on the bipartisan, but every provision in the bill has Democratic support as individual bills in other sectors. We brought only bipartisan bills into this alternative.

Mr. Chair, I yield back the balance of my time.

Ms. PORTER. Mr. Chairman, the gentleman is correct that there are many provisions in the amendment that do have strong bipartisan support, including, for example, making permanent the medical expense tax deduction.

The problem with the amendment is it doesn't tackle the fundamental problem, which is reducing drug prices. This amendment fails to solve the main problem of actually lowering drug prices.

This is why Senator GRASSLEY has been a sponsor on the Republican side in the Senate of the kinds of things I have worked on that are included in this bill that would address price gouging, the ability of pharmaceutical companies to raise prices multiple times in a single year. This bill, H.R. 3, would let us capture the taxpayer savings from that.

The GAO found that fewer than one in five new drugs are truly innovative. It is true that we need new cures, new cures for Alzheimer's, new cures for ALS, but H.R. 3 makes sure not just that we have new cures by increasing science research, but makes sure that those new cures are going to be affordable and can actually get into the hands of Americans.

Mr. Chair, I reserve the balance of my time.

Mr. WALDEN. Mr. Chairman, let me say in response, the CBO also said 38 new cures as a result of H.R. 3 will never come about. The Council of Economic Advisers says 100 new cures will never come about.

H.R. 3, the underlying bill the majority wants to put into law, actually denies people who are desperately hoping for cures, that innovation.

To answer further your question, there are 138 different Democratic sponsors of the bill that we have put together here.

Mr. Chair, I yield 2 minutes to the gentlewoman from North Carolina (Ms. FOXX).

Ms. FOXX of North Carolina. Mr. Chairman, Democrats are putting politics over progress by advancing a socialist drug pricing scheme that will hurt the development of money-saving treatments and, more importantly, people's lives.

Sadly, workers and families are being let down by Democrats. That is why I am proud to sponsor and support H.R. 19, the Lower Costs, More Cures Act. This legislation includes 40 provisions backed by Democrats and Republicans, and it can go to the President's desk today.

□ 1100

Unlike H.R. 3, which the nonpartisan Congressional Budget Office predicts will result in 38 fewer cures, H.R. 19 protects access to new medicines and cures. It also lowers out-of-pocket spending, strengthens transparency and accountability, and champions competition.

Mr. Chair, the Lower Costs, More Cures Act is policy that acts in the interests of hardworking Americans. I urge my colleagues to support this bipartisan, commonsense amendment.

Ms. PORTER. Mr. Chair, claims that H.R. 3 will devastate research and stop cures are fearmongering.

H.R. 3 makes substantial investment in public research to help create new cures and, most importantly, will make sure those cures actually can help people in their lives.

It is only fair that the government, elected by the taxpayers, and the administration, appointed by elected officials, should get to negotiate drug prices, and it will not come at the expense of innovation.

Mr. Chair, may I inquire as to how much time remains.

The Acting CHAIR. The gentlewoman has 30 seconds remaining.

Ms. PORTER. Mr. Chair, I look forward to working with my colleagues on both sides of the aisle to continue to come up with ways to support drug innovation and support the kind of innovation that is happening in Orange County, the area that I represent.

But we have to tackle the fundamental problem here, which is that pharmaceutical companies are gouging Americans; they are overcharging them; and they are leaving lifesaving drugs out of the hands of the American people each and every day. This amendment does not tackle that fundamental problem. Today, 9 out of 10 big pharmaceutical companies spend more on marketing, sales, and overhead than they do on research.

I am proud to support the package of H.R. 3 because it will tackle the fundamental problem of permitting price negotiation and making drugs more affordable for Americans.

Mr. Chair, I yield back the balance of my time.

Mr. WALDEN. Mr. Chairman, I yield myself such time as I may consume.

I appreciate the gentlewoman's comments.

Ours is the only bipartisan bill. Thirty-six different provisions passed out of either the Ways and Means or Energy and Commerce Committee with unanimous, bipartisan support, all these provisions cosponsored by Democrats. Seventeen different bills passed out of the House of Representatives with bipartisan support in here. This is the bipartisan package.

I have always worked across the line to get things done, whether it was in opioids or 21st Century Cures or modernizing the FDA. I pledge to continue to do that.

The partisan bill on the floor today is H.R. 3. The facts of the matter show that it will deny new innovation in America and new cures for patients whose lives are on the line.

Mr. Chair, I urge a ''no'' vote on H.R. 3 and a ''yes'' on the substitute.

Mr. Chair, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Oregon (Mr. WALDEN).

The question was taken; and the Acting Chair announced that the noes appeared to have it.

Mr. WALDEN. Mr. Chairman, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Oregon will be postponed.

AMENDMENT NO. 2 OFFERED BY MR. TONKO

The Acting CHAIR. It is now in order to consider amendment No. 2 printed in part B of House Report 116–334.

Mr. TONKO. Mr. Chair, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Add at the end of title VIII the following (and conform the table of contents accordingly):

SEC. 812. ADDITION OF NEW MEASURES BASED ON ACCESS TO BIOSIMILAR BIOLOGICAL PRODUCTS TO THE 5-STAR RATING SYSTEM UNDER MEDICARE ADVANTAGE.

(a) IN GENERAL.—Section 1853(o)(4) of the Social Security Act (42 U.S.C. 1395w–23(o)(4)) is amended by adding at the end the following new subparagraph:

''(E) ADDITION OF NEW MEASURES BASED ON ACCESS TO BIOSIMILAR BIOLOGICAL PRODUCTS.—

''(i) IN GENERAL.—For 2021 and subsequent years, the Secretary shall add a new set of measures to the 5-star rating system based on access to biosimilar biological products covered under part B and, in the case of MA–PD plans, such products that are covered part D drugs. Such measures shall assess the impact a plan's benefit structure may have on enrollees' utilization of or ability to access biosimilar biological products, including in comparison to the reference biological product, and shall include measures, as applicable, with respect to the following:

''(I) COVERAGE.—Assessing whether a biosimilar biological product is on the plan formulary in lieu of or in addition to the reference biological product.

''(II) PREFERENCING.—Assessing tier placement or cost-sharing for a biosimilar biological product relative to the reference biological product.

''(III) UTILIZATION MANAGEMENT TOOLS.—Assessing whether and how utilization management tools are used with respect to a biosimilar biological product relative to the reference biological product.

''(IV) UTILIZATION.—Assessing the percentage of enrollees prescribed the biosimilar biological product when the reference biological product is also available.

''(ii) DEFINITIONS.—In this subparagraph, the terms 'biosimilar biological product' and 'reference biological product' have the meaning given those terms in section 1847A(c)(6).

''(iii) PROTECTING PATIENT INTERESTS.—In developing such measures, the Secretary shall ensure that each measure developed to address coverage, preferencing, or utilization management is constructed such that patients retain equal access to appropriate therapeutic options without undue administrative burden.''.

(b) CLARIFICATION REGARDING APPLICATION TO PRESCRIPTION DRUG PLANS.—To the extent the Secretary of Health and Human Services applies the 5-star rating system under section 1853(o)(4) of the Social Security Act (42 U.S.C. 1395w–23(o)(4)), or a similar system, to prescription drug plans under part D of title XVIII of such Act, the provisions of subparagraph (E) of such section, as

added by subsection (a) of this section, shall apply under the system with respect to such plans in the same manner as such provisions apply to the 5-star rating system under such section 1853(o)(4).

The Acting CHAIR. Pursuant to House Resolution 758, the gentleman from New York (Mr. TONKO) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from New York.

Mr. TONKO. Mr. Chair, I yield myself as much time as I may consume.

Despite the passage in 2010 of the Biologics Price Competition and Innovation Act through the Affordable Care Act, which created the modern pathway for bringing biosimilar drugs to market, consumers in the United States are still not reaping the cost-saving benefits that a full, mature biosimilars market would provide. As of May, only 19 biosimilars had been approved by the FDA, and many of those that have been approved are not on the market for a number of reasons.

Economics 101 teaches us that, when more competition is introduced into the market, prices come down. We have seen this with the overwhelming success of the generic pharmaceuticals market here at home, and we are seeing it with biosimilars in other parts of the globe.

In Europe, for example, the introduction of biosimilar competition for Humira led to the brand manufacturer dropping the price by more than 80 percent in some countries.

Unfortunately, here in the United States, biosimilars still face very low market share and utilization, despite the fact they could generate much-needed savings for patients and for taxpayers.

If we want to continue to meaningfully lower drug costs for American patients, Congress can, and should, do more to create a policy environment that is ripe for greater biosimilar adoption.

That is the underlying rationale behind my amendment, which is based on legislation I introduced with Congressman BOB GIBBS, known as the Star Ratings for Biosimilars Act.

This amendment would require the Department of Health and Human Services to incorporate into the existing Star Ratings system for Medicare Advantage and part D plans a measure that evaluates how plans promote access to biosimilar drugs.

In creating such a measure, HHS would look at things such as coverage on a plan's formulary, tier placement, cost sharing, and other utilization management techniques.

By evaluating plans on biosimilar access, this amendment would motivate health plans to improve performance and implement changes to improve access to biosimilars, creating a policy environment ripe for further biosimilar development. A similar measure has already been adopted by the Senate Finance Committee as they worked through their prescription drug legislation.

I have heard from some criticism that the Star Ratings system has traditionally not been used for this type of measure. To that, I would contend that star ratings have already been used in several ways to influence plan behavior and improve plan quality, such as evaluating plans on how well they provide cancer screenings, care coordination, and Medicaid management, for example.

All of these metrics are designed to incent plans into behavior that will improve plan transparency and beneficiary health.

Likewise, access to affordable medications has significant implications for beneficiary health, as patients will abstain from needed medications if costs are simply too high. The CBO score for the underlying legislation makes this connection crystal clear.

By evaluating plans on biosimilar access, we are ensuring that patients have the information they need that will allow them to live healthier lives.

In closing, Mr. Chair, I would simply urge my colleagues to support this important amendment that will help lay the groundwork for greater biosimilar adoption and continue to lower drug costs for patients, obviously a common cause for each and every person in this Chamber.

Mr. Chair, I reserve the balance of my time.

Mr. WALDEN. Mr. Chairman, I rise in opposition to the amendment.

The Acting CHAIR. The gentleman from Oregon is recognized for 5 minutes.

Mr. WALDEN. Mr. Chair, I yield myself such time as I may consume.

Mr. Chair, I commend my friend, and he is my friend, Mr. TONKO. He is a very thoughtful legislator, and we have worked together on a lot of different bills.

He offered and withdrew this amendment at full committee markup of H.R. 3, and I continue to extend the offer to sit down and try to work out the differences in the language.

Unfortunately, as it is currently constructed, though, this could have unintended consequences, we believe, including actually increasing drug prices, which none of us wants, which I know is not the gentleman's goal either.

Star ratings to measure the quality of an insurance plan or a specific benefit are a good tool for consumers and the government, but to apply an automatic star rating change to a plan's coverage of biosimilars could give a manufacturer too much negotiating leverage, and we don't want to do that.

This would be a major shift in the type of quality measure the plans would be rated on and would actually affect the way they would negotiate with manufacturers and, unfortunately, we believe, not necessarily be in a way that lowers costs for consumers in Medicare Advantage.

Star ratings are an important factor consumers consider when they are choosing their plan. If a plan knows they will be rated and reimbursed based on coverage of one biosimilar, they do not have much ground to stand on if they want to negotiate the cost of that drug down to benefit the patient.

That means the manufacturer of the biosimilar has all the leverage and they can keep the price high, knowing they will likely still be placed on the plan's formulary because the plan is being rated on it.

But the gentleman is right. We should do more to incentivize biosimilar development and coverage in this country. This is an important issue. And, again, I would be happy to work with him and others on the other side of the aisle on this and many other provisions.

Mr. Chair, how much time do I have remaining?

The Acting CHAIR. The gentleman from Oregon has 3½ minutes remaining.

Mr. WALDEN. Mr. Chair, I yield 3 minutes to the gentleman from Montana (Mr. GIANFORTE).

Mr. GIANFORTE. Mr. Chair, I thank the gentleman for yielding, and I appreciate the intent that the gentleman has here with this bill.

The costs of prescription drugs have continued to rise, putting Montanans with critical health issues in jeopardy.

I recently heard from a senior in Libby, Montana, with colon cancer. He was diagnosed in 2010, and his disease has bankrupted his family.

He confided that the cancer drug he takes costs $17,000 per month. It is the only drug that works for his cancer, and Medicare only covers $11,000. He is forced to either give up his fight against cancer or pay an extra $6,000 a month for a lifesaving drug. That is an extra $72,000 a year.

As he put it: ''I find it rather disconcerting that one must sell his home and all his possessions just to survive cancer.''

I agree. This has to stop. No one should have to end up like my constituent in Libby.

The fact is that we could lower prescription costs while capping seniors' out-of-pocket costs by the end of 2019. It is also disheartening that Republicans have been working in good faith all year on a bipartisan basis to do just that.

Unfortunately, House Democrats, led by Speaker NANCY PELOSI, are putting partisan politics in front of patients. Her plan would have devastating consequences for Montanans. It will lead to rationing of lifesaving medication, Big Government price fixing, and government bureaucrats between you and your medication.

The truth is her partisan bill will never move past the House floor.

We have heard from Majority Leader MCCONNELL that the Pelosi plan is dead on arrival in the Senate, and it doesn't have a chance of being signed into law by President Trump.

Unfortunately, as we wait on Democrats to act in a bipartisan way, costs

continue to rise and hardworking Montanans continue to choose between their needed medication and paying their bills.

On the other hand, Republicans have introduced the Lower Costs, More Cures Act. This is a bipartisan bill that could be signed into law by the end of 2019. This bill increases transparency, encourages innovation for new drugs and cures, and places a cap on seniors' out-of-pocket costs.

I have also been working to lower costs and shed light on the true cost of prescription drugs. Last week, I introduced bipartisan legislation to bring much-needed transparency into the practice of middlemen in the pharmaceutical supply chain, called pharmacy benefit managers. My bill increases competition between PBMs and lowers costs for patients. It is truly a win-win.

Waiting any longer to pass bills that lower costs for patients to score political points is unacceptable. Enough is enough. Let's stop the political theater and get back to work.

Mr. TONKO. Mr. Chair, we have no further speakers on this side, and I am prepared to close.

Mr. Chair, I respect the opinions of Mr. WALDEN. We have worked in a bipartisan fashion on several issues before in Energy and Commerce, but I believe the claim that this would increase costs is simply false. Like the Senate Finance Committee that is moving forward with this proposition on biosimilars, we believe it is a way to lower costs.

To date, the nine biosimilars accessible to patients are at an average discount of 28 percent. It is simply a false claim that a biosimilar would not launch at a lower price.

Certainly, we must do better. We are reminded constantly that we can do better and we must do better. As the namesake of this legislation had constantly implored, Representative Elijah Cummings always knew that we must score for the public. That is why we must pass this amendment.

Mr. Chair, I yield back the balance of my time.

Mr. WALDEN. Mr. Chairman, I understand my friend's comments. None of us wants to accidentally create a situation where prices go up rather than down, and I know that is not his intent. We have that concern on this side.

Perhaps we can work this out along the way and get to the same place here, because I think we share a similar goal.

Mr. Chair, I yield back the balance of my time.

□ 1115

The Acting CHAIR. The question is on the amendment offered by the gentleman from New York (Mr. TONKO).

The amendment was agreed to.

AMENDMENT NO. 3 OFFERED BY MR. PETERS

The Acting CHAIR. It is now in order to consider amendment No. 3 printed in part B of House Report 116–334.

Mr. PETERS. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 195, line 9, strike ''$500,000,000'' and insert ''$400,000,000''.

At the end of subtitle A of title VII, add the following:

SEC. 703. INNOVATION NETWORK.

Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by section 702, is further amended by adding at the end the following:

''SEC. 404P. INNOVATION NETWORK.

''(a) FUNDS.—The Director of NIH shall award grants or contracts to eligible entities to develop, expand, and enhance the commercialization of biomedical products.

''(b) ELIGIBLE ENTITY.—In this section, the term 'eligible entity' means an entity receiving funding under—

''(1) the Small Business Innovation Research program of the National Institutes of Health; or

''(2) the Small Business Technology Transfer program of the National Institutes of Health.

''(c) USE OF FUNDS.—An eligible entity shall use the funds received through such grant or contract to support—

''(1) the Commercialization Readiness Pilot program of the National Institutes of Health;

''(2) the Innovation Corps program of the National Institutes of Health;

''(3) the Commercialization Accelerator program of the National Institutes of Health;

''(4) the Commercialization Assistance program of the National Institutes of Health; and

''(5) such other programs and activities as the Director of NIH determines to be appropriate, to support the commercialization stage of research, later stage research and development, technology transfer, and commercialization technical assistance.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $100,000,000 for each of fiscal years 2021 through 2025, to be available until expended.''.

The Acting CHAIR. Pursuant to House Resolution 758, the gentleman from California (Mr. PETERS) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from California.

Mr. PETERS. Mr. Chair, I yield myself such time as I may consume.

H.R. 3 is not perfect. No bill is. But I will support it today because it is our best chance to get moving on the very pressing issue of high prescription drug prices. I hope the Senate will work with us in a good-faith manner to come up with a final bill that both lowers prices and preserves incentives for innovation.

The concerns and some outstanding questions about the effect of this bill on innovation in the private sector are legitimate. My colleagues have referenced the CBO studies. Also, the California Life Sciences Association released a report in October that predicted that H.R. 3 would make drug development particularly challenging for small and emerging companies in California.

The amendment I offer today will go a long way toward preserving and supporting biopharmaceutical innovation, and that is not an abstraction. It can be measured in jobs, breakthrough cures, and even state-of-the-art research facilities.

Innovation, research, and development are the economic lifeblood of California and, particularly, San Diego. Over the past decade, California firms have received more than 30 percent of total biotech investment in the country, and in San Diego County there are over 48,000 jobs in the life sciences sector supported by $1.5 billion in venture capital.

In San Diego alone, we have five institutions that rank among the top recipients of National Institutes of Health funding in the country, and they are doing amazing things.

One La Jolla-based research and development facility in my district recently launched a one-time gene replacement therapy that essentially halts the progression of a rare and deadly genetic childhood disorder: spinal muscular atrophy. This company is also currently investing in research to cure a genetic form of ALS.

If we aren't careful, we might put those kinds of breakthrough therapies at risk of never treating a single patient.

From the NIH and academic research institutions to philanthropy and biopharmaceutical industry, there is a network of capital today in the public and private sectors that supports innovation.

At the risk of oversimplifying, the NIH focuses on basic biomedical science, investigating the underlying mechanisms of disease, while smaller biotech companies supported by institutional investors take the basic science to the preclinical and early-phase stages of drug development.

Drug companies conduct later-stage research, fund clinical trials, and invest in startups. These financial backers, like drug companies and venture capitalists, are important because they can help close the funding gap that exists between preclinical research and the early-and later-stage clinical trials.

If H.R. 3 changes investor behavior as some predict, that could widen the gap for smaller biotech companies, the so-called ''valley of death.'' I think we can all agree that these are consequences we want to avoid.

Securing funding for the high cost of clinical trials is often cited as the key hurdle facing smaller biotech companies at the precipice of the so-called valley of death.

While the biopharmaceutical industry and the Federal Government both fund clinical trials, NIH's ability to bring drugs to market is constrained by its limited budget and a mandate to carry out its core mission of advancing biomedical research, which is not necessarily the same as bringing drugs to market.

Over time, these limitations have resulted in the declining number of NIH-

sponsored clinical trials. The biopharma industry is really good at bringing drugs to market because it can afford expensive failures. The Federal Government is really good at research and development because it can ignore constraining signals of the commercial market.

We do patients no favors by pitting biopharma against government. And I want to thank Chairman PALLONE and his staff on the Energy and Commerce Committee for working with me to include two priorities of mine in his bill.

I establish a pilot program that will award multiyear contracts to public and private entities like research institutions, medical centers, and biotech companies to support phase 2 and phase 3 clinical trials. That pilot program will receive $500 million every year for 5 years.

The bill also includes this amendment No. 3 before you today, which is based on my bill, the Innovation and Capital Network Act of 2019.

My amendment creates an innovation startup fund at NIH that will support the commercialization stage of research, later-stage research and development, as well as technology, transfer, and technical assistance. Specifically, it directs $500 million over 5 years to incentivize incubators, accelerators, and other financial backers to support biotech companies through early- to mid-stage clinical studies.

These two things are mutually reinforcing. NIH is free to do more drug development, and more small to midsize biotech companies can freely follow the science. In other words, these small biotechs can pursue unforeseen opportunities that could lead to a cure for cancer.

Whether you vote for H.R. 3 or not, we must continue to support and strengthen the network of capital that sustains innovation.

Mr. Chair, I hope my colleagues will support this amendment and the freedom to follow science, and I yield back the balance of my time.

Mr. WALDEN. Mr. Chair, I am opposed to the amendment and seek time in opposition.

The Acting CHAIR. The gentleman from Oregon is recognized for 5 minutes.

Mr. WALDEN. Mr. Chairman, I appreciate my colleague's amendment on this. I understand it. And I think it is important because it does strike at the heart of the issue and the concerns many of us on this side of the aisle have.

The California Life Sciences Association told us that, if enacted, H.R. 3's Medicare part D foreign reference pricing proposal would reduce by 88 percent the number of drugs brought to market by small and emerging companies in California alone due to changed investor behavior.

So they think up to 88 percent of the great innovations and cures they are working on will never come to market. They also think it would eliminate 80,000 biotech R&D jobs nationwide and reduce revenues by $71 billion a year.

So, these are the people, predominantly out in California, that do this every day, that are living in this world of trying to create innovation and new lifesaving drugs. And they are saying up to 88 percent of the new drugs they are working on would never come to market. These are the small startups.

We have heard a lot from others on the floor in the last 24 hours about Big Pharma. Well, we are not talking about Big Pharma here. We are talking about small, little startups, American entrepreneurs. If you think about Silicon Valley in the high-tech world, this is the equivalent in the biotech world.

These are individuals who have an idea and a big brain, and they are coming together to come up with a cure to these diseases like SMA, Alzheimer's, sickle cell anemia, and things like that that we all struggle with in our communities.

Our fear on this side of the aisle, as Republicans, is we know, based on the facts and the independent analysis of our Congressional Budget Office, based on the Council of Economic Advisers, based on the input of the very people who are in the trenches every day in these laboratories across America, where two-thirds of the world's innovation comes from in this space, that H.R. 3 will significantly reduce new cures coming to market.

Now, we are all for lowering drug prices. I think we would have a unanimous vote on the provisions in our alternative here if we had a fair opportunity to take these one at a time. We are glad we have the opportunity to have the vote.

I think, because there are 138 Democrats on the measures that are in what I would call our bipartisan proposal here, that we could get bipartisan support for it. And we could lower drug costs. We can stop the gaming in the system. And we can continue to have more cures in America, not less.

And, let's face it—I do not believe it is an overstatement to say people will die if we have fewer cures. We know that to be a fact. It is not just a talking point. It is a fact. It is a truth. And in a time when we should rely on more facts, this is one we should think about seriously before we vote on H.R. 3.

That is why, Mr. Chairman, we came up with this combination of really thoughtful proposals, some of which have passed out of committees in the House or in the Senate—bipartisan support for them.

Now, on the Peters amendment itself: It is a laudable amendment. It will not be able to substitute for the destruction, however, of the American biomedical industry under H.R. 3.

The Congressional Budget Office says the effects on the new drug introductions from increased Federal spending under the bill on biomedical research would be modest. That is CBO.

I will let our Members vote as they want. Certainly, we all want to do more to invest in our National Institutes of Health.

I have no real objection to the gentleman's amendment, but the underlying bill eviscerates what he is trying to accomplish here in terms of medical research and breakthrough cures.

Mr. Chairman, with that, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from California (Mr. PETERS).

The amendment was agreed to.

AMENDMENT NO. 4 OFFERED BY MR. KENNEDY

The Acting CHAIR. It is now in order to consider amendment No. 4 printed in part B of House Report 116–334.

Mr. KENNEDY. Mr. Chair, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

In section 1192 of the Social Security Act, as proposed to be added by section 101(a)—

(1) in subsection (a), strike ''the Secretary shall'' and insert ''subject to subsection (h), the Secretary shall''; and

(2) by adding at the end the following new subsection:

''(h) CONFLICT OF INTEREST.—

''(1) IN GENERAL.—In the case the Inspector General of the Department of Health and Human Services determines the Secretary has a conflict, with respect to a matter described in paragraph (2), the individual described in paragraph (3) shall carry out the duties of the Secretary under this part, with respect to a negotiation-eligible drug, that would otherwise be such a conflict.

''(2) MATTER DESCRIBED.—A matter described in this paragraph is—

''(A) a financial interest (as described in section 2635.402 of title 5, Code of Federal Regulations (except for an interest described in subsection (b)(2)(iv) of such section)) on the date of the selected drug publication date, with respect the price applicability year (as applicable);

''(B) a personal or business relationship (as described in section 2635.502 of such title) on the date of the selected drug publication date, with respect the price applicability year;

''(C) employment by a manufacturer of a negotiation-eligible drug during the preceding 10-year period beginning on the date of the selected drug publication date, with respect to each price applicability year; and

''(D) any other matter the General Counsel determines appropriate.

''(3) INDIVIDUAL DESCRIBED.—An individual described in this paragraph is—

''(A) the highest-ranking officer or employee of the Department of Health and Human Services (as determined by the organizational chart of the Department) that does not have a conflict under this subsection; and

''(B) is nominated by the President and confirmed by the Senate with respect to the position;''.

The Acting CHAIR. Pursuant to House Resolution 758, the gentleman from Massachusetts (Mr. KENNEDY) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Massachusetts.

Mr. KENNEDY. Mr. Chair, I yield myself such time as I may consume.

I want to thank Speaker PELOSI, Chairman PALLONE, Chairman NEAL,

and Chairman SCOTT for their extraordinary leadership on this legislation and for helping bring this historic reform of our prescription drug system to the floor today.

In the last few years, President Trump has demonstrated how quickly the revolving door between industry lobbyists and high-ranking government officials and offices can spin.

It is a practice that may not have started when he entered office, but it is certainly one that he has perfected. Even after promising to drain the swamp, President Trump has appointed more former industry lobbyists to his cabinet in under 3 years than both President Obama and President Bush did in their entire time in office.

With those appointments, conflicts of interest run rampant, and corruption has not been hard to find. That is what this amendment attempts to address. It is about good, clean, ethical governance.

If we are giving the Secretary of Health and Human Services the authority to negotiate drug prices, which we absolutely should, we must ensure that those negotiations cannot be tainted by past business relationships or potential personal financial gain, because it is not fair for a secretary to be put into a position where his or her motives may be questioned. And it is certainly not fair to the public to be forced to question the intentions of that secretary.

Put simply, a secretary who was previously responsible for price increases on insulin and numerous other drugs while working for a Big Pharma company may be inclined to choose profits of that former employer over the patients he now serves. That same secretary may choose to increase those prices higher or negotiate in something other than good faith based on inside knowledge, past relationships, or a potential future return to that same job after his government service has ended.

That would give patients rightful doubt that their interests will guide the negotiations taking place on their behalf.

Mr. Chair, I reserve the balance of my time.

Mr. BRADY. Mr. Chairman, I would like to claim time in opposition to the amendment.

The Acting CHAIR. The gentleman from Texas is recognized for 5 minutes.

Mr. BRADY. Mr. Chair, at first glance, Mr. KENNEDY's amendment sounds like a good idea. Of course Republicans don't want administration officials to have a conflict of interest in carrying out their official duties on behalf of the American people.

But, in reality, this amendment is narrowly tailored to be a petty jab at the current Secretary of Health and Human Services.

Look, people want more cures and lower drug costs. They don't want more cheap political shots. Luckily, the underlying bill, H.R. 3, stands no chance of becoming law, so this amendment means nothing.

We do, as Republicans, oppose H.R. 3's government price-setting regime because it will kill lifesaving cures for Americans struggling with the ravages of Alzheimer's and dementia, ALS, Parkinson's, the many cancers we face, leukemia, pulmonary hypertension—all those costly and stubborn diseases.

□ 1130

We know, and the Congressional Budget Office has already confirmed, at least 38 fewer medicines and cures the next two decades. The Council of Economic Advisers estimates it will be close to 100 lost cures. Even in the Speaker's home State of California, the California Life Sciences Association, those small firms that do three-fourths of our clinical trials to bring new drugs to America, they modeled the gentlewoman's bill and said nearly 9 out of 10 of the drugs that they would be working on would never come to market if this Democratic drug bill becomes laws.

We think, rather than kill cures, you should accelerate it. Because when you look at the ravages to these families and our loved ones, really the costliest drug is the one that never gets developed. That is what we strongly oppose.

For those reasons, I urge my colleagues to oppose this amendment. I reserve the balance of my time.

Mr. KENNEDY. Mr. Chairman, how much time do I have remaining?

The Acting CHAIR. The gentleman from Massachusetts has 2½ minutes remaining.

Mr. KENNEDY. Mr. Chair, I yield 1½ minutes to the gentlewoman from Michigan (Mrs. DINGELL.)

Mrs. DINGELL. Mr. Chairman, I thank my colleague, Representative KENNEDY, for adding an amendment to this bill that will tighten it even further. I also thank Speaker PELOSI, Chairman PALLONE, Chairman NEAL, and Chairman SCOTT for their leadership and efforts on this historic legislation, which brings desperately needed relief to America's patients and seniors from the high drug prices that are scaring too many of them.

There is a reason that we pay nearly four times more for prescription drugs than other industrialized nations. They use negotiation to lower drug prices. We don't.

Negotiating lower drug prices is a promise that the President, Democrats, and Republicans have made, and the Elijah E. Cummings Lower Drug Costs Now Act makes good to this commitment.

Representative KENNEDY's amendment further strengthens this provision to ensure that the Secretary of Health and Human Services, who is responsible for these negotiations, is free from conflicts of interest. A public office is a public trust, and America's seniors and patients deserve to have confidence that the Secretary's interests are aligned with theirs.

That is why this amendment is so important. It puts American people first when negotiating drug prices so that they receive the best deal possible.

I urge my colleagues to support this amendment, which will ensure that the American people, not special interests, are represented in drug price negotiations.

Mr. KENNEDY. Mr. Chairman, I would like to close by stating a couple of things.

First, to my friend, the chairman from Texas, the intent of this amendment is not directed at any one individual. It is directed at an intent, which I think we do share, to ensure the integrity of a position and an office that is focused on the well-being of every American.

Second, nobody here wants to do anything that is somehow going to hinder anyone's cure or the potential for a new cure to come to market.

We do, however, have to wrestle with the fact that 26 percent of the patients across this country in need of insulin ration it. We have to reconcile the fact that 55 percent of the counties in this country do not have a single practicing psychiatrist, psychologist, or social worker. We have to wrestle with the fact that one-third of the donations on GoFundMe are for healthcare costs.

The existing system that we have is failing American families day in and day out. They are asking for this for a reason, and we are delivering it. I urge my colleagues to vote ''yes.''

Mr. Chair, I yield back the balance of my time.

Mr. BRADY. Mr. Chairman, let me talk about the underlying bill here.

I was on the Ways and Means Committee when we worked with President Bush to create the first affordable drug plan for seniors. Then-leader PELOSI and Democrats tried their best to kill it. They all voted against it.

The gentlewoman famously predicted that creating the part D drug program for our seniors would end ''Medicare as we know it.'' Can you imagine how many seniors' lives would have been lost if Democrats had succeeded in stopping the affordable Medicare drug program that 43 million seniors have come to depend upon?

NANCY PELOSI and Democrats were dangerously wrong then. Can Americans afford the pain and lost lives of our loved ones when they are dangerously wrong again?

We oppose this amendment, and we oppose the underlying bill. I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Massachusetts (Mr. KENNEDY).

The amendment was agreed to.

AMENDMENT NO. 5 OFFERED BY MR. O'HALLERAN

The Acting CHAIR. It is now in order to consider amendment No. 5 printed in part B of House Report 116–334.

Mr. O'HALLERAN. I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Add at the end of title VIII the following new section (and conform the table of contents accordingly):

SEC. 812. GRADUATE MEDICAL EDUCATION IMPROVEMENTS IN RURAL AND UNDERSERVED COMMUNITIES.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following new section:

''SEC. 399V–7. GRADUATE MEDICAL EDUCATION IMPROVEMENTS IN RURAL AND UNDERSERVED COMMUNITIES.

''(a) RURAL AND UNDERSERVED COMMUNITY GME GRANT PROGRAM.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the 'Secretary'), acting through the Administrator of the Health Resources and Services Administration, shall establish a rural and underserved community graduate medical education grant program under which the Secretary shall award grants to specified hospitals (as defined in subsection (b)) that have not established an approved medical residency training program (as defined for purposes of section 1886(h) of the Social Security Act (42 U.S.C. 1395ww(h))) in order to encourage such hospitals to establish such a program, or to establish an affiliation with a hospital that has established such a program in order to host residents under such program.

''(b) USE OF FUNDS.—Grants awarded under subsection (a) may be used by a specified hospital for any initial costs associated with establishing such a program or such an affiliation, including costs associated with faculty development, administration, infrastructure, supplies, and legal and consultant services.

''(c) SPECIFIED HOSPITAL DEFINED.—For purposes of subsection (a), the term 'specified hospital' means a hospital or critical access hospital (as such terms are defined in section 1861 of the Social Security Act (42 U.S.C. 1395x)) that—

''(1) is—

''(A) located in a rural area (as defined in section 1886(d)(2)(D) of such Act (42 U.S.C. 1395ww(d)(2)(D))); or

''(B) treated as being located in a rural area pursuant to section 1886(d)(8)(E) of such Act (42 U.S.C. 1395ww(d)(8)(E)); and

''(2) is located in a medically underserved area (as defined in section 330I(a) of the Public Health Service Act (42 U.S.C. 254c–14(a))).

''(d) CRITICAL ACCESS HOSPITAL GRANT PROGRAM.—Not later than 1 year after the date of the enactment of this Act, the Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a grant program under which the Secretary awards grants to critical access hospitals (as defined in section 1861 of the Social Security Act (42 U.S.C. 1395x)) that do not have in effect an affiliation with a hospital with an approved medical residency training program to host residents of such program in order to assist such critical access hospitals in setting up such affiliations in order to host such residents.

''(e) LIMITATION ON GRANT AMOUNTS.—No hospital may receive an aggregate amount of grants under this section in excess of $250,000.

''(f) REPORTS.—

''(1) HHS.—Not later than 5 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on graduate medical residency training programs of hospitals that received a grant under subsection (a) or (d). Such report shall include the following:

''(A) The number of hospitals that applied for a grant under this section.

''(B) The number of hospitals that were awarded such a grant.

''(C) The number of residency positions created by hospitals receiving such a grant.

''(D) An estimate of the number of such positions such hospitals will create after the date of the submission of such report.

''(E) A description of any challenges faced by hospitals in applying for such a grant or using funds awarded under such a grant.

''(2) GAO.—Not later than 10 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report containing an analysis of—

''(A) the number of residents who trained at a hospital or critical access hospital that received a grant under subsection (a) or (d); and

''(B) whether such residents continued to practice medicine in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) or in a medically underserved area (as defined in section 330I(a) of the Public Health Service Act (42 U.S.C. 254c–14(a))) after completing such training.

''(g) FUNDING.—There are authorized to be appropriated such sums as are necessary for purposes of making grants under this section for each of fiscal years 2020 through 2029.''.

The Acting CHAIR. Pursuant to House Resolution 758, the gentleman from Arizona (O'HALLERAN) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Arizona.

Mr. O'HALLERAN. Mr. Chairman, today, I rise in support of my amendment to H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act.

I would first like to thank Chairman PALLONE and Chairman NEAL for committing to work with me on this amendment and the committee staff for their efforts as well.

I am proud to represent Arizona's First Congressional District. Our district is larger than the State of Illinois and is one of the most rural in the country.

This year, I have held 26 townhalls across the vast district. At each and every one, I heard from rural residents struggling to access quality healthcare close to home. That is why I introduced my amendment.

My amendment would reward grants to hospitals in rural and medically underserved areas so these hospitals are able to establish a graduate medical education program or partner with an approved hospital to host residents.

According to the Congressional Research Service, more than half of family medicine physicians reside within 100 miles of where they trained as residents. My amendment will incentivize doctors to stay in practice in our rural communities by providing opportunities to bring medical students to rural areas for residency training. Hospitals are not reimbursed for hosting graduate medical education programs until they are fully established.

The grants awarded under my amendment would cover associated startup costs for hospitals, including necessary infrastructure, equipment, and fees.

My amendment also requires the nonpartisan Government Accountability Office to issue a report on the success of the changes that this education will implement, including analysis of whether residents stayed in the rural communities where they trained.

According to the Association of American Medical Colleges, our country will suffer a shortage of over 120,000 physicians by the year 2032. We are already losing physicians across rural America, and rural areas will be hit especially hard.

I am offering my amendment today to mitigate the effects that those seeking care in rural areas will experience. As we move forward with H.R. 3, we must not leave our rural communities on the back burner. Our rural communities will not be able to access their medications in the first place if they cannot access providers.

My amendment takes an all-of-the-above approach to improving rural healthcare by expanding access and revamping the ways we recruit qualified medical professionals in the area where we need them most. I reserve the balance of my time.

Mr. BRADY. Mr. Chairman, I claim the time in opposition to the amendment.

The Acting Chair. The gentleman from Arizona is recognized for 5 minutes.

Mr. BRADY. Mr. Chair, this amendment requires the Secretary of Health and Human Services to award grants to hospitals, including critical access hospitals, located in rural or medically underserved areas to establish and improve medical residency training programs. The goals in this amendment are laudable.

But like so much around here, bipartisan work in this area has been stopped because of impeachment. The rush to impeachment has created a toxic atmosphere and prevented parties from working on the people's business, creating a constitutional crisis for purely political reasons.

It is a nice change to hear this discussion because earlier this year, we offered in the Ways and Means Committee an amendment to reallocate these GME slots exactly to these rural and medically underserved areas. Unfortunately, those amendments were rejected on a largely partisan basis. I wish the gentleman from Arizona would have been with us that day because almost all Democrats voted no.

That said, I do have real concerns. This amendment provides more Medicare-funded payments to hospitals for these GME slots but without making any immediate reforms that everyone knows need to happen. An Institute of Medicine report called for innovative approaches to finance these slots in order to improve the match between the physician workforce that we need and national healthcare needs.

Just last week, the Journal of American Medical Association Internal Medicine published a study and found Medicare is overpaying for GME and that this wasted money could actually be used to address the physician shortages in underserved areas.

According to the study's lead author, Medicare GME may be overpaying some hospitals up to $1.28 billion annually. So instead of creating another grant program on a bill that is deader than a doornail, let's make a serious attempt at GME reform.

After impeachment is over, if it wastes all of next year as well as this, maybe we can build upon MedPAC recommendations, establish a permanent performance-based incentive program that actually reaches what I think we as Democrats and Republicans want and create the standards needed for these rural underserved areas.

These overpayments identified in the report could actually go toward expanding the teaching health center program, which would be terrific because that focuses on training in community-based primary care settings. That is where healthcare providers are needed the most. That is where they tend to stay to serve the community. That is a win-win for everyone.

While I look forward to working with the gentleman from Arizona on ways to reform graduate medical education, I urge my colleagues to oppose the amendment, and I reserve the balance of my time.

Mr. O'HALLERAN. Mr. Chairman, I yield 1 minute to the gentlewoman from New Mexico (Ms. TORRES SMALL), my colleague.

Ms. TORRES SMALL of New Mexico. Mr. Chair, I thank the gentleman from Arizona for yielding and for his tireless work fighting for improved healthcare in rural communities.

Congressman O'HALLERAN's amendment, which I am proud to cosponsor, is vital in rural areas like those in New Mexico's Second Congressional District. Hospitals often run on small margins and do not have the necessary resources to establish new residency training programs.

This is especially problematic given the shortage of up to more than 100,000 physicians by 2030 in the United States. Rural communities, in particular, already struggle to attract and keep medical professionals. Therefore, it is only fitting that the Federal Government invests a portion of the savings earned by H.R. 3 into rural areas to improve healthcare accessibility, and this amendment would do just that.

As we continue debating healthcare legislation, I urge my colleagues to support initiatives that provide rural residents greater access to basic healthcare. I ask my colleagues to join me in support of this amendment and the underlying bill.

Mr. BRADY. Mr. Chairman, I am prepared to close after the gentleman from Arizona finishes his remarks. I reserve the balance of my time.

Mr. O'HALLERAN. Mr. Chairman, how much time do I have remaining?

The Acting CHAIR. The gentleman from Arizona has 1 minute remaining.

Mr. O'HALLERAN. Mr. Chair, I thank Representative TORRES SMALL, and I thank all of my colleagues for standing with me today in support of this important amendment that has received an endorsement from the National Association of Rural Health Clinics. I look forward to joining my colleagues to vote for the Elijah E. Cummings Lower Drug Costs Now Act later today.

This sweeping legislation will lower high-cost prescription drugs, enable Medicare to negotiate prices, and save real dollars that can be reinvested for drug research and development. This bill has the potential to better the lives of countless American seniors, veterans, and families. No family should have to choose between the medication they need and putting food on the table.

I urge my colleagues on both sides of the aisle to vote in support of my amendment and H.R. 3 later today, and I yield back the balance of my time.

Mr. BRADY. Mr. Chairman, impeachment has really ruined most of these bipartisan efforts in healthcare, including the underlying bill. Democrats and Republicans were working well together. Speaker PELOSI shut it all down for this partisan, secretly written bill. Impeachment has stopped most of this.

When and if impeachment is ever done, finished—and I know that Congressman GREEN, my colleague, has said that they can impeach again multiple times—when all of that foolish wasted time finishes, maybe we can work together. I think it would be tremendous.

I have rural areas, underserved areas. They need these GME slots, and the whole thing needs to be reformed in a positive way.

Mr. Chair, I oppose the amendment and the underlying bill, and I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Arizona (Mr. O'HALLERAN).

The question was taken; and the Acting Chair announced that the ayes appeared to have it.

Mr. O'HALLERAN. Mr. Chair, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Arizona will be postponed.

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AMENDMENT NO. 6 OFFERED BY MR. KENNEDY

The Acting CHAIR. It is now in order to consider amendment No. 6 printed in part B of House Report 116–334.

Mr. KENNEDY. Mr. Chairman, as the designee of Ms. JACKSON LEE, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

At the end of title VIII, add the following new section (and update the table of sections accordingly):

SEC. _____. SENSE OF CONGRESS REGARDING THE IMPACT OF THE HIGH COST OF PRESCRIPTION DRUGS ON COMMUNITIES OF COLOR AND PERSONS LIVING IN RURAL OR SPARSELY POPULATED AREAS OF THE UNITED STATES.

It is the sense of the Congress that—

(1) the United States has the highest drug prices in the world and for millions of Americans the cost of prescription drugs is increasing as a barrier to proper disease treatment, especially for communities of color and for persons living in rural or sparsely populated areas of the nation;

(2) the Patient Protection and Affordable Care Act (Public Law 111–148) substantially reduced the number of uninsured Americans, but over 28 million Americans remain without insurance and approximately 55 percent of uninsured Americans under the age of 65 are persons of color;

(3) without health insurance, paying retail prices for medications is invariably burdensome or financially impossible;

(4) the median net worth of Caucasian households in 2016 was 9.7 times higher than African-American households and 8.3 times higher than Hispanic households, which contributes to disparities in negative health consequences, including for example the underuse of insulin among insured adults with diabetes; and

(5) due to the high cost of prescription drugs to communities of color and for persons living in rural or sparsely populated areas of the nation, this Act should positively impact such communities and persons (and the Secretaries of Health and Human Services, Labor, and Treasury should monitor such impact).

The Acting CHAIR. Pursuant to House Resolution 758, the gentleman from Massachusetts (Mr. KENNEDY) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Massachusetts.

Mr. KENNEDY. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, I rise today as the designee of my esteemed colleague SHEILA JACKSON LEE from Houston to offer this amendment. She was unavoidably detained at the Judiciary Committee to consider Articles of Impeachment against our President.

Mr. Chairman, I am grateful for this opportunity to discuss the Jackson Lee amendment to the Elijah E. Cummings Lower Drug Prices Now Act.

Let me also express my gratitude to the chairmen of the committees of jurisdiction for their hard work in crafting this important legislation: Chairman PALLONE of Energy and Commerce, Chairman NEAL of Ways and Means, and Chairman SCOTT of Education and Labor.

The Elijah E. Cummings Lower Drug Prices Now Act levels the playing field for American patients and taxpayers by:

One, giving Medicare the power to negotiate directly with the drug companies and creating powerful new tools to force drug companies to the table to

agree to real price reductions, while ensuring seniors never lose access to the prescriptions they need;

Two, making the lower drug prices negotiated by Medicare available to Americans with private insurance, not just Medicare beneficiaries;

Three, stopping drug companies from ripping off Americans while charging other countries less for the same drugs and limiting the maximum price for any negotiated drug to be in line with the average price in countries like ours;

Four, creating a new, $2,000 out-of-pocket limit on prescription drug costs for Medicare beneficiaries;

Five, reinvesting in the most transformational improvement to Medicare since its creation—delivering vision, dental, and hearing benefits—and turbocharging the search for new cures.

High drug prices are harmful. Medical costs and out-of-pocket expenses result in high rates of bankruptcies, and 10 to 25 percent of patients either delay, abandon, or compromise treatments because of financial constraints.

Survival is also compromised. For example, in chronic myeloid leukemia, the 8- to 10-year survival rate is 80 percent in Europe where treatment is universally affordable, but the 5-year survival rate is only 60 percent in the United States.

The high out-of-pocket expenses discourages patients from seeking care or purchasing drugs. In a recent survey, one-third of insured persons in Ms. JACKSON LEE's home State of Texas delayed or did not pursue care because of high out-of-pocket expenses.

The Jackson Lee amendment is simple and straightforward. The Jackson Lee amendment improves the bill by expressing the sense of Congress regarding the harmful impact of the high cost of prescription drugs on communities of color and persons living in rural or sparsely populated areas of the United States.

According to the Center for American Progress, the negotiation authority provided in H.R. 3 could save some diabetics more than $700 on an annual supply of certain types of insulin. Moreover, negotiations could bring down the net price for other types of drugs that are particularly needed in minority and poor communities—including expensive treatments for cancer and multiple sclerosis—by thousands every month.

Reform is desperately needed, and nearly one in four Americans currently taking prescription drugs find them difficult to afford. Some people struggling to afford medication for chronic illnesses even turn to drug rationing in desperation, which can be lethal. In fact, a recent study found that one in four patients with diabetes rations their insulin in response to rising prices.

The American public overwhelmingly agrees that it is time to allow the government to negotiate with pharmaceutical companies: 85 percent of Americans support this tactic to reduce prices for Medicare and private insurance.

Mr. Chairman, I am grateful for the opportunity to explain the Jackson Lee amendment. I urge our colleagues to agree to the amendment, and I reserve the balance of my time.

Mr. WALDEN. Mr. Chairman, I claim the time in opposition.

The Acting CHAIR. The gentleman from Oregon is recognized for 5 minutes.

Mr. WALDEN. Mr. Chairman, I recognize the serious impact prescription drug prices have on all Americans. We all have constituents facing the same problem: drug prices are too high. We all want to come together to find a way to lower drug prices.

Where we separate is our proposal would lower drug prices, put a cap on what seniors pay, and, for the first time, in Medicare part D, reduce their insulin costs but not end the kind of incredible innovation in America we see today. It would not cost 88,000 American innovators their jobs, and it would not reduce this innovation that is producing two-thirds of the world's cures.

Unfortunately, H.R. 3 would do that. H.R. 3—the underlying bill that is a very disappointingly partisan bill—would cost patients cures to their diseases. We know that.

It is not my conclusion. These are the people who innovate in this space. These are Congressional Budget Office analysts and the Council of Economic Advisers. There has not been a single piece of evidence presented on this floor that says that H.R. 3 will do anything but reduce investment and outcome of overall new cures.

In fact, a colleague of mine and I were talking during the last amendment debate. In effect, we are trading $1 trillion in private-sector investment in new innovation in America for medical cures for $100 million—in this case, the Peters amendment—in taxpayer money.

So you are trading $100 million for $1 trillion, and $1 trillion is private-sector investment coming in, because we know a lot of these new paths that our innovators pick to go down to find a cure just simply end up being a dry hole and all that money is lost. So it takes a lot to find a cure, but we stand on the cusp of something big and bold, and that is cures for diseases where there is none today. We do have a problem in America trying to figure out how to pay for that.

I am going to be retiring at the end of this Congress, and I know my colleague is going off to the Senate at the end of this Congress if voters in Massachusetts have their way, but together, we still, as a country, have to come together and figure out with precision medicine that may produce a cure for you and you only: How are we going to pay for that?

We don't have a lot of answers. I don't think giving the government the biggest club in history to take 95 percent of revenues if you don't agree with what the government wants to pay for something is the right approach. That is what H.R. 3 does. We know it takes $1 trillion out of the pipeline of investment in innovation in America and costs 80-some thousand jobs in innovation.

But in terms of the Jackson Lee amendment which was so ably brought and described by Mr. KENNEDY, I share the concern about what the costs of medicines are putting as a burden on people, especially in rural areas. My district would stretch from the Atlantic to Ohio—we could put a lot of Massachusetts in my district—and our people are suffering.

So I look forward to a day when, after our substitute becomes law, we can continue to work together on these other issues.

I hope my friend will support our substitute because I think it is all bipartisan; 138 Democrats have supported provisions in our substitute amendment. There isn't a single partisan poison pill in our substitute amendment. I think that is why it is attracting support on both sides of the aisle.

Mr. Chairman, I know we have a lot of business to do. I appreciate Mr. KENNEDY bringing this to the floor on behalf of Ms. JACKSON LEE, and I yield back the balance of my time.

Mr. KENNEDY. Mr. Chairman, I urge our colleagues to vote ''yes'' on the amendment, and I yield back the balance of my time.

Ms. JACKSON LEE. Mr. Chair, thank you for this opportunity to discuss the Jackson Lee Amendment to the Elijah E. Cummings Lower Drug Prices Now Act.

Let me also express my thanks to the chairmen of the committees of jurisdiction for their hard work in crafting this critically important legislation: Chairman PALLONE of Energy and Commerce; Chairman NEAL of Ways and Means; and Chairman SCOTT of Education and Labor.

The Elijah E. Cummings Lower Drug Prices Now Act levels the playing field for American patients and taxpayers by:

1. Giving Medicare the power to negotiate directly with the drug companies and creating powerful new tools to force drug companies to the table to agree to real price reductions, while ensuring seniors never lose access to the prescriptions they need.

2. Making the lower drug prices negotiated by Medicare available to Americans with private insurance, not just Medicare beneficiaries.

3. Stopping drug companies from ripping off Americans while charging other countries less for the same drugs and limiting the maximum price for any negotiated drug to be in line with the average price in countries like ours;

4. Creating a new, $2,000 out-of-pocket limit on prescription drug costs for Medicare beneficiaries; and

5. Reinvesting in most transformational improvement to Medicare since its creation—delivering vision, dental and hearing benefits—and turbocharging the search for new cures.

High drug prices are harmful. Medical costs and out-of-pocket expenses result in high

rates of bankruptcies, and 10 to 25 percent of patients either delay, abandon or compromise treatments because of financial constraints.

Survival is also compromised.

For example, in chronic myeloid leukemia, the 8 to 10 year survival rate is 80 percent in Europe (where treatment is universally affordable), but the 5-year survival rate is only 60 percent in the United States.

The high out-of-pocket expenses discourages patients from seeking care or purchasing drugs.

And in a recent survey, one-third of insured persons in my home state of Texas delayed or did not pursue care because of high out-of-pocket expenses.

The Jackson Lee Amendment is simple and straightforward.

The Jackson Lee Amendment improves the bill by expressing the Sense of Congress regarding the harmful impact of the high cost of prescription drugs on communities of color and persons living in rural or sparsely populated areas of the United States.

According to the Center for American Progress, the negotiation authority provided in H.R. 3 could save some diabetics more than $700 on an annual supply of certain types of insulin.

Moreover, negotiation could bring down the net price for other types of drugs that are particularly needed in minority and poor communities—including expensive treatments for cancer and multiple sclerosis—by thousands per month.

Reform is desperately needed and nearly 1 in 4 Americans currently taking prescription drugs find them difficult to afford.

Some people struggling to afford medication for chronic illnesses even turn to drug rationing in desperation, which can be lethal.

In fact, a recent study found that 1 in 4 patients with diabetes ration their insulin in response to rising prices.

The American public overwhelmingly agrees that it is time to allow the government to negotiate with pharmaceutical companies: 85 percent of Americans support this tactic to reduce prices for Medicare and private insurance.

The Acting CHAIR. The question is on the amendment offered by the gentleman from Massachusetts (Mr. KENNEDY).

The amendment was agreed to.

AMENDMENT NO. 7 OFFERED BY MR. GOTTHEIMER

The Acting CHAIR. It is now in order to consider amendment No. 7 printed in part B of House Report 116–334.

Mr. GOTTHEIMER. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

At the end of subtitle B of title VII, insert the following:

SEC. 712. STUDY ON HIGH-RISK, HIGH-REWARD DRUGS.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall conduct a study to identify—

(1) diseases or conditions that lack a treatment approved by the Food and Drug Administration and instances in which development of a treatment for such diseases or conditions could fill an unmet medical need for the treatment of a serious or life-threatening disease or condition or a rare disease or condition; and

(2) appropriate incentives that would lead to the development, approval, and marketing of such treatments.

(b) REPORT TO CONGRESS; RECOMMENDATIONS.—Not later than one year after the date of enactment of this Act, the Secretary shall submit to the Congress a report that includes—

(1) findings from the study under subsection (a); and

(2) recommendations regarding legislation necessary to create appropriate incentives identified pursuant to subsection (a)(2).

The Acting CHAIR. Pursuant to House Resolution 758, the gentleman from New Jersey (Mr. GOTTHEIMER) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from New Jersey.

Mr. GOTTHEIMER. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, I rise today in support of my amendment to H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act of 2019.

My amendment will ensure continued innovation and research to further the development of lifesaving medicines for rare diseases, including cancer, Alzheimer's, ALS, and rare disorders.

The challenge now is that, at best, only 1 out of every 20 clinical trials result in a cure. This, of course, means that manufacturers invest billions before they can find a medicine that can go to market to help save lives. They don't just bet on the winners; they have to also bet and take a lot of risks that don't turn out to succeed and get to market.

America has the best medical innovators in the world. When our health is on the line, we can't stop taking those risks to make sure that we find those cures. We can't risk falling behind.

My amendment provides investment in qualified clinical testing for drug applications that address unmet medical needs to treat rare and life-threatening diseases, diseases that may go unaddressed without extra incentives. My amendment requires HHS to conduct a study to identify diseases without an FDA-approved treatment and where the development of a treatment would fill an unmet medical need for these rare diseases.

My amendment also requires HHS to identify appropriate incentives that would ensure the continued investment in the development of these treatments, treatments that will save lives of the children, adults, and seniors of our families.

The Congressional Budget Office and other studies have shown potential reductions in the number of drug approvals each year as a potential risk of H.R. 3. This amendment helps address that concern.

Targeted therapies and medicines serving smaller populations stand to lose the most from this blow to R&D. These are areas where the science is the most difficult but also the most important, such as cancers and other rare diseases. Cures for these horrific diseases could always be just around the corner, but not if we are forced to abandon what might be the next cure.

While I appreciate the intention of H.R. 3 to reinvest savings in medical research, including at NIH and FDA, without this amendment, there would still be no clear answer to explain what might happen to the incredible research and development work that occurs every day in the private sector. This amendment addresses that.

I know how critical NIH funding is and have consistently advocated for increasing the investment in research there. However, NIH does not manufacture medication, and neither does the FDA. The private sector, including all the research being done every day in my home State of New Jersey, manufactures the lifesaving medications that Americans rely on every single day.

It is also why my Republican colleague from Michigan, FRED UPTON, and I introduced bipartisan legislation this week, the Protecting America's Life Saving Medicines Act, to ensure that life sciences companies continue to invest in these innovative drugs with a tax credit for qualified clinical research, again, to ensure that this research keeps getting done and that they keep making the bets on moonshot drugs that, without those investments, might not save lives like they do today, again, in the greatest country in the world where we innovate like no one else.

It is critical that we never give up hope that the next cure is within our reach. My amendment today will help us to reach the goal of curing our most life-threatening diseases.

Mr. Chairman, I reserve the balance of my time.

Mr. WALDEN. Mr. Chairman, I claim the time in opposition.

The Acting CHAIR. The gentleman from Oregon is recognized for 5 minutes.

Mr. WALDEN. Mr. Chairman, I thank the gentleman for offering his amendment today, and I really do. We work a lot of with Mr. GOTTHEIMER on a number of issues before the Congress, and I appreciate his commitment to this cause.

Republicans fully support the goal of the amendment: to identify those diseases and conditions in which there is an unmet medical need and exploring ways to further incentivize getting treatments to market.

In fact, a study in unmet medical needs is especially timely with the consideration of this underlying bill, H.R. 3, because we believe it will crush development and hope for new treatments.

We are not alone. We have come to this conclusion based on others' factual evaluation of the bill. There is no shortage of sources warning us that H.R. 3 will lead to fewer cures. In fact, independently, the Council of Economic Advisers estimates as many as

100 new treatments will be lost over the next decade under the partisan H.R. 3.

I think the most disturbing, Mr. Chairman, is that the California Life Sciences Association, the great innovators in America who come up with these new cures that we all are counting on, predicts an 88 percent reduction in the number of drugs brought to market by small and emerging companies. And that is only in California, apparently.

The nonpartisan Congressional Budget Office, another source here, our third independent source, estimates that, under H.R. 3, we will have nearly 40 fewer drugs over, roughly, the next two decades; and then, after that, you would see an annual—every year—reduction of 10 percent in the number of drugs entering the market in the later years.

□ 1200

That is what has led so many of us Republicans to oppose H.R. 3. We support the goal of getting drug prices down. We think there are other ways to do that, and we are open to working on those issues.

No President has ever leaned further forward on this matter and taken the pharma companies' CEOs head on than President Trump. But even he, after reading through the bill, said it goes too far. And you can't sacrifice innovation and lifesaving cures for what else is in the bill.

H.R. 3 will undoubtedly lead to an increase in patients with unmet medical needs, fewer drugs. Republicans believe the value of fostering innovation is essential, that is why we led on 21st Century Cures, and passed it into law, led by my friend from Michigan, Mr. UPTON, and my friend from Colorado, DIANA DEGETTE, a bipartisan effort.

But we know there are diseases out there that still long for a cure. This is why our bipartisan solution to lower drug prices, the substitute amendment, H.R. 19, will lower costs, but also promote innovation, and promote it from the private sector side. We want that private venture capital money to continue to flow into this pipeline.

H.R. 3, we are told, the independent analysis tells us, a trillion dollars in private sector money will leave this sector because the punishment is so harsh.

Can you imagine, you are working your whole life, you have gone to college, you have got this great degree, this big brain, you are coming up with a solution to ALS or something, you finally get it done. It goes through all the trials. It is perfected. It works. You get a patent.

And then the government says, We are going to set the price, and if you don't agree to that price, we are going to take 95 percent of the revenues for wherever else you sell this.

By the way, Congressional Research Services warned Congress, and we have had other constitutional experts tell us for sure, H.R. 3 is so punitive and so unfair, it would violate the Fifth Amendment of the Constitution and the Eighth Amendment of the Constitution.

So the underlying bill, as we have been told, is unconstitutional. We all stand down here and take an oath of office to uphold the Constitution. We are being told by our own Congressional Research Service it likely upends, is in violation of, the Constitution. We have other experts say for sure it is.

I appreciate the gentleman's amendment. I do. We know there are unmet needs that need to be dealt with. I think it makes a lot of sense.

Mr. Chairman, I reserve the balance of my time.

Mr. GOTTHEIMER. Mr. Chair, I thank the ranking member for his thoughtful comments and his thoughts about what I think is clearly an unmet need and one we need to continue to invest in, so I thank him for his leadership, too, sir.

Before I finish, let me just say that I urge all my colleagues to vote ''yes'' on this amendment, because we need to keep making those investments to keep our leadership as a country when it comes to R&D innovation. It is one of the reasons why our country is so great and why so many lives have been saved and so many families and children helped.

We need to make sure that we get drug prices down overall, which is why this legislation is so important, to make sure we have competition, more development of generics in the marketplace and, of course, overall the best quality healthcare in the world. It is critical for our country.

Mr. Chairman, I yield back the balance of my time.

Mr. WALDEN. Mr. Chairman, may I inquire how much time I have remaining?

The Acting CHAIR (Mr. CARTWRIGHT). The gentleman from Oregon has 30 seconds remaining.

Mr. WALDEN. Mr. Chair, I yield myself such time as I may consume.

Again, I appreciate the gentleman's hard work on this issue. I know we share a common goal of getting drug prices down and meeting unmet needs of cures. But, tragically, the Democrat bill, H.R. 3, is a very partisan bill.

We are told by the California Life Sciences Association that, if enacted, you could see an 88 percent reduction in the number of drugs brought to market by small and emerging companies in California alone. That is their estimate. These are the people who do this work. They also estimate we would lose 80,000—that is a lot—80,000 biotech R&D jobs nationwide. That is what H.R. 3 does.

So, if you are for cutting jobs in America in biotechnical research, and if you are for 88 percent fewer drugs coming to market from small and emerging innovators in California, then I guess you are going to vote for H.R. 3. I am not going to. I think we can do better.

Mr. Chairman, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from New Jersey (Mr. GOTTHEIMER).

The question was taken; and the Acting Chair announced that the ayes appeared to have it.

Mr. GOTTHEIMER. Mr. Chair, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from New Jersey will be postponed.

AMENDMENT NO. 8 OFFERED BY MRS. AXNE

The Acting CHAIR. It is now in order to consider amendment No. 8 printed in part B of House Report 116–334.

Mrs. AXNE. Mr. Chair, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

At the end of title VII, add the following:

Subtitle D—Reducing Administrative Costs and Burdens in Health Care

SEC. 731. REDUCING ADMINISTRATIVE COSTS AND BURDENS IN HEALTH CARE.

Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

''PART E—REDUCING ADMINISTRATIVE COSTS AND BURDENS IN HEALTH CARE

''SEC. 281. ELIMINATING UNNECESSARY ADMINISTRATIVE BURDENS AND COSTS.

''(a) REDUCING ADMINISTRATIVE BURDENS AND COSTS.—The Secretary, in consultation with providers of health services, health care suppliers of services, health care payers, health professional societies, health vendors and developers, health care standard development organizations and operating rule entities, health care quality organizations, health care accreditation organizations, public health entities, States, patients, and other appropriate entities, shall, in accordance with subsection (b)—

''(1) establish a goal of reducing unnecessary costs and administrative burdens across the health care system, including the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, and the private health insurance market, by at least half over a period of 10 years from the date of enactment of this section;

''(2) develop strategies and benchmarks for meeting the goal established under paragraph (1);

''(3) develop recommendations for meeting the goal established under paragraph (1); and

''(4) take action to reduce unnecessary costs and administrative burdens based on recommendations identified in this subsection.

''(b) STRATEGIES, RECOMMENDATIONS, AND ACTIONS.—

''(1) IN GENERAL.—To achieve the goal established under subsection (a)(1), the Secretary, in consultation with the entities described in such subsection, shall not later than 1 year after the date of enactment of this section, develop strategies and recommendations and take actions to meet such goal in accordance with this subsection. No strategies, recommendation, or action shall undermine the quality of patient care or patient health outcomes.

''(2) STRATEGIES.—The strategies developed under paragraph (1) shall address unnecessary costs and administrative burdens. Such

strategies shall include broad public comment and shall prioritize—

''(A) recommendations identified as a result of efforts undertaken to implement section 3001;

''(B) recommendations and best practices identified as a result of efforts undertaken under this part;

''(C) a review of regulations, rules, and requirements of the Department of Health and Human Services that could be modified or eliminated to reduce unnecessary costs and administrative burden imposed on patients, providers, payers, and other stakeholders across the health care system; and

''(D) feedback from stakeholders in rural or frontier areas on how to reduce unnecessary costs and administrative burdens on the health care system in those areas.

''(3) RECOMMENDATIONS.—The recommendations developed under paragraph (1) shall include—

''(A) actions that improve the standardization and automation of administrative transactions;

''(B) actions that integrate clinical and administrative functions;

''(C) actions that improve patient care and reduce unnecessary costs and administrative burdens borne by patients, their families, and other caretakers;

''(D) actions that advance the development and adoption of open application programming interfaces and other emerging technologies to increase transparency and interoperability, empower patients, and facilitate better integration of clinical and administrative functions;

''(E) actions to be taken by the Secretary and actions that need to be taken by other entities; and

''(F) other areas, as the Secretary determines appropriate, to reduce unnecessary costs and administrative burdens required of health care providers.

''(4) CONSISTENCY.—Any improvements in electronic processes proposed by the Secretary under this section should leverage existing information technology definitions under Federal Law. Specifically, any electronic processes should not be construed to include a facsimile, a proprietary payer portal that does not meet standards specified by the Secretary, or an electronic form image.

''(5) ACTIONS.—The Secretary shall take action to achieve the goal established under subsection (a)(1), and, not later than 1 year after the date of enactment of this section, and biennially thereafter, submit to Congress and make publically available, a report describing the actions taken by the Secretary pursuant to goals, strategies, and recommendations described in this subsection.

''(6) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the development of the goal, strategies, recommendations, or actions described in this section.

''(7) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to authorize, or be used by, the Federal Government to inhibit or otherwise restrain efforts made to reduce waste, fraud, and abuse across the health care system.

''SEC. 282. GRANTS TO STATES TO DEVELOP AND IMPLEMENT RECOMMENDATIONS TO ACCELERATE STATE INNOVATION TO REDUCE HEALTH CARE ADMINISTRATIVE COSTS.

''(a) GRANTS.—

''(1) IN GENERAL.—Not later than 6 months after the date of enactment of this section, the Secretary shall award grants to at least 15 States, and one coordinating entity designated as provided for under subsection (e), to enable such States to establish and administer private-public multi-stakeholder commissions for the purpose of reducing health care administrative costs and burden within and across States. Not less than 3 of such grants shall be awarded to States that are primarily rural, frontier, or a combination thereof, in nature.

''(2) ENTITIES.—For purposes of this section, the term 'State' means a State, a State designated entity, or a multi-State collaborative (as defined by the Secretary).

''(3) PRIORITY.—In awarding grants under this section, the Secretary shall give priority to applications submitted by States that propose to carry out a pilot program or support the adoption of electronic health care transactions and operating rules.

''(b) APPLICATION.—

''(1) IN GENERAL.—To be eligible to receive a grant under subsection (a) a State shall submit to the Secretary an application in such a manner and containing such information as the Secretary may reasonably require, including the information described in paragraph (2).

''(2) REQUIRED INFORMATION.—In addition to any additional information required by the Secretary under this subsection, an application shall include a description of—

''(A) the size and composition of the commission to be established under the grant, including the stakeholders represented and the degree to which the commission reflects important geographic and population characteristics of the State;

''(B) the relationship of the commission to the State official responsible for coordinating and implementing the recommendations resulting from the commission, and the role and responsibilities of the State with respect to the commission, including any participation, review, oversight, implementation or other related functions;

''(C) the history and experience of the State in addressing health care administrative costs, and any experience similar to the purpose of the commission to improve health care administrative processes and the exchange of health care administrative data;

''(D) the resources and expertise that will be made available to the commission by commission members or other possible sources, and how Federal funds will be used to leverage and complement these resources;

''(E) the governance structure and procedures that the commission will follow to make, implement, and pilot recommendations;

''(F) the proposed objectives relating to the simplification of administrative transactions and operating rules, increased standardization, and the efficiency and effectiveness of the transmission of health information;

''(G) potential cost savings and other improvements in meeting the objectives described in subparagraph (F); and

''(H) the method or methods by which the recommendations described in subsection (c) will be reviewed, tested, adopted, implemented, and updated as needed.

''(c) MULTI-STAKEHOLDER COMMISSION.—

''(1) IN GENERAL.—Not later than 90 days after the date on which a grant is awarded to a State under this section, the State official described in subsection (b)(2)(B), the State insurance commissioner, or other appropriate State official shall convene a multi-stakeholder commission, in accordance with this subsection.

''(2) MEMBERSHIP.—The commission convened under paragraph (1) shall include representatives from health plans, health care providers, health vendors, relevant State agencies, health care standard development organizations, and operating rule entities, relevant professional and trade associations, patients, and other entities determined appropriate by the State.

''(3) RECOMMENDATIONS.—Not later than one year after the date on which a grant is awarded to a State under this section, the commission shall make recommendations and plans, consistent with the application submitted by the State under subsection (b), and intended to meet the objectives defined in the application. Such recommendations shall comply with, and build upon, all relevant Federal requirements and regulations, and may include—

''(A) common, uniform specifications, best practices, and conventions, for the efficient, effective exchange of administrative transactions adopted pursuant to the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191);

''(B) the development of streamlined business processes for the exchange and use of health care administrative data; and

''(C) specifications, incentives, requirements, tools, mechanisms, and resources to improve—

''(i) the access, exchange, and use of health care administrative information through electronic means;

''(ii) the implementation of utilization management protocols; and

''(iii) compliance with Federal and State laws.

''(d) USE OF FUNDS FOR IMPLEMENTATION.—A State may use amounts received under a grant under this section for one or more of the following:

''(1) The development, implementation, and best use of shared data infrastructure that supports the electronic transmission of administrative data.

''(2) The development and provision of training and educational materials, forums, and activities as well as technical assistance to effectively implement, use, and benefit from electronic health care transactions and operating rules.

''(3) To accelerate the early adoption and implementation of administrative transactions and operating rules designated by the Secretary and that have been adopted pursuant to the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191), including transactions and operating rules described in section 1173(a)(2) of the Social Security Act.

''(4) To accelerate the early adoption and implementation of additional or updated administrative transactions, operating rules, and related data exchange standards that are being considered for adoption under the Health Insurance Portability and Accountability Act of 1996 or are adopted pursuant to such Act, or as designated by the Secretary, including the electronic claim attachment.

''(5) To conduct pilot projects to test approaches to implement and use the electronic health care transactions and operating rules in practice under a variety of different settings. With respect to the electronic attachment transaction, priority shall be given to pilot projects that test and evaluate methods and mechanisms to most effectively incorporate patient health data from electronic health records and other electronic sources with the electronic attachment transaction.

''(6) To assess barriers to the adoption, implementation, and effective use of electronic health care transactions and operating rules, as well as to explore, identify, and plan options, approaches, and resources to address barriers and make improvements.

''(7) The facilitation of public and private initiatives to reduce administrative costs and accelerate the adoption, implementation, and effective use of electronic health care transactions and operating rules for State programs.

''(8) Developing, testing, implementing, and assessing additional data exchange specifications, operating rules, incentives, requirements, tools, mechanisms, and resources to accelerate the adoption and effective use of the transactions and operating rules.

''(9) Ongoing needs assessments and planning related to the development and implementation of administrative simplification initiatives.

''(e) COORDINATING ENTITY.—

''(1) FUNCTIONS.—Not later than 6 months after the date of enactment of this section, the Secretary shall designate a coordinating entity under this subsection for the purpose of—

''(A) providing technical assistance to States relating to the simplification of administrative transactions and operating rules, increased standardization, and the efficiency and effectiveness of the transmission of health care information;

''(B) evaluating pilot projects and other efforts conducted under this section for impact and best practices to inform broader national use;

''(C) using consistent evaluation methodologies to compare return on investment across efforts conducted under this section;

''(D) compiling, synthesizing, disseminating, and adopting lessons learned to promote the adoption of electronic health care transactions and operating rules across the health care system; and

''(E) making recommendations to the Secretary and the National Committee on Vital and Health Statistics regarding the national adoption of efforts conducted under this section.

''(2) ELIGIBILITY.—The entity designated under paragraph (1) shall be a qualified nonprofit entity that—

''(A) focuses its mission on administrative simplification;

''(B) has demonstrated experience using a multi-stakeholder and consensus-based process for the development of common, uniform specifications, operating rules, best practices, and conventions, for the efficient, effective exchange of administrative transactions that includes representation by or participation from health plans, health care providers, vendors, States, relevant Federal agencies, and other health care standard development organizations;

''(C) has demonstrated experience providing technical assistance to health plans, health care providers, vendors, and States relating to the simplification of administrative transactions and operating rules, increased standardization, and the efficiency and effectiveness of the transmission of health care information;

''(D) has demonstrated experience evaluating and measuring the adoption and return on investment of administrative transactions and operating rules;

''(E) has demonstrated experience gathering, synthesizing, and adopting common, uniform specifications, operating rules, best practices, and conventions for national use based on lessons learned to promote the adoption of electronic health care transactions and operating rules across the health care system;

''(F) has a public set of guiding principles that ensure processes are open and transparent, and supports nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory practices;

''(G) builds on the transaction standards issued under Health Insurance Portability and Accountability Act of 1996; and

''(H) allows for public review and updates of common, uniform specifications, operating rules, best practices, and conventions to support administrative simplification.

''(f) PERIOD AND AMOUNT.—A grant awarded to a State under this section shall be for a period of 5 years and shall not exceed $50,000,000 for such 5-year period. A grant awarded to the coordinating entity designated by the Secretary under subsection (e) shall be for a period of 5 years and shall not exceed $15,000,000 for such 5-year period.

''(g) REPORTS.—

''(1) STATES.—Not later than 1 year after receiving a grant under this section, and biennially thereafter, a State shall submit to the Secretary a report on the outcomes experienced by the State under the grant.

''(2) COORDINATING ENTITY.—Not later than 1 year after receiving a grant under this section, and at least biennially thereafter, the coordinating entity shall submit to the Secretary and the National Committee on Vital and Health Statistics a report of evaluations conducted under the grant under this section and recommendations regarding the national adoption of efforts conducted under this section.

''(3) SECRETARY.—Not later than 6 months after the date on which the States and coordinating entity submit the report required under paragraphs (1) and (2), the Secretary, in consultation with National Committee on Vital and Health Statistics, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the outcomes achieved under the grants under this section.

''(4) GAO.—Not later than 6 months after the date on which the Secretary submits the final report under paragraph (3), the Comptroller General of the United States shall conduct a study, and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the outcomes of the activities carried out under this section which shall contain a list of best practices and recommendations to States concerning administrative simplification.

''(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $250,000,000 for the 5-fiscal-year period beginning with fiscal year 2020.''.

The Acting CHAIR. Pursuant to House Resolution 758, the gentlewoman from Iowa (Mrs. AXNE) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentlewoman from Iowa.

Mrs. AXNE. Mr. Chair, I yield myself such time as I may consume.

Mr. Chair, as a mom, I have spent hours in doctors' offices with sick kids. Nothing is more frustrating than when a doctor has to spend more time looking at their computer screen than helping our children.

I have taken time off work only to end up sitting in waiting rooms because a doctor is running behind, all because of a mountain of paperwork that they must do for every single person that they see. And I have seen doctors who are frustrated at their computers trying to find the information they need.

I have also heard from my constituents in Iowa that when they go to the doctor's office, they don't want to feel like it is an oil change, a quick ''check under the hood'' and then a mountain of forms. And it is not the doctor's fault. They have to comply with all of these administrative rules and codes.

Parents like myself, those doctors, and everyone in the healthcare industry, know that something has to change. And that is why I am offering my amendment today.

My goal is to create a grants program to help reduce all this excessive and unnecessary paperwork on doctors and healthcare workers. It will help doctors spend more time with their patients, including children like mine and those across Iowa. It will save money, because it makes required medical administration more efficient. My amendment will reduce the time crying kids have to wait for their parents to fill out that paperwork before they go into the doctor's office. And my amendment will cut red tape and Federal spending.

This amendment cuts Federal healthcare administrative work by 50 percent in 10 years. I spent 10 years working for the State of Iowa, and I focused on making government more efficient, so I absolutely know how to find government waste and how to cut it, and I think it is important that we look at that.

As an efficiency expert and a mom of two boys, I am proud to introduce this amendment today. Health administration costs are out of control. We spend $500 billion on all types of duplicate administration every year. My amendment creates $250 million in grants for States each year, because when excess administrative work costs nearly $250 billion per year, that is 1,000 times more. In other words, if we reduce administrative waste by more than 0.1 percent, these grants would already pay for themselves. And this amendment is going to cut away way more waste than 0.1 percent.

I have the opportunity to travel all 16 counties in my district every month, and I have met with doctors, nurses, and physician assistants, they have all told me how exhausting and unnecessary all that extra work is.

In 2016 doctors said they are spending almost twice as much time on administrative work than they are with their patients. That is just wrong. And that same study also found that when a doctor is in the exam room, more than one-third of that time is spent on desk work.

Our rural and small communities are struggling to hire enough doctors, and I am already working on attracting doctors to our State, but we also need to protect and keep the doctors that we have, and doctors want to help patients, not do paperwork.

Last month, the Centers for Medicare and Medicaid Services released new guidance to help reduce documentation burdens and ensure doctors have more time with their patients. That was the first time in 25 years we have updated these regulations with the specific purpose of reducing paperwork. My amendment creates grant programs to get that done.

Look, I get it, Mr. Chair, if you are filling out 30 pages of paperwork, you probably won't like this amendment if you like doing that. If your favorite place is a doctor's waiting room and you want to spend more time there, I will understand you not wanting to support my amendment. Or if you always dreamed of being treated like you are a computer code and not a patient, then you can vote ''no'' on this amendment.

But I am pretty confident you are like me and you hate those things. So vote ''yes'' if you want doctors to focus on your kids. Vote ''yes'' if you want shorter wait times and more time with your doctor. Vote ''yes'' for all that, while you are also saving Federal Government money. And by the way, if you are going to miss the waiting room, I would be happy to sign you up for a ''Highlights'' magazine subscription to come to your home.

Mr. Chairman, I reserve the balance of my time.

Mr. BRADY. Mr. Chairman, I claim the time in opposition to the amendment, even though I am not opposed to it.

The Acting CHAIR. Without objection, the gentleman from Texas is recognized for 5 minutes.

There was no objection.

Mr. BRADY. Mr. Chair, though I oppose the dangerous fewer cures act by Speaker PELOSI because it was written in secret, it is partisan and it will delay or kill the cures that our patients are hoping and praying for with Alzheimer's, ALS, Parkinson's, and so many cancers.

This amendment reduces unnecessary costs, administrative burdens across the healthcare system. I share this goal with my colleague from Iowa. This amendment includes a lot of just smart ways to achieve this goal, including identifying best practices, reviewing existing regulations to see if they are adding unnecessary burdens, and studying how we might be able to standardize and just automate certain of these administrative actions.

All of this is pretty good common sense. This amendment would help the public and, I think, the private sectors and the Federal Government and States work better together. I hope Mrs. AXNE offers this amendment again on another legislation, maybe one that will become law, because, obviously, H.R. 3 will not.

And, of course, impeachment has poisoned the water and delayed so many bipartisan things that are important to the American people. I hope she continues to offer it. I imagine that that ''Highlights'' magazine on the doctor's table will be all about impeachment. We want to make it all about healthcare.

Mr. Chair, I urge my colleagues to support the amendment, and I yield back the balance of my time. Let's vote.

Mrs. AXNE. Mr. Chairman, I thank Representative BRADY for his support for this amendment.

I appreciate anybody who also wants to look at efficiencies within government. It is something that we need to spend more time on, so I am grateful for your support and I look forward to working with you and moving this agenda forward.

Mr. Chair, I would still continue to urge all of my colleagues to vote for H.R. 3, so that we can make this a reality, and I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentlewoman from Iowa (Mrs. AXNE).

The amendment was agreed to.

AMENDMENT NO. 9 OFFERED BY MS. FINKENAUER

The Acting CHAIR. It is now in order to consider amendment No. 9 printed in part B of House Report 116–334.

Ms. FINKENAUER. Mr. Chair, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Add at the end of the bill the following new section (and conform the table of contents accordingly):

SEC. 812. REGULATIONS REQUIRING DIRECT-TO-CONSUMER ADVERTISEMENTS FOR PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS TO INCLUDE TRUTHFUL AND NOT MISLEADING PRICING INFORMATION.

(a) IN GENERAL.—Not later than the date that is one year after the date of the enactment of the Elijah E. Cummings Lower Drug Costs Now Act, the Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services (referred to in this section as the ''Administrator''), shall promulgate final regulations requiring each direct-to-consumer advertisement on television (including broadcast, cable, streaming, and satellite television) for a prescription drug or biological product for which payment is available under title XVIII or XIX of the Social Security Act to include a textual statement, which shall be truthful and not misleading, indicating the list price, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast, for a typical 30-day regimen or typical course of treatment (whichever is most appropriate).

(b) DETERMINATIONS.—In promulgating final regulations under subsection (a), the Administrator shall determine—

(1) whether such regulations should apply with respect to additional forms of advertising;

(2) the manner and format of textual statements described in such subsection;

(3) appropriate enforcement mechanisms; and

(4) whether such textual statements should include any other price information, as appropriate.

The Acting CHAIR. Pursuant to House Resolution 758, the gentlewoman from Iowa (Ms. FINKENAUER) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentlewoman from Iowa.

Ms. FINKENAUER. Mr. Chair, I yield myself such time as I may consume.

Mr. Chair, I wanted to start, before I get to the amendment, to actually talk about why all of this is so important here today.

You see, I hold prescription drug roundtables all across the district, and there is a recent one that comes to mind and a story that I want this body to hear.

We were doing a roundtable in Dubuque, where we invited folks to come and talk about their issues with drug prices and how that is impacting their lives personally. And there was a family that came, a young woman who was in her teens, with her mom and her dad. You see, she has diabetes, and they struggle every month to try to figure out how they are going to keep affording insulin and her meters, and different meters with different insurances happen almost every single year.

And they are telling me these stories, and in the middle of the roundtable, the young woman and her mother had to leave to go to a doctor's appointment, and it was her dad that stayed for the rest of it. And as I am going around saying ''thank you for coming and sharing your story today,'' I shook the dad's hand, and he looked at me and he said, ''Please do everything you can to fight for my daughter and fight to make sure that she is going to be able to afford the care that she needs.''

He told me he is very worried about when she turns 26, and if she is not on their insurance what does that look like. Is she going to be able to keep affording it? And he told me that he wanted to be able to walk his daughter down the aisle one day at her wedding, not her funeral.

□ 1215

I will never forget that conversation, and I will never stop fighting to make sure that we lower the costs of these lifesaving medications that so many folks across our country and in my district need and rely on.

It is why I am so proud to support the Elijah E. Cummings Lower Drug Costs Now Act of 2019, which puts measures in place to make sure that drug companies aren't charging us double, triple, or quadruple what countries like Canada and Australia currently pay.

However, H.R. 3 is currently missing a bipartisan drug pricing reform that has been supported by Senator GRASSLEY, by President Trump, and Members of both parties alike. It is requiring drug companies to disclose pricing information on prescription drugs when they advertise directly to consumers like us and folks in my district.

We have all seen the TV commercials that promote prescription drugs. What we may not realize is that pharmaceutical companies spend billions on this advertising. Last year, they spent over $6 billion, and a lot of that was actually to encourage people to get expensive, brand-name drugs.

My amendment would require TV advertisements for prescription drugs to include the list price for a 30-day regimen or a typical course of treatment. With this transparency, we can all be empowered to make informed choices

and bring down costs to our healthcare system.

When drug companies use advertising to boost demand for drugs whose prices just keep going up, the American people deserve to know what these drugs cost. My amendment will ensure that we get a complete picture of the prescription drug options we see on TV.

Mr. Chair, I urge my colleagues today to support this amendment, support this bill, and I reserve the balance of my time.

Mr. BRADY. Mr. Chair, I would like to claim the time in opposition, even though I support the amendment.

The Acting CHAIR. Without objection, the gentleman from Texas is recognized for 5 minutes.

There was no objection.

Mr. BRADY. Mr. Chair, this is a good amendment. It would require H.R. 3 include a provision requiring each drug ad on TV to include the list price of the drug.

I support this policy; Republicans do, as well. It is just a simple way to increase openness in healthcare, transparency that patients are, I think, searching for.

In fact, this bipartisan approach is already in the Republican bill in front of us today, H.R. 19. I don't know why it was rejected in the initial Democrats' bill. I think perhaps it was written in secret. It was all partisan measures.

We know, at the end of the day, it is deader than a doornail. But I think, after that is done, after impeachment—I don't know how many years that thing goes on and wastes our lives. But after all that foolishness is done, I hope our Democrat friends will come back to the negotiating table so we can work on more commonsense, bipartisan ideas like this one.

Despite my strong opposition to H.R. 3—it is such a cruel and false choice to force people to choose between lower drugs and lifesaving cures for Alzheimer's, ALS, Parkinson's, and so many cancers; that is just wrong—I do support this amendment. I urge my colleagues to support it, too.

And I hope the gentlewoman from Iowa will continue to demonstrate her support for more openness by also supporting the bipartisan H.R. 19 when it comes to a vote later today.

Let's vote.

Mr. Chair, I yield back the balance of my time.

Ms. FINKENAUER. Mr. Chair, may I check the balance of my time?

The Acting CHAIR. The gentlewoman from Iowa has 1½ minutes remaining.

Ms. FINKENAUER. Mr. Chair, I yield myself the balance of my time.

I am happy to hear that my colleagues across the aisle will be supporting this important amendment, and I would like to end with another story that I heard at another roundtable, one from one of our farmers in our district who came to our Waterloo roundtable and came with his wife, Heidi, who is battling MS, and was so concerned about how he was going to continue to make it with the ongoing trade war with China that has been taking his soybean markets, and the attacks on renewable fuels that have been hurting him every single day as a corn grower as well, and the $80,000 every 6 months that they were going to have to pay for the MS medication that he went to his lawyer and asked his lawyer how is he going to keep the farm and make sure his wife gets what she needs. His lawyer looked at him and said: If you want to keep your farm, you should consider divorcing your wife.

That is another story that I will never forget. These are the reasons we are here today, that we fight for legislation like this, that we get these things done, and that we put our constituents and people over the politics that we continue to see here from folks who like to divide us instead of unite us.

Mr. Chair, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentlewoman from Iowa (Ms. FINKENAUER).

The amendment was agreed to.

AMENDMENT NO. 10 OFFERED BY MRS. LURIA

The Acting CHAIR. It is now in order to consider amendment No. 10 printed in part B of House Report 116–334.

Ms. LURIA. Mr. Chairman, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

At the end of section 101(b), add the following:

(3) FEHBP.—Section 8902 of title 5, United States Code, is amended by adding at the end the following:

''(p) A contract may not be made or a plan approved under this chapter with any carrier that has affirmatively elected, pursuant to section 1197 of the Social Security Act, not to participate in the Fair Price Negotiation Program established under section 1191 of such Act for any selected drug (as that term is defined in section 1192(c) of such Act).''.

The Acting CHAIR. Pursuant to House Resolution 758, the gentlewoman from Virginia (Mrs. LURIA) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentlewoman from Virginia.

Mrs. LURIA. Mr. Chair, I yield myself such time as I may consume.

Mr. Chair, I rise in support of my amendment to H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act of 2019. My amendment would ensure that Federal employees benefit from the same contracting practices as stated in the fair price negotiation program established by the underlying bill.

Close to 30,000 of our constituents in Virginia's Second Congressional District are Federal employees, and they should all be able to benefit from this monumental legislation to lower prescription drug costs.

Making healthcare more affordable is among my top priorities in Congress. As the costs of prescription drugs seem to skyrocket, I know I must do everything I can to ease that burden on coastal Virginians. Nobody should need to choose between lifesaving medications or bankruptcy.

A vote in favor of this amendment is one to support broader access to affordable prescription drugs. I urge all of my colleagues to support my amendment and the underlying bill, and I reserve the balance of my time.

Mr. UPTON. Mr. Chair, I seek time in opposition to the amendment.

The Acting CHAIR. The gentleman from Michigan is recognized for 5 minutes.

Mr. UPTON. Mr. Chair, I do rise in opposition to the amendment. I would like to make a couple of points.

According to the Office of Personnel Management, OPM, the FEHB program, the Federal Employee Health Benefits program, is, in fact, the largest employer-sponsored group health insurance program in the world. It covers nearly 9 million—9 million—Federal employees and their families.

This amendment says that any private health plan that chooses to offer coverage in the FEHB program must accept the government price controls for prescription drugs established under this bill, H.R. 3.

So, clearly, we are not satisfied in this amendment with only setting prices for Medicare and private businesses. It also creates another harmful mandate and expands the already-radical scope of H.R. 3 to other programs as well.

As my colleagues have noted again and again today and yesterday, governments don't negotiate; they dictate. Taxing up to 95 percent of a drug manufacturer's revenue if it refuses to agree with a government-mandated price is not free market negotiation.

And, as we have heard from both the CBO—nonpartisan body, Congressional Budget Office—and the CEA, they tell us that we are going to lose drugs that will solve cures, as they just won't happen with this bill.

Government price controls lead to lower and fewer cures; and, as the CEA said, nearly 100 cures for rare and difficult diseases likes Alzheimer's, ALS, and cancer just aren't going to happen, or they are going to be much delayed under H.R. 3.

So I would ask my colleagues to vote ''no'' on this amendment, and I reserve the balance of my time.

Mrs. LURIA. Mr. Chair, I yield myself such time as I may consume.

I stand here today in strong support of H.R. 3, in opposition to my colleague.

If, in fact, we are going to offer lower prescription drug costs to those covered by Medicare and private insurance, it is the least that we can do to include our Federal employees in these cost-saving benefits.

Federal employees live in nearly every district in this country, and we must ensure that they, too, can benefit

from lower drug prices secured by this landmark legislation.

I urge my colleagues to support my amendment, as well as the underlying bill, and I yield back the balance of my time.

Mr. UPTON. Mr. Chair, I yield myself the balance of my time.

I would also just like to say that the CRS, Congressional Research Service, has found that price controls in this bill, H.R. 3, the underlying bill, may be unconstitutional under the Fifth Amendment's Takings Clause and the Eighth Amendment Excessive Fines Clause.

So, instead of considering yet another amendment which expands radical government-mandated price controls at the expense of developing lifesaving cures, our time would be better spent considering bipartisan policies such as what is in the substitute, H.R. 19.

So I would encourage my colleagues to, instead, vote for the amendment on H.R. 19 and vote against H.R. 3.

Mr. Chair, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentlewoman from Virginia (Mrs. LURIA).

The question was taken; and the Acting Chair announced that the ayes appeared to have it.

Mr. WALDEN. Mr. Chair, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentlewoman from Virginia will be postponed.

AMENDMENT NO. 11 OFFERED BY MR. CUNNINGHAM

The Acting CHAIR. It is now in order to consider amendment No. 11 printed in part B of House Report 116–334.

Mr. CUNNINGHAM. Mr. Chair, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 62, after line 2, insert the following:

(4) OPTION OF SECRETARY OF VETERANS AFFAIRS TO PURCHASE COVERED DRUGS AT MAXIMUM FAIR PRICES.—Section 8126 of title 38, United States Code, is amended—

(A) in subsection (a)(2), by inserting ``, subject to subsection (j),'' after ``may not exceed'';

(B) in subsection (d), in the matter preceding paragraph (1), by inserting ``, subject to subsection (j)'' after ``for the procurement of the drug''; and

(C) by adding at the end the following new subsection:

``(j)(1) In the case of a covered drug that is a selected drug, for any year during the price applicability period for such drug, if the Secretary determines that the maximum fair price of such drug for such year is less than the price for such drug otherwise in effect pursuant to this section (including after application of any reduction under subsection (a)(2) and any discount under subsection (c)), at the option of the Secretary, in lieu of the maximum price (determined after application of the reduction under subsection (a)(2) and any discount under subsection (c), as applicable) that would be permitted to be charged during such year for such drug pursuant to this section without application of this subsection, the maximum price permitted to be charged during such year for such drug pursuant to this section shall be such maximum fair price for such drug and year.

``(2) For purposes of this subsection:

``(A) The term 'maximum fair price' means, with respect to a selected drug and year during the price applicability period for such drug, the maximum fair price (as defined in section 1191(c)(2) of the Social Security Act) for such drug and year.

``(B) The term 'negotiation eligible drug' has the meaning given such term in section 1192(d)(1) of the Social Security Act.

``(C) The term 'price applicability period' has, with respect to a selected drug, the meaning given such term in section 1191(b)(2) of such Act

``(D) The term 'selected drug' means, with respect to a year, a drug that is a selected drug under section 1192(c) of such Act for such year.''.

The Acting CHAIR. Pursuant to House Resolution 758, the gentleman from South Carolina (Mr. CUNNINGHAM) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from South Carolina.

Mr. CUNNINGHAM. Mr. Chair, I rise today in support of my amendment to ensure that the VA and the veterans that it serves are able to take advantage of lower drug prices made possible by H.R. 3.

I am proud to support the underlying bill, which will result in lower drug prices for millions of Americans, but we cannot forget those who have sacrificed so much for our country. Veterans have earned our support, and they should never have to compromise on healthcare.

H.R. 3 will establish a fair price negotiation program which will enable the Secretary of Health and Human Services to negotiate with drug companies and obtain a fair price for Medicare recipients as well as the privately insured. My amendment would simply allow the VA to purchase drugs at the same price if it is lower than what they would otherwise pay on their own.

□ 1230

Put simply, everyone deserves to pay a fair price for their lifesaving medication.

This is not just about fiscal responsibility. It is about moral responsibility. The hard-earned tax dollars Americans are willing to put toward caring for their veterans should be spent on veterans, not on lining the pockets of drug companies.

The Lowcountry is home to over 80,000 veterans, and I want them to know that when they seek VA care, they are receiving the best care at the best price. I, for one, refuse to allow Big Pharma to profit off our veterans. I ask my colleagues on both sides of the aisle to join me in ensuring our veterans have access to the lowest possible drug prices.

Mr. Chairman, I reserve the balance of my time.

Mr. DAVID P. ROE of Tennessee. Mr. Chairman, I rise in opposition to the amendment.

The Acting CHAIR. The gentleman is recognized for 5 minutes.

Mr. DAVID P. ROE of Tennessee. Mr. Chairman, there is no question that prescription drug prices in this country are too high and that too many Americans cannot afford the lifesaving medications that they need, and I wish the bill we were debating today would solve that problem. Sadly, it does not.

The premise of this amendment is that the VA should be able to lower drug costs if the savings predicted materialize. But make no mistake about it, a bill that stops cures from coming to market and discourages innovation is bad for veterans and bad for America, regardless of the effects of this amendment.

Further, with this amendment, we would be putting the brave men and women who have served our Armed Forces and are seeking care from the Department of VA at risk. Congressman CUNNINGHAM's amendment would expand the scope of this bill to include the prescription drugs provided by VA. As well intentioned as Congressman CUNNINGHAM's amendment might be, this is the wrong thing for veterans.

Mr. Chairman, let me reminisce a little bit. When I graduated from medical school, there was a disease out there we did not know the name of. We didn't even know the name of it. We later discovered it was hepatitis C. We have gone from not even knowing the name of this disease to being able to cure it in 8 to 12 weeks.

Let me tell you what this incredible innovation has done for our Nation's veterans. The VA has cured more than 100,000 veterans of hepatitis C since 2014, remarkable, cutting the death rate by 50 percent.

That is innovation that has done that. Because of this treatment, veterans cured are estimated to have a 72 percent less likely chance of developing cancer of the liver. Fewer than 25,000 veterans out there are now untested that are at risk, and the VA is to be applauded for this.

Let me digress to my first pediatric rotation in medical school in Memphis many years ago. My first inpatient rotation was St. Jude Children's Hospital. At that time when I saw those children, 80 percent of them, Mr. Chairman, died of their disease. Because of innovation and research, and doctors and nurses and others who went in every day and saw these children die, today, 80 percent of those children live. If we don't stifle innovation, my prayer is that 100 percent of these children live.

My concern with this bill, H.R. 3, is not what it will do. It is what will be left undone when we don't have these cures. I know that is not the intent of my friend. We serve on the committee together, and I know that is not his intent. My concern is that is exactly what will happen.

I submit for the RECORD this list of drugs right now that the VA does not have on its formulary because it is closed.

TOP MEDICARE PART B DRUGS NOT COVERED BY THE VA (EXCLUDING VACCINES)

BRAND NAME/GENERIC NAME

Remodulin/Treprostinil Sodium
Provenge/Sipuleucel-T/Lactated Ringers
Soliris/Eculizumab
Synvisc/Hylan G-F 20
Tyvaso/Treprostinil
Abraxane/Paclitaxel Protein-Bound
Actemra/Tocilizumab
Advate/Antihemophil.FVIII, full Length
Aloxi/Palonosetron HCL
Brovana/Arformoterol Tartrate
Budesonide/Budesonide
Entyvio/Vedolizumab
Erbitux/Cetuximab
Faslodex/Fulvestrant
Injectafer/Ferric Carboxymaltose
Kadcyla/Ado-Trastuzumab Emtansine
Neulasta/Pegfilgrastim
NPlate/Romiplostim
Orencia/Abatacept
Prolia/Denosumab
Remicade/Infliximab
Simponi Aria/Golimumab
Xolair/Omalizumab
Yervoy/Ipilimumab

Mr. DAVID P. ROE of Tennessee. Mr. Chairman, further with this amendment, we have a system now that works, and I would encourage my colleagues to not support this amendment.

Mr. Chairman, I reserve the balance of my time.

Mr. CUNNINGHAM. Mr. Chairman, I thank my colleagues on the Committees on Energy and Commerce, Ways and Means, and Education and Labor for their work on this historic piece of legislation, which will save lives. I also thank Chairman MCGOVERN and my colleagues on the Rules Committee for ruling my amendment in order.

I urge all of my colleagues to vote to lower the exorbitant cost of prescription drugs for every single American.

Mr. Chairman, I yield back the balance of my time.

Mr. DAVID P. ROE of Tennessee. Mr. Chairman, I agree with my colleagues that we should do everything possible to lower prescription drug costs, but I can tell you that H.R. 3 will not do it. One of the problems I have with this bill is to stifle the incredible innovation that I have seen in my career.

Let me give another example before I close, Mr. Chairman. I had a professor in medical school, Dr. Lemuel Diggs, my hematology professor. He spent his entire career trying to cure sickle-cell anemia. I have sat by the bedside of pregnant women and done exchange transfusions on women nearing term who have sickle-cell disease so they can deliver a baby that is well and the mother would be healthy. I have done that.

Dr. Diggs passed before we found out incredible research that has been done, that we can do alterations of the HIV virus, an attenuated virus it is called, and place the right code in the genetic code and potentially cure sickle-cell disease for African Americans. We do not want to stifle this innovation.

Mr. Chairman, I oppose this amendment, and I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentleman from South Carolina (Mr. CUNNINGHAM).

The question was taken; and the Acting Chair announced that the ayes appeared to have it.

Mr. DAVID P. ROE of Tennessee. Mr. Chairman, I demand a recorded vote.

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from South Carolina will be postponed.

AMENDMENT NO. 12 OFFERED BY MS. HOULAHAN

The Acting CHAIR. It is now in order to consider amendment No. 12 printed in part B of House Report 116–334.

Ms. HOULAHAN. Mr. Chairman, as the designee of Ms. SCANLON, I have an amendment at the desk.

The Acting CHAIR. The Clerk will designate the amendment.

The text of the amendment is as follows:

Add at the end of title VIII the following new section (and conform the table of contents accordingly):

SEC. 812. IMPROVING TRANSPARENCY AND PREVENTING THE USE OF ABUSIVE SPREAD PRICING AND RELATED PRACTICES IN MEDICAID.

(a) PASS-THROUGH PRICING REQUIRED.—

(1) IN GENERAL.—Section 1927(e) of the Social Security Act (42 U.S.C. 1396r–8(e)) is amended by adding at the end the following:

''(6) PASS-THROUGH PRICING REQUIRED.—A contract between the State and a pharmacy benefit manager (referred to in this paragraph as a 'PBM'), or a contract between the State and a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D)) that includes provisions making the entity responsible for coverage of covered outpatient drugs dispensed to individuals enrolled with the entity, shall require that payment for such drugs and related administrative services (as applicable), including payments made by a PBM on behalf of the State or entity, is based on a pass-through pricing model under which—

''(A) any payment made by the entity or the PBM (as applicable) for such a drug—

''(i) is limited to—

''(I) ingredient cost; and

''(II) a professional dispensing fee that is not less than the professional dispensing fee that the State plan or waiver would pay if the plan or waiver was making the payment directly;

''(ii) is passed through in its entirety by the entity or PBM to the pharmacy that dispenses the drug; and

''(iii) is made in a manner that is consistent with section 1902(a)(30)(A) and sections 447.512, 447.514, and 447.518 of title 42, Code of Federal Regulations (or any successor regulation) as if such requirements applied directly to the entity or the PBM;

''(B) payment to the entity or the PBM (as applicable) for administrative services performed by the entity or PBM is limited to a reasonable administrative fee that covers the reasonable cost of providing such services;

''(C) the entity or the PBM (as applicable) shall make available to the State, and the Secretary upon request, all costs and payments related to covered outpatient drugs and accompanying administrative services incurred, received, or made by the entity or the PBM, including ingredient costs, professional dispensing fees, administrative fees, post-sale and post-in-voice fees. Discounts, or related adjustments such as direct and indirect remuneration fees, and any and all remuneration; and

''(D) any form of spread pricing whereby any amount charged or claimed by the entity or the PBM (as applicable) that is in excess of the amount paid to the pharmacies on behalf of the entity, including any post-sale or post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees or assessments (after allowing for a reasonable administrative fee as described in subparagraph (B)), is not allowable for purposes of claiming Federal matching payments under this title.''.

(2) CONFORMING AMENDMENT.—Clause (xiii) of section 1903(m)(2)(A) of such Act (42 U.S.C. 1396b(m)(2)(A)) is amended—

(A) by striking ''and (III)'' and inserting ''(III)''; and

(B) by inserting before the period at the end the following: '', and (IV) pharmacy benefit management services provided by the entity, or provided by a pharmacy benefit manager on behalf of the entity under a contract or other arrangement between the entity and the pharmacy benefit manager, shall comply with the requirements of section 1927(e)(6)''.

(3) EFFECTIVE DATE.—The amendments made by this subsection apply to contracts between States and managed care entities, other specified entities, or pharmacy benefits managers that are entered into or renewed on or after the date that is 18 months after the date of enactment of this Act.

(b) SURVEY OF RETAIL PRICES.—

(1) IN GENERAL.—Section 1927(f) of the Social Security Act (42 U.S.C. 1396r–8(f)) is amended—

(A) by striking ''and'' after the semicolon at the end of paragraph (1)(A)(i) and all that precedes it through ''(1)'' and inserting the following:

''(1) SURVEY OF RETAIL PRICES.—The Secretary shall conduct a survey of retail community drug prices, to include at least the national average drug acquisition cost, as follows:

''(A) USE OF VENDOR.—The Secretary may contract services for—

''(i) with respect to retail community pharmacies, the determination on a monthly basis of retail survey prices of the national average drug acquisition cost for covered outpatient drugs for such pharmacies, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available), the average reimbursement received for such drugs by such pharmacies from all sources of payment, including third parties, and, to the extent available, the usual and customary charges to consumers for such drugs; and'';

(B) by adding at the end of paragraph (1) the following:

''(F) SURVEY REPORTING.—In order to meet the requirement of section 1902(a)(54), a State shall require that any retail community pharmacy in the State that receives any payment, administrative fee, discount, or rebate related to the dispensing of covered outpatient drugs to individuals receiving benefits under this title, regardless of whether such payment, fee, discount, or rebate is received from the State or a managed care entity directly or from a pharmacy benefit manager or another entity that has a contract with the State or a managed care entity, shall respond to surveys of retail prices conducted under this subsection.

''(G) SURVEY INFORMATION.—Information on retail community prices obtained under this paragraph shall be made publicly available and shall include at least the following:

''(i) The monthly response rate of the survey including a list of pharmacies not in compliance with subparagraph (F).

''(ii) The sampling frame and number of pharmacies sampled monthly.

''(iii) Characteristics of reporting pharmacies, including type (such as independent or chain), geographic or regional location, and dispensing volume.

''(iv) Reporting of a separate national average drug acquisition cost for each drug for independent retail pharmacies and chain operated pharmacies.

''(v) Information on price concessions including on and off invoice discounts, rebates, and other price concessions.

''(vi) Information on average professional dispensing fees paid.

''(H) PENALTIES.—

''(i) FAILURE TO PROVIDE TIMELY INFORMATION.—A retail community pharmacy that fails to respond to a survey conducted under this subsection on a timely basis may be subject to a civil monetary penalty in the amount of $10,000 for each day in which such information has not been provided.

''(ii) FALSE INFORMATION.—A retail community pharmacy that knowingly provides false information in response to a survey conducted under this subsection may be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information.

''(iii) OTHER PENALTIES.—Any civil money penalties imposed under this subparagraph shall be in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceedings under section 1128A(a).

''(I) REPORT ON SPECIALTY PHARMACIES.—

''(i) IN GENERAL.—Not later than 1 year after the effective date of this subparagraph, the Secretary shall submit a report to Congress examining specialty drug coverage and reimbursement under this title.

''(ii) CONTENT OF REPORT.—Such report shall include a description of how State Medicaid programs define specialty drugs, how much State Medicaid programs pay for specialty drugs, how States and managed care plans determine payment for specialty drugs, the settings in which specialty drugs are dispensed (such as retail community pharmacies or specialty pharmacies), whether acquisition costs for specialty drugs are captured in the national average drug acquisition cost survey, and recommendations as to whether specialty pharmacies should be included in the survey of retail prices to ensure national average drug acquisition costs capture drugs sold at specialty pharmacies and how such specialty pharmacies should be defined.'';

(C) in paragraph (2)—

(i) in subparagraph (A), by inserting '', including payments rates under Medicaid managed care plans,'' after ''under this title''; and

(ii) in subparagraph (B), by inserting ''and the basis for such dispensing fees'' before the semicolon; and

(D) in paragraph (4), by inserting '', and $5,000,000 for fiscal year 2020 and each fiscal year thereafter,'' after ''2010''.

(2) EFFECTIVE DATE.—The amendments made by this subsection take effect on the 1st day of the 1st quarter that begins on or after the date that is 18 months after the date of enactment of this Act.

(c) MANUFACTURER REPORTING OF WHOLESALE ACQUISITION COST.—Section 1927(b)(3) of such Act (42 U.S.C. 1396r–8(b)(3)) is amended—

(1) in subparagraph (A)(i)—

(A) in subclause (I), by striking ''and'' after the semicolon;

(B) in subclause (II), by adding ''and'' after the semicolon;

(C) by moving the left margins of subclause (I) and (II) 2 ems to the right; and

(D) by adding at the end the following:

''(III) in the case of rebate periods that begin on or after the date of enactment of this subclause, on the wholesale acquisition cost (as defined in section 1847A(c)(6)(B)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act);''; and

(2) in subparagraph (D)—

(A) in the matter preceding clause (i), by inserting ''and clause (vii) of this subparagraph'' after ''1847A'';

(B) in clause (v), by striking ''and'' after the comma;

(C) in clause (vi), by striking the period and inserting '', and''; and

(D) by inserting after clause (vi) the following:

''(vii) to the Secretary to disclose (through a website accessible to the public) the most recently reported wholesale acquisition cost (as defined in section 1847A(c)(6)(B)) for each covered outpatient drug (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), as reported under subparagraph (A)(i)(III).''.

Page 195, line 9, strike ''$500,000,000'' and insert ''$680,000,000''.

The Acting CHAIR. Pursuant to House Resolution 758, the gentlewoman from Pennsylvania (Ms. HOULAHAN) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentlewoman from Pennsylvania.

Ms. HOULAHAN. Mr. Chair, I yield myself such time as I may consume.

Mr. Chairman, I rise to offer this amendment sponsored today by my friend and neighbor, Ms. SCANLON from Pennsylvania. This commonsense amendment has two parts.

First, it would require pharmacy benefit managers, or PBMs, to pass discounts on drugs through to State Medicaid programs. PBMs are an important part of our drug pricing system, but Republicans and Democrats alike agree on the need for PBM reform. This provision is a feature of the Senate's bipartisan drug pricing bill.

According to the Pennsylvania Department of Human Services, Pennsylvania taxpayers paid $2.86 billion to PBMs for Medicaid enrollees in 2017. That is a 100 percent increase over 4 years. Under current law, PBMs can bill Medicaid one price for a drug, reimburse the pharmacy at a lower price, and profit, as a result, millions from the difference.

This amendment would stop that practice from Medicaid plans and simply require PBMs to pass along any discounts they get from pharmaceutical companies to the State's Medicaid program.

The amendment also requires pharmacies to participate in the CMS survey of acquisition costs for drugs so that States, consumers, and lawmakers alike all can have greater transparency into what these prescription drugs should cost.

Again, this is a feature of the Republican drug pricing proposals included in Mr. WALDEN's proposal, and it is all about increasing transparency into costs, especially PBM pricing.

Lastly, this amendment invests in NIH research for new cures and treatments, especially for high-need conditions.

I am a proud cosponsor of my friend Ms. SHERRILL's Biomedical Innovation Expansion Act, which would invest $10 billion over 10 years in the NIH. As an engineer and former chemistry teacher, I know how important both basic and applied research is to advancing science and medicine. I am very pleased that this bill builds off Ms. SHERRILL's legislation and establishes a pilot program at NIH that provides additional funding for clinical trials.

This stage of development is often costly and complicated, and this amendment would provide $900 million to this important program. With this investment, we are boosting support for an initiative that will assist the development of new cures and treatments.

Mr. Chairman, for our Medicaid beneficiaries, for the patient out there right now with a condition that has no cure, I ask that my colleagues on both sides of the aisle support this amendment.

Mr. Chairman, I reserve the balance of my time.

Mr. WALDEN. Mr. Chairman, I rise in opposition to this amendment.

The Acting CHAIR. The gentleman is recognized for 5 minutes.

Mr. WALDEN. Mr. Chairman, I reserve the balance of my time.

Ms. HOULAHAN. Mr. Chairman, I stand here in strong support of Ms. SCANLON's amendment to H.R. 3 and in strong support of H.R. 3, as well.

I can say, as a freshman Member of this delegation and this Congress, the number one thing that all of our constituents ask of us each and every day is to address this issue of prescription drug pricing and transparency into that process.

This bill and the underlying amendment therein support and affirm both those things. I urge my colleagues on both sides of the aisle to support this bill and its underlying amendment.

Mr. Chairman, I yield back the balance of my time.

Mr. WALDEN. Mr. Chair, we certainly support clinical trials at the National Institutes of Health. In fact, the Republicans have led on this issue. In fact, Republicans have led for decades in increasing the funding for NIH, going clear back to about 1995 when then-Speaker Gingrich led an effort to double the funding for the NIH.

Our colleague Mr. UPTON from Michigan led the effort to dramatically increase the funding for NIH. We know that is extraordinarily important to do.

Of course, while that is important, it is kind of the basic science. The real

work that gets done takes that and then turns it into drugs eventually through a whole clinical trial process with lots more innovation and investment.

Tragically, H.R. 3 rips $1 trillion out of that innovation funding cycle. That is why, for the life of me, I can't understand why my friends are voting for that knowing that, and how they can vote for H.R. 3 knowing that upward of 100 or more cures, lifesaving drugs, medicines never will be developed.

Those aren't my numbers. Those are the numbers of the Council of Economic Advisers. Those are the numbers from CBO. They tell us in literally the next 20 years, 38 new drugs will never be developed, at a minimum, upward of 38. It could be more. I suppose it could be less. After that, it is 10 percent every year that don't get developed. We think it is actually higher than that, but those are the facts. Those are facts.

I want to emphasize that the ban on spread pricing in Medicaid offered here as a Democratic amendment is actually, as my friend recognizes, in H.R. 19. We agree. There are 138 Democrats who have sponsored different provisions that are bipartisan in the substitute amendment, and it should do no damage.

Why would you vote against your own stuff? I mean, it is in here. It is good policy. It is bipartisan. I hope that some will have the opportunity to be strong and vote for really good bipartisan legislation. I would argue that H.R. 19, the substitute, is the most bipartisan bill on the floor today, the only bipartisan bill on the floor today.

This comprehensive collection of bipartisan policies from both the House and the Senate are contained in the substitute, H.R. 19. We looked a lot at the work that Senator GRASSLEY and my own State Senator RON WYDEN put together in their legislation. We probably got 90 percent of that one way or the other incorporated in here.

I have learned over the years, from the time I got here as a freshman until now, you don't get everything. Sometimes, you can make more progress by getting together and getting what you can agree on done and then continuing to work on the issues where you don't agree, and I would say that is an issue that we face right now.

We have before us a substitute that could become law, and the President basically indicated he would sign it. He clearly has indicated he will veto H.R. 3. We have had word out of the Senate that they have no plans to take up H.R. 3. To me, it makes it a nonstarter.

I also believe it is dangerous to innovation. It will cost 88,000 jobs U.S.-wide, and 80-something percent of new drugs coming out of California won't be developed. That is according to the people who do this work, California Life Sciences.

□ 1245

I don't think you have to trade that reduction in innovation and new cures for lower prices. I think you can actually have both.

We have a common commitment here to lower drug prices. We have a common commitment here to increase investment in NIH and to stop the bad behaviors by the pharmaceutical companies, to stop them from withholding samples so that generics don't get to market or actually paying all generic brands not to come to market.

I wrote the legislation last Congress that modernized the FDA's approval process for medical devices, generic devices, so we couldn't get stuck—that is a bit of a pun—by another EpiPen issue. Because there was no competitor, they raised the price the way they wanted to, and they stuck it to people like my wife, who used to use an EpiPen, and many other consumers.

We now have competition in that space, and the FDA has approved more generic drugs as a result of our unanimous work on the FDA reform. More generic drugs in the last year than at any time in the history of the FDA were approved, over 1,100 new generic drugs, because, I think, when you get more competition in the market, consumers benefit with more choice and lower price.

Now, there is still some gaming that goes on, and we agree on that, and we are putting a stop to that wherever we can find it. But I don't want to vote for H.R. 3 as an unconstitutional measure, as we have been warned by our own Congressional Research Service lawyers who looked at it. They said it likely violates two provisions of the Constitution because it is so punitive and damaging.

We had the outside science people look at it and say it is going to cost cures.

Mr. Chair, I yield back the balance of my time.

The Acting CHAIR. The question is on the amendment offered by the gentlewoman from Pennsylvania (Ms. HOULAHAN).

The amendment was agreed to.

ANNOUNCEMENT BY THE ACTING CHAIR

The Acting CHAIR. Pursuant to clause 6 of rule XVIII, proceedings will now resume on those amendments printed in part B of House Report 116–334 on which further proceedings were postponed, in the following order:

Amendment No. 1 by Mr. WALDEN of Oregon.

Amendment No. 5 by Mr. O'HALLERAN of Arizona.

Amendment No. 7 by Mr. GOTTHEIMER of New Jersey.

Amendment No. 10 by Ms. LURIA of Virginia.

Amendment No. 11 by Mr. CUNNINGHAM of South Carolina.

The Chair will reduce to 2 minutes the minimum time for any electronic vote after the first vote in this series.

AMENDMENT NO. 1 OFFERED BY MR. WALDEN

The Acting CHAIR. The unfinished business is the demand for a recorded vote on the amendment offered by the gentleman from Oregon (Mr. WALDEN) on which further proceedings were postponed and on which the noes prevailed by voice vote.

The Clerk will redesignate the amendment.

The Clerk redesignated the amendment.

RECORDED VOTE

The Acting CHAIR. A recorded vote has been demanded.

A recorded vote was ordered.

The vote was taken by electronic device, and there were—ayes 201, noes 223, not voting 12, as follows:

[Roll No. 676]

AYES—201

Abraham	Granger	Palmer
Aderholt	Graves (GA)	Pence
Allen	Graves (LA)	Perry
Amash	Graves (MO)	Peters
Amodei	Green (TN)	Posey
Armstrong	Griffith	Radewagen
Arrington	Grothman	Ratcliffe
Babin	Guest	Reed
Bacon	Guthrie	Reschenthaler
Baird	Hagedorn	Rice (SC)
Balderson	Harris	Riggleman
Banks	Hartzler	Roby
Barr	Hern, Kevin	Rodgers (WA)
Bergman	Herrera Beutler	Roe, David P.
Biggs	Hice (GA)	Rogers (AL)
Bilirakis	Higgins (LA)	Rogers (KY)
Bishop (NC)	Hill (AR)	Rose, John W.
Bishop (UT)	Holding	Rouda
Bost	Hollingsworth	Rouzer
Brady	Hudson	Roy
Brindisi	Huizenga	Rutherford
Brooks (AL)	Hurd (TX)	Scalise
Brooks (IN)	Johnson (LA)	Schrader
Buchanan	Johnson (OH)	Schweikert
Buck	Johnson (SD)	Scott, Austin
Bucshon	Jordan	Sensenbrenner
Budd	Joyce (OH)	Shimkus
Burgess	Joyce (PA)	Simpson
Byrne	Katko	Smith (MO)
Calvert	Keller	Smith (NE)
Carter (GA)	Kelly (MS)	Smith (NJ)
Carter (TX)	Kelly (PA)	Smucker
Chabot	King (IA)	Spano
Cheney	King (NY)	Stauber
Cline	Kinzinger	Stefanik
Cloud	Kustoff (TN)	Steil
Cole	LaHood	Steube
Collins (GA)	LaMalfa	Stewart
Comer	Lamborn	Stivers
Conaway	Latta	Suozzi
Cook	Lesko	Taylor
Crawford	Long	Thompson (PA)
Crenshaw	Loudermilk	Thornberry
Curtis	Lucas	Timmons
Davidson (OH)	Luetkemeyer	Tipton
Davis, Rodney	Marchant	Turner
DesJarlais	Marshall	Upton
Diaz-Balart	Mast	Van Drew
Duncan	McAdams	Wagner
Dunn	McCarthy	Walberg
Emmer	McCaul	Walden
Estes	McClintock	Walker
Ferguson	McHenry	Walorski
Fitzpatrick	McKinley	Waltz
Fleischmann	Meadows	Watkins
Flores	Meuser	Weber (TX)
Fortenberry	Miller	Webster (FL)
Foxx (NC)	Mitchell	Wenstrup
Fulcher	Moolenaar	Westerman
Gaetz	Mooney (WV)	Williams
Gallagher	Mullin	Wilson (SC)
Gianforte	Murphy (NC)	Wittman
Gibbs	Newhouse	Womack
Gohmert	Norman	Woodall
Gonzalez (OH)	Nunes	Wright
Gooden	Olson	Yoho
Gottheimer	Palazzo	Young

NOES—223

Adams	Bishop (GA)	Butterfield
Aguilar	Blumenauer	Carbajal
Allred	Blunt Rochester	Cárdenas
Axne	Bonamici	Carson (IN)
Barragán	Boyle, Brendan F.	Cartwright
Bass	Brown (MD)	Case
Beatty	Brownley (CA)	Casten (IL)
Bera	Bustos	Castor (FL)
Beyer		Castro (TX)

Chu, Judy
Cicilline
Cisneros
Clark (MA)
Clarke (NY)
Clay
Cleaver
Clyburn
Cohen
Connolly
Cooper
Correa
Costa
Courtney
Cox (CA)
Craig
Crist
Crow
Cuellar
Cunningham
Davids (KS)
Davis (CA)
Davis, Danny K.
Dean
DeFazio
DeGette
DeLauro
DelBene
Delgado
Demings
DeSaulnier
Deutch
Dingell
Doggett
Doyle, Michael F.
Engel
Escobar
Eshoo
Espaillat
Evans
Finkenauer
Fletcher
Foster
Frankel
Fudge
Gallego
Garamendi
García (IL)
Garcia (TX)
Golden
Gomez
Gonzalez (TX)
González-Colón (PR)
Green, Al (TX)
Grijalva
Haaland
Harder (CA)
Hastings
Hayes
Heck
Higgins (NY)
Himes
Horn, Kendra S.
Horsford
Houlahan
Hoyer
Huffman
Jackson Lee
Jayapal
Jeffries
Johnson (GA)
Johnson (TX)
Kaptur
Keating
Kelly (IL)
Kennedy
Khanna
Kildee
Kilmer
Kim
Kind
Kirkpatrick
Krishnamoorthi
Kuster (NH)
Lamb
Langevin
Larsen (WA)
Larson (CT)
Lawrence
Lawson (FL)
Lee (CA)
Lee (NV)
Levin (CA)
Levin (MI)
Lipinski
Loebsack
Lofgren
Lowenthal
Lowey
Luján
Luria
Lynch
Malinowski
Maloney, Carolyn B.
Maloney, Sean
Massie
Matsui
McBath
McCollum
McEachin
McGovern
Meeks
Meng
Moore
Morelle
Moulton
Mucarsel-Powell
Murphy (FL)
Nadler
Napolitano
Neal
Neguse
Norcross
Norton
O'Halleran
Ocasio-Cortez
Omar
Pallone
Panetta
Pappas
Pascrell
Payne
Perlmuter
Peterson
Phillips
Pingree
Plaskett
Pocan
Porter
Pressley
Price (NC)
Quigley
Raskin
Rice (NY)
Richmond
Rose (NY)
Roybal-Allard
Ruiz
Ruppersberger
Rush
Ryan
Sánchez
Sarbanes
Scanlon
Schakowsky
Schiff
Schneider
Schrier
Scott (VA)
Scott, David
Sewell (AL)
Shalala
Sherman
Sherrill
Sires
Slotkin
Smith (WA)
Soto
Spanberger
Speier
Stanton
Stevens
Swalwell (CA)
Takano
Thompson (CA)
Thompson (MS)
Titus
Tlaib
Tonko
Torres (CA)
Torres Small (NM)
Trahan
Trone
Underwood
Vargas
Veasey
Vela
Velázquez
Visclosky
Wasserman Schultz
Waters
Watson Coleman
Welch
Wexton
Wild
Wilson (FL)
Yarmuth

NOT VOTING—12

Burchett
Gabbard
Gosar
Hunter
Lewis
Lieu, Ted
McNerney
Rooney (FL)
Sablan
San Nicolas
Serrano
Zeldin

□ 1318

Mses. SLOTKIN, PLASKETT, Messrs. GALLEGO, CASTRO of Texas, CLEAVER, Ms. SÁNCHEZ, Mr. DOGGETT, Mses. BONAMICI, DELAURO, Miss GONZÁLEZ-COLÓN of Puerto Rico, and Mrs. MURPHY of Florida changed their vote from ''aye'' to ''no.''

Messrs. BROOKS of Alabama, SCHWEIKERT, PETERS, and SUOZZI changed their vote from ''no'' to ''aye.''

So the amendment was rejected.

The result of the vote was announced as above recorded.

Stated against:

Mr. MCNERNEY. Mr. Chair, had I been present, I would have voted "nay" on rollcall No. 676.

AMENDMENT NO. 5 OFFERED BY MR. O'HALLERAN

The Acting CHAIR (Mr. CARTWRIGHT). The unfinished business is the demand for a recorded vote on the amendment offered by the gentleman from Arizona (Mr. O'HALLERAN) on which further proceedings were postponed and on which the ayes prevailed by voice vote.

The Clerk will redesignate the amendment.

The Clerk redesignated the amendment.

RECORDED VOTE

The Acting CHAIR. A recorded vote has been demanded.

A recorded vote was ordered.

The Acting CHAIR. This will be a 2-minute vote.

The vote was taken by electronic device, and there were—ayes 351, noes 73, not voting 12, as follows:

[Roll No. 677]

AYES—351

Adams
Aguilar
Allen
Allred
Amodei
Armstrong
Axne
Baird
Balderson
Banks
Barr
Barragán
Bass
Beatty
Bera
Bergman
Beyer
Bilirakis
Bishop (GA)
Bishop (UT)
Blumenauer
Blunt Rochester
Bonamici
Bost
Boyle, Brendan F.
Brindisi
Brooks (IN)
Brown (MD)
Brownley (CA)
Buchanan
Bucshon
Burgess
Bustos
Butterfield
Calvert
Carbajal
Cárdenas
Carson (IN)
Carter (GA)
Cartwright
Case
Casten (IL)
Castor (FL)
Castro (TX)
Chabot
Cheney
Chu, Judy
Cicilline
Cisneros
Clark (MA)
Clarke (NY)
Clay
Cleaver
Cline
Clyburn
Cohen
Cole
Collins (GA)
Connolly
Cook
Cooper
Correa
Costa
Courtney
Cox (CA)
Craig
Crist
Crow
Cuellar
Cunningham
Curtis
Davids (KS)
Davis (CA)
Davis, Danny K.
Davis, Rodney
Dean
DeFazio
DeGette
DeLauro
DelBene
Delgado
Demings
DesJarlais
Deutch
Diaz-Balart
Dingell
Doggett
Doyle, Michael F.
Duncan
Dunn
Emmer
Engel
Escobar
Eshoo
Espaillat
Evans
Ferguson
Finkenauer
Fitzpatrick
Fleischmann
Fletcher
Fortenberry
Foster
Frankel
Fudge
Gallagher
Gallego
Garamendi
García (IL)
Garcia (TX)
Gianforte
Gibbs
Gohmert
Golden
Gomez
Gonzalez (TX)
González-Colón (PR)
Gottheimer
Graves (LA)
Graves (MO)
Green (TN)
Green, Al (TX)
Griffith
Grijalva
Guest
Guthrie
Haaland
Hagedorn
Harder (CA)
Hartzler
Hastings
Hayes
Heck
Herrera Beutler
Higgins (LA)
Higgins (NY)
Himes
Hollingsworth
Horn, Kendra S.
Horsford
Houlahan
Hoyer
Huffman
Huizenga
Hurd (TX)
Jackson Lee
Jayapal
Jeffries
Johnson (GA)
Johnson (OH)
Johnson (SD)
Johnson (TX)
Joyce (OH)
Kaptur
Katko
Keating
Keller
Kelly (IL)
Kelly (MS)
Kennedy
Khanna
Kildee
Kilmer
Kim
Kind
King (IA)
King (NY)
Kinzinger
Kirkpatrick
Krishnamoorthi
Kuster (NH)
Kustoff (TN)
LaMalfa
Lamb
Langevin
Larsen (WA)
Larson (CT)
Latta
Lawrence
Lawson (FL)
Lee (CA)
Lee (NV)
Lesko
Levin (CA)
Levin (MI)
Lipinski
Loebsack
Lofgren
Long
Loudermilk
Lowenthal
Lowey
Lucas
Luetkemeyer
Luján
Luria
Lynch
Malinowski
Maloney, Carolyn B.
Maloney, Sean
Marshall
Matsui
McAdams
McBath
McCaul
McCollum
McEachin
McGovern
McKinley
McNerney
Meeks
Meng
Meuser
Moolenaar
Mooney (WV)
Moore
Morelle
Moulton
Mucarsel-Powell
Mullin
Murphy (FL)
Murphy (NC)
Nadler
Napolitano
Neal
Neguse
Newhouse
Norcross
Norton
O'Halleran
Ocasio-Cortez
Omar
Palazzo
Pallone
Panetta
Pappas
Pascrell
Payne
Pence
Perlmutter
Peters
Peterson
Phillips
Pingree
Plaskett
Pocan
Porter
Posey
Pressley
Price (NC)
Quigley
Radewagen
Raskin
Reed
Reschenthaler
Rice (NY)
Rice (SC)
Richmond
Riggleman
Roby
Rodgers (WA)
Roe, David P.
Rogers (AL)
Rogers (KY)
Rose (NY)
Rose, John W.
Rouda
Rouzer
Roybal-Allard
Ruiz
Ruppersberger
Rush
Ryan
Sánchez
Sarbanes
Scanlon
Schakowsky
Schiff
Schneider
Schrader
Schrier
Scott (VA)
Scott, Austin
Scott, David
Sewell (AL)
Shalala
Sherman
Sherrill
Simpson
Sires
Slotkin
Smith (MO)
Smith (NE)
Smith (NJ)
Smith (WA)
Smucker
Soto
Spanberger
Spano
Stanton
Stauber
Stefanik
Steil
Stevens
Stewart
Stivers
Suozzi
Swalwell (CA)
Takano
Thompson (CA)
Thompson (MS)
Thompson (PA)
Thornberry
Tipton
Titus
Tlaib
Tonko
Torres (CA)
Torres Small (NM)
Trahan
Trone
Turner
Underwood
Upton
Van Drew
Vargas
Veasey
Vela
Velázquez
Visclosky
Wagner
Walberg
Walden
Walorski
Waltz
Wasserman Schultz
Waters
Watkins
Watson Coleman
Webster (FL)
Welch
Wenstrup
Wexton
Wild
Wilson (FL)
Wilson (SC)
Wittman
Woodall
Yarmuth
Yoho
Zeldin

NOES—73

Abraham
Aderholt
Amash
Arrington
Babin
Bacon
Biggs
Bishop (NC)
Brady
Brooks (AL)
Buck
Budd
Byrne
Carter (TX)
Cloud
Comer
Conaway
Crawford
Crenshaw
Davidson (OH)
Estes
Flores
Foxx (NC)
Fulcher
Gaetz
Gonzalez (OH)
Gooden
Granger
Graves (GA)
Grothman
Harris
Hern, Kevin
Hice (GA)
Hill (AR)
Holding
Hudson
Johnson (LA)
Jordan
Joyce (PA)
Kelly (PA)
LaHood
Lamborn
Marchant
Massie
Mast
McCarthy
McClintock
McHenry
Meadows
Miller
Mitchell
Norman
Nunes
Olson
Palmer
Perry
Ratcliffe
Roy
Rutherford
Scalise
Schweikert
Sensenbrenner
Shimkus
Steube
Taylor
Timmons
Walker
Weber (TX)
Westerman
Williams
Womack
Wright
Young

NOT VOTING—12

Burchett
DeSaulnier
Gabbard
Gosar
Hunter
Lewis
Lieu, Ted
Rooney (FL)
Sablan
San Nicolas
Serrano
Speier

ANNOUNCEMENT BY THE ACTING CHAIR

The Acting CHAIR (Mr. MCGOVERN) (during the vote). There is 1 minute remaining.

□ 1324

Mr. JOYCE of Pennsylvania changed his vote from ''aye'' to ''no.''

Mr. WALBERG changed his vote from ''no'' to ''aye.''

So the amendment was agreed to.

The result of the vote was announced as above recorded.

AMENDMENT NO. 7 OFFERED BY MR. GOTTHEIMER

The Acting CHAIR. The unfinished business is the demand for a recorded vote on the amendment offered by the gentleman from New Jersey (Mr. GOTTHEIMER) on which further proceedings were postponed and on which the ayes prevailed by voice vote.

The Clerk will redesignate the amendment.

The Clerk redesignated the amendment.

RECORDED VOTE

The Acting CHAIR. A recorded vote has been demanded.

A recorded vote was ordered.

The Acting CHAIR. This will be a 2-minute vote.

The vote was taken by electronic device, and there were—ayes 380, noes 45, not voting 11, as follows:

[Roll No. 678]

AYES—380

Abraham
Adams
Aguilar
Allen
Allred
Amodei
Arrington
Axne
Bacon
Baird
Balderson
Banks
Barr
Barragán
Bass
Beatty
Bera
Bergman
Beyer
Bilirakis
Bishop (GA)
Blumenauer
Blunt Rochester
Bonamici
Bost
Boyle, Brendan F.
Brady
Brindisi
Brooks (AL)
Brooks (IN)
Brown (MD)
Brownley (CA)
Buchanan
Buck
Bucshon
Budd
Burgess
Bustos
Butterfield
Calvert
Carbajal
Carson (IN)
Carter (GA)
Cartwright
Case
Casten (IL)
Castor (FL)
Castro (TX)
Chabot
Cheney
Chu, Judy
Cicilline
Cisneros
Clark (MA)
Clarke (NY)
Clay
Cleaver
Cline
Clyburn
Cohen
Cole
Collins (GA)
Comer
Connolly
Cook
Cooper
Correa
Costa
Courtney
Cox (CA)
Craig
Crenshaw
Crist
Crow
Cuellar
Cunningham
Curtis
Davids (KS)
Davidson (OH)
Davis (CA)
Davis, Danny K.
Davis, Rodney
Dean
DeFazio
DeGette
DeLauro
DelBene
Delgado
Demings
DeSaulnier
DesJarlais
Deutch
Diaz-Balart
Dingell
Doyle, Michael F.
Duncan
Dunn
Emmer
Engel
Escobar
Eshoo
Espaillat
Estes
Evans
Finkenauer
Fitzpatrick
Fleischmann
Fletcher
Fortenberry
Foster
Foxx (NC)
Frankel
Fudge
Fulcher
Gaetz
Gallagher
Gallego
Garamendi
Garcia (TX)
Gianforte
Gibbs
Golden
Gomez
Gonzalez (OH)
Gonzalez (TX)
González-Colón (PR)
Gooden
Gottheimer
Graves (GA)
Graves (LA)
Graves (MO)
Green, Al (TX)
Griffith
Grijalva
Grothman
Guest
Guthrie
Haaland
Hagedorn
Harder (CA)
Hartzler
Hastings
Hayes
Heck
Hern, Kevin
Herrera Beutler
Higgins (LA)
Higgins (NY)
Hill (AR)
Himes
Hollingsworth
Horn, Kendra S.
Horsford
Houlahan
Hoyer
Hudson
Huffman
Huizenga
Hurd (TX)
Jackson Lee
Jeffries
Johnson (GA)
Johnson (LA)
Johnson (OH)
Johnson (SD)
Johnson (TX)
Joyce (OH)
Joyce (PA)
Kaptur
Katko
Keating
Keller
Kelly (IL)
Kelly (MS)
Kelly (PA)
Kennedy
Khanna
Kildee
Kilmer
Kim
Kind
King (IA)
King (NY)
Kinzinger
Kirkpatrick
Krishnamoorthi
Kuster (NH)
Lamb
Langevin
Larsen (WA)
Larson (CT)
Latta
Lawrence
Lawson (FL)
Lee (CA)
Lee (NV)
Lesko
Levin (CA)
Levin (MI)
Lipinski
Loebsack
Lofgren
Long
Loudermilk
Lowenthal
Lowey
Lucas
Luetkemeyer
Luján
Luria
Lynch
Malinowski
Maloney, Carolyn B.
Maloney, Sean
Marshall
Mast
Matsui
McAdams
McBath
McCarthy
McCaul
McCollum
McEachin
McGovern
McHenry
McKinley
McNerney
Meadows
Meeks
Meng
Meuser
Miller
Mitchell
Moolenaar
Mooney (WV)
Moore
Morelle
Moulton
Mucarsel-Powell
Mullin
Murphy (FL)
Nadler
Napolitano
Neal
Neguse
Newhouse
Norcross
Norman
Norton
Nunes
O'Halleran
Ocasio-Cortez
Omar
Palazzo
Pallone
Palmer
Panetta
Pappas
Pascrell
Payne
Perlmutter
Peters
Peterson
Phillips
Pingree
Plaskett
Porter
Posey
Pressley
Price (NC)
Quigley
Radewagen
Raskin
Reed
Reschenthaler
Rice (NY)
Rice (SC)
Richmond
Riggleman
Roby
Rodgers (WA)
Roe, David P.
Rogers (AL)
Rogers (KY)
Rose (NY)
Rose, John W.
Rouda
Rouzer
Roybal-Allard
Ruiz
Ruppersberger
Rush
Ryan
Sánchez
Sarbanes
Scalise
Scanlon
Schiff
Schneider
Schrader
Schrier
Schweikert
Scott (VA)
Scott, Austin
Scott, David
Sensenbrenner
Sewell (AL)
Shalala
Sherman
Sherrill
Simpson
Sires
Slotkin
Smith (MO)
Smith (NJ)
Smith (WA)
Smucker
Soto
Spanberger
Spano
Speier
Stanton
Stauber
Stefanik
Steil
Stevens
Stewart
Stivers
Suozzi
Swalwell (CA)
Takano
Taylor
Thompson (CA)
Thompson (MS)
Thompson (PA)
Thornberry
Timmons
Tipton
Titus
Tlaib
Tonko
Torres (CA)
Torres Small (NM)
Trahan
Trone
Turner
Underwood
Upton
Van Drew
Vargas
Veasey
Vela
Velázquez
Visclosky
Wagner
Walberg
Walden
Walorski
Waltz
Wasserman Schultz
Waters
Watkins
Watson Coleman
Webster (FL)
Welch
Wenstrup
Westerman
Wexton
Wild
Williams
Wilson (FL)
Wilson (SC)
Wittman
Womack
Woodall
Wright
Yarmuth
Yoho
Young
Zeldin

NOES—45

Aderholt
Amash
Armstrong
Babin
Biggs
Bishop (NC)
Bishop (UT)
Byrne
Carter (TX)
Cloud
Conaway
Crawford
Doggett
Ferguson
Flores
García (IL)
Gohmert
Granger
Green (TN)
Harris
Hice (GA)
Holding
Jayapal
Jordan
Kustoff (TN)
LaHood
LaMalfa
Lamborn
Marchant
Massie
McClintock
Murphy (NC)
Olson
Pence
Perry
Pocan
Ratcliffe
Roy
Rutherford
Schakowsky
Shimkus
Smith (NE)
Steube
Walker
Weber (TX)

NOT VOTING—11

Burchett
Cárdenas
Gabbard
Gosar
Hunter
Lewis
Lieu, Ted
Rooney (FL)
Sablan
San Nicolas
Serrano

ANNOUNCEMENT BY THE ACTING CHAIR

The Acting CHAIR (during the vote). There is 1 minute remaining.

□ 1328

Mr. WALBERG changed his vote from ''no'' to ''aye.''

So the amendment was agreed to.

The result of the vote was announced as above recorded.

AMENDMENT NO. 10 OFFERED BY MRS. LURIA

The Acting CHAIR. The unfinished business is the demand for a recorded vote on the amendment offered by the gentlewoman from Virginia (Mrs. LURIA) on which further proceedings were postponed and on which the ayes prevailed by voice vote.

The Clerk will redesignate the amendment.

The Clerk redesignated the amendment.

RECORDED VOTE

The Acting CHAIR. A recorded vote has been demanded.

A recorded vote was ordered.

The Acting CHAIR. This will be a 2-minute vote.

The vote was taken by electronic device, and there were—ayes 231, noes 192, not voting 13, as follows:

[Roll No. 679]

AYES—231

Adams
Aguilar
Allred
Axne
Barragán
Bass
Beatty
Bera
Beyer
Bishop (GA)
Blumenauer
Blunt Rochester
Bonamici
Boyle, Brendan F.
Brindisi
Brown (MD)
Brownley (CA)
Bustos
Butterfield
Carbajal
Cárdenas
Carson (IN)
Cartwright
Case
Casten (IL)
Castor (FL)
Castro (TX)
Chu, Judy
Cicilline
Cisneros
Clark (MA)
Clarke (NY)
Clay
Cleaver
Clyburn
Cohen
Connolly
Cooper
Correa
Costa
Courtney
Cox (CA)
Craig
Crist
Crow
Cuellar
Cunningham
Davids (KS)
Davis (CA)
Davis, Danny K.
Dean
DeFazio
DeGette
DeLauro
DelBene
Delgado
Demings
DeSaulnier
Deutch
Dingell
Doggett
Doyle, Michael F.
Engel
Escobar
Eshoo
Espaillat
Evans
Finkenauer
Fitzpatrick
Fletcher
Fortenberry
Foster
Frankel
Fudge
Gallego
Garamendi
García (IL)
Garcia (TX)
Golden
Gomez
Gonzalez (TX)
Gottheimer
Green, Al (TX)
Grijalva
Haaland
Harder (CA)
Hastings
Hayes
Heck
Higgins (NY)
Himes
Horn, Kendra S.
Horsford
Houlahan
Hoyer
Huffman
Jackson Lee
Jayapal
Jeffries
Johnson (GA)
Johnson (TX)
Kaptur
Keating
Kelly (IL)
Kennedy
Khanna
Kildee
Kilmer
Kim
Kind
Kirkpatrick
Krishnamoorthi
Kuster (NH)
Lamb
Langevin
Larsen (WA)
Larson (CT)
Lawrence
Lawson (FL)
Lee (CA)
Lee (NV)
Levin (CA)
Levin (MI)
Lipinski
Loebsack
Lofgren
Lowenthal
Lowey
Luján
Luria
Lynch
Maloney, Carolyn B.
Maloney, Sean
Matsui
McAdams
McBath
McCollum
McEachin
McGovern
McNerney
Meng
Moore
Morelle
Moulton
Mucarsel-Powell
Murphy (FL)
Nadler
Napolitano
Neal
Neguse
Norcross
Norton
O'Halleran
Ocasio-Cortez
Omar
Pallone
Panetta
Pappas
Pascrell
Payne
Perlmutter
Perry
Peters
Peterson
Phillips
Pingree
Plaskett
Pocan
Porter
Pressley
Price (NC)
Quigley
Raskin
Rice (NY)
Richmond
Rose (NY)
Rouda
Roybal-Allard
Ruiz
Ruppersberger
Rush
Ryan
Sánchez
Sarbanes
Scanlon
Schakowsky
Schiff
Schneider
Schrader
Schrier
Scott (VA)
Scott, David
Sewell (AL)
Shalala
Sherman
Sherrill
Sires
Slotkin
Smith (WA)
Soto
Spanberger
Speier
Stanton
Stevens

Suozzi
Swalwell (CA)
Takano
Thompson (CA)
Thompson (MS)
Titus
Tlaib
Tonko
Torres (CA)
Torres Small (NM)
Trahan
Trone
Underwood
Van Drew
Vargas
Veasey
Vela
Velázquez
Visclosky
Wasserman Schultz
Waters
Watson Coleman
Welch
Wexton
Wild
Wilson (FL)
Yarmuth

NOES—192

Abraham
Aderholt
Allen
Amash
Amodei
Armstrong
Arrington
Babin
Bacon
Baird
Balderson
Banks
Barr
Bergman
Biggs
Bilirakis
Bishop (NC)
Bishop (UT)
Bost
Brady
Brooks (AL)
Brooks (IN)
Buchanan
Buck
Bucshon
Budd
Burgess
Byrne
Calvert
Carter (GA)
Carter (TX)
Chabot
Cheney
Cline
Cloud
Cole
Collins (GA)
Comer
Conaway
Cook
Crawford
Crenshaw
Curtis
Davidson (OH)
Davis, Rodney
DesJarlais
Diaz-Balart
Duncan
Dunn
Emmer
Estes
Ferguson
Fleischmann
Flores
Foxx (NC)
Fulcher
Gaetz
Gallagher
Gianforte
Gibbs
Gohmert
Gonzalez (OH)
González-Colón (PR)
Gooden
Granger
Graves (GA)
Graves (LA)
Graves (MO)
Green (TN)
Griffith
Grothman
Guest
Guthrie
Hagedorn
Harris
Hartzler
Hern, Kevin
Herrera Beutler
Hice (GA)
Higgins (LA)
Hill (AR)
Holding
Hollingsworth
Hudson
Huizenga
Hurd (TX)
Johnson (LA)
Johnson (OH)
Johnson (SD)
Jordan
Joyce (OH)
Joyce (PA)
Katko
Keller
Kelly (MS)
Kelly (PA)
King (IA)
Kinzinger
Kustoff (TN)
LaHood
LaMalfa
Lamborn
Latta
Lesko
Long
Loudermilk
Lucas
Luetkemeyer
Marchant
Marshall
Massie
Mast
McCarthy
McCaul
McClintock
McHenry
McKinley
Meadows
Meuser
Miller
Mitchell
Moolenaar
Mooney (WV)
Mullin
Murphy (NC)
Newhouse
Norman
Nunes
Olson
Palazzo
Palmer
Pence
Posey
Radewagen
Ratcliffe
Reed
Reschenthaler
Rice (SC)
Riggleman
Roby
Rodgers (WA)
Roe, David P.
Rogers (AL)
Rogers (KY)
Rose, John W.
Rouzer
Roy
Rutherford
Scalise
Schweikert
Scott, Austin
Sensenbrenner
Shimkus
Simpson
Smith (MO)
Smith (NE)
Smith (NJ)
Smucker
Spano
Stauber
Stefanik
Steil
Steube
Stewart
Stivers
Taylor
Thompson (PA)
Thornberry
Timmons
Tipton
Turner
Upton
Wagner
Walberg
Walden
Walker
Walorski
Waltz
Watkins
Weber (TX)
Webster (FL)
Wenstrup
Westerman
Williams
Wilson (SC)
Wittman
Womack
Woodall
Wright
Yoho
Young
Zeldin

NOT VOTING—13

Burchett
Gabbard
Gosar
Hunter
King (NY)
Lewis
Lieu, Ted
Malinowski
Meeks
Rooney (FL)
Sablan
San Nicolas
Serrano

ANNOUNCEMENT BY THE ACTING CHAIR

The Acting CHAIR (during the vote). There is 1 minute remaining.

□ 1332

So the amendment was agreed to.

The result of the vote was announced as above recorded.

AMENDMENT NO. 11 OFFERED BY MR. CUNNINGHAM

The Acting CHAIR. The unfinished business is the demand for a recorded vote on the amendment offered by the gentleman from South Carolina (Mr. CUNNINGHAM) on which further proceedings were postponed and on which the ayes prevailed by voice vote.

The Clerk will redesignate the amendment.

The Clerk redesignated the amendment.

RECORDED VOTE

The Acting CHAIR. A recorded vote has been demanded.

A recorded vote was ordered.

The Acting CHAIR. This is a 2-minute vote.

The vote was taken by electronic device, and there were—ayes 234, noes 192, not voting 10, as follows:

[Roll No. 680]

AYES—234

Adams
Aguilar
Allred
Axne
Barragán
Bass
Beatty
Bera
Beyer
Bishop (GA)
Blumenauer
Blunt Rochester
Bonamici
Boyle, Brendan F.
Brindisi
Brown (MD)
Brownley (CA)
Bustos
Butterfield
Carbajal
Cárdenas
Carson (IN)
Cartwright
Case
Casten (IL)
Castor (FL)
Castro (TX)
Chu, Judy
Cicilline
Cisneros
Clark (MA)
Clarke (NY)
Clay
Cleaver
Clyburn
Cohen
Connolly
Cooper
Correa
Costa
Courtney
Cox (CA)
Craig
Crist
Crow
Cuellar
Cunningham
Davids (KS)
Davis (CA)
Davis, Danny K.
Davis, Rodney
Dean
DeFazio
DeGette
DeLauro
DelBene
Delgado
Demings
DeSaulnier
Deutch
Dingell
Doggett
Doyle, Michael F.
Engel
Escobar
Eshoo
Espaillat
Evans
Finkenauer
Fitzpatrick
Fletcher
Fortenberry
Foster
Frankel
Fudge
Gallego
Garamendi
García (IL)
Garcia (TX)
Golden
Gomez
Gonzalez (TX)
Gottheimer
Green, Al (TX)
Grijalva
Haaland
Harder (CA)
Hastings
Hayes
Heck
Higgins (NY)
Himes
Horn, Kendra S.
Horsford
Houlahan
Hoyer
Huffman
Jackson Lee
Jayapal
Jeffries
Johnson (GA)
Johnson (TX)
Kaptur
Katko
Keating
Kelly (IL)
Kennedy
Khanna
Kildee
Kilmer
Kim
Kind
Kirkpatrick
Krishnamoorthi
Kuster (NH)
Lamb
Langevin
Larsen (WA)
Larson (CT)
Lawrence
Lawson (FL)
Lee (CA)
Lee (NV)
Levin (CA)
Levin (MI)
Lipinski
Loebsack
Lofgren
Lowenthal
Lowey
Luján
Luria
Lynch
Malinowski
Maloney, Carolyn B.
Maloney, Sean
Matsui
McAdams
McBath
McCollum
McEachin
McGovern
McNerney
Meeks
Meng
Moore
Morelle
Moulton
Mucarsel-Powell
Murphy (FL)
Nadler
Napolitano
Neal
Neguse
Norcross
Norton
O'Halleran
Ocasio-Cortez
Omar
Pallone
Panetta
Pappas
Pascrell
Payne
Perlmutter
Peters
Peterson
Phillips
Pingree
Plaskett
Pocan
Porter
Pressley
Price (NC)
Quigley
Raskin
Rice (NY)
Richmond
Rose (NY)
Rouda
Roybal-Allard
Ruiz
Ruppersberger
Rush
Ryan
Sánchez
Sarbanes
Scanlon
Schakowsky
Schiff
Schneider
Schrader
Schrier
Scott (VA)
Scott, David
Sewell (AL)
Shalala
Sherman
Sherrill
Sires
Slotkin
Smith (WA)
Soto
Spanberger
Speier
Stanton
Stevens
Suozzi
Swalwell (CA)
Takano
Thompson (CA)
Thompson (MS)
Titus
Tlaib
Tonko
Torres (CA)
Torres Small (NM)
Trahan
Trone
Underwood
Van Drew
Vargas
Veasey
Vela
Velázquez
Visclosky
Wasserman Schultz
Waters
Watson Coleman
Welch
Wexton
Wild
Wilson (FL)
Yarmuth

NOES—192

Abraham
Aderholt
Allen
Amash
Amodei
Armstrong
Arrington
Babin
Bacon
Baird
Balderson
Banks
Barr
Bergman
Biggs
Bilirakis
Bishop (NC)
Bishop (UT)
Bost
Brady
Brooks (AL)
Brooks (IN)
Buchanan
Buck
Bucshon
Budd
Burgess
Byrne
Calvert
Carter (GA)
Carter (TX)
Chabot
Cheney
Cline
Cloud
Cole
Collins (GA)
Comer
Conaway
Cook
Crawford
Crenshaw
Curtis
Davidson (OH)
DesJarlais
Diaz-Balart
Duncan
Dunn
Emmer
Estes
Ferguson
Fleischmann
Flores
Foxx (NC)
Fulcher
Gaetz
Gallagher
Gianforte
Gibbs
Gohmert
Gonzalez (OH)
González-Colón (PR)
Gooden
Granger
Graves (GA)
Graves (LA)
Graves (MO)
Green (TN)
Griffith
Grothman
Guest
Guthrie
Hagedorn
Harris
Hartzler
Hern, Kevin
Herrera Beutler
Hice (GA)
Higgins (LA)
Hill (AR)
Holding
Hollingsworth
Hudson
Huizenga
Hurd (TX)
Johnson (LA)
Johnson (OH)
Johnson (SD)
Jordan
Joyce (OH)
Joyce (PA)
Keller
Kelly (MS)
Kelly (PA)
King (IA)
King (NY)
Kinzinger
Kustoff (TN)
LaHood
LaMalfa
Lamborn
Latta
Lesko
Long
Loudermilk
Lucas
Luetkemeyer
Marchant
Marshall
Massie
Mast
McCarthy
McCaul
McClintock
McHenry
McKinley
Meadows
Meuser
Miller
Mitchell
Moolenaar
Mooney (WV)
Mullin
Murphy (NC)
Newhouse
Norman
Nunes
Olson
Palazzo
Palmer
Pence
Perry
Posey
Radewagen
Ratcliffe
Reed
Reschenthaler
Rice (SC)
Riggleman
Roby
Rodgers (WA)
Roe, David P.
Rogers (AL)
Rogers (KY)
Rose, John W.
Rouzer
Roy
Rutherford
Scalise
Schweikert
Scott, Austin
Sensenbrenner
Shimkus
Simpson
Smith (MO)
Smith (NE)
Smith (NJ)
Smucker
Spano
Stauber
Stefanik
Steil
Steube
Stewart
Stivers
Taylor
Thompson (PA)
Thornberry
Timmons
Tipton
Turner
Upton
Wagner
Walberg
Walden
Walker
Walorski
Waltz
Watkins
Weber (TX)
Webster (FL)
Wenstrup
Westerman
Williams
Wilson (SC)
Wittman
Womack
Woodall
Wright
Yoho
Young
Zeldin

NOT VOTING—10

Burchett
Gabbard
Gosar
Hunter
Lewis
Lieu, Ted
Rooney (FL)
Sablan
San Nicolas
Serrano

ANNOUNCEMENT BY THE ACTING CHAIR

The Acting CHAIR (during the vote). There is 1 minute remaining.

□ 1339

So the amendment was agreed to.

The result of the vote was announced as above recorded.

The Acting CHAIR (Mr. PAYNE). There being no further amendments, under the rule, the committee rises.

Accordingly, the Committee rose; and the Speaker pro tempore (Mr. MCGOVERN) having assumed the chair,

Mr. PAYNE, Acting Chair of the Committee of the Whole House on the state of the Union, reported that that Committee, having had under consideration the bill (H.R. 3) to establish a fair price negotiation program, protect the Medicare program from excessive price increases, and establish an out-of-pocket maximum for Medicare part D enrollees, and for other purposes, and, pursuant to House Resolution 758, he reported the bill, as amended by that resolution, back to the House with sundry further amendments adopted in the Committee of the Whole.

The SPEAKER pro tempore. Under the rule, the previous question is ordered.

Is a separate vote demanded on any amendment reported from the Committee of the Whole? If not, the Chair will put them en gros.

The amendments were agreed to.

The SPEAKER pro tempore. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time, and was read the third time.

MOTION TO RECOMMIT

Mr. UPTON. Mr. Speaker, I have a motion to recommit at the desk.

The SPEAKER pro tempore. Is the gentleman opposed to the bill?

Mr. UPTON. I am in its current form.

The SPEAKER pro tempore. The Clerk will report the motion to recommit.

The Clerk read as follows:

Mr. Upton moves to recommit the bill H.R. 3 to the Committee on Energy and Commerce with instructions to report the same back to the House forthwith with the following amendment:

At the end of title VIII, insert the following new section (and update the table of sections accordingly):

SEC. _____. EFFECTIVE DATE CONDITIONED ON CERTIFICATION.

Notwithstanding any other provision of this Act, none of the provisions of this Act shall go into effect unless the Secretary of Health and Human Services certifies that the implementation of such provisions are not projected to result in fewer new drug applications with respect to unmet medical needs and life saving cures.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Michigan is recognized for 5 minutes in support of his motion.

Mr. UPTON. Mr. Speaker, here is the beef: Tomorrow marks the third anniversary of the enactment of 21st Century Cures, a bill that passed this House at 392–26. In looking back at that legislation now, 3 years later, we have made wonderful strides in finding the cures for the diseases that have impacted every family, be it cystic fibrosis, Alzheimer's and pancreatic cancer, just to name a few.

And just last week, a number of us met with a young girl who had been in a trial for SMA. That is often a fatal disease known as spinal muscular atrophy. She was in a wheelchair, barely able to talk. But after 15 days on this trial, she could actually move her head and her neck for the first time in more than a decade, all really because of what we did on 21st Century Cures.

The CBO/CEA and Scott Gottlieb, in today's ''Wall Street Journal'' writes that H.R. 3, the underlying bill: ''The price-control approach would increase uncertainty and reduce returns from biotech investment, raising the cost of capital for these invaluable endeavors.''

You know, we are on the cusp of gene therapy for deadly inherited diseases like MS, literally, finding cures to solve blindness. But let's not stop. Let's build on what we did.

The language in this motion to recommit assures that cures will not be slowed down, because we have the requirement that unless the Secretary of HHS certifies the implementation of such provisions are not projected to result in fewer new drug applications. That is what this amendment is about.

We want to make sure that we have the resources to develop the cures that all of us want for the thousands of diseases where we don't have a cure.

Mr. Speaker, I would yield to the gentleman from Texas to talk about his personal story, that many of us did not know until this bill came up in the last couple of days.

Mr. Speaker, I yield to the gentleman from Texas (Mr. WRIGHT).

Mr. WRIGHT. Mr. Speaker, I rise today in staunch opposition to H.R. 3.

I can add to what my colleagues have said with statistics and legalese, but I would rather offer you my personal experience.

I was diagnosed with Stage 4 lung cancer. I was told that the average life expectancy was 16 months. That was 16 months ago. By the grace of Almighty God and American biotech ingenuity, I am still here, and I will get to spend another Christmas with my family.

I was prescribed a rigorous regimen of chemotherapy and an immunotherapy wonder-drug called Keytruda, which had only just been approved for my regimen in May of 2017. Keytruda's discovery is as a result of significant financial investment by the private sector, not the government. Today, I feel great. My last CAT scan showed nothing in my liver and lymph nodes, and the primary tumor had shrunk to about the size of a raisin.

Now, 5 years ago, my diagnosis would have been a death sentence. Today, I am beating it. Millions of Americans are diagnosed with life-threatening illnesses every year. And thanks to medical innovation in the United States, miraculous outcomes like mine are not uncommon either.

If H.R. 3 becomes law, stories like mine would be rare. If these socialist policies had been implemented earlier, I probably would not be here. For too many in this Chamber, this has become part of their political agenda, but for me and millions of Americans, this is a matter of life or death.

H.R. 3 will not save American lives. It will end them. I urge my colleagues to think of their loved ones who will face deadly diseases in the future. Many cures are on the horizon. We cannot stop. We cannot slow down. We cannot stifle research and development of new cures by onerous government control. Too many lives hang in the balance.

Mr. Speaker, I beg my colleagues to support this motion to recommit, and let's take action that will actually save lives.

Mr. UPTON. Mr. Speaker, I yield back the balance of my time.

Ms. SCHRIER. Mr. Speaker, I rise in opposition to the motion.

The SPEAKER pro tempore. The gentlewoman from Washington is recognized for 5 minutes

Ms. SCHRIER. Mr. Speaker, I am so glad that my colleague from Texas, Mr. WRIGHT, is well and I am so glad that he could afford the treatment that he needed.

But we have people suffering from the cost of prescription drugs now, and intentionally holding up this bill hurts them. We absolutely must remain the leader in the world in innovation, but the thing is, we can reduce drug prices and still have money for research.

The money U.S.-based drug companies made in 2015 by charging Americans high prices was nearly double what was needed to fund their global R&D. An H.R. 3 uses the savings to reinvest billions in the research and clinical trials needed to get cures faster.

I am so excited about H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. I am the first pediatrician ever elected to Congress, and currently the only female doctor here. I am also a patient with type 1 diabetes. My life depends on insulin, so the high cost of prescription drugs affects me and people like me every day.

I have driven over 7,000 miles this year traversing my district talking to people about what matters to them. And you know what the biggest thing is? The cost of prescription drugs. Because it doesn't matter if you are a Democrat or Republican if you cannot afford your medication.

I understand this issue both as a doctor and a patient, because it is not theoretical for me or for my patients. When we talk about the cost of insulin, I have felt that personally. I have seen the price of my insulin go from $40 a bottle to $300. That is the price for a bottle that holds 10 milliliters, 2 teaspoons.

Before being elected to Congress, I worked for nearly 20 years as a pediatrician in the suburbs of Seattle, just 3 hours from the Canadian border. Mostly, I sent electronic prescriptions, but when patients asked for paper ones, I knew it was because they were going to Canada to fill it. EpiPens are $600 here; $50 there. In Canada, insulin costs $50.

Right now, we pay three to four times what our colleagues overseas pay, and that is why we must use the negotiating power of Medicare to bring prices down. Our districts are alike.

And we need to take on this out-of-control pricing. The people who sent us here asked us to do it. Let's deliver today. I encourage my colleagues to vote ''no'' on this MTR and ''yes'' on H.R. 3.

Mr. Speaker, I yield to the gentlewoman from Delaware (Ms. BLUNT ROCHESTER), my colleague, a champion of this bill.

Ms. BLUNT ROCHESTER. Mr. Speaker, I thank the gentlewoman for yielding.

I respect my Committee on Energy and Commerce colleagues, but I cannot support this motion to recommit. What we have today is an opportunity to live up to our promise.

Democrats promised.

Republicans promised.

Even the President promised to lower prescription drug costs.

Let's not get this confused or mixed up. Colleagues, I want to just make it plain: The Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, is about three things: Fairness, hope, and legacy.

Fairness: Is it fair that the United States pays 2, 3, or 60 times more for the same drug as other countries?

Is it fair that in a capitalist country our government can't negotiate? We can negotiate for planes, but we can't negotiate for insulin?

The Congressional Budget Office says that H.R. 3 will lower out-of-pocket costs and premiums for those on Medicare and it will reduce premiums for 180 million Americans who have private insurance. American households will save $120 billion over 10 years.

Let me put it another way: These same Americans will see their cash wages increase by $116 billion. It is about fairness. H.R. 3 is about hope.

As AARP has shared, it gives seniors hope that with savings from this bill, we will modernize and expand Medicare and cap part D out-of-pocket costs. The $2,000 cap could be the difference between a lifesaving pill and somebody's rent.

Hope: With the savings generated from this bill, we can expand Medicare coverage to include hearing, vision, and dental.

Hope: We can accelerate the great American tradition of innovative research for scientific breakthroughs and cures for the National Institutes of Health.

And with H.R. 3, we will provide patients like David Mitchell, who testified before our committee about his personal experience with cancer. And what he said is that it taught him something: Drugs don't work if people can't afford them. In other words, if you can't afford it, you don't have it.

So, lastly, this will provide us a legacy.

Ms. SCHRIER. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. Without objection, the previous question is ordered on the motion to recommit.

There was no objection.

The SPEAKER pro tempore. The question is on the motion to recommit.

The question was taken; and the Speaker pro tempore announced that the noes appeared to have it.

Mr. UPTON. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 9 of rule XX, the Chair will reduce to 5 minutes the minimum time for any electronic vote on the question of passage.

The vote was taken by electronic device, and there were—yeas 196, nays 226, not voting 8, as follows:

[Roll No. 681]

YEAS—196

Abraham
Aderholt
Allen
Amodei
Armstrong
Arrington
Babin
Bacon
Baird
Balderson
Banks
Barr
Bergman
Biggs
Bilirakis
Bishop (NC)
Bishop (UT)
Bost
Brady
Brooks (AL)
Brooks (IN)
Buchanan
Buck
Bucshon
Budd
Burgess
Byrne
Calvert
Carter (GA)
Carter (TX)
Chabot
Cheney
Cline
Cloud
Cole
Collins (GA)
Comer
Conaway
Cook
Crawford
Crenshaw
Curtis
Davidson (OH)
Davis, Rodney
DesJarlais
Diaz-Balart
Duncan
Dunn
Emmer
Estes
Ferguson
Fitzpatrick
Fleischmann
Flores
Fortenberry
Foxx (NC)
Fulcher
Gaetz
Gallagher
Gianforte
Gibbs
Gohmert
Gonzalez (OH)
Gooden
Gottheimer
Granger
Graves (GA)
Graves (LA)
Graves (MO)
Green (TN)
Griffith
Grothman
Guest
Guthrie
Hagedorn
Harris
Hartzler
Hern, Kevin
Herrera Beutler
Hice (GA)
Higgins (LA)
Hill (AR)
Holding
Hollingsworth
Hudson
Huizenga
Hurd (TX)
Johnson (LA)
Johnson (OH)
Johnson (SD)
Jordan
Joyce (OH)
Joyce (PA)
Katko
Keller
Kelly (MS)
Kelly (PA)
King (IA)
King (NY)
Kinzinger
Kustoff (TN)
LaHood
LaMalfa
Lamborn
Latta
Lesko
Long
Loudermilk
Lucas
Luetkemeyer
Marchant
Marshall
Massie
Mast
McAdams
McCarthy
McCaul
McClintock
McHenry
McKinley
Meadows
Meuser
Miller
Mitchell
Moolenaar
Mooney (WV)
Mullin
Murphy (NC)
Newhouse
Norman
Nunes
Olson
Palazzo
Palmer
Pence
Perry
Posey
Ratcliffe
Reed
Reschenthaler
Rice (SC)
Riggleman
Roby
Rodgers (WA)
Roe, David P.
Rogers (AL)
Rogers (KY)
Rose, John W.
Rouzer
Roy
Rutherford
Scalise
Schweikert
Scott, Austin
Sensenbrenner
Sherrill
Shimkus
Simpson
Smith (MO)
Smith (NE)
Smith (NJ)
Smucker
Spano
Stauber
Stefanik
Steil
Steube
Stewart
Stivers
Taylor
Thompson (PA)
Thornberry
Timmons
Tipton
Turner
Upton
Wagner
Walberg
Walden
Walker
Walorski
Waltz
Watkins
Weber (TX)
Webster (FL)
Wenstrup
Westerman
Williams
Wilson (SC)
Wittman
Womack
Woodall
Wright
Yoho
Young
Zeldin

NAYS—226

Adams
Aguilar
Allred
Amash
Axne
Barragán
Bass
Beatty
Bera
Beyer
Bishop (GA)
Blumenauer
Blunt Rochester
Bonamici
Boyle, Brendan F.
Brindisi
Brown (MD)
Brownley (CA)
Bustos
Butterfield
Carbajal
Cárdenas
Carson (IN)
Cartwright
Case
Casten (IL)
Castor (FL)
Castro (TX)
Chu, Judy
Cicilline
Cisneros
Clark (MA)
Clarke (NY)
Clay
Cleaver
Clyburn
Cohen
Connolly
Cooper
Correa
Costa
Courtney
Cox (CA)
Craig
Crist
Crow
Cuellar
Cunningham
Davids (KS)
Davis (CA)
Davis, Danny K.
Dean
DeFazio
DeGette
DeLauro
DelBene
Delgado
Demings
DeSaulnier
Deutch
Dingell
Doggett
Doyle, Michael F.
Engel
Escobar
Eshoo
Espaillat
Evans
Finkenauer
Fletcher
Foster
Frankel
Fudge
Gallego
Garamendi
García (IL)
Garcia (TX)
Golden
Gomez
Gonzalez (TX)
Green, Al (TX)
Grijalva
Haaland
Harder (CA)
Hastings
Hayes
Heck
Higgins (NY)
Himes
Horn, Kendra S.
Horsford
Houlahan
Hoyer
Huffman
Jackson Lee
Jayapal
Jeffries
Johnson (GA)
Johnson (TX)
Kaptur
Keating
Kelly (IL)
Kennedy
Khanna
Kildee
Kilmer
Kim
Kind
Kirkpatrick
Krishnamoorthi
Kuster (NH)
Lamb
Langevin
Larsen (WA)
Larson (CT)
Lawrence
Lawson (FL)
Lee (CA)
Lee (NV)
Levin (CA)
Levin (MI)
Lipinski
Loebsack
Lofgren
Lowenthal
Lowey
Luján
Luria
Lynch
Malinowski
Maloney, Carolyn B.
Maloney, Sean
Matsui
McBath
McCollum
McEachin
McGovern
McNerney
Meeks
Meng
Moore
Morelle
Moulton
Mucarsel-Powell
Murphy (FL)
Nadler
Napolitano
Neal
Neguse
Norcross
O'Halleran
Ocasio-Cortez
Omar
Pallone
Panetta
Pappas
Pascrell
Payne
Perlmutter
Peters
Peterson
Phillips
Pingree
Pocan
Porter
Pressley
Price (NC)
Quigley
Raskin
Rice (NY)
Richmond
Rose (NY)
Rouda
Roybal-Allard
Ruiz
Ruppersberger
Rush
Ryan
Sánchez
Sarbanes
Scanlon
Schakowsky
Schiff
Schneider
Schrader
Schrier
Scott (VA)
Scott, David
Sewell (AL)
Shalala
Sherman
Sires
Slotkin
Smith (WA)
Soto
Spanberger
Speier
Stanton
Stevens
Suozzi
Swalwell (CA)
Takano
Thompson (CA)
Thompson (MS)
Titus
Tlaib
Tonko
Torres (CA)
Torres Small (NM)
Trahan
Trone
Underwood
Van Drew
Vargas
Veasey
Vela
Velázquez
Visclosky
Wasserman Schultz
Waters
Watson Coleman
Welch
Wexton
Wild
Wilson (FL)
Yarmuth

NOT VOTING—8

Burchett
Gabbard
Gosar
Hunter
Lewis
Lieu, Ted
Rooney (FL)
Serrano

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). There are 2 minutes remaining.

□ 1401

Mrs. DEMINGS changed her vote from ''yea'' to ''nay.''

So the motion to recommit was rejected.

The result of the vote was announced as above recorded.

The SPEAKER pro tempore. The question is on the passage of the bill.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. WALDEN. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore (Ms. CRAIG). This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 230, nays 192, not voting 8, as follows:

[Roll No. 682]

YEAS—230

Adams
Aguilar
Allred
Axne
Barragán
Bass
Beatty
Bera
Beyer
Bishop (GA)
Blumenauer
Blunt Rochester
Bonamici
Boyle, Brendan F.
Brindisi
Brown (MD)
Brownley (CA)
Bustos
Butterfield
Carbajal
Cárdenas
Carson (IN)
Cartwright
Case
Casten (IL)
Castor (FL)
Castro (TX)
Chu, Judy
Cicilline
Cisneros
Clark (MA)
Clarke (NY)
Clay
Cleaver
Clyburn
Cohen
Connolly
Cooper
Correa
Costa
Courtney
Cox (CA)
Craig
Crist
Crow
Cuellar
Cunningham
Davids (KS)
Davis (CA)
Davis, Danny K.
Dean
DeFazio
DeGette
DeLauro
DelBene
Delgado
Demings
DeSaulnier
Deutch
Dingell
Doggett
Doyle, Michael F.
Engel
Escobar
Eshoo
Espaillat
Evans
Finkenauer
Fitzpatrick
Fletcher
Foster
Frankel
Fudge
Gallego
Garamendi
García (IL)
Garcia (TX)
Golden
Gomez
Gonzalez (TX)
Gottheimer
Green, Al (TX)
Grijalva
Haaland
Harder (CA)
Hastings
Hayes
Heck
Herrera Beutler
Higgins (NY)
Himes
Horn, Kendra S.
Horsford
Houlahan
Hoyer
Huffman
Jackson Lee
Jayapal
Jeffries
Johnson (GA)
Johnson (TX)
Kaptur
Keating
Kelly (IL)
Kennedy
Khanna
Kildee
Kilmer
Kim
Kind
Kirkpatrick
Krishnamoorthi
Kuster (NH)
Lamb
Langevin
Larsen (WA)
Larson (CT)
Lawrence
Lawson (FL)
Lee (CA)
Lee (NV)
Levin (CA)
Levin (MI)
Lipinski
Loebsack
Lofgren
Lowenthal
Lowey
Luján
Luria
Lynch
Malinowski
Maloney, Carolyn B.
Maloney, Sean
Matsui
McAdams
McBath
McCollum
McEachin
McGovern
McNerney
Meeks
Meng
Moore
Morelle
Moulton
Mucarsel-Powell
Murphy (FL)
Nadler
Napolitano
Neal
Neguse
Norcross
O'Halleran
Ocasio-Cortez
Omar
Pallone
Panetta
Pappas
Pascrell
Payne
Perlmutter
Peters
Peterson
Phillips
Pingree
Pocan
Porter
Pressley
Price (NC)
Quigley
Raskin
Rice (NY)
Richmond
Rose (NY)
Rouda
Roybal-Allard
Ruiz
Ruppersberger
Rush
Ryan
Sánchez
Sarbanes
Scanlon
Schakowsky
Schiff
Schneider
Schrader
Schrier
Scott (VA)
Scott, David
Sewell (AL)
Shalala
Sherman
Sherrill
Sires
Slotkin
Smith (WA)
Soto
Spanberger
Speier
Stanton
Stevens
Suozzi
Swalwell (CA)
Takano
Thompson (CA)
Thompson (MS)
Titus
Tlaib
Tonko
Torres (CA)
Torres Small (NM)
Trahan
Trone
Underwood
Van Drew
Vargas
Veasey
Vela
Velázquez
Visclosky
Wasserman Schultz
Waters
Watson Coleman
Welch
Wexton
Wild
Wilson (FL)
Yarmuth

NAYS—192

Abraham
Aderholt
Allen
Amash
Amodei
Armstrong
Arrington
Babin
Bacon
Baird
Balderson
Banks
Barr
Bergman
Biggs
Bilirakis
Bishop (NC)
Bishop (UT)
Bost
Brady
Brooks (AL)
Brooks (IN)
Buchanan
Buck
Bucshon
Budd
Burgess
Byrne
Calvert
Carter (GA)
Carter (TX)
Chabot
Cheney
Cline
Cloud
Cole
Collins (GA)
Comer
Conaway
Cook
Crawford
Crenshaw
Curtis
Davidson (OH)
Davis, Rodney
DesJarlais
Diaz-Balart
Duncan
Dunn
Emmer
Estes
Ferguson
Fleischmann
Flores
Fortenberry
Foxx (NC)
Fulcher
Gaetz
Gallagher
Gianforte
Gibbs
Gohmert
Gonzalez (OH)
Gooden
Granger
Graves (GA)
Graves (LA)
Graves (MO)
Green (TN)
Griffith
Grothman
Guest
Guthrie
Hagedorn
Harris
Hartzler
Hern, Kevin
Hice (GA)
Higgins (LA)
Hill (AR)
Holding
Hollingsworth
Hudson
Huizenga
Hurd (TX)
Johnson (LA)
Johnson (OH)
Johnson (SD)
Jordan
Joyce (OH)
Joyce (PA)
Katko
Keller
Kelly (MS)
Kelly (PA)
King (IA)
King (NY)
Kinzinger
Kustoff (TN)
LaHood
LaMalfa
Lamborn
Latta
Lesko
Long
Loudermilk
Lucas
Luetkemeyer
Marchant
Marshall
Massie
Mast
McCarthy
McCaul
McClintock
McHenry
McKinley
Meadows
Meuser
Miller
Mitchell
Moolenaar
Mooney (WV)
Mullin
Murphy (NC)
Newhouse
Norman
Nunes
Olson
Palazzo
Palmer
Pence
Perry
Posey
Ratcliffe
Reed
Reschenthaler
Rice (SC)
Riggleman
Roby
Rodgers (WA)
Roe, David P.
Rogers (AL)
Rogers (KY)
Rose, John W.
Rouzer
Roy
Rutherford
Scalise
Schweikert
Scott, Austin
Sensenbrenner
Shimkus
Simpson
Smith (MO)
Smith (NE)
Smith (NJ)
Smucker
Spano
Stauber
Stefanik
Steil
Steube
Stewart
Stivers
Taylor
Thompson (PA)
Thornberry
Timmons
Tipton
Turner
Upton
Wagner
Walberg
Walden
Walker
Walorski
Waltz
Watkins
Weber (TX)
Webster (FL)
Wenstrup
Westerman
Williams
Wilson (SC)
Wittman
Womack
Woodall
Wright
Yoho
Young
Zeldin

NOT VOTING—8

Burchett
Gabbard
Gosar
Hunter
Lewis
Lieu, Ted
Rooney (FL)
Serrano

□ 1408

So the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

MOMENT OF SILENCE MOURNING THOSE KILLED IN TERRORIST ATTACK AT NAVAL AIR STATION PENSACOLA ON DECEMBER 6, 2019

(Mr. GAETZ asked and was given permission to address the House for 1 minute.)

Mr. GAETZ. Mr. Speaker, I am joined here with members of the Florida, Georgia, and Alabama delegations because on December 6, in the early hours of the day, our Nation learned of a terrorist attack unfolding at Naval Air Station Pensacola. The attack took the lives of Ensign Joshua Kaleb Watson of Coffee County, Alabama; Airman Mohammed Sameh Haitham of St. Petersburg, Florida; and Airman Apprentice Cameron Scott Walters of Richmond Hill, Georgia.

We congregate here today to honor the memory of those who lost their lives and those who were wounded during the course of this egregious attack.

Those who wear the uniform inspire the best within us because they are truly the best among us. They are our sons and daughters, our fathers and mothers. Last Friday, three of them were taken from us, and we shall not forget their names, or those who have been impacted by that terrible attack.

I request all present, both on the floor and in the gallery, to rise for a moment of silence; and I am proud and honored to be joined by my colleagues.

□ 1415

LEGISLATIVE PROGRAM

(Mr. SCALISE asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. SCALISE. Mr. Speaker, I rise for the purpose of inquiring of the majority leader the schedule for next week. I yield to the gentleman from Maryland (Mr. HOYER), my friend.

Mr. HOYER. Mr. Speaker, I thank the gentleman for yielding.

Mr. Speaker, on Monday, the House will meet at noon for morning-hour debate and 2 p.m. for legislative business. Members are advised that no votes are expected in the House on Monday. Again, no votes on Monday, but we will do legislative business. We will be debating suspension bills, and the votes will be rolled until the following day.

On Tuesday, Wednesday, Thursday, and Friday, the House will meet at 9 a.m. for legislative business. Let me stress that so that every Member understands. We normally go in at noon for a schedule like this on Tuesday, Wednesday, and Thursday, but we will be going in at 9 a.m. on those days, as well as Friday.

Members are advised that the first votes of the week on Tuesday are expected between 9 and 10. Again, I want to emphasize that, although we do not have any votes on Monday night, we expect Tuesday to be a full workday, so Members really ought to come into town on Monday.

We will consider several bills, Mr. Speaker, under suspension of the rules. The complete list of suspensions will be announced by the close of business tomorrow.

As Members know, the current continuing resolution expires on December 20. The House will consider some appropriation measures. Hopefully, and my expectation is, they are making progress in the Appropriations Committee on coming to a resolution on the 12 appropriation bills.

It is my hope that we will consider those appropriation bills on the floor on Tuesday, perhaps a series of minibus packages to fund all of government for the remainder of the fiscal year.

I would urge all of my colleagues on the Appropriations Committee to do