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PRESCRIPTION DRUG AFFORDABILITY AND INNOVATION: ADDRESSING CHALLENGES IN TODAY'S MARKET

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

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CONTENTS

OPENING STATEMENTS

	Page
Hatch, Hon. Orrin G., a U.S. Senator from Utah, chairman, Committee on Finance	1
Wyden, Hon. Ron, a U.S. Senator from Oregon	4

ADMINISTRATION WITNESS

Azar, Hon. Alex M., II, Secretary, Department of Health and Human Services, Washington, DC	6

ALPHABETICAL LISTING AND APPENDIX MATERIAL

Azar, Hon. Alex M., II:	
Testimony	6
Prepared statement	45
Responses to questions from committee members	46
Hatch, Hon. Orrin G.:	
Opening statement	1
Prepared statement	80
McCaskill, Hon. Claire:	
"Agent Eligibility and Underwriting Guide," Humana*One* Health and Life Products	82
Whitehouse, Hon. Sheldon:	
Letters submitted for the record	166
Wyden, Hon. Ron:	
Opening statement	4
Prepared statement	169

COMMUNICATIONS

America's Health Insurance Plans (AHIP)	171
American Hospital Association	177
Association of American Physicians and Surgeons	201
Campaign for Sustainable Rx Pricing (CSRxP)	202
Center for Fiscal Equity	209
National Community Pharmacists Association (NCPA)	209

PRESCRIPTION DRUG AFFORDABILITY AND INNOVATION: ADDRESSING CHALLENGES IN TODAY'S MARKET

TUESDAY, JUNE 26, 2018

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 9:25 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Orrin G. Hatch (chairman of the committee) presiding.

Present: Senators Cornyn, Thune, Isakson, Portman, Toomey, Heller, Scott, Cassidy, Wyden, Stabenow, Cantwell, Nelson, Menendez, Carper, Cardin, Brown, Bennet, Casey, Warner, McCaskill, and Whitehouse.

Also present: Republican staff: Brett Baker, Health Policy Advisor; Jennifer Kuskowski, Chief Health Policy Advisor; Ryan Martin, Senior Human Services Advisor; Stuart Portman, Health Policy Advisor; and Jeffrey Wrase, Deputy Staff Director and Chief Economist. Democratic staff: Laura Berntsen, Senior Advisor for Health and Human Services; Michael Evans, General Counsel; Elizabeth Jurinka, Chief Health Advisor; Matt Kazan, Health Policy Advisor; Joshua Sheinkman, Staff Director; and Beth Vrable, Senior Health Counsel.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. I would like to welcome everyone to today's hearing on prescription drug affordability and innovation.

We are pleased to have our Secretary here, Secretary Azar—who I think is doing a great job—before the committee today, and I know members on both sides of the aisle are eager to hear from him on the Trump administration's plan to lower prescription drug costs.

I was in the Rose Garden when the President announced his plan to put patients first by lowering prescription drug and out-of-pocket costs to consumers. And I commend the President and the Secretary for their focus in this area and for releasing this comprehensive blueprint.

I also appreciate that HHS is seeking feedback from the public on the policy ideas in the blueprint. The administration is prudent to work through options by properly consulting those affected by these policies first. As we continue to develop policy options, it is

imperative to understand the impact on patient access, affordability, and innovation before taking any specific action.

To that end, today, in my opinion, is a golden opportunity for members to discuss policy proposals and ideas in the blueprint, which contemplates many weighty issues that would seriously change the current way of doing things. And on that note, I believe that those who have criticized the blueprint as insufficient are either responding from a lack of knowledge or purely for political gain.

Now, I bring to the table decades of experience of working on drug pricing. That is why we have titled today's hearing in a way that clearly explains the heart of these issues, quote: "Prescription Drug Affordability and Innovation." This hearing title references a concept that has been very important to me throughout my time in the Senate. After all, the goal is to help consumers, and the best way to do that is to balance both affordability and innovation.

Over 3 decades ago, I championed the Drug Price Competition and Patent Term Restoration Act, which has since become known as Hatch-Waxman. As I noted in an editorial that ran in *Roll Call* yesterday, the Hatch-Waxman law established a system for regulating drugs that rewards new products while encouraging generic competitors.

Around that same time, I sponsored the Orphan Drug Act. And I am proud to say that law has resulted in new treatment options that have enhanced care and dramatically improved the quality of life for hundreds of thousands, if not millions, of people who live with rare diseases. At the time, we thought we were just taking care of some rare diseases, but it has become a very important law.

Those two bills are just the tip of the iceberg, though. I have since spearheaded numerous other legislative initiatives to address shortcomings in the system and to capitalize on opportunities for improvement. I brokered the agreement that allowed physician-administered biologics to flourish, providing effective treatment for many cancers and other serious medical conditions. More recently, I have successfully advocated policies that promote development of biosimilars as a way to foster competition and lower costs.

Now, I do not bring up this history to boast, but to point out that the pursuit of the balance of affordability and innovation has served us well. Now, nearly 90 percent of prescription drugs dispensed to patients are generics, yet we also have realized life-altering breakthroughs in treatment. Maintaining this balance must be a part of the conversation here today. And, as we move forward, I want to keep it that way. And any lasting solution must continue to be market-driven.

The Medicare Part D prescription drug program is built on a system of private entities competing on price and service. This private-sector approach is engrained in the design of the Part D program, which wisely forbids the government from interfering with the negotiations between these private entities. For Part B drugs and biologics, Medicare pays based on the average price that the manufacturer charges to other payers. This effectively represents a rate negotiated in the private sector.

Now, do not take this to mean the way Medicare pays for prescription drugs is perfect. There is certainly room for improvement.

But the fact that the United States continues to be a pharmaceutical research and development powerhouse is in large part because we have long preserved the market-based approach. It is vastly superior to the alternative of direct government involvement and price-setting. After all, the private sector has proven time and again that it is far better suited to identifying challenges and turning them into opportunities.

One persistent challenge is that certain key drugs and items are in such short supply that hospitals and other providers simply cannot even purchase them in sufficient quantity. These drug shortages, which include generic medications, threaten patient care and demonstrate a weakness in our system.

Now, I am pleased to say that my home State of Utah is taking a leadership role by creating a market-based response. Utah-based Intermountain Healthcare has joined with other like-minded systems across the country to form a generic drug company. This new venture will fill a market need by producing and distributing drugs that are in short supply. This new company will also provide more competition that will improve prices and opportunities for consumers.

There are others too, like some commercial health plans, that have responded to market demand by offering prescription drug coverage options that pass along the negotiated discounts and rebates to their enrollees at the point of sale, rather than only through lower premiums.

Turning back to the President's blueprint, it contains policy ideas related to Medicare and Medicaid that merit serious consideration. For example, the idea of paying for a drug based on its success in achieving the intended patient benefit holds promise, especially for novel, breakthrough therapies that do not yet have competition. We should explore how these value-based arrangements can work within our Federal health programs.

We should also assess how we can modernize the popular Part D program, because it is now more than 10 years old. And a review of the Part D program should involve action to mitigate the change in the bipartisan budget deal enacted earlier this year that increased the discount that manufacturers are required to provide on drugs in the coverage gap. This misguided change has only dampened some of the competitive forces that have made the program so successful.

We will soon hear from Secretary Azar on the policy ideas in the blueprint. It will be important to understand how the policies in the blueprint would impact not only the list price, but patient access, beneficiary premiums, and other cost-sharing, as well as innovation. As the vast majority of the blueprint's policies are in the jurisdiction of the Finance Committee, this engagement with the Secretary will inform how we move forward.

Now, before I conclude my opening remarks, I must say that I suspect that some of my colleagues may want to talk about other pressing issues that touch on HHS's jurisdiction. To head off just one such issue, I have made my position on the situation at our southern border known: we must keep families together as we work to avoid illegal border crossings. We also need to ensure that chil-

dren who have been separated from their parents are reunited, and I know the Secretary is working aggressively to do so.

However, my experience tells me that our time at this hearing will be best spent discussing the issues we all have prepared for weeks to talk about with Secretary Azar. After all, the cost, innovation, and availability of prescription drugs is a deeply important and often life-or-death issue for millions of our constituents each day. My hope is that we can all take advantage of the opportunity before us today and stay focused on the agreed-upon subject matter of this hearing.

With that, I am going to turn to our ranking member, my good friend and partner, Senator Wyden, for his opening statement.

[The prepared statement of Chairman Hatch appears in the appendix.]

OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON

Senator WYDEN. Thank you very much, Mr. Chairman. And, Mr. Chairman, thank you for holding this hearing.

I am going to get to rescuing Americans who are getting mugged by their prescription drug bills, as well as the administration gutting safeguards for those with preexisting conditions.

First, the American people are owed an answer about what is going to be done to protect the thousands of children the Trump administration separated from their mothers and fathers and put in the custody of today's witness.

As of this morning, Health and Human Services, Homeland Security, and the Justice Department seem to be doing more to add to the bedlam and deflect blame than they are doing to tell parents where their kids are. According to news reports, the government is ransoming these children by telling their parents they can have their kids back if they agree to leave the country.

The President tweeted that the U.S. should forget about due process rights for immigrants, essentially an endorsement of judging people by the color of their skin.

The White House Chief of Staff floated this family-shredding policy in the press more than a year ago. It was not conjured out of thin air this spring. But with news reports that the Department is scrambling to collect resumes of individuals with experience in child care, it is clear that the Department was woefully unprepared.

This committee has oversight of the child welfare system. Members here have worked hard on bipartisan child welfare policies that keep families together whenever it is safe. That is because unnecessarily ripping children away from their families and putting them in institutions is harmful to them. It is harmful to their health. It is scarring to their emotional well-being. It is detrimental to their growth. That is a fact, and the Department of Health and Human Services knows it.

Secretary Azar, you are certainly going to get questions about this today. An administration that has traumatized thousands of child refugees, dehumanized these kids and their parents, and tried to normalize this behavior through deception, has a lot to answer for.

Now I am going to shift to discuss Americans getting hit with those enormous bills when they walk up to the pharmacy window.

When the President said in early 2017 that drug companies were "getting away with murder," he offered his diagnosis of the prescription drug cost problem. A year and a half later, it sure looks like he has decided not to treat the problem.

The President made prescription drug costs a key part of his pitch to the American people on health care. But the party in power has not done any legislating on it. They have put out a so-called blueprint, essentially a collection of the same questions that have been asked on these issues for a decade or more.

To me, this so-called administration blueprint looks less like a blueprint than it does like blue smoke and mirrors. And a lot of what the President and his team have said is just head-scratching.

For example, the administration says that European countries are "freeloaders." He said that if drugs got more expensive overseas, in effect fattening the wallets of the pharmaceutical companies, prices fall at home. That is just fantasy land.

I do not know what magic wand the administration plans on using to hike drug prices in other countries, and I do not know if that power today exists.

Second, even if drug companies did come into a windfall from overseas, it is laughable to expect that they would take that as a reason to slash prices in America. Look at the Trump tax law. Huge amounts of cash were showered on these multinational drug companies. What did they do with it? They put it into stock buybacks that benefit shareholders, not consumers.

One other trip to pharmaceutical fantasy land: on May 30th, the President said that in 2 weeks, drug companies would be announcing, and I quote here, "voluntary massive drops in prices." Two weeks went by, 3 weeks went by. It has been nearly a month. No massive drops in prescription drug bills, folks. As long as Americans are getting mugged at pharmacy counters from sea to shining sea, this issue demands serious, bipartisan action.

To begin that effort in a serious bipartisan way this morning, I am releasing a comprehensive report that looks at exactly what makes this industry complicated and why those policies do so much to make sure that prices just go up and up and up.

And it is not just a look at the drug manufacturers. There are a lot of pieces to the puzzle: middlemen, distributors, misplaced incentives, and broken, out-of-date policies on the law books. So the report is a comprehensive look under the hood of the entire pharmaceutical industry for the first time.

Otherwise, what Americans get from the Trump administration, and the President in particular, when you look at the record, is talk. The fact is, their blueprint has raised issues that have been raised for quite some time.

The administration needs to stop pretending that asking the same questions that have already been asked is the equivalent to getting results. The fact is there is a big gap between the triumphant headlines the Trump administration tries to grab on prescription drugs and the lack of serious proposals put forward.

So today, I hope we will see that gap getting closed.

One last issue. The Trump administration said recently it was going to get out of the business of defending protections for Americans who have preexisting health conditions. These protections, as millions of Americans know—because they let them sleep more soundly at night—are the law of the land.

And it is not a narrow policy that applies to only a handful of people. There are more than 150 million Americans who get insurance through their employers, and I would bet they are going to be very surprised to learn this Trump decision can hurt them too.

If you do not have a preexisting condition, I guarantee you know somebody who does. And the Trump administration decided it just is not interested in protecting them.

So we have a lot to do this morning, Mr. Chairman. And as always, as we have done so often in the past, I look forward to working with you in a bipartisan way.

The CHAIRMAN. Well, thank you. Thank you very much.

[The prepared statement of Senator Wyden appears in the appendix.]

The CHAIRMAN. Once again, I would like to thank Secretary Azar for coming here today. We appreciate you, sir.

Secretary Azar was sworn in as Secretary of Health and Human Services on January 29, 2018. And because there is a lot of ground to cover—we all have come to know Secretary Azar quite well—I would like to move right along. As such, Secretary Azar, please proceed with your opening statement.

STATEMENT OF HON. ALEX M. AZAR II, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Secretary AZAR. Thank you, Mr. Chairman, Ranking Member Wyden, and members of the committee. I appreciate the opportunity to appear before you today to discuss an important issue: why American prescription drug prices are too high and what we are doing about it.

Drug pricing was one of the very first topics that I mentioned before this committee during my confirmation process earlier this year. I know members of this committee are serious about taking on this challenge, and I appreciate your efforts in this area.

From day one of his administration, President Trump has directed HHS to make drug pricing a top priority. Earlier this year, the President's 2019 budget laid out a range of proposals on the issue, including reforms to Medicare and Medicaid, topics that I testified about when presenting the President's budget earlier this year before this committee.

In May, building on the budget, the President released a blueprint to put American patients first. This blueprint is a plan for bringing down drug prices while keeping our country the world's leader in biopharmaceutical innovation and access. It lays out dozens of possible ways that HHS and Congress, working together, can address this vital issue.

We face four significant problems in the pharmaceutical market: high list prices set by manufacturers, seniors and government programs overpaying for drugs due to the lack of the latest negotiation tools, rising out-of-pocket costs, and foreign governments free-riding off of American investment.

The President's blueprint lays out four strategies for tackling these problems, and we have begun acting on each of them already.

First, we need to create the right incentives for list prices. Everybody in today's system makes money as a percentage of list prices, including pharmacy benefit managers, who are supposed to keep prices down. Everybody wins when list prices rise except for the patient, whose out-of-pocket cost is typically calculated based on that price.

One of HHS's initial actions is working to require drug companies to include their list price in advertisements. For example, Americans deserve to know the price of a wonderful new drug that they hear about on TV, before going to ask their doctor about a product they may find unaffordable.

More fundamentally, we may need to move to a system without rebates, where PBMs and drug companies negotiate fixed-price contracts. Such a system's incentives, detached from artificial list prices, would likely serve patients far better.

Second, we need better negotiation for drugs within Medicare. That is what President Trump has promised, and it is what we are going to deliver.

In Medicare Part D, HHS will work to give private plans the market-based tools that they need to negotiate better deals with drug companies. Part D is a tremendously successful program, but it has not kept pace with innovations in the private marketplace. For instance, well-intended patient protections may be preventing plans from appropriately managing utilization. While everybody agrees on the importance of the drugs that are in the protected classes, manufacturers often use that list as a protection from paying rebates.

We also want to bring negotiation to Medicare Part B physician-administered drugs. Right now, HHS just gets the bill and we pay it. The system may actually be driving doctors to prescribe more expensive drugs, while potentially tempting manufacturers to develop drugs that fit into Part B rather than D.

We are going to look at ways to merge Part B drugs into Part D and leverage existing private-sector options within Part B.

Third, we need a more competitive pharmaceutical marketplace. Thanks to the reforms that Congress passed in the 1980s, America has the strongest generic drug market in the world. But there are many ways that manufacturers still unfairly block competition.

Since the rollout of the President's blueprint, FDA has publicized the names of companies that may be abusing safety programs to block competition and has issued new guidance to help lessen the effects these actions may have on generic access.

Finally, we need to bring down out-of-pocket costs for American patients. Since the blueprint rollout, CMS has reminded Medicare Part D plans that it is unacceptable to have gag clauses barring pharmacists from working with patients to identify lower-cost options.

More broadly, we are going to work to ensure patients know how much a drug costs, how much it is going to cost them, and whether there are cheaper options, long before they get to the pharmacy counter.

These are just some of the elements of an aggressive, long-term plan to solve this problem we all care deeply about.

Thank you again for having me here today. And I look forward to taking your questions and discussing how together we can help American patients.

The CHAIRMAN. Well, thank you, Mr. Secretary.

[The prepared statement of Secretary Azar appears in the appendix.]

The CHAIRMAN. One of the ideas, both mentioned in the blueprint and that you have discussed publicly since its release, is doing away with rebates in Medicare Part D through changes to anti-kickback statute safe harbors. You have stated that rebates could be replaced with something called a, quote, "fixed price discount," unquote. Now, the terms "fix" and "price" in the same phrase do make me a little bit nervous.

I am sure it does not mean setting a price, but can you explain what that term means, how it would be different from a rebate, and how it would limit list price increases from year to year or over a longer period of time?

Secretary AZAR. Absolutely, Mr. Chairman. Right now, the problem is that the pharmacy benefit managers make their money often on getting a high list price, negotiating a big rebate off of that, and then keeping a percent of that rebate that they do not necessarily pass to the patient or to the insurance companies that they work for. And that is just the business model. It is not saying that they are doing anything wrong; it is just the business model.

What we are thinking about proposing—and have been asking for comment on with the request for information that we have—is moving to a system where, instead of encouraging a very high list price with a rebate that gets administered after the fact, what if our contracts that the PBMs have instead just say, here is the price, here is what we will pay. You have market power as a pharmacy benefit manager, you control the formulary and you are going to get this level of discount, here is the price. And that actually gets administered at the point of sale.

So you take list price out of the equation. The pharmacy benefit manager has no incentive for a higher list price; it is just administered right there. It is an actual discount, the money flows with it, and we just take list price off the table.

The CHAIRMAN. States continue to evaluate the concept of a closed formulary in Medicaid. With the recent examples of Massachusetts and Arizona and other States, with a bipartisan mix of Governors considering the idea, there is growing interest in exploring the outcomes of imposing a closed formulary in Medicaid through a demonstration project.

How would the Medicaid Drug Rebate Program interact with such a proposal? And do you envision carve-in protections for certain drugs or classes of drugs, or required coverage of medically necessary treatments for which there is no alternative?

Secretary AZAR. So, as you mentioned, Mr. Chairman, the President's 2019 budget does propose having five States have the opportunity to see if they can do better than the Medicaid statutory rebate program in negotiating.

So right now, the system we have is that all drugs are available in Medicaid, but in return for that, there is a statutory rebate that the drug manufacturers have to pay. Some have suggested that the States, if they could run their formulary the way Medicare Part D runs its formulary, or the way any of us with our commercial insurance have a formulary managed, could get a better deal. We would like to give them that chance to try to see if they can in fact do so.

Now, there would still be patient protections, there would still be medical appeals, clinical necessity. Everything you mentioned, Mr. Chairman, would be there, just as it is for your insurance, my insurance, anybody else's insurance, to protect you from unreasonable or non-clinically based formulary utilization management. Absolutely, Mr. Chairman.

The CHAIRMAN. Well, thank you. I am pleased that this administration reversed an Obama-era payment policy that sent the wrong signal to the nascent biosimilars market. Underpaying biosimilars, which studies estimate will cost 20 to 40 percent less than the biologics with which they compete, is not a recipe for a development of new biosimilars.

What else can be done to increase the use of biosimilars as a way to increase competition and lower spending?

Secretary AZAR. So, Mr. Chairman, we want to do for the biosimilars market exactly what you did for the generics market, which is create a very robust, highly competitive sector here that competes against branded products. And that is why that payment change was made: to ensure that there is adequate incentive for biosimilars to come in.

Since we made that change, we actually saw a biosimilar enter the market at significantly below what analysts thought the pricing would be—we think, in part, because of our rule change.

We believe at the FDA that we can get rid of these abuses by drug companies that are preventing access to their products for the biosimilar companies to be able to do the clinical trials needed to bring products to market. We also are going to keep building the scientific and evidence space for genuinely interchangeable biosimilars that would really allow the development of that generic market, as you did under Hatch-Waxman.

The CHAIRMAN. Well, thank you so much.

Senator Wyden?

Senator WYDEN. Mr. Secretary, your agency plays a crucial role in child safety, so I have a few questions that I think are pretty brief, and I want to see if you can give me some specific answers.

How many kids who were in your custody because of the zero tolerance policy have been reunified with a parent or a relative?

Secretary AZAR. So I believe we have had a high of over 2,300 children who were separated from their parents as a result of the enforcement policy. We now have 2,047——

Senator WYDEN. How many have been reunified?

Secretary AZAR. So they would be unified with either parents or other relatives under our policy. So, of course, if the parent remains in detention, unfortunately, under rules that are set by Congress and the courts, they cannot be reunified while they are in detention.

Senator WYDEN. So is the answer zero? I mean, you have——

Secretary AZAR. No, no. No. We have had hundreds of children who had been separated who are now with—for instance, if there was another parent who is here in the country——

Senator WYDEN. I want to know about the children in your department's custody. How many of them have been reunified?

Secretary AZAR. Well, that is exactly what I am saying. They have been placed with a parent or other relative who is here in the United States.

Senator WYDEN. How many? How many?

Secretary AZAR. Several hundred. Now, of the——

Senator WYDEN. Of the——

Secretary AZAR. Of the 2,300-plus that came into our care——

Senator WYDEN. Okay.

Secretary AZAR [continuing]. We probably have 2,047.

Senator WYDEN. How many parents have been told where their kids are?

Secretary AZAR. Every parent has access to know where their child is. We want to ensure that the process is more efficient.

Senator WYDEN. That is the 800 number.

Secretary AZAR. Well, that is not—that is, actually the 800 number would be the backup on that. But that should be the failsafe. Every parent should know where their—we have actually deployed a Public Health Service officer for every one.

Senator WYDEN. But how many parents——

The CHAIRMAN. Let him answer the question.

Senator WYDEN. Mr. Chairman, the time is short and——

The CHAIRMAN. Well, I will give you more time.

Senator WYDEN. The American people have been getting lots of deception, lots of rosy answers, not many facts.

So how many parents—not have access—how many parents have been told where their kids are?

Secretary AZAR. Well, they all—that information is available for every parent. And we have actually deployed Public Health Service officers to work with the ICE case managers to meet with all of those parents. We are progressing through them, to help them fill out the reunification paperwork that they need for their background check and to confirm parentage, as well as to ensure that they make contact, they know where their child is, they make contact, get them on the phone, get them on Skype if that is available.

We want to have every child and every parent connected and in regular communication. And we are making that happen.

Senator WYDEN. I asked twice, how many parents were actually told where their kids are? You said they have access.

And this is just, in my view, part of the rosy responses the American people have been getting. And it sure does not line up with the firsthand accounts of parents that I hear from who desperately want to know where their kids are.

We will hold the——

Secretary AZAR. There is no reason why any parent would not know where their child is located. I could—I have sat on the ORR portal—with just basic keystrokes, within seconds, find any child in our care for any parent. It is available right now.

Senator WYDEN. And, Mr. Secretary, suffice it to say portals are not part of the daily existence of these people.

Secretary AZAR. That is why we have case managers and the 800 number for their lawyers or them to use.

Senator WYDEN. I would like to hold the record open so you can tell me specifically as of today how many parents were told where their kids are.

Now, on drug prices, not less than 14 days after the President's speech on prescription drugs, Bayer announced the price of two of its cancer drugs was going up a thousand dollars per month. That was the second price hike in 6 months. So it sure does not look like the drug makers are taking your blueprint particularly seriously.

We have 42 million Americans who get their drugs through Part D of Medicare. They are getting price hikes every day.

After a year and a half in office, I do not see any evidence of this administration taking real action until possibly January 1, 2020, a thousand days after the President said drug companies were getting away with murder.

So are there any policies in your so-called blueprint that have actually taken effect and will hold drug prices down?

Secretary AZAR. So patients have already saved $8.8 billion from added generics. They have saved $320 million a year from the change to Part B Medicare reimbursement.

We have already listed the 150 branded companies that are hiding behind the REMS program to prevent access to their product for generic or biosimilar testing. We have put a dashboard out that shows the price increases. We have already told the Part D plans that we find the gag clauses unacceptable.

And I am disappointed by those price increases. And I want to put the drug companies on notice. You know, we are hitting July 1st. That is a traditional time for drug price increases. And I hope they will exercise restraint as we come across this period.

We have seen fewer increases than we historically do, lower increases than we historically do as a result of the President's——

Senator WYDEN. My time is up. You did not answer the question. I asked about Part D changes. And we have not seen, for those 42 million Americans who get their drugs through Part D, we have not seen any change.

I will hold the record open for this, as well as the other matters that you did not respond to. And tell us specifically what Medicare Part D changes are being made—and when they are going to be made—that are going to help those 42 million people.

The CHAIRMAN. Senator Stabenow?

Senator STABENOW. Thank you, Mr. Chairman.

Let me first speak to the issue of the children who have been separated at the border—and I talked to you privately about this. This is obviously appalling what has happened. It is an American tragedy. It is a tragedy for these parents and these children.

And I want to start by calling on you to make sure the over 2,000 children in your custody at HHS are able to get back to their parents as quickly as possible and that you make this a priority.

As I indicated to you, we have over 60 children in Michigan right now. They are in loving, safe foster homes, but that is not the point. As of my last contact with the agencies, they did not know,

they were not given any information up to this point about where the parents are. And there was not communication going on in terms of what is happening for these children.

So every single day in a child's life—you know, the kids keep growing up no matter what we do or how long we take, how bureaucratic we are. Whatever is happening with this administration, however long you take, every day these children are growing and changing and experiencing trauma and pain.

And so I just want to go on record as saying that this needs to get fixed and needs to be the top priority for what you are focused on in terms of children and families right now.

This is on your watch, and we will hold you accountable.

So let me go on to the question, the topic of the day, and speak specifically about what is happening with the outrageous prices of naloxone.

We have an opioid crisis. We have talked about this before. And let me just speak again about the history of pricing on naloxone, which is an overdose-reversal drug that has saved countless lives, as you know.

The drug was first approved by the FDA in 1971—long off patent. Generic versions have been available since 1985.

As of 2005, a generic vial of naloxone was available for about a dollar—about a dollar in 2005. But by 2013, now that we have a crisis, the generic companies are selling the drug for 15 times as much. And Evzio, a naloxone autoinjector, now sells for more than $4,000—$4,000—for a two-pack. It was a dollar in 2005, now a two-pack for the autoinjector is over $4,000. And as you know, Narcan, the nasal spray version, is sold for about $150 for a two-pack.

So at your confirmation hearing, I raised this issue, and I raised the fact that the President's commission on the crisis, the opioid crisis, recommended negotiating the best price. And at the time, you said, quote, "I want to look at that, learn more about the situation, but if the government is the purchaser—so let us say, for instance, if we are going to be buying that as part of the opioid crisis program and are directly buying that and supplying it to States and first responders, which is what we are doing, there is absolutely nothing wrong with the government negotiating that."

I followed up with a letter with colleagues. You sent a response that did not even include the word "negotiation."

So is naloxone price negotiation in the drug pricing blueprint?

Secretary AZAR. So the blueprint does not address any specific drug price. Narcan is the nasal formulation of naloxone, which tends to be a preferred formulation for opioid overdose first responders. That is actually available—I looked into this—under the Federal Supply Schedule for acquisition at $78 a package. And our other first responders, State and locals, have, through group purchasing, access to that same kind of pricing there.

We are also working at FDA to bring over-the-counter naloxone to the market and also to increase even more generic competition. There, of course, are different formulations, different administration devices——

Senator STABENOW. I understand. And in the interest of time, Mr. Secretary, so the answer is "no," negotiation is not part of what you will be doing.

Secretary AZAR. Well, the supply schedule is at $78.

Senator STABENOW. Seventy-eight dollars. It was a dollar, now $78. Such a deal.

Secretary AZAR. Well, it was not nasal. I do not know if it was nasal at a dollar, to correct you.

Senator STABENOW. Okay. All right. So it was something slightly different with a naloxone——

Secretary AZAR. Nasal is a preferred first responder vehicle.

Senator STABENOW. It was administered in a different way. Naloxone itself was a dollar, now with this particular way of administering, it is $78.

And I just want to share with you that Southwest Michigan Behavioral Health is planning to spend $366,100 next year on this particular discounted price that you are talking about—$366,100 that they could be spending on treatment for people in Michigan who have an opioid addiction. And instead, they are paying, even at this discounted rate, 78 times more than what was available in 2005.

I just have to say, Mr. Chairman, if we want to talk about rigged systems, there is not a more rigged system than the way prescription drugs are priced.

The CHAIRMAN. Thank you, Senator.

Senator Cornyn?

Senator CORNYN. Thank you, Mr. Chairman.

Mr. Azar, I appreciate your service. I cannot think of anybody better qualified to serve in the position you are serving in, so I appreciate the expertise and experience you bring to this role.

I wanted to just raise the issue because, in addition to the blueprint that you rolled out to try to control prescription drug costs, there are other cost drivers that we see in the health-care system that the administration has tried to address.

One is, the Department of Labor has now issued regulations to make it possible for more people to get access to association health-care plans so they can take advantage, not of the individual market, but of the employer-provided insurance market and find their premiums substantially lower.

I would note that people in the individual market, the 9 million people in the individual market, do not have any subsidies, and they have seen their costs rise by 105 percent since 2013, which is unaffordable by any measure.

The second thing I just wanted to raise with you—and I am sure you are aware of—is the good work being done by Senator Collins and Senator Alexander, Representative Walden, and Representative Costello, to try to make sure people 250 percent and below get access to lower premiums for their health-care coverage. Again, the problem is the unaffordable Obamacare model, which has all the mandates and provides spotty subsidies, particularly to people below 250 percent of poverty. That would result—if embraced by Congress, the Alexander-Collins-Walden-Costello bill would lower premiums for people in the individual market by 40 percent and make it much more affordable.

The tragedy is, unfortunately, the resistance, the never-Trump approach to the work here in the Congress and in Washington, has resulted in what used to be a bipartisan bill basically being aban-

doned by our Democratic colleagues who refuse to even work with Senator Alexander and Senator Collins to come up with a solution for these skyrocketing premiums under Obamacare.

So in addition to the good work that you are doing on prescription drugs, which I applaud and encourage you to continue, these are two other areas that I just wanted to highlight: one, an initiative by the administration through the Department of Labor, and the other legislative, but which has been rejected pending the outcome of the midterm elections by our Democratic colleagues.

But since I was in Brownsville on Friday—and our colleagues across the aisle want to talk about this issue and not prescription drug costs so much—I had the chance to visit two facilities in Brownsville and was enormously impressed with the quality of care being provided to these young people who have been brought across the border without their parents and some with their parents.

Isn't it true that 83 percent of the individual children in care were brought or were sent without a parent? Does that figure sound about right to you?

Secretary AZAR. It is true, Senator. Yes. Most of the kids in our care came here unaccompanied, sent by their parents, or came here on their own and then they found themselves in our custody. Yes.

Senator CORNYN. And I have not heard a word from any of our Democratic colleagues about the 83 percent of the children who were sent here by their parents, voluntarily separated by their parents, because of the conditions in the country in which they live and the hope for a better life here in the United States, which certainly we all understand.

But it seems to me that what is being advocated here is not zero tolerance when it comes to violating immigration laws, but zero enforcement. Indeed, our friend the Senator from California, Senator Feinstein, whom I have worked with on a number of occasions, has persuaded all the Democrats in the Congress, in the Senate I should say, to sign on to a bill that basically provides a no-enforcement zone for a violation of immigration laws within 100 miles of the border. And indeed, you have probably seen where some Democrats in the House have introduced bills that would literally abolish Immigration and Customs Enforcement. If you go on Twitter or any of the social media sites, you will find a hashtag #abolishICE, which essentially wants to do away with any enforcement of our immigration laws.

We can all agree that these children ought to be treated humanely and compassionately and joined together with their parents where possible. And indeed, there is legislation that would do that. I hope we can pass that this week.

The CHAIRMAN. Senator your time is up.

We will go to Senator Nelson.

Senator NELSON. Thank you, Mr. Chairman.

Mr. Secretary, I would like to seek some answers, respectfully—to have a civil discourse. You are a friend of a close friend of mine. And I respect that.

On Saturday, I was not allowed in the detention facility in Homestead, FL to speak with the 70 children whom I was told were there who had been separated from their parents.

Do you know what has changed since Saturday with those 70?

Secretary AZAR. So, Senator, we are very happy to arrange visits for Senators and members of Congress to these facilities. We do need to do so in a way that is orderly, because they are trying. First and foremost priority is the safety and well-being of these children whom we and our grantees care deeply about.

And you should have been and would have been able to interact with them, but not, of course, interview them. These are minor children. They are not there to be deposed or interviewed. So I do want to be careful about that. That is just simply not acceptable.

We have to protect these children. They are in care. They are in shelter. This is a difficult situation for all of them. And we all—I am sure you share that desire that we are doing our best and our utmost to be respectful of those children.

Senator NELSON. Mr. Secretary, I did not ask that. I asked what has happened since Saturday to those 70 children.

Secretary AZAR. Well, I do not know which 70 children you met with. I can tell you——

Senator NELSON. No, no. No, no. I did not meet with any of them. I was not allowed to, as you just stated.

Secretary AZAR. You are allowed to be in their presence, but you cannot depose them. And that is quite clear.

Senator NELSON. I understand. So my question—please, I am trying to be respectful——

Secretary AZAR. Yes.

Senator NELSON. My question is, the 70 children who I was told were in that facility, who had been separated from their parents, what has happened to them?

Secretary AZAR. So they would either continue to be in our care or, if they have reached a point where a sponsor who is in the United States who is a parent or a relative has been vetted and has been approved for sponsorship, they would have been released as expeditiously as possible to those sponsors.

Senator NELSON. How many of those children have been able to be in contact by telephone with their parents from whom they were separated?

Secretary AZAR. So for any of them who have been separated from their parent at the time of the parent's detention by the Customs and Border Patrol, within 24 hours of arriving at an ORR shelter, we endeavor to put them in touch, get on the phone with their parent. Sometimes that cannot happen if, for instance, if the parent has been located for criminal prosecution and placed by the Bureau of Prisons, say, with a county jail. It may be harder to arrange that communication.

We are actually sending, deploying Public Health Service officers out there to facilitate that. We want every child and every parent to be in communication at least twice a week so that they are talking by Skype or by phone if available. We want this to happen.

And so I cannot say as to those 70, but all should have been, within 24 hours of arriving, made in touch, if at all possible, with the parent, if the parent was accessible where the parent was being kept.

Senator NELSON. Okay. Now, I asked that question of the lady who is overseeing the facility of getting the children in touch and she said that a handful of the children had not been able to be on

the telephone. So I said, well, what is your plan for reuniting these children? And she said there is a lady named Barbara Flotus who, since I was there on Saturday—she does not work except on the weekdays—and I said, well, I will try to reach Barbara Flotus to tell me what is the plan.

I was prevented from speaking with Barbara Flotus yesterday, Monday. Can you help arrange that so that I can know what the plan is to reunite the children?

Secretary AZAR. So we will be happy to work with you to arrange through the grantee—of course, she is not an employee of my department; she works for a grantee.

Senator NELSON. Through the grantee.

Secretary AZAR. So, of course, it would be their decision if they want to make her available to you. But we will continue to work with your staff to facilitate, if you wish to speak with her.

Senator NELSON. You will not hinder me talking——

Secretary AZAR. No, of course not. Of course not.

Senator NELSON. Well, yesterday that occurred. So what is the plan to reunite 2,300 children?

Secretary AZAR. Absolutely. So the first thing we need to do is, for any of the parents, we have to confirm parentage. So that is part of the process with any child in our care, we have to ensure—there are traffickers, there are smugglers, there are frankly just some bad people occasionally. We have to ensure that the parentage is confirmed.

We have to vet those parents to ensure there is no criminality or violent history on them. That is part of the regular process for any placement with an individual. At that point, they will be ready to be reconnected to their parents. This is where our very broken immigration laws come into play. We are not allowed to have a child be with the parent who is in custody of the Department of Homeland Security for more than 20 days. And so until we can get Congress to change that law—the forcible separation there of the parent or the family units—we will hold them or place them with another family relative in the United States.

But we are working to get all these kids ready to be placed back with their parents, get that all cleared up as soon as Congress passes a change or if those parents complete their immigration proceedings; we can then reunify.

So we want to be ready. The President shares this. We do not want any children separated from their parents any longer than absolutely necessary under the law. And we want to effectuate that and make that happen, Senator.

The CHAIRMAN. Senator, your time is up.

Senator Thune?

Senator THUNE. Thank you, Mr. Chairman.

Mr. Secretary, back to the subject at hand. You have talked at length about the goal of lowering list prices, drug prices, as part of the administration's plan. If manufacturers were to announce a reduction in list prices, has the administration considered what that would mean throughout the supply chain in the Part D program? And particularly, if an announcement came midyear, how would such a change impact plans and PBMs?

And then I would like to ask, if you can hold that thought, what then would the beneficiary experience be in the way of changes in premiums and copays at the pharmacy counter?

Secretary AZAR. So I will answer the second first, which is, if list prices go down, the patient benefits. They pay less at the pharmacy. That is why list prices matter. Most patients, whether in Part B, Part D, or just in commercial plans, pay less at the pharmacy when the list price is lower.

Now your first question. We have heard from many major drug companies with major products that want to make substantial and material price decreases. This has shown just how broken our system of drug pricing and drug distribution is in the United States, because the pharmacy benefit managers and the wholesalers are all dependent on getting a percent of list price.

And the reaction to some has been, if you were to decrease your price, you will actually be harmed in terms of formulary status and patient access versus your competitor who has a higher price.

I would encourage the Senate and Congress to inquire of pharmacy benefit managers as to whether they have received suggestions or approaches from drug companies for lower list prices and what has the reaction been.

I believe still that this will be solved. These are adults. This is so absurd, it has to be, it will be fixed. But this is what is keeping the individual companies, so far, from moving.

I do not want to excuse them. The prices are their prices. Okay? They set their prices; they are accountable for that. But the channel is definitely not making it easier.

Senator THUNE. Okay. Well—and I just think that the concern in all of this is, does it get passed on in the form of savings to the ultimate consumer, to the beneficiary?

And then a follow-up question would be, how could that reduction in list prices be sustained over time?

Secretary AZAR. So we are, of course, not counting on just voluntary reductions in price. It would be nice if that happens, based on them seeing this is the northbound train, this is where it is going: we are going to lower list prices, better negotiations, lower net prices in this country. Get on the train, get a competitive advantage by moving their first. That is the idea.

But our plan will be reversing the incentives to ever-increasing list prices. I mentioned to Chairman Hatch that means getting after this whole rebate system based on list prices. It means asking Congress to overturn the Obamacare gift to the pharma companies of capping rebates in the Medicaid program at 100 percent.

As they increased their list price, it used to be your rebate would keep going up. Obamacare capped that at 100 percent. That would bring in billions of dollars and create a major financial disincentive to higher list prices and would sustain any lower prices that we would see.

Senator THUNE. Okay. Let me ask you something, just switching gears for just a minute. And you know, because I have shared with you, how important the 340B program is in my State to our hospitals. And I think that is probably a view shared by a number of folks on this panel and all across the Congress.

But could you talk a little bit about what you foresee happening in terms of proposed changes to the drug rebate program and how it might impact the 340B program and, perhaps even more broadly, what you see happening in terms of the 340B program, realizing there is litigation and regulatory action underway at the moment?

Secretary AZAR. So, as we have seen the 340B program expand, it has, in some respects, perhaps gotten untethered from its purpose of helping those hospitals and those uninsured individuals who have trouble affording access to their medicines. And I think we want to keep working with Congress to ensure the 340B program is delivering on that promise and is not being used for abuse and expanding beyond anything resembling its actual intent.

Because as it expands, as now more and more drugs go through that and as the flow of money comes out of that, it can lead to a cross-subsidization problem. That is what we mention in our blueprint, where, if it is abused, more money might get paid elsewhere in the system for people in Medicare, Medicaid, commercial plans. It might actually be an incentive towards higher list prices.

So we want to work with you to ensure 340B is there, it is healthy, it has integrity, and it is tied to its purpose of helping these hospitals and these patients.

Senator THUNE. And we want to make sure there is integrity in the program too. But most of the players in the field that I work with and I am familiar with in my State are folks who operate those programs with great integrity. And it is important to their bottom lines, which is why I think you hear us raise this issue so often to you and other members of your team.

So we will continue to do that, and I hope that you will continue to work with us and be responsive and try to work with the affected hospitals to come up with a good path forward.

Thank you, Mr. Secretary.

The CHAIRMAN. Your time is up.

Senator Menendez?

Senator MENENDEZ. Thank you, Mr. Chairman.

Mr. Secretary, thank you for coming today.

Before I start my questions, I want to urge your staff at CMS to carefully consider the requests of the entire bipartisan New Jersey delegation to extend the imputed rural floor. This is critical to New Jersey hospitals. Both Democratic and Republican administrations have extended it. And I hope that you will have your staff pay some critical attention to it.

CMS predicts prescription drug price growth in 2018 will be double what it was in 2017, contrary to the President's pronouncement that there would be a, quote, "voluntary, massive" drop in prices in early June.

And one of the reasons that we are not seeing reduced prescription drug prices is because some bad actors continue to game the system to prevent cheaper drugs from coming to market. In fact, the FDA recently named and shamed some of the worst actors who were deliberately blocking the development of cheaper generic drugs.

Congress is working to pass the CREATES Act, which is a bipartisan bill that would go after the abuse of some companies that are preventing cheaper drugs from coming to market.

Does the administration support the CREATES Act?

Secretary AZAR. So, Senator, we do not have the formal administration's support on it, but, obviously, what is in the CREATES Act resonates completely with what we have been saying and what FDA has been doing to prevent the very abuses that you have correctly laid out there.

Senator MENENDEZ. Well, I hope that the administration can come to a formal position.

Secretary AZAR. Thank you.

Senator MENENDEZ. This is bipartisan legislation.

Secretary AZAR. Thank you.

Senator MENENDEZ. It does exactly what the President's blueprint said he sought to do by ending bad actors in the pharma world.

And so let me ask you, after the FDA named and shamed on May 17th, have there been any behavioral changes by these companies?

Secretary AZAR. I do not know if there has been any change. Let me check with Commissioner Gottlieb on that and get back to you, if that is okay.

We have put out two guidances as a follow-up to that also, making clear that they should not be able to hide behind our regulatory processes to protect safety. That was part of the follow-on to that.

But if I can get back to you to see if we have seen any greater access——

Senator MENENDEZ. Okay; I would appreciate that.

Would you commit to working with me and my colleagues in a bipartisan way to ensure customers see generics come quickly and as safely to the market as possible?

Secretary AZAR. Absolutely. In fact, I would love to hear from you as you learn of abuses in the system or entities that are manipulating patent processes. Please consider me an open door for any input or pointing us to those. Absolutely.

Senator MENENDEZ. I appreciate that.

Are you familiar with the Reducing Drug Waste Act of 2017, also bipartisan legislation?

Secretary AZAR. I am not, Senator. I would be happy——

Senator MENENDEZ. Okay. I would like to call it to your attention. This is including members of this committee who have joined together because the HHS Office of Inspector General found millions of dollars in waste due to drug packaging. And so——

Secretary AZAR. Yes, yes. I am sorry. You did mention this to me in the confirmation. I am sorry, but I have not yet learned enough of the detail on that. I am sorry. Yes.

Senator MENENDEZ. Okay. Well, this is bipartisan legislation. The Senator from Iowa and Senator Klobuchar and many others, on a bipartisan basis, are looking at this as a way to stop the, basically, waste of drugs as a result of drug packaging.

So I ask you to look at that as well.

Let me just turn to the question of the children who are being stripped away from their parents at the border.

I have to differ with you. The reason we have a crisis is that the administration has decided that even those who come to a border crossing, present themselves, and ask for asylum, are turned away at a legitimate border crossing.

They come back the second day; they are turned away again. They come back a third day; they are turned away again. And after traveling thousands of miles, obviously fleeing horrific violence, they are not about to not have an opportunity for asylum.

And so the administration criminally prosecutes them, and in doing so separates children, who have been sent thousands of miles. I was looking at a map of where these children are. Primarily, it seems to be in blue States—and we are happy to house them—but we do not want to really have them stripped away from their parents.

So I heard your response to Senator Nelson. Let me ask you this. Will those parents who have been deported and whose children are here—are they going to be reunified? And if so, how?

And secondly, my understanding is there are still 2,000 minors who are separated from their parents who have not been reunited. What is the time frame?

I heard what you said is going to take place. What is the time frame that you estimate when that will take place?

Secretary AZAR. So, as to any parent who is deported, of course, the child has independent rights. We often do find that when a parent is deported, they ask the child to remain separated and remain in this country. That happens in normal proceedings. I do not know in the last couple of months——

Senator MENENDEZ. But a child who is a minor cannot make that case for themselves.

Secretary AZAR. They have counsel, and sometimes they actually decide to remain or the parent actually asks that we have them remain in the country. We keep them in touch, though. As long as the child is in our care, we keep them in touch, even if the parent is outside the country.

So in terms of timing, again, we are working rapidly to confirm parentage and do the vetting and proper criminal background checks, et cetera on any parents who are in custody so that we are ready to go as soon as either the parent's immigration proceedings are complete and we can reunify at the time, say, of deportation, or, if asylum were granted, if they were entered into the country, we could connect them then.

Or we, of course, have alternatives, if there are other relatives, a parent who is already in the country, we would put them with that parent or with other relatives here in the country. We have to expeditiously get children out of care and custody.

Senator MENENDEZ. But you do not have a time frame?

Secretary AZAR. Well, it is very much dependent—right now, I would gladly put these children back with their parents in the custody of ICE or Customs and Border Patrol, but I legally cannot, because at the 20-day mark they have to be sent back. We need Congress to change this 20-day limit on parent unification.

Senator MENENDEZ. Or we need to stop criminally prosecuting them and allow them to alternatively——

The CHAIRMAN. Senator, your time is up.

Senator Portman?

Senator PORTMAN. Thank you, Mr. Chairman.

I look forward to talking about drug pricing in a second. But let me just comment briefly on this.

As you know, we spent a couple of years studying the issue of unaccompanied kids, UACs. And HHS has, in my view, a very difficult job to do, which is to help with regard to kids who come without their parents. These are unaccompanied kids.

Now we have added to that with the separation of kids from families, which I think was a bad idea. And I commend the President for the executive order which changes that approach. We now have to deal with the kids who are already in the system.

But even though you have a very tough job to do, as you may know, in the Obama administration and in the Trump administration, I have not felt as though HHS has done a very good job in a very tough situation, because they have not come up with this agreement between the Department of Homeland Security and HHS. There is a memorandum of understanding and a commitment to come up with an operating agreement so we can understand how the handoff occurs, who is in charge.

But as recently as April of this year, we had a hearing on this. And HHS said that they were willing to take a fresh look at the question of who has responsibility for these kids once they leave an HHS detention facility or are placed with a sponsor.

My concern is that nobody is responsible. And you know, I got involved in this initially because of these eight children who ended up coming from Guatemala, ended up at an egg farm in Ohio because they were given to their traffickers—in the Obama administration—rather than to a family that was going to take care of them.

So my question to you today is—and again, I will get to drug pricing in a second, which is next in my questions—but one, you are taking a fresh look at this, as I understand it. You have a July deadline to come up with this operations agreement.

I do not know if you have followed this closely, but are you on track on the operations agreement with DHS? And who is going to be accountable or responsible for these children once they leave a Federal Government agency's custody and go off with a sponsor?

Secretary AZAR. So we have a memorandum of agreement with the Department of Homeland Security to ensure adequate and full vetting of any potential sponsor. These are relatives. They are either parents or aunts, uncles, adult relatives.

Senator PORTMAN. Well, again, in the case of the egg farm, they were traffickers.

Secretary AZAR. Well, and that was—obviously, there was a mistake; something happened. And so we have to have vetting, including fingerprinting.

Senator PORTMAN. Right. This is how we got into it, right? So better screening, that is a good thing.

Secretary AZAR. Screening, exactly.

Senator PORTMAN. Yes.

Secretary AZAR. Once they are placed with a sponsor, they are no longer subject to our jurisdiction. We cannot sort of pull a child back from a relative. We do not have the legal authority. They are then under the State and local child welfare laws, as well as, of course, they are subject to any immigration proceedings that they may have.

But we do not have any authority to go out and pull a child back from a sponsor once they are in that sponsor's custody. That would be local child welfare authorities that would, at that point, be accountable. Obviously, if we learn about it, we would let the authorities know.

Senator PORTMAN. And again, I want to get on to drug pricing for a second here, but one of the concerns obviously is that we were not even—and this goes back to the Obama administration again, and the first part of the Trump administration—not even telling the States that the kid was in their jurisdiction. So, kind of hard for child welfare to step in.

And again, there is an issue of getting these kids to their hearing. I mean, that is the idea. More than half of them, we think, are not showing up for the hearing, which is the whole idea: to get them with a family pending their hearing on their immigration status. So we have some work to do still.

I know you are aware of that. I just want to make sure you knew that we are going back and forth with your team, and we expect to have this operations agreement in place by July. It was also committed to during our April hearing.

On drug pricing for a second, I know Senator Stabenow talked about one of the issues that is a big deal to me, which is how you deal with the opioid crisis and the people who need naloxone, which is this miracle drug that reverses the effects of an overdose. And specifically, the Evzio cost increases: 575 bucks for a naloxone autoinjector in 2014, just 4 years ago; today over $4,000 for one of these things.

And so you go on your dashboard—which I applaud you for. You have a dashboard now where you can see drug pricing information more transparently, but it is very confusing because it shows Part D spending per unit—this is for Medicare, obviously—increased from 739 bucks to $4,500, and the list price was actually below both of these. And when we push on this, we are told, well, this does not include some other information like the manufacturers' rebates or other price concessions, which seem to run the other way.

But anyway, we have been pushing on this and trying to get HHS to give us an answer. Why can't all that information be on the dashboard? If consumers are really going to have the transparency that you want and we want, why can't we also include what is going on with regard to the rebates or other prices concessions?

Secretary AZAR. Well, taking it beyond the naloxone and that particular drug instance, disclosing publicly negotiated rebate rates is disclosing highly confidential information. Let us say we took just any other regular drug and we started publicly disclosing negotiated discounts. There could be very serious anticompetitive issues with that, as there would be if Walmart were forced to disclose their Tide discounts. Their competitors would love to have that information more than anything. So we have to be careful here.

We are happy to get you whatever information we have, but that is just an initial reaction on that issue of disclosing whatever the discounted rate would be on a particular product. It would be a concern.

Senator PORTMAN. I would think, you know——

The CHAIRMAN. Senator, your time is up.

Senator PORTMAN. Well, these drugs are bought by the taxpayer, not Tide. Tide is bought by some taxpayers, but it is a different issue. So, one, with regard to us and consumers getting the transparency on Medicare and Medicaid, I would think we are going to end up there. We have to figure out a way to provide that information.

The CHAIRMAN. Senator Bennet?

Senator BENNET. Thank you, Mr. Chairman.

Thank you, Mr. Secretary, for coming back to the hearing. And thank you for your service.

Just along the lines of—slightly along the lines of Senator Portman's original questions—did HHS have a role in participating in the design of the administration's zero tolerance policy at the border?

Secretary AZAR. We deal with the children once they are given to us, if they are unaccompanied. So we are not the experts on immigration.

Senator BENNET. But you were not involved in planning meetings on implementing——

Secretary AZAR. It would not be appropriate for me to discuss interactions within the administration. Our role is on receiving the children, though, not on setting immigration policy or the border.

Senator BENNET. To that end, Mr. Secretary, is the process you described today a special process for reuniting the 2,300 kids with their families, or is this the existing process that ORR uses for unaccompanied minors?

Secretary AZAR. This would be the process we use for any child in our care to ensure safe placement. Because, again, unfortunately, it may seem like, oh, their parents, they came across the border with them, they were separated, oh, just reunite them automatically.

Unfortunately, these children are often being captured by traffickers, gangs, cartels. That journey through Mexico is a horrific journey of rape and violence and deprivation. And often, the—not often, but we do see traffickers and very evil people sometimes claiming to be the parent of children. So the same protections we have for any unaccompanied children are vitally important here in terms of confirming parentage and vetting.

Senator BENNET. So I can appreciate why you cannot answer precisely when every single child will be reunited with their parents, but could you give the committee a sense of whether you are talking about days or weeks or months? What is your—what direction have you given HHS employees or contractors who do the work that I am sure you feel as urgently about as we do?

Secretary AZAR. So, yes, I and the President share the goal of doing all the work, getting the children reunited. I cannot reunite them, though, while the parents are in custody because of the court order that does not allow the kids to be with their parents for more than 20 days. I find it hard to imagine, but we need Congress to fix that.

What I have ordered our team to do—I want the kids ready, I want the parents confirmed and vetted so that we can place them as soon as either Congress changes the law or the parents are

through their immigration proceedings and ready to be deported or released, so that we are ready to reconnect them.

Now, in the interim, I have a separate legal obligation to keep working to expedite if there are other sponsors in the country—a different parent or other relatives whom I can place them with—because I cannot have them with us any longer than necessary.

Senator BENNET. So do you imagine that we will be having this conversation weeks from now, or do you think this will be resolved weeks from now?

Secretary AZAR. If Congress does not change the 20-day limit on family unification, then it depends on the process for any individual parent going through their immigration proceedings. As long as they are in detention, they cannot be together for more than 20 days—absurdly, but it is the case.

Senator BENNET. What is the age of the youngest child who is in HHS's care?

Secretary AZAR. We have infants in our care. Senator, as shocking as it sounds, we have always had infants in our care, even just straight unaccompanied children just left on the border as infants.

Senator BENNET. What is the youngest? What is the youngest?

Secretary AZAR. It is zero. I mean, infants.

Senator BENNET. Infants.

Secretary AZAR. We have infants. We always have, from parents or smugglers or traffickers who leave or have lost a child at the border and they are placed in our care. So we have always, the program has always had, as devastatingly tragic as that sounds——

Senator BENNET. And what happens, Mr. Secretary, if a child's parent has already completed expedited removal proceedings and has been deported? How is the child notified and how long does a child have to wait to be reunified under those circumstances?

Secretary AZAR. So if the parent wishes to have the child reunified, we will work, of course—because we have to confirm the parentage and the vetting to ensure, even in a foreign country, that the parent does not have any information, that we do not have any information suggesting that we are placing the child in jeopardy.

We work then, of course, with the home country for the transfer of the child there if that is the parent's wish for the child to be reunified. There are instances, however, where a child may assert their own right to pursue asylum or other claims that they have independent of their parents and may seek to remain in the country and remain in our care because of their or their lawyer's assertions.

Senator BENNET. And are children, Mr. Secretary, from certain countries treated differently from children from other countries? Or is everybody treated the same?

Secretary AZAR. Everybody is treated the same within our care. Immigration laws, as you know, are different, especially with regard to contiguous countries, Mexico and Canada. There are provisions that the Department of Homeland Security would be expert in that are different on immigration laws and the processes there around deportation that I am not the expert in.

But children in our care—we treat all of these children the same and attempt to reconnect them, get them to sponsorship as quickly as possible. And of course, it might be dependent on cooperation

with home countries getting us birth certificates or other confirmation information.

Senator BENNET. Thank you, Mr. Secretary. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Who is next now? Senator Carper?

Senator CARPER. Thanks. Thanks so much.

Mr. Secretary, welcome. It is good to see you. Thank you for your being here today and responding to our questions.

I want to just follow up just briefly on the issue of children at our borders and families on our borders.

We are paying a lot of attention to the symptoms of the problems, and we should. It is serious, and it needs to be dealt with. It is not an easy issue to deal with.

I spent part of yesterday in New York City, and I was with Jeh Johnson, who was the previous Secretary of Homeland Security, talking about these very same issues from his perspective as a Secretary of Homeland Security.

And one of the things that we discussed was how important it is to get right what is going on on the border. And in the spirit of Matthew 25—"When I was a stranger in your land, did you welcome me?"—I think it is important for us to focus on that and treat these kids the way we would want our kids to be treated.

The other thing is, it is important for us to focus on the root cause for why these kids and these families are coming to our border. And I would remind my colleagues that about 20 years ago in Colombia, a bunch of gunmen rounded up the Colombian Supreme Court members, took them into a room and shot them to death. Shot them to death. And you had the drug lords, you had the FARC, the leftist guerillas, almost working in concert to bring down, weaken and bring down the government of Colombia at a very desperate time.

Some leaders of that country stood up and said, "We are not going to let this happen to Colombia." And those leaders were supported by Bill Clinton, President, Joe Biden, the chairman of the Foreign Relations Committee, Dick Lugar, who was the senior Republican on Foreign Relations, to come up with something called Plan Colombia—Plan Colombia—which was, you can do it, we can help in terms of stabilizing your country, security for your country, economic opportunity in your country. They had to do the heavy lifting, but we helped.

We have a similar approach. It is not called Plan Colombia for Honduras, Guatemala, El Salvador. I call it—it is a Plan Colombia for those countries, and it does many of the same things that Plan Colombia has done.

We are in our third year on this program, and we need to continue to fund it; we need to continue to do oversight on that.

And the reason why these people are coming to our country is because they live horrific lives. They are lives of desperation—dangerous, high homicide rates, lack of economic opportunity. We are complicit in their misery. That is why we have a moral obligation to help them, and we are trying to do that. So I would just leave that at your feet and my colleagues' feet really.

I want to talk a little bit about value-based pricing. We have talked about this before. I like to say, "Everything I do, I know I can do better." And I think that is true of all of us, and that is true about the delivery of health care, and a big piece of that is pharmaceuticals.

And as we have discussed before, transitioning to value-based reimbursements for drugs is top priority to not just reduce drug prices for seniors who might be in Medicare, but also for our government, for our taxpayers, and for just regular, ordinary people.

What are stakeholders and your policy experts telling you about value-based contracting of prescription drugs and how this policy could improve affordability for consumers and our government programs and, ultimately, for taxpayers?

Secretary AZAR. Well, Senator, thank you for your leadership in the area of value-based payment. We are already moving forward on that. Commissioner Gottlieb has just recently, a couple of weeks ago, put guidance out to create a better pathway for sharing of information and discussions between pharmaceutical manufacturers and insurers around health economic information and to plan on new product launches so that they can actually collaborate and build those value-based arrangements as quickly as possible.

We are working on guidance around government price reporting and anti-kickback statute rules that can, again, create a greater pathway around how private actors, and we, can set up these value-based arrangements there. We all believe, as you said, it is the future of how we need to pay for drugs, pay for outcomes, pay for health care.

Frankly, I would love to see it if they could be more incorporated into the overall holistic health of the patient, more of a bundled notion. I think that is probably, long-term, the future of value-based health care, more than just the payment on the drug itself.

Senator CARPER. What action do you need from us on this side of the dais to enable you to implement value-based pricing and to ensure that the spending for health-care services and products is aligned to lower overall health-care costs? What do we need to do?

Secretary AZAR. So I believe we have the authority to create these pathways around value-based reimbursement models directly through the anti-kickback statute and government price reporting.

If I find that our regulatory authority is limited, I will come back to you and ask you for that authority, because it is so critical.

The CHAIRMAN. Senator, your time is up.

Senator CARPER. Mr. Chairman, I just want to commend you and the ranking member for holding this hearing. I think this is terrific.

The proposal from the administration is a broad proposal. I just think it is like a baseball team that hits a lot of singles and doubles. I do not know that there are any home runs in their proposal, but a lot of singles and doubles.

And my hope is that we can work together and score some points on the board for taxpayers and for citizens. It is great that we are here doing this. And I appreciate the Secretary being here.

The CHAIRMAN. That sounds like a triple to me, Senator. [Laughter.]

Senator Cassidy?

Senator CASSIDY. Secretary Azar, thank you for being here.

Let me start off with a specific drug, and then we will build from that into a line of questioning.

You and I in the past have spoken of Gleevec, a drug which was released in 2001, which used to be probably a couple thousand dollars a year. Now I am told that it costs $8,800 a year in Canada, and it costs $144,000 here in the United States.

Now, as you and I both know, the way that the catastrophic coverage works is that once somebody moves into the catastrophic portion, the beneficiary is responsible for 5 percent of the list price, not the net price. And so I have a former patient—only "former" because I am no longer practicing. She is paying 5 percent of $144,000 for a drug which has been released since 2001.

Now, my staff tells me that the company that has Gleevec has extended the ability, the patent protection if you will, with an agreement with the generic competition.

Now, Senator Stabenow asked, "What do we do about this?" And you responded, "We need competition." I would say, what do we do about Gleevec? Available since 2001, Canadians spend less than $9,000; we spend $144,000. That is egregious, and my patient can't afford 5 percent of the list price.

What do we do about that?

Secretary AZAR. So, Senator, I may be misinformed here, and I want to get back to you on this, but I do believe that generic Gleevec is actually available.

Senator CASSIDY. So then let us say that we are back in 2015 or 2016 in which this would apply and which, again, a drug 15 years after release is $144,000 a year. Because there will be another Gleevec; if now there is a generic, there will be another Gleevec.

How do we address that?

Secretary AZAR. So one of the items in terms of affordability that we have is in the President's budget—which I would love the chance to work with the Congress and this committee on—which would be to reform the Part D drug benefit to actually create several changes, one of which would be a genuine, for the first time ever—and I think Ranking Member Wyden has a separate piece of legislation to this effect—a genuine, out-of-pocket catastrophic——

Senator CASSIDY. So let me pause on that. So one of the, as we both know, but just for context, one of the pernicious effects of the rebate system which we have is, it moves people more quickly into the catastrophic. But even if the patient is protected, the taxpayer is on the hook.

So I am looking here at a CMS report which says that the Federal taxpayer outlays to PBMs had increased from roughly $11 billion in 2010 to $33 billion in 2015. And so the taxpayer is getting hosed because of this. So even if we protect the patient with our 5 percent, how do we protect the taxpayer?

Secretary AZAR. And you are absolutely correct, and I am really glad you raised that, because that is one of the five-point changes to Part D that we have proposed in our budget to actually reverse that incentive structure and the catastrophic benefit to ensure that the pharmacy benefit manager is bearing 80 percent of the cost, taxpayers only 20 percent, so that the PBMs have more skin in the

game to get that list price controlled, because we are going to be on the hook for that.

Senator CASSIDY. So would we change so that it is only the net price that counts in moving the patient to the catastrophic as opposed to the list price?

Secretary AZAR. It would be total expenditure, but that would be because the list would do that. The PBMs would actually have more incentive to get that list price controlled, not just the net, because they are going to be bearing 80 percent of that in the catastrophic.

Senator CASSIDY. Okay. And then I also see that one of the proposals is that currently, or maybe one proposal is to get rid of the rebate structure altogether, but another proposal is that a third, at least a third, of the rebate would be returned to the patient at point of sale. Why not 100 percent? Why should the patient be forfeiting two-thirds of that rebate amount?

Secretary AZAR. I think as we get after the issue of whether rebates should be allowed at all, that may be where we end up in terms of fixed-price discounting pulled forward at the point of sale completely.

In the budget proposal, we proposed a third. There obviously is significant debate about the issue of pulling forward rebates. We think it is the right thing that patients should get the benefit of these rebates——

Senator CASSIDY. So let me—because I only have 20 seconds——

Secretary AZAR. It is not set in stone.

Senator CASSIDY. I do not mean to cut you off. I am sorry. Just in the interest of time—one more thing. If Part B does not come into D, let us imagine another Gleevec within the Part B space in which we are paying that, the U.S. taxpayer is paying this, we are basically a price-taker, as you said, but overseas they are paying far less. Why not reference pricing?

Why not say, okay, let us take our five biggest developed countries—Germany, Japan, Australia, Canada, Britain, France, you name them, pick five or six of those—and we are going to have a price which is some multiple. It might be 1.6, it might be 1.2, but it will not be 14 times, such as was the case with Gleevec.

And so just imagining, again, within the Part B space, why not reference pricing?

Secretary AZAR. It is something we could look at. I would rather use the tools of the competitive marketplace than price fixing at the national level to keep patient choice and patient——

Senator CASSIDY. I will point out, that did not work with Gleevec.

The CHAIRMAN. Senator, your time is up.

Senator Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman.

I am sorry I had to step out for a while, but I did hear your opening statement. And I wanted to, because you mentioned four things: list price, negotiating tools, cost share, and the foreign outlook.

On plans for negotiating, one of the best negotiating tools I think that is out there is the provision of the basic health plan or essential plan that is now operating in a few States, where families can

have affordable—basically, the State ends up negotiating. The State negotiates on behalf of a large group of individuals, those who may not belong to a large employer or an employer that does not have insurance.

So those can see as little as a $6 copay for generic drugs, $15 copay for brand drug formularies, or a $3 copay for brand drugs off the formulary. So in my mind, that is a great model. Why? Because it is a negotiating tool by creating market leverage by a large group of individuals who would not have market power.

You know, I call it the Costco model. If you buy in bulk, you should get a discount. So that State, in this case New York or Minnesota, buying in bulk is getting a discount. Why shouldn't we continue to look at that as a model?

Secretary AZAR. So I want to learn more about how the basic health plans are doing that. And as long as it is done in a competitive framework of competitive insurance, as opposed to with any preferential thumb on the scale that hinders any other private insurance actors and choice in the system, I mean, any kind of those collective aggregations that allow you to negotiate is exactly what we do in Part D with the negotiating. That is why we get such good deals in Part D through our private plans.

Senator CANTWELL. Well, I think you will find that in New York, I think there are 13 different insurers that are bidding into that market. What they like is that they know they are bidding on 650,000 people, so they are willing to give a discount.

Secretary AZAR. Sure.

Senator CANTWELL. So I am looking for market power for individuals who are not finding it in other ways.

Secretary AZAR. I am happy to look at that with you.

Senator CANTWELL. Great; great.

Secretary AZAR. Yes.

Senator CANTWELL. I am sure a more thorny question—I have in our State a woman, Ms. Guzman Colindres, who is being held in Washington State. She was from Honduras and was seeking asylum and now is separated from her child.

So I want to know—I know you have had a bunch of questions here already—but what, beyond confirming the relationship between child and parent and the criminal check, the background, what else needs to happen for her to be processed?

Secretary AZAR. Okay. So in terms of reunifying her with her child?

Senator CANTWELL. Yes.

Secretary AZAR. Okay. First off, I want to ensure that she knows where her child is. I want to make sure she is in touch and they are able to communicate. If that is not happening, please offline let me know, and we will, as with all of the children and parents, want to make sure that is happening.

Senator CANTWELL. She has not been able to talk to her child, so I want to make sure that that happens.

Secretary AZAR. We want to make sure that happens. We are working—every parent and child, we want them in regular touch, regular communication. So please, let me know offline; we will get on that and make sure that that is happening.

In terms of reunification, once she is cleared, you know, from a background check perspective, at that point it is really if she completes her immigration proceedings, if she is granted asylum into the United States, then she can be reunified.

If she ends up having a deportation order, we reunify at that point.

The only thing that I cannot do is send the child back to be with her while she is in a detention facility, because of a court order allowing a max of 20 days. Congress could change that; we hope they will so we could get these kids reunified.

Senator CANTWELL. No, no. Mr. Azar, I think what you need to hear is that this problem in her case, Ms. Guzman's case, did not exist prior to this administration changing the law. In that case, Ms. Guzman seeking asylum would have come to our border, asked for asylum, and would have been processed in a way that she was able to stay in the community with her child and not be seen as a threat.

This administration is turning her into a threat. We want due process. We want people to be understood. But people seeking asylum should not be treated the same way as some criminal that the President is now talking about incessantly.

We want people with criminal backgrounds to be stopped before they even get into the United States, but we want those who are seeking asylum not to end up in a detention center never to be heard from again or have to be brought up at a hearing as a way to get attention to their case.

Secretary AZAR. And if they—I do not want to speak about her case because I do not know it—but if they present at a lawful border crossing as opposed to coming illegally into the country, they will not be separated, they will not be arrested, they are not violating the law.

So the challenge here is, she came in the country illegally, and we have laws, and we are enforcing the laws.

Senator CANTWELL. And I will want to find out, besides doing that background check and the parentage, how long is it going to take her to have that process? What are the other steps that she will have to take?

Secretary AZAR. Those would be the steps we would have to take, but she has to be able to receive the child. And if she is in custody, I cannot legally, because of the 20-day limit, reunite her with her child.

Senator CANTWELL. I am asking you how long it is going to take you to do both of those things. So we are going to get back to you on both.

Secretary AZAR. Yes. We cannot—there is no deadline on it, but as quickly as possible.

Senator CANTWELL. I think that is what we want.

Secretary AZAR. Well, the problem is, one has to confirm parentage. If she is from Honduras, I have to get a birth certificate from Honduras perhaps.

Senator CANTWELL. I am going to talk to you about that too, because I think there is technology that can help speed up this process.

Thank you.

Secretary AZAR. We would be happy to. Anything that will speed it up.

Senator CANTWELL. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Casey?

Senator CASEY. Thank you, Mr. Chairman.

And, Mr. Secretary, thank you for being here.

I wanted to ask you about the issue of preexisting conditions. We are told this affects 130 million Americans, so a lot of people are affected by it.

I know that when you were here last or, I am sorry, when you were at the HELP Committee, Senator Hassan asked you a question about it, and you said, regarding the issue of preexisting conditions and the Attorney General's legal position, you said, quote, "We share the view of working to ensure that individuals with preexisting conditions can have access to affordable health insurance," unquote, and that you also look forward to working with Congress, quote, "under all circumstances," unquote, to achieve that shared goal.

Because it does affect that many tens of millions of Americans, to say there is an uncertainty with regard to this because of what the administration said in a legal proceeding, in a case, and what you have said here as Secretary—there is a lot of uncertainty.

And if there is one aspect of our health-care policy that needs absolute certainty, it is that both parties, both houses, with the administration, are going to guarantee that no one who has coverage now that has a preexisting condition will lose it and no one in the future will have that uncertainty.

So I guess one of the first questions I have for you is, what have been your recommendations to the President regarding how you and the administration generally are going to maintain those protections for people with preexisting conditions?

Secretary AZAR. So, of course, my discussions with the President are not something I am at liberty to discuss. But the administration's position is we support, of course, Graham-Cassidy, the proposal that is in the budget, the 2019 budget. And as part of that, it would provide for States to have alternative mechanisms to, say, an individual mandate as a means of protecting preexisting conditions.

In terms of litigation, the litigation in *Texas versus Azar* that you are referring to, in that litigation, that is a legal position first, a constitutional matter regarding the impact of the removal of the tax provision and then the impact on the mandate and then, following the Obama administration's views of construction there, that the other provisions must fall if that provision falls.

We are operating the 2019 program under existing authority, existing interpretations, as if everything is remaining as it is. So we are doing everything to keep stability in the program and operate the program as it is there.

Senator CASEY. Yes. Mr. Secretary, why not take the uncertainty off the table, just say we will support this policy no matter what? You are not forced as a legal matter to take a position. The administration has chosen to take that position. There is no mandate that you take that position in a court of law or otherwise.

Why not just say, we are going to make sure, by way of policy, by way of any other action the administration takes, that everyone who has a preexisting condition will have coverage and treatment no matter what? Why not just make that the position of the administration?

You do not have to tell me what you told the President, but it ought to be clear to the American people what the administration's policy is on preexisting conditions.

One hundred thirty million people—why not make it very clear that that is, in essence, a broad statement of the administration's policy or whatever the hell we call it these days?

Just be clear about it and say that there is no question that this administration, HHS, the White House, the Department of Justice, no one, no institution, no entity in this administration has a position other than we will guarantee—not have access to coverage, guarantee—because that is what the law provides today.

Why not say, we are just going to uphold existing law? You can have your debates with us about a lot of other issues. But, my God, why is this—why is there any uncertainty at all?

Secretary AZAR. Well, of course we are upholding existing law. And the position of the Attorney General is the position as to what the existing law is in the statute and before the courts.

But the policy position of the administration is that, in whatever framework we have around the individual markets, we support solutions to ensure people with preexisting conditions have access to affordable insurance.

And we will work with Congress. If the Affordable Care Act, if those provisions are found to be invalid, we will work with Congress to continue the efforts to find alternative ways to provide affordable insurance for people, including for those with preexisting conditions.

Senator CASEY. But, Mr. Secretary, that sounds like a lot of legal mumbo-jumbo to people. Why not just make it clear that the policy——

Secretary AZAR. We are a country of laws, so we follow the law, whatever the law happens to be.

Senator CASEY. But this is not found in law, this is——

Secretary AZAR. My policy preference does not become law.

Senator CASEY. You can get to the same policy outcome by saying we will ensure that people will have this protection.

The CHAIRMAN. Your time is up.

Senator McCaskill?

Senator MCCASKILL. Thank you.

I am going to follow up with the same topic Senator Casey was on.

On Saturday, the President of the United States said at a very public rally—he was being critical of Senator McCain who voted "no" on the Republican plan to repeal and replace the ACA. And then he said, I am quoting, "It is all right, because we have essentially gutted it anyway."

Do you agree with the President's statement?

Secretary AZAR. What the President I believe was referring to——

Senator MCCASKILL. It is a simple "yes" or "no."

Secretary AZAR [continuing]. Is that fact that without——

Senator MCCASKILL. Either you agree with the President——

Secretary AZAR. Without the individual mandate, individuals now are free, they are liberated from having to pay a tax to buy insurance they do not want and cannot afford. And that is, I believe, what the President was referring to.

Senator MCCASKILL. And have there not been other steps that have also been taken that have gutted it, that are resulting in much higher premiums on the individual markets this year?

Secretary AZAR. No, the steps that we are taking are to try to provide affordable options to individuals, the forgotten men and women, the 28 million who have been locked out of this unaffordable insurance in the individual market. We continue to try to find affordable options for them in the system.

We have tried to work on a bipartisan basis to get Congress to appropriate CSRs to stabilize that market there for this year. Congress would not do that.

Senator MCCASKILL. So do you support CSRs being paid and stabilized?

Secretary AZAR. We did support what was at the time bipartisan legislation to fund CSRs and create reinsurance. There was not, at the end of the day, bipartisan support on the Alexander-Collins-Nelson package that was at play.

Senator MCCASKILL. I think there is bipartisan support.

Secretary AZAR. If there were, it would have passed, but it did not.

Senator MCCASKILL. Well, I will just tell you, no, it has not——

Secretary AZAR. The President personally pushed for its passage.

Senator MCCASKILL. Mr. Secretary, that bill has not even been brought to the floor. Mitch McConnell has decided we are not allowed to vote on that bill.

You all are in charge of health care. You control the White House, you control Congress. And this bipartisan bill you speak of, first of all, the President went back and forth as to whether CSRs would ever be paid. You know that.

So, yes, we got together in a bipartisan way. And I think the chairman will not argue with me about this. Those bills are sitting there, and I think they've got 60 votes.

Inexplicably to me, the Republican Party—I have not seen the President at a rally saying, "Let us pass the CSRs." I have not heard him at a rally saying. "Let us stabilize with reinsurance."

I have heard him say, "We have gutted it."

So to just sit there——

The CHAIRMAN. Well, if I could interrupt for a second.

I have to say that Senator McConnell, the leader, would have included this in the omni, but the Democrats objected to that.

Senator MCCASKILL. Mr. Chairman, I will guarantee you this. If Mitch McConnell will put on the floor the bipartisan pieces of legislation that have been negotiated to stabilize the markets, you will pass that by—I cannot imagine there is any Democrat who would vote against that.

I do not know what the negotiations are in these magic rooms that none of us gets to see. The same place the tax bill was done,

the same place appropriations bills are done—we do not get to see what is going on. I do not know what is going on in those rooms.

The CHAIRMAN. That is what happened.

Senator MCCASKILL. Well, I am not sure what happened, Mr. Chairman, because we are not allowed to be——

The CHAIRMAN. I am.

Senator MCCASKILL [continuing]. Told or we do not see.

But I know this, that the President is proud that they have gutted this.

And I want to offer into the record a very important document, which is a document that was received, and it has not been made public before, back in 2010 when the House was investigating the way preexisting conditions were handled before the ACA protections.

Mr. Chairman, I would ask unanimous consent to enter into the record the "Humana Agent Eligibility and Underwriting Guide."

The CHAIRMAN. Without objection.

[The document appears in the appendix on p. 82.]

Senator MCCASKILL. This document goes through—and by the way, all the companies have this. I want people to remember what it was like, because the administration has gone to court to do away with preexisting conditions.

The Attorney General in my State has gone to court to do away with preexisting conditions protections in the United States.

There were 400 things listed, including high blood pressure. And what it says in this document is, "Below conditions are permanent declines unless otherwise indicated," everything from autism to diabetes to pregnancy to high blood pressure. Denying air traffic controllers and miners and steelworkers the ability to get insurance—they were told they were not supposed to write insurance for them.

It is stunning to me that we find ourselves in this place, that this administration—and what they do is more important than what they say, and what they are doing right now is going to court and saying, do away with all of the consumer protections that were put in the ACA to prevent millions of people who have the 400 different conditions that said, do not write insurance for these people, we do not want them.

So I understand that you can say that somehow it is our fault that this legislation is not getting passed, but I think the American people are going to make an independent judgment on that.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Brown?

Senator BROWN. Thanks, Mr. Chairman.

Chairman Hatch mentioned during his opening remarks that over a month ago, President Trump hosted many of my colleagues in the Rose Garden to tout his drug pricing blueprint, promising, quote—this is our chairman quoting our President—"massive cuts" to drug prices. Weeks later, as the ranking member pointed out, he doubled down on his commitment to the American people.

I would like to point out that now a month later, we are still waiting for these, quote, unquote, "massive cuts" that the President promised. My guess is we will see dozens more prices increase before we see any massive cuts.

So, Mr. Secretary, if you would answer this "yes" or "no." Do you agree there are scenarios where pharmaceutical companies increase the list price of their product and price gouge consumers for no reason other than to increase their profit margin?

Secretary AZAR. Of course. We have seen examples of that. Yes.

Senator BROWN. Okay. Thank you. The fact that there is absolutely no repercussion for a company that engages in this type of predatory behavior is a problem surely that contributes to our broken drug pricing system.

Do not take my word for it. Let me read briefly from a letter I received from an Ohioan whose husband has Parkinson's disease. She wrote, "My husband takes numerous medications, some of which are expensive, but one in particular gets my attention. I noticed last year when I was preparing our tax return, the retail price of this generic drug fluctuated between $1,000 and $3,000 for a 90-day supply." She said, "I thought this was exorbitant, started asking why the price was so high, though I did not get a satisfactory answer. So I was doubly shocked when we last refilled our prescription, again, for a 90-day supply. The price: over $6,000."

It is getting so generic brands of drugs are costing more than those that have not gone off patent yet. "Because Medicare cannot negotiate drug prices, it seems," her words again, "some unscrupulous companies see that as an open door to gouge the government and to gouge all the rest of us too," unquote.

The incentives included in the administration's drug pricing blueprint to lower prices or shift costs along the supply chain are not enough to fix this broken system. There is nothing in your proposal that will prohibit or penalize the actions that are gouging Ohioans.

The government needs tools to prevent these companies from jacking up the price of lifesaving drugs, like EpiPen or naloxone, to jack them up overnight and make millions off the backs of hardworking Americans whose lives—literally, lives in these cases—depend on these medicines.

My Stop Price Gouging Act would give the government the tools it needs to hold these bad actors accountable by imposing penalties on corporations proportionate to the severity of their price gouging—proportionate to the severity of their price gouging.

It would hold bad actors accountable, something we rarely do around here.

My question, Mr. Secretary, is, will you commit to reviewing this legislation, which I introduced last year? And will you commit to working with me on finding a way to prevent pharmaceutical companies from price-gouging consumers, as you acknowledge they sometimes do?

Secretary AZAR. Absolutely—happy to work with you on that. We agree, the price-gouging by sole-source generics—and our plan actually does address that. We want to give Part D plans the ability even midyear, if there is any price increase on a sole-source generic, to allow the formulary to be reopened immediately rather than waiting for the end of the year.

We also want to open up Medicaid rebates for those drugs so that there would be uncapped liability based on that kind of a price increase. And if there is a Part B drug, we have as part of our budget

proposal an inflation penalty there for any drug increased above the rate of medical inflation, as you have suggested also.

Senator BROWN. Okay. I mean, that is just Part D, not everyone. That is not everyone we need to protect, so work with us on that.

Last thing, Mr. Chairman, in my last minute or so.

I know that many of my colleagues have already raised our collective concern over the administration's actions to separate children from their parents, something that is shameful and embarrasses all of us as members of this government.

While I understand policies at DHS and ORR remain in flux, the situation continues, of course, to be extremely troubling to anyone paying attention.

Last week, in response to reports that facilities under your purview were preventing children from comforting one another, I sent a letter to you and Secretary Nielsen concerning the care provided for traumatized children at HHS facilities.

Regardless of the topic, I have had trouble getting written answers to my letters in this administration. So in the interest of getting a timely response, I would like to ask you to please commit to getting me a response to that letter by the end of this week.

Secretary AZAR. I have not seen that particular letter. I will get you a response. I just responded this morning to—and it may have been including your questions in the letter.

I can tell you, in terms of comforting, there are no ORR restrictions on comforting of tender-age children or any other provision other than, of course, State child protection laws around that.

There was some media story. I have no idea. I have asked about this. There is no basis for what that individual reported. These are normal child care facilities subject to State law.

These grantees, these charities, I cannot tell you how seriously they take their mission to care for these children. It is actually inspiring to see their work.

Senator BROWN. I wish the administration, of which you are a part, took equal care in caring for our children.

Thanks.

The CHAIRMAN. Senator, your time is up.

Senator Whitehouse?

Senator WHITEHOUSE. Thank you, Mr. Chairman.

Secretary Azar, welcome.

I want to begin by echoing Senator Menendez's comments about the imputed rural floor problem. Unless that is corrected, you will be creating a market-shifting reimbursement cliff around Rhode Island, differentiating it from Massachusetts and from Connecticut.

We are not a very big State, so it really does not make any sense to undo what has been the status quo for years. And we will continue to work to try to make sure that we do not create that anomaly.

I think we have had this conversation before. But as you know, I think one can generally divide the pharmaceutical market into three categories. One category is where there is a functioning competitive marketplace. The other category is where there is a legally approved monopoly protected under patent law, for instance. And the third is where a company enjoys a de facto monopoly, because there is not real competition. And it is in that third sector of the

pharmaceutical industry that I think we have seen the worst misbehavior.

And my concern is that you get these companies that come in that buy up a drug manufacturer, add no value, invest in no research, but simply crank up the price for speculative purposes.

First of all, do you agree with me that these de facto monopolies do exist in the prescription drug market?

Secretary AZAR. I do. We have seen that with some of these sole-source generics that Senator Brown and I were just talking about.

Senator WHITEHOUSE. Or even not a generic; just a pharmaceutical that is outside of its patent could still have a monopoly.

Secretary AZAR. You could, if you see a branded company abusing the patent system, the REMS programs, or other things that we want to get after——

Senator WHITEHOUSE. Or after the expiration of their patent.

Secretary AZAR. Exactly, anything that——

Senator WHITEHOUSE. They could continue to have a de facto monopoly.

Secretary AZAR [continuing]. Prevents entry of a generic. Right.

Senator WHITEHOUSE. So the concern that I have is that we are not seemingly addressing that problem. I know that you have proposed reopening a formulary, but if you have a situation in which a drug manufacturer has a de facto monopoly, they were able to succeed at the original low price that the speculator then came in, bought the company, and bid up, it is always going to be within their capability, should a competitor emerge, to drop back to their original price and price out the competitor. So you can play the market in that way.

And the threat that somebody might reopen a formulary is not very helpful in that case, because a wise speculator will happily bet that nobody will come into that marketplace because they can drop their price back again and price them back out.

It seems to me that we have tools that go back to the age of grain silos and railroads and Ma Bell for dealing with monopolistic behavior. Why not just use those time-tested tools once a particular entity has been determined to have a de facto monopoly and, in many cases, is not even a member of the pharmaceutical industry, just a speculator trying to squeeze money out of the system?

Secretary AZAR. I think, Senator, that is a fair question, to look at antitrust policies and competition law there in those circumstances to see if monopoly power is being abused.

I do not purport to be an expert in DOJ or FTC antitrust policies, but I think that is a fair question. I will follow up on that. I think that is a fair thing to look into.

We do need to increase competition, though. I do think still——

Senator WHITEHOUSE. I think we all agree on that.

Secretary AZAR. One of the things we asked about in the blueprint was whether we are actually, in this country, underpaying for and under-reimbursing for generics. We need a strong, robust generic market.

We may be driving those prices so low that we are creating manufacturing anomalies that lead to sole-source products there with others exiting. We need to look at that and be open-minded about whether we have actually made it too low even.

Senator WHITEHOUSE. I think in the area of de facto monopoly, it would be hard to identify an agency of government that actually has responsibility in that area. And I do not see DOJ showing any signs of life. So I think that is part of the problem right there.

I will ask you a question for the record related to what I am hearing are very significant problems getting drugs in emergency rooms. And so just to flag that between us now so that, when you see the QFR, you know that this was a question that I was concerned about.

Mr. Chairman, thank you.

The CHAIRMAN. Senator Warner?

Senator WARNER. Thank you, Mr. Chairman.

Mr. Secretary, it is good to see you again.

And I know this is a hearing about drug pricing today—and I will come back to that—but I, like a number of my colleagues, have some questions about the ongoing crisis of the children at the border.

The Department of Health and Human Services has contracted facilities to house thousands of unaccompanied minors, including one in my State in the Shenandoah Valley, the juvenile center near Stanton, VA, where there have been very disturbing reports of abuse and lawsuits filed as a result of those accusations.

I sent the administration multiple letters on the need for us to get information back—Senator Kaine and I have. And my hope would be that we can get those responses. And I would be anxious to know if you would be able or willing to comment on any of the accusations made about the center in Stanton.

Secretary AZAR. Sure. So without regard to the particular individuals involved, it is important to know that when we get these children into our care, they are immediately evaluated with a mental health and behavioral evaluation. As there are with any children, with 12,000 children in our care, 60,000 per year, there are going to be some children who need extra care, some of which is mental health or may present a risk to themselves or others.

We have contracted with some facilities, including the one you mention, that specialize in juvenile care of a special need for those who may be a risk to themselves or others. Our children are kept separate from the rest of the juvenile population. It is a separate grant provision. They are required to fully comply with all State licensure, State laws around medication, et cetera.

We oversee that. The State licensing authorities oversee that. Obviously, we take any allegations very seriously here. We want proper and appropriate care for these children, so any allegations are quite disturbing.

I have seen nothing to confirm the nature of those allegations, but we will certainly respond to and work with you on that.

Senator WARNER. My hope would be—the reports have come up of minors being kept in solitary confinement for 23 to 24 hours, to being strapped to a chair, to being strapped to a chair without any clothing, to having bags put over their head, all practices that both seem inhumane and worthy of a great deal of review.

Now, I just wonder—understanding you may not be able to speak to the specifics of what happened in Stanton—what level of training does the ORR provide for guards in these type of facilities? If

in fact these actions took place, I would hope that we would put training regimes in place that would not sanction such behavior.

Secretary AZAR. So again, without in any way being able to confirm the validity of any of those types of allegations, this would be subject to State requirements and licensure around the care of children in any kind of custodial arrangement, and so whatever the commonwealth of Virginia's licensure requirements are and oversight there, in addition to ORR oversight.

I do not know that we have separate training in addition to State licensure requirements around the care in those juvenile detention facilities. I will be happy to get back to you on that, because I do not know the answer to that question.

Senator WARNER. We have sent a couple of letters. The sooner you can get me a response on those, the better.

Secretary AZAR. Thank you.

Senator WARNER. Let me move for a moment to an area that Senator Whitehouse was already talking about, and that is around the pricing of generic drugs.

We saw a great deal of relief 15 years ago. But as you have indicated, generics were priced right below the price point or sometimes margins were so thin that companies would not continue to produce, particularly, older patented drugs. And the ability to keep competition in the generic marketplace has dramatically declined. In many areas, we may only have one generic.

What tools has the administration proposed or can you or CMMI use to try to increase more generic competition and actually build enough of a market here where there might actually be, in addition to the brand, three or four generics to provide the kind of price competition that we need to bring drug prices down?

Secretary AZAR. I absolutely agree with you. And certainly, if you have any suggestions, I would welcome them.

We are working, the FDA Commissioner is working, to ensure that as we have any product approaching sole-source status as a generic that we are making clear to the other manufacturers that that is a market opportunity. We will make expedited pathways for generic approval, streamlining any processes we have to get products to market there to compete and bring them in.

We need to look on the reimbursement side. That is where the request for information has asked for insight there.

Again, any help you can provide, ideas—open door, please.

Senator WARNER. I would love to sit down with you on that, because I do think with pricing transparency and, again, more knowledge within the marketplace of possible opportunities, we can actually see whether the market will perform or not or whether we need, as Senator Whitehouse and I tend to agree, other things to kind of spur this type of competition.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

My partner would like to ask a question or two.

Senator WYDEN. Thank you, Mr. Chairman.

I have one last pharmaceutical question and then a matter that we have to clear up. And I will do that as part of my closing remarks.

Now, Mr. Secretary, earlier I asked you what you were doing to help the 42 million seniors on Medicare Part D with their skyrocketing prescription drug bills. You deflected the question by talking about other matters.

And after asking you again what you were going to do to help the seniors on Part D—and I have your exact quote here—you said this morning you hope that the big drug companies will exercise pricing restraint.

As we begin to wrap this up, Mr. Secretary, I just have to tell you, to get real pricing relief for those millions of seniors I have been asking about on Part D, it is going to take a whole lot more than your hopes that your former CEO pharmacy colleagues are just going to step in and help those seniors.

So my last pharmaceutical question is going to deal with another matter that will determine whether we are actually going to get some results here or just continue to make these vague promises.

Press reports indicate you and your office are negotiating directly with drug makers to lower the price of drugs like insulin for patients who pay cash for their drugs. Is that correct?

Secretary AZAR. That story was a mystery to everybody I have spoken to at my department. We have no idea what that was in reference to.

Senator WYDEN. So it is not correct.

Secretary AZAR. I am not aware of negotiating that CMS is doing around cash payment on any product.

We are having discussions, of course, with drug companies that are thinking about decreasing their list prices to see if we can help clear barriers, do anything in the channel—as I have mentioned to you privately—working to see how that can be facilitated to drive prices down.

But that story was a mystery to everyone I asked about it.

Senator WYDEN. Then let us make sure we understand what these conversations are all about. You do not see them as negotiating about anything.

Secretary AZAR. No. No. If companies are seeking to lower their prices and they are facing barriers from wholesalers or pharmacy benefit managers, we are attempting to see if we can clear any barriers that we have—regulatory, political, or otherwise—around that to help facilitate that.

Also, you know, anything that we do, Senator—you made a statement about my previous answer, and I think you sort of cabined it as if it did not relate to Part D. Anything that we do to lower list prices will help our patients in Part D because of their cost sharing. Our five-point plan that is in our President's budget would decrease patient out-of-pocket cost sharing by tens of billions of dollars if only Congress will pass the five-point plan that we have.

We want to fix the Stars system and protected-class system to allow genuine negotiation against the drug companies in Part D, where now they are not paying commercial-level rebates in Part D. We would empower greater competition there.

Senator WYDEN. Mr. Secretary, you are a smart fellow and good at this, but that is not what you said. You said——

Secretary AZAR. Well, I have said it now.

Senator WYDEN. Well, great. But you earlier said you hope—I am just reading it to you—you hope they will exercise restraint.

Secretary AZAR. That is one we can all—listen, I would love it if drug companies cut their drug prices just on their own now. It would be great also if there were no price increases. That is not our plan.

Our plan is that we create the regulatory and financial incentives—competition, negotiation, out-of-pocket payment incentives—to lower list price. That is our plan. Those would simply be ancillary benefits.

Our plan is to get that to happen by our actions. That is what I meant.

Senator WYDEN. Well, Mr. Secretary, I just want to wrap up with one other very disturbing aspect of the hearing.

You told me a little bit ago that the Department has 2,047 kids in its custody, so——

Secretary AZAR. That are separated. We have about 12,000 unaccompanied minors in our program.

Senator WYDEN. So a little bit after you made that statement, you said the Department has 2,053 kids. And that was the same number that was reported 6 days ago.

Secretary AZAR. Actually, that was the number in a press release yesterday. By the evening, it was down to 2,047. It is obviously a fluid situation, but by evening—it is just the press release shows the 2,053. But as of last night, the last information is 2,047. We have them, they are in the system. It is not like there is a mystery here. It is just—as we outplace these kids to parents or to their relatives, that number will change.

Senator WYDEN. Mr. Secretary, the point is, in both of these areas that we have talked about today, and with respect to prescription drugs, I do not think you are going to fix the problem of skyrocketing prescription drug bills if your former industry colleagues get off the hook by your signaling at a hearing like this that you hope that something might happen.

And I do not think we are going to solve this calamity of kids being separated from their parents at this kind of pace. I mean, no matter whether we are talking about 2,053 or 2,047, it is going to take you months and months and months to bring these kids back to their parents and back to safety.

So on both counts, I sure hope—and you are a smart guy, there is no question about that—I sure hope we are going to see action rather than this continued effort to offer us rosy projections and happy thoughts that, for seniors, are not going to help them when they get mugged at the pharmacy window and, for the kids, are not going to help them get to safety anytime soon.

Thank you, Mr. Chairman.

The CHAIRMAN. Okay.

Senator WHITEHOUSE. Mr. Chairman, may I ask unanimous consent before we conclude?

The CHAIRMAN. You want to ask a unanimous consent? Go ahead.

Senator WHITEHOUSE. I would like to, related to the imputed rural floor issue.

The CHAIRMAN. Sure.

Senator WHITEHOUSE. I have a letter from the Hospital Association of Rhode Island expressing its concern about the boundary effects that this will create. Also, a letter from our Governor, Governor Raimondo, expressing her concern. And also, a delegation letter from the entire Rhode Island delegation to Administrator Verma.

Mr. Chairman, this is important to us. It is not like——

The CHAIRMAN. We will make those part of the record.

[The letters appear in the appendix beginning on p. 166.]

Senator WHITEHOUSE. Thank you.

The CHAIRMAN. Okay. Thank you.

Senator CASEY. Mr. Chairman?

The CHAIRMAN. Yes?

Senator CASEY. I know we went to a second round, may I ask——

The CHAIRMAN. No, we are not going to a second round. I think we have to respect—what?

Senator WYDEN. Can Senator Casey ask one question, like I did?

The CHAIRMAN. Sure, you can ask one question, but I am not going to a second round.

Senator CASEY. Okay.

The CHAIRMAN. I think the Secretary has been more than gracious. He has answered every question, and he has answered them well, as far as I am concerned.

Go ahead.

Senator CASEY. Mr. Chairman, thank you.

I know the Secretary has been here a while.

Just very briefly. This issue of children at the border and the separation policy—I have said it is a policy straight from the pit of hell. I think most people agree with that.

I know the executive order is in place. The problem, though, is zero tolerance led to the problem of separation. Zero tolerance will continue to separate children, unless you change and have alternatives to that policy.

But here is my question. You have read, I know, Mr. Secretary, all of the statements made by medical professionals all across the country. This is one from *The Washington Post,* Dr. Charles Nelson, pediatrics professor at Harvard Medical School, quote: "The effect on children" would be, quote, "catastrophic."

You heard from the Academy of Pediatrics. We have all read those statements about the adverse and long-term, permanent damage it does to children, some of those damages being inflicted as well even if they are with the parent in detention.

So the one question I have for you is, what, if any, of these organizations that live their lives to give us information about the effect of policy like this on children, whether it is the Academy of Pediatrics, the American Psychiatric Association, for folks with children and individuals with disabilities, the Association of University Centers on Disabilities—did HHS in the lead-up to this policy or once the Attorney General announced zero tolerance, did you or anyone at HHS—and if you are aware, did anyone at the Justice Department—ever consult with the American Academy of Pediatrics?

Secretary AZAR. So first, I want to share your concern. None of us—none of us—wants impacts on these children, none of us wants

the separation. We do everything we can to mitigate any impact on these children with mental health care, medical care, dental, vision, education, activities, athletics.

We try to ensure as happy, as safe, as good an environment for these children through people who exercise real compassion on them.

I am not aware of engagement with any of those particular groups. I believe Dr. Ellie McCance-Katz, our administrator for SAMHSA, has been working with ORR with her expertise, her psychiatric expertise. I believe that is the case.

Certainly, our grantees are trained in and are expert in clinician care. Every child goes through mental health evaluation and mental health care when they are there. But it is not a desirable situation to have children separated from their parents.

Listen, at the up-front, if the parents did not bring them across illegally, this would never happen. We are where we are in terms of—once they are separated, we want to reunite them. If Congress will get rid of the 20-day ban on family unification, we will act so quickly to get those kids back together with their parents. But as long as I have a court order not allowing that integration with the family, it blocks me.

We want that to happen. We want the reunification. We want these kids well cared for.

Senator CASEY. Well, I know we have to go.

But, Mr. Secretary, I will submit to you some questions in writing for you to answer as part of the record with regard to kids with a disability, kids with Down syndrome, how they are being cared for, how many kids you have under your care. So I will be submitting those for the record.

Mr. Chairman, thank you for the extra time.

The CHAIRMAN. Thank you, Senator.

And I just want to say, you know, I have been here 42 years. And I have seen a lot of witnesses in my time, and certainly a lot of them on health care, and a lot of witnesses who have been in your position. I have never seen a better witness than you. You are clearly very competent. You are clearly doing a really good job. You clearly have been saddled with some really, really tough problems. And I have confidence that you will handle them expeditiously and well.

So I am really, really proud of you, to be honest with you. And I think everybody in America ought to be proud of you and ought to be glad that you are in this position.

Finally, to add further clarity to what occurred on the Alexander-Collins stability package, I want to note that when Senator Collins asked for a unanimous consent agreement to call up and pass the amendment, Senator Murray objected. The Democrats seem to have no interest in working with us to stabilize the individual market. So it is nice to pretend otherwise, but that is really what happened. And it was pretty disturbing to me.

Mr. Azar, I have been around a lot of Secretaries in my day and have chaired three major committees. You have had some of the worst problems I have seen in the history of my 42 years.

And I want to personally extend my congratulations and compliment you for the efforts that you have put forth, for the work

that you have done, for the care that you have exhibited, and for the kindness that I have seen.

Keep it up. These are tough times; these are tough issues. These families are all suffering. These kids are in danger. And I am just glad you are there. And I think people ought to be thanking you rather than criticizing you.

Well, I would like to thank everybody for their attendance here and participation today in this particular hearing. And again, thank you, Secretary Azar, for your excellent testimony.

I ask that any member who wishes to submit questions for the record do so by the close of business on Tuesday, July 10th.

And with that then, this hearing is adjourned.

[Whereupon, at 11:50 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF HON. ALEX M. AZAR II, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, Ranking Member Wyden, and members of the committee, thank you for the opportunity to appear before you to discuss an important issue: why prescription drug prices are too high, and what we are doing about it. I know members of this committee are serious about taking on this challenge.

Drug pricing was one of the very first topics I mentioned when I appeared before this committee during my confirmation process earlier this year, and I appreciate the Finance Committee's efforts in this area.

From Day One of his administration, President Trump has directed HHS to make drug pricing a top priority. Too many of our family members, neighbors, and friends have worked hard their entire lives only to see their savings wiped out just to afford drugs they need to live.

Earlier this year, the President's 2019 Budget laid out a range of proposals for lowering drug prices, including through reforms to Medicare and Medicaid.

In May, building on the budget, the President released a blueprint to put American patients first by lowering drug prices and reducing out-of-pocket costs. This blueprint is a plan of action for how to bring prices down while keeping our country the world's leader in biopharmaceutical innovation, and lays out dozens of possible ways HHS and Congress can address this vital issue. Some of these proposals came out of Congress, and we look forward to working with you as we take action.

Over the last decade, four significant problems have arisen in the pharmaceutical market: high list prices set by pharmaceutical manufacturers; seniors and government programs overpaying for drugs due to lack of the latest negotiation tools; rising out-of-pocket costs; and foreign governments free-riding off of American investment in innovation.

The President's blueprint lays out four strategies for tackling these problems, and we have begun to take action on each of them already.

First, we need to create the right incentives for list prices. I know firsthand the serious problems with today's complex system of drug pricing. Right now, everyone in the system makes their money off of a percentage of list prices: both drug companies and pharmacy benefit managers, who are supposed to keep prices down. Everybody wins when list prices rise—except for the patient, whose out-of-pocket cost is typically calculated based on that price.

One of HHS's initial actions is working to require drug companies to include their list price on their television commercials. For example, Americans deserve to know the price of a wonderful new drug they hear about on TV—before going to ask their doctor about a product they may find unaffordable. But more fundamentally, we may need to move toward a system without rebates, where PBMs and drug companies just negotiate fixed-price contracts. Such a system's incentives, detached from artificial list prices, would likely serve patients far better.

Second, we need better negotiation for drugs within Medicare—that is what President Trump has promised, and it's what we're going to deliver.

In Medicare Part D, HHS will work to give private plans the market-based tools they need to negotiate better deals with drug companies. Part D is a tremendously

successful program, but it has just not kept pace with innovations in the private marketplace, leading seniors and taxpayers to lose out. Well-intended patient protections may be preventing prescription drug programs from appropriately managing utilization, even in accordance with the formulary created by doctors and pharmacists and approved by CMS. While everyone agrees in the importance of the drugs in Part D's protected classes list, manufacturers often use that list as protection from paying rebates.

We also want to bring negotiation to Medicare Part B, physician-administered drugs. Right now, HHS just gets the bill, and we pay it. This system may actually be driving doctors to prescribe more expensive drugs, while potentially tempting drug companies to develop drugs that fit into Part B rather than D. We are going to look at ways to merge Part B drugs into Part D, to create competition where savings can be safely obtained, and leverage existing private-sector options within Part B.

Third, we need a more competitive pharmaceutical marketplace. Thanks to the reforms Congress passed in the 1980s, America has the strongest generic drug market of any country in the world.

But there are still too many ways that drug companies are unfairly blocking competition. Since the rollout of the Trump administration blueprint, FDA has publicized the names of companies who may be using safety programs to block competition, and issued two new guidances to help lessen the effects these actions may have on generic approvals. This work follows many FDA accomplishments under Commissioner Scott Gottlieb, including record-setting generic drug approvals in 2017 and measures to build on Congress's work to build a market for biosimilars.

Finally, we need to bring down out-of-pocket costs for American patients. Patients should not be dropping their drug regimen because of high costs. Since the blueprint rollout, CMS has reminded Medicare Part D plans of its existing policy which requires plan sponsors to ensure enrollees pay the lesser of the Part D negotiated price or copay, or be subject to CMS compliance actions making it unacceptable to bar pharmacists from working with patients to identify lower cost options. More broadly, you ought to know how much a drug costs, how much it's going to cost you, and whether there are any cheaper options, long before you get to the pharmacy counter. We look forward to working with Congress and stakeholders to understand how best to deliver this level of transparency.

Thank you again for having me here today. What I have laid out are just some elements of an aggressive, long-term plan to solve the problem we all care deeply about. I look forward to taking your questions and discussing ways we can work together to bring down prescription drug prices and help American patients.

QUESTIONS SUBMITTED FOR THE RECORD TO HON. ALEX M. AZAR II

QUESTION SUBMITTED BY HON. ORRIN G. HATCH

Question. One of the world's most pressing public health problems is the emergence of bacterial infections that are resistant to antibiotics. According to the Centers for Disease Control and Prevention (CDC), at least 2 million Americans fall sick every year with antibiotic-resistant infections—and of that number, sadly, approximately 23,000 people die.

Federally mandated infection control and stewardship programs, combined with clinical best practices, encourage limiting antibiotic use to appropriate cases. While reducing the inappropriate and unnecessary use of antibiotics can slow how quickly bacteria become resistant to current therapies, this alone will not solve the problem.

Manufacturers must develop new or improved antimicrobials. But when used appropriately, antibiotic therapies designed to treat high-priority infections are generally going to be low-revenue, low-volume products. As a result, drug development in the antimicrobial space is expensive and risky. The financial reward to bring priority antibiotics to market is low. One study estimates that there have been sixteen new, brand name antibiotics approved for use since 2000. Only 5 generated annual sales of more than $100 million. Poor return on manufacturer investment as well as gaps in scientific research pose significant barriers to develop new and novel antibiotic therapies.

At today's hearing we are examining ways to encourage greater prescription drug innovation, competition, and affordability. Part of that plan should include appro-

priately incentivizing drug manufacturers to create new antibiotics. Over the years, Congress has implemented a number of new policies to respond to this crisis. Specifically, in 2012, legislation I authored called the Generating Antibiotic Incentives Now (GAIN) Act was signed into law. This law gave companies enhanced tools that encouraged development of new antibiotics and allowed an expedited FDA approval process for antibiotics that treat life-threatening infections.

Mr. Secretary, I would like you to provide me specific and detailed recommendations outlining how you believe Congress and the administration—this time working together on solutions—can refine the Medicare inpatient prospective payment system to help hospitals cover the cost of new antimicrobial drugs that are designed to be used only as a last line of defense to treat resistant infections. Just last month FDA Commissioner Scott Gottlieb announced he has talked to CMS Administrator Verma about the feasibility of designing a new demonstration program focused on a license-based reimbursement model. While the specific details of this policy have not been publicly unveiled, I ask for your personal commitment to regularly provide me, and the other members of the Senate Finance Committee, updated information about the administration's work on this cross-agency initiative. It is critical that you share any research, data, and recommendations that identify ways Congress can improve current law in order to spur innovation in the antibiotic class.

Answer. The increase in serious antimicrobial drug resistant infections is a critical public health concern and a growing threat to patients. Developing new drugs is a costly endeavor. If product developers know that they will not be able to recoup their investments, there may be reduced incentive to invest the significant money needed to discover and develop such a drug.

We are currently discussing ideas as part of the FDA's broader policy work in this area. We plan to release more information soon and look forward to working with Congress as we further our thinking.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

UDI

Question. Secretary Azar, Senator Warren and I have long supported the inclusion of medical device identifiers on the Medicare claim form [1] and have urged both CMS

[1] Letter from Senator Elizabeth Warren and Senator Chuck Grassley to Marilyn Tavenner, Administrator, Centers for Medicare and Medicaid Services (December 22, 2014); letter from Senator Elizabeth Warren and Senator Chuck Grassley to Daniel Levinson, Inspector General, Department of Health and Human Services, August 12, 2015, *https://www.grassley.senate.gov/sites/default/files/news/upload/2015.08.06%20UDI%20Letter%20to%20OIG.pdf;* letter from Senator Elizabeth Warren and Senator Chuck Grassley to Sylvia Matthews Burwell, Secretary, Department of Health and Human Services, March 8, 2016, *https://www.grassley.senate.gov/sites/default/files/news/upload/2016_03_09%20CEG%20to%20HHS%20regarding%20UDI.PDF;* letter from Senator Elizabeth Warren and Senator Chuck Grassley to Gary Beatty, Chair, Accredited Standards Committee X12, August 29, 2016, *https://www.warren.senate.gov/files/documents/2016-8-29_UDI_letter_to_ASC_X12.pdf;* "Senators Warren and Grassley Comment on HHS Report on Medicare Savings From Inclusion of Medical Device Identifiers on Claim Forms," October 4, 2016, *https://www.warren.senate.gov/?p=press_release&id=1270;* letter from Senators Elizabeth Warren and Chuck Grassley to Seema Verma, Administrator, Centers for Medicare and Medicaid Services, November 8, 2017, *https://www.warren.senate.gov/files/documents/2017_11_08_Letter_to_CMS_re_UDI_and_claims.pdf;* letter from Senators Elizabeth Warren and Chuck Grassley to Scott Gottlieb, Commissioner, Food and Drug Administration, June 12, 2018, *https://www.warren.senate.gov/imo/media/doc/2018.06.12%20Letter%20to%20Gottlieb%20on%20UDI%20and%20claims.pdf;* letter from Senators Elizabeth Warren and Chuck Grassley to Seema Verma, Administrator, Centers for Medicare and Medicaid Services, November 8, 2017, *https://www.warren.senate.gov/files/documents/2017_11_08_Letter_to_CMS_re_UDI_and_claims.pdf;* letter from Seema Verma, Administrator, Centers for Medicare and Medicaid Services, to Senators Warren and Grassley, January 8, 2018; letter from Senators Elizabeth Warren and Chuck Grassley to Scott Gottlieb, Commissioner, Food and Drug Administration June 12, 2018, *https://www.warren.senate.gov/imo/media/doc/2018.06.12%20Letter%20to%20Gottlieb%20on%20UDI%20and%20claims.pdf.*

and FDA to work together to implement this recommendation supported by HHS OIG[2] and MedPAC.[3]

Do you agree with HHS OIG and MedPAC that including device identifier information in the Medicare claim form could improve identification and tracking of medical devices and strengthen post-marketing safety efforts at the FDA?

In addition, do you feel the addition of device identifier information to the Medicare claim form could be a crucial addition to the program integrity of Medicare?

Answer. It is CMS's understanding that the Accredited Standards Committee X12 (ASC X12) proposed package for the next version of the claims form will include the device identifier (DI) portion of the unique device identifier (UDI) for high-risk implantable devices between willing trading partners. After ASC X12 moves forward the package for the next version of the claims form, the process continues with consideration by the National Committee on Vital and Health Statistics (NCVHS). NCVHS may hold hearings and obtain input from stakeholders in preparation for development of its recommendations to HHS. CMS looks forward to receiving recommendations from NCVHS and the completion of the standards development process. CMS would then consider whether to proceed with notice and comment rulemaking, which would be necessary to adopt the standards.

LIVER TRANSPLANTS/UNOS

Question. On June 27, 2018 a bipartisan Iowa delegation wrote your office regarding the Organ Procurement and Transplantation Network/United Network for Organ Sharing (OPTN/UNOS) and a proposal published in August of 2016 titled *Redesigning Liver Distribution.*

The delegation expressed grave concerns about this proposal as the University of Iowa estimates it would reduce by 15 percent the number of liver transplants performed annual at UI (the only liver transplant center in Iowa).

The letter went on to say that a compromise was reached by the OPTN board in December 2017. Our letter was written to draw this important topic to your attention.

Will you work with my office and the offices of the State of Iowa to ensure that the distribution of livers for transplantation remains fair and unbiased?

Answer. The Health Resources and Services Administration (HRSA) is committed to ensuring fairness and equity in organ allocation policies consistent with the statutory and regulatory requirements. HRSA continues to rely on the independent expertise of the Organ Procurement and Transplantation Network (OPTN) and its members, which includes stakeholders that are part of the transplant community and other interested members of the public, to consider and address the requirements of the OPTN final rule as organ allocation policies are developed and revised. This approach ensures that transplant professionals who directly engage in patient care as well as transplant patients, donors, and donor family members have the opportunity to bring their experiences and public comments directly to the process of developing organ allocation policies.

HRSA encouraged all stakeholders and members of the public with an interest in liver allocation policy to share their views with the OPTN as part of the public comment process. The OPTN will continue to evaluate any proposed liver allocation policy in light of all of the requirements of the OPTN Final Rule, public comments received, and any relevant data.

DIR FEES AND PBM TRANSPARENCY

Question. Recently, you stated that you will direct HHS' OIG to study PBM practices specifically as they impact community pharmacies. Given the lack of transparency surrounding PBM practices, how will this study or other efforts by the administration bring increased transparency to PBMs keeping "spread" profits that effectively increase patients' out-of-pocket costs?

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[2] Department of Health and Human Services Office of Inspector General, "Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices," September 2017, *https://oig.hhs.gov/oas/reports/region1/11500504.pdf.*

[3] Medicare Payment Advisory Commission, "Report to the Congress: Medicare and the Health Care Delivery System," June 2017, p. 234, *http://medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.*

Will a study address retroactive DIR fees that also effectively increase patients' out-of-pocket costs?

Answer. The Department believes addressing the role of PBM practices under the Part D program is an important component to addressing high drug prices for American consumers. As pointed out in the President's blueprint to lower drug prices, because health plans, pharmacy benefit managers (PBMs), and wholesalers receive higher rebates and fees when list prices increase, there is little incentive to control list prices. Consumers, however, pay higher copayments, coinsurance, or pre-deductible out-of-pocket costs when list prices rise. The President's blueprint recognizes the major role played by PBMs in using new utilization management tools to widen the gap between list prices and net prices. Such recognition is a starting point for debating and considering potential policy alternatives to ameliorate these misaligned incentives in the Part D program.

In releasing the blueprint, the Department also issued a Request for Information (RFI) on issues raised by the blueprint, including comment from stakeholders on possible changes to the Part D benefit structure. Further, CMS issued a RFI as part of the 2019 proposed Parts C and D rule (CMS–4182–P) which sought feedback from stakeholders regarding issues relating to Part D drug prices in which PBMs play a major role. The Part C/D Drug Pricing rule recently proposed by CMS describes action it is considering in future benefit years to address retrospective pharmacy DIR.

Additionally, the President's FY 2019 budget contains several policies to modernize the Part D drug benefit to improve plans' ability to deliver affordable drug coverage for seniors and reduce their costs at the pharmacy counter, including efforts to address the misaligned incentives of the Part D drug benefit structure, such as requiring Medicare Part D plans to apply a substantial portion of rebates at the point of sale.

DRUG PRICES AND COMPETITION

Question. In the President's blueprint to lower drug prices, the need to increase competition is highlighted. In addition, the blueprint focuses on the need to end the gaming of the regulatory processes that keep drug prices high or that hinder generic competition. I could not agree more.

S. 974, CREATES, is a bill that targets abuses that undermine free-market competition and the integrity of the Hatch-Waxman Act process. The CREATES Act will actually send more parties to the bargaining table instead of the courtroom by improving and streamlining existing litigation options. CBO estimates that the CREATES Act would save Federal programs approximately $3.8 billion by increasing generic drug competition and associated cost savings.

Will the administration offer its support for CREATES?

Answer. The administration supports the goal of preventing the delay or deterrence of generic drug and biosimilar development by ensuring that interested developers have access to the reference listed drug (RLD) or reference product supplies they need to support generic and biosimilar applications.

LYMPHEDEMA

Question. One and one-half million Medicare beneficiaries suffer from a medical condition called lymphedema. According to a 2001 CMS decision memo (CAG 00016N), Medicare beneficiaries with lymphedema were advised to use compression garments in between pneumatic pump sessions (and occupational and physical therapy sessions) to prevent re-accumulation of fluid and worsening of the condition. One year later, a National Coverage Determination policy (# 280.6) stated that compression garments must be included as part of a conservative treatment regimen for this condition.

In 2004, CMS determined that for an item to be covered by Medicare it must fall under at least one statutorily defined benefit category. CMS has determined the lack of coverage in these situations was because compression garments did not fall under one of these categories. However, FEHBP (BC/BS), Tricare, VA, and many State Medicaid programs recognize and cover compression garments as DME.

Would you please review the CMS regarding whether compression garments for the treatment of lymphedema should be considered DME for Medicare purposes as well? This would seem to be consistent with previous CMS decision memos and NCDs.

Answer. In order for compression garments to be covered by Medicare, they would have to meet the definition of a Medicare-covered benefit category. CMS has carefully considered Part B coverage of compression garments and found that these items do not qualify. CMS is happy to provide you and your staff with technical assistance as you consider legislation on this subject.

340B

Question. With so many different terms used to talk about hospital "charity"—uncompensated care, charity care, community benefit—it is imperative that the metric used most accurately reflects direct benefit to the most vulnerable patient populations.

In the President's FY 2019 Budget, the administration proposed restructuring the 340B program by redistributing hospital 340B program savings to hospitals providing a minimum level of charity care, set at uncompensated care levels of 1 percent of patient costs. What data did you utilize to support setting a charity care level of 1 percent as a requirement for hospitals to receive redistributed 340B savings? Is there additional data that you do not currently have that you need? HHS has asked for additional transparency surrounding charity care in the proposed IPPS payment rule. What insights is HHS hoping to gain? What other data points or metrics are needed here? Does HHS have the appropriate authority to gather this data?

Answer. The President's FY 2019 Budget would modify hospital payment for drugs acquired through the 340B drug discount program by rewarding hospitals that provide charity care and reducing Medicare payments for 340B drugs to hospitals that provide little to no charity care. Under a regulation that went into effect in calendar year 2018, certain Medicare Part B payments for 340B drugs have been reduced to better reflect the minimum average discount 340B hospitals receive. Current law requires the savings to be redistributed within the payment system in a budget neutral manner. Under the FY 2019 budget proposal, the savings from hospitals that provide uncompensated care equaling at least one percent of their patient care costs would be redistributed based on their share of aggregate uncompensated care. Hospitals not meeting that threshold would not be eligible for the redistribution and the savings from their payment reduction will be returned to the Medicare Trust Funds.

CMS currently distributes a prospectively determined amount to Medicare disproportionate share hospitals based on their relative share of uncompensated care nationally. In the fiscal year 2019, Hospital Inpatient Prospective Payment System final rule, CMS requires Medicare disproportionate share-eligible hospitals to submit a detailed listing of its charity care and uninsured discounts corresponding to the amount claimed in the hospital's cost report. Currently, charity care, as well as discounts given to uninsured patients who qualify under the hospital's charity care or financial assistance policy, are included in a hospital's total uncompensated care. With this additional information on a hospital's charity care and uninsured discounts, CMS will be better able to ensure the accuracy of payments for uncompensated care under section 1886(r) of the Social Security Act.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

MEDICAID BEST PRICE

Question. Secretary Azar, pharmaceutical manufacturers that voluntarily participate in Medicaid are required to pay rebates to States on covered outpatient drugs, which help Medicaid receive manufacturers' lowest or best price. The administration's blueprint asks, "Does the best price reporting program pose a barrier to price negotiation and certain value-based agreements in other markets, or otherwise shift costs to other markets?"

Is the administration considering safe harbors or other mechanisms to allow for value-based agreements? Would you need additional authorities from Congress in order to take those steps?

How would changes to best price affect other payers?

Answer. As the President's blueprint to lower drug prices notes, the Department is considering further use of value-based purchasing in Federal programs, including indication-based pricing and long-term financing. For example, the Department is reviewing comments solicited in the blueprint on the relationship between such pro-

grams as Medicaid Best Price requirements on efforts to promote value-based arrangements in the States.

Additionally, under current Federal law, drug manufacturers must provide Medicaid programs the best prices for prescription drugs that they offer to any wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity within the United States. The President's FY 2019 budget proposes a new statutory demonstration authority that will allow up to five States to test a closed formulary under which they negotiate prices directly with manufacturers, rather than participating in the Medicaid Drug Rebate Program. Prices negotiated under this demonstration will also be exempted from Best Price reporting. I am happy to work with Congress regarding this proposal.

BIOSIMILARS

Question. Biologics are a rapidly growing class of drugs that treat complex diseases like cancer, rheumatoid arthritis, and Crohn's disease. While we have seen a robust generic market with small molecule drugs (over 1,000 generic approvals in 2017), we have not seen the same development of biosimilars to increase competition and provide more choices to patients. For instance there are currently 10 FDA-approved biosimilars yet only three are currently being marketed.

What payment policies has the administration implemented to date to support the uptake of biosimilars? Are there instances in Federal programs, for example under the new 340B payment rate, where biosimilars could be disadvantaged?

I understand that FDA has developed educational materials to better inform physicians about biosimilars, and had launched an educations campaign in late 2017 to help providers gain a better understanding of these products. Has CMS considered disseminating those materials to providers to increase their utilization?

Answer. CMS is committed to providing physicians with the resources and information they need to provide high quality care to their patients. Through the CMS website, we offer numerous resources for providers, including the ability to subscribe to the *MLN (Medicare Learning Network) Connects® Provider eNews* weekly electronic publication with the latest Medicare program information. CMS has sent several *MLN Connects®* newsletters with information on biosimilars, along with a newsletter[4] about payment for biosimilar products. CMS has also published several informational materials to inform providers about important payment policy changes as they relate to biosimilars.

In the calendar year 2018 Medicare Physician Fee Schedule final rule, CMS changed the Part B biosimilar payment policy to provide for the separate coding and payment for products approved under each individual abbreviated application, rather than grouping all biosimilars with a common reference product into codes. We believe that this policy change will encourage greater manufacturer participation in the marketplace and the introduction of more biosimilar products, thus creating a stable and robust market, driving competition and decreasing uncertainty about access and payment.

In addition, in the calendar year 2019 Hospital Outpatient Prospective Payment System rule, we changed to our Medicare Part B drug payment methodology for biosimilars acquired under the 340B Program. Specifically, we will pay biosimilars not on pass-through payment status acquired under the 340B program at ASP minus 22.5 percent of the *biosimilar's* Average Sales Price (ASP) instead of the biosimilar's ASP minus 22.5 percent of the *reference product's* ASP. We agreed with concerns that stakeholders raised about the current payment policy that it could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B program. We stated that we believe that these changes would better reflect the resources and production costs that biosimilar manufacturers incur and that this approach is more consistent with the payment methodology for 340B-acquired drugs and biologicals, for which the 22.5 percent reduction is calculated based on the drug or biological's ASP, rather than the ASP of another product.

Question. Additionally, the blueprint asks, "Are government programs causing underpricing of generic drugs, and thereby reducing long-term generic competition?" Is the administration also looking at whether Federal program pricing is also reducing long-term biosimilar competition?

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[4] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1509.pdf.*

Answer. The administration is taking a holistic look at the issue of prescription drug pricing, including effects of Federal program pricing in the marketplace.

Question. FDA is in the process of developing a Biosimilar Action Plan that is supposed to be geared toward promoting biosimilar entry into the market. Can you share when the plan is expected to be released and if the plan may include revisions to how the agency treats manufacturing issues for reference biologics?

Answer. In July, FDA released a Biosimilars Action Plan. This plan is an important piece of the administration's bold Blueprint to Lower Drug Prices and demonstrates the progress being made against the deliverables the President laid out.

The plan is aimed at promoting competition and affordability across the market for biologics and biosimilar products. Our Biosimilars Action Plan applies many of the lessons learned from our experience with generic drugs to accelerate biosimilar competition with four key strategies.

First, improving the efficiency of the biosimilar and interchangeable product development and approval process. Second, maximizing scientific and regulatory clarity for the biosimilar product development community. Third, developing effective communications to improve understanding of biosimilars among patients, providers, and payors. And fourth, supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay market competition to follow-on products.

REBATES AND ANTI-KICKBACK

Question. The administration's blueprint suggests that the OIG could remove the anti-kickback statutes safe harbor for drug manufacturer rebates and you've talked about moving to fixed-price discounts. But as we understand a 22-year-old class-action lawsuit settlement, manufacturers may be reticent to move to up-front volume discounts for payers to replace rebates.

How would the fixed-price discounts you've talked about work? Would they require a change to antitrust law for manufacturers to be willing to provide them?

Answer. This proposal aims to change the incentives in our system that reward list price increases. Removing the anti-kickback safe harbor for rebates and replacing it with a safe-harbor for up front discounts would encourage the drug industry to shift toward a system that offers true discounts to the patient at the point of sale.

Drug companies pay rebates and other payments to PBMs, but these payments are not reflected in patient out-of-pocket drug costs. The average difference between the list price of a drug and the net price after a rebate is 26 to 30 percent. These rebates, negotiated in Medicare Part D and private plans, are typically not used to reduce patients' cost sharing for a particular drug.

By removing the safe harbor for rebates and creating one for point-of-sale discounts, drug manufacturers will be encouraged to offer discounts that may drive volume for their product, because patients who have out-of-pocket costs based on the discounted price will save. This includes patients who are spending through a deductible, using a drug not covered by their insurance, or who pay co-insurance on the price at point of sale. It would also better align patients and plans' incentives to prefer drugs with larger up-front discounts, which would encourage plans to offer preferential formulary position for drugs with greater discounts.

INDICATION-BASED PRICING

Question. The administration's blueprint includes actions HHS may take to increase competition. One of those actions would be to evaluate options to allow high-cost drugs to be priced or covered differently based on their indication. Currently, Part D plans must cover and pay the same price for a drug regardless of the indication for which it is prescribed.

How would you operationalize indication-based pricing in Part D? What authorities would you need to do so?

Answer. On August 29, 2018, CMS announced additional flexibilities in the Medicare Part D program to allow for innovative formulary design as a valuable approach to expand drug choices and address the challenge of high drug costs for seniors and government programs. This includes giving Part D plan sponsors the choice of implementing indication-based formulary design beginning in CY 2020.

QUESTION SUBMITTED BY HON. JOHN THUNE

Question. As we continue to drive toward quality and outcomes-based reimbursement, I am interested in the inclusion of value-based arrangements in the President's blueprint. I understand that FDA issued guidance intended to help in facilitating these arrangements a couple of weeks ago with respect to manufacturer communication with payors. Do you expect that CMS will issue guidance on this topic as well? How much will the administration be able to pursue through regulatory action and what would be needed from Congress to apply this idea in the Medicare and Medicaid space?

Answer. If you talk to any patient about what they want from health care, it is outcomes, not process. The outcome that we want is that when a relative leaves that rehab hospital, he'll be walking out the door, rather than leaving in a wheelchair. But when the model involves paying for outcomes, we expect to see some real results. This should be no surprise: Incentives work. People respond to bonuses, but they really respond to penalties.

So we are especially interested in ways that we can expand outcome-based payment and sharing of risk to as many sectors of the healthcare system as possible. A broken drug pricing system, always under threat of price controls or national formularies, is not going to support the next generation of cures. We need a real market for drugs, one that encourages competition and serves the consumer. We are open to ideas about how to get there.

QUESTIONS SUBMITTED BY HON. RON WYDEN

PART D NONINTERFERENCE CLAUSE

Question. Under current law, the "noninterference" clause stipulates that the Secretary of the Department of Health and Human Services (HHS) "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors"—this explicitly prohibits the Secretary from negotiating directly with drug manufacturers on behalf of Medicare Part D enrollees.

During the hearing, you stated that your office has been "having discussions . . . with drug companies that are thinking about decreasing their list prices to see if we can help clear barriers." One barrier you identified in the hearing was pharmaceutical benefit managers (PBMs), many of whom offer Part D prescription drug plans (PDPs).

Since the hearing, despite your "hopes" that drug manufactures would practice restraint, news reports are riddled with examples of manufacturers increasing their prices since the administration announced its Blueprint. It is obvious your discussions have not worked.

Describe the activities and discussions you have had with individual drug manufacturers in an effort to "clear barriers" and how do those discussions differ from what is prohibited under the non-interference clause?

Answer. President Trump and I have committed to the American people that we will work to lower the list prices of prescription drugs. We are delivering on that commitment. However, there is no single silver bullet that solves the problem of high drug prices. That is why I testified before your committee that Congress has a role to play as well, and I stand ready to meet with you on how we can accomplish this goal together.

Question. If some of the barriers you have identified are practices by PBMs or PDP sponsors, have you engaged in similar conversations with PBMs or PDP sponsors in an effort to have those practices changed? If so, how do those discussions differ from what is prohibited under the non-interference clause?

Answer. Yes. Our proposed rule to change the system of rebates under the anti-kickback safe harbor aims to address these barriers. Major drug companies have told us that they have at times tried to make substantial and material price decreases, but the current system made it difficult to do so, showing just how broken our system of drug prices and drug distribution is in the United States. I would encourage the Congress to ask pharmacy benefit managers whether they have been approached by drug companies about lowering their list prices and what has the reaction been. Manufacturers set their prices, but the current distribution system is not necessarily making it easier to lower them.

HHS is not counting on voluntary price reductions from drug companies. We are instead focusing on reversing the incentives that keep list prices high.

Question. Please provide an update on President Trump's promise 6 weeks ago that drug manufacturers would be lowering their prices voluntarily? How many manufacturers have announced plans to lower prices? For which drugs? And by how much?

Answer. The industry and Congress can and should take specific action to lower list prices of drugs. For example, the industry could move further to a fixed price discount system at the point of sale. There's nothing stopping them. There's nothing stopping pharmacy benefit managers from changing the contracts they have with their plans or their employers to enable discount pricing or to move to net pricing regimes and away from guaranteed rebate structures that lock in existing incentives toward ever higher list prices.

Americans are already seeing real results thanks to President Trump's efforts. In the 100 days following the release of the President's sweeping blueprint to lower drug costs, there were 60 percent fewer brand-drug price increases and 54 percent more generic and brand-drug price decreases, compared to the same time period in 2017.

More than a dozen drug companies reduced their list prices, rolled back planned price increases, or froze their prices for the rest of the year.

Congress can and should evaluate the Obamacare giveaway to drug manufacturers that caps rebates in the Medicaid program, which benefits actors who increase list prices faster than the rate of inflation, and Congress can and should act to get rid of the abuse of the 180-day generic exclusivity window currently being abused by generic and branded pharmaceutical companies to delay entry of competitive generic products.

REQUIRING FOREIGN GOVERNMENTS TO PAY MORE FOR PHARMACEUTICALS

Question. The blueprint indicates that HHS will support better negotiation of drug prices by working with the Department of Commerce, the U.S. Trade Representative (USTR), and the U.S. Intellectual Property Enforcement Coordinator to develop the knowledge base needed to "address the unfair disparity between drug prices in America and other developed countries." The blueprint additionally suggests that the administration will make regulatory changes and request legislative reforms in connection with this initiative.

What specific policies is the administration considering to increase the amount foreign countries pay for their drugs?

Answer. The administration recently released an advanced notice of proposed rulemaking to seek feedback on a potential payment and service delivery model for Medicare Part B drugs known as the "International Pricing Index model." This model would test the success of an international referencing pricing index that encourages manufacturers to either lower the prices of the drugs they sell to Americans under Medicare Part B to be more in line with the prices that patients in other developed countries pay, or to increase the prices paid by those countries.

Question. How will the administration ensure that raising prices in other countries will result in drug makers voluntarily lowering their prices here in the U.S. to decrease costs for American patients?

Answer. Pursuant to the President's blueprint to lower drug prices, the administration is updating a number of historical studies to analyze drug prices paid in countries that are a part of the Organisation for Economic Co-operation and Development (OECD).

SHIFTING DRUGS FROM MEDICARE PART B TO MEDICARE PART D: IMPACT ON BENEFICIARIES' OUT-OF-POCKET COSTS

Question. Similar to a policy included in the President's FY 2019 Budget, the Blueprint directs HHS to identify instances in which moving a drug from Medicare Part B to Medicare Part D would be appropriate. Stakeholders have raised concerns that shifting drugs from Part B to Part D could result in higher out-of-pocket costs for some Medicare beneficiaries and negatively impact beneficiaries' access to needed medications, particularly for those beneficiaries who do not currently have Part D coverage. A recent analysis by Avalere found that in 2016 average out-of-pocket costs for Medicare beneficiaries were about 33 percent higher for Part D-covered new cancer therapies than for those covered in Part B.

As HHS Secretary, will you guarantee that no Medicare beneficiary will be faced with higher out-of-pocket costs under the proposal to shift drugs from Part B to Part D described in the President's FY 2019 budget and the blueprint?

What are the specific mechanisms that would prevent increased out-of-pocket costs for Medicare beneficiaries as a result of shifting drugs from Part B to Part D, including those beneficiaries who do not currently have Part D coverage?

Please describe in detail the criteria that HHS will use to determine which drugs would be appropriate to move from Part B to Part D. How will HHS evaluate and weigh the impact on beneficiaries' out-of-pocket costs in the context of that determination?

What is the anticipated timeline for HHS to identify drugs that would be appropriate to move from Part B to Part D as required by the blueprint?

Will that information be made publicly available? If so, how and when?

Answer. I look forward to working with Congress to explore ways that we can bring the negotiation strategies that are currently working in Medicare Part D, where we receive deals like the commercial marketplace, into Part B, where prices are modestly negotiated by providers though Medicare does not have a role in these negotiations. I hope to work with you and your colleagues to develop legislation that will provide us with the authority to re-classify Part B drugs into Part D when appropriate, while taking into consideration the projected impacts on beneficiary access and cost-sharing, as well as costs to the Medicare program.

COMPETITIVE ACQUISITION PROGRAM FOR PART B DRUGS AND BIOLOGICALS

Question. The blueprint indicates that HHS may use the existing authority for the Competitive Acquisition Program (CAP) for Part B Drugs & Biologicals to provide physicians a choice between obtaining Part B drugs and biologicals from vendors selected through a competitive bidding process or continuing to purchase these drugs as they do today.

Please describe in detail how HHS plans to structure and implement the CAP described in the blueprint under the existing authority.

The CAP that was in place from mid-2006 through 2008 faced challenges due to low physician enrollment and the vendor's limited ability to negotiate discounts. How will the CAP described in the blueprint differ from the CAP that was in place from mid-2006 through 2008?

Under the CAP described in the blueprint, what specific tools would vendors have to negotiate discounts?

How would payments to vendors and providers be structured?

How would any savings achieved be distributed among providers, beneficiaries, vendors, and the Medicare program?

Does HHS plan to monitor and evaluate the effect of the CAP on Medicare beneficiaries' access to Part B drugs and biologicals and the quality of care provided to beneficiaries? If so, please describe in detail how HHS will monitor and evaluate access and quality of care.

What is the anticipated timeline for HHS to implement the CAP described in the blueprint?

Answer. Currently, Medicare payment for separately payable outpatient drugs in physician offices, hospital outpatient departments, and certain other settings is generally based on drug manufacturers' average sales prices in the United States plus a six percent add-on payment (ASP +6 percent), and is subject to the sequestration, which effectively reduces the add-on to +4.3 percent. The dollar amount of the add-on is larger as drug prices increase, which may encourage physicians to prescribe higher-cost drugs, and raise beneficiary and program spending.

The Competitive Acquisition Program (CAP) for Part B drugs and biologicals, in section 1847B of the Social Security Act (the Act), is an alternative to the ASP methodology that is used to pay for the majority of separately payable Part B drugs. Under the CAP, which operated for a limited time (July 1, 2006, until December 31, 2008), instead of buying drugs for their offices, physicians who chose to participate in the CAP placed a patient-specific drug order with an approved CAP vendor, and the vendor provided the drug to the office and then billed Medicare and collected cost-sharing amounts from the patient.

Recently, we have heard from stakeholders, including physician and hospital groups, manufacturers, distributors, and beneficiary advocates, that a CAP-like approach with substantial improvements, particularly in regards to onsite availability of drugs, could potentially address concerns about the financial burdens associated with furnishing Part B drugs and their rising costs. CMS sought input on all of these considerations in the CY 2019 OPPS/ASC proposed rule and its recent ANPRM for an International Pricing Index (IPI) Model for Medicare Part B Drugs.

CMS intends to utilize a number of private-sector vendors that would supply physicians, hospital outpatient departments, and other included providers and suppliers with the drugs and biologicals that CMS decides to include in the model. Similar to the CAP, the model vendors, rather than the health care providers, would take on the financial risk of acquiring the drugs and would also bill for the drugs. Instead of paying the model vendors based on bid amounts, as section 1847B of the Act prescribes, under the IPI model, Medicare would pay the vendor for the included drugs based on the target price driven by the international pricing index, which would lower both the amount Medicare pays for included drugs and beneficiary cost-sharing.

The model vendors would have flexibility to offer innovative delivery mechanisms to encourage physicians and hospitals to obtain drugs through the vendor's distribution arrangements, such as electronic ordering, frequent delivery, onsite stock replacement programs, and other technologies. We plan to provide physicians and hospitals in the model test areas with an opportunity to select the vendors that best provide customer service and support beneficiary choice of treatments. Physicians and hospitals would be able to contract with multiple vendors for different drugs and to change vendors. Vendors would not operate formularies. CMS seeks comment in the IPI Model ANPRM on whether group purchasing organizations, wholesalers, distributors, specialty pharmacies, Part D sponsors, and potentially individual or groups of physicians and hospitals and/or manufacturers could perform the role of model vendor.

MEDICAID EXPANSION

Question. Nearly 12 million low-income Americans gained access to quality, affordable health care under the Medicaid expansion. As a result, millions of previously uninsured Americans now have access to affordable prescription drug coverage for essential medications like insulin for diabetes, oncology drugs for cancer, and medication-assisted treatment to help tackle substance use disorders. Yet, the President's FY 2019 budget request proposes slashing Medicaid by $1.4 trillion and eliminating the Medicaid expansion. These severe funding cuts could force States to eliminate optional benefits, such as coverage for prescription drugs.

Please explain how gutting Medicaid and repealing the Medicaid expansion supports State efforts to help millions of Americans to access and afford vital prescription drugs?

Answer. The FY 2019 budget establishes a block grant or per capita cap for the traditional Medicaid populations and repeals the ACA Medicaid expansion. States would have the option to cover the former Medicaid expansion population through the new Market-Based Health Care Grants included in the Graham-Cassidy-Heller-Johnson legislation. These new financing mechanisms will harmonize the treatment of States over time and allow States to better target resources to their most needy citizens. To that end, we need reforms to provide States flexibility to design their Medicaid programs to meet the spectrum of diverse needs of their Medicaid populations. Currently, outdated Federal rules and requirements prevent States from pioneering delivery system reforms and from prioritizing Federal resources to their most vulnerable populations, which hurts access and health outcomes. Reforms like block grants, when paired with additional authority and flexibility, can incentivize and empower States to develop innovative solutions to challenges like high drug costs and fraud, waste, and abuse. We must make health care more tailored to what individuals want and need in their care. The President's FY 2019 budget takes a significant step in that direction by putting the Medicaid program on a sustainable course and returning local healthcare decisions back to where they should be made.

EPIPEN MISCLASSIFICATION

Question. Since the fourth quarter of 1997, EpiPen, now owned by Mylan Pharmaceutical, appears to have been incorrectly reported as a generic drug. As a result, Medicaid grossly overpaid for EpiPen by not getting its full due in rebates. After my letters to your predecessor and public outcry on this issue, Mylan agreed to set-

tle with the Department of Justice in August 2017 and pay $465 million to resolve claims that they knowingly misclassified EpiPen as a generic drug to avoid paying rebates owed to Medicaid. However, the reality is that they paid less to settle than what they should have paid in rebates in the first place. An analysis by the U.S. Department of Health and Human Services' Office of Inspector General released this past year found the U.S. government may have in essence overpaid EpiPens by as much as $1.27 billion between 2006 and 2016.

What actions do you think Congress should take to ensure companies like Mylan cannot get away with short shrifting taxpayers and the Medicaid program as they have done with the EpiPen?

Answer. The President's FY 2019 budget contained a legislative proposal to remove ambiguity regarding how drugs should be reported under the Medicaid Drug Rebate Program so that manufacturers pay their fair share in rebates. As indicated in the blueprint, HHS is also manually reviewing each new drug that has been reported in the Medicaid rebate system on a quarterly basis to make sure classifications are correct.

PREEXISTING CONDITIONS

Question. The Trump administration has decided to argue against the constitutionality of the Affordable Care Act's important provision that protects people with preexisting conditions. If the administration is successful, once again insurance companies will be able to discriminate against people with preexisting conditions by denying them coverage or charging them unaffordable premiums. The American people do not want to go back to the days when health care was reserved for the healthy and wealthy. At the June 26th hearing before the Senate Finance Committee, you reiterated that the administration's refusal to defend the law is a "legal position." Later, you affirmed that the "policy position of the administration is . . . to ensure people with preexisting conditions have access to affordable insurance." You are named as a defendant in this law suit.

Do you believe insurers should be able to deny coverage or charge more for Americans with preexisting conditions?

Answer. The Trump administration stands ready to work with Congress on policy solutions that will deliver more insurance choices, better healthcare, and lower costs while continuing to protect individuals with preexisting conditions. The Affordable Care Act (ACA) statutory requirements here are very strict and burdensome. While this may help some consumers, it also prevents States from developing innovative solutions that are tailored to their populations. I believe that when States are not permitted to innovate, everyone is worse off. Affordability, accessibility, benefit options, and procedural safeguards are all valuable, but our current top-down, Federally-driven approach is not working well for Americans. I will work with States to allow innovation within the confines of the ACA.

Question. What did you and your General Counsel advise Attorney General Sessions and the Department of Justice regarding the administration's legal approach to the case and the policy implications of the administration's legal position on individuals with preexisting conditions?

Answer. The Trump administration remains committed to ensuring more Americans have access to affordable health coverage and has supported legislation to protect Americans with preexisting conditions. The administration's legal position is that the individual mandate is unconstitutional and that the guaranteed issue and community rating provisions of Obamacare are not severable from the individual mandate.

FAMILY SEPARATION

Question. During the hearing on June 26, 2018, you said there were 2,047 children who had been separated from their parents due to the zero tolerance policy. On July 5, 2018, you shared an updated figure of under 3,000 and said this figure includes data from prior to the start of the "zero tolerance" policy in May.

What is the exact number of separated children? Please disaggregate this data by age and country of origin.

Answer. HHS identified a total of 2,816 possible children of potential *Ms. L* class members. There were 107 minors under the age of 5 (as of February 20, 2019) and 2,713 between the ages of 5 and 17. The breakdown of these 2,816 minors by country of origin is as follows:

	Total by Country
Angola	1
Belize	1
Brazil	48
Columbia	1
Congo	4
Ecuador	3
El Salvador	208
Guatemala	1,543
Honduras	937
India	4
Kyrgyzstan	1
Mexico	44
Nicaragua	2
Peru	2
Romania	16
United Kingdom	1
Total	**2,816**

Question. How many children have been separated from their parents specifically as a result of the "zero tolerance" policy? Please disaggregate this data by age and country of origin.

Answer. HHS does not distinguish between minors who were separated from parents or legal guardians as a result of the "zero tolerance" policy from other causes of separation. Additionally, the *Ms. L* court decision does not distinguish separated minors by whether they were separated due to the "zero tolerance" policy or due to separation by the Department of Homeland Security (DHS) prior to the announcement of the "zero tolerance" policy. HHS identified a total of 2,816 children who were potentially separated from their parents or legal guardians and whose parents were potentially *Ms. L* class members. DHS subsequently determined that 79 had not been separated from parents by DHS.

CHILD PLACEMENT FACILITIES

Question. Some children's facilities including Casa Padre and the Shenandoah Valley Juvenile Center have documented health violations, allegations of abuse, or other failures to adhere to child welfare standards.

What resources is HHS providing to ensure that children receive appropriate mental health services, as required by ORR policy?

Answer. The Office of Refugee Resettlement (ORR) provides routine and emergency medical and mental health care for all UAC in its care, including an initial medical examination and follow-up care, as needed. Under the *Flores* Settlement Agreement, UAC in licensed care provider facilities, in particular, must receive at least weekly individual and two weekly group clinical counseling sessions to address their mental health needs.

Care provider facilities develop their own (ORR-approved) policies and procedures for their individual clinical programs, including standards on licensing and education for staff, according to staff role or discipline. For example, at one facility, mental health clinicians must have earned an advanced university degree and main-

tain licensure through continuing education requirements, while case managers must have earned a university degree.

Across the national UAC program, ORR works to ensure that care provider staff are trained in techniques for child-friendly and trauma-informed techniques in interviewing, assessment, and observation, as well as on identifying children who have been smuggled (*i.e.,* transported illegally over a national border) and/or trafficked while in the United States. Care providers must deliver services in a manner that is sensitive to the age, culture, native language, and needs of each child.

ORR also places children in one of two residential treatment centers (RTC) for those who have severe diagnosed mental health needs, per the DSM–5 *(Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition).* These UAC have psychiatric and/or psychological disorders that are not treatable in an outpatient setting and who pose a danger to themselves or others, as determined by a licensed psychologist or psychiatrist. While at an RTC, children and youth receive a combination of intensive therapeutic treatments by an interdisciplinary team of mental health clinicians. (Please see the *ORR Policy Guide, Section 1.4.6 Residential Treatment Center Placements* for more information.)

Question. How does HHS ensure that, in accordance with ORR policy, children in custody are aware that certain disclosures to staff are not confidential and may be shared with other government agencies such as ICE?

Answer. ORR provides orientations to newly arrived UAC within 48 hours of placement. In these orientations, minors are taught about their rights and responsibilities, which include general legal-related information and notification regarding self-disclosures made while in ORR custody. (Please see the *ORR Policy Guide, Section 3.2.2 Orientation* for more information).

In preparing and managing case files and documentation, care providers must ensure compliance with all requirements imposed by Federal statutes concerning the collection and maintenance of data that includes personal identifying information. Care providers must ensure that all records are maintained and protected so that confidential information and data are secure and not accessed, used, or disclosed to unauthorized parties or improperly altered. There must be established administrative and physical controls to prevent unauthorized access to both electronic and paper records.

There are certain situations in which ORR will communicate a minor's personal information with other Federal agencies.

When a UAC is referred to ORR's care from another Federal agency, ORR will request background information to assess whether the minor is a danger to self or others, whether there are any known medical and/or mental health issues, and whether other special concerns or needs are known. ORR uses this information to determine an appropriate placement for the child or youth in the least restrictive setting.

In situations where a minor is a material witness to a crime and has information relevant to a criminal proceeding, is a victim of a crime, or has been charged with a serious criminal offense, ORR will collaborate with law enforcement on the placement of these minors. (Please see *ORR Policy Guide, Section 1.2.3 Safety Issues.*)

If a care provider suspects that a child has been trafficked at any point in the child's life, the care provider must refer the child's case to the HHS's Office on Trafficking in Persons (OTIP) for further assessment. In addition, ORR must refer any trafficking concerns to the ICE Homeland Security Investigations (HSI) and the Human Smuggling and Trafficking Center (HSTC), at the Department of Homeland Security. Referrals to OTIP, HSI, and HSTC may include supporting documents relevant to investigative purposes. ORR may also request assistance from other Federal agencies (*e.g.,* Department of Labor) in assessing a child's case for potential trafficking concerns. (Please refer to the *ORR Policy Guide, Section 3.3.3 Screening for Child Trafficking and Services for Victims* for more information.)

If a care provider suspects that a UAC has been sexually abused while in ORR's custody, whether by another minor or staff, they must immediately report the allegation within 4 hours to HHS's Office of the Inspector General, the Federal Bureau of Investigation, Child Protective Services and/or State Licensing, local law enforcement, and, in some cases, the Federal Protective Service at DHS. The same reporting procedure applies in circumstances where a UAC has allegedly perpetrated sexual abuse on another minor while in ORR's custody.

FAMILY COMMUNICATION

Question. You noted the speed and accuracy with which you could locate children who have been separated from their parents, saying that you could find any child "within seconds" through an ORR portal. However, ORR has only provided family members with a 1–800 number and email address, and parents and lawyers have reported challenges in accessing information with these tools—for example, busy signals or long wait times. Moreover, many of these parents are detained themselves without easy access to phones or the Internet.

What steps is HHS taking to ensure timely and prompt communication between separated parents and children?

Answer. Within 24 hours of arriving at a UAC care facility, UAC are given the opportunity to communicate with a verified parent, legal guardian, or relative (when contact information is available), whether they reside in the United States or abroad. If a minor's parents are in Federal custody, the child's case manager will engage with the parents' case managers and Federal law enforcement officials to verify their relationship, so that they may communicate.

UAC are allowed a minimum of two telephone calls per week to family members or sponsors, in a private setting. Some care providers facilitate video calls between minors and their families, especially for tender age and non-verbal children. UAC are also allowed unlimited telephone access to their legal representatives. A minor may also speak with her or his consulate official, case coordinator, and child advocate.

Care providers also ensure that all mail, letters, packages, baggage, or any other items delivered to the care provider and addressed to the minor are promptly delivered and that UAC can send letters to family members, sponsors, legal representatives, and others.

Question. How is HHS ensuring communication between non-verbal children and their parents?

Answer. As previously noted, some care providers facilitate video calls between tender age and non-verbal children and their families, so that they may see one another. Also, a child's case manager or clinician may act as an intermediary for communication between a non-verbal child in care and her or his parent or legal guardian.

Question. How is HHS coordinating with DHS in instances where adequate documentation was not collected at the time of separation, or in instances where family identification numbers were not preserved?

Answer. An interagency team of data analysts, consisting of staff from various HHS operating divisions (the Administration for Children and Families' Office of Refugee Resettlement and the Assistant Secretary for Preparedness and Response, among others), U.S. Customs and Border Protection (CBP), and U.S. Immigration and Customs Enforcement (ICE), identified separated children who are in care and matched them to the parent or legal guardian from whom they were separated.

This matching effort was conducted during the summer of 2018, identifying the separated parent for all separated minors in ORR care. ORR care provider programs facilitated contact between all separated children and their parents.

FAMILY REUNIFICATION

Question. You emphasized your desire to "expeditiously" reunify families and you have reportedly asked for volunteers to help with these efforts. I share this goal of getting children and parents back together as quickly and safely as possible. As you know, family separation has traumatic and harmful effects on children's health and well-being.

Has HHS engaged with international aid organizations, such as the International Committee of the Red Cross, that have experience reuniting families that have been separated? Please describe your Department's efforts to engage entities with expertise in this arena.

Answer. HHS is actively coordinating with the governments of El Salvador, Honduras, Guatemala, and Mexico on family reunification efforts, consistent with the plan developed by the Federal Government for the reunification of children with parents outside the United States and approved by Judge Dana Sabraw of the U.S. District Court for the Southern District of California in the *Ms. L* case.

HHS is also coordinating its family reunification mission with the American Civil Liberties Union on the safe reunification of children in their home countries. This effort includes other non-governmental organizations such as Kids in Need of Defense and Justice in Motion.

Question. How many separated children have been reunified with their parents? Please disaggregate this data by age and country of origin.

Answer. As of February 20, 2019, there are 2,155 minors who have been reunified with the parent from whom they were separated. These minors are further disaggregated below by age and country of origin:

Country	Ages 0–4	Ages 5–17	Total by Country
Belize		1	1
Brazil		41	41
Colombia		1	1
Ecuador		3	3
El Salvador	9	163	172
Guatemala	32	1,110	1,142
Honduras	36	721	757
India		3	3
Kyrgyzstan		1	1
Mexico	3	16	19
Nicaragua		1	1
Peru		2	2
Romania	2	10	12
Total	**82**	**2,073**	**2,155**

Question. What are the circumstances of these reunifications (in the community, as part of deportation processes, etc.)?

Answer. Consistent with plans developed by the Federal Government and approved by the U.S. District Court for the Southern District of California, minors in ORR's care have been reunified with their parents in a variety of settings. HHS has reunified children with parents in ICE detention at designated ICE reunification sites. Then, using its administrative authority, ICE has either released the reunited family unit to the interior of the United States or has detained the family unit together in ICE Family Residential Centers. HHS has also reunified children with parents released to the interior of the United States by physically bringing children to the parent. For parents who have since left the United States, HHS and ICE have transported children to their home country for reunification at reception centers operated under the authority of the home country government.

Question. For separated children who have been released to sponsors, please provide data on how many have been released to each of the four categories of sponsors, in accordance with section 2.2.1 of the ORR policy manual.

Answer. The table below shows the breakdown of separated minors released through the TVPRA process not through the court ordered process, as of February 20, 2019 joint status filing. Please note that there are three Categories of sponsors (Categories 1–3).

Reunified Minors

Sponsor Category	# of minors
Category 1	106
Category 2	281
Category 3	90
Grand Total	**477**

Question. In order to complete the reunification process, HHS is collecting DNA samples to match parents and children as quickly as possible.

How is this information being stored and protected?

Which government agencies have access to this information and under what conditions?

What happens to this information once the family has been reunified?

Answer. All DNA data, samples, and results were ordered destroyed pursuant to the order of Judge Dana Sabraw in *Ms. L,* and they have been certified destroyed by the DNA laboratory. No government agencies have access to DNA data, samples, or results. The information was allowed to be used only for the specific matching of a child with a parent, and for no other purpose.

Question. HHS officials told congressional staffers during a briefing on June 29, 2018 that there were 42 Federal Field Specialists helping with the reunification process and making reunification decisions, but that there were plans to increase this capacity.

What are the roles of staff assisting with the reunification process?

Answer. The Secretary of HHS tasked the Assistant Secretary for Preparedness and Response (ASPR) with the reunification mission on behalf of HHS. ASPR designated a Federal Health Coordinating Official (FHCO) to lead the HHS reunification mission (the FHCO is also the "HHS operational lead" as identified in *Ms. L* court filings). The FHCO leads the Incident Management Team (IMT), which conducts HHS reunification operations.

The IMT has included ASPR field and headquarters personnel, ORR field and headquarters personnel, including Federal Field Specialists, and deployed assets from the U.S. Public Health Service Commissioned Corps, National Disaster Medical System Disaster Medical Assistance Teams (NDMS DMAT), and contracted case management and logistics personnel.

Question. As of July 10, 2018 how many Federal Field Specialists are assisting with the reunification process?

Answer. As of July 10, 2018, the HHS Incident Management Team (IMT) included 177 HHS personnel, including 41 at HHS headquarters and 136 in the field. These included Federal Field Specialists as well as other ACF personnel, ASPR personnel, USPHS Officers, NDMS DMAT team members, and contractors.

Question. DOJ reported that 19 young children in HHS custody could not be reunified with their parents because the parents had already been deported.

What steps is HHS taking to communicate with DOJ and prevent any additional deportations prior to reunification?

Answer. Judge Dana Sabraw of the U.S. District Court for the Southern District of California stayed removals in *Ms. L.*

Question. How many parents accepted voluntary departures as a means of family reunification?

Answer. HHS defers to the Department of Homeland Security (DHS) regarding questions on the legal decisions of the parents in DHS custody.

Question. Some news outlets are reporting instances of parental or sponsor responsibility to cover the cost of the child's transportation—for example, a case where a father was asked for pay $1,250 for his daughter's flight in order to be reunified.

What is HHS's current policy with regard to covering the cost of transportation to achieve reunification?

If a family is responsible for arranging transportation, how does HHS address financial barriers, especially if impeding reunification or sponsor placement?

Answer. HHS pays for the transportation costs of separated minors to be reunified with parents from appropriated funds from ORR's UAC Program.

INFORMATION SHARING BETWEEN HHS AND DHS

Question. HHS and DHS recently entered into a Memorandum of Agreement to share information between the two agencies.

How does HHS ensure that sponsors and adult household members have provided informed consent related to sharing their information with law enforcement?

Answer. Sponsors and adult household members are provided and sign an Authorization for Release of Information, which notifies them that their information will be shared with law enforcement.

Question. What steps is HHS taking to verify DHS allegations of youth gang activity, particularly given past inaccuracies?

Answer. Allegations of youth criminal activity are verified through a review of multiple sources of information, including: (1) attestations from law enforcement, and/or criminal history documentation (police records, arrest records, court records, probation records, etc.); (2) non-law enforcement records pertaining to dangerousness (*e.g.,* school records, child welfare agency records, or other government institutions); (3) interviews with the child's family or other caregivers; (4) Significant Incident Reports indicative of dangerousness or flight risk; and (5) information that indicates that the child may not be a danger (*i.e.,* reports from school or counselor).

NEWLY MIGRATED FAMILIES

Question. Your repeated references to the *Flores* settlement and related court order present a false choice of family separation or family detention. As you know, *Flores* does not require family separation and does not prevent families from being released into the community while their case is processed.

For families who have migrated since the executive order on June 20, 2018, how is HHS facilitating the release of families into the community and providing referrals to any necessary supports and services?

Answer. The UAC Program is not responsible for the release of families from ICE custody into the community. However, for UAC who are released from ORR care to a sponsor in the community, ORR may provide discharged UAC and their sponsors with referrals for support and services including behavioral health supports in the sponsor's community.

QUESTIONS SUBMITTED BY HON. BILL NELSON

Question. On June 19th, your department informed me that 174 children had been separated from their families between May 6, 2018 and June 17, 2018 and held in Office of Refugee Resettlement (ORR) shelters in Florida, including 94 at Homestead.

During my June 23rd visit to Homestead, I was told that the number had decreased from 94 to approximately 70. I was also told that just 62 of those 70 had been in contact with their parents and that the remaining eight had not yet been in contact because of difficulties locating their parents.

Since President Trump signed an executive order on June 20th intended to end the policy of systematically separating children from their parents, I have only received one update indicating that, as of June 25th, the number of children held in Florida had actually increased to 179. Additional efforts by my colleagues and me to obtain information and statistics related to separated children have been repeatedly rebuffed.

How many children separated from their parents since May 6, 2018, have been held at ORR or ORR-sponsored facilities in Florida?

Answer. As of the February 20th joint status filing, there had been a total of 264 separated minors who are children of *Ms. L* class members who are either currently

in a Florida ORR facility or were at any time during their time in ORR care previously in a Florida ORR facility and discharged from that facility.

Question. How many total children separated since May 6, 2018, are currently being held at facilities in Florida and how many are being held at each ORR or ORR-sponsored facility in Florida?

Answer. As of November 15th, there were 28 minors still in care who were included in the minors originally identified as potentially separated. Most of these children are on a pathway to standard sponsorship discharge, based on a parental decision to waive reunification.

Question. How many of the total number of children separated from their families have been reunited with their parents or legal guardians since President Trump signed his June 20th executive order?

Answer. Of the 2,816 minors identified as potentially separated in the *Ms. L vs. ICE* class, as of December 12, 2018, 2,149 have been reunified with the parent from whom they were separated. An additional 508 have been discharged under other appropriate circumstances—most through discharge to family member sponsors based on parents' waiving reunification. There are 79 children who were subsequently determined not to have been separated from a parent by the government. There were 123 children who were separated from parents and were still in care who were on a pathway to standard sponsorship because their parents had waived reunification or a final determination had been made that they could not safely be reunified with their parent. As of December 12th, there were 8 children remaining to be reunified with parents.

Question. How many children separated from their families and held at ORR or ORR-sponsored facilities in Florida have been reunited with their parents or legal guardians since President Trump signed his June 20th executive order?

Answer. Because children move in and out of shelters during their admission, this information is not readily reportable.

Question. How many children separated from their families and currently held at ORR or ORR-sponsored facilities in Florida have made contact with their parents or legal guardians?

Answer. All separated children in ORR care in all States have made contact with their parents or legal guardians.

Question. Have any parents of children held at ORR or ORR-sponsored facilities in Florida been deported? If so, how many and what is HHS doing to make contact with these parents?

Answer. The Report to Congress on Separated Children provides data on the number of children in ORR custody who parents were deported, disaggregated by status as of November 6th.[5] There are no separated minors in ORR care for whom HHS or the child's grantee shelter program has not made contact with the parent. Children are routinely in contact with parents.

Question. On June 26th, I sent a letter opposing this administration's decision to support a dangerous lawsuit filed by Republican Attorneys General—including in Florida—that would destroy our health-care system and hurt as many as 7.8 million Floridians with preexisting conditions.

If this administration and these Attorneys General prevail, health insurers across the country will once again be able to charge unlimited premiums for older adults, and discriminate against people with preexisting conditions by denying them coverage or charging higher premiums simply because of their past medical history. A preexisting condition includes cancer, acne, Alzheimer's or simply being a woman.

In making this decision, your administration is turning its back on 133 million Americans with preexisting conditions, including 17 million children and 7.8 million Floridians.

Do you believe that people with preexisting conditions should be guaranteed access to health coverage?

Answer. The Trump administration remains committed to ensuring more Americans have access to affordable health coverage, and has supported legislation to pro-

[5] *https://www.hhs.gov/programs/social-services/unaccompanied-alien-children/report-to-congress-on-separated-children/index.html.*

tect Americans with preexisting conditions. The administration's legal position is that the individual mandate is unconstitutional and that the guaranteed issue and community rating provisions of Obamacare are not severable from the individual mandate.

Question. Do you support allowing insurers to discriminate against folks with substance use disorders, like opioid addiction, thereby denying them adequate access to treatment?

Answer. Discussed in response to next question below.

Question. Should these individuals be forced to pay more for their health insurance?

Answer. HHS, along with the Departments of Labor (DOL) and Treasury, are committed to enforcing the Mental Health Parity and Addiction Equity Act (MHPAEA), promoting compliance, providing guidance, assisting consumers, and conducting investigations of non-compliance. In July 2017, the Departments, together with other Federal and State partners convened a meeting to develop an Action Plan for improved Federal and State coordination of enforcement of the Mental Health Parity and Addiction Equity Act (MHPAEA). As part of that process, the Departments also accepted written comments from stakeholders. More information about this process can be found here: *https://www.hhs.gov/programs/topic-sites/mental-health-parity/achieving-parity/cures-act-parity-listening-session/index.html.*

On April 23, 2018, HHS released the Mental Health and Substance Use Disorder Parity Action Plan. In addition, the Departments have finalized the parity compliance program guidance document required by section 13001(a) of the 21st Century Cures Act. The compliance program guidance document, referred to as the 2018 MHPAEA Self-Compliance Tool, can be found on the dedicated mental health and substance use disorder webpage of DOL's Employee Benefits Security Administration (EBSA), *https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-and-substance-use-disorder-parity.* This compliance tool is designed to assist plans and issuers in advancing MHPAEA compliance and is largely informed by the audit tool that is used by EBSA investigators and is made available to HHS and State regulators. It includes comprehensive guidance regarding non-quantitative treatment limitations (NQTLs) and required disclosures. The compliance tool includes both examples of potential parity violations as well as compliant practices, and is based on EBSA's experience with enforcing mental health parity. As required by section 13001(a) of Cures, this document was developed in consultation with respective Inspector General of each Department. Accordingly, this document satisfies the requirements of section 13001(a), and will be updated every 2 years. HHS, along with the Departments of Labor and Treasury, also proposed additional guidance on NQTLs and disclosure, as well as issued a draft model disclosure template to assist consumers in obtaining the information they need to effectuate their rights under the law.

Finally, in December 2017, HHS posted a Mental Health Parity and Addiction Equity Act Enforcement Report. That report is available here: *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/HHS-2008-MHPAEA-Enforcement-Period.pdf.* DOL issued its own enforcement fact sheet in April 2018, which is available here: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/fact-sheets/mhpaea-enforcement-2017.pdf.*

Question. If successful, this lawsuit would break the President's promise to protect guaranteed health coverage for individuals with preexisting conditions. You would put insurance companies back in charge and give them free rein to deny care to those who need it most. Are you comfortable with the DOJ arguing insurers should be able to do just that in your name? How do you plan to uphold the President's promise to protect these children, women, seniors and the millions of other Americans with preexisting conditions?

Answer. The Trump administration remains committed to ensuring more Americans have access to affordable health coverage, and has supported legislation to protect Americans with preexisting conditions. The administration's legal position is that the individual mandate is unconstitutional and that the guaranteed issue and community rating provisions of Obamacare are not severable from the individual mandate.

Question. The President's budget and the blueprint suggest moving some of the drugs paid for under Medicare Part B, which covers drugs administered in the hos-

pital outpatient department or the doctor's office, into Medicare Part D to facilitate price negotiations.

How would this change assure access to Part B drugs for the millions of seniors on Medicare who are not enrolled in Part D?

Answer. I look forward to working with Congress to explore ways that we can bring the negotiation strategies that are currently working in Medicare Part D into Part B, where prices are modestly negotiated by providers though Medicare does not have a role in these negotiations. I hope to work with you and your colleagues to develop legislation that will provide us with the authority to re-classify Part B drugs into Part D, when appropriate, while taking into consideration the projected impacts on beneficiary access and cost-sharing, as well as costs to the Medicare program.

Question. During your testimony before the HELP Committee, you said that moving Medicare Part B drugs into Part D would result in billions of dollars in savings and that these savings would be more than enough to take care of Medicare beneficiaries who are not enrolled in Part D or who suddenly face higher cost sharing.

Does HHS have data to support this claim? If so, please share it with this committee.

Answer. Under the President's FY 2019 Budget that describes this proposal, the Secretary will exercise this authority only when there are savings to be gained from price competition. However, a budget impact will not be available until specific categories or classes of drugs are chosen. The President's blueprint includes a Request for Information (RFI) seeking comment on which drugs or classes of drugs would be good candidates for moving from Part B to Part D.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. In the President's drug price plan, American Patients First, one of the accomplishments is creating incentives to lower list prices.

Given recent announcements by several pharmaceutical companies that they were increasing list prices, would you consider existing incentives to lower prices failures?

Will there be follow up measures taken to refine the incentives to ensure that list prices decrease?

How will savings from lower list prices trickle down to consumers?

Answer. Among efforts by the administration to address high list prices, one is addressing the role of PBM practices under the Part D program. As pointed out in the President's blueprint to lower drug prices, because health plans, pharmacy benefit managers (PBMs), and wholesalers receive higher rebates and fees when list prices increase, there is little incentive to control list prices. Consumers, however, pay higher copayments, coinsurance, or pre-deductible out-of-pocket costs when list prices rise.

The President's blueprint recognizes the major role played by PBMs to widen the gap between list prices and net prices. Such recognition is a starting point for debating and considering potential policy alternatives to ameliorate these misaligned incentives in the Part D program. In releasing the blueprint, the Department issued a Request for Information (RFI) on issues raised by the blueprint, including comment from stakeholders on possible changes to the Part D benefit structure.

Further, CMS issued a RFI as part of the 2019 Parts C and D rule (CMS–4182–P) which sought feedback from stakeholders regarding issues relating to Part D drug prices in which PBMs play a major role. Comments received in response to the RFI will be used for possible consideration in future rulemaking. Additionally, the President's FY 2019 budget contains several policies to modernize the Part D drug benefit to improve plans' ability to deliver affordable drug coverage for seniors and reduce their costs at the pharmacy counter, including efforts to address the misaligned incentives of the Part D drug benefit structure, such as requiring Medicare Part D plans to apply a substantial portion of rebates at the point of sale.

Question. The President's plan calls for Part D plan sponsors to provide information about drug price increases and lower-cost alternatives in the Explanation of Benefits they send to their beneficiaries. What protections can be included to ensure beneficiaries aren't steered toward alternatives that may be unsuitable for their particular medical needs in an effort to save money by the plan?

Answer. As indicated by the blueprint, the Department sought comment from stakeholders in the recently proposed Part C and D rule (CMS–4182–P) on ways to improve the usefulness of the Part D Explanation of Benefits by including information about drug price increases and lower cost alternatives. Additionally, as we designed these proposed changes to Medicare Advantage (MA) and Part D, foremost in our minds was the impact on beneficiaries and ensuring affordability and access to medications. The changes we are proposing bring tools to Medicare that are widely used in private plans. However, it's important to remember that if seniors don't like a plan that takes advantage of these new flexibilities, they are in the driver's seat. They have the option to choose a different plan that better meets their needs. These new tools will only become as common as beneficiaries want them to be. Further, CMS reviews plan formularies to guard against discriminatory practices, and the agency has in place an expedited appeals process for cases in which a physician recommends an exception to prior authorization or other forms of management. There are also additional requirements for plans to cover at least two drugs per class, including in the protected classes. Ultimately, the changes we are proposing would reduce costs for protected class medicines and therefore expand access to these important medicines.

Question. The President's plan calls for shifting some drugs from Medicare Part B to Part D.

What will the impact be for consumers in what their out-of-pocket costs will be for their medications if all medicines are moved over?

Do you anticipate an increase in Medicare Part D premiums due to the shift of drugs from Part B to Part D?

Do you have concerns about rising list prices impacting out-of-pocket costs for beneficiaries?

Answer. I look forward to working with Congress to explore ways that we can bring the negotiation strategies that are currently working in Medicare Part D, into Part B, where prices are modestly negotiated. I hope to work with you and your colleagues to develop legislation that will provide us with the authority to re-classify Part B drugs into Part D, when appropriate, while taking into consideration the projected impacts on beneficiary access and cost-sharing, as well as costs to the Medicare program.

Question. Some older generic drugs have increased in price, what proposals are possible to incentivize companies to keep older generics in production to prevent monopoly suppliers who are then able to increase costs without the fear of market share loss?

Answer. I understand the importance of having multiple generic applications approved, including for older generics, to help provide American consumers with lower cost medicines. Under the FDA Commissioner's Drug Competition Action Plan (DCAP), FDA has taken substantial steps to facilitate increased competition through the approval of lower-cost generic medicines. In the coming months, FDA will continue to take actions to enhance the efficiency of the generic drug review process, to maximize scientific and regulatory clarity with respect to generic drugs, and to reduce "gaming tactics" by brand name drug companies that delay the generic competition Congress intended when it enacted the Hatch-Waxman Amendments. All these actions are intended to help ensure consumers can get the medicines they need at affordable prices.

FDA cannot determine the precise amount of funding that will go toward older generics, as it does not ultimately control for which drugs the generics industry chooses to submit marketing applications, but the actions it is taking should help encourage industry to invest in the development of older generics that have minimal competition.

FAMILY REUNIFICATION

Question. On July 6, 2018, the Department of Health and Human Services (HHS) sent a press release entitled "HHS is executing on its mission with care and compassion."[6] In particular, HHS states there are under 3,000 children who are currently in ORR care where HHS has evidence that they could possibly have been separated from a parent, with approximately 100 of those children under the age of 5. The

[6] *https://www.hhs.gov/about/news/2018/07/06/hhs-executing-its-mission-care-and-compassion.html.*

Department of Justice attorneys provided additional information during a recent court proceedings regarding the children under age 5: 83 kids have been linked to 86 parents; 16 kids have not yet been linked with parents; 46 of those parents remain in the custody of ICE; and 19 of those parents having been deported from the United States.[7]

Do the statistics provided by the Department of Justice include children who have been reunified with a sponsor who is not the parent from whom they were separated? If so, how many of those children have been reunified with a close relative, legal guardian, or other sponsor?

Answer. Yes, statistics provided to the Department of Justice included children who were reunified to sponsors other than their separated parents. Based on February 20, 2019 joint filing report, there were 580 children reunified with sponsors who were not their separated parents.

Question. If not, what are the number of children who have been identified to have close relatives, legal guardians, or other sponsors instead of parents—as DOJ asserts that 16 kids have not yet been linked to parents?

Answer. All children in the *Ms. L* class are linked to the parent from whom they were separated.

Question. For the parents who have been deported, what actions is HHS taking to ensure that the child will be reunited with his or her parent? Are there plans for the parent to return to the United States and be reunified with his or her child? Please outline in detail the plan for reunifying deported parents whose children remain in the United States.

Answer. The court-approved Federal interagency plan for reunification of minors with parents who are no longer in the United States provides information responsive to this question and was submitted to the Court in a filing dated August 16, 2018.

Question. Have the parents who have been deported been notified of their child's whereabouts/condition/status? Have the parents who have been deported had any communication with his or her child since their deportation?

Answer. There are no separated minors in ORR care for whom HHS or the child's grantee shelter program has not made contact with the parent. Children are routinely in contact with parents.

DNA TESTING

Question. HHS notes that it is using DNA testing to expedite verification of parentage. HHS also notes that a DNA test will only be done when there is a specific parent-child relationship that needs to be validated.

What is the criteria that is required for HHS to conclude that a specific parent-child relationship needs validation?

Answer. Initially, HHS attempted to meet the parent-child relationship verification standard for sponsorship by a parent under the TVPRA-governed process for safe and timely discharge to a sponsor. This standard would require birth certificates validated by the consular authorities of the issuing country, or, if such documents could not be obtained, DNA biological maternity or paternity validation. Subsequently, Judge Sabraw ordered that HHS should assume the putative parentage established at apprehension was accurate unless there was specific reason to doubt parentage, and that DNA would only be permitted to be used if required in circumstances where there were such specific doubts about parentage.

Question. What actions are you taking to ensure that these requirements are met—and that all other avenues for parent-child relationship validation are exhausted—before DNA testing is used?

Answer. As of November 2018, all outstanding questions about parentage are resolved, and there are no separated minors in ORR care with red flags for doubts about parentage.

Question. Once the DNA tests and the reunification of the family is complete, is HHS destroying the DNA record?

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[7] *http://m.cnn.com/en/article/h_a05a00c0075bb46ed2c485af560667c3.*

Answer. All DNA data, samples, and results were ordered destroyed by the judge in *Ms. L,* and they have been certified destroyed by the DNA laboratory.

Question. If so, how long does HHS wait to destroy the DNA record, and is the information shared with other agencies?

Answer. The information was allowed to be used only for matching of a child with a parent, and for no other purpose. It was not shared with any other agencies. All data, samples, and results were ordered destroyed within 7 days.

Question. If the DNA record is not destroyed, where is it stored and who has access to it?

Answer. All DNA data, samples, and results were destroyed.

UNMATCHED CHILDREN

Question. The information regarding the number of children who have not been linked to his or her parent is concerning. How is HHS working with DHS to determine the parentage of unmatched children? How many total children under the age of 5 years old and above the age of five remain unmatched to his or her parent?

Answer. There are no separated minors in ORR care who are not matched to a separated parent.

QUESTIONS SUBMITTED BY HON. THOMAS R. CARPER

Question. The HHS OIG recently issued a troubling report on drug prices in Medicare Part D in the period from 2011 to 2015. In particular, the OIG's findings that the number of seniors paying $2,000 or more almost doubled, and that the 20 drugs with the highest cost increases have almost no alternatives. Have you reviewed this HHS OIG report? How will your proposals to introduce value-based pricing to Medicare Part D bring down these costs for patients?

Answer. As the President's blueprint to lower prescription drug costs notes, the Department is considering use of value-based purchasing in Federal programs. For example, the Department is reviewing comments solicited in the blueprint on the relationship between programs such as the Medicaid Best Price requirement and efforts to promote value-based arrangements in the States.

Question. Physician and patient groups have expressed great concerns with your proposal to shift drugs from Medicare Part B to Part D. They are especially concerned that this shift could increase beneficiary cost-sharing and out-of-pocket costs, such as for patients suffering from cancer. Beneficiaries with supplemental coverage for Part B but no Part D coverage might pay much higher out-of-pocket costs under this change. On recent Avalere study found that Medicare patients' out-of-pocket costs for new cancer drugs were about 33 percent higher for Part D-covered new cancer therapies than for cancer therapies covered in Part B. Do you agree that any policy change that moves covered drugs from Medicare Part B to Part D should be accompanied by reforms to reduce patients' out-of-pocket costs and co-payments in Medicare Part D?

Answer. I look forward to working with Congress to explore ways that we can bring the negotiation strategies that are currently working in Medicare Part D into Part B, which modestly negotiates prices by providers though Medicare does not have a role in these negotiations. I hope to work with you and your colleagues to develop legislation that will provide us with the authority to re-classify Part B drugs into Part D when appropriate, while taking into consideration the projected impacts on beneficiary access and cost-sharing, as well as costs to the Medicare program.

Question. Like most of my colleagues, I was deeply troubled by the administration's policies that led to separating children from their parents at the U.S. southern border. On June 20, 2018, the president signed an executive order that would end his own policy. However, the solution he seeks to put in place is costly and flawed. I believe that without addressing the root causes of migration to the U.S. southern border, we will continue to see this problem. The Department of Health and Human Services is charged with housing and care of unaccompanied migrant children after they arrive at the border. As you are aware, HHS already had difficulty keeping track of the children it was charged with before the administration put its zero tolerance policy in place, which added hundreds of additional children in to ORR's care. What steps is HHS taking to improve its oversight of these facilities?

Answer. ORR conducts oversight visits at least monthly to ensure that care providers meet minimum standards for the care and timely release of unaccompanied alien children, and that they abide by all Federal and State laws and regulations, licensing and accreditation standards, ORR policies and procedures, settlement agreements, and child welfare standards. ORR increases the frequency of monitoring if it is warranted by issues identified at a facility. In addition, if ORR monitoring finds a care provider to be out of compliance with requirements, ORR issues corrective action findings and requires the care provider to resolve the issue within a specified time frame. ORR also provides technical assistance, as needed, to ensure that deficiencies are addressed.

These ORR monitoring and compliance activities are divided among various Federal ORR teams. The teams work collaboratively, but also independently in order to provide a higher level of scrutiny and focused attention on various tasks. HHS updates and improves the monitoring tools, processes, and resources regularly to meet changing procedures and regulations.

Question. It's my understanding that the Joint Concept of Operations between the Office of Refugee Resettlement (ORR), and the Department of Homeland Security is supposed to be completed soon. This Joint Concept of Operations would outline how the agencies keep track of children transferred into HHS custody from DHS. Are you on track to meet that deadline? What have your communications been like with Scott Lloyd, the Director of the Office of Refugee Resettlement? Do you believe his office is prepared to meet the deadline? If not, what needs to be changed?

Answer. The Joint Concept of Operations (JOC) was finalized on July 31, 2018, and addresses intersecting responsibilities between HHS's ORR and DHS as it relates to transporting, processing, and caring for UAC, including during an influx.

Question. Recent reporting by *The New Yorker* indicated that the Office of Refugee Resettlement, a part of the Department of Health and Human Services, did not have adequate plans in place to reunite parents with children who are being held at the border. Nonprofit agencies, such as Kids in Need of Defense, have stepped up to fill the void, making phone calls to ICE and HHS to try to find out the location of parents and children in order to make sure they can keep track of each other. Over the weekend of June 23–24, Customs and Border Protection stated that it had reunited 538 children in its custody with their parents, and that it had halted referring all border crossers to the Department of Justice. How many children has HHS reunited with their families? When do you expect this process to be completed?

Answer. Of the 2,816 minors identified as potentially separated from parents in the *Ms. L vs. ICE* class, as of December 12, 2018, 2,149 have been reunified with the parent from whom they were separated. An additional 508 have been discharged under other appropriate circumstances—most through discharge to family member sponsors based on parents' waiving reunification. There are 79 children who were subsequently determined not to have been separated from a parent by the government. There were 123 children who were separated from parents and were still in care who were on a pathway to standard sponsorship because their parents had waived reunification or a final determination had been made that they could not safely be reunified with their parent. As of December 12, there were 8 children remaining to be reunified with parents. HHS anticipates prompt completion of the reunification of children with parents from whom they were separated.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

DRUG PRICING

Question. While the administration has come up with a number of proposals to address the cost of drugs, in reality none of these policies address the core problem which is that the prices for prescription drugs continue to sky rocket. Particularly, drug manufacturers continue to increase the prices of their drugs despite President Trump's promise that the opposite would occur. Under your blueprint, I see nothing that changes the status quo or discourages drug manufacturers from exponentially increasing prices. For example, what consequences would a drug maker face if they raise their price of a Part D drug under the administration's blueprint?

Answer. The President's blueprint to lower prices acknowledges that a growing number of complex high-cost drugs account for a growing percentage of health-care spending, and that the pharmaceutical industry has shifted its attention to high-cost drugs that face little to no competition, because they offer the freedom to set

high launch prices and increase them over time. In an effort to address the problem of high-cost drugs, the Trump administration believes it is time to realign the system in four ways, outlined in the President's blueprint to lower drug prices: increasing competition, improving government negotiation tools, creating incentives for lower list prices, and bringing down out-of-pocket costs for consumers. The Department has solicited, and is currently reviewing, comments on these ideas for consideration in actions to address high drug prices.

DRUG SHORTAGES

Question. Drug shortages pose a threat to an individual's access to care. These shortages can occur due to range of issues from problems in drug quality, to unforeseen events such as natural disasters. For instance, Hurricane Maria impacted Puerto Rican drug manufacturing facilities, which worsened shortages of IV fluids. Drug shortages lead to delays in or rationing of care, difficulties finding alternative drugs, risk associated with medication errors, higher costs, reduced time for patient care, and hoarding or stockpiling of drugs in shortage.

I have been contacted by providers in Maryland regarding the dangers and prevalence of these shortages, and believe we must do everything possible to assist them, so they have the resources to care for their patients. I was disappointed to see that the Trump administration's drug pricing blueprint did not address drug shortages.

Does the Trump administration have a plan to tackle the issue of drug shortages? If so, what actions can Congress take in order to assist in that plan?

Answer. In July 2018, FDA announced the formation of a new Drug Shortages Task Force charged with delving more deeply into the reasons behind some of the more persistent shortages and looking for solutions to address these ongoing challenges. While FDA is directed to convene the group, we are working with our partners across the administration and seeking input from industry and other members of the public to evaluate the current authorities to consider how we might better help prevent and mitigate shortages. The new task force includes Federal partners on the shortage issues, including the Centers for Medicare and Medicaid Services, the Department of Defense, the Department of Veterans Affairs, the Office of the Assistant Secretary for Preparedness and Response, and the Federal Trade Commission.

The task force expands upon the work of a group that was created by FDASIA, which gave the FDA new authorities to help address drug shortages. This includes creating the requirements that manufacturers of certain drugs that are life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition notify us of a permanent discontinuation or temporary interruption in manufacturing that is likely to lead to a meaningful disruption in the supply of such drugs in the United States.

NALOXONE NEGOTIATION

Question. An effective way to save those who are suffering from an opioid overdose is to provide them with naloxone, which can quickly restore normal respiration to a person whose breathing has slowed or stopped as a result of overdosing with opioids. The city of Baltimore has been aggressive in combatting the opioid crisis.

Since 2015, everyday Baltimore residents have saved more than 1,800 lives with naloxone. Baltimore first responders have saved more than 10,000 lives over the same time period. However, the city cannot afford all the naloxone needed, so it is having to ration its supply, prioritizing distribution to individuals at highest risk of overdose.

No police officer, no firefighter, no public health provider, and no person should be unable to save a life because of the high price. By bringing down the cost of naloxone, we can get this life-saving drug in the hands of more people. Doing so will save countless lives. One way to help bring down the cost is to allow CMS to negotiate lower prices for naloxone under Medicare Part D.

Do you support allowing CMS to negotiate lower prices for naloxone under Medicare Part D?

Answer. The administration's drug pricing strategy is intended to address the price of all prescription drugs, including naloxone.

Question. Additionally, the Federal Government has the authority under 28 U.S.C. § 1498, to make or purchase a patented invention, including medication, without the permission of the patent holder in exchange for reasonable compensa-

tion. The government could then either produce or contract with generic producers to make naloxone, which would drastically reduce its price. This would allow localities and first responders the ability to have enough access to the medication to save more lives.

What is the Trump administration's position on using its "government use authority" to help drive down the cost of naloxone?

Answer. The administration's drug pricing strategy is intended to address the price of all prescription drugs, including naloxone.

CHILDREN SEPARATED AT THE BORDER

Question. President Trump purposely chose to use children as leverage to try to keep parents from crossing the border. He underestimated the universal opposition to such a callous and inhumane policy. Signing an executive order that changes policy from keeping toddlers in jails and cages to keep families in jail, is not a solution. The damage he has done to our country, to these children, and to America's standing in the world is incalculable.

Our Maryland Attorney General, Brian Frosh, has written to you and asked for data on the children being held at Maryland facilities that are under the custody of the Office of Refugee Resettlement, under the Administration for Children and Families, which you oversee.

Can you provide me now with the number of children and their ages separated from their parents that are placed in Maryland under ORR custody, the number of locations being used in Maryland, and the timeline for reunification of these children with their parents?

Answer. There are at least 21 UAC that were possible children of potential class members that were placed in the State of Maryland. Out of 21 children, 18 were 5 years and older and 3 were below 5. There are two programs in Maryland namely Bethany Christian Services Maryland and Board of Child Care Shelter. The 21 UAC have all been discharged.

Question. Are parents provided with information on the status of their children?

Answer. Yes. All parents of separated children have been contacted by the case manager working with the child.

Question. Why shouldn't the State be told about the number of children within ORR custody in their State?

Answer. This information is routinely available to the State. State licensure authorities license ORR shelter facilities to provide residential care to children, and can inspect the sites at will.

TEEN PREGNANCY PREVENTION PROGRAM

Question. I'd like to ask you about the future of the evidence-based Teen Pregnancy Prevention (TPP) Program. As you may know, this program has been recognized by independent experts as a stellar example of how to implement evidence-based policymaking—something that should be expanded, not cut short. Last fall, the bipartisan Commission on Evidence-Based Policymaking, established by House Speaker Paul Ryan, highlighted the TPP Program as an example of a Federal program "developing increasingly rigorous portfolios of evidence."

Baltimore City's teen pregnancy rate is three times as high as the national average. Last summer, your agency terminated the existing TPPP grants. There were three Maryland entities that stood to lose funding: the Baltimore City Health Department, Health Teen Network, Inc., and Johns Hopkins University's Center for American Indian Health. Maryland grantees were set to lose over $6.7 million in funding.

This spring HHS released two new funding opportunity announcements for the TPP Program that prioritize ideology over evidence. Thankfully, five Federal courts, including a class action, have ruled in favor of the health and well-being of American teens, parents, and families—stating that the Trump-Pence administration's early termination of Teen Pregnancy Prevention Program (TPPP) grants is unlawful.

These important programs have a growing body of evidence-based approaches that meet the diverse needs of young people. Moving forward, will HHS rely on the agency's own high quality research on evidence-based programs?

In making decisions about TPPP in FY18, please share what body of evidence did HHS rely on to justify the shift toward funding to emphasize risk reduction or returning to abstinence-only regardless of the actual needs of young people?

Answer. HHS relied on findings from the rigorous evaluation of 37 TPP-funded studies for a 2016 longitudinal study of TPP Program Grantees (FY 2010–2014). Overall, 73 percent of the evaluated projects either had no impact or had a negative impact on teen behavior. Though there were some positive effects on teens' knowledge, attitudes, and intentions, changes in attitude are of limited value in measuring the success of a program that seeks to change behavior. Moving forward, HHS will continue to comply with the applicable appropriations statute(s). Decisions by the Department are being guided by science and a firm commitment to giving all youth the information and skills they need to improve their prospects for optimal health outcomes.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

TRANSPARENCY

Question. As part of your written testimony, you mentioned that one of HHS's initial actions to address drug pricing is "working to require drug companies to include their list price on their television commercials."

Why is this one of your first priorities?

How will this effort lower the cost of lifesaving prescription drugs?

Answer. We aim to reduce the price to consumers of prescription drugs and biological products. HHS has proposed a rule which would require direct-to-consumer (DTC) television advertisements for prescription drug and biological products for which payment is available, directly or indirectly, through or under Medicare or Medicaid to include the list price of that product. We are proposing this regulation to improve the efficient administration of the Medicare and Medicaid programs by ensuring that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize not only their out-of-pocket costs, but also unreasonable expenditures borne by Medicare and Medicaid, both of which are significant problems.

Markets operate more efficiently and competitively when consumers have relevant information about a product, including its price, as well as alternative products and their prices, before making an informed decision whether to buy that product or, instead, a competing one. Consumers price shop when looking to purchase a new car, a new house, or even a new coffee maker. Price shopping is the mark of rational economic behavior. To facilitate price shopping, sellers invariably provide potential buyers with the prices of their products; consumers gauge the reasonableness of these prices against alternatives. Even automobile dealerships, as result of Federal law, post the retail or "sticker" price on the side window of each new car offered for sale.

That has not been the case with prescription drugs or biological products, where consumers often need to make decisions without information about a product's price. Price transparency is a necessary element of an efficient market that allows consumers to make informed decisions when presented with relevant information, but for consumers of prescription drugs, including those whose drugs are covered through Medicare or Medicaid, both the list price and actual price to the consumer remain hard to find.

DRUG IMPORTATION

Question. Following your confirmation hearing, I submitted a question for the record (QFR) on drug importation and whether or not you would support the safe importation of prescription drugs from countries with rigorous safety standards, like Canada.

More than 25,000 Ohioans currently rely on Canadian pharmacies for more affordable prescription drugs.

In response to my question, you answered: "If confirmed, I commit to exploring whether any pilots or demonstrations might be utilized to see if a system could be set up in a way such that public health officials would support a determination of no additional risk to the public's health and safety and of a significant reduction

in costs for American consumers, when appropriately scaled up to represent the likely level of importation."

Have you explored any pilots or demonstrations to test safe importation as described in your answer to my QFR?

Do you have plans to do so prior to the end of the year?

Answer. One thing that President Trump and I have been clear about on drug pricing is that we consider this a serious issue, in need of serious solutions. The Congressional Budget Office has assessed full-scale reimportation multiple times and has said it would have no meaningful effect.

One of the main reasons is that Canada's drug market is simply too small to bring down prices here. Canada simply doesn't have enough drugs to sell them to us for less money, and drug companies won't sell to Canada or Europe more just to have them imported here.

On top of that, the last four FDA Commissioners have said there is no effective way to ensure drugs coming from Canada really are coming from Canada, rather than being routed from, say, a counterfeit factory in China. The United States has the safest regulatory system in the world. Opening our borders to potentially unsafe drugs in search of savings is too great a risk.

We know, however, that for certain critical medicines, where there are no blocking patents or exclusivities associated with the drugs, and where there is only a single manufacturer (sole-source), conditions may develop that create significant barriers to, and ultimately threaten, patient access.

The FDA is presently examining whether—for certain critical medicines, where there are no blocking patents or exclusivities associated with the drugs, but where there is only a single manufacturer (sole-source)—sudden, significant price increases have created significant barriers to, and ultimately threaten, patient access. To pursue these considerations, FDA has formed a work group to explore various policy frameworks that, through the exercise of enforcement discretion or otherwise, would involve the importation of drugs under circumstances that meet these criteria and that would be suitable substitutes for the FDA-approved version of the medically-necessary drugs. We will consider whether and how the foreign versions of these medicines can be imported with adequate assurances of safety and effectiveness.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

ON DELIVERY SYSTEM REFORM IN RURAL AREAS

Question. You have identified value-based care are one of your four priorities. As you know, rural providers face unique challenges in undertaking value-based payment models. What specific options are you exploring and steps are you taking to help rural providers pursue delivery system reform?

Answer. We are committed to bringing a rural health-care focus to health-care delivery and payment reform initiatives. This includes engaging stakeholders and rural health-care providers on delivery system reform and innovation opportunities. One example of our focus on rural health care is CMS's Pennsylvania Rural Health Model, which seeks to increase rural Pennsylvanians' access to high-quality care and improve their health, while also reducing the growth of hospital expenditures across payers, including Medicare, and increasing the financial viability of rural Pennsylvania hospitals to ensure continued access to care.

ON DRUG PRICING

Question. I have heard concerns that your proposal to move drugs from Medicare Part B into Medicare Part D could result in increased out-of-pocket costs for Medicare beneficiaries. Have you done any analysis on the direct impact this change will have on patients with cancer and other serious illnesses? What are you doing to protect these beneficiaries?

Answer. I look forward to working with Congress to explore ways that we can bring the negotiation strategies that are currently working in Medicare Part D into Part B, where prices are modestly negotiated, by providers though Medicare does not have a role in these negotiations. I hope to work with you and your colleagues to develop legislation that will provide us with the authority to re-classify Part B drugs into Part D, when appropriate, while taking into consideration the projected

impacts on beneficiary access and cost-sharing, as well as costs to the Medicare program.

ON FAMILY SEPARATION AND REUNIFICATION

Question. Secretary Azar, during your testimony you said several times that Congress or the courts should change the requirement that children not be kept in detention facilities for more than 20 days under most circumstance. You said that the 20-day requirement impedes the ability of the administration to re-unify families and keep families together, and so it was really a problem for the Courts and Congress. Are you suggesting that HHS should have the ability to indefinitely keep children in detention? Do you disagree with the American Academy of Pediatrics that "even brief detention can cause psychological trauma and induce long-term mental health risks for children" and that the government should "[e]liminate exposure to conditions or settings that may retraumatize children, such as those that currently exist in detention, or detention itself," *http://pediatrics.aappublications.org/content/early/2017/03/09/peds.2017-0483.* Do you believe that keeping children and families in immigrant detention facilities, which are a prison-like environment, is in the best interest of children?

Answer. HHS defers to ICE to respond to questions about conditions in ICE Family Residential Centers. Family Residential Centers are not the same as adult detention facilities.

Question. What efforts were made by the Trump administration to ensure that children who were forcibly separated from their parents were able to remain together with their siblings in detention?

Answer. In accordance with *ORR Policy Guide, Section 1.2.7,* ORR routinely keeps sibling groups together, except in highly unusual circumstances. UAC are placed in the least restrictive setting that is in the child's best interest in accordance with the law. Generally, the vast majority of UAC are placed in non-secure State-licensed residential child care facilities or transitional foster care homes or group homes.

Question. Are there cases in which a parent had more than one of their children forcibly separated from them and the children were sent to different detention centers? If this occurred, are children being held in detention facilities able to regularly contact their sibling(s) who is being held in a different detention center(s)? Please provide the total number of siblings who were separated from their families, the number of siblings who remained together in detention, and the number who were separated. Please break these numbers down by age group.

Answer. In accordance with *ORR Policy Guide, Section 1.2.7,* ORR routinely keeps sibling groups together, except in highly unusual circumstances. From the 2,816 possible children of potential Ms. L class members, there are 328 with siblings. Out of 328 children, 316 children were placed together and 12 children were placed in a different program.

Question. The American Academy of Pediatrics recently released a statement opposing the detention of immigrant children, saying that: "In 2017, the AAP published a policy statement that immigrant children seeking safe haven in the United States should never be placed in detention facilities. Studies of detained immigrants have shown that children and parents may suffer negative physical and emotional symptoms from detention, including anxiety, depression and posttraumatic stress disorder. Conditions in U.S. detention facilities, which include forcing children to sleep on cement floors, open toilets, constant light exposure, insufficient food and water, no bathing facilities, and extremely cold temperatures, are traumatizing for children. No child should ever have to endure these conditions." Are you aware that the American Academy of Pediatrics released this statement opposing the detention of immigrant children? Do you disagree with the American Academy of Pediatrics statement? Were statements like this from medical experts taken into consideration before the Trump administration's policy of "zero tolerance," and thus de facto family separation, was implemented? If yes, please state which medical experts or organization were consulted.

Answer. All UAC receive a high standard of medical care while in the government's custody. UAC receive an initial screening for visible and obvious health issues when they first arrive at U.S. Border Patrol facilities. Children must be considered "fit to travel" before they are moved from a border patrol station to an HHS-funded care provider. UAC are medically screened and receive initial vaccinations within 48 hours of arriving at a HHS-funded care provider. The initial screening includes a general health assessment, including a mental health screening and a re-

view of vaccination history. If a vaccination record is not located or a child is not up-to-date, the child receives all vaccinations recommended by the Centers for Disease Control and Prevention (CDC). Some health conditions may manifest after the UAC is transferred to an influx care facility. If a health issue arises, the UAC will receive prompt attention and medical care is provided.

Question. Has HHS, DHS, or DOJ consulted with medical experts and child welfare experts when implementing their policies pertaining to the forced separation, detention, and care of children? If yes, which groups were consulted and what issues were discussed? Did the groups support the administration proposal?

Answer. Care of children in ORR custody is informed by child welfare and medical expertise, including that of social workers and physicians on the ORR staff. When ORR receives a child that another Federal agency has referred to its care, ORR performs several different clinical assessments. These include:

- The UAC Assessment, which covers biographic, family, legal/migration, medical, substance abuse, and mental health history.
- A trafficking assessment, which is part of the UAC Assessment and identifies whether a child has been trafficked.
- An educational assessment, which determines academic level.
- A medical assessment, which occurs within 48 hours of arrival in the ORR care provider facility.
- The Assessment for Risk, which occurs within 72 hours of admission and every 30 days thereafter to reduce the risk that a child is sexually abused or abuses someone else in ORR care.
- The UAC Case Review, which updates the child's file initially on the child's 30th day in care and subsequently every 30 days (or 90 days for children in long-term foster care).

Question. Do HHS, DHS, or DOJ have plans to consult with medical experts and child welfare experts now and in the future regarding the detention of children and the care that is provided for these children? If yes, which experts will be consulted and how?

Answer. HHS provision of care to children in the Unaccompanied Alien Children program is routinely informed by evidence and practice models in child welfare.

Question. What policies and resources do you have in place to provide long-term services and supports for children who will suffer ongoing trauma and possible mental health issues as a result of being forcibly separated from their parents?

Answer. All children in ORR care receive mental health services while in care. Every child in care has a mental health clinician. ORR is not appropriated or authorized to provide long-term mental health or other medical services to minors who are discharged from ORR care, but referrals and resource connections to available services are provided at discharge.

Question. Do you know, does HHS know, where all of the children separated from their parent(s) since the implementation of this zero tolerance policy are, including their names and locations and the names and locations of their parent(s)?

Answer. HHS is continuously aware of the locations of all children in ORR care, including those minors who were separated. HHS identified 2,816 children who are or were in ORR care who were potentially separated, and all of these children have been linked to a parent. HHS or the ORR shelter program case manager has established contact with all parents of separated children.

Question. Can you, with 100-percent accuracy, link a child held in a facility to the location of his or her parent(s)?

Answer. HHS is continuously aware of the locations of all children in ORR care, including those minors who were separated. HHS identified 2,816 children who are or were in ORR care who were potentially separated, and all of these children have been linked to a parent. HHS or the ORR shelter program case manager has established contact with all parents of separated children. For parents who are outside the United States, the government provides the ACLU with contact information for the parents, and the wishes of parents are conveyed to the government by the ACLU Steering Committee.

Question. How many unaccompanied immigrant minors are currently residing in Pennsylvania? Where are these children currently residing?

Answer. As of November 19, 2018, there were 164 unaccompanied alien children in ORR care in Pennsylvania.

Question. In addition, please provide a list of all Office of Refugee Resettlement contracted facilities with unaccompanied children (UACs) in Pennsylvania, as well as a description of the vetting and oversight conducted by your department over these facilities.

Answer. There are three Pennsylvania-based ORR residences for unaccompanied children: (1) Holy Family Institute, (2) KidsPeace Shelter, and (3) KidPeace Long Term Foster Care. All ORR residences in Pennsylvania must to comply with Pennsylvania licensing requirements and the ORR Policy Guide located at *https://www.acf.hhs.gov/orr/resource/children-entering-the-united-states-unaccompanied.* Their compliance is monitored by periodic on and off site review by ORR monitors, program officers, and Federal field staff.

Question. What efforts have you made to comply with the court order requiring that all children under 5 be reunited with their parent or guardian by 2 weeks from the order and that all additional children be reunited within the month of the order? Will you comply with the order? When will you have reunited all of the children with their families?

Answer. As of December 12, 2018, there were 103 children under the age of 5 identified as potentially separated in the Ms. L case. Of these, 99 were discharged from ORR care, 80 of them through reunification with the parent from whom they were separated. Two children under the age of 5 remain in care who were subsequently determined not to have been separated, and two children remain in care who cannot be reunified with the parent due to a final determination by the government that reunification with the parent would pose a risk to child safety and well-being. The efforts of the government to reunify the children with their parents, consistent with the safety needs of the child, has elicited positive comments from Judge Sabraw.

Question. The Attorney General made the zero tolerance policy (*i.e.,* defacto child separation policy) announcement on May 7th. When did you know you would be responsible for the care of these children? When were you told you would need to provide the physical, emotional, and other necessary support for these children?

Answer. Though HHS has been involved in interagency discussions related to a myriad of options for responding to increasing migration numbers, HHS was informed of the zero tolerance policy when it was announced by the Attorney General. HHS has a strong history of providing excellent care to all UAC referred from DHS.

Question. I understand that HHS contracts with private residential facilities to care for Unaccompanied Alien Children (UACs). Please provide a list of entities that have been contracted for these services. In addition, provide documentation of the requirements for each of these facilities, including the background and training requirements for those providing care.

Answer. An accompanying document lists the residential facilities in the UAC Care Provider Network. Each facility must comply with the licensing requirements for the State in which it is located, as well as the guidelines set forth in the ORR Policy Guide. Staff who are required to have professional certifications must maintain licensure through continuing education requirements. In addition, all care provider staff must complete 40 hours of training annually. Foster care providers and foster families are subject to all ORR training and documentation requirements.

Question. What training do the staff who care for these children have to address the trauma the children have experienced?

Answer. HHS prioritizes the physical and emotional safety and well-being of all children in ORR care and custody. ORR works to ensure that care provider staff are trained in techniques for child-friendly and trauma-informed interviewing, assessment, observation and other techniques, and are also trained to identify children who have been smuggled (*i.e.,* transported illegally over a national border) and/or trafficked in the United States. Furthermore, staff who are required to have professional certifications (*i.e.,* mental health clinicians) must maintain licensure through continuing education requirements.

Question. Please describe what, if any, protocols and training are in place to ensure adequate care for the needs of children that have been separated from their families, including those with disabilities, those with chronic health conditions,

those with emotional support needs and the services and treatments you are providing to them.

Answer. All children in ORR care receive mental health services while in care. Every child in care has a mental health clinician. Children in the UAC Program often have severe trauma histories, and the program is trauma-focused to respond to those needs.

Question. Are there any children in your care who have disabilities? Please describe, without personally identifiable information, the number of separated children in your care with Down syndrome, autism, or any other type of disability. In addition, please provide these numbers grouped by age as well as a description of the services available and being provided to them.

Answer. Within ORR's Unaccompanied Alien Children (UAC) Program, the Division of Health for Unaccompanied Children (DHUC) oversees public health screening and the provision of health services to UAC. DHUC monitors for serious medical conditions and infectious diseases of public health importance. DHUC responds to ORR-funded programs caring for UAC 24 hours a day, 7 days a week and provides management guidance on infectious diseases and complex medical cases.

Each ORR-funded program that cares for UAC, including UAC with special health-care needs, has an established network of health-care providers, including specialists, emergency care services, mental health practitioners, and dental providers. ORR-funded programs are required to facilitate an initial medical examination (IME) within 2 business days of admission into ORR custody. The IME is administered by an MD, DO, NP, or PA, who must review and assess specific components such as current health complaints, family history, mental health issues, sexual and physical abuse, and infectious disease screening. If the provider feels a health condition, including conditions identified among children with special health-care needs, warrants additional follow-up, a referral is made. Once approval from ORR is obtained, the ORR-funded program schedules the soonest available appointment.

The requested information of separated children with special health-care needs is not captured in a currently accessible format. Children with special health-care needs, regardless of circumstances, are medically managed in a manner consistent with current medical best-practices.

Question. What have been your recommendations to the President regarding the care and treatment of the children who have been separated from their families?

Answer. HHS is continuing a strong history of providing excellent care to unaccompanied alien children (UAC) referred to us from the Department of Homeland Security. Our goal is, and always has been, to return these children to the care of a parent or, if a parent is not available, to safely release the child to a close relative or an unrelated sponsor designated by a parent. In this mission, we are carrying out the responsibilities given to HHS by Congress in the Homeland Security Act of 2002 and further developed in the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA). We are protecting and providing care for these UAC.

Question. Have you shared with the President and Attorney General information about the trauma that separation and detention causes to these children and their parents?

Have you shared with the President the recommendations of the American Academy of Pediatrics that separation of children from their parents and family detention can "cause serious dangers to children's health and can result in lifelong consequences for educational achievement, economic productivity, health status, and longevity" itself?

Have you shared with the President the recommendations of the over 230 child welfare organizations that have condemned the separation and detention of children?

Answer. The Unaccompanied Alien Children (UAC) Program at HHS was created by Congress in the Homeland Security Act of 2002. In the past 16 years, HHS has seen more than 250,000 children who have experienced the sadness and loss of absent parents. These parents may have left their children behind in their home country when they came to the United States, resulting in years of separation during which the children were often left in the care of relatives, or sent the children to the United State for work or education. The President and the Attorney General

know the trauma that the decisions of parents, such as committing a crime, can have on their children.

Question. What has been your recommendation, as the administration's leader on health and human services, regarding separation of children from families and long-term detention of children?

Answer. HHS has made reunification of separated children, consistent with the President's executive order and the orders of the U.S. District Court for the Southern District of California, a priority for the Department.

Question. HHS has been caring for some of these children for months. How is the administration paying for this care? Where are the funds coming from? What is the total cost of this policy? Please provide a full accounting of how HHS is paying for the facilities and services necessary to care for these children, and to the extent applicable their families, and where those funds are diverted from.

Answer. Funding for care of all Unaccompanied Alien Children in FY 2018 came from appropriations for that year, carryover funding from prior years, reprogramming within the Refugee and Entrant Assistance account, and transfers from other sources within the Secretary's transfer authority.

The estimate of expenditures in FY 2018 and FY 2019 related to the care and reunification (or other appropriate discharge) of possible children of potential *Ms. L.* class members is below. ORR estimates the shelter costs, including clothing, education, recreation, and food at $58,800,000. The estimated DNA screening costs are $1,400,000. The estimated medical services are $2,670,000. The estimated legal services are $4,010,000. The estimated case management and program support costs are $13,470,000. As of November 1, 2018, the total estimated cost is $80,350,000, or four percent of the total amount of funds obligated for the UAC program in FY 2018. This cost is only a small part of total UAC costs in FY 2018. The costs incurred are ongoing as separated children remain in ORR custody.

QUESTIONS SUBMITTED BY HON. SHELDON WHITEHOUSE

Question. Secretary Azar, I have heard from hospitals in my State about the effect that drug shortages are having on the ability to safely and effectively practice medicine in emergency rooms and throughout the hospital. While I have been pleased to see the progress on addressing the shortage of saline after Hurricane Maria, that is far from the only drug shortage problem our country is facing. Hospitals in my State report shortages of local anesthetics, injectable opiates, epinephrine, sodium bicarbonate, parenteral nutrition, and more. One hospital system in my State has noted the need to use "creative" purchasing practices, changing up the products and dosages it buys, and thus increasing the risk of providers making errors when needing to get up to speed on a new product.

In 2017, we know there were 39 new and 41 ongoing shortages, despite what the FDA is already doing. What else is the FDA going to do to alleviate these shortages, and prevent future shortages from disrupting the practice of medicine? Does FDA have all the authority it needs to intervene in the case of a potential or ongoing drug shortage? Many of the drugs in shortage are low-margin, generic products with limited competition. How can the FDA and Congress prevent instances of limited competition from jeopardizing access to needed medications?

Answer. In July 2018, FDA announced the formation of a new Drug Shortages Task Force charged with delving more deeply into the reasons behind some of the more persistent shortages and looking for solutions to address these ongoing challenges. FDA is directed to convene the group, we are working with our partners across the administration and seeking input from industry and other members of the public to evaluate the current authorities to consider how we might better help prevent and mitigate shortages. The new task force includes FDA's Federal partners on the shortage issues, including the Centers for Medicare and Medicaid Services, the Department of Defense, the Department of Veterans Affairs, the Office of the Assistant Secretary for Preparedness and Response, who collectively provide or pay for health-care services and prescription medicines for millions of Americans, and the Federal Trade Commission.

The task force expands upon the work of a group that was created by FDASIA, which gave the FDA new authorities to help address drug shortages. This includes creating the requirements that manufacturers of certain drugs that are life-supporting, life-sustaining, or intended for use in the prevention or treatment of a

debilitating disease or condition notify us of a permanent discontinuation or temporary interruption in manufacturing that is likely to lead to a meaningful disruption in the supply of such drugs in the United States.

PREPARED STATEMENT OF HON. ORRIN G. HATCH,
A U.S. SENATOR FROM UTAH

WASHINGTON—Senate Finance Committee Chairman Orrin Hatch (R–Utah) today delivered the following opening statement at a hearing on drug pricing and innovation with Health and Human Services (HHS) Secretary Alex Azar.

We are pleased to have Secretary Azar appear before the committee today, and I know members on both sides of the aisle are eager to hear from him on the Trump administration's plans to lower prescription drug costs.

I was in the Rose Garden when the President announced his plan to put patients first by lowering prescription drug and out-of-pocket costs to consumers.

I commend the President and the Secretary for their focus in this area and for releasing this comprehensive blueprint.

I also appreciate that HHS is seeking feedback from the public on the policy ideas in the blueprint. The administration is prudent to work through options by properly consulting those affected by these policies first.

As we continue to develop policy options, it is imperative to understand the impact on patient access, affordability and innovation before taking any specific action.

To that end, today is a golden opportunity for members to discuss policy proposals and ideas in the blueprint, which contemplates many weighty issues that would seriously change the current way of doing things.

And on that note, I believe that those who have criticized the blueprint as insufficient are either responding from a lack of knowledge or purely for political gain.

Now, I bring to the table decades of experience of working on drug pricing. That's why we've titled today's hearing in a way that clearly explains the heart of these issues: "Prescription Drug Affordability and Innovation."

This hearing title references a concept that has been very important to me throughout my time in the Senate.

After all, the goal is to help consumers, and the best way to do that is to balance both affordability and innovation.

Over 3 decades ago, I championed the Drug Price Competition and Patent Term Restoration Act, what has since become known as Hatch-Waxman.

As I noted in an editorial that ran in Roll Call yesterday, the Hatch-Waxman law established a system for regulating drugs that rewards new products while encouraging generic competitors.

Around that same time, I sponsored the Orphan Drug Act.

And I am proud to say that law has resulted in new treatment options that have enhanced care and dramatically improved the quality of life for hundreds of thousands, if not millions, of people who live with rare diseases.

Those two bills are just the tip of the iceberg though. I have since spearheaded numerous other legislative initiatives to address shortcomings in the system and to capitalize on opportunities for improvement.

I brokered the agreement that allowed physician-administered biologics to flourish—providing effective treatment for many cancers and other serious medical conditions.

More recently, I have successfully advocated for policies that promote development of biosimilars as a way to foster competition and lower costs.

I do not bring up this history to boast, but to point out that the pursuit of the balance of affordability and innovation has served us well.

Now, nearly 90 percent of prescription drugs dispensed to patients are generics. Yet, we also have realized life-altering breakthroughs in treatment.

Maintaining this balance must be a part of the conversation here today and as we move forward. And any lasting solution must continue to be market-driven.

The Medicare Part D prescription drug program is built on a system of private entities competing on price and service. This private-sector approach is ingrained in the design of the Part D program, which wisely forbids the government from interfering with the negotiations between these private entities.

For Part B drugs and biologics, Medicare pays based on the average price that the manufacturer charges to other payers. This effectively represents a rate negotiated in the private sector.

Don't take this to mean the way Medicare pays for prescription drugs is perfect. There is certainly room for improvement.

But the fact that the United States continues to be a pharmaceutical research and development powerhouse is in large part because we have long preserved the market-based approach.

It is vastly superior to the alternative of direct government involvement and price-setting.

After all, the private sector has proven time and again that it is far better suited to identifying challenges and turning them into opportunities.

One persistent challenge is that certain key drugs and items are in such short supply that hospitals and other providers can't even purchase them in sufficient quantity. These drug shortages, which include generic medications, threaten patient care and demonstrate a weakness in our system.

I am proud to say that my home State of Utah is taking a leadership role by creating a market-based response.

Utah-based Intermountain Healthcare has joined with other like-minded systems across the country to form a generic drug company.

This new venture will fill a market need by producing and distributing drugs that are in short supply.

This new company will also provide more competition that will improve prices and opportunities for consumers.

There are others, too, like some commercial health plans that have responded to market demand by offering prescription drug coverage options that pass along the negotiated discounts and rebates to their enrollees at the point of sale, rather than only through lower premiums.

Turning back to the President's blueprint, it contains policy ideas related to Medicare and Medicaid that merit serious consideration. For example, the idea of paying for a drug based on its success in achieving the intended patient benefit holds promise, especially for novel, breakthrough therapies that do not yet have competition.

We should explore how these value-based arrangements can work within our Federal health programs.

We should also assess how we can modernize the popular Part D program, because it is now more than 10 years old.

And a review of the Part D program should involve action to mitigate the change in the bipartisan budget deal enacted earlier this year that increased the discount that manufacturers are required to provide on drugs in the coverage gap.

This misguided change has only dampened some of the competitive forces that have made the program so successful.

We will soon hear from Secretary Azar on the policy ideas in the blueprint. It will be important to understand how the policies in the blueprint would impact not only the list price but patient access, beneficiary premiums and other cost-sharing, as well as innovation.

As the vast majority of the blueprint's policies are in the jurisdiction of the Finance Committee, this engagement with the secretary will inform how we move forward.

Before I conclude my opening remarks, I must say that I suspect that some of my colleagues may want to talk about other pressing issues that touch on HHS's jurisdiction.

To head off just one such issue, I have made my position on the situation at our southern border known: we must keep families together as we work to avoid illegal border crossings.

We also need to ensure that children who have been separated from their parents are reunited, and I know the Secretary is working aggressively to do so.

However, my experience tells me that our time at this hearing will be best spent discussing the issues we all have prepared for weeks to talk about with Secretary Azar.

After all, the cost, innovation and availability of prescription drugs is a deeply important and often life-or-death issue for millions of our constituents each day.

My hope is that we can all take advantage of the opportunity before us today and stay focused on the agreed upon subject matter of this hearing.

SUBMITTED BY HON. CLAIRE MCCASKILL,
A U.S. SENATOR FROM MISSOURI

Agent Eligibility and Underwriting Guide

Humana*One* Health and Life Products

e-Query service (Ask an Underwriter)

e-Query is a service which allows you to assess your client's insurance eligibility more accurately with the assistance of a Humana underwriter. It directly links you to a dedicated team of underwriters by means of an electronic form hosted on Humana*One* agent workbench.

e-Query does not replace the Underwriting Guidelines herein, but rather compliments it. To access the e-Query form you will need to log onto the Humana*One* Agent Workbench from the Agent Portal on *www.humana.com,* and click on the "e-Query/Ask an Underwriter" link under the questions section. e-Query is not currently available in the state of Wisconsin.

Eligibility requirements

For health coverage

> Issue ages: 2 weeks—64½ years
Newborns on family and child only applications will be eligible for coverage when they have had a two week well baby exam with normal results.
Please Note: This applies to full term babies. If they are born premature or with complications, we will underwrite as necessary.

> Maximum issue age of a dependent child varies by state.

> Dependents may include stepchildren, and/or legally adopted children. (Dependent definitions vary by state.)

Children-only health coverage

Children can be insured alone. The custodial parent or legal guardian who can attest to child's health history must complete the application. If an underwriting interview is required, the person that completed the application will be interviewed. The youngest child will be the primary applicant, and any others will be listed as dependents. Newborns applying for coverage require a two week well baby exam with normal results. Medical records are required for any child that is 2 weeks to 2 months of age. A child only health policy is ineligible, if any family member of the applicant(s) is pregnant or currently an expectant parent. See the terms indicated under Current/Pregnancy/Expectant parent.

Application scenarios:

(1) Parent A has custody and resides in a state in which Humana offers coverage. Parent B will be paying for the health insurance. Parent A must complete and sign the application to verify the health history. Parent B must sign the payer portion of the application.

(2) Parent A has custody and resides in a state in which Humana does NOT offer coverage. Parent B will be paying for the health insurance. Because benefits are based on the applicant's primary resident, Humana will not be able to accept an application for the child(ren).

(3) Both parents share custody and reside in a state in which Humana offers coverage. Either parent can complete and sign the application.

(4) Both parents share custody and reside in a state in which Humana offers coverage, however, their dependent student attends school in a state where Humana does not offer coverage. Coverage may be extended to the parents and their dependent college student(s).

Current pregnancy/expectant parent

For family applications, before applying for coverage, the mother must be two weeks postpartum, with no adverse findings, and the newborn must be two weeks old and have had a normal two week baby exam.

For child-only health policies, if any family member of the child is currently an expectant parent, the application is ineligible. Before applying for coverage, the mother must be two weeks postpartum, with no adverse findings, and the newborn must be 2 weeks of age, and have had a normal 2 week well baby exam with normal results.

Other coverage

A person who is currently covered by another plan must replace that coverage with Humana. However, it is important that he or she does not cancel existing coverage until written notification is received from Humana that coverage will be issued. Some states may require a replacement form.

U.S. citizenship

The applicant's primary residence must be in a state where the product is approved for sale. If the applicant is not a U.S. citizen, he or she must have lived in the U.S. for a minimum of one year, plans to remain in the U.S. for over 3 years, has had a normal physical exam with blood work from a U.S. physician, and has no plans of foreign travel of greater than three months continuously. An immigration physical does not meet the criteria for an acceptable physical exam.

Foreign travel

An applicant who lives in a foreign country is not eligible for coverage, nor is an applicant who has plans for extended foreign travel of three consecutive months at a time or longer. (May vary by state.)

Exceptions: An applicant who, for the purpose of Missionary Work, has plans for extended foreign travel for 0–2 years from the time of the application is eligible for coverage. An applicant with foreign travel plans exceeding 2 years for Missionary Work would not be eligible.

An applicant who, for the purpose of studying abroad or occupational/business travel has plans for extended foreign travel for 0–2 years from the time of the application is eligible for coverage. An applicant with foreign travel plans exceeding 2 years for studying abroad or occupational/business travel would not be eligible.

Tobacco usage—health

Humana has two tobacco classes:

1. Non-user: Does not use ANY form of tobacco currently or has not used ANY tobacco cessation products in the last 12 months.
2. Tobacco user

People who do not smoke or use any form of tobacco have their premium discounted. Humana conducts random nicotine testing during underwriting review.

Health underwriting guidelines

The following circumstances may result in a person not being eligible for health coverage:

(1) Currently pregnant, an expectant parent (including fathers and/or other family members)—entire application is ineligible;

(2) Health history that includes one of the ineligible health conditions:

(3) Height/weight that exceeds the limits identified in the health build chart; or

(4) Employment in an ineligible occupation. Not applicable in Florida.

(5) Non-U.S. citizen who has not consulted a physician in the U.S.

(6) Health history that includes 3 or more risk factors (build/overweight, elevated cholesterol/elevated triglycerides, hypertension, tobacco use).

(7) Hypertension with 50% rateable build.

(8) Hypertension with current treatment for Sleep Apnea.

A "yes" answer to any one of these circumstances may result in a declination of coverage. However, this information only provides their potential eligibility; it is not a final determination. All final coverage decisions are made by our Underwriting department upon receipt of an application. This assessment is not an offer of coverage or a notice of declination for your client.

Ineligible occupations (applicable to Florida for applications 2/2/2010 and after)

> Air traffic controllers
> Asbestos and toxic chemical workers
> Commercial fishermen who do not return to port every day
> Divers (professional scuba or skin)
> Explosive workers
> High-risk aviation (experimental and test pilots, crop dusters)
> Jockeys
> Oil and natural gas workers, including offshore operations
> Professional auto racers
> Professional rodeo participants
> Professional and semi-professional athletes (*Note:* Golfers are acceptable)
> Structural steel workers, iron workers and steeplejacks
> Underground miners

Health build charts

Use this table as a guide to determine if an applicant is rateable because of his or her build. Humana may request a paramedical exam (at our expense) to confirm an applicant's height and weight. An applicant must have maintained an acceptable build within the 12 months prior to applying to be considered eligible. If an individual's weight exceeds our "Standard" class but less than our "Decline" limit, they will be subject to a premium increase of 25–50%.

To qualify for the lower build rating, an applicant must lose the weight to reach the lower range and maintain the weight loss for 12 months.

Applicants who have applied for individual insurance and who have been offered a rating due to build may also have an obesity rider added to his or her offer. Any diagnostic procedure, treatment, or surgery for obesity including any complications thereof, will be excluded from coverage. In states where riders are not offered, coverage may be declined.

If an applicant is applying for both a Humana One health plan as well as for Humana*One* Term Life Insurance, the Health Build Chart will be followed during the underwriting process. (May vary by state.)

Female

	Standard	Decline
4′11″	88–151 lbs.	175 lbs.
5′0″	90–155 lbs.	180 lbs.
5′1″	93–160 lbs.	187 lbs.
5′2″	97–167 lbs.	193 lbs.
5′3″	100–172 lbs.	199 lbs.
5′4″	102–178 lbs.	206 lbs.
5′5″	106–183 lbs.	212 lbs.
5′6″	110–189 lbs.	219 lbs.
5′7″	113–195 lbs.	225 lbs.
5′8″	116–200 lbs.	232 lbs.

Female—Continued

	Standard	Decline
5′9″	119–206 lbs.	239 lbs.
5′10″	123–212 lbs.	246 lbs.
5′11″	127–219 lbs.	253 lbs.
6′0″	130–224 lbs.	260 lbs.
6′1″	134–232 lbs.	266 lbs.

Male

	Standard	Decline
5′2″	97–177 lbs.	198 lbs.
5′3″	100–182 lbs.	205 lbs.
5′4″	102–189 lbs.	211 lbs.
5′5″	106–194 lbs.	218 lbs.
5′6″	110–200 lbs.	224 lbs.
5′7″	113–206 lbs.	232 lbs.
5′8″	116–212 lbs.	238 lbs.
5′9″	119–219 lbs.	245 lbs.
5′10″	123–225 lbs.	252 lbs.
5′11″	127–232 lbs.	260 lbs.
6′0″	130–238 lbs.	267 lbs.
6′1″	134–245 lbs.	274 lbs.
6′2″	138–252 lbs.	282 lbs.
6′3″	141–259 lbs.	289 lbs.
6′4″	145–266 lbs.	298 lbs.

Ineligible health conditions

A series of medical questions will be asked of each of the proposed insured. Any applicant age 18 and older must review and attest to the questions individually (age requirements vary by state). Below is a partial listing of conditions that may cause Humana to decline coverage. The list is not all-inclusive.

Please note that if your client is applying for both a health plan and a life policy at the same time, and they are denied a health plan based on their health status, the process will discontinue as well for the life policy.

Below conditions are permanent declines, unless otherwise indicated. Handling of the below conditions may vary by state.

A

Achalasia, cardio spasm	Achondroplasia
Acromegaly	Addison's disease
Adrenal disorders	AIDS, ARC, or HIV

Alcohol dependence or abuse—individual consideration after 5 years of recovery	Alport syndrome
Alzheimer's disease	Amyloidosis
Amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease)	Anemia—aplastic Cooley's, B–12 deficiency, hemolytic, Mediterranean, pernicious, sickle cell or Thalassemia Major
Anencephaly	Aneurysm—if present or within 5 years
Angina	Angioplasty
Ankylosing spondylitis	Anorexia nervosa—individual consideration, after 8 years of recovery
Anticoagulant therapy	Antiphospholipid syndrome
Anticardiolipin antibody syndrome	Aortic arch arteritis
Aortic insufficiency/stenosis/ regurgitation—moderate or severe	Aortic Stenosis, Aortitis
Arnold-Chiari malformation	Arterial embolism (clot)
Arterial occlusion	Arteriosclerosis, atherosclerosis
Arteriosclerosis obliterans (ASO)	Arteriovenous malformation (A–V malformation)
Arteritis	Artificial heart valve
Asperger's syndrome—except in Indiana	Ascites
Ataxia telangiectasia	Atherosclerosis obliterans
Atherosclerosis thrombotic disease	Atrial fibrillation—one event less than 2 years ago or multiple events or chronic or with Pacemaker or Cardiverter
Atrial septal defect—present or if surgically corrected with complications	Autism—varies by state

B

Banti's syndrome	Basal cell carcinoma—if present
Berger's disease	Biliary cirrhosis
Bipolar disorders	Bladder entropy—symptomatic
Blastomycosis	Brachial plexus disorder
Brain attack	Brain tumors
Bright's disease	Bronchiectasis—if lung resection, no residuals, no tobacco—individual consideration
Bronchiolectasis	Bruit
Buerger's disease (thromboangiitis obliterans)	Bulimia—individual consideration, after 8 years of recovery
Burkitt's lymphoma {malignant lymphoma)	Bypass surgery

C

Cachexia	Cancer with lymph node involvement or metastasis
Cardiac decompensation	Cardiac defibrillator (implantable)
Cardiac or comorbidity risk factors—3 or more (build/overweight, elevated cholesterol/ triglyercerides, hypertension, tobacco use)	Cardiomegaly
Cardiomyopathy	Cardiospasm
Celiac Disease	Central serous retinopathy
Cerebral palsy	Cerebrovascular accident
Cerebrovascular disease	Charcot-Marie-Tooth disease
Chediak Kigaski syndrome	Chondrocalcinosis
Christmas disease	Chromosomal abnormalities
Chronic granulomatous disease	Chronic glomerulonephritis

Chronic hepatitis	Chronic obstructive pulmonary disease (COPD)
Chronic progressive external opthalmoplegia (CPEO)	Cirrhosis of the liver
Coarctation of the aorta	Cocaine abuse
Colitis (ulcerative)	Collagen diseases
Congenital heart anomalies	Congenital lymphedema
Congestive heart failure (CHF)	Connective tissue disorder
Cor pulmonale	Coronary artery bypass surgery (CABS)
Coronary artery disease (CAD)	Coronary Fistula
Coronary heart disease (CHO)	CREST syndrome
Creutzfeldt-Jakob disease	Crigleer-NaJaar syndrome
Curvature of the spine with pulmonary, cardiac or spinal cord involvement	Cushing syndrome/disease
Cystic fibrosis	Cystic kidney diseases
Cystic medial necrosis	Crohn's disease

D

Dejerine type sclerosis	Delirium
Delusions	Dementia
Demyelinating diseases	Depressant addiction—current history of addiction with current usage
Dermatitis herpetiformis—with evidence of significant immunologic compromise	Dermatomyositis
Depression—major, if hospitalization required or with suicidal attempt or ideation	DiGeorge syndrome
Diabetes insipidus	Diabetes mellitus (type 1 and type 2)
Down syndrome	Drug dependence or abuse (illicit, illegal, over the counter or prescription)
Drug psychosis	Dwarfism

E

Eaton-Lambert syndrome	Ebstein's malformation (Ebstein's anomaly)
Edward's syndrome	Ehlers-Danlos syndrome
Eisenmenger's complex (Eisenmenger's syndrome)	Ejection Fraction—less than 50% or more than 75%
Embolism—arterial is permanent decline; pulmonary depends on frequency, treatment, etc	Emphysema
Encephalocele	Encephalocystocele
Encephalopathy	Eosinophilic granuloma
Epidermolysis bullosa	Erythema Multiforee (Stevens Johnson syndrome)—if present or less than one year since complete recovery or residuals
Esophageal varices	

F

Fabry disease	Factor V deficiency
Factor VIII or IX deficiency	Familial Aadenomatous polyposis
Fanconi syndrome—fanconi anemia	Fibromyalgia
Flexure-hepatic or splenic	Fragile X syndrome
Fragilitas ossium	

G

Galactorrhea—if present	Galactosemia

Gargoylism (mucopolysaccharidosis)
Gastrectomy—total removal
Gastric bypass/stapling
Gastroparesis
Gaucher's disease
Gender identity disorder
General paresis
Glycogen storage disease
Guillain-Barre Syndrome/Polyneuritis—if present or less than 3 years since recovered or if residual disability/permanent impairment

H

Hallucinations
Hand-Schueller-Christian disease
Heart attack or disease
Heart enlargement/hypertrophy
Heart-lung transplants
Heavy chain disease
Hemiplegia
Hemochromatosis
Hemophilia A or B
Hemophilia vascular
Henoch-Schoenlein purpura
Hepatic flexure
Hepatomegaly
Hepatitis (autoimmune)
Hepatitis A—if less than 6 months after complete recovery
Hepatitis B carrier
Hepatitis C
Hepatitis D (HDC or delta virus)
Hepatitis E (HEV)
Hepatitis G (HGV)
Hepatomegaly
Hereditary angioedema
Hereditary spherocytosis—if present
Hirschsprung's disease—if unoperated or symptomatic
Histocytosis X
Histoplasmosis—if present or disseminated and less than 3 years since complete recovery
HIV positive
Hodgkin's disease
Hughes syndrome
Human T-cell leukemia virus
Human T-cell lymphotropic virus
Hunner's ulcer
Huntington's chorea
Hydrocephalus
Hydronephrosis—if present or bilateral
Hyperhydrosis—if present or if surgically corrected with residual symptoms or any complications
Hyperparathyroidism—if unoperated
Hypersplenism
Hypogonadism (primary)
Hypoparathyroidism
Hypoplastic anemia
Hysteria

I

Idiopathic thrombocytopenic purpura (child form)—if present
IgA nephropathy/Berger's Disease
IgG subclass deficiency
Immune deficiency
Infectious neuritis—if present or multiple episodes
Intermittent claudication
Interstitial cystitis (chronic)/Hunner's Ulcer
Intestinal infarction/Intestinal ischemia—unless acute with complete recovery more than 6 weeks ago
Intestinal obstruction—if present
Iritis—if one episode, less than 6 months ago or multiple episodes
Ischemic heart disease
Ischemic/ulcerative colitis
IV drug use
Insulin resistance

J

Jaundice (adult)—present or less than 6 months since complete recovery
Juvenile dermatomyositis—if present or less than 2 years since complete recovery

K

Kahler's disease	Karposi's sarcoma
Kartagener's syndrome	Keratoconus—present and surgery recommended
Kidney injury—major injury with history of dialysis	Kidney failure—if chronic or acute less than 2 months since recovery
Kidney stone—if present or if more than 4 episodes	Kidney transplant
Korsakoff's psychosis	Klinefelter's syndrome

L

Left bundle branch block	Left ventricular hypertrophy
Legionella pneumophilia (Legionnaire's disease)	Letterer-Siwe disease
Leukemia	Leukoencephalopathy
Lipidosis (Niemann Pick disease)	Liver abscess with residuals
Liver cancer	Liver transplant
Lobstein's disease	Lou Gehrig's disease (ALS)
Lung cancer	Lung transplant
Lyme's disease—if present	Lymphoblastoma
Lymphoma	Lymphoma, Hodgkins
Lyinphomatoid papulosis	

M

Malaria—more than one occurrence with complications or frequent disabling attacks	Manic disorders
Marchiatava-Micheli syndrome	Marfan's syndrome
Medullary cystic kidney	Medullary sponge kidney—if present or less than 18 years of age or if more than 18 years of age—bilateral
Mental retardation—severe, emotionally unstable, seizures or psychiatric impairments	Mesenteric vascular disease
Metabolic syndrome	Microcephaly
Milroy's disease	Mitral insufficiency
Mitral stenosis	Mixed connective tissue disease
Moebius syndrome/Mobius syndrome	Mucopolysaccharidosis
Multicystic kidney	Multiple myeloma
Multiple personality disorder	Multiple sclerosis
Muscular dystrophy	Myasthenia gravis
Myelitis—if present or less than 6 months since complete recovery	Myocardial infarction (MI)
Myocardial ischemia	Myotonic dystrophy
Myxedema—if present	

N

Nall-Patella syndrome	Narcotic use/addiction
Nephritis (chronic)	Nephrocalcinosis
Nephrosclerosis	Nephrotic syndrome
Neuritis—if present	Neurofibromatosis
Neurogenic bladder—if present	Neuromuscular disorders
Niemann-Pick disease (Lipidosis)	

O

Occlusion	Organic brain disorder/syndrome
Organ transplant recipient	Osteitis fibrosa cystica

Osteitis fibrosa cystica disseminata	Osteitis fibrosa cystica generalisata
Osteogenesis imperfecta/Lobstein's Disease	Ovarian cancer

P

Pacemaker	Paget's disease
Pancreatic cyst or pseudocyst	Pancytopenia
Paralysis	Paranoid disorder
Paraplegia	Parkinson's disease
Paroxysmal nocturnal hemoglobinuria	Pathological fractures
Pemphigus	Percutaneous transluminal coronary angioplasty
Periarteritis nodosa	Peripheral occlusive arterial disease (POAD)
Peripheral vascular disease or intermittent claudication	Pernicious anemia
Pick's disease	Pierre Robin's syndrome
Pituitary Adenoma—if present	Pituitary dwarfism/Achondroplasia
Plasmacytoma	Pneumocystis carinii pneumonia (PCP)
Pneumonitis	Poliomyelitis—if present or more than one limb involved
Polyarteritis	Polycystic kidney
Polycystic ovarian syndrome (PCOS)	Polycythemia vera
Polyglandular autoimmune disease	Polyneuritis (Guillain-Barre syndrome)—if present or less than 3 years since recovered or residual disability/permanent impairment
Porphyria—diagnosed less than 5 years prior to application	Portal hypertension
Post-Polio syndrome	Pregnant, an expectant parent (induding fathers and/or other family members)—the entire application is ineligible
Primary biliary cirrhosis	Primary pulmonary hypertension
Primary sclerosing cholangitis	Prinzmental's angina
Pseudocyst—if present	Pseudotumor cerebri
Psittacosis—with extensive respiratory involvement	Psoriasis—if severe or use of UV light
Psychiatric disorder—severe including childhood and adolescence	Psychosis
Pulmonary embolism/thrombosis—if present, on anticoagulants or if less than 1 year	Pulmonary fibrosis
Pulmonary heart disease	Pulmonic insufficiency—it moderate to severe
Pulmonic stenosis	Pulseless disease
Pyloric Stenosis—if present	Pyogenic arthritis

Q

Quadriplegia

R

Reflex sympathetic dystrophy	Renal failure—chronic, uremia
Renal hypertension	Renal Insufficiency—chronic or renal failure
Respiratory failure	Retinal detachment—if present
Retinopathy—central serous and diabetic	Rhabdomyosarcoma
Rheumatic heart disease	Rheumatoid arthritis

Russel-Silver syndrome—if less than 24 years of age

S

Sarcoidosis	Schizo-affective disorders
Schizophrenia	Scleroderma—generalized
Senility	Severe combined immunodeficiency
Sexual deviation or disorder	Shunt
Sialadenitis	Sialdenosis
Sick sinus syndrome	Sickle cell anemia
Silent myocardial ischemia	Sjogren's disease
Sleep apnea—central or mixed sleep apnea, or current tobacco user, or with ratable build, or with hypertemion or if surgery suggested	
Spherocytosis/Hereditary Spherocytosis—if present	Spina bifida (Manifesta)
Splenic flexure	Spondylitis
Sprue disease	Spurway's disease
Status Asthmaticus	Stents—artery or blood vessel
Stevens Johnson syndrome/Erythema Multiforme—if present or less than one year since complete recovery or history of with residuals	Still's disease
Stimulant usage	Stokes-Adams syndrome
Stroke	Sturge-Weber syndrome
Suicide attempt/ideation	Syndrome X
Syphilis—if present or less than one year since complete recovery or more than 1 year since complete recovery without two normal lab results	Syringomyelia
Systemic fibrosclerosing syndrome	Systemic lupus erythematosis (SLE or lupus)
Systemic sclerosis	

T

Takayasu's arteritis	Tetrology of fallot
Thalassemia major	Thrombocythemia
Total anomalous pulmonary venous connection	Transient ischemic attack (TIA)
Transplant (except corneal)	Transposition of the great vessels
Transsexualism	Tricuspid atresia
Tricuspid insufficiency/regurgitation—moderate or severe	Tricuspid stenosis
Trisomy 21 syndrome (Down syndrome)	Truncus arteriosus
Tuberous sclerosis	Turner's syndrome

U

Ulcerative colitis/proctitis	Underdeveloped left ventricle syndrome
Urachal remnant—if present	Uveitis—if chronic or less than 6 months since recovery

V

Valve disorder	Valve replacement
Varicose veins of the esophagus	Vascular hemophilia
Ventricular arrhythmias	Ventricular septal defect—present or less than 1 year since repaired or if surgically corrected with complications

Von Hypple-Lindau syndrome

Von Willebrand's disease/ Pseudohemophilia

W

Waldenstrom's macroglobulinemia

Wegener's granulomatosis (Wegener's syndrome)

Williams syndrome

Wiskott-Aldrich syndrome

Warnick's disease

Weight reduction surgery—other than gastric banding

Wilson's disease

X

XYY syndrome

Z

Zollinger-Ellison syndrome

Actions for Common Medical Conditions—Rider States

These guidelines may vary due to state-specific laws and regulations but can be followed as a general outline. This is not all inclusive. Final decision is based on underwriting review. Underwriting assessments in the below grid are based on customary and usual treatment seen for the conditions noted. Below are examples only; Humana will be solely responsible for the final underwriting decision, which is based on the completed application and the applicant's health history. Guidelines are subject to change without prior notice.

NOTE: If an applicant on an application requires more than three exclusion riders (two in Indiana), the applicant will be declined.

Condition *We reserve the right to rate for the condition and /or medication use when appropriate. A modified rating is determined based on the severity of the condition and treatment and /or prescription medication cost, dosage, and premium amount.*	**$1,500 or lower deductable plus Rx**	**$2,500–$5,000 deductable plus Rx**	**$2,000–$5,200 deductable no Rx**	**$6,000 or higher deductable plus Rx**
Acid Reflux/GERD/ Heartburn				
Present, no hiatal hernia, non prescription medication (OTC only) no recommended consultations or testing	Standard	Standard	Standard	Standard
Present, prescription medication, no hiatal hernia present	Rider	Standard or Rate Up KY or OH: Standard or Rider	Standard	Standard or Rate Up KY or OH: Standard or Rider
Prescription medication use currently, hiatal hernia present	Rider	Rider	Rider	Rider
Acne/Rosacea				
Present, no treatment or OTC medication	Standard	Standard	Standard	Standard
Prescription meds, or < 6 months since med use, no Accutane or equivalent	Rider	Standard or Rating KY & OH. Standard or Rider	Standard	Standard or Rating KY & OH. Standard or Rider
Prescription meds, completed ≥ 6 months ago, complete recovery, no Accutane or equivalent	Standard	Standard	Standard	Standard
Accutane treatment of equivalert or ≤ 1 year since treatment completed	Rider	Rider	Rider	Rider
Accutane treatment of equivalent or > 1 yer ago since treatment, complete recovery	Standard	Standard	Standard	Standard
Allergies				

Actions for Common Medical Conditions—Rider States—Continued

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Recommended, pending or scheduled testing	Rate 50% NV: Decline if tobacco user	Rate 50% NV: Decline if tobacco user	Rate 50% NV: Decline if tobacco user	Standard
Seasonal prescription meds (3 refills or less per year or OTC), no immunotherapy treatment	Standard	Standard	Standard	Standard
Prescription meds, more than 3 refills per year, no immunotherapy treatment	Standard or Rating KY & OH: Standard or Rider	Standard or Rating KY & OH: Standard or Rider	Standard	Standard or Rating KY & OH: Standard or Rider
With or without prescribed medications, current or recent immunotherapy	Rider	Rider	Standard—for prescribed medications Rider—immunotherapy	Rider
Amputation/Prosthesis				
Finger or toes, with or without prosthesis	Standard	Standard	Standard	Standard
Eye	Standard	Standard	Standard	Standard
All other amputations, with or without prosthesis	Rider KY, NM: Decline	Rider KY, NM: Decline	Rider KY, NM: Decline	Rider KY, NM: Decline
Caused by diabetes, severe artery disease or other disease	Decline	Decline	Decline	Decline
Anemia—other than anemia listed in the ineligible health conditions list				

Present	Standard	Standard	Standard	Standard
Aneurysm				
Present	Decline	Decline	Decline	Decline
History of, more than 5 years after repaired	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Anxiety				
Well controlled with prescription medication, no counseling, no more than 2 ER visits in the last 12 months	Standard or Rating KY & OH: Standard or Rider	Standard or Rating KY & OH: Standard or Rider	Standard	Standard or Rating KY & OH: Standard or Rider
Counseling only, no medication	Rate 10–20%	Rate 10–20%	Standard	Rate 10–20%
Asthma				
Exercise induced, no regular medication required	Standard	Standard	Standard	Standard
Medication use only	Rider	Standard or Rating KY & OH: Standard or Rider	Standard	Standard or Rating KY & OH: Standard or Rider
Medication use, steroid treatment (not including Albuterol inhaler) less than 3 times and/or no more than two emergency room visits in the past 12 months	Rider	Rider	Rider	Standard or Rating KY & OH: Standard or Rider
Oral steriods required ≥ 3 times or more than 2 ER visits in the past 12 months	Decline	Decline	Decline	Decline
Attention Deficit Disorder/ADD/ADHD				
No medication or counseling, more than 2 years	Standard	Standard	Standard	Standard

Actions for Common Medical Conditions—Rider States—Continued

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One medication	Rider IN: Rate only KY & OH: Standard or Rider	Rider or Rating IN: Rate only KY & OH: Standard or Rider	Standard	Rating IN: Rate only KY & OH: Standard or Rider
More than one medication	Rider IN: Rate only KY & OH: Standard or Rider	Rider or Rating IN: Rate only KY & OH: Standard or Rider	Standard	Rating IN: Rate only KY & OH: Standard or Rider
Atrial Fibrillation				
Single event, no continued medications, complete recovery, more than 2 years ago	Standard	Standard	Standard	Standard
Single event, < 2 years ago	Decline	Decline	Decline	Decline
Multiple events or continued use of medication or chronic atrial fibrillation	Decline	Decline	Decline	Decline
Pacemaker or carioverter defibrillator	Decline	Decline	Decline	Decline
Back Sprain/Strain/Whiplash				
≥ 1 year ago—complete recovery	Standard	Standard	Standard	Standard
Less than 1 year ago or not recovered	Rider	Rider	Rider	Standard
Baker's Cyst				

History of no recurrence	Standard	Standard	Standard	Standard
Present, asymptomatic	Rider	Standard	Standard	Standard
Present, symptomatic	Rider	Rider	Rider	Standard
Basal Cell Carcinoma				
Present	Decline	Decline	Decline	Decline
Single occurrence, complete recovery	Standard	Standard	Standard	Standard
Multiple occurences, or recurrent, removed (regardless of time frame)	Rider—permanent	Rider—permanent	Rider—permanent	Standard
Benign Prostatic Hypertrophy/BPH				
Incidental finding, no symptoms, no treatment or medication use	Standard	Standard	Standard	Standard
Well controlled on one medication	Standard or Rate up OH & KY Rider for med	Standard or Rate up OH & KY Rider for med	Standard or Rate up	Standard or Rate up OH & KY Rider for med
More than one medication	Permanent Rider plus Rating for meds UT—Decline	Permanent Rider plus Rating for meds UT—Decline	Permanent Rider UT—Decline	Permanent Rider plus Rating for meds UT—Decline
Prostatectomy, TURP, TUNA, TUIP, TUMT, or Lazer surgery completed, no follow up needed, complete recovery, no residual complications or medication use	Standard	Standard	Standard	Standard
Bladder Infections (Cystitis)				
Less than 4 per year	Standard	Standard	Standard	Standard
Four to six episodes per year	Decline	Standard	Standard	Standard
More than 6	Decline	Decline	Decline	Decline

Actions for Common Medical Conditions—Rider States—Continued

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Breast Cyst, Nodule or Mass				
Present and benign	Rider VA: Rate 25%	Rider VA: Rate 25%	Rider VA: Rate 25%	Standard
Removed and benign	Standard	Standard	Standard	Standard
Present, pathology unknown	Decline	Decline	Decline	Decline
Breast Implants				
Present, no complications, placed for cosmetic purposes	Standard	Standard	Standard	Standard
Breast Reduction/Macromastia				
Condition present, no surgery completed	Rider	Rider	Rider	Rider
Surgery completed < 1 year ago, with complete recovery	Standard	Standard	Standard	Standard
Surgery completed < 1 year ago, with residuals	Rider	Rider	Rider	Rider
Bronchitis				
1–3 episodes in the past year, non tobacco user, complete recovery	Standard	Standard	Standard	Standard
1–2 episodes in the past year, tobacco user, complete recovery	Standard	Standard	Standard	Standard
3 episodes a year, tobacco user, complete recovery	Individual consideration	Individual consideration	Individual consideration	Individual consideration

> 3 episodes a year or Chronic Bronchitis	Decline	Decline	Decline	Decline
Bundle Branch Block (right)				
Complete, no tobacco use for the last 12 months, symptoms and treatment free for last 12 months, build not ratable	Standard	Standard	Standard	Standard
Bursitis/Tendonitis/Tenosynovitis				
Single occurrence with complete recovery	Standard	Standard	Standard	Standard
Single occurrence, not recovered	Rider	Standard	Standard	Standard
Multiple occurrences	Rider	Rider	Rider	Standard
Carpal Tunnel				
Present or residuals	Rider	Rider	Rider	Standard
Surgical repair complete recovery	Standard	Standard	Standard	Standard
Cataracts				
Present	Rider KY: Decline	Rider KY: Decline	Rider KY: Decline	Standard
Surgically corrected, fully recovered, no residuals	Standard	Standard	Standard	Standard
Chlamydia				
Present or under treatment, no other STD history	Standard	Standard	Standard	Standard
Complete recovery	Standard	Standard	Standard	Standard
Colon Polyps				
Present	Decline	Decline	Decline	Decline

Actions for Common Medical Conditions—Rider States—Continued

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More than 1 benign polyp removed within the past 5 years during colonoscopy, scheduled follow up is every 10 years	Rider (permanent)—UT: Non-tobacco—Max rating applies—tobacco user IC CO: rating	Rider (permanent)—UT: Non-tobacco—Max rating applies—tobacco user IC CO: rating	Rider (permanent)—UT: Non-tobacco—Max rating applies—tobacco user IC CO: rating	Rider (permanent)—UT: Non-tobacco—Max rating applies—tobacco user IC CO: rating
Single benign polyp removed during colonoscopy within the last 5 years, no colon resection, follow up scheduled more than 5 years	Standard	Standard	Standard	Standard
Single benign polyp removed during colonoscopy, within the past 5 years no colon resection, follow up schedued every 3–5 years	Rider (permanent)—UT: Non-tobacco—Max rating applies—tobacco user IC CO: rating	Rider (permanent)—UT: Non-tobacco—Max rating applies—tobacco user IC CO: rating	Rider (permanent)—UT: Non-tobacco—Max rating applies—tobacco user IC CO: rating	Rider (permanent)—UT: Non-tobacco—Max rating applies—tobacco user IC CO: rating
More than 1 polyp removed within the past 5 years. Surgically removed (not during colonoscopy) or part of colon surgically removed or follow up scheduled every 1–2 years	Decline	Decline	Decline	Decline
1–2 polyps removed within the past 5 years during colonoscopy, only 1 colonoscopy completed within the past 5 years. Follow up scheduled every 3–5 years	Rider (permanent) UT: Non-tobacco—Max rating applies—tobacco user IC CO: rating	Rider (permanent) UT: Non-tobacco—Max rating applies—tobacco user IC CO: rating	Rider (permanent) UT: Non-tobacco—Max rating applies—tobacco user IC CO: rating	Rider (permanent) UT: Non-tobacco—Max rating applies—tobacco user IC CO: rating

More than 2 polyps removed within the past 5 years, follow up scheduled every 3–5 years	Decline	Decline	Decline	Decline
Condyloma				
Present or history of—no HPV	Rider UT: 55% rating, non tobacco users UT: Decline tobacco users	Standard	Standard	Standard
Present of history of—with HPV	Rider UT: 55% rating, non tobacco users UT: Tobacco users—Decline HPV underwritten separately	Rider UT: 55% rating, non tobacco users UT: Tobacco users—Decline HPV underwritten separately	Rider UT: 55% rating, non tobacco users UT: Tobacco users—Decline HPV underwritten separately	Rider UT: 55% rating, non tobacco users UT: Tobacco users—Decline HPV underwritten separately
Deep Vein Thrombosis (DVT)				
On anticoagulants or one episode less than 3 months ago	Decline	Decline	Decline	Decline
One episode—3 mos–2 years with complete recovery	Rider MI: 25% rating for non-tobacco user: Tobacco user—individual consideration	Rider MI: 25% rating for non-tobacco user: Tobacco user—individual consideration	Rider MI: 25% rating for non-tobacco user: Tobacco user—individual consideration	Standard
Recurrent	Decline	Decline	Decline	Decline
Depression				
Well controlled with prescription medication, no counseling	Standard or Rating KY & OH: Standard or Rider	Standard or Rating KY & OH: Standard or Rider	Standard	Standard or Rating KY & OH: Standard or Rider
Counseling only, no medication	Rate 10–20%	Rate 10–20%	Rate 10–20%	Rate 10–20%

Actions for Common Medical Conditions—Rider States—Continued

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Condition *We reserve the right to rate for the condition and /or medication use when appropriate. A modified rating is determined based on the severity of the condition and treatment and /or prescription medication cost, dosage, and premium amount.*	**$1,500 or lower deductable plus Rx**	**$2,500–$5,000 deductable plus Rx**	**$2,000–$5,200 deductable no Rx**	**$6,000 or higher deductable plus Rx**
Deviated Septum (nasal)				
Present, asymptomatic or surgically repaired	Standard	Standard	Standard	Standard
Symptomatic	Rider	Rider	Rider	Rider
Disc Disorder (herniated, bulging, ruptured)				
Present, surgically repaired less than 1 year ago or with residuals	Rider	Rider	Rider	Rider
Asymptomatic, surgically repaired more than 1 year ago with full recovery	Standard	Standard	Standard	Standard
Diverticulitis				
Present, No Surgery	Rider	Rider	Rider	Rider
Surgery within 0–2 years	Rider	Rider	Rider	Rider
Surgically corrected > 2 years ago	Standard	Standard	Standard	Standard
Diverticulosis				
Present or with history of diverticulitis	Standard	Standard	Standard	Standard
Surgery within 0–2 years	Decline	Decline	Decline	Decline
Surgically corrected > 2 years ago	Standard	Standard	Standard	Standard

DUI—Paramed exam is required				
Single occurrence, within 5 years	Rate 30%—Decline	Rate 30%—Decline	Rate 30%—Decline	Rate 30%—Decline
Single occurrence, more than 5 years	Standard	Standard	Standard	Standard
Multiple occurrences, within 5 years	Decline	Decline	Decline	Decline
Multiple occurrences, more than 5 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Ear Infection (Otitis Media)				
< 3 in the past 12 months	Standard	Standard	Standard	Standard
> 3 in the past 12 months	Rider	Rider	Rider	Standard
Tubes Present	Rider	Standard	Standard	Standard
Tubes no longer present, no recurrence	Standard	Standard	Standard	Standard
Eczema				
Present or less than 2 years since symptomatic	Rider	Standard or Rating KY & OH: Standard or Rider	Standard	Standard or Rating KY & OH: Standard or Rider
> 2 years since treatment or symptoms	Standard	Standard	Standard	Standard
Endometriosis				
Present or within 5 years of treatment	Rider KY: Decline	Rider KY: Decline	Rider KY: Decline	Rider KY: Decline
> 5 years since symptoms or treatment	Standard	Standard	Standard	Standard
Surgery < 3 years ago	Rider KY: Decline	Rider KY: Decline	Rider KY: Decline	Standard
Surgery > 3 years ago	Standard	Standard	Standard	Standard
Enlarged Prostate—See Benign Prostatic Hypertrophy				

Actions for Common Medical Conditions—Rider States—Continued

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Epilepsy, Grand Mal (Generalized)				
Seizure within past 2 years	Decline	Decline	Decline	Decline
Last seizure > 2 years ago	Standard or Rate-up	Standard or Rate-up	Standard	Standard or Rate-up
Epilepsy, Petit Mal (Generalized)				
Seizure within past 2 years	Decline	Decline	Decline	Decline
Last seizure > 2 years ago	Standard or Rate-up	Standard or Rate-up	Standard	Standard or Rate-up
Epilepsy, Temporal Lobe (Partial)				
Seizure < 1 year ago	Decline	Decline	Decline	Decline
Seizure > 1 year ago	Standard or Rate-up	Standard or Rate-up	Standard	Standard or Rate-up
Fibromyalgia				
Present or history of	Decline	Decline	Decline	Decline
Fractures				
Present—No fixation device	Rider	Standard	Standard	Standard

Present—with permanent fixation device	Standard	Standard	Standard	Standard
Present—with temporary fixation device	Rider	Standard	Standard	Standard
Recovered & released from care with no fixation device or permanent fixation device	Standard	Standard	Standard	Standard
Recovered, released from care with temporary fixation device	Standard	Standard	Standard	Standard
Pathological	Decline	Decline	Decline	Decline
Ganglion Cyst				
Present & symptomatic	Rider	Standard	Standard	Standard
Surgically removed or history of and resolved	Standard	Standard	Standard	Standard
Gastric banding—weight loss surgery				
Lap band removed, no rateable build, weight maintained for one year	Standard	Standard	Standard	Standard
Lap Band removed, rateable build, or weight loss not maintained for one year	Decline	Decline	Decline	Decline
Lap Band present	Decline	Decline	Decline	Decline
Gastric Bypass/Gastric Stapling	Decline	Decline	Decline	Decline
GERD (reflux)—see Acid Reflux/GERD				
Gestational Diabetes				
< 5 yrs ago, diet controlled during pregnancy, no recurrence	Rate 25%—UT: tobacco users, individual consideration	Rate 25%—UT: tobacco users, individual consideration	Rate 25%—UT: tobacco users, individual consideration	Rate 25%—UT: tobacco users, individual consideration
> 5 yrs ago, diet controlled during pregnancy, no recurrence	Standard	Standard	Standard	Standard

Actions for Common Medical Conditions—Rider States—Continued

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< 5 yrs ago, controlled with insulin during pregnancy, no recurrence	Rate 50%—UT: tobacco users, individual consideration	Rate 50%—UT: tobacco users, individual consideration	Rate 50%—UT: tobacco users, individual consideration	Rate 50%—UT: tobacco users, individual consideration
> 5 yrs ago, controlled with insulin during pregnancy, no recurrence	Rate 25%—UT: tobacco users, individual consideration	Rate 25%—UT: tobacco users, individual consideration	Rate 25%—UT: tobacco users, individual consideration	Rate 25%—UT: tobacco users, individual consideration
History of, no glucose test following pregnancy or Glucose levels did not return to normal	Decline	Decline	Decline	Decline
Glaucoma				
Symptomatic, but not diagnosed	Rider and rating for medications	Rider and rating for medications	Rider for condition, no action for medications	Rider and rating for medications
Present, well controlled	Rating OH & KY: Rider	Rating OH & KY: Rider	Standard	Rating OH & KY: Rider
Present, not controlled: with or without medications	Rider	Rider	Rider	Rider
Surgically corrected both eyes, with or without medications	If no medications: Standard; Medication use: Rating OH & KY: Rider	If no medications: Standard; Medication use: Rating OH & KY: Rider	Standard	If no medications: Standard; Medication use: Rating OH & KY: Rider

Surgically corrected in one eye: with or without medication use	Rider	Rider	Rider	Rider
Gout				
Present or within 2 years of symptoms or treatment	Rider	Rider	Rider	Standard
Recovered and time from last symptoms or treatment > 2 years	Standard	Standard	Standard	Standard
Grave's Disease—See Hyperthyroidism				
Guillain-Barre Syndrome				
Present or < 3 years since recovered or Residual disability/permanent impairment	Rate 25%—UT: Tobacco user—Individual consideration	Decline	Decline	Decline
> 3 years since recovered, no disability, minimal weakness, no relapse	Rate 25%	Standard	Standard	Standard
Gynecomastia				
Present	Rider	Rider	Rider	Rider
Surgical correction > 6 months ago	Standard	Standard	Standard	Standard
Hashimoto's Thyroiditis—See Hypothyroidism				
Heartburn—see Acid Reflux				
Heart Murmur				
Functional/Innocent, Grade I or II—Systolic	Standard	Standard	Standard	Standard
Organic, Grade III or greater, continuous—Diastolic	Decline	Decline	Decline	Decline
Hemorrhoids				
Present, asymptomatic	Standard	Standard	Standard	Standard

Actions for Common Medical Conditions—Rider States—Continued

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Present, symptomatic	Rider	Standard or Rate up	Standard	Standard
> 1 yr since symptoms or surgery	Standard	Standard	Standard	Standard
Hepatitis A				
> 6 months since treatment with normal liver tests	Standard	Standard	Standard	Standard
Hepatitis B				
Carrier	Decline	Decline	Decline	Decline
Present or < 6 months since treatment	Decline	Decline	Decline	Decline
Others	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Hernia				
Present, all types other than Hiatal Hernia	Rider	Rider	Rider	Rider
Surgically repaired	Standard	Standard	Standard	Standard
Herpes				
OTC medication	Standard	Standard	Standard	Standard

Prescription medication	Rating or Rider KY & OH: Standard or Rider	Rating or Rider KY & OH: Standard or Rider	Standard	Rating or Rider KY & OH: Standard or Rider
Herpes Zoster (shingles)				
Present	Standard or Rate-up	Standard or Rate-up	Standard	Standard
Complete recovery, no medication	Standard	Standard	Standard	Standard
Hiatal Hernia—see Acid Reflux/GERD				
High Blood Pressure/Hypertension				
Underwritten based on age of onset, stability and comorbidity				
Stable, average readings 150/90 or less, no other cardiac risk factors, controlled with medication	Standard or Rate-up	Standard or Rate-up	Standard	Standard or Rate-up
High Blood Pressure + 50% Ratable Build				
	Decline	Decline	Decline	Decline
High Blood Pressure + Ratable Build + Tobacco User				
	Decline	Decline	Decline	Decline
High Blood Pressure + High Cholesterol controlled with medication				
	Standard or Rating KY & OH: Hypertenstion: Standard or Rating Cholesterol: Standard or Rider	Standard or Rating KY & OH: Hypertension: Standard or Rating Cholesterol: Standard or Rider	Standard	Standard or Rating KY & OH: Hypertension: Standard or Rating Cholesterol: Standard or Rider
High Blood Pressure + Sleep Apnea				

Actions for Common Medical Conditions—Rider States—Continued

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	Decline	Decline	Decline	Decline
High Blood Pressure + High Cholesterol + Ratable Build				
	Decline	Decline	Decline	Decline
High Blood Pressure + High Cholesterol + Tobacco User				
	Decline	Decline	Decline	Decline
High Cholesterol				
Lipid panel results within normal limits, compliant with follow up, controlled with medication	Standard or Rating KY & OH: Standard or Rider	Standard or Rating KY & OH: Standard or Rider	Standard	Standard or Rating KY & OH: Standard or Rider
High Cholesterol + Ratable Build + Tobacco User				
	Decline	Decline	Decline	Decline
High Cholesterol + Ratable Build + Hypertension				
	Decline	Decline	Decline	Decline
Human Papilloma Virus (HPV)				
Low risk—no condyloma	Standard	Standard	Standard	Standard

Low risk, with condyloma	Rider CO, KY, & MI: Rate 100% UT: Rate 55%—non tobacco user—individual consideration	Rider CO, KY, & MI: Rate 100% UT: Rate 55%—non tobacco user—individual consideration	Rider CO, KY, & MI: Rate 100% UT: Rate 55%—non tobacco user—individual consideration	Rider CO, KY, & MI: Rate 100% UT: Rate 55%—non tobacco user—individual consideration
High risk	Rider CO & KY: Decline UT: Rate 55%—non tobacco user, Decline tobacco user	Rider CO & KY: Decline UT: Rate 55%—non tobacco user, Decline tabacco user	Rider CO & KY: Decline UT: Rate 55%—non tobacco user, Decline tabacco user	Rider CO & KY: Decline UT: Rate 55%—non tobacco user, Decline tabacco user
Hyperthyroidism				
Present—untreated	Decline	Decline	Decline	Decline
Present—treated with medication	Rider	Standard	Standard	Standard
Hypoglycemia				
Present, follow up recommended	Decline	Decline	Decline	Decline
Present, or history of, diet controlled, no follow-up recommended	Standard	Standard	Standard	Standard
Present, treated with medication	Decline	Decline	Decline	Decline
Hypothyroid				
Present or history of	Standard	Standard	Standard	Standard
Infertility Treatment—male and female				
Current infertility drug treatment	Decline—entire family	Decline—entire family	Decline—entire family	Decline—entire family
Last treatment with infertility drugs ≤ a year without a live birth	Decline—entire family	Decline—entire family	Decline—entire family	Decline—entire family

Actions for Common Medical Conditions—Rider States—Continued

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Last treatment with infertility drugs with a live birth, family planning complete	Standard	Standard	Standard	Standard
Last treatment with infertility drugs with a live birth, family planning is not complete	Decline—entire family	Decline—entire family	Decline—entire family	Decline—entire family
Last treatment with IVF, ZIFT, GIFT or others, family planning complete	Standard	Standard	Standard	Standard
Last treatment with IVF, ZIFT, GIFT or others, family planning is not complete	Decline—entire family	Decline—entire family	Decline—entire family	Decline—entire family
Insomnia				
Treated with medication	Standard or Rating KY & OH: Standard or Rider	Standard or Rating KY & OH: Standard or Rider	Standard	Standard or Rating KY & OH: Standard or Rider
Irritable Bowel Syndrome				
Treated with OTC medication	Standard	Standard	Standard	Standard
Controlled w/prescription GI medication	Rider	Standard or Rating KY & OH: Standard or Rider	Standard	Standard or Rating KY & OH: Standard or Rider
Treated w/non-GI prescription medication	Rider and Rating for non-GI meds	Standard or Rating	Standard	Standard or Rating

ITP (blood disorder)				
Child form, complete recovery, platelet count returned to normal	Standard	Standard	Standard	Standard
Child form, present	Decline	Decline	Decline	Decline
Adult form or chronic, less than 40 years of age, more than 3 years since treatment and a complete recovery	Rate 25% UT: tobacco user—individual consideration	Rate 25% UT: tobacco user—individual consideration	Rate 25% UT: tobacco user—individual consideration	Rate 25% UT: tobacco user—individual consideration
Adult form or chronic, more than 6 years since treatment and a complete recovery, no current treatment, normal platelet count	Standard	Standard	Standard	Standard
Joint replacement				
Hip replaced	Permanent Rider KY & NM: Decline	Permanent Rider KY & NM: Decline	Permanent rider KY & NM: Decline	Permanent Rider KY & NM: Decline
Knee replaced	Permanent Rider KY & NM: Decline	Permanent Rider KY & NM: Decline	Permanent Rider KY & NM: Decline	Permanent Rider KY & NM: Decline
Shoulder replaced	Permanent Rider KY & NM: Rate 100%—Decline tobacco user	Permanent Rider KY & NM: Rate 100%—Decline tobacco user	Permanent Rider KY & NM: Rate 100%—Decline tobacco user	Standard
Kidney Infection/Pyelonephritis/Pyelitis				
1 episode, within 0–3 years	Rider UT: 25% rating, non tobacco users—Tobacco users, individual consideration	Standard	Standard	Standard
1 episode > 3 years ago	Standard	Standard	Standard	Standard

Actions for Common Medical Conditions—Rider States—Continued

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2 episodes, < 2 years ago	Decline	Decline	Decline	Standard
2 episodes, 2–5 years ago	Rider	Standard	Standard	Standard
2 episodes, > 5 years ago	Standard	Standard	Standard	Standard
3 or more episodes, regardless of time frame	Decline	Decline	Decline	Decline
Kidney Stones				
Present	Decline	Decline	Decline	Rider
Passed or surgically removed < 2 years ago	Rider	Rider	Rider	Standard
Passed or surgically removed > 2 years	Standard	Standard	Standard	Standard
5 or more episodes	Decline	Decline	Decline	Decline
Lichen Planus				
Mild infrequent attacks	Standard	Standard	Standard	Standard
Frequent or severe attacks	Rider plus Rate	Standard or Rate-up	Rider	Standard or Rate-up
Lipoma				
Present, asymptomatic, no surgery anticipated	Standard	Standard	Standard	Standard

Present and symptomatic	Rider	Standard	Standard	Standard
Lyme Disease				
Present or treatment completed less than 6 months ago	Decline	Decline	Decline	Decline
> 6 months since recovery, no residuals	Standard	Standard	Standard	Standard
Macular Degeneration				
Dry or wet	Rider	Rider	Rider	Rider
Meniere's Disease				
Present, confirmed diagnosis, stable, current or history of med use, no ongoing follow-up or treatment	Standard or Rating KY & OH: Standard or Rider (permanent)	Standard or Rating KY & OH: Standard or Rider (permanent)	Standard	Standard
Present, confirmed diagnosis, stable, current or history of med use, ongoing follow-up or treatment	Rider (permanent)	Rider (permanent)	Rider (permanent)	Rider (permanent)
Migraines				
Occasional (≤ 3 episodes yearly) treated with OTC medication	Standard	Standard	Standard	Standard
≥ 4 episodes in the last 12 months, or severe. Workup completed, symptoms controlled with current treatment	Rider	Standard or Rating KY & OH: Standard or Rider	Standard	Standard or Rating KY & OH: Standard or Rider
≥ 4 episodes in the last 12 months. No workup completed	Decline	Decline	Decline	Decline
Miscarriage				
1–2, no underlying cause	Standard	Standard	Standard	Standard

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> 2, no full term deliveries	Rider UT: non tobacco user rate 50%, tobacco user individual consideration	Rider UT: non tobacco user rate 50%, tobacco user individual consideration	Rider UT: non tobacco user rate 50%, tobacco user individual consideration	Rider UT: non tobacco user rate 50%, tobacco user individual consideration
History of with full term delivery	Standard	Standard	Standard	Standard
Mitral Valve Prolapse				
No symptoms or treatment	Standard	Standard	Standard	Standard
Mild symptoms controlled with one med, no other heart disorder	Standard or Rate-up	Standard or Rate-up	Standard	Standard or Rate-up
Molluscum Contagiosum				
Present or complete recovery < 1 year	Rider	Standard	Standard	Standard
Complete recovery > 1 year	Standard	Standard	Standard	Standard
MRSA—Methicillin-Resistant Staphylococcus Aureus				
Present, currently under treatment	Decline	Decline	Decline	Decline
Completed treatment, follow-up pending	Decline	Decline	Decline	Decline
Treated, full recovery of over 60 days	Standard	Standard	Standard	Standard

Nephritis/Glomerulonephritis				
1 episodes > 3 years ago, normal blood & urine results	Standard	Standard	Standard	Standard
All other scenarios	Rating, individual consideration or decline	Rating, individual consideration or decline	Rating, individual consideration or decline	Rating, individual consideration or decline
Osteoarthritis				
Present, only OTC meds, no PT or OT, no shoulder, hip, pelvis, back or spine, knee or ankle involvement	Standard	Standard	Standard	Standard
Present, all treatment except OTC meds, no shoulder, hip, pelvis, back or spine, knee or ankle involvement	Rider	Rider	Rider	Standard or Rating
Present, regardless of treatment, with shoulder, hip, pelvis, back or spine, knee or ankle involvement and no joint replacement	Rider	Rider	Rider	Rider
Joint replacement (see joint replacements)				
Osteoporosis/Osteopenia				
Current use of Prophylactic medication, due to age/menopause, no diagnosis of osteoporosis or osteopenia, no fractures or Dexa scans done	Standard or Rate-up	Standard or Rate-up	Standard	Standard or Rate-up
Diagnosis of Osteoporosis or Osteopenia with or without medication use, Dexa scans stable or improved	Rider (permanent)	Rider (permanent)	Rider (permanent)	Standard or Rate-up
Present, severe, history of pathologic fractures, crippling, Dexa scans worsening	Decline	Decline	Decline	Decline
Ovarian Cyst				
Present, asymptomatic	Standard	Standard	Standard	Standard

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Symptomatic	Rider UT: Decline	Rider UT: Non-tobacco user 50% rating, user individual consideration	Rider UT: Non-tobacco user 50% rating, user individual consideration	Rider UT: Non-tobacco user 50% rating, user individual consideration
Removed	Standard	Standard	Standard	Standard
Pancreatitis				
History of attack, no underlying cause, resolved	Individual consideration, medical records required	Individual consideration, medical records required	Individual consideration, medical records required	Individual consideration, medical records required
Chronic or recurrent	Decline	Decline	Decline	Decline
Pap Smear—Abnormal				
ASCUS, no high risk HPV, Class II or Class III followed by one normal pap, Class IV, treated, followed by three normal pap smears	Standard	Standard	Standard	Standard
Phlebitis				
Current use of blood thinners	Decline	Decline	Decline	Decline
One episode, < 3 months, complete recovery, no varicose veins or edema	Rider	Rider	Rider	Standard

One episode, 3 months–2 years, complete recovery, no varicose veins or edema	Standard	Standard	Standard	Standard
Recurrent episodes within 0–2 years	Rider	Rider	Rider	Standard
History of ≥ 2 years ago	Standard	Standard	Standard	Standard
Varicose Veins—(see Varicose Veins)				
Pneumonia				
Present	Decline	Decline	Decline	Decline
Complete recovery	Standard	Standard	Standard	Standard
Prostatitis				
One episode, full recovery	Standard	Standard	Standard	Standard
> 1 episode or chronic	Rider	Rider	Rider	Rider
Prosthesis/Prosthetics Device (See Amputation)				
Prostate—Enlarged (See Benign Prostatic Hypertrophy/BPH)				
Psoriasis				
Mild symptoms, OTC medications or no treatment	Standard	Standard	Standard	Standard
Mild to moderate symptoms, conservative treatments, including prescription topical agents	Rider	Standard or Rating KY & OH: Standard or Rider	Standard	Standard or Rating KY & OH: Standard or Rider
Severe symptoms requiring Rx medication such as Enbrel, Remicade, Sulfasalazine, gold therapy or Methotrexate	Decline	Decline	Decline	Decline
Use of tanning bed only	Standard	Standard	Standard	Standard
Use of UVA/PUVA light at a medical facility	Decline	Decline	Decline	Decline

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Psoriatic Arthritis				
All cases	Decline	Decline	Decline	Decline
Pyloric Stenosis				
Present	Decline	Decline	Decline	Decline
Surgically corrected with complete recovery	Standard	Standard	Standard	Standard
Respiratory Syncytial Virus (RSV)/Bronchiolitis				
Present or history of, < 2 years of age, Synagis/Palivizumab use	Decline	Decline	Decline	Decline
> 2 years of age, Last occurrence < 1 year ago and Synagis/Palivizumab use	Decline	Decline	Decline	Decline
> 2 years of age, Last occurrence > 1 year ago, No medications for > 1 year, Complete recovery, No other respiratory conditions	Standard	Standard	Standard	Standard
Restless Leg Syndrome				
No medication or treatment for 12 months	Standard	Standard	Standard	Standard
Controlled with medication or treatment or no meds for < 12 months	Standard or Rating KY & OH: Standard or Rider	Standard or Rating KY & OH: Standard or Rider	Standard	Standard or Rating KY & OH: Standard or Rider
Follow-up not completed, or testing pending or recommended	Decline	Decline	Decline	Decline

Retinal Detachment				
Present	Decline	Decline	Decline	Decline
Surgically corrected < 2 years	Rider	Standard	Standard	Standard
Scoliosis				
Present, no surgery, under age of 20	Rider	Rider	Rider	Rider
Present, over age of 20	Standard	Standard	Standard	Standard
Surgery completed, rod in place, full recovery	Standard	Standard	Standard	Standard
Any cardiac, pulmonary or spinal cord involvement	Decline	Decline	Decline	Decline
Sinusitis				
< 3 episodes in the past year	Standard	Standard	Standard	Standard
3–6 episodes in the past 12 months	Rider	Standard	Standard	Standard
> 6 episodes in the past 12 months	Rider	Rider	Rider	Standard
Sleep Apnea				
Controlled with CPAP	Rider	Rider	Rider	Standard
Surgically corrected	Standard	Standard	Standard	Standard
Sleep Apnea + Ratable build	Decline	Decline	Decline	Decline
Sleep Apnea + Tobacco User	Decline	Decline	Decline	Decline
Sleep Apnea + Hypertension	Decline	Decline	Decline	Decline
Central or Mixed	Decline	Decline	Decline	Decline
Spina Bifida				

Actions for Common Medical Conditions—Rider States—Continued

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Condition *We reserve the right to rate for the condition and /or medication use when appropriate. A modified rating is determined based on the severity of the condition and treatment and /or prescription medication cost, dosage, and premium amount.*	**$1,500 or lower deductable plus Rx**	**$2,500–$5,000 deductable plus Rx**	**$2,000–$5,200 deductable no Rx**	**$6,000 or higher deductable plus Rx**
Occulta, incidental finding, asymptomatic	Standard	Standard	Standard	Standard
Occulta—symptomatic	Decline	Decline	Decline	Decline
Manifesta	Decline	Decline	Decline	Decline
Spinal Manipulations				
0–2 visits per year	Standard	Standard	Standard	Standard
3–5 visits per year	All states Standard except: NV: Rider Portrait plan only (all other plans standard)	All states Standard except: NV—Rider Portrait plan & Autoshare 80 plus RX only (all other plans standard)	Standard	All states Standard except: NV—Rider Autoshare 80 plus RX only (all other plans standard)
6–10 visits per year	All states Ridered except: AZ, CO, NM & WI: Rate 25%	All states Standard except: NV—Rider Portrait plan & Autoshare 80 plus RX only (all other plans standard)	Standard	All states Standard except: NV—Rider Autoshare 80 plus RX only (all other plans standard)

11–15 visits per year	All states Ridered except: AZ, CO, NM & WI: Rate 50%	All states Standard except: NV—Rider Portrait plan & Autoshare 80 plus RX only (all other plans standard)	Standard	All states Standard except: NV—Rider Autoshare 80 plus RX only (all other plans standard)
16–20 visits per year	All states Ridered except: AZ, CO, NM & WI: Rate 75%	All states Ridered except: AZ, CO, NM & WI: Rate 15%	All states Ridered except: AZ, CO, NM & WI: Rate 15%	All states Standard except: NV—Rider Autoshare 80 plus RX only (all other plans standard)
21—25 visits per year	All states Ridered except: AZ, CO, NM & WI: Rate 100%	All states Ridered except: AZ, CO, NM & WI: Rate 25%	All states Ridered except: AZ, CO, NM & WI: Rate 25%	All states Standard except: NV—Rider Autoshare 80 plus RX only (all other plans standard)
26–30 visits per year	All states ridered except: AZ, CO, NM & WI: Rate 125%	All states ridered except: AZ, CO, NM & WI: Rate 40%	All states ridered except: AZ, CO, NM & WI: Rate 40%	All states Standard except: NV—Rider Autoshare 80 plus RX only (all other plans standard)
31–35 visits per year	All states ridered except: AZ, CO, NM & WI: Rate 150%	All states ridered except: AZ, CO, NM & WI: Rate 50%	All states ridered except: AZ, CO, NM & WI: Rate 50%	All states Standard except: NV—Rider Autoshare 80 plus RX only (all other plans standard)

Actions for Common Medical Conditions—Rider States—Continued

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36+ visits per year	All states ridered except: AZ, CO, NM & WI: Decline	All states ridered except: AZ, CO, NM & WI: Rate 75%	All states ridered except: AZ, CO, NM & WI: Rate 75%	All states ridered except: AZ, CO, LA, MI, NM & WI: Rate 15%
Stents				
Heart	Decline	Decline	Decline	Decline
Other locations	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Tachycardia				
No attacks in past 12 months, maintained and well controlled on medications to control attacks and symptoms, no other cardiovascular disorders	Rider + Rating for meds UT: tobacco user—individual consideration	Rider + Rating for meds UT: tobacco user—individual consideration	Rider + Rating for meds UT: tobacco user—individual consideration	Standard or Rate-up UT: tobacco user—individual consideration
≤ 3 attacks per year, < 1 year since last attack	Decline	Decline	Decline	Decline
≤ 3 attacks per year, 1–3 years since last attack, prompt response to treatment, no other cardivascular disorders	Rider UT: tobacco user—individual consideration	Rider UT: tobacco user—individual consideration	Rider UT: tobacco user—individual consideration; UT: individual consideration	Rider UT: tobacco user—individual consideration; MI: Rate 75%

< 3 attacks per year, > 3 years since last attack, prompt response to treatment, no other cardiovascular disorders	Standard	Standard	Standard	Standard
Others	Decline	Decline	Decline	Decline
Surgical ablation ≤ 6 months ago	Decline	Decline	Decline	Decline
Surgical ablation > 6 months ago, no residuals	Standard	Standard	Standard	Standard
Tendonitis—see Bursitis				
Tenosynovitis—see Bursitis				
Tonsillitis				
< 3 episodes per year	Standard	Standard	Standard	Standard
3–5 episodes per year	Rider	Standard	Standard	Standard
> 5 episodes per year	Rider	Rider	Rider	Standard
Tourettes Syndrome				
Simple tics, no behavioral disorders	Standard	Standard	Standard	Standard
Controlled with medication	Standard or Rate-up	Standard or Rate-up	Standard	Standard or Rate-up
Disabling, behavioral issues, extensive psychotherapy	Decline	Decline	Decline	Decline
Tuberculosis				
TB infection without disease, + skin test, Negative bacteriologic studies, Negative chest x-ray, No evidence of active disease, Prophylactic drug therapy complete > 6 months ago	Standard	Standard	Standard	Standard
TB infection without disease, + skin test, Negative bacteriologic studies, Negative chest x-ray, No evidence of active disease, Current use of < 6 months of prophylactic drugs	Decline	Standard	Standard	Standard

Actions for Common Medical Conditions—Rider States—Continued

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Ulcer (Peptic)				
One episode, complete recovery	Standard	Standard	Standard	Standard
> 1 episode, well controlled with medications	Rider UT: Individual consideration	Rider UT: Individual consideration	Rider UT: Individual consideration	Standard
History of bleeding or perforation, < 2 years after episode, OR multiple occurrences of bleeding or perforation	Decline	Decline	Decline	Decline
History of bleeding or perforation, > 2 years after episode, single occurrence, no known cause OR NSAID's discontinued, Vagotomy performed > 3 years ago, No symptoms	Standard	Standard	Standard	Standard
Uterine Fibroids				
Post-menopausal, no HRT, asymptomatic or myomectomy or hysterectomy completed	Standard	Standard	Standard	Standard
Others	Rider	Rider	Rider	Rider
Vaginitis				
One occurrence, complete recovery	Standard	Standard	Standard	Standard
> 1 occurrence, < 1 year since last occurrence	Rider	Standard	Standard	Standard
Varicose Veins of the lower extremities—UT only				

Present-asymptomatic, no recommendations for treatment	Standard	Standard	Standard	Standard
Present with ulcer	Decline	Decline	Decline	Decline
Treated with lazer, stripping or sclerotherapy, full recovery no symptoms or treatment < 1 yr ago	Rider	Standard	Standard	Standard
Treated with lazer, stripping or sclerotherapy, full recovery no symptoms or treatment > 1 yr ago	Standard	Standard	Standard	Standard
Varicose Veins				
Present-asymptomatic, no recommendations for treatment	Standard	Standard	Standard	Standard
Present with ulcer	Decline	Decline	Decline	Decline
Treated with lazer, stripping or sclerotherapy, full recovery no symptoms or treatment < 1 yr ago	Rider	Standard	Standard	Standard
Treated with lazer, stripping or sclerotherapy, full recovery no symptoms or treatment > 1 yr ago	Standard	Standard	Standard	Standard
Ventricular Septal Defect—APS Required				
Repaired > 1 year ago, complete recovery, normal cardiac exam	Standard	Standard	Standard	Standard
Present or repaired with symptoms or abnormal cardiac exam	Decline	Decline	Decline	Decline
Weight loss medication use				
Use of any weight loss medication (other than Xenical) or combination with hypertension or cardiac issues	Indivdual consideration—medical records required	Indivdual consideration—medical records required	Indivdual consideration—medical records required	Indivdual consideration—medical records required
Continuous use of weight loss medication for more than one year	Decline	Decline	Decline	Decline
All other scenarios or Xenical use in combination with hypertension or cardiac disease	Standard	Standard	Standard	Standard

Actions for Common Medical Conditions—Rider States—Continued

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Weight loss surgery—Gastric banding				
Lap band removed, no rateable build, weight maintained for one year	Standard	Standard	Standard	Standard
Lap band removed, rateable build, or weight loss not maintained for one year	Decline	Decline	Decline	Decline
Lap band present	Decline	Decline	Decline	Decline
Gastric Bypass/Gastric Stapling	Decline	Decline	Decline	Decline
Cancer Guidlines—APS Required for all—Mazimum allowable rating varies by state				

Actions for Common Medical Conditions—Non-Rider States (LA & MI)

Below are underwriting actions for conditions for which Humana does not place exclusion riders.

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Acid Reflux/GERD/ Heartburn				

Present, no hiatal hernia, non prescription medication (OTC only) no recommended consultations or testing	Standard	Standard	Standard	Standard
Present, prescription medication, no hiatal hernia present	Standard or Rating	Standard or Rating	Standard	Standard or Rating
Prescription medication use currently, hiatal hernia present	Decline	Decline	Decline	Standard or Rating
Acne/Rosacea				
Present, no treatment or OTC medication	Standard	Standard	Standard	Standard
Prescription meds, or < 6 months since med use, no Accutane or equivalent	Standard or Rating	Standard or Rating	Standard	Standard or Rating
Prescription meds, completed ≥ 6 months ago, complete recovery, no Accutane or equivalent	Standard	Standard	Standard	Standard
Accutane treatment of equivalent or ≤ 1 year since treatment completed	Decline	Decline	Decline	Decline
Accutane treatment of equivalent or > 1 year ago since treatment complete recovery	Standard	Standard	Standard	Standard
Allergies				
Recommended, pending or scheduled testing	Rate 50%	Rate 50%	Rate 50%	Standard
Seasonal prescription meds (3 refills or less per year or OTC), no immunotherapy treatment	Standard	Standard	Standard	Standard
Prescription meds, more than 3 refills per year, no immunotherapy treatment	Standard or Rating	Standard or Rating	Standard	Standard or Rating
With or without prescribed medications, current or recent immunotherapy	Individual Consideration with Max Rating	Individual Consideration with Max Rating	Individual Consideration with Max Rating	Individual Consideration with Max Rating
Amputation/Prosthesis				

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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Finger or toes—with or without prosthesis	Standard	Standard	Standard	Standard
Eye	Standard	Standard	Standard	Standard
All other amputations, with or without prosthesis	Decline	Decline	Decline	Decline
Caused by diabetes, severe artery disease or other disease	Decline	Decline	Decline	Decline
Anemia—other than anemia listed in the ineligible health conditions list				
Present	Standard	Standard	Standard	Standard
Aneurysm				
Present	Decline	Decline	Decline	Decline
Surgically repaired > 5 years, no residuals	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Anxiety				
Well controlled with prescription medication, no counseling, no more than 2 ER visits in the last 12 months	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Counseling only, no medication	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Asthma				

Exercise induced, no regular medication required	Standard	Standard	Standard	Standard
Medication use only	Standard or Rate up	Standard or Rate up	Standard or Rate up	Standard or Rate up
Medication use, steroid treatment (not including Albuterol inhaler) less than 3 times and/or no more than two emergency room visits in the past 12 months	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Oral steroids required ≥ 3 times or more than 2 ER visits in the past 12 months	Decline	Decline	Decline	Decline
Attention Deficit Disorder/ADD/ADHD				
No medication or counseling, more than 2 years	Standard	Standard or Rate up	Standard	Standard
One medication	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
More than one medication	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Atrial Fibrillation				
Single event, more than 2 years ago	Standard	Standard	Standard	Standard
Chronic or ongoing treatment	Decline	Decline	Decline	Decline
Single events less than 2 years ago or multiple events or Pacemaker/defibrillation	Decline	Decline	Decline	Decline
Back Sprain/Strain/Whiplash				
≥ 1 year ago—complete recovery	Standard	Standard	Standard	Standard
Less than 1 year ago or not recovered	Rate 50%	Rate 50%	Rate 50%	Standard
Baker's Cyst				

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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Present and symptomatic	Decline	Decline	Decline	Standard
Present and asymptomatic	Decline	Standard	Standard	Standard
History of no recurrence	Standard	Standard	Standard	Standard
Basal Cell Carcinoma				
Present	Decline	Decline	Decline	Decline
Single occurrence removed within 2 years	Rate 25%	Rate 25%	Rate 25%	Standard
Single occurrence, complete recovery	Standard	Standard	Standard	Standard
Multiple occurences, or recurrent, removed (regardless of time frame)	Rate 25% permanent	Rate 25% permanent	Rate 25% permanent	Standard
Benign Prostatic Hypertrophy/BPH				
Incidental finding, no symptoms, no treatment or medication use	Standard	Standard	Standard	Standard
Well controlled on one medication	Standard or Rate up	Standard or Rate up	Standard or Rate up	Standard or Rate up
More than one medication	Decline	Decline	Decline	Decline
Prostatectomy, TURP, TUNA, TUIP, TUMT, or Lazer surgery completed, no follow up needed, complete recovery, no residual complications or medication use	Standard	Standard	Standard	Standard

Bladder Infections (Cystitis)				
Less than 4 per year	Standard	Standard	Standard	Standard
4–6 episodes per year	Decline	Standard	Standard	Standard
More than 6 per year	Decline	Decline	Decline	Decline
Breast Cyst, Nodule or Mass				
Present and benign	Rate 25%	Rate 25%	Rate 25%	Standard
Removed and benign	Standard	Standard	Standard	Standard
Present, pathology unknown	Decline	Decline	Decline	Decline
Breast Implants				
Present, no complications, placed for cosmetic purposes	Standard	Standard	Standard	Standard
Breast Reduction/Macromastia				
Condition present, no surgery completed	Decline	Decline	Decline	Decline
Surgery completed < 1 year ago, with complete recovery	Standard	Standard	Standard	Standard
Surgery completed < 1 year ago, with residuals	Rate 25%	Rate 25%	Rate 25%	Rate 25%
Bronchitis				
1–3 episodes in the past year, non tobacco user, complete recovery	Standard	Standard	Standard	Standard
1–2 episodes in the past year, tobacco user, complete recovery	Standard	Standard	Standard	Standard
3 episodes a year, tobacco user, complete recovery	Individual consideration	Individual consideration	Individual consideration	Individual consideration
> 3 episodes a year or Chronic Bronchitis	Decline	Decline	Decline	Decline
Bundle Branch Block (right)				

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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Complete, no tobacco use for the last 12 months, symptom and treatment free for last 12 months, build not ratable	Standard	Standard	Standard	Standard
Bursitis/Tendonitis/Tenosynovitis				
Single occurrence with complete recovery	Standard	Standard	Standard	Standard
Single occurrence, not recovered	Rate 25%	Standard	Standard	Standard
Multiple occurrences	Rate 25%	Rate 25%	Rate 25%	Standard
Carpal Tunnel				
Present or residuals	Decline	Decline	Decline	Decline
Surgical repair, complete recovery	Standard	Standard	Standard	Standard
Cataracts				
Present	Decline	Decline	Decline	Standard
Surgically corrected, fully recovered, no residuals	Standard	Standard	Standard	Standard
Chlamydia				
Present or under treatment, no other STD history	Standard	Standard	Standard	Standard
Complete recovery	Standard	Standard	Standard	Standard

Colon Polyps				
Present	Decline	Decline	Decline	Decline
More than 1 benign polyp removed within the past 5 years during colonoscopy, scheduled follow up is every 10 years	Max Rating or Individual Consideration	Max Rating or Individual Consideration	Max Rating or Individual Consideration	Max Rating or Individual Consideration
Single benign polyp removed during colonoscopy within the last 5 years, no colon resection, follow up scheduled more than 5 years	Standard	Standard	Standard	Standard
Single benign polyp removed during colonoscopy, within the past 5 years, no colon resection, follow up schedued every 3–5 years	Max Rating or Individual Consideration	Max Rating or Individual Consideration	Max Rating or Individual Consideration	Max Rating or Individual Consideration
More than 1 polyp removed within the past 5 years. Surgically removed (not during colonoscopy) or part of colon surgically removed or follow up scheduled every 1–2 years	Decline	Decline	Decline	Decline
1–2 polyps removed within the past 5 years during colonoscopy, only 1 colonoscopy completed within the past 5 years. Follow up scheduled every 3–5 years	Max Rating or Individual Consideration	Max Rating or Individual Consideration	Max Rating or Individual Consideration	Max Rating or Individual Consideration
More than 2 polyps removed within the past 5 years, follow up scheduled every 3–5 years	Decline	Decline	Decline	Decline
Condyloma				
Present or history of—No HPV	Rate 100%: LA: 84%	Standard	Standard	Standard
Present or history of—with HPV	Rate 100%: LA: Rate 84%: HPV underwritten separately	Rate 100%: LA: Rate 84%: HPV underwritten separately	Rate 100%: LA: Rate 84%: HPV underwritten separately	Rate 100%: LA: Rate 84%: HPV underwritten separately
Deep Vein Thrombosis (DVT)				
On anticoagulants or one episode less than 3 months ago	Decline	Decline	Decline	Decline

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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1 episode 3 months–2 years	Rate: 25%	Rate: 25%	Rate: 25%	Standard
Recurrent	Decline	Decline	Decline	Decline
Depression				
Well controlled with prescription medication, no counseling	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Counseling only, no medication	Rate 10–20%	Rate 10–20%	Rate 10–20%	Rate 10–20%
Deviated Septum (nasal)				
Present, asymptomatic or surgically repaired	Standard	Standard	Standard	Standard
Symptomatic	Rate 100%: LA: 84%	Rate 100%: LA: 84%	Rate 100%: LA: 84%	Rate 100%: LA: 84%
Disc Disorder (herniated, bulging, ruptured)				
Present, surgically repaired less than 1 year ago or with residuals	Decline	Decline	Decline	Decline
Asymptomatic for more than 1 year without surgery or surgically repaired more than 1 year ago with full recovery	Standard	Standard	Standard	Standard
Diverticulitis				
Present, No Surgery	Decline	Decline	Decline	Decline
Surgery within 0–2 years	Decline	Decline	Decline	Decline

Surgically corrected > 2 years ago	Standard	Standard	Standard	Standard
Diverticulosis				
Present or with history of diverticulitis. No surgery	Standard	Standard	Standard	Standard
Surgery within 0–2 years	Decline	Decline	Decline	Decline
Surgically corrected > 2 years ago	Standard	Standard	Standard	Standard
DUI—Paramed exam is required				
Single occurrence, within 5 years	Rate 30%—Decline	Rate 30%—Decline	Rate 30%—Decline	Rate 30%—Decline
Single occurrence, more than 5 years	Standard	Standard	Standard	Standard
Multiple occurrences, within 5 years	Decline	Decline	Decline	Decline
Multiple occurrences, more than 5 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Ear Infection (Otitis Media)				
< 3 in the past 12 months	Standard	Standard	Standard	Standard
3 or more in the past 12 months	Decline	Decline	Decline	Standard
Tubes Present	Rate 25%	Standard	Standard	Standard
Tubes no longer present, no recurrence	Standard	Standard	Standard	Standard
Eczema				
Present or less than 2 years since symptomatic	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
> 2 years since treatment or symptoms	Standard	Standard	Standard	Standard
Endometriosis				

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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Present or within 5 years of treatment	Decline	Decline	Decline	Decline
> 5 years since symptoms or treatment	Standard	Standard	Standard	Standard
Surgery < 3 years ago	Decline	Decline	Decline	Standard
Surgery > 3 years ago	Standard	Standard	Standard	Standard
Enlarged Prostate—See Benign Prostatic Hypertrophy				
Epilepsy, Grand Mal (Generalized)				
Seizure within past 2 years	Decline	Decline	Decline	Decline
Last seizure > 2 years ago	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Epilepsy, Petit Mal (Generalized)				
Seizure within past 2 years	Decline	Decline	Decline	Decline
Last seizure > 2 years ago	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Epilepsy, Temporal Lobe (Partial)				
Seizure < 1 year ago	Decline	Decline	Decline	Decline

Seizure > 1 year ago	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Fibromyalgia				
Present or history of	Decline	Decline	Decline	Decline
Fractures				
Present—No fixation device	Rate 75%	Standard	Standard	Standard
Present—with permanent fixation device	Standard	Standard	Standard	Standard
Present—with temporary fixation device	Decline	Decline	Decline	Decline
Recovered & released from care with no fixation device or permanent fixation device	Standard	Standard	Standard	Standard
Recovered, released from care with temporary fixation device	Decline	Decline	Decline	Decline
Pathological	Decline	Decline	Decline	Decline
Ganglion Cyst				
Present & symptomatic	Rate 25%	Standard	Standard	Standard
Surgically removed, asymptomatic or history and resolved	Standard	Standard	Standard	Standard
Gastric banding—weight loss surgery				
Lap band removed, no rateable build, weight maintained for one year	Standard	Standard	Standard	Standard
Lap Band removed, rateable build, or weight loss not maintained for one year	Decline	Decline	Decline	Decline
Lap Band present	Decline	Decline	Decline	Decline
Gastric Bypass/Gastric Stapling	Decline	Decline	Decline	Decline
GERD (reflux)—see Acid Reflux/GERD				

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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Gestational Diabetes				
< 5 yrs ago, diet controlled during pregnancy, no recurrence	Rate 25%	Rate 25%	Rate 25%	Rate 25%
> 5 yrs ago, diet controlled during pregnancy, no recurrence	Standard	Standard	Standard	Standard
< 5 yrs ago, controlled with insulin during pregnancy, no recurrence	Rate 50%—UT: tobacco users, individual consideration	Rate 50%—UT: tobacco users, individual consideration	Rate 50%—UT: tobacco users, individual consideration	Rate 50%—UT: tobacco users, individual consideration
> 5 yrs ago, controlled with insulin during pregnancy, no recurrence	Rate 25%	Rate 25%	Rate 25%	Rate 25%
History of, no glucose test following pregnancy or glucose levels did not return to normal	Decline	Decline	Decline	Decline
Glaucoma				
Symptomatic, but not diagnosed	Rate 25% for condition and additional rating for meds	Rate 25% for condition and additional rating for meds	Rate 25% for condition and additional rating for meds	Rate 25% for condition and additional rating for meds
Present, well controlled	Rating	Rating	Standard	Rating
Present, not controlled: with or without medications	Decline	50–75% rating for condition, and additional rating for medications	Rate 50% no actions for meds	Rate 50% and additional rating for meds

Surgically corrected both eyes, with or without medications	If no medications: Standard Medication use: Rating	If no medications: Standard Medication use: Rating	Standard	If no medications: Standard Medication use: Rating
Surgically corrected in one eye: with or without medication use	Decline	50–75% rating for condition, and additional rating for medications	Rate 50% no actions for meds	Rate 50% and additional rating for meds
Surgically corrected	Standard	Standard	Standard	Standard
Gout				
Present or within 2 years of symptoms or treatment	Rate 25%	Rate 25%	Rate 25%	Standard
Recovered and time from last symptoms or treatment > 2 years	Standard	Standard	Standard	Standard
Grave's Disease—See Hyperthyroidism				
Guillain-Barre Syndrome				
Present or < 3 years since recovered or Residual disability/permanent impairment	Decline	Decline	Decline	Decline
> 3 years since recovered, no disability, minimal weakness, no relapse	Rate 25%	Standard	Standard	Standard
Gynecomastia				
Present	Decline	Decline	Decline	Decline
History of, complete recovery	Standard	Standard	Standard	Standard
Hashimoto's Thyroiditis—See Hypothyroidism				
Heartburn—see Acid Reflux				
Heart Murmur Diastolic				

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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Functional/Innocent, Grade I or II—Systolic	Standard	Standard	Standard	Standard
Organic, Grade III or greater, continuous—Diastolic	Decline	Decline	Decline	Decline
Hemorrhoids				
Present, asymptomatic	Standard	Standard	Standard	Standard
Present, symptomatic	Rate 50%	Standard or Rate up	Standard	Standard or Rate up
> 1 year since symptoms or surgery	Standard	Standard	Standard	Standard
Hepatitis A				
> 6 months since treatment with normal liver tests	Standard	Standard	Standard	Standard
Hepatitis B				
Carrier	Decline	Decline	Decline	Decline
Present or < 6 months since treatment	Decline	Decline	Decline	Decline
Others	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Hernia				
Present, all types other than Hiatal Hernia	Decline	Decline	Decline	Decline

Surgically repaired, with complete recovery and no residuals	Standard	Standard	Standard	Standard
Hiatal Hernia—see Acid Reflux/GERD				
Herpes				
OTC medication	Standard	Standard	Standard	Standard
Prescription medication	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Herpes Zoster (shingles)				
Present	Standard or Rate up	Standard or Rate up	Standard	Standard
Complete recovery, no medication	Standard	Standard	Standard	Standard
High Blood Pressure/Hypertension				
Underwritten based on age of onset, stability and comorbidity				
Stable, average readings 150/90 or less, no other cardiac risk factors, controlled with medication	Standard or Rate-up	Standard or Rate-up	Standard	Standard or Rate-up
High Blood Pressure + 50% Ratable Build				
	Decline	Decline	Decline	Decline
High Blood Pressure + Ratable Build + Tobacco User				
	Decline	Decline	Decline	Decline
High Blood Pressure + High Cholesterol controlled with medication				
	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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High Blood Pressure + High Cholesterol + Ratable Build				
	Decline	Decline	Decline	Decline
High Blood Pressure + High Cholesterol+ Tobacco User				
	Decline	Decline	Decline	Decline
High Blood Pressure + Rateable Build + Tobacco User				
	Decline	Decline	Decline	Decline
High Blood Pressure + Sleep Apnea				
	Decline	Decline	Decline	Decline
High Cholesterol				
Lipid panel results within normal limits, compliant with follow up	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
High Cholesterol + Ratable Build + Tobacco User				
	Decline	Decline	Decline	Decline
High Cholesterol + Ratable Build + Hypertension				
	Decline	Decline	Decline	Decline

Human Papilloma Virus (HPV)				
Low risk—no condyloma	Standard	Standard	Standard	Standard
High risk	Decline	Decline	Decline	Decline
Hyperthyroidism				
Present—untreated	Decline	Decline	Decline	Decline
Present—treated with medication	Rate 25% or higher	Standard	Standard	Standard
Hypoglycemia				
Present, follow up recommended	Decline	Decline	Decline	Decline
Present, or history of, diet controlled, no follow-up recommended	Standard	Standard	Standard	Standard
Present, treated with medication	Decline	Decline	Decline	Decline
Hypothyroid				
Present or history of	Standard	Standard	Standard	Standard
Infertility Treatment—male and female				
Current infertility drug treatment	Decline—entire family	Decline—entire family	Decline—entire family	Decline—entire family
Last treatment with infertility drugs ≤ a year without a live birth	Decline—entire family	Decline—entire family	Decline—entire family	Decline—entire family
Last treatment with infertility drugs with a live birth, family planning complete	Standard	Standard	Standard	Standard
Last treatment with infertility drugs with a live birth, family planning is not complete	Decline—entire family	Decline—entire family	Decline—entire family	Decline—entire family

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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Last treatment with IVF, ZIFT, GIFT or others, family planning complete	Standard	Standard	Standard	Standard
Last treatment with IVF, ZIFT, GIFT or others, family planning is not complete	Decline—entire family	Decline—entire family	Decline—entire family	Decline—entire family
Insomnia				
Treated with medication	Standard or Rating up	Standard or Rating up	Standard	Standard or up
Irritable Bowel Syndrome				
Treated with OTC medication	Standard	Standard	Standard	Standard
Treated with medication	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Treated with non-GI prescription medication	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
ITP (blood disorder)				
Child form, complete recovery, platelet count returned to normal	Standard	Standard	Standard	Standard
Child form, present	Decline	Decline	Decline	Decline
Adult form or chronic, less than 40 years of age, more than 3 years since treatment and a complete recovery	Rate 25%	Rate 25%	Rate 25%	Rate 25%

Adult form or chronic, more than 6 years since treatment and a complete recovery, no current treatment, normal platelet count	Standard	Standard	Standard	Standard
Joint replacement				
Hip replaced	Decline	Decline	Decline	Decline
Knee replaced	Decline	Decline	Decline	Decline
Shoulder replaced	Rate 100%: LA: Rate 84%	Rate 100%: LA: Rate 84%	Rate 100%: LA: Rate 84%	Standard
Kidney Infection/Pyelonephritis/Pyelitis				
1 episode, within 0–3 years	Rate 25%	Standard	Standard	Standard
1 episode > 3 years ago	Standard	Standard	Standard	Standard
2 episodes, < 2 years ago	Decline	Decline	Decline	Standard
2 episodes, 2–5 years ago	Rate 25%	Standard	Standard	Standard
2 episodes, > 5 years ago	Standard	Standard	Standard	Standard
3 or more episodes, regardless of time frame	Decline	Decline	Decline	Decline
Kidney Stones				
Present	Decline	Decline	Decline	Decline
Passed on its own or surgically > 2 years	Standard	Standard	Standard	Standard
> 5 episodes	Decline	Decline	Decline	Decline
Lichen Planus				
Mild infrequent attacks	Standard	Standard	Standard	Standard
Frequent or severe attacks	Rate 25% or higher	Rate	Rate 25%	Rate

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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Lipoma				
Present, asymptomatic, no surgery anticipated	Standard	Standard	Standard	Standard
Present and symptomatic	Rate 25%	Standard	Standard	Standard
Lyme Disease				
Present or treatment completed less than 6 months ago	Decline	Decline	Decline	Decline
> 6 months since recovery	Standard	Standard	Standard	Standard
Macular Degeneration				
Dry or wet	Decline	Decline	Decline	Decline
Meniere's Disease				
Present, confirmed diagnosis, stable, current or history of med use, no ongoing follow-up or treatment	Standard or Rating	Standard or Rating	Standard	Standard
Present, confirmed diagnosis, stable, current or history of med use, ongoing follow-up or treatment	Decline	Decline	Decline	Decline
Migraines				
Occasional (≤ 3 episodes yearly) treated with OTC medication	Standard	Standard	Standard	Standard

≥ 4 episodes in the last 12 months, or severe. Workup completed, symptoms controlled with current treatment	Rating	Rating	Standard	Rating
≥ 4 episodes in the last 12 months. No workup completed	Decline	Decline	Decline	Decline
Prescription medication	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Miscarriage				
1–2, no underlying cause	Standard	Standard	Standard	Standard
> 2, no full term deliveries	Rate 50%	Rate 50%	Rate 50%	Rate 50%
History of with full term delivery	Standard	Standard	Standard	Standard
Mitral Valve Prolapse				
No symptoms or treatment	Standard	Standard	Standard	Standard
Mild symptoms controlled with one med, no other heart disorder	Standard or Rate-up	Standard or Rate-up	Standard	Standard or Rate-up
Molluscum Contagiosum				
Present or complete recovery < 1 year	Rate 50%	Standard	Standard	Standard
Complete recovery > 1 year	Standard	Standard	Standard	Standard
Nephritis/Glomerulonephritis				
One episode > 3 years ago	Standard	Standard	Standard	Standard
One episode < 3 years ago	Decline	Decline	Decline	Decline
Osteoarthritis				
Present, only OTC meds, no PT or OT, no shoulder, hip, pelvis, back or spine, knee or ankle involvement	Standard	Standard	Standard	Standard

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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Present, all treatment except OTC meds, no shoulder, hip, pelvis, back or spine, knee or ankle involvement	Rating	Rating	Rating	Rating
Present, regardless of treatment, with shoulder, hip, pelvis, back or spine, knee or ankle involvement and no joint replacement	Decline	Decline	Decline	Decline
Osteoporosis/Osteopenia				
Current use of Prophylactic medication, due to age/menopause, no diagnosis of osteoporosis or osteopenia, no fractures or Dexa scans done	Standard or Rate-up	Standard or Rate-up	Standard	Standard or Rate-up
Diagnosis of Osteoporosis or Osteopenia with or without medication use, Dexa scans stable or improved	Minimum rate of 25% + Pharmacy rating if on meds or 50% Rate if not on meds	Minimum rate of 25% + Pharmacy rating if on meds or 50% Rate if not on meds	Rate 25%	Standard or Rate-up
Present, severe, history of pathologic fractures, crippling, Dexa scans worsening	Decline	Decline	Decline	Decline
Ovarian Cyst				
Present, asymptomatic	Standard	Standard	Standard	Standard
Symptomatic	Decline	Rate 50%	Rate 50%	Standard
Removed	Standard	Standard	Standard	Standard

Pancreatitis				
History of attack, no underlying cause, resolved	Individual consideration, medical records required	Individual consideration, medical records required	Individual consideration, medical records required	Individual consideration, medical records required
Chronic or recurrent	Decline	Decline	Decline	Decline
Pap Smear—Abnormal				
ASCUS, no high risk HPV, Class II or Class III followed by one normal pap, Class IV, treated, followed by three normal pap smears	Standard	Standard	Standard	Standard
Phlebitis				
Current use of blood thinners	Decline	Decline	Decline	Decline
One episode, < 3 months, complete recovery, no varicose veins or edema	Rate 25%	Rate 25%	Rate 25%	Standard
One episode, 3 months–2 years, complete recovery, no varicose veins or edema	Standard	Standard	Standard	Standard
Recurrent episodes within 0–2 years	Rate 25%	Rate 25%	Rate 25%	Standard
History of ≥ 2 years ago	Standard	Standard	Standard	Standard
Varicose Veins—(see Varicose Veins)				
Pneumonia				
Present	Decline	Decline	Decline	Decline
Complete recovery	Standard	Standard	Standard	Standard
Prostatitis				
One episode, full recovery	Standard	Standard	Standard	Standard

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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> 1 episode or chronic	Rate 25%	Rate 25%	Rate 25%	Rate 25%
Prosthesis/Prosthetics Device (See Amputation)				
Prostate—Enlarged (See Benign Prostatic Hypertrophy/BPH)				
Psoriasis				
Mild symptoms, OTC medications or no treatment	Standard	Standard	Standard	Standard
Mild to moderate symptoms, conservative treatments, including prescription topical agents	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Severe symptoms requiring Rx medication such as Enbrel, Remicade, Sulfasalazine, gold therapy or Methotrexate	Decline	Decline	Decline	Decline
Use of tanning bed only	Standard	Standard	Standard	Standard
Use of UVA/PUVA light at a medical facility	Standard	Standard	Standard	Standard
Psoriatic Arthritis				
All cases	Decline	Decline	Decline	Decline
Pyloric Stenosis				
Present	Decline	Decline	Decline	Decline
Surgically corrected with complete recovery	Standard	Standard	Standard	Standard

Respiratory Syncytial Virus (RSV)/Bronchiolitis				
Present or history of, < 2 years of age, Synagis/Palivizumab use	Decline	Decline	Decline	Decline
> 2 years of age, Last occurrence < 1 year ago and Synagis/ Palivizumab use	Decline	Decline	Decline	Decline
> 2 years of age. Last occurrence > 1 year ago, no medications for > 1 year. Complete recovery, no other respiratory conditions	Standard	Standard	Standard	Standard
Restless Leg Syndrome				
No medication or treatment for 12 months	Standard	Standard	Standard	Standard
Controlled with medication	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up
Diagnosis not confirmed, secondary condition not ruled out	Decline	Decline	Decline	Decline
Retinal Detachment				
Present	Decline	Decline	Decline	Decline
Surgically corrected < 2 years	Rate 50%	Standard	Standard	Standard
Rheumatoid Arthritis				
	Decline	Decline	Decline	Decline
Scoliosis				
Present, no surgery, under age of 20	Decline	Decline	Decline	Decline
Present, over age of 20	Standard	Standard	Standard	Standard
Surgery completed, rod in place, full recovery	Standard	Standard	Standard	Standard
Any cardiac, pulmonary or spinal cord involvement	Decline	Decline	Decline	Decline
Sinusitis				

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< 3 episodes in the past year	Standard	Standard	Standard	Standard
3–6 episodes in the past 12 months	Rate 25%	Standard	Standard	Standard
> 6 episodes in the past 12 months	Rate 25%	Rate 25%	Rate 25%	Standard
Sleep Apnea				
Controlled with CPAP	Rate 150%: LA Decline	Rate 150%: LA Decline	Rate 150%: LA Decline	Standard
Surgically corrected	Standard	Standard	Standard	Standard
Sleep Apnea + Ratable build	Decline	Decline	Decline	Decline
Sleep Apnea + Tobacco User	Decline	Decline	Decline	Decline
Sleep Apnea + Hypertension	Decline	Decline	Decline	Decline
Central or Mixed	Decline	Decline	Decline	Decline
Spina Bifida				
Occulta, incidental finding, asymptomatic	Standard	Standard	Standard	Standard
Occulta—symptomatic	Decline	Decline	Decline	Decline
Manifesta	Decline	Decline	Decline	Decline

Spinal Manipulations				
0–5 visits per year	Standard	Standard	Standard	Standard
6–10 visits per year	Standard	Standard	Standard	Standard
11–15 visits per year	Rate 50%	Standard	Standard	Standard
16–20 visits per year	Rate 25%	Rate 15%	Rate 15%	Standard
21—25 visits per year	Rate 75% Except: LA: Rate 84%	Rate 15% Except: LA: Rate 84%	Rate 15% Except: LA: Rate 84%	Standard
26–30 visits per year	Rate 75% Except: LA: Rate 84%	Rate 15% Except: LA: Rate 40%	Rate 15% Except: LA: Rate 40%	Standard
31–35 visits per year	Rate 75% Except: LA: Rate 84%	Rate 15% Except: LA: Rate 50%	Rate 15% Except: LA: Rate 50%	Standard except: NV—Rider Autoshare 80 plus Rx only (all other plans standard)
36+ visits per year	Rate 75% Except: LA: Decline	Rate 75% Except: LA: Decline	Rate 15% Except: LA: Rate 75%	Rate 15%
Stents				
Heart	Decline	Decline	Decline	Decline
Other locations	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Tachycardia				
No attacks in past 12 months, maintained and well controlled on medications to control attacks and symptoms, no other cardiovascular disorders	Rate 25% or higher	Rate 25% or higher	Rate 25%	Standard Rate
≤ 3 attacks per year, < 1 year since last attack	Decline	Decline	Decline	Decline

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≤ 3 attacks per year, 1–3 years since last attack, prompt response to treatment, no other cardivascular disorders	Rate 75%	Rate 75%	Rate 75%	Rate 75%
< 3 attacks per year, > 3 years since last attack, prompt response to treatment, no other cardiovascular disorders	Standard	Standard	Standard	Standard
Others	Decline	Decline	Decline	Decline
Surgical ablation ≤ 6 months ago	Decline	Decline	Decline	Decline
Surgical ablation > 6 months ago, no residuals	Standard	Standard	Standard	Standard
Tendonitis—see Bursitis				
Tonsillitis				
Less than 3 episodes per year	Standard	Standard	Standard	Standard
3–5 episodes per year	Decline	Standard	Standard	Standard
> 5 episodes per year	Decline	Decline	Decline	Standard
Tourettes Syndrome				
Simple tics, no behavioral disorders	Standard	Standard	Standard	Standard
Controlled with medication	Standard or Rate up	Standard or Rate up	Standard	Standard or Rate up

Disabling, behavioral issues, extensive psychotherapy	Decline	Decline	Decline	Decline
Tuberculosis				
TB infection without disease, + skin test, negative bacteriologic studies, negative chest x-ray, no clinical evidence of active TB disease, prophylactic drug therapy complete > 6 months ago	Standard	Standard	Standard	Standard
TB infection without disease, + skin test, negative bacteriologic studies, negative chest x-ray, no clinical evidence of active TB disease, current use of < 6 months of prophylactic drugs	Decline	Standard	Standard	Standard
Ulcer (Peptic)				
One episode, complete recovery	Standard	Standard	Standard	Standard
History of bleeding or perforation less than 2 years ago or multiple occurrences of bleeding or perforation	Decline	Decline	Decline	Decline
One episode of bleeding or perforation > 2 years ago, no symptoms or vagotomy completed > 3 years ago	Standard	Standard	Standard	Standard
Uterine Fibroids				
Post-menopausal, no HRT, asymptomatic or myomectomy or hysterectomy completed	Standard	Standard	Standard	Standard
Others	Decline	Decline	Decline	Decline
Vaginitis				
One occurrence, complete recovery	Standard	Standard	Standard	Standard
> 1 occurrence, < 1 year since last occurrence	Rate 25%	Standard	Standard	Standard
Varicose Veins				
Present-asymptomatic, no recommendations for treatment	Standard	Standard	Standard	Standard

Actions for Common Medical Conditions—Non-Rider States (LA & MI)—Continued

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Present with ulcer	Decline	Decline	Decline	Decline
Treated with lazer, stripping or sclerotherapy, full recovery no symptoms or treatment < 1 year ago	Rate 25%	Standard	Standard	Standard
Treated with lazer, stripping or sclerotherapy, full recovery no symptoms or treatment > 1 year ago	Standard	Standard	Standard	Standard
Ventricular Septal Defect—APS Required				
Repaired > 1 year ago complete recovery, normal cardiac exam	Standard	Standard	Standard	Standard
Present or repaired with symptoms or abnormal cardiac exam	Decline	Decline	Decline	Decline
Weight loss medication use				
Use of any weight loss medication (other than Xenical) in combination with hypertension or cardiac issues	Individual consideration, medical records required	Individual consideration, medical records required	Individual consideration, medical records required	Individual consideration, medical records required
Continuous use of any weight loss medication for more than one year	Decline	Decline	Decline	Decline
All other scenarios or Xenical use in combination with hypertension or cardiac disease	Standard	Standard	Standard	Standard
Weight loss surgery—Gastric banding				
Lap band removed, no rateable build, weight maintained for one year	Standard	Standard	Standard	Standard

Lap band removed, ratable build, or weight loss not maintained for one year	Decline	Decline	Decline	Decline
Lap band present	Decline	Decline	Decline	Decline

Actions for Cancer

The following grid includes possible underwriting actions for applicants with cancer history. This is not an all-inclusive list. Medical records are required for all cancer history, regardless of the original diagnosis date.

Eligibility is determined based on the underwriter assessment of complete medical records, confirmation of compliance with all physician recommended follow-up, a current physician assessment of the condition, supporting stability and no recurrence of the condition. Treatment for cancer may be defined as: office visits, preventive maintenance medication, screenings, monitoring, diagnostics, and lab work.

Condition *We reserve the right to rate for the condition and/or medication use when appropriate. A modified rating is determined based on the severity of the condition and treatment and/or prescription medication cost, dosage, and premium amount.*	**$1,500 or lower deductible plus Rx**	**$2,500–$5,000 deductible plus Rx**	**$2,000–$5,200 deductible no Rx**	**$6,000 or higher deductible plus Rx**
Basal Cell Carcinoma				
Present	Decline	Decline	Decline	Decline
Single occurrence, complete recovery	Standard	Standard	Standard	Standard
Multiple occurences, or recurrent, removed (regardless of time frame)	Rate 25%—permanent	Rate 25%—permanent	Rate 25%—permanent	Standard
Breast				
Stage 0, > 4 years from treatment	All states except FL and UT: Rate 25% UT: tobacco user—individual consideration FL: see below	All states except FL and UT: Rate 25% UT: tobacco user—individual consideration FL: see below	All states except FL and UT: Rate 25% UT: tobacco user—individual consideration FL: see below	All states except FL and UT: Rate 25% UT: tobacco user—individual consideration FL: see below
Stage 0, ≥ 2 yrs from treatment	FL only: Rating if cancer free for ≥ 2 years	FL only: Rating if cancer free for ≥ 2 years	FL only: Rating if cancer free for ≥ 2 years	FL only: Rating if cancer free for ≥ 2 years

Actions for Cancer—Continued

The following grid includes possible underwriting actions for applicants with cancer history. This is not an all-inclusive list. Medical records are required for all cancer history, regardless of the original diagnosis date.

Eligibility is determined based on the underwriter assessment of complete medical records, confirmation of compliance with all physician recommended follow-up, a current physician assessment of the condition, supporting stability and no recurrence of the condition. Treatment for cancer may be defined as: office visits, preventive maintenance medication, screenings, monitoring, diagnostics, and lab work.

Condition *We reserve the right to rate for the condition and/or medication use when appropriate. A modified rating is determined based on the severity of the condition and treatment and/or prescription medication cost, dosage, and premium amount.*	**$1,500 or lower deductible plus Rx**	**$2,500–$5,000 deductible plus Rx**	**$2,000–$5,200 deductible no Rx**	**$6,000 or higher deductible plus Rx**
Stage I, > 11 yrs from treatment	All states: Rate 25–50%	All states: Rate 25–50%	All states: Rate 25–50%	All states: Rate 25–50%
Stage I, ≥ 2 years from treatment	FL only: Rating if cancer free for ≥ 2 years	FL only: Rating if cancer free for ≥ 2 years	FL only: Rating if cancer free for ≥ 2 years	FL only: Rating if cancer free for ≥ 2 years
Stage II, III, IV	Decline FL only: Exception ≥ 2 years cancer free, 150% rating applies	Decline FL only: Exception ≥ 2 years cancer free, 150% rating applies	Decline FL only: Exception ≥ 2 years cancer free, 150% rating applies	Decline FL only: Exception ≥ 2 years cancer free, 150% rating applies
Bladder				
Stage 0, 10+ years from treatment	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Stage I, > 10 years from treatment	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Cervical				
Stage 0 (carcinoma in situ), > 3 years from treatment	Rate 25%	Rate 25%	Rate 25%	Rate 25%
Stage I, IA1, IA2, IB1, IB2 (lymph node removed), > 10 years from treatment	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Stage IA, IIA, IIIA, IBA & IVB, > 10 years ago	Individual consideration	Individual consideration	Individual consideration	Individual consideration

Colon				
Stage 0 or Carcinoma in situ, 3+ years from treatment	Rate 25–50%	Rate 25–50%	Rate 25%	Rate 25%
Stage I or Duke's A, > 5 years from treatment	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Stage II or Duke's B, > 12 years from treatment	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Stage III or IV, Duke's C or D, > 10 years from treatment	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Kidney				
Stage I & II, normal kidney function, > 10 years from treatment:	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Stage I & II, abnormal kidney function, > 10 years from treatment	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Stage III & IV, > 10 years from treatment	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Melanoma, localized				
Clark's Level I, II & III—.76–1.5 mm thick, > 5 years	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Clark's Level I, II & III, > 1.5 mm thick, > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Clark's Level I, II & III, < .75 mm thick, > 3 years	Rate 25%	Rate 25%	Rate 25%	Rate 25%
Clark's Level I, II & III, unknown thickness, > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Clark's level IV or V, > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Melanoma In Situ, > 2 years	Rate 25%	Rate 25%	Rate 25%	Rate 25%

Actions for Cancer—Continued

The following grid includes possible underwriting actions for applicants with cancer history. This is not an all-inclusive list. Medical records are required for all cancer history, regardless of the original diagnosis date.

Eligibility is determined based on the underwriter assessment of complete medical records, confirmation of compliance with all physician recommended follow-up, a current physician assessment of the condition, supporting stability and no recurrence of the condition. Treatment for cancer may be defined as: office visits, preventive maintenance medication, screenings, monitoring, diagnostics, and lab work.

Condition *We reserve the right to rate for the condition and/or medication use when appropriate. A modified rating is determined based on the severity of the condition and treatment and/or prescription medication cost, dosage, and premium amount.*	**$1,500 or lower deductible plus Rx**	**$2,500–$5,000 deductible plus Rx**	**$2,000–$5,200 deductible no Rx**	**$6,000 or higher deductible plus Rx**
Multiple Malignant Melanoma, > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Osteoid Osteoma Removed with complete recovery	Standard	Standard	Standard	Standard
Prostate				
Stage I or Gleason score 2–4, > 2 years	Rate 25%	Rate 25%	Rate 25%	Rate 25%
Gleason Score 5, > 3 years	Rate 25%	Rate 25%	Rate 25%	Rate 25%
Stage II or Gleason Score 6, > 5 years	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Gleason score 7, > 5 years	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Stage III or Gleason Score 8–10, > 10 years	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Stage IV or Recurrent, > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Skin, Sarcoma				
Adult				
Stage I, G1 or G2, T1, > 3 years	Rate 25%	Rate 25%	Rate 25%	Rate 25%
Stage I, G1 or G2, T2, > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration

Stage II, III or IV, > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Under age 20:				
Group I, > 3 years	Rate 25%	Rate 25%	Rate 25%	Rate 25%
Group II, > 5 years	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Group II, IV or Recurrent, > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Skin, Squamous Cell				
Present	Decline	Decline	Decline	Decline
Single occurrence, complete recovery—margins free of tumor	Standard	Standard	Standard	Standard
Multiple occurrences or recurrent, last removal < 3 years ago	Rider—permanent	Rider—permanent	Rider—permanent	Rider—permanent
Multiple occurrences or recurrent, last removal ≥ 3 years ago	Rider—permanent	Rider—permanent	Rider—permanent	Standard
Deep Tumor: invaded muscle, cartilage or bone, no metastasis	Decline	Decline	Decline	Decline
Metastasis	Decline	Decline	Decline	Decline
Stomach				
	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Testicular				
Nonseminoma & Seminoma combination, Stage I, > 3 years ago	Rate 25%	Rate 25%	Rate 25%	Rate 25%
Nonseminoma & Seminoma Combination Stage II or Stage III > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Nonseminoma Stage I, > 3 years	Rate 25%	Rate 25%	Rate 25%	Rate 25%

Actions for Cancer—Continued

The following grid includes possible underwriting actions for applicants with cancer history. This is not an all-inclusive list. Medical records are required for all cancer history, regardless of the original diagnosis date.

Eligibility is determined based on the underwriter assessment of complete medical records, confirmation of compliance with all physician recommended follow-up, a current physician assessment of the condition, supporting stability and no recurrence of the condition. Treatment for cancer may be defined as: office visits, preventive maintenance medication, screenings, monitoring, diagnostics, and lab work.

Condition *We reserve the right to rate for the condition and/or medication use when appropriate. A modified rating is determined based on the severity of the condition and treatment and/or prescription medication cost, dosage, and premium amount.*	**$1,500 or lower deductible plus Rx**	**$2,500–$5,000 deductible plus Rx**	**$2,000–$5,200 deductible no Rx**	**$6,000 or higher deductible plus Rx**
Nonseminoma, Stage II or III, > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Seminoma State I, > 3 years	Rate 25%	Rate 25%	Rate 25%	Rate 25%
Seminoma Stage II or III, > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Throat				
	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Tongue—oropharyngeal				
Stage 0, > 5 years	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Stage I, no alcohol or tobacco use within the past 2 years, > 5 years from treatment	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Stage I, current alcohol or tobacco use, > 10 years from treatment	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Stage II, no alcohol or tobacco use within the past 2 years, > 10 years from treatment	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Stage II, current alcohol or tobacco use, > 10 years from treatment	Individual consideration	Individual consideration	Individual consideration	Individual consideration

Stage III, IV or Recurrent, > 10 years from treatment	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Thyroid, Papillary				
> 5 years from treatment	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Uterine				
Stage I, II, > 5 years from treatment	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Stage III, > 10 years from treatment	Rate 25–50%	Rate 25–50%	Rate 25–50%	Rate 25–50%
Stage IV, > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration
Uterine sarcoma, > 10 years	Individual consideration	Individual consideration	Individual consideration	Individual consideration

Humana*One* Short Term Medical Plans

Humana*One*'s Short Term Medical Plans are not subject to complete underwriting like other Humana*One* plans. Instead, applicants will be asked four or five eligibility and health questions to determine their eligibility. The following questions must be answered fully and truthfully; including information related to spouse and/or dependents applying for coverage:

> ☐ No ☐ Yes Are you or is any immediate family member (whether or not named in this application) pregnant, an expectant parent, in the process of adopting a child, or undergoing infertility treatment?

> ☐ No ☐ Yes Have/Are you, your spouse, or any person applying for coverage resided in the U.S. for less than 6 months?

> ☐ No ☐ Yes Are you, your spouse, or any person applying for coverage over 300 pounds if male, or over 250 pounds if female?

> ☐ No ☐ Yes For any of the following conditions, has any person to be insured received, in the past 5 years, any abnormal test results; medical or surgical consultation, treatment, or advice; consulted a health care professional; or taken medication for: diabetes, emphysema, cancer or tumor, stroke, heart disorder including but not limited to heart attack or chest pain, AIDS or tested positive for HIV, kidney disorder (excluding kidney stones), alcoholism, chemical dependency, drug or alcohol abuse?

In Colorado, an additional question will be asked of the applicants:

> ☐ No ☐ Yes Have you or any other person to be insured been covered under two or more non-renewable short term plans during the past 12 months?

Eligibility

If "no" is answered to all of the following questions, your client will be eligible for coverage. If "yes" is answered to any of the following questions, your client will need to provide the name of the person the answer applies to. The person(s) named will not be covered under the policy. If your client is not eligible for coverage, they may choose to apply for a different Humana*One* plan that is fully underwritten.

If you have any questions about Humana*One*'s Short Term Medical plans, please contact your local sales representative.

SUBMITTED BY HON. SHELDON WHITEHOUSE,
A U.S. SENATOR FROM RHODE ISLAND

Hospital Association of Rhode Island (HARI)

&

Lifespan

June 21, 2018

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1694–P
P.O. Box 8011
Baltimore, MD 21244–1850

RE: CMS–1694–P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims (Vol. 83, No. 88), May 7, 2018

Dear Administrator Verma:

On behalf of the ten acute care hospitals in Rhode Island, the Hospital Association of Rhode Island (HARI) and Lifespan appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposal to not extend the imputed rural floor wage index policy for federal fiscal year (FY) 2019.

We would like to express our disappointment that CMS proposes to not extend the imputed rural floor provision past the September 30, 2018 expiration date. This payment policy is critical to address a hospital wage index reclassification system that does not reflect the unique size and location of Rhode Island. Specifically, since Rhode Island is just 1,000 square miles, many Rhode Island residents commute to and from jobs in nearby Massachusetts and Connecticut every day. The fiscal condition of hospitals in Rhode Island will be severely impacted if this policy is discontinued, and a competitive disadvantage will be created for the state's entire healthcare system. Many hospitals in our state are located very close to hospitals in neighboring states that are benefitting from a higher reimbursement rate due to their state's rural floor. The imputed rural floor policy provides Rhode Island with the same protections that Massachusetts and Connecticut currently benefit from.

In the FY 2005 IPPS, CMS proposed, then finalized, an imputed "rural floor" policy for all-urban states. Part of the agency's rationale was that hospitals in all-urban states did not have any protection, or "floor," from declines in their wage index (69 FR 49110), which all other states have through the traditional rural floor. However, this imputed rural floor methodology was not beneficial to Rhode Island due to the entire state being located in one core-based statistical area (CBSA). In the FY 2013 IPPS, CMS amended the policy to establish an alternative methodology for computing the imputed floor wage index and address this concern (77 FR 53368 through 53369). **The hospitals in Rhode Island have strongly supported the policy ever since, as it creates wage index consistency and equity between states with rural areas and states that are entirely urban.**

In addition, we would like to address the following policy views in favor of maintaining the imputed floor policy and the alternative calculation that was established in the FY 2013 IPPS.

Wage Index System Reform

In both the FY 2014 and FY 2015 inpatient PPS final rules, CMS extended the imputed floor for an additional year, during which time the agency would continue to explore potential wage index reform. While recommendations for wage index reform continue to be researched and evaluated, no comprehensive reform of the Medicare wage index system has been established nor have plans to do so been announced. **CMS should maintain the status quo for the entirety of the Medicare wage index system—including the imputed floor policy and alternative calculation current in place—until such reform is achieved.**

Elimination of the Rural Floor Reinstates the Anomaly

Part of CMS' reasoning for eliminating the imputed floor provision is that it creates "a disadvantage in the application of the wage index to hospitals in States with rural hospitals but no urban hospitals receiving the rural floor" (83 FR 20363). However, those urban hospitals in states with rural hospitals retain all future wage index protections associated with the rural floor. **Eliminating the imputed rural floor ultimately reinstates the disadvantages that existed prior to its inclusion, where all-urban states have no protections from declines in the wage index.**

There is precedent for CMS to restore, in the final rule, policies or provisions that were scheduled for elimination or discontinuation in the proposed rule. Last year, CMS proposed to allow the imputed rural floor to expire in FY 2018. That decision was reversed in the final rule and the policy was extended through FY 2018. Additionally, in the FY 2012 inpatient PPS proposed rule, CMS stated that the imputed floor would expire on Sept. 30, 2011. However, in the final rule CMS announced that the imputed floor provision was extended (and every year after), during which time the agency would continue to explore potential wage index reform.

HARI and Lifespan, on behalf of the hospitals in Rhode Island, advocate that maintaining the imputed floor wage index policy and the alternative calculation creates equity and consistency in the Medicare reimbursement process. **We are committed to working with you to ensure that Rhode Island and other all-urban states benefiting from the imputed rural floor continue to have the same protections provided to states with rural areas and hospitals.** Thank you for your consideration of this matter.

Sincerely,

M. Teresa Paiva Weed
President,
Hospital Association of Rhode Island

David A. Balasco
Vice President of Government Relations,
Lifespan

State of Rhode Island and Providence Plantations
State House
Providence, Rhode Island 02903–1196
401–222–2080

Gina M. Raimondo
Governor

June 13, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

I am writing to request your assistance in helping to reinstate the imputed rural floor provision in the FY 2019 Inpatient Prospective Payment System (IPPS) final rule promulgated by the Centers for Medicare and Medicaid Services (CMS).

Last year, we had the opportunity to discuss this issue in Rhode Island during the National Governor's Association Conference. Specifically, the IPPS proposed rule for FY 2019, recently released by CMS, eliminates the imputed rural floor and its alternative calculation for "all-urban" states. The "imputed" rural floor policy was first created by CMS in FY 2005 because CMS believed that there was merit to the concept that all-urban states were disadvantaged by the wage index system. Since FY 2013, the IPPS rules have included an alternative methodology for calculating the imputed rural floor in Rhode Island, which has been key for our state's hospitals to preserve access to care for Rhode Islanders. The elimination of this provision will reduce hospital Medicare payments in our state by approximately $28.6 million in FY 2019.

Hospitals are among Rhode Island's top employers and the impact of the discontinuation of this policy would adversely impact this important sector of our economy. This loss of funding will put Rhode Island at a competitive disadvantage for recruiting and maintaining staff. Hospitals in Rhode Island must compete with our neighboring states, which are located just miles away and are benefitting from a much higher reimbursement rate.

I want to thank you again for continuing this long-standing policy in the FY 2018 IPPS final rule, which addresses a wage index disparity for hospitals in Rhode Island and ask for your consideration of restoring this provision in the final rule again this year.

Sincerely,

Gina M. Raimondo
Governor

Congress of the United States

Washington, DC 20515

June 20, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Administrator Verma:

We write to express grave concern that your proposed Fiscal Year (FY) 2019 Inpatient Prospective Payment System (IPPS) rule ends a longstanding policy correcting a wage index disparity for hospitals in Rhode Island. Since FY 2013, the IPPS rules have included an alternative methodology for calculating the imputed rural floor in Rhode Island, which has been key to improving the overall fiscal condition of Rhode Island's health care system and maintaining access to care for Rhode Islanders.

The alternative methodology for calculating the imputed rural floor has been in place for many years to address the disadvantages faced by all-urban states, like Rhode Island, which do not benefit from any other payment programs for rural areas. This policy protects our hospitals from falling to some of the lowest reimbursement rates in the country, all the while competing with some of the most highly reimbursed urban and academic hospitals in New England.

If the alternative methodology for calculating the imputed rural floor is not reinstated in the IPPS final rule later this summer, we expect Medicare reimbursement rates for hospitals in Rhode Island to be cut by $28 million. These cuts will also have a ripple effect throughout the insurance market in the state, because private insurance reimbursement rates under the Medicare Advantage program are based on underlying Medicare reimbursements. This would effectively double down on cuts to hospitals in Rhode Island, which already have some of the lowest operating margins in the country.

The alternative methodology for calculating the imputed floor has been a crucial lifeline for hospitals in our state, many of which continue to report operating losses each year. Hospitals are often the economic backbone in a community, providing well-paying jobs for health care workers, researchers, laboratory technicians, as well as maintenance and administrative workers. A cut of this magnitude to hospitals in Rhode Island would have a devastating impact throughoutour economy.

We urge you to reverse your decision to end this payment policy for hospitals in Rhode Island and reinstate the alternative methodology for calculating the imputed rural floor in the final FY 2019 IPPS rule. Thank you for your consideration of this important request and we look forward to working with you to see this policy extended.

Sincerely,

Jack Reed
United States Senator

Sheldon Whitehouse
United States Senator

James R. Langevin
Member of Congress

David N. Cicilline
Member of Congress

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

There's a lot to cover this morning. I'll get to rescuing Americans who are getting mugged by their prescription drug bills, as well as the administration gutting safeguards for those with preexisting conditions. But first, the American people are owed an answer about what's going to be done to protect the thousands of children the Trump administration separated from their mothers and fathers and put in the custody of the witness.

As of this morning, HHS, Homeland Security, and the Justice Department seem to be doing a lot more to add to the bedlam and deflect blame than they're doing to tell parents where their kids are. According to new reports, the government is ransoming these children by telling their parents they can have their kids back if they agree to leave the country. The president tweeted that the U.S. should forget about due process rights for immigrants, essentially an endorsement of judging people by the color of their skin.

The White House chief of staff floated their family-shredding policy in the press more than a year ago. It wasn't conjured out of thin air this spring. But with news reports that HHS is scrambling to collect resumes of individuals with experience in child care, it's clear the Department was woefully unprepared.

This committee has oversight of the child welfare system. Members have worked hard on bipartisan child welfare policies that keep families together whenever it's possible and safe. That's because unnecessarily ripping children away from their families and putting them in institutions is harmful. It's harmful to their health.

It's scarring to their emotional well-being. It's detrimental to their growth. That is a fact, and your department knows it. You should know it.

Secretary Azar, I'd be ready for a lot of questions about this today. An administration that has traumatized thousands of child refugees, dehumanized these kids and their parents, and tried to normalize this behavior through deception has a lot to answer for.

Now let's shift to discuss Americans getting hit with enormous bills when they walk up to the pharmacy window. When the President said in early 2017 that drug companies were "getting away with murder," he offered his diagnosis of the prescription drug cost problem. A year and a half later, it sure looks like he's decided not to treat the problem.

The President made prescription drug costs a key part of his pitch to the American people on health care. But the party in power hasn't done any legislating on it. The White House put out a 44-page, so-called "blueprint"—essentially a collection of the same questions people have been asking about this issue for a decade or more. To me, it looks less like a blueprint than it looks like blue smoke and mirrors.

A lot of what the President and his team have said is head-scratching stuff. For example, the President labeled European countries "freeloaders." He said that if drugs got more expensive overseas, fattening big pharma's wallets, prices would fall here at home. You've got to be living in fantasy land to buy that theory.

First of all, I don't know what magic wand the administration is planning on using to hike drug prices in other countries, but that's not a power the U.S. has today.

Second, even if drug companies did come into a windfall from overseas, it's naive and laughable to expect that they'd take that as a reason to slash prices in America. Look at the Trump tax law. Huge amounts of cash were showered onto these multinational drug companies. They funneled it into stock buybacks that benefit shareholders, not consumers.

Another trip to fantasyland: on May 30th, the President said that in 2 weeks, drug companies would be announcing, quote, "voluntary massive drops in prices." Two weeks went by, then 3 weeks, and now it's been nearly a month. No massive drops in prices to report.

As long as Americans are getting mugged at the pharmacy counter, this situation demands serious, bipartisan action. That's why today I am releasing a comprehensive report that looks at exactly what makes this industry so complicated, and why it seems like prices only ever go up.

It's not just a look at the drug manufacturers. There are a lot of pieces to the puzzle of holding drug prices down, including the middlemen, the distributors, the misplaced incentives, and broken, out-of-date policies on the law books. This report is all about getting a comprehensive look under the hood of the entire drug industry in America for the first time. That information is key to having a full debate.

Otherwise, what Americans are getting from the Trump administration, and the president in particular, is mostly a lot of empty talk. The fact is, many of the questions raised in the administration's 44 page document are important. They reflect an interest in some of the challenges I've worked on with respect to drug costs. But it's discouraging to see the Trump administration pretend that repeating the same questions is equivalent to getting results.

There's a big gap between the triumphant headlines the Trump administration tries to grab on prescription drugs and the lack of serious proposals they've put forward. I want to see that gap close, starting today.

I'll wrap up on this last issue. The Trump administration announced recently that it was going to get out of the business of defending protections for Americans with preexisting conditions—protections which are the law of the land.

This isn't some narrow regulation that only applies to a handful of people. There are more than 150 million Americans who get insurance through their employers, and I'd wager most of them would be surprised to learn this Trump decision hurts them too. If you don't have a pre-existing condition, I guarantee you know somebody who does. And the Trump administration decided it isn't going to protect them.

COMMUNICATIONS

AMERICA'S HEALTH INSURANCE PLANS (AHIP)
601 Pennsylvania Avenue, NW, Suite 500, South Building
Washington, DC 20004

America's Health Insurance Plans (AHIP) appreciates this opportunity to comment on challenges in the pharmaceutical market and solutions that are needed to help millions, of Americans who are burdened by out-of-control prescription drug prices. We thank the committee for calling attention to these important issues and for inviting Secretary Azar to testify on the Trump Administration's proposals.

AHIP is the national association whose-members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solution and public-private partnership that improve affordability, value access, and well-being for consumers.

As the committee addresses concern about rising drug prices, we urge you to recognize that the entire pricing process is driven entirely by the original list price of a branded drug—which is determined solely by the drug company, not by the market or. Any other participant in the pharmaceutical supply chain. Congress needs to address this reality—**the problem is the price**—as part of any strategy for reducing pharmaceutical costs for the people.

Out-of-control prescription drug prices are a direct consequence of pharmaceutical companies taking advantage of a broken market for their own financial gain at the expense of patients. The lack of competition, transparency and accountability in the prescription drug market has created extended, price-dictating monopolies with economic power that exist nowhere else in the U.S. economy. The end result is that everyone pays more-from patients, businesses and taxpayers to hospitals, doctors, and pharmacists.

Bold steps are needed, at both the legislative and regulatory levels, to ensure that people have access to affordable medications. With solutions that deliver real competition, create more consumer choice, and ensure open and honest drug prices, we can deliver more affordable pharmaceutical products—while at the same time protecting and supporting innovations to deliver new treatments and cures for patients. Accessible, affordable medicines are the cornerstone to keeping patients with chronic disease healthier and out of emergency rooms. Reducing the price of medicines is a necessary step toward achieving this goal.

Our statement focuses on the following topics:

- Our initial perspectives on the Trump Administration's "Blueprint to Lower Drug Prices," including policies that address the role of Medicare and Medicaid in providing access to affordable medications;
- The consequences that out-of-control prescription drug prices have on consumers; and
- How health plans work hard on behalf of all consumers to negotiate lower prescription drug costs.

The Trump Administration's "Blueprint to Lower Drug Prices"

We commend President Trump and his Administration for focusing on out-of-control prescription drug prices by releasing a "Blueprint for Lower Drug Prices" and publishing a request for information (RFI) that solicits comments from stakeholders and interested parties on policy proposals to lower prescription drug prices and reduce out-of-pocket costs.

We are working closely with AHIP members to develop a formal response to the Administration's RFI and we will submit comments and recommendations by the July 16 deadline. In the meantime, we want to emphasize that we share the Administration's goal of getting the most clinically effective drugs into the hands of patients at the lowest cost. Several of the President's proposed solutions will have a real impact on lowering drug prices for Americans.

We support the Administration's overall goals of:

- Stopping the pharmaceutical industry from gaming the patient and the regulatory systems to keep drug prices high;
- Keeping drug prices from increasing at out-of-control rates;
- Increasing flexibility for insurance providers to negotiate lower prices;
- Encouraging doctors to prescribe lower-priced medications; and
- Getting patients clear information about costs as they consider treatments.

To provide consumers relief from high prescription drug costs, AHIP has developed recommendations for effective, market-based solutions in three areas: (1) delivering real competition; (2) ensuring open and honest drug pricing; and (3) delivering value to patients. Specific solutions in each of these areas are outlined in an appendix to our statement.

Various elements of the Administration's Blueprint are aligned with AHIP's policy recommendations. Below we highlight several examples that offer significant promise for putting downward pressure on prescription drug prices.

Promote Generic Competition: We support the Administration's efforts to prevent brand name drug manufacturers from using risk evaluation and mitigation strategies (REMS) to block competition front generic drug makers. The Food and Drug Administration (FDA) recently issued two draft guidance documents addressing this priority.

Promoting Biosimilars: We support the Administration's efforts to improve the availability, competitiveness, and adoption of biosimilars as affordable alternatives to branded biologics. We appreciate that these efforts will include steps to educate clinicians, patients, and payors about biosimilar and interchangeable products to increase awareness about these treatments.

Benefit Flexibility: We support the Administration's consideration of a proposal to allow Medicare Part D plans to address price increases for a sole source generic drug through changes to their formulary or benefit design during the coverage year. This flexibility would allow plan sponsors to quickly respond to price increases imposed by the only manufacturer of a generic drug.

Negotiation Tools: We support the Administration's consideration of a proposal to provide Medicare Part D plans with "full flexibility" in using formulary management tools for high-cost drugs for which rebates are often limited or unavailable (*e.g.,* protected class drugs, drugs without competition). These tools, which are widely used in the private sector outside of the Medicare program would allow plan sponsors to negotiate better drug prices on behalf of Medicare beneficiaries.

Increased Transparency: We support the Administration's release of enhanced CMS Drug Pricing Dashboards for Medicare Part B, Medicare Part D, and Medicaid. The Dashboards can provide patients, families, and caregivers with additional information to make informed decisions and predict their cost-sharing. By increasing transparency the updated Dashboards have the potential to help hold pharmaceutical manufacturers accountable for drug price increases, highlight drugs that have not increased in price, and recognize when competition is working.

Star Ratings: We support the Administration's consideration of a proposal to update the methodology used to calculate Drug Plan Customer Service Star Ratings for Medicare Part D plans that are appropriately managing the utilization of high-cost drugs. This would be an important step toward ensuring that Star Rating measures are aligned with the goal of reducing unnecessary use of high-cost drugs.

While the Blueprint and RFI offer mostly positive steps for addressing out-of-control drug prices, we have concerns that several other ideas the Administration appears to be considering would actually lead to higher costs for Americans by weakening the ability of plans to negotiate lower prices. For example, health insurance providers already share the savings from negotiations with drug manufacturers by lowering premiums and cost-sharing for all consumers. However, requiring drug rebates

to be passed through the point-of-sale to individual beneficiaries at the pharmacy counter, rather than be distributed to all enrollees, would likely lead to higher drug prices from manufacturers, higher Part D premiums for all seniors, greater cost-sharing for non-rebated drugs, as well as over $40 billion in additional costs for hardworking taxpayers.[1] Similarly, policies that would eliminate or make it more difficult for plans to negotiate lower prices through rebates without replacing the rebating process with an alternative would similarly drive up costs for all beneficiaries.

On a host of other issues, we are continuing to hold discussions and solicit feedback from AHIP work groups to develop detailed recommendations for HHS. We look forward to working together with the Administration, Congress, and other stakeholders to lower drug prices through market-based solutions that deliver real competition, create more consumer choice, and ensure open and honest drug prices that are driven by their value to patients.

The Impact of Out-of-Control Prescription Drug Prices

Rising prescription drug prices and costs impose a heavy burden on all Americans. From patients who cannot afford life-saving medications, to consumers who pay higher and higher premiums because of higher and higher drug prices, to employers who must divert dollars that could be used for salaries to pay for more expensive prescriptions, to hardworking taxpayers who fund public programs like Medicaid and Medicare, the consequences are profound.

It is important to understand the unambiguous root causes of this problem: lack of real market competition due to the extension and distortion of government-granted exclusivity and patent protections, opaque pharmaceutical pricing practices, questionable sales and marketing practices, and limited correlation between drug prices and the value they deliver to patients.

A May 2018 AHIP analysis concluded that 23.2 cents out of every premium dollar goes to pay for prescription drugs—making this the largest component of health care spending.[2] Our analysis found that prescription drug spending outpaces the amount spent on physician services, office and clinic visits, and hospital stays. These costs impose a heavy burden on consumers, employers, government programs, taxpayers, and the entire health care system. When prescription drug prices go up, the cost of health insurance goes up. That is a fundamental economic reality: rising health care costs, including drug costs, are driving increases in the cost of health coverage.

Even for products that have been on the market for decades, sharp price increases are not uncommon. One study shows that the price of insulin has increased more than 240 percent over the past decade; for example, the price of Lantus increased from $88.20 per vial in 2007 to $307.20 per vial in late 2017, while the price of Levemir increased from $90.30 per vial to $322.80 per vial during the same time period.[3] These sharp price increases harm patients and reduce the affordability of coverage for all consumers and payers who must bear the cost through higher insurance premiums.

A June 2018 report from the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) found that unit costs for brand-name drugs in the Medicare Part D program rose nearly six times faster than inflation from 2011 to 2015, with the average Part D unit cost increasing 29 percent over this time frame.[4]

The HHS OIG report identifies 20 brand-name drugs that experienced the largest percentage increases in Part D unit costs from 2011 to 2015. This includes six drugs with unit cost increases of more than 4,000 percent and four other drugs with unit cost increases exceeding 2,000 percent. For example:

- Isordil Titradose, used to treat angina, increased by 6,112 percent from 2011 to 2015;
- Timentin, used to treat infections, increased by 4,661 percent;

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[1] *FY 2019 Budget in Brief* (page 61), Department of Health and Human Services, *https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf.*

[2] *Where Does Your Health Care Dollar Go?,* AHIP, May 22, 2018, *https://www.ahip.org/where-does-your-health-care-dollar-go-ahip-has-the-answer/.*

[3] *Several Probes Target Insulin Drug Pricing,* Kaiser Health News, October 28, 2017, *https://www.nbcnews.com/health/health-news/several-probes-target-insulin-drug-pricing-n815141.*

[4] *Increases in Reimbursement for Brand-Name Drugs in Part D,* Department of Health and Human Services' (HHS) Office of Inspector General (OIG), June 2018, *https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf.*

- Levsin, used to treat irritable bowel syndrome, increased by 4,212 percent;
- Salex, used to treat shin disorders, increased: by 4,202 percent;
- Miacalcin, used to treat osteoporosis, increased by 2,771 percent;
- Thiola, used for kidney stone prevention, increased by 2,465 percent; and
- Cuprimine, used to treat rheumatoid arthritis, increased by 2,143 percent;

The pharmaceutical cost crisis is clearly demonstrated by numerous other research findings:

- **Price Inflation is a Primary Cost Driver:** Segal Consulting, a prominent benefits consulting firm, estimates that prescription drug spending for employer-sponsored plans will increase by 10.3 percent in 2018—with a 17.7 percent cost increase in specialty drugs and biologics.[5] Prescription drug spending trends are primarily driven by price inflation (8.8%) as opposed to increases in utilization (2.1%) according to the Segal Consulting study.[6]
- **Financial Burden on Hospitals and Providers:** An October 2016 study commissioned by the American Hospital Association and the Federation of American Hospitals cautioned that hospitals "bear a heavy financial burden when the cost of drugs increases and must make tough choices about how to allocate scarce resources." This study highlighted an example of one hospital for which the price increases of four common drugs (which ranged between 479 and 1,261 percent) cost the same amount in 2015 as the salaries of 55 full-time nurses.[7]
- **Unfair Burden of High Drug Prices for American Consumers, Businesses and Taxpayers:** In a March 2017 *Health Affairs* blog, researchers at the Memorial Sloan Kettering Center for Health Policy and Outcomes analyzed the 15 companies selling the top 20 drugs (by sales) in the United States. Researchers reported that: (1) list prices in other developed countries averaged just 41 percent of U.S. net drug prices; and (2) the additional income generated by higher U.S. net drug prices totaled $116 billion in 2015.[8] The authors further stated: "We found that the premiums pharmaceutical companies earn from charging substantially higher prices for their medications in the U.S. compared to other Western countries generates substantially more than the companies spend globally on their research and development. This finding counters the claim that the higher prices paid by U.S. patients and taxpayers are necessary to fund research and development. Rather, there are billions of dollars left over even after worldwide research budgets are covered."
- **Higher Prices Often Do Not Mean Better Outcomes:** While some recent high-priced, breakthrough medications have improved patient outcomes, this is not always the case. For example, an April 2015 study by researchers from the National Institutes of Health (NIH) in *JAMA Oncology* examined 51 oncology drugs approved by the Food and Drug Administration (FDA) from 2009 through 2013. Researchers concluded that current pricing models were irrational and had no connection to better patient outcomes. Remarkably, the NIH researchers found that prices had no significant correlation to improvements in progression-free survival or overall survival.[9] With new cancer drugs now often costing well over $100,000 annually, manufacturers appear to be setting the price of new therapies based on the highest-priced oncology treatment approved most recently by the FDA—a practice known as "shadow-pricing"—rather than the value or the improved outcomes they deliver to patients.
- **"Unreasonable" Drug Prices Forcing Tradeoffs Between Taking Medicines and Other Necessities:** A September 2016 tracking poll from the Kaiser Family Foundation found that 77 percent of Americans believe that prescription drug costs are "unreasonable."[10] The difficulty in affording unreasonably priced

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[5] *High Rx Cost Trends Projected to Be Lower for 2018,* Segal Consulting, Fall 2017.

[6] *Ibid.*

[7] *Trends in Hospital Inpatient Drug Costs: Issues and Challenges,* NORC, October 11, 2016, *http://www.aha.org/content/16/aha-fah-rx-report.pdf.*

[8] *R&D Costs for Pharmaceutical Companies Do Not Explain Elevated U.S. Drug Prices,* Nancy Yu, Zachary Helms, and Peter Bach, March 7, 2017, *http://healthaffairs.org/blog/2017/03/07/rd-costs-for-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices/.*

[9] "Five Years of Cancer Drug Approvals: Innovation, Efficacy, and Costs," Sham Mailankody, MB, BS; Vinay Prasad, MD, MPH, *JAMA Oncology,* July 2015, *http://oncology.jamanetwork.com/article.aspx?articleid=2212206.*

[10] Kaiser Health Tracking Poll: September 2016, *http://www.kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016/.*

prescription drugs can lead to treatment non-adherence, which can harm patient health, creating adverse outcomes, and lead to expensive complications. According to a survey by *Consumer Reports,* many respondents took "potentially dangerous" steps to limit the impact of high drug costs: not filling a prescription (17 percent), skipping a scheduled dose (14 percent); or taking an expired medication (14 percent). This survey also found that 19 percent of respondents spent less on groceries, and 15 percent postponed paying other bills so they could afford their prescription drugs.[11]

These facts paint a clear picture of the crisis we face: drug companies exploit a broken market to set seemingly unbounded prices for seemingly unlimited periods while consumers, businesses, and taxpayers bear the staggering costs.

While some have tried to divert attention away from high prescription drug prices and, instead, point to others in the supply chain—namely, pharmacy benefit managers (PBMs) and rebates—as the source of the problem, we should focus on how the supply chain actually functions and the true root of the cost crisis when evaluating polity options.

The Role of Health Plans in Negotiating Lower Costs for All Consumers

AHIP's members negotiate with health care providers and pharmaceutical manufacturers on behalf of consumers and other health care purchasers (*e.g.,* employers, government) to provide coverage for high-quality treatments and services at the most competitive prices possible. Health insurance providers offer comprehensive coverage under the pharmacy benefit for prescription drugs delivered through retail mail order and specialty pharmacies. Health plans also provide coverage under the medical benefit for physician-administered drugs, biologics, and devices in outpatient and inpatient settings. This gives health plans a unique perspective into the pharmaceutical supply chain and a 360-degree view of the broader U.S. health care system—working with PBMs and negotiating with drug and device manufacturers, pharmacies, physicians, and hospitals to ensure that enrollees have coverage for the treatments and services they need.

While prescription drug pricing and the pharmaceutical supply chain are complex, health plans are still, on the whole, able to successfully navigate the system and provide significant savings. Health plans aggressively negotiate with drug manufacturers for lower prices—and then pass those savings directly on in the form of both lower out-of-pocket costs and lower premiums for all consumers.

Health plans negotiate for price concessions from manufacturers, just as they do with providers. Health plans leverage competition between manufacturers to drive deeper discounts in exchange for preferred formulary placement and lower cost-sharing for their products, just as they do with providers. However, in discussing how plans obtain discounts from manufacturers, it is important to understand the role rebates play within the broader system and why the rebate structure is used to obtain cost savings for pharmaceuticals rather than the "negotiated rates" typically used to obtain savings for health services.

Though not broadly understood, plans do not directly reimburse pharmaceutical manufacturers for their products even though they do negotiate directly for price concessions. Instead, distributors and some large pharmacies and health systems directly purchase drugs from manufacturers. The price paid by these entities is highly correlated to the list price set by the manufacturer with only modest discounts based on volume or prompt pay. Distributors resell pharmaceutical products to smaller and mid-sized pharmacies and providers after a small markup above the discounted price.[12] Finally, plans directly reimburse pharmacies or providers (depending on where the drug is obtained) once a claim is filed and any consumer cost-sharing obligations are accounted for.

Since pharmacies and providers obtain drugs at or near the list price, plans must also reimburse them at (or very close to) this rate, plus an additional negotiated add-on fee to ensure these entities are not "underwater" for their purchase. Because there is no interaction between plans and manufacturers at the point-of-sale, all price concessions must come after the fact through rebates. These rebate amounts are typically calculated and paid by a manufacturer to a health plan on an aggre-

[11] "Some Americans take risks with needed drugs due to high costs," *Consumer Reports,* September 2014, *http://www.consumerreports.org/cro/2014/09/some-americans-take-risks-with-needed-drugs-due-to-high-costs/index.htm.*

[12] *Prescription Drug Pricing in the Private Sector,* Congressional Budget Office, 2007, *https://www.cbo.gov/.sites/default/files/11Oth-congress-2007-2008/reports/01-03-prescriptiondrug.pdf.*

gate basis, accounting for all fulfilled claims for a product long after an individual prescription is filled by a consumer.

Since drug costs comprise a significant portion of a health plan's total costs, plans may use these estimated discounts to reduce the premiums they charge for the overall benefit. They also incorporate the savings into the overall cost-sharing design for the benefit, including for individual rebated drugs. Plan benefit design and premiums are heavily regulated by state departments of insurance and/or the Centers for Medicare and Medicaid Services (CMS). By contrast, pharmaceutical manufacturers are not subject to any governmental oversight or regulation before setting list prices or pushing through price increases.

It is important to understand that while plans are able to negotiate significant price concessions from manufacturers, this only applies to a subset of drugs that have therapeutic alternatives. For most branded drugs and biologics without therapeutic alternatives, manufacturers' wi1lingness to negotiate on price is small or nonexistent and they have no rebates. Evidence shows that the percentage of rebated drugs is decreasing and that list prices are also consistently rising whether drugs are rebated or not. In fact, the recent HHS OIG report states: "Total reimbursement for all brand-name drugs in Part D increased 77 percent from 2011 to 2015, despite a 17-percent decrease in the number of prescriptions for these drugs. . . . After accounting for manufacturer rebates, reimbursement for brand-name drugs in Part D still increased 62 percent from 2011 to 2015. . . . In addition, the percentage of brand-name drugs for which manufacturers paid rebates decreased [over this period]." [13] Further, rebates are not commonly found for physician-administered drugs, which account for 30 percent of prescription drug spending.[14]

The bottom line is that whether a drug is rebated or not, the original list price of a drug drives costs in the entire system. This price is solely determined and controlled by the drug company, and if the original list price is high, the final cost that a consumer pays will be high. **It is that simple: the problem is the price.**

Conclusion

Thank you for considering our perspectives on these important issues. We are strongly committed to solving the pharmaceutical cost crisis. With the right solutions that deliver real competition and create more consumer choices, we can bring down the cost of prescription drugs. We look forward to working with the committee to advance market-based solutions to ensure that consumers have access to affordable medications.

Appendix: AHIP Recommendations to Reduce Drug Prices and Costs

Rising prescription drug costs hurt everyone. From patients who cannot access breakthroughs and consumers who pay higher and higher premiums to taxpayers who fund public programs like Medicaid and Medicare, the consequences are profound. Pharmacy now accounts for approximately 23 percent of all medical spending. We need effective market-based solutions that deliver real competition, create more consumer choice, and ensure that open and honest drug prices are driven by the value they bring to patients.

Solution #1: Real Competition

✓ **Create a Robust Biosimilars Market:** Ensure that providers and patients have unbiased information available to them about the benefits of biosimilars. Address anti-competitive strategies, such as the development of "patent estates," and tactics aimed at delaying the availability of biosimilars. Policies for labeling, naming, and interchangeability should provide clarity, ensure safety, and avoid unnecessary regulatory hurdles.

✓ **Reduce Rules and Red Tape to Generic Entry:** Provide FDA with the necessary resources to clear the backlog of generic drug applications, particularly for classes of drugs with no or limited generic competition. Anti-competitive tactics such as "pay for delay" settlements and "product hopping" should be prohibited, and the Inter Partes Review (IPR) process should be preserved. Legislation requiring brand manufacturers to share needed information and samples to promote generic development should be advanced.

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[13] *Increases in Reimbursement for Brand Name Drugs in Part D,* Department of Health and Human Services' (HHS) Office of Inspector General (OIG), June 2018, *https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf.*

[14] *Trends in Specialty Drug Benefits,* Pharmacy Benefit Management Institute, 2017.

✓ **Revisit and Revise Orphan Drug Incentives:** Ensure that the Orphan Drug Act's incentives are used by those developing medicines to treat rare diseases—not as a gateway to premium pricing and blockbuster sales beyond orphan indications. In cases of rare diseases for which no effective therapy yet exists, ensure that newly approved drugs are priced in accordance with their efficacy.

Solution #2: Open and Honest Price Setting

✓ **Publish Rx Prices, True R&D Costs, and Price Increases:** As part of the FDA approval process, require that manufacturers disclose information regarding intended launch price, use, and direct and indirect R&D costs. After approval, require manufacturer reporting of list price increases over a percentage threshold amount that explains why such price increases are justified.

✓ **Limit Third-Party Schemes That Raise Costs:** Examine and address the impact of drug coupons and co-pay card programs—and related charitable foundations—on overall pharmaceutical cost trends. Ensure that existing protections aimed at prohibiting their use in all federal programs are sufficient.

✓ **Evaluate DTC Advertising Impact:** Assess impacts of the growth in direct-to-consumer (DTC) advertising, particularly broadcast advertising, and evaluate the best approaches for conveying information to consumers.

Solution #3: Delivering Value to Patients

✓ **Inform Patients on Effectiveness and Value:** Increase funding for private and public efforts to provide information on the comparative and cost-effectiveness of different treatments to physicians and their patients. These tools can help them make appropriate assessments about the value and effectiveness of different treatment approaches, particularly those with very high costs.

✓ **Expand Value-Based Formulary Programs:** Promote value-based payments in public programs like Medicare for drugs and medical technologies, based on agreed-upon standards for quality and outcomes.

✓ **Reduce Regulatory Barriers to Value-Based Pricing:** Address existing statutory and regulatory requirements (*e.g.,* Medicaid best price) that may inhibit the development of pay-for-indication and other value-based strategies in public programs.

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On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners—including more than 270,000 affiliated physicians, 2 million nurses and other caregivers—and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to submit for the record our comments on the out of control cost of medications.

America's hospitals rely on innovative drug therapies to save lives every day. Without them, more lives would be lost to diseases like cancer and AIDS, and others who now can live comfortably while managing their chronic conditions would see their quality of life deteriorate. In short, modern pharmaceuticals play a critical role in getting and keeping patients healthy. Hospitals are major purchasers and dispensers of pharmaceuticals; they also play a crucial role in the development of new drug therapies.

Spending on pharmaceuticals has increased dramatically over the past several years. The burden of this increase falls on all purchasers, including patients and the providers who treat them. For example, hospitals frequently see patients show up in the emergency department or return for follow up care sicker than when they left because they were unable to afford their medications. As drug purchasers, hospitals and health systems face significant resource constraints and trade-offs as spending on drugs increases.

The primary driver behind increased drug spending is higher prices, not increases in utilization. Within the health care field, "pharmaceuticals" was "the fastest growing category" in terms of pricing for every month of 2016 and for most months of 2017.[1] We see both higher launch prices for new drugs and increases in prices for existing drugs. **Drug manufacturers have full control over the initial price for a drug and any subsequent price increases.** They are responsible for setting the price of a drug at $89,000,[2] $159,000,[3] or even $850,000[4] for a course of treatment. They also solely decide whether to increase that price by 20 percent,[5] 948.4 percent,[6] or 1,468 percent.[7] Limited competition and drug shortages have facilitated this price growth.

We explore these challenges in more detail below.

HOSPITALS AND HEALTH SYSTEMS AND DRUG INNOVATION

Hospitals and health systems rely on continued innovation in drug therapies, and they play an important role in the development of new drugs. Academic medical centers play a leading role in both the development of the underlying science supporting new drug therapies (basic science research), as well as the development and testing of new therapies (applied or translational research). A combination of public and private funding supports this work, including grants from the National Institutes of Health, philanthropy and biopharmaceutical companies.

A report from Tufts University underlined that "a close and synergistic relationship between [the biopharmaceutical and academic medical center] sectors is critical to ensuring a robust national capacity."[8] The report noted that more than 50 percent of researchers at academic medical centers contribute to drug and device medical trials, and partnerships between biopharmaceutical companies and academic hospitals have increased in recent years.

A *New England Journal of Medicine* report underscored the benefits provided by public-sector research institutions (PSRI), which include academic medical centers and their affiliated universities. Specifically, the study's authors found that PSRI were responsible for 153 drugs, vaccines or new indicators for existing drugs approved by the Food and Drug Administration (FDA) between 1970 and 2009. They also found that hospitals and PSRIs were predisposed to discover drugs that have a disproportionately important clinical effect[9] and those that could be used for widespread public health concerns, including the treatment of cancer and infectious diseases, as well as vaccination development.[10]

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[1] Altarum Institute, "Price Briefs," October 2017 *(https://altarum.org/sites/default/files/uploaded-related-files/CSHS-Price-Brief_October_2017.pdf)*, September 2017 *(https://altarum.org/sites/default/files/uploaded-related-files/CSHS-Price-Brief_Sept_2017.pdf)*, August 2017 *(https://altarum.org/sites/default/files/uploaded-related-files/CSHS-Price-Brief_Aug_2017.pdf)*, July 2017 *(https://altarum.org/sites/default/files/uploaded-related-files/CSHS-Price-Brief_July_2017.pdf)*, June 2017 *(https://altarum.org/sites/default/files/uploaded-related-files/CSHS-Price-Brief_June_2017.pdf)*.

[2] Triblle, S.J., "Duchenne Drug Delayed After Outrage Over Price," National Public Radio, February 14, 2017, *https://www.npr.org/sections/health-shots/2017/02/14/515046376/duchenne-drug-delayed-after-outrage-over-price.*

[3] Szabo, L., "As Drug Costs Soar, People Delay or Skip Cancer Treatments," National Public Radio, March 15, 2017, *https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments.*

[4] Fox, M., "Luxturna gene therapy for blindness to cost $850,000," NBC News, January 3, 2018, *https://www.nbcnews.com/health/health-news/luxturna-gene-therapy-blindness-cost-850-000-n834261.*

[5] Herman, B., "Drug prices are still going through the roof," Axios, March 21, 2018, *https://www.axios.com/drug-prices-exploding-2017-1521564090-aa025591-9e50-491d-b3e2-c981e85adb60.html.*

[6] Tirrell, M., "Martin Shkreli's legacy: Putting a 'fine point' on the drug pricing debate," CNBC, March 9, 2018, *https://www.cnbc.com/2018/03/09/martin-shkrelis-legacy-shaping-the-drug-pricing-debate.html.*

[7] Herman, B., "Drug prices are still going through the roof," Axios, March 21, 2018, *https://www.axios.com/drug-prices-exploding-2017-1521564090-aa025591-9e50-491d-b3e2-c981e85adb60.html.*

[8] Milne, Christopher-Paul, et al., "Academic-Industry Partnerships for Biopharmaceutical Research and Development: Advancing Medical Science in the U.S.," Tufts Center for the Study of Drug Development, April 2012, *http://csdd.tufts.edu/files/uploads/tuftscsdd_academic-industry.pdf.*

[9] Forty-six percent of drugs developed by PSRIs received priority reviews from the FDA—an indication that the drugs offered a substantial improvement over existing treatments. Only 20 percent of new drugs from the private sector received a priority review designation.

[10] Stevens, Ashley J., et al., "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines," *New England Journal of Medicine* 364: 535–541, February 2011.

HOSPITAL EXPERIENCE WITH DRUG PRICES AND SPENDING

Hospitals purchase drugs that clinicians use to treat patients in their facilities. Nearly all hospitals work with group purchasing organizations (GPOs) to negotiate prices with manufacturers. GPOs enable hospitals to achieve the best price as they benefit from the negotiating power of aggregate purchasing volume over many hospitals. They can save hospitals 10 to 18 percent on the cost of drugs.[11] And one report found that GPOs save the health care system between $25 billion and $55 billion per year.[12]

Most hospitals do retain some direct contracting with drug manufacturers. This is primarily true for branded therapies for which there is no competition. In these instances, manufacturers are not compelled to negotiate with GPOs. Hospitals may directly negotiate with the manufacturer and contract with the wholesaler for delivery. Only a handful of hospitals directly contract for all of their drug supply. These are larger organizations that have both the patient volume and the staff capacity to make one-on-one negotiations worthwhile. A significant challenge arises for small hospitals that have neither the staff capacity nor the volume to enter into direct negotiations with manufacturers. In some instances, small, rural hospitals have been unable to obtain access to certain therapies.

Whether hospitals are contracting directly or relying on GPOs, the pharmaceutical manufacturers set the starting price in negotiations. The ability of the GPO or hospital to obtain a discount off this initial price largely has to do with volume and whether, and how much, competition for such a therapy exists. In instances where no competition exists, such as for many of the new, high-cost specialty drugs, large discounts are not available.

Like other purchasers, hospitals and health systems have faced significant increases in spending over the past several years. Recently, the Centers for Medicare and Medicaid Services (CMS) released updated National Health Expenditures (NHE) data that showed that retail drug spending increased by 1.3 percent in 2016. While this level of growth may appear low, it follows two consecutive years of expansive growth in retail drug spending: 12.4 percent in 2014 and 8.9 percent in 2015. In other words, the lower growth comes on top of a much higher spending base for drugs. In addition, these figures capture *retail* drug spending only; they do *not* include spending on drugs purchased by providers, such as hospitals. Detailed non-retail drug spending data is not publicly available, as it is not easily collected.

In order to explore the experience of non-retail drug purchasers, the AHA and the Federation of American Hospitals worked with the NORC at the University of Chicago to collect and evaluate data on inpatient drug spending. The NORC found that increases in drug spending for inpatient care outpaced what the NHE reported for retail drug spending. **Specifically, the NORC found that, while retail spending on prescription drugs increased by 10.6 percent between 2013 and 2015, hospital spending on drugs in the inpatient space rose 38.7 percent per admission during the same period.**[13, 14]

Drug prices, not volume, are the primary driver of this increased spending. After examining data from two GPOs that collectively purchase drugs for more than 1,400 hospitals, the NORC was able to track changes in price, utilization, and total spending for a select group of drugs. Consistently, changes in pricing drove increases in spending. These price increases, from the hospitals' perspective, appeared to be random, inconsistent and unpredictable: large unit price increases occurred for both low- and high-volume drugs and for both branded and generic drugs.

Our members were not surprised to learn that their purchasing experience differs from what the NHE reports for retail drugs. In testimony to the Committee on Oversight and Government Reform of the U.S. House of Representatives, one drug manufacturer acknowledged targeting hospital-administered drugs for price increases. Howard Schiller, then-interim CEO and director of Valeant Pharmaceuticals, stated: "Because these drugs are hospital-administered, and not purchased

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[11] DeBenedette, V., "The Evolution of Group Purchasing Organizations," *Modern Medicine,* October 10, 2016, *http://drugtopics.modernmedicine.com/drug-topics/news/evolution-group-purchasing-organizations?page=0,3.*

[12] *Ibid.*

[13] National Health Expenditure Data for 2013–2015.

[14] "Trends in Hospital Inpatient Drug Costs: Issues and Challenges," American Hospital Association and the Federation of American Hospitals, October 11, 2016, *http://www.aha.org/content/16/aha-fah-rx-report.pdf.*

by patients directly, increasing the cost of the drugs to hospitals would affect the hospital's profits on these procedures, but it should not reduce patient access."[15]

While the NORC study supports Mr. Schiller's admission that manufacturers target hospitals for price increases, we challenge his assessment that such practices do not reduce patient access. Researchers at the Cleveland Clinic found that patient access to Valeant drugs nitroprusside and isoproterenol declined after the company increased the prices for both substantially. From 2012 to 2015, 53 percent fewer patients were treated with nitroprusside and 35 percent less were treated with isoproterenol.[16] This is because hospitals bear a heavy burden when the cost of drugs increases, in large part due to how hospital reimbursement it structured, and this has direct implications for the availability of certain drug therapies.

Most payments to hospitals for inpatient care are made on a bundled basis—either per discharge (Diagnostic Related Group or DRG) or per diem. In other words, all input costs are reimbursed under a single, predetermined reimbursement. Hospitals are responsible for managing input costs within that fixed payment amount and reimbursement does not necessarily increase as input costs, such as those for drugs, increase. Medicare, which is one of the largest payers for most hospitals and on which many commercial insurers base their rates, cannot keep up with new and frequently changing drug prices. The program relies on drug pricing data collected and reported by the Bureau of Labor Statistics, which does a full "refresh" of drug pricing information only every five to seven years. This data lag means that hospital reimbursement does not necessarily increase proportionally to drug price increases. As a result, hospitals must divert resources to cover the cost, which also has implications for other hospital costs. Managing skyrocketing prescription drug costs forces difficult choices between providing adequate compensation to employees, many of whom are highly skilled in professions facing shortages; upgrading and modernizing facilities; purchasing new technologies to improve care; or paying for drugs.

A number of factors contribute to the increase in drug spending, and those factors have evolved over time. In the past several years, hospital have faced widespread price increases on existing drugs. While drug manufacturers have increased some prices by multiple hundreds or even thousands of percent, hospitals report that the 10 to 20 percent increases on widely used generic drugs often have a greater impact on their budgets given the high volumes of these drugs that hospitals purchase.

Increasingly, our members report that high launch prices and increased spending due to drug shortages are new challenges they face, as well as budget pressures associated with the ancillary service costs associated with highly complex and potent drugs. Launch prices are the basis for negotiations with purchasers. Examples of recent launch prices include:

- Talz (Eli Lilly), used for treating psoriasis, costs $50,000 a year.[17]
- Keytruda (Merck), used for treating melanoma, costs $152,400 a year.[18]
- Kymriah (Novartis), used for treating leukemia, costs $475,000 for a course of treatment.[19]
- Spinraza (Biogen), used to treat spinal muscular atrophy, costs $750,000 for the first year of treatment and $375,000 per year thereafter.[20]

Many new drug therapies are highly potent and come with significant side effects. A recent example is Kymriah, a new blood cancer drug using "CAR–T cell therapy"

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[15] Statement of Howard B. Schiller, Interim Chief Executive Officer and Director, Valeant Pharmaceuticals International, Inc. before the Committee on Oversight and Government Reform of the U.S. House of Representatives, February 4, 2016, *https://oversight.house.gov/wp-content/uploads/2016/02/Statement-of-Howard-Schiller-2016-02-04.pdf.*

[16] Khot, U.N., et al., "Nitroprusside and Isoproterenol Use After Major Price Increases," *New England Journal of Medicine,* August 10, 2017, *http://dx.doi.org/10.1056/NEJMc1700244.*

[17] Waxman, H., et. al., "Getting to the Root of High Prescription Drug Prices: Drivers and Potential Solutions," Commonwealth Fund, July 2017, *http://www.commonwealthfund.org/~/media/files/publications/fund-report/2017/jul/waxman_high_drug_prices_drivers_solutions_report.pdf?la=en.*

[18] Szabo, L., "As Drug Costs Soar, People Delay or Skip Cancer Treatments," National Public Radio, March 15, 2017, *https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments.*

[19] Sagonowsky, E., "At $475,000, is Novartis' Kymriah a bargain—or another example of skyrocketing prices?", *FiercePharma,* August 31, 2017, *https://www.fiercepharma.com/pharma/at-475-000-per-treatment-novartis-kymriah-a-bargain-or-just-another-example-skyrocketing.*

[20] Picci, A., "The cost of Biogen's new drug: $750,000 per patient," CBS News, December 16, 2016, *https://www.cbsnews.com/news/the-cost-of-biogens-new-drug-spinraza-750000-per-patient/.*

through which patients' own genes are extracted, modified and reinjected to kill leukemia cells. The potential side effects require extensive ancillary services to monitor patients and prevent infections and other adverse events for a prolonged period of time. While these services do not directly increase the cost of the drug, they do impact the overall cost of care.

According to the FDA, "Treatment with Kymriah has the potential to cause severe side effects. It carries a boxed warning for cytokine release syndrome (CRS), which is a systemic response to the activation and proliferation of CAR T-cells causing high fever and flu-like symptoms, and for neurological events. Both CRS and neurological events can be life-threatening. Other severe side effects of Kymriah include serious infections, low blood pressure (hypotension), acute kidney injury, fever, and decreased oxygen (hypoxia). Most symptoms appear *within 1 to 22 days* following infusion of Kymriah. Since the CD19 antigen is also present on normal B-cells, and Kymriah will also destroy those normal B cells that produce antibodies, there may be an increased risk of infections *for a prolonged period of time*"[21] (emphasis added).

Drug shortages also are a major contributor to increases in drug spending. Medications that experience shortages are largely injectable products that are off patent and have few suppliers; shortages typically arise from quality concerns that cause a halt to production. If a product has few competitors, this disruption cannot be absorbed by other companies and demand outpaces supply. This not only results in a shortage, but also causes prices to rise. For drugs with a sole manufacturer, shortages are exacerbated—since there is no alternative, clinicians must scramble to find the drug or compound the drug in cases where it is possible. They also may recommend an alternative (often less effective) therapy, if one exists. This, in turn, can result in higher spending because manufacturers often capitalize on the situation by increasing the price of the alternative therapy. For example, a 2017 study that examined how drug prices change during supply disruptions[22] found that after quality-control issues forced a manufacturer of glycopyrrolate—an injectable agent commonly used before surgery to reduce secretions—to suspend production, the remaining manufacturer increased the price of its product by 855 percent. The list price remained at the new level even after production capacity was restored.

HOSPITALS' APPROACH TO REDUCING DRUG COSTS

Hospitals and health systems are committed to ensuring patients receive high-value care. Hospital pharmacists continually work to reduce the costs of drug therapies in order to maintain and expand access to care. Specific examples of approaches taken by hospitals include:

- Identifying equally effective and safe alternative therapies that may be less costly;
- Ongoing monitoring of pricing changes to anticipate upcoming needs;
- Improving inventory management, including by changing how and where medicines are stocked and how they are delivered to clinicians;
- Reducing waste by identifying safe approaches to splitting excessively large single dose vials into multiple doses; and
- Compounding therapies in-house.

Despite these efforts, increased drug spending remains a challenge and one which we believe requires legislative and regulatory intervention. We urge Congress and the Administration to support patients and providers by taking immediate action to reign in the rising cost of drugs, including by passing the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act) and protecting the 340B Program. We also offer a broader set of comprehensive solutions in Appendix A.

The CREATES Act. Generic drugs are one tool for reducing drug prices, as they increase competition after the monopoly enjoyed by drug manufacturer ends when a drug's patent expires. The CREATES Act targets two forms of anticompetitive behavior that are being used to block and delay entry of generic drugs. The first is known as sample-sharing. This occurs when brand-name drug companies refuse to sell samples of their product to potential generic competitors so the generic company cannot perform testing to show that its product is bioequivalent to the brand-name product, a prerequisite for approval by the FDA. The second involves participation

[21] Food and Drug Administration, "FDA approval brings first gene therapy to the United States," August 30, 2017, *https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm574058.htm.*

[22] Davies, B., Hwang, T., and Kesselheim, A., "Ensuring Access to Injectable Generic Drugs—The Case of Intravesical BCG for Bladder Cancer," *New England Journal of Medicine,* April 13, 2017.

in a shared safety protocol. This occurs when brand-name manufacturers whose products require a distribution safety protocol refuse to allow generic competitors to participate in that safety protocol, which is needed to gain FDA approval. The CREATES Act allows a generic drug manufacturer facing the sample-sharing delay tactic to bring an action in federal court for injunctive relief, such as to obtain the sample it needs. The bill also authorizes a judge to award damages to deter future delaying conduct. **We urge Congress to pass the CREATES Act.**

The 340B Program. Congress created the 340B program to permit safety-net hospitals that care for communities with a high number of low-income and uninsured patients "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[23] Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to these health care organizations. For 25 years, the 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to communities across the country with a high number of low-income and uninsured individuals, *at no cost to the federal government.*

Given the increasingly high cost of pharmaceuticals, the 340B program provides critical support to help hospitals' efforts to build healthy communities. In 2015, the 340B program accounted for only 2.8 percent of the $457 billion in annual drug purchases made in the U.S. However, hospitals were able to use those savings to support many programs that are improving and saving lives.[24]

Thirty percent of the hospitals that serve 340B communities are located in rural communities. Nearly 50 percent of those hospitals' communities significantly exceeded the minimum Medicare disproportionate share hospital (DSH) adjustment percentage of 11.75 percent, which is the qualifying threshold for the 340B program. In fact, one-fifth of these hospitals have a Medicare DSH adjustment percentage of more than 25 percent. Many 340B hospitals are financially vulnerable and, in 2015, one out of every four hospitals had a negative operating margin.[25]

The 340B program enables these hospitals to serve their communities by reinvesting savings from reduced drug pricing into programs that benefit their patients, particularly their vulnerable patients. In 2015, 340B hospitals provided $23.8 billion in uncompensated care.[26] Examples of programs provided by 340B hospitals include:

- Financial assistance programs for patients unable to afford their prescriptions;
- Provision of clinical pharmacy services, such as disease management programs or medication therapy management;
- Increased access to other medical services, such as obstetrics, diabetes education, oncology services and other ambulatory services;
- Establishment of additional outpatient clinics to improve access to care;
- Community outreach programs; and
- Free vaccinations for vulnerable populations.

In addition, an examination of hospital services illustrates that 340B hospitals provide access to essential services to their communities:[27]

- Nearly two-thirds of 340B hospitals provide **trauma care.**
- Three-quarters of 340B hospitals provide **pediatric medical surgical services.**
- Nearly all 340B hospitals have **obstetrics (OB) units.**
- Approximately two-thirds of 340B hospitals provide **psychiatric services.**
- 42 percent of 340B hospitals provide **substance abuse or dependency services.**
- 58 percent of 340B hospitals have **Neonatal Intensive Care Units (NICUs).**
- Nearly all 340B hospitals provide **breast cancer screening.**

The 340B program is under threat, especially as a result of a recent change in Medicare payment policy that reduces by nearly 30 percent, or $1.6 billion, Medicare pay-

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[23] *https://www.hrsa.gov/opa/index.html.*

[24] Assistant Secretary for Planning and Evaluation, "Issue Brief: Observations on Trends in Prescription Drug Spending," March 2016, *https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf;* and The Health Resources and Services Administration, "FY 2018 Justification of Estimates for Appropriations Committees," *https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf.*

[25] AHA 2015 Annual Survey Data.

[26] AHA 2015 Annual Survey Data.

[27] *Ibid.*

ments to certain hospitals for outpatient drugs purchased under the 340B program. Cuts of this magnitude will negate the intent of the program, reducing resources that hospitals use to expand access to care and services to vulnerable communities. **We urge Congress to pass H.R. 4392, which would prevent these cuts from going into effect and reducing critical health care resources in vulnerable communities.**

CONCLUSION

We appreciate the opportunity to provide these comments and support the Committee's efforts and attention to examining the issue of the cost of medications. We remain deeply committed to working with Congress, the Administration and other health care stakeholders to ensure that all Americans can access the drug therapies they need to lead healthy, happy and productive lives.

FINAL REPORT

Trends in Hospital Inpatient Drug Costs: Issues and Challenges

October 11, 2016

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Preface

The price of prescription drugs has skyrocketed over the past several years. It seems that every day we hear a new report of how the cost of drugs hurts patients. When the price of a two-pack of Epipens jumped from $100 to $600 between 2007 and 2016—an increase of 500 percent—parents around the country wondered if they would be able to acquire this life-saving medication for their children. When the cost of the infection-control drug Daraprim went from $13.50 to $750 a pill overnight, real patients ended up in the hospital when they could not follow their treatment regimens.

These price increases are extremely troublesome throughout the health care system. They not only threaten patient access to drug therapies, but also challenge providers' abilities to provide the highest quality of care. Drug costs also are a major factor in the rising cost of health care coverage.

Hospitals bear a heavy financial burden when the cost of drugs increases and must make tough choices about how to allocate scarce resources. One hospital put the challenge starkly: last year, the price increases for just four common drugs, which ranged between 479 and 1,261 percent, cost the same amount as the salaries of 55 full-time nurses. And while nearly everyone can agree that price increases in the hundreds or thousands of percent are unjustifiable, many hospitals report that annual price increases of 10 or 20 percent on widely-used older generic drugs can have an even greater effect, given the large quantities that a hospital must purchase. Managing these skyrocketing cost increases forces difficult choices between providing adequate compensation to employees, many of whom are highly skilled in professions facing shortages; upgrading and modernizing facilities; purchasing new technologies to improve care; or paying for drugs, especially when these price increases are not linked to new therapies or improved outcomes for patients.

The American Hospital Association and the Federation of American Hospitals commissioned this study to better understand how drug prices are changing in the inpatient hospital setting. Given that inpatient hospital services are generally reimbursed under a bundled payment model, there is no single source for information on how much hospitals spend on drugs and how that amount has changed over time. We intend for this study to help inform policymakers and other stakeholders about the challenges hospitals face in acquiring life-saving treatments, and serve as a basis for further evaluating how drug prices impact the patients we serve.

Richard J. Pollack
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EXECUTIVE SUMMARY

While there has been recent high profile media coverage of retail drug price increases, the hospital inpatient pharmaceutical market is often overlooked and is not systematically evaluated. This report presents recent trends in hospital inpatient drug prices and spending, providing policymakers and others with quantifiable information on challenges posed by recent increases in inpatient drug prices.

In conjunction with the American Hospital Association and the Federation of American Hospitals, NORC conducted a survey of all U.S. community hospitals and analyzed survey results of 712 responding to the survey. Additionally, two group purchasing organizations (GPOs) representing over 1,400 community hospitals contributed price and spending data on a subset of drugs. The drugs sampled were identified by expert hospital pharmacy workgroups as being high-spend due to volume, price, or both, or as having experienced substantial price increases in recent years.

Between FY 2013 and FY 2015, inpatient drug spending increased an average 23.4 percent annually, and on a per admission basis, by 38.7 percent. Over 90 percent of responding hospitals reported that recent inpatient drug price increases had a moderate or severe effect on their ability to manage the overall cost of patient care, with one-third of the respondents indicating that the impact was severe. Many of the sampled drugs that experienced substantial unit price increases in CY 2014 and CY 2015 were high volume drugs. In most cases, the sampled drugs were not new entrants. This report provides a valuable look at a section of the pharmaceutical market that affects hospitals and the patients they serve.

Key Findings

- Average annual inpatient drug spending increased by 23.4 percent between FY 2013 and FY 2015.
- Inpatient drug spending increased on a per admission basis by 38.7 percent during the same period.
- Growth in unit price—not volume—was primarily responsible for the increase in total inpatient drug spending.
- Over 90 percent of surveyed hospitals reported that inpatient drug price increases had a moderate or severe effect on their ability to manage costs.
- Due to delays in refreshing the pharmaceutical index, Medicare reimbursement cannot keep pace with rapidly increasing drug prices.
- The growth in spending on inpatient drugs exceeds the growth in spending on retail drugs.
- Price increases appear to be random, inconsistent, and unpredictable: large unit price increases occurred for both low- and high-volume drugs and for both branded and generic drugs. About half of the drugs sampled had no generic competition.

Background

Total net spending on prescription drugs, inclusive of discounts, has accelerated over the past year to $309.5 billion annually, making prescription drugs the fastest growing segment of the U.S. healthcare economy.[1,2] Growth in spending on drugs in 2014 (12.2 percent) dwarfs the overall rate of health care spending growth (5.3 percent) as well as the rate of spending growth on hospital and physician care (4.1 and 4.6 percent, respectively).[3] The price of drugs—not utilization—is the predominant contributor to increased drug spending. While spending on drugs rose 8.5 percent in 2015, total prescriptions dispensed increased by only 1 percent.[4] The Bureau of Labor Statistics (BLS) Producer Price Index (PPI) suggests that pharmaceutical

[1] IMS Health, "Medicines Use and Spending in the U.S.—A Review of 2015 and Outlook to 2020," *http://www.imshealth.com/en/thought-leadership/ims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020#form.*

[2] Total spending on an invoice price basis in FY 2015 was $425 billion.

[3] Centers for Medicare and Medicaid Services, "National health expenditure fact sheet," Baltimore, MD, U.S. Department of Health and Human Services (2015).

[4] IMS Health, "IMS Health Study: U.S. Drug Spending Growth Reaches 8.5 Percent in 2015," April 14, 2016, *http://www.imshealth.com/en/about-us/news/ims-health-study-us-drug-spending-growth-reaches-8.5-percent-in-2015.*

price inflation was 7.2 percent in 2015, greatly outpacing both general inflation (0.7 percent) and medical inflation (2.7 percent).[5]

Healthcare purchasers, including federal and state governments, insurers, individual consumers, and providers, have identified the rising cost of drugs as a major challenge for retaining patient access to care. Hospitals bear a heavy financial burden when the cost of drugs increases. Hospitals are significant purchasers of prescription drugs, such as anesthesia and antibiotics to prevent infections during surgery. They also treat patients suffering the repercussions of being unable to afford or otherwise access their medications, often when these individuals return through the emergency department.

While existing studies have quantified the rate of increase in retail drug prices and spending, data limitations have prevented a more detailed examination of the impact of high and rising drug prices on hospitals and their patients.[6, 7] This study sought to document the extent to which inpatient drug prices and spending have increased in the inpatient setting, allowing policymakers and others to examine the impact such changes may have on patients.

As large purchasers, hospitals appear to be particular targets for drug price increases. At least one pharmaceutical company, Valeant, specifically looked to increase prices for hospital-administered drugs.[8] These increases can be dramatic. In 2015, Valeant raised the list prices of Isuprel and Nitropress, common heart medications, by an average of more than 200 percent and 500 percent respectively.[9] These increases may be higher at individual hospitals: for example, the Cleveland Clinic reported price increases for these two drugs of 310 and 718 percent, respectively, and the hospital spent more than $5.3 million on them alone that year. These are just some examples of the price increases reflected in national data.[10]

> From the beginning, a key selling point advanced by Marathon was data that it had accumulated showing that Nitropress and Isuprel were mispriced relative to their value to hospitals . . . we elected to implement significant price increases immediately upon purchasing the drugs. In retrospect, we relied too heavily on the industry practice of increasing the price of brand name drugs in the months before generic entry.
>
> — J. Michael Pearson, Chief Executive of Valeant Pharmaceuticals

The way in which hospitals are reimbursed compounds the impact of increasing drug costs. Most hospitals are not directly reimbursed for the drugs they purchase for use in the inpatient setting.[11] Instead, they generally receive a single payment for all non-physician services, including drugs, that they provide during an inpatient stay or, less commonly, each inpatient day (per diem). For example, Medicare, which accounts for a significant source of payments to hospitals for inpatient services nationally, uses a reimbursement system that cannot keep pace with changes in drug prices. Some commercial and other payers either use the Medicare payment model, called the Inpatient Prospective Payment System (IPPS),[12] or pay directly based on

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[5] U.S. Department of Labor, U.S. Bureau of Labor Statistics, PPI Detailed Report, December 2015, *http://www.bls.gov/ppi/ppidr201512.pdf.*

[6] Leigh Purvis and Stephen Schondelmeyer, "Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2006 to 2013," AARP Public Policy Institute, *http://www.aarp.org/health/drugs-supplements/info-08-2010/rx_price_watch.html.*

[7] Allan Coukell and Chuck Shih, "What's Driving Increased Pharmaceutical Spending?", The Pew Charitable Trust, 2016, *http://www.pewtrusts.org/en/research-and-analysis/analysis/2016/05/26/whats-driving-increased-pharmaceutical-spending.*

[8] Committee on Oversight and Government Reform, "Memorandum Re: Documents Obtained by Committee From Valeant Pharmaceuticals," 2016, *http://democrats.oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Valeant%20Documents0.pdf.*

[9] Brady Dennis, "Rattled by Drug Price Increases, Hospitals Seek Ways to Stay on Guard," *The Washington Post,* March 13th, 2016, *https://www.washingtonpost.com/national/health-science/rattled-by-drug-price-increases-hospitals-seek-ways-to-stay-on-guard/2016/03/13/1c593dea-c8f3-11e5-88ff-e2d1b4289c2f_story.html.*

[10] Katie Thomas, "Valeant Promised Price Breaks on Drugs. Heart Hospitals Are Still Waiting," *The New York Times,* May 11, 2016, *http://www.nytimes.com/2016/05/12/business/valeant-promised-price-breaks-on-drugs-heart-hospitals-are-still-waiting.html.*

[11] Some small, rural hospitals, called Critical Access Hospitals, are reimbursed on a cost basis.

[12] Under the IPPS, hospitals are paid a single pre-determined amount that is based on a national base payment rate, which is adjusted to account for factors such as a patient's condition, the treatment provided, and local market conditions that affect hospitals' costs of providing care. The national base payment rate reflects the capital and operating costs that "efficient" hospitals are expected to incur for providing inpatient services. The capital and operating base payments

Continued

the Medicare rate, *e.g.,* as a percentage of Medicare reimbursement. When reimbursement rates cannot keep up with input costs, such as drugs, hospitals must absorb the excess.

Each year, CMS evaluates changes in the prices of goods and services required to furnish acute inpatient care for purposes of updating the IPPS. For purposes of evaluating changes in drug prices, CMS uses the BLS PPI prescription drug component, which in turn relies on manufacturers to provide timely information on prices. The BLS reviews a sample of drugs that it selects based on probability proportionate to size (dollar value). The BLS refreshes the pharmaceuticals index every 5 to 7 years to allow entirely new products or new trends in the market to be incorporated into the sample.[13] To address the continuous introduction of new drugs, the BLS draws supplemental samples every year.[14] However, these annual samples do not include existing drugs that may have experienced significant price increases in a very short period of time. Thus, the delay in refreshing the pharmaceuticals index fails to capture sudden price increases. Rapid and unpredictable changes in drug prices adversely affect hospitals due to their reimbursement model.

Study Objectives

This study aims to evaluate trends in hospital inpatient drug prices and spending nationwide and assess the impact of such trends on hospitals. Because most payers reimburse hospitals for inpatient services using a predetermined, fixed payment model, data does not readily exist on the price of drugs or other services that are used in the inpatient setting. This study used a large sample survey design to obtain data on this largely unknown market. The study targeted the following research questions:

- Did inpatient drug spending increase between FY 2013 and FY 2015?
- To what extent was price—not volume—a contributor to changes in inpatient drug spending?
- To what extent have changing drug costs impacted hospitals' ability to manage costs within a predetermined, fixed-amount payment system?

Definitions

This study used the following definitions:

Inpatient drug spending per admission. This study includes hospital-based pharmacy spending on prescription drugs (injectable, non-injectable, and biological products) in inpatient settings during the fiscal year net of discounts. Radiopharmaceuticals are excluded from the estimates. Inpatient drug spending is divided by total admissions per year[15] to calculate inpatient drug spending per admission for each sampled hospital.

Community hospitals: All nonfederal, short-term general, and other specialty hospitals. Other specialty hospitals include obstetrics and gynecology; eye, ear, nose, and throat; rehabilitation; orthopedic; and other individually described specialty services. Community hospitals include academic medical centers or other teaching hospitals if they are nonfederal short-term hospitals. Excluded are hospitals not accessible by the general public, such as prison hospitals or college infirmaries.

Price: Price in this report is typically referred to as unit cost or unit purchase cost. For average price, weighted averages were taken based on spending on a drug across different suppliers, formulations and dosages. Prices are inclusive of all discounts, including those offered as volume-based discounts as well as those rebates offered for drugs of varying market competitiveness and relative efficacy.

Total spending: The total amount spent on a drug across inpatient community hospitals responding to the survey.

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are updated annually to account for changes in patient case mix, market conditions, and other factors.

[13] Bureau of Labor Statistics (U.S.), The Pharmaceutical Industry: An Overview of CPI, PPI, and IPP Methodology, 2011.

[14] The FDA Orange Books list all new drugs approved for marketing in the United States.

[15] Number of hospital admissions are derived from the AHA annual survey.

METHODS

Study Population and Data Sources

The study population includes all U.S. community hospitals. According to the 2014 AHA Annual Survey, there are 4,369 community hospitals in the United States.

This study utilized several complementary data sources. First, we share data collected through a survey sponsored by the American Hospital Association (AHA) and the Federation of American Hospitals (FAH) that targeted all U.S. community hospitals (the Drug Survey). Second, we analyze aggregate prescription drug purchasing information from two group purchasing organizations (GPOs). Third, the study uses information on hospitals' characteristics from the 2014 AHA Annual Survey. Finally, NORC, the AHA and the FAH interviewed key stakeholders from a variety of inpatient settings to supplement the study with qualitative findings on changes in inpatient drug prices.

The Drug Survey was administered using the AHA's Annual Survey web-based platform, and was fielded for two months between April and June 2016. Of the sampled hospitals, 778 hospitals responded. Of the 778 responding hospitals, data from 712 hospitals remained in the survey after data cleaning and quality assurance processes (Table 1).

The GPO data include aggregate inpatient prescription drug purchase cost information for 28 selected drugs for more than 1,400 U.S. community hospitals. Approximately, 38% percent of these hospitals also responded to the Drug Survey. The sampled drugs were selected by expert pharmacist and hospital budget workgroups because they are either drugs with high inpatient spend or drugs that have experienced substantial price increases in the past several years. Total spending for these drugs for all hospitals in the two GPO networks amounted to $972,208,384 in CY 2015.

Table 1. Target Population and Study Sample

Population and Sample Definition	Number of Hospitals
All U.S. Community Hospitals *	4,369
U.S. Community Hospitals Responding to AHA-FAH Drug Survey †	712
All Community Hospitals Belonging to Two Sampled GPO Networks ‡	More than 1,400

* Source: 2014 AHA Annual Survey.
† Source: AHA-FAH Drug Survey.
‡ Source: 2014 AHA Annual Survey; GPO Rx Data.

Analysis

The study used survey weights to account for overall selection probability of each responding community hospital in the Drug Survey and make the results nationally representative. We used Taylor series variance estimation to compute standard errors. We applied post-stratification weight adjustments to calibrate the survey weights so that they sum to known population totals for key hospital characteristics. We obtained the population totals from the recent census of U.S. community hospitals in the 2014 AHA Annual Survey data set. Post-stratification weight adjustments resulted in reduced variance and bias in the final survey estimates. As shown in Table 2, compared to all U.S. community hospitals, a larger proportion of hospitals responding to the survey were for-profit; belonged to a hospital system; participated in a GPO network; were located in an urban setting; lacked a critical access hospital designation; were designated as teaching hospitals; and were larger in size in terms of number of beds and total Medicare discharges. After post-stratification adjustments were made to the survey weights, survey respondents matched the census of U.S. community hospitals from the 2014 AHA Annual Survey, across all key characteristics.

To estimate inpatient drug spending per hospital admission, information on number of admissions for each surveyed hospital was sourced from the 2013 and 2014 AHA Annual Surveys. Information on number of admissions for FY 2015 was not available at the time this report was published. Since volume of admissions was similar

between 2013 and 2014, we assumed that volume of admissions in 2015 was similar to 2014.[16]

Table 2. Key Characteristics of Sampled Hospitals Compared to all U.S. Community Hospitals

Hospital Characteristic	All U.S. Community Hospitals	Sampled Community Hospitals	
		Unweighted	Weighted [95% CI]
Number of Hospitals	4,369	712	4,369
Ownership			
Government	22.5%	13.9%	22.5% [18.5%–27.2%]
Not-for-profit	61.8%	57.3%	61.8% [57.3%–66.1%]
For-profit	15.6%	28.8%	15.6% [13.3%–18.2%]
Hospital System			
Yes	60.9%	75.4%	60.9% [56.2%–5.4%]
No	39.1%	24.6%	39.1% [34.6%–43.8%]
Group Purchasing Organization			
Yes	74.7%	76.3%	74.7% [70.5%–78.5%]
No	1.8%	1.4%	1.8% [0.8%–3.8%]
Not Available	23.5%	22.3%	23.5% [19.8%–27.6%]
Geography (Core Based Statistical Area)			
Division	14%	14.9%	14.0% [11.5%–16.9%]
Metropolitan	41.4%	48.7%	41.4% [37.3%–45.7%]
Micropolitan	18.9%	21.2%	18.9% [15.8%–22.4%]
Rural	25.7%	15.2%	25.7% [21.4%–30.5%]
Critical Access Hospital			
Yes	29.6%	14.8%	29.2% [24.6%–34.2%]
No	70.2%	85.3%	70.8% [65.8%–75.4%]
Teaching Status			
Yes	26.3%	31.9%	26.3% [23.0%–30.0%]
No	73.7%	68.1%	73.7% [70.0%–77.0%]
Bed Size			
Up to 99	49.4%	35.0%	49.4% [44.9%–53.8%]
100 to 399	40.4%	51.7%	40.4% [36.4%–44.6%]
400 or more	10.2%	13.3%	10.2% [8.3%–12.5%]

[16] 2013 AHA Annual Survey; 2014 AHA Annual Survey.

Table 2. Key Characteristics of Sampled Hospitals Compared to all U.S. Community Hospitals—Continued

Hospital Characteristic	All U.S. Community Hospitals	Sampled Community Hospitals	
		Unweighted	Weighted [95% CI]
Medicare Discharges			
4th Quartile (highest)	25%	10.0%	25% [20.4%–30.2%]
3rd Quartile	25%	23.7%	25% [21.5%–28.8%]
2nd Quartile	25%	35.1%	25% [21.9%–28.4%]
1st Quartile	25%	31.2%	25% [21.9%–28.5%]

Source: AHA–FAH Drug Survey; 2014 AHA Annual Survey.

To identify the drugs that had the greatest impact on hospital budgets due to changes in price and not volume, we analyzed the GPO data containing information on spending, price, and volume for the 28 selected drugs over a three-year period (CY 2013 to CY 2015). Total spending and pricing information was aggregated across dosage/strength combinations and branded/generic versions for each drug.[17] We then identified the 10 drugs that had the highest total inpatient drug spending by the GPOs during CY 2015, and computed growth in total spending and unit price for these drugs. We also identified the 10 drugs with the largest unit price growth between 2013 and 2015. As shown in Table 3, compared to all U.S. community hospitals, a larger proportion of GPO hospitals were for-profit; belonged to a hospital system; were located in an urban setting; were not a critical access hospital; were designated as teaching hospitals; and were larger in size in terms of number of beds. The GPO hospital sample is a convenience sample; in other words, no sampling weights are used. Because the information from the GPOs was aggregated, we could not apply post-stratification weighting. However, as shown in Table 3, on aggregate, the characteristics of GPO hospitals are quite similar to that of all U.S. community hospitals.

Table 3. Key Characteristics of Sampled GPO Hospitals Compared to all U.S. Community Hospitals

Hospital Characteristic	All Community Hospitals	Community Hospitals Belonging to the Two GPO Networks
Number of Hospitals	4,369	More than 1,400
Ownership		
Government	22.5%	19.2%
Not-for-profit	61.8%	64.3%
For-profit	15.6%	16.5%
Hospital System		
Yes	60.9%	67.1%
No	39.1%	32.9%
Geography (Core Based Statistical Area)		
Division	14%	11.4%

[17] Prices are inclusive of all discounts, including those offered as volume based discounts as well as those rebates offered for drugs of varying market competitiveness and relative efficacy.

Table 3. Key Characteristics of Sampled GPO Hospitals Compared to all U.S. Community Hospitals—Continued

Hospital Characteristic	All Community Hospitals	Community Hospitals Belonging to the Two GPO Networks
Metropolitan	41.4%	45.8%
Micropolitan	18.9%	22%
Rural	25.7%	20.9%
Critical Access Hospital		
Yes	29.6%	24.6%
No	70.2%	75.4%
Teaching Status		
Yes	26.3%	31.2%
No	73.7%	68.8%
Bed Size		
Up to 99	49.4%	46.4%
100 to 399	40.4%	40.7%
400 or more	10.2%	12.9%
Medicare Discharges		
4th Quartile (highest)	25%	18.7%
3rd Quartile	25%	27.4%
2nd Quartile	25%	25.8%
1st Quartile	25%	28.1%

Source: 2014 AHA Annual Survey; GPO Rx Data

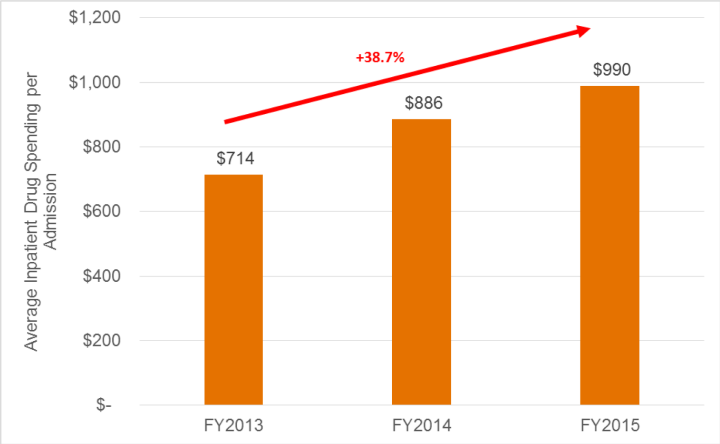
KEY FINDINGS

Inpatient drug spending increased significantly between FY 2013 and FY 2015. Average annual inpatient drug spending at U.S. community hospitals increased by 23.4 percent between FY 2013 and FY 2015 (from $5.2 million to $6.5 million).[18] Over the same period, average inpatient drug spending increased 38.7 percent on a per admission basis (from $714 to $990, see Figure 1).[19]

[18] Average annual spending was estimated to increase 11.5 percent between FY 2013 and FY 2014 from $5.2 million to $5.8 million. Between FY 2014 and FY 2015, average annual spending increased by 10.7 percent to $6.5 million.

[19] On a per-admission basis, average inpatient drug spending was estimated to be $714 during FY 2013. Between FY 2013 and FY 2014, spending increased by 24 percent to $886 [$795–$976]. Between FY 2014 and FY 2015, spending increased by 12 percent to $990 [$893–$1,086].

Figure 1. Inpatient Drug Spending per Admission Has Increased Substantially Since 2013



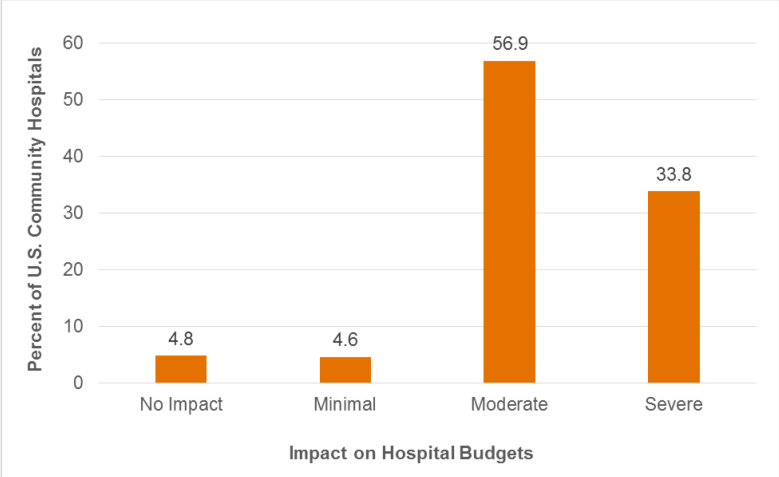
Source: AHA-FAH Drug Survey; 2012-2014 AHA Annual Survey

Changes in inpatient drug spending impacted hospitals' ability to manage costs within a fixed payment system between FY 2013 and FY 2015. Over 90 percent of the hospitals responding to the Drug Survey reported that recent changes in drug prices had a moderate or severe impact on their budgets, with a third of hospitals rating the impact as "severe" (Figure 2). These observations are reinforced by the fact that growth in inpatient drug spending during this period exceeded the Medicare hospital rate update (IPPS market basket plus/minus adjustments), the pharmaceutical price inflation rate, as well as the spending in the retail drug market (Figures 3 and 4).[20]

> There might be upgrades you were trying to do, but there is only [so much] budget to do those things. Is it mandated? Can we duct tape this equipment? If it breaks in six months, we'll buy it out of contingency. These are the tough choices that a small community hospital needs to make. . . . Drug volume has gone down while dollars [prices] have gone up. . . . We'll do anything to drive costs down, even [cut] costs like gas and electricity. It's really like a household budget.
>
> — Pharmacy Administrator

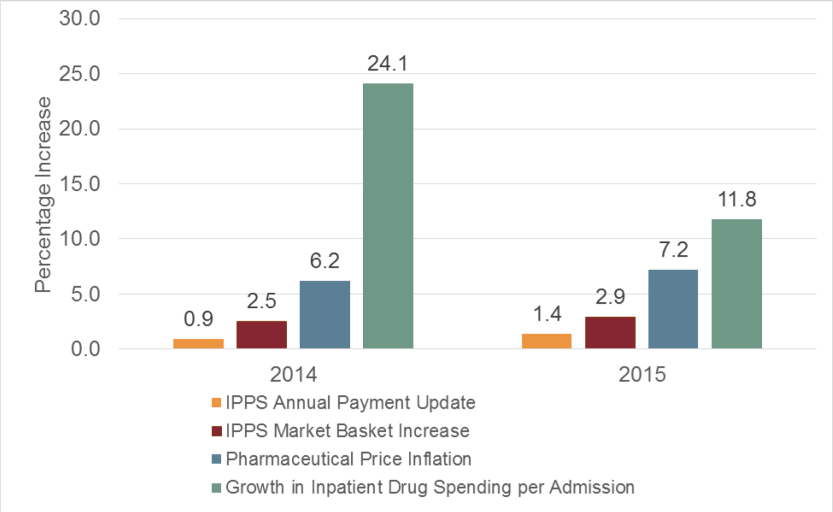
[20] Medicare payments are adjusted annually based on changes to the cost of goods and services ("market basket") plus or minus any other adjustments as a result of other policy changes, such as coding adjustments.

Figure 2. Over 90% of Hospital Administrators Reported That Higher Drug Prices Had a Moderate or Severe Impact on Their Budgets



Source: AHA-FAH Drug Survey

Figure 3. Growth in Inpatient Drug Spending Has Far Outpaced Payer Reimbursement and Pharmaceutical Price Inflation

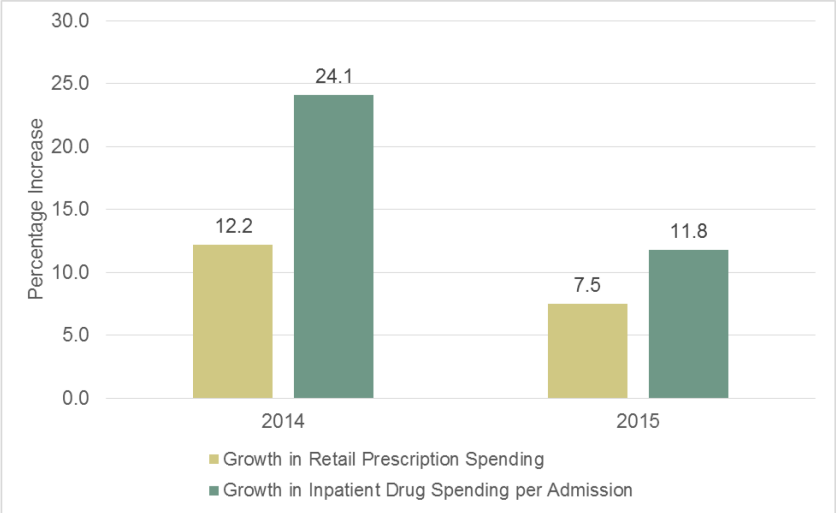


Source: CMS, Bureau of Labor Statistics, National Health Expenditure Data, AHA-FAH Drug Survey

Note: Pharmaceutical Price Inflation refers to the pharmaceutical preparation manufacturing Producer Price Index. Alternative measures include the pharmaceutical indexes for the Consumer Price Index (CPI) and the Import/Export Price Index (IPP).

Note: Adding growth in annual inpatient drug spending per admission in FY2014 and FY2015 (i.e. 24.1% + 11.8%) will not equal the compounded growth rate during the two period (38.7%)

Figure 4. Inpatient Drug Spending Growth Eclipsed Retail Prescription Drug Spending Growth



Source: CMS, Bureau of Labor Statistics, National Health Expenditure Data, AHA-FAH Drug Survey

Note: Data for the 2015 retail prescription price increase is provided by DHHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) projections of NHE data. Medical inflation refers to medical component of the CPI (Consumer Price Index).

Note: Adding growth in annual inpatient drug spending per admission in FY2014 and FY2015 (i.e. 24.1% + 11.8%) will not equal the compounded growth rate during the two period (38.7%)

Drug price increases had a larger impact on hospital drug spending than utilization between CY 2013 and CY 2015. The data from the two GPOs included information on total inpatient spending, unit price, and change in unit price between CY 2013 and CY 2015 for the selected drugs. From this data, we were able to calculate total utilization for each year and evaluate how utilization changed over the three year period. By comparing changes in drug prices and changes in utilization on total spend for a drug, we were able to identify where spending was more significantly impacted by price or volume. Consistently, changes in prices drove increases in spending. Figure 5 and Appendix Table A.1 presents information for the 10 drugs with the highest spending; Figure 6 and Appendix Table A.2 presents information for the 10 drugs with the greatest change in unit cost.

Drug price increases appear to be random and inconsistent from one year to the next. The unit price of many of the drugs changed significantly and unpredictably. Many of these drugs—but not all—were high-volume drugs (*e.g.,* calcitonin, nitroprusside, isoproterenol, neostigmine methylsulfate, phytonadione, and glycopyrrolate; Figures 5 and 6). Most were not innovator drugs, that is, brand name drugs under patent protection. While some drugs increased at similar rates each year (*e.g.,* glucagon), others varied dramatically one year to the next (*e.g.,* acetaminophen, calcitonin).

The rationale for changes in price is not immediately clear. For some, it appears that the instigator for the price change was simply a change in the drug's ownership. For example, the leukemia drug Oncaspar (pegaspargase) was originally approved in 1994. The price of the drug increased by nearly $10,000 last year after Baxalta Inc.'s purchase. The antiparasitic Daraprim (pyrimethamine) was originally approved in 1953, yet cost hospitals substantially more in CY 2015 after new owner Turing Pharmaceuticals increased the price by more than 3,000 percent. As previously noted, Valeant increased the prices of Isuprel and Nitropress by hundreds of percent between CY 2013 and CY 2015 after they purchased the rights to those drugs from Marathon Pharmaceuticals.[21]

[21] These figures still reflect aggregated GPO data and represent the price change across 2 years, *see* Table A.2.

> You can pretty much ballpark medications that were already high priced, but it's for the ones that were $5 last year and $300 this year. Those are the ones that make it very difficult to budget. These types of increases are being more commonly found for generics. It used to be you could buy these generics and save, now all of a sudden these generics are not cheap anymore. For Isuprel, which is in all your crash carts and increased 500 percent overnight, there is no way to budget ahead of time. It's taking up pretty much the entire DRG reimbursement on cases.
>
> — Pharmacy Vice President

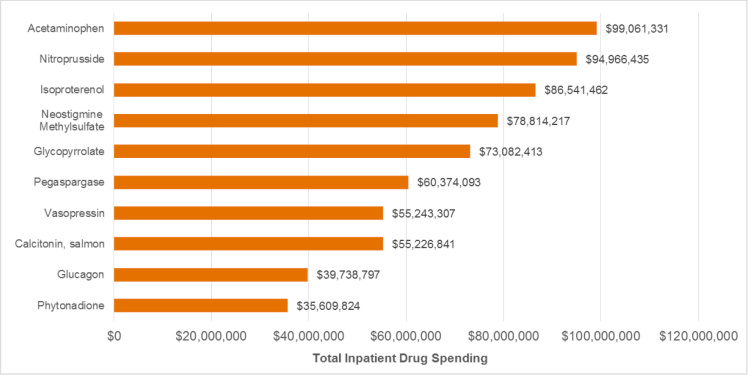
Temporary market failures also appear to impact drug pricing, sometimes with lasting consequences. In 2012 Luitpold Pharmaceuticals, one of only two makers of glycopyrrolate (a drug used to dry secretions prior to surgery) temporarily closed its factory to fix quality control problems.[22] Hikma Pharmaceuticals, the other manufacturer, then raised its prices of the injectable version in 2013. As a result, GPOs experienced a 334 percent increase in the drug's price in CY 2014. However, once both manufacturers were making it again, its price decreased by just 5 percent in CY 2015.

> We did a presentation on nitroprusside and other old drugs to our CEO and our executive team. Our CEO was a former surgeon so he was familiar with the drug. He couldn't believe the magnitude of the increases—he knew it's been around forever.
>
> — Chief Pharmacy Officer

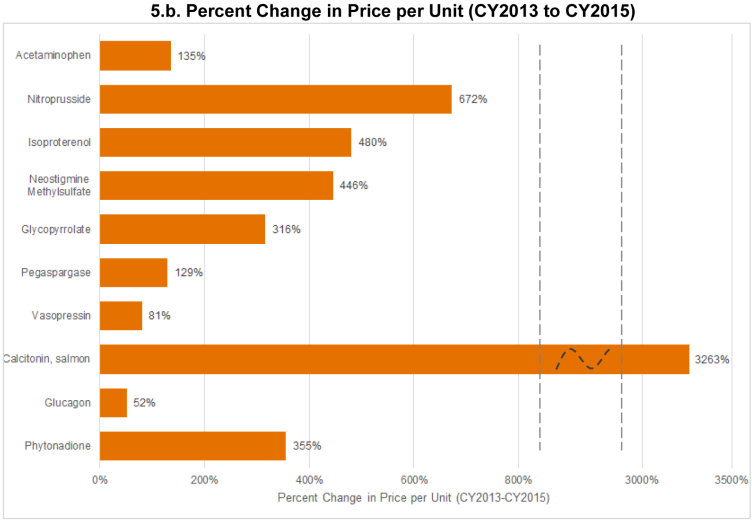
[22] Cynthia Koons, "Broken Markets for Old Drugs Means Price Spikes Are Here to Stay," *Bloomberg,* November 18, 2015, *http://www.bloomberg.com/news/articles/2015-11-18/the-law-of-pharma-pricing-physics-what-goes-up-often-stays-up.*

Figure 5. Drugs with the Highest Spending Experienced Significant Price Increases in 2014 and 2015

5.a. Total Inpatient Spending (CY2015)



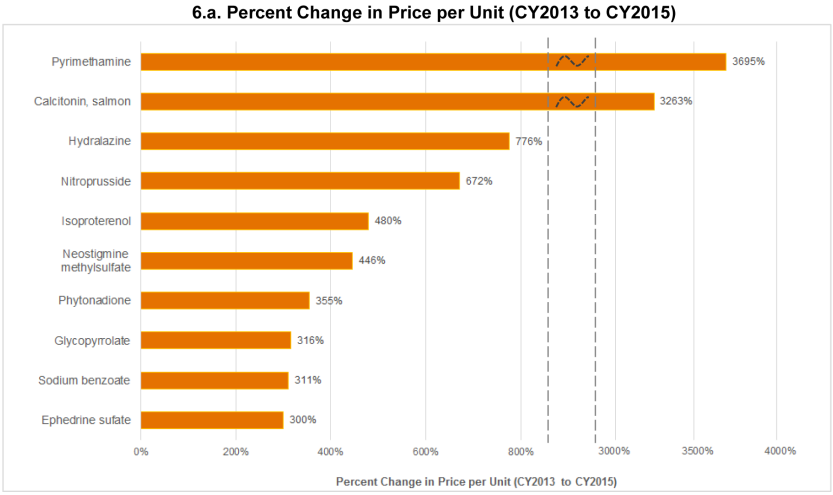
5.b. Percent Change in Price per Unit (CY2013 to CY2015)

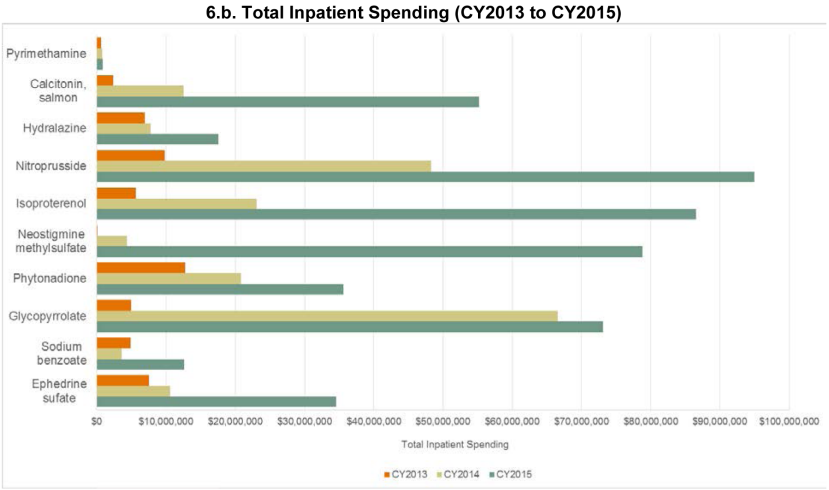


Source: GPO Rx Data

Note: Spending and price increases do not necessary correlate exactly due to changes in volume. In other words, a 100 percent price increase may not result in a 100 percent spending increase due to changes in patient mix, prescribing patterns, and whether the hospital was able to find an alternative drug.

Figure 6. Drugs with the Highest Price Increases between 2013 and 2015 Also Experienced Significant Spending Increases





Source: GPO Rx Data

Note: Spending and price increases do not necessary correlate exactly due to changes in volume. In other words, a 100 percent price increase may not result in a 100 percent spending increase due to changes in patient mix, prescribing patterns, and whether the hospital was able to find an alternative drug.

CONCLUSIONS

This study examines trends in inpatient drug spending for hospitals nationwide in order to determine the quantitative impact and to discover how such changes may have impacted hospitals' ability to manage costs. Findings show:

- Drug spending in the hospital inpatient setting is quickly increasing. Growth in annual inpatient drug spending between FY 2013 and FY 2015 increased on average 23.4 percent, and on a per admission admission basis, 38.6 percent. Growth in spending in the inpatient setting exceeded the growth in retail spending, which increased 9.9 percent during this period. In contrast, CMS's update to hospital rates through the IPPS increased by only 2.7 percent. Large

and unpredictable increases in the price of drugs used in the inpatient setting significantly impacted hospitals' ability to manage costs within a fixed price based payment system.

- Many of the sampled drugs that accounted for a substantial proportion of total inpatient drug spending experienced dramatic unit price increases in CY 2014 and CY 2015. In most cases, the identified top ten drugs were not new entrants.[23] About half of the 28 drugs had no active generic competition, leaving hospitals no lower cost alternatives. For most of the drugs, growth in unit price—not volume—was primarily responsible for the increase in total inpatient drug spending.
- Stakeholder interviews suggest that significant budgetary accommodations are needed to keep up with rising drug prices. Most of those interviewed raised concerns about older generic drugs whose prices have increased unpredictably and the lack of alternatives available in order to provide high quality care to their patients.

Limitations

The conclusions of this study should be considered in the context of the following limitations:

- The information on total spending for inpatient drugs between FY 2013 and FY 2015 gathered from the Drug Survey was self-reported.
- Of the 4,369 hospitals that met the criteria to participate in the survey, only 778 responded and the data from only 712 was sufficiently clean to be used.
- Although the survey solicited responses from individual hospitals, some hospitals systems reported aggregate information for the entire system. The analysis took account such responses where it was readily evident that the response was at the system level.
- Not all hospitals participate in GPOs (the GPO data include information on 1,409 of 4,369 U.S. community hospitals), which allow hospitals to consolidate their collective purchasing power. As such, the GPO data may not be reflective of the experience of all hospitals, and likely understates the actual rate of growth.

[23] The drugs received FDA approval prior to CY 2013.

APPENDIX

Table A1. Change in Unit Cost for Top Ten Drugs With Highest Total Spending in CY 2015 (GPO Data)

Generic name	Total Inpatient Spending CY 2013	Total Inpatient Spending CY 2014	Total Inpatient Spending CY 2015	Unit Price CY 2013	Unit Price CY 2014	Unit Price CY 2015	Percent Change in Unit Price (CY 2013–CY 2014)	Percent Change in Unit Price (CY 2014–CY 2015)
Acetaminophen	43,156,542.02	87,113,521.07	99,061,331.23	12.94	27.64	30.46	114%	10%
Nitroprusside	9,802,140.32	48,278,606.78	94,966,434.83	102.34	150.31	790.46	47%	426%
Isoproterenol	5,602,447.81	23,066,826.13	86,541,461.54	278.67	804.16	1,617.62	189%	101%
Neostigmine methylsulfate	56,818.46	4,311,153.48	78,814,217.26	15.69	16.44	85.59	5%	421%
Glycopyrrolate	4,932,748.72	66,606,577.06	73,082,412.98	5.46	23.83	22.70	337%	−5%
Pegaspargase	32,142,583.64	34,337,561.15	60,374,093.00	5,605.44	5,617.24	12,858.14	0%	129%
Vasopressin	1,923,293.58	3,698,147.36	55,243,306.86	–	48.76	88.16	–	81%
Calcitonin, salmon	2,372,551.94	12,529,284.26	55,226,841.19	67.98	923.51	2,286.23	1,259%	148%
Glucagon	23,427,876.25	26,041,923.88	39,738,796.65	109.66	132.91	166.80	21%	25%
Phytonadione	12,731,141.91	20,809,335.38	35,609,824.48	549.84	1,241.61	2,502.80	126%	102%

Source: GPO Rx Data

Table A2. Top Ten Drugs With Highest Unit Price Increases in CY 2015 (GPO Data)

Generic name	Total Inpatient Spending CY 2013	Total Inpatient Spending CY 2014	Total Inpatient Spending CY 2015	Unit Price CY 2013	Unit Price CY 2014	Unit Price CY 2015	Percent Change in Price per Unit (CY 2013–CY 2015)
Pyrimethamine	595,748.81	801,690.28	812,109.32	919.10	1,045.52	34,882.24	3,695%
Calcitonin, salmon	2,372,551.94	12,529,284.26	55,226,841.19	67.98	923.51	2,286.23	3,263%
Hydralazine	6,951,150.65	7,725,372.30	17,568,936.99	4.72	5.02	41.32	776%
Nitroprusside	9,802,140.32	48,278,606.78	94,966,434.83	102.34	150.31	790.46	672%
Isoproterenol	5,602,447.81	23,066,826.13	86,541,461.54	278.67	804.16	1,617.62	480%
Neostigmine methylsulfate	56,818.46	4,311,153.48	78,814,217.26	15.69	16.44	85.59	446%
Phytonadione	12,731,141.91	20,809,335.38	35,609,824.48	549.84	1,241.61	2,502.80	355%
Glycopyrrolate	4,932,748.72	66,606,577.06	73,082,412.98	5.46	23.83	22.70	316%
Sodium benzoate	4,857,185.90	3,559,993.22	12,651,343.86	11,118.66	5,192.88	45,665.71	311%
Ephedrine sulfate	7,533,234.15	10,528,689.87	34,552,474.48	5.98	8.90	23.96	300%

Source: GPO Rx Data.

Table A3. Glossary

Generic Name	Therapeutic Class	Medical Use	Approval in Past Four Years	Any Generic Competition
Acetaminophen	Analgesic	Treats minor aches and pains, and reduces fever	No	Yes
Calcitonin, salmon	Calcitonin	Treats bone pain and other symptoms of Paget's disease, hypercalcemia, and osteoporosis	No	Yes
Ephedrine sulfate	Sympathomimetics; decongestants, vasopressors	Used to prevent low blood pressure during spinal anesthesia	No	Yes
Glucagon	Hormone, hyperglycemic agent	Treats severe low blood sugar	No	Yes
Glycopyrrolate	Synthetic anticholinergic	Reduces secretions in the mouth, throat, airway and stomach before surgery	No	Yes
Hydralazine	Vasodilator, arteriolar vasodilator	Direct-acting smooth muscle relaxant used to treat high blood pressure	No	Yes
Isoproterenol	Nonselective beta-agonist; sympathomimetic	Used to improve breathing while a patient is under anesthesia, or to treat certain types of heart problems	No	No
Neostigmine methylsulfate	Antianginal, antihypertensive	Reversal agent of certain kinds of muscle relaxants used in surgery	May 31, 2013 Approval	No
Nitroprusside	Vasodilator	Used to treat congestive heart failure and life threatening high blood pressure, or to keep blood pressure low during a surgery	No	No
Pegaspargase	Chemotherapy, asparaginase	Leukemia treatment	No	No
Phytonadione	Vitamin K	Aids blood clotting	No	Yes

Table A3. Glossary—Continued

Generic Name	Therapeutic Class	Medical Use	Approval in Past Four Years	Any Generic Competition
Pyrimethamine	Antiparasitic, antimalarial agent	Treats toxoplasmosis, can also prevent malaria and other infections	No	No
Sodium benzoate	Metabolic Agent	Treatment of urea cycle disorders and hyperammonemia	No	Yes
Vasopressin	Hormone, vasoconstrictor	A blood vessel constricting agent used in emergencies, also used to treat diabetes insipidus, after stomach surgery or before stomach x-rays	April 17, 2014 Approval	Yes

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ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS
1601 N. Tucson Blvd., Suite 9
Tucson, AZ 85716

Statement of Jane M. Orient, M.D., Executive Director

Chairman Hatch, Ranking Member Wyden, and Members of the U.S. Senate Committee on Finance:

There are many obstacles impeding prescription drug affordability. Yet, one especially responsible culprit is the safe harbor to Medicare anti-kickback law enjoyed by Group Purchasing Organizations (GPOs) that has been further extended by administrative guidance to Pharmacy Benefit Managers (PBMs).

The Federal statute granting this "safe harbor" is 42 U.S.C. 1320a–7b(b)(3)(C), the language of which was established by the "Omnibus Budget Reconciliation Act of 1986," strengthened by the "Medicare and Medicaid Patient and Program Protection Act of 1987," and subsequently ensconced in federal regulation at 42 CFR 1001.952(j).

The provision ostensibly facilitates greater bargaining power for the purchasing of supplies and drugs. However, the safe harbor has in practice driven up costs and scarcity by perpetuating a system rife with hidden kickbacks, rebates, and single source contracts that financially benefit GPOs, PBMs, and large manufacturers, but constrain competition and ultimately harm patients.

It is time to repeal 42 U.S.C. 1320a–7b(b)(3)(C) and direct HHS to revoke any related regulations and guidance that protect such improper kickbacks.

Physicians Against Drug Shortages calculates that such "corrupt practices have driven up the prices of drugs sold by PBMs to individual consumers by at least $100 billion annually." This is in addition to the $100 billion per year in inflated supply costs that result from kickbacks to GPOs. For additional details *see http://www.physiciansagainstdrugshortages.com/*.

Diabetes patients are one group particularly hard hit by the collusion between PBMs and manufacturers. CBS News recently reported that "the cost of two common types of insulin increased 300 percent in the past decade" thanks in large part to kickbacks to PBMs. Contracts between GPOs, PBMs, suppliers, and manufacturers are hidden from public view, despite the fact that taxpayers fund nearly two-thirds of every dollar spent on medical care.

This Committee should request, subpoena if needed, and make public, contracts related to the sale of insulin to help shine sunlight on these secret backroom deals. In addition it should similarly obtain copies of contracts related to other medical products that have recently seen a dramatic rise in scarcity or price: *e.g.,* Baxter's contracts related to saline market allocation, the Hospira (now Pfizer) contracts for fentanyl, and Mylan's contracts for Epipen.

Meanwhile, independent physicians are providing tremendous savings to patients with in-office dispensing of prescriptions that cut out the cost increases caused by middlemen like PBMs. For example, a 72 year old female patient with multiple chronic conditions purchases all nine of her medications through a Direct Primary Care office for $14.63/month. Through her Medicare "coverage" her cost would be $294.25 per month.

The Senate Committee on Finance has jurisdiction over S 1358, the Direct Primary Care Enhancement Act, which would increase patient access to this promising delivery model by simply clarifying that Health Savings Accounts can be used for these arrangements. We urge the Committee to expedite consideration and approval of S. 1358.

In conclusion, lowering costs for care is going to mean ending the improper flow of money to middlemen profiting without adding value to patient care. We encourage the Committee to take action to end failed policies that benefit the bottom lines of these special interests and simultaneously implement solutions that hand control back to patients.

Please do not hesitate to reach out to us for further discussion about our concerns.

Sincerely,

Jane M. Orient, MD
AAPS Executive Director

CAMPAIGN FOR SUSTAINABLE RX PRICING (CSRxP)

Testimony of Lauren Aronson, Executive Director

Chairman Hatch, Ranking Member Wyden, and members of the Senate Finance Committee, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record on the critically important issue of increasing prescription drug affordability for consumers and taxpayers while at the same time fostering a marketplace for the development of innovative medicines.

CSRxP is a nonpartisan coalition of organizations committed to promoting an informed discussion on sustainable drug pricing and to developing bipartisan, market-based solutions that improve affordability while maintaining access to innovative prescription drugs for American patients and their families. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and health insurance providers.

We very much appreciate the leadership of this Committee and Department of Health and Human Services (HHS) Secretary Azar in finding ways to address the unsustainable growth in prescription drug costs. Consumers currently spend 23 cents of every healthcare dollar on prescription drugs—an amount that can and must come down, as needlessly high drug prices and out-of-pocket spending can threaten the financial security, health and well-being of American patients and their families, as well as strain Federal and State budgets.[1]

CSRxP welcomes HHS's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" as a good first step in the effort to reduce needlessly high list prices and lower overall prescription drug costs for consumers and taxpayers.[2] The Blueprint includes a number of thoughtful and creative ideas on innovative methods to reduce prescription drug spending and we would like to work with the Committee and HHS to ensure that those policy ideas are successfully implemented. However, we believe that more can and should be done to bring prices down. Policies must be implemented to address the root of the problem: brand drug makers set list prices too high and increase them at excessively high rates. Prescription drug costs will continue to grow at unacceptably unsustainable rates unless serious actions are taken to thwart the pricing practices of the brand industry. Without addressing the root cause of the problem, many American patients, particularly those on limited incomes, will continue facing choices they should never have to make between buying groceries for their families or purchasing the medications they need to get well and stay healthy.

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[1] America's Health Insurance Plans, "Where Does Your Health Care Dollar Go?", May 22, 2018.
[2] 83 Fed. Reg. 22692–22700.

Below, CSRxP expresses support for policies in the Blueprint that will improve the affordability of prescription drugs while at the same time fostering a competitive market, which drives innovation in drug development. We then discuss our concern with certain policy ideas that, while very well-intentioned, unfortunately will not lower prescription drug costs for most consumers and taxpayers. Finally, we recommend a limited number of additional bipartisan, market-based policies for adoption that will increase affordability and promote innovation in drug development.

CSRxP looks forward to working with the Committee and HHS to successfully implement policies that will help address the goal we all mutually share: to make prescription drugs more affordable and accessible for U.S. consumers and taxpayers without imperiling the discovery of innovative breakthrough therapies that can improve the health and well-being of patients.

I. Policies That Improve Market Competition and Lower Out-of-Pocket Costs for Consumers

A. Increasing Transparency in Prescription Drug Pricing

CSRxP strongly agrees with HHS that improving transparency in prescription drug pricing is a critical component to making prescription drugs more affordable for consumers and taxpayers. Among other benefits, increased transparency will support and better enable transformation of the U.S. health care system toward one based on value; will better inform patients, prescribers, and dispensers of actual drug costs as they determine the most appropriate treatments to meet individual patient needs; and encourage drug makers to justify the high prices they set for their products. Hence, CSRxP welcomes policies in the Blueprint that promote drug pricing transparency, including:

- **Requiring drug manufacturers to include list prices in direct-to-consumer (DTC) advertisements:** DTC advertising has come under scrutiny as prescription drug spending takes up a bigger portion of health care dollars each year both for consumers and taxpayers. DTC advertising has the potential to lead to over-utilization of high-cost medicines. Presenting list prices—as well as price increases—in DTC advertising will make patients much more aware of prescription drug costs when they talk with their providers about treatment options for their individual health care needs. Thus, CSRxP urges the Committee to work with HHS and the Food and Drug Administration (FDA) to require drug makers to include list prices and list price increases in DTC advertisements for their products.
- **Updating routinely, and expanding, the amount of information available on the Medicare and Medicaid Drug Dashboards:** The Medicare and Medicaid Dashboards have provided valuable data and information to consumers and providers on prescription drug costs in a transparent manner. Hence, CSRxP urges the Committee to encourage HHS to routinely update information on both dashboards, including list prices, price increases, and year-over-year pricing data, among other data points, so that consumers have a more transparent understanding of the prescription drug cost increases they face each year.

Furthermore, CSRxP urges the Committee and HHS to build on the important policy initiatives ongoing at the Department and described in the Blueprint that will increase transparency in prescription drug pricing, including:

- **Mandating that drug makers release details of a drug's unit price, cost of treatment, and projection on federal spending before FDA approval:** Given the significant impact pharmaceuticals have on overall health care spending, manufacturers should be required to disclose information on the estimated unit price for the product, the cost of a course of treatment, and a projection of federal spending on the product so that patients, providers, taxpayers and policymakers have a better understanding of actual treatment costs.
- **Requiring drug companies to annually report increases in their drugs' list prices:** Similar to requirements already in place for other entities like health insurance providers, hospitals and nursing facilities, pharmaceutical companies should be required to report increases in a drug's list price on an annual basis, as well as how many times during the year the price has increased.
- **Compelling drug manufacturers to disclose R&D costs:** Drug makers should be required to disclose how much research was funded by public entities like the National Institute of Health (NIH), other academic entities, or other

private companies, so that regulators and taxpayers can properly weigh return on investment.

- **Producing annual HHS reports on overall prescription drug spending trends and price increases for individual prescription drugs:** HHS should produce and publicly release annual reports covering (1) overall prescription drug pricing trends similar to the one produced by the HHS Assistant Secretary for Planning and Evaluation (ASPE) in March 2016; and (2) the top 50 price increases per year by branded or generic drugs; the top 50 drugs by annual spending and how much the government pays in total for these drugs; and historical price increases for common drugs, including those in Medicare Part B.[3] These important pieces of information will better inform patients, prescribers, dispensers, policymakers, and taxpayers of the significant costs of prescription drugs that consumers face today.

B. Thwarting Anti-Competitive REMS Abuses by Brand Drug Makers

The FDA uses the Risk Evaluation and Mitigation Strategy (REMS) program to allow products with potential safety issues to enter the market. When employed effectively and appropriately, REMS improves patient safety and makes accessible medicines that otherwise might not be available due to safety concerns. However, as described in the HHS Blueprint, drug manufacturers often engage in abusive, anti-competitive behaviors that manipulate REMS to block generic drug companies from obtaining samples of brand drugs under the guise of addressing patient safety concerns, effectively preventing them from pursuing the research needed to bring less expensive generic drugs to market. CSRxP appreciates the leadership of FDA Administrator Gottlieb in using administrative action to help curb these abuses. However, we believe more can be done and therefore urge the Committee to encourage and welcome further actions by the FDA to thwart anti-competitive abuses of REMS by brand drug makers identified in the Blueprint, including:

- **Evaluating current REMS programs to determine whether existing limited distribution programs are appropriate:** CSRxP urges FDA to assess whether existing REMS programs inappropriately restrict access to samples necessary for testing by generic drug makers. Lifting any inappropriate and anti-competitive restrictions in sample access will better enable generic drug makers to develop products that can inject competition into the marketplace and bring drug prices down for consumers and taxpayers.
- **Applying the same scrutiny to reference biologic manufacturers as applied to brand drug companies when assessing potential anti-competitive REMS abuses by reference biologic manufacturers:** CSRxP welcomes HHS's recognition in the Blueprint that reference biologic manufacturers have the potential to engage in the same shenanigans that certain brand drug manufacturers do with respect to REMS; namely, developers of biosimilars and interchangeable biologic products may face challenges in obtaining samples of reference biologics for testing due to anti-competitive REMS abuses by reference biologic manufacturers. As such, CSRxP urges FDA to apply the same scrutiny to reference biologic manufacturers as it does to brand drug companies when evaluating REMS programs for reference biologics.

Support for the CREATES Act and FAST Generics Act: In addition to the actions described in the Blueprint to curb REMS abuses, bipartisan legislation has been introduced in the Senate and the House—the CREATES Act and the FAST Generics Act—that would inhibit anti-competitive REMS practices by brand drug makers. CSRxP urges enactment of these bipartisan pieces of legislation, which will build on the important and ongoing work at FDA to curb REMS abuses and better enable generic drugs to enter the market.

C. Fostering a Robust Market for Biosimilar and Interchangeable Biologic Products

Biosimilars and interchangeable biologic products have the potential to expand treatment options and substantially lower prescription drug costs for consumers and taxpayers. For example, one study found that 11 biosimilars already approved for sale in Europe and elsewhere could generate approximately $250 billion in savings over 10 years if they were available in the U.S.[4] Thus, CSRxP welcomes implementation of policies identified in the Blueprint that promote and incentivize the development of biosimilars and interchangeable biologic products to compete against

[3] HHS ASPE, "Observation on Trends in Prescription Drug Spending," March 8, 2016.
[4] Express Scripts, "The $250 Billion Potential of Biosimilars," April 23, 2013.

high-priced specialty brands and lower costs for consumers and taxpayers, including:

- **Improving the interchangeability of biosimilars:** CSRxP strongly supports efforts to improve the interchangeability of biosimilars, which will provide enhanced competition in the marketplace particularly for high-cost specialty drugs. FDA has approved eleven biosimilar products since enactment of the Biologics Price Competition and Incentive Act (BPCIA) over 8 years ago. However, the agency has not deemed any as interchangeable, which means they cannot be substituted without the intervention of a health care provider. CSRxP is concerned that this continued dynamic will discourage further investment from biosimilar developers and ultimately reduce the number of interchangeable biologics that reach the market.

  FDA has not finalized its draft guidance entitled "Considerations in Demonstrating Interchangeability With a Reference Product," which outlines the process a biosimilar manufacturer must follow to obtain an interchangeable designation from FDA.[5] CSRxP urges the Committee to encourage FDA to finalize this guidance as soon as possible. Developers of interchangeable products need the final guidance for certainty so that they have a clear and consistent pathway for demonstrating interchangeability, fostering the ability of more of these products to enter the market.

- **Educating providers and patients on the value, safety, and efficacy of biosimilars:** CSRxP strongly agrees with HHS that, "[p]hysician and patient confidence in biosimilar and interchangeable products is critical to the increased market acceptance of these products."[6] Hence, we firmly support efforts by the FDA to educate patients, prescribers and dispensers about the value, safety, and efficacy of biosimilar and interchangeable biologic products. Along similar lines, we further recommend that the Centers for Medicare and Medicaid Services (CMS) engage with patients, prescribers, dispensers and health plans to develop and implement tools that offer education on the value, safety, and efficacy of biosimilars and interchangeable products specifically for Medicare beneficiaries enrolled in Part Band Part D. Enhanced education efforts from FDA and CMS on biosimilars and interchangeable biologics will help to generate improved comfort, acceptance and increased utilization of these more affordable products over time.

- **Improving FDA's Purple Book:** CSRxP supports improvements to FDA's Purple Book that make it a more useful tool for developers of biosimilars and interchangeable biologics, as well as patients and prescribers. Researchers have documented how the Purple Book does not include the same level of information as that available in FDA's Orange Book for small molecule drugs and have suggested that the lack of sufficient information has the potential to hinder development of biosimilars.[7] Moreover, these same researchers described how the limited information available in the Purple Book is not easily accessible and searchable online, particularly compared to the Orange Book, which can create additional challenges for biosimilar developers, patients, prescribers, dispensers, and health plans.[8] As such, CSRxP would welcome efforts by the Committee to encourage FDA to make modifications to the Purple Book so that the Purple Book for biologics maintains similar levels to—or improves upon—the information and online accessibility of the Orange Book for small molecule drugs.

Shortening the market exclusivity period for brand biologics: In addition to these policies included in the HHS Blueprint, CSRxP urges the Committee to work with the Administration on shortening the market exclusivity period for brand biologics to foster a more robust marketplace for biosimilars and interchangeable biologic products. Currently, reference biologics enjoy a 12-year market exclusivity period. Analyses suggest this amount of time may be unnecessary and prevents lower-cost alternatives from entering the market. Although providing for intellectual property protections is important to encourage innovation and the introduction of medical advancements in the U.S. market, consideration should be given to shortening the periods of exclusivity. It is important to find the right balance of incentives for pharmaceutical companies while alleviating cost pressures for consumers and pay-

[5] FDA, "Considerations in Demonstrating Interchangeability With a Reference Product," Guidance for Industry, Draft Guidance, January 2017.
[6] 83 Fed. Reg. 22696.
[7] Feldman, Robin et al., "May Your Drug Price Ever Be Green," UC Hastings Research Paper No. 256, October 29, 2017, page 89.
[8] *Ibid.,* page 90.

ers. CSRxP believes that action in this area is particularly important, as a growing proportion of the drug development pipeline is comprised of high cost biologics.

D. Promoting Value-Based Arrangements in Federal Health Programs

Currently Medicare and Medicaid purchase prescription drugs for their beneficiaries, but not generally in a manner to accommodate value-based payment models. CSRxP agrees with HHS that steps should be taken to ensure these programs can best take advantage of recent developments in value-based purchasing so that all parts of the U.S. health care system benefit from market-based negotiating efforts to lower drug prices. In particular, certain value-based arrangements such as indications-based pricing have the potential to lower drug costs and would benefit from more comparative effectiveness research on the value of various treatment options. Public and private institutions such as the Institute for Clinical and Economic Review have introduced important information into the public domain on the value of particularly high-cost efforts and should receive additional funding for this critical work.

However, CSRxP cautions that value-based arrangements remain in their infancy and oftentimes do not directly lower costs for U.S. patients and their families. More importantly, any savings that accrue from such arrangements are not expected to occur in the near-term, severely limiting their ability to provide meaningful price relief. While representing innovative and important steps in helping to lower drug costs, value-based arrangements do not address the root of the problem, namely that drug prices are too high and brand pharmaceutical companies alone are responsible the high cost of prescription drugs that American consumers and taxpayers face every day.

E. Better Management of High-Cost Medications

High-cost drugs are significant drivers in the unsustainable growth in prescription drug costs. CSRxP supports efforts to lower this unsustainable growth in spending through the extension of increased flexibility to health insurance providers in managing prescription drug costs. With increased flexibility, health plans can employ their substantial private sector experience to Medicare and lower costs particularly for high-cost medications while maintaining appropriate beneficiary access to treatments needed to get well and stay healthy.

As part of these changes, CSRxP strongly urges HHS to revisit its existing exceptions and appeals processes to ensure that they are transparent, easy-to-understand, and fair. HHS also should be willing to regularly revisit and make changes to such processes as necessary.

II. Policies That Ultimately Will Not Lower Prescription Drug Costs for Consumers and Taxpayers

HHS requests information in the Blueprint on a number of policies that it believes have potential to slow the unsustainable growth in prescription drug costs and increase the affordability of medications for consumers. While CSRxP supports many of the policies under consideration, we are concerned that certain policies identified in the Blueprint unfortunately will have the unintended consequence of increasing—not decreasing—the costs of prescription drugs for most consumers and taxpayers. While we very much share the Department's goal of lowering out-of-pocket costs for patients and reducing government spending on prescription drugs, we are very concerned that certain policies will harm consumers and further strain Federal and State health budgets. In particular, policies that would limit or prohibit rebates in Medicare Part D or establish long-term financing models for purchase of prescription drugs in Federal health care programs, will harm consumers and further strain Federal and State health budgets.

A. Limiting or Prohibiting Rebates in Medicare Part D

HHS asks in the Blueprint whether limiting or prohibiting pharmacy benefit managers (PBMs) from negotiating rebates for Part D drugs could lower costs for consumers and taxpayers would lower drug list prices. While CSRxP very much shares HHS's concern that list prices for drugs are too high and welcomes actions that will actually bring down list prices, we disagree that PBMs are responsible for high list prices. In fact, brand drug companies alone set excessively high list prices and continuously implement significant price increases. By contrast, PBMs, negotiate with drug manufacturers to lower costs for Medicare beneficiaries enrolled in Part D plans, as well as employers, unions, and government plans offering prescription drug coverage.

Indeed, a recent study found that there is no correlation between the prices set by drug companies set and the rebates they negotiate with PBMs and that drug companies increase prices regardless of rebate levels.[9] In certain instances, the study pointed to prominent cases of higher-than-average price increases in drug categories where manufacturers negotiated relatively low rebates and, conversely, prominent cases of lower-than-average price increases in drug categories where manufacturers negotiate relatively high rebates.[10]

In fact, rebates and other discounts negotiated by PBMs and Medicare Part D plans produce significant savings for the program and its beneficiaries. One recent analysis estimated that PBMs and Part D plans saved the Part D program and its beneficiaries over $20 billion in drug costs in 2017.[11] Similarly, in their most recent report, the Medicare Trustees projected significantly slower growth in Part D spending in part due to higher manufacturer rebates negotiated by PBMs.[12] Again, while CSRxP appreciates the intent of the question in looking to solve this critical problem, we disagree that PBMs are the cause. Instead, the root cause of the problem belongs to drug makers and drug makers alone, which set high list prices and routinely raise them.

B. Establishing Long-Term Financing Models for Purchase of Prescription Drugs

HHS asks in the Blueprint about the feasibility of establishing long-term financing models for the purchase of prescription drugs. Once more, while CSRxP welcomes the goal of looking for innovative methods to lower drug costs, we are concerned that implementing long-term financing models for the purchase of prescription drugs actually will make prescription drugs less—not more—affordable for consumers and taxpayers.

Indeed, long-term financing mechanisms could encourage drug makers to continue increasing their prices at excessively high rates for years, knowing that the multi-year financing would blunt the total upfront cost of the drug—all at the expense and burden of patients and Federal and State health programs that unfairly would bear such costs. Any lower drug prices generated from market competition incented in traditional insurance benefit designs would be eliminated under long-term financing models, enabling drug makers to increase prices throughout the term of the long-term financing model. Such financing mechanisms merely would function as perpetual debt payments and cost shifts, unfairly transferring the burden of prescription drug affordability from manufacturers to consumers and taxpayers; patients would have to make onerous debt payments for years while Federal and State health programs already faced with significant budgetary challenges would have to absorb even more long-term costs that they simply cannot afford in the current fiscal environment.

Moreover, long-term financing models would be very challenging to implement and operate. Drug makers likely would insist that State and Federal health programs develop the infrastructure and continuously operate a highly complex financing mechanism, increasing government administrative spending for years. Administrators of these financing programs would have to determine how to handle situations where a patient takes a drug for a meaningful period time, burdened with significant continuous costs, only to find out during the course of treatment that the drug has not been effective. These patients should not have to bear those costs, although it is unclear how a long-term financing model would handle such unfortunate situations. These represent just a few of the many complexities and operational difficulties long-term financing models present.

Insurers currently manage many costly diseases and conditions such as cancer, traumatic brain injury, and organ transplant, belying the notion that traditional insurance cannot handle the management of expensive treatments today. As such, CSRxP firmly believes that using traditional insurance rather than long-term financing models will better address prescription drug pricing problems for consumers and taxpayers. While we appreciate thoughtful and creative approaches to tackling

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[9] Visante, "No Correlation Between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories," April 2017.

[10] *Ibid.*

[11] Milliman, "Value of Direct and Indirect Remuneration: Impact on Part D Prescription Drug Plan (PDP) Stakeholders," July 2017.

[12] The Board of Trustees, Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds, "2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds," page 112.

the challenging problem of prescription drug pricing, long-term financing models are not the solution as they simply serve to prop up an unsustainable pricing market.

III. Additional Policies to Slow the Unsustainable Growth in Prescription Drug Costs

Brand biopharmaceutical companies employ a variety of anti-competitive tactics to delay competition and keep lower cost generic drugs and biosimilars from entering the market. These inappropriate and unfair abuses effectively extend the period of market exclusivity for brand products and, consequently, cause consumers to continue experiencing needlessly high out-of-pocket expenses and Federal and State governments to engage in unnecessary spending on prescription drugs. To help combat these anti-competitive tactics by brand drug makers, CSRxP urges the Committee and the Administration to work together to adopt the bipartisan, market-based solutions described below, which inject more competition into the market particularly after brand products already have benefitted from market exclusivity post FDA approval.

A. Enhancing Oversight of "Pay-for-Delay" Settlements

Brand and generic drug makers enter into patent dispute settlements—often referred to as "pay-for-delay" settlements—that result in a generic company agreeing to refrain from marketing its products for a specific period of time in return for compensation (often undisclosed) from the branded company. The Federal Trade Commission (FTC) has cited these arrangements as anti-competitive and estimates that they cost consumers and taxpayers $3.5 billion in higher drug costs every year.[13] More recently, these settlements unfortunately have extended to biologics, delaying the entry of less costly biosimilars into the market. For example, the top-selling product in the world, Humira, with global sales exceeding $18 billion in 2017 and a more than doubling of its price over the past 5 years, will not face biosimilar competition until 2023 due to a settlement agreed to by the brand and biosimilar manufacturer of the product.[14, 15, 16]

"Pay-for-delay" settlements hurt consumers who need to have lower out-of-pocket costs, especially when taking high-cost specialty medications like Humira, as well as taxpayers who effectively have to foot the bill of delayed competition. As such, CSRxP urges robust oversight and opposition to settlements that are deemed anti-competitive and prevent generics and biosimilars from entering the market in a timely manner.

B. Targeting Exclusivity Protections to Truly Innovative Products

Currently, pharmaceutical manufacturers can extend patent and market exclusivity protections by seeking approval for a "new" product that is essentially the same as the original product, such as extended release formulations or combination therapies that simply combine two existing drugs into one pill. These anti-competitive tactics—often referred to as "evergreening" or "product hopping"—inhibit entry of generic drugs into the market. For example, a recent analysis suggested that anti-competitive drug reformulations potentially can result in up to $2 billion in losses per anti-competitive reformulation for consumers each year.[17] Prohibiting these anti-competitive "evergreening" and "product hopping" tactics by brand drug makers will foster increased availability of generic drugs, resulting in lower costs for consumers and taxpayers. Therefore, CSRxP urges the appropriate federal agencies to closely monitor and increase scrutiny of these schemes and prosecute if they are found to be in violation of antitrust laws.

IV. Conclusion

In conclusion, CSRxP appreciates the leadership from the Committee on the critically important issue of prescription drug pricing and thanks the Committee for the opportunity to submit testimony for the record on this issue that impacts consumers and taxpayers every day. CSRxP looks forward to continued work with the Com-

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[13] FTC, "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions," January 2010.

[14] AbbVie, "AbbVie Reports Full-Year and Fourth-Quarter 2017 Financial Results," January 26, 2018.

[15] Reuters, "AbbVie. Amgen settlement sets Humira U.S. biosimilar launch for 2023," September 28, 2017.

[16] The Center for Biosimilars, "Latest Humira Price Increase Could Add $1 Billion to U.S. Healthcare System in 2018," January 5, 2018.

[17] Shadowen, Steve et al., "Anticompetitive Product Changes in the Pharmaceutical Industry," *Rutgers Law Journal,* Vol. 41, No. 1–2, Fall/Winter 2009, page 78.

mittee on developing and implementing market-based policies that promote competition, transparency, and value to make prescription drugs more affordable for all American patients and their families while at the same time maintaining access to the innovative treatments that can improve health outcomes and save lives.

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Statement of Michael G. Bindner

Chairman Hatch and Ranking Member Wyden, thank you for the opportunity to submit these comments for the record to the Committee on Finance.

As you may recall, we have in the past written urging a combination of catastrophic insurance, health savings accounts (Archer) and medical lines of credit, which is a bit more liquid version of a flexible spending account, with all accessed by one card with costs allocated based on account balances and income levels. Poor people would have minimum or even no copays, but would always have credit access. As income rises, so would copays and available balances, as well as catastrophic deductibles.

This plan would offer little incentive for the poor to shop for cheaper drugs; however, wealthier patients could be made to feel the pain of drug prices a bit more, but only if they were denied comprehensive insurance. Good luck passing that; it may be what cost Senator McCain the White House in 2008. Additionally, the Archer accounts and lines of credit are designed to assure universal access to care and drugs with little pain. It only helps the well who can redirect funds to asset accumulation (thus causing asset inflation, speaking of 2008).

Single Payer and negotiation by government payers, state or federal price controls or taxing away excess profits would all control prices, which are monopolistically high. Unless an economist is far out on the rightward fringe, there is no doubt about the equity of stopping monopoly prices. The only question is how.

While some favor restricting patent rights, I would argue in favor of having every drug approval disclose all government-supported research used to develop the product, giving the sponsoring agency the right to both share in the profits and have a say in the pricing. This both keeps the research dollars flowing and limits cost.

The last possibility is through our proposed Net Business Receipts Tax/Subtraction Value-Added Tax. It would replace corporate income taxes and proprietary and pass-through taxes and treat all business income the same. It would provide for the health insurance exclusion or fund single payer insurance. Companies who hire their own doctors and pharmacists and buy their own drugs would get a tax exclusion from single payer (third party insurance would be discouraged), and would negotiate with drug makers for lower prices, although this would leave small firms at a distinct disadvantage and would discourage such practices as franchising and 1099 employment. Still, on the whole, it would decrease cost while not discouraging innovation.

Short of that, an NBRT subsidized Public Option would allow sicker, poorer and older people to enroll for lower rates, allowing some measure of exclusion to private insurers and therefore lower costs. Drug prices would also decrease if the Public Option is allowed to negotiate with drug companies. Of course, the profit motive will ultimately make the patient exclusion pool grow until private insurance would not be justified, leading again to Single Payer if the race to cut customers leads to no one left in private insurance who is actually sick.

Thank you for the opportunity to address the committee. We are, of course, available for direct testimony or to answer questions by members and staff.

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Chairman Hatch and Ranking Member Wyden, and Members of the Committee:

Thank you for conducting this hearing on prescription drug affordability, innovation, and the President's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs." In this statement, NCPA will offer support and suggestions on a number of policy considerations outlined in the President's Blueprint. NCPA represents America's community pharmacists, including the owners of more than 22,000 independent community pharmacies. Together they represent an $80 billion health care marketplace and employ more than 250,000 individuals on a full or part-time basis. Independent community pharmacies are typically located in traditionally underserved rural and urban communities, providing critical access to residents of these communities.

Importantly, community pharmacists are health care providers on the front-lines who regularly talk to patients about their concerns with prescription drug costs and work diligently to address these concerns. NCPA addresses a number of these concerns below in the hopes that community pharmacists can add meaningful solutions for patients, especially those seniors in the Medicare Part D program.

Changes to the application and usage of manufacturer rebates and pharmacy DIR

NCPA recognizes that this administration, through the President's Budget or recent request for information pending at HHS, largely has focused on changes to the application and usage of manufacturer rebates. However, rebates are not the only concession that leads to inflated drug prices and higher out-of-pocket costs for seniors. In fact, while the application of rebates is an important aspect to the drug pricing conversation, the out-of-pocket costs conversation is incomplete without specific discussion regarding all direct and indirect remuneration (DIR), including all pharmacy price concessions in the Part D program and how PBMs leverage these fees to pad their pockets at the expense of patients, the government, and small businesses.

DIR fees imposed on pharmacies participating in Medicare Part D networks by plan sponsors and their PBMs have exploded in recent years.[1] The treatment of these pharmacy price concessions as DIR rather than as reductions in the "negotiated price" of a drug at the point of sale has had a crippling impact on patients, the government, and community pharmacies. The retroactive nature of these fees means beneficiaries face higher cost-sharing for drugs and are accelerated into the coverage gap or "donut hole" phase of their benefit.

What's more, beneficiaries reach the catastrophic phase of the benefit, for which CMS incurs approximately eighty percent of the cost. Costs to the government have surged as liability for Part D costs is increasingly being shifted from Part D plan sponsors to CMS. Finally, all retroactive pharmacy DIR fees are taken back from community pharmacies months later rather than deducted from claims on a real-time basis. This reimbursement uncertainty makes it extremely difficult for community pharmacists to operate their small businesses.

As this administration has discussed the possibility of prohibiting PBMs from using rebates in contracts with manufacturers, NCPA argues that the same policy should be applied to pharmacy price concessions. Therefore, *NCPA requests that the administration or Congress eliminate pharmacy DIR in the Medicare Part D program.*

If this administration or Congress does not eliminate all DIR including pharmacy price concessions, *the administration or Congress should prohibit all retroactive pharmacy DIR fees leveraged against pharmacies,* as policymakers have considered this policy move several times over the past few years. Just this spring, CMS collected information on what it could mean if DIR, including pharmacy price concessions, were included in the negotiated price at point of sale. CMS has yet to do anything with this information, but it is clear that the need for change is sorely needed.

Finally, this administration or Congress should seek to limit and control the way in which PBMs and plan sponsors impose arbitrary and inconsistent performance-based standards and incentive payment schemes on community pharmacies. While not all pharmacy DIR is performance based, the proliferation of pharmacy DIR is now intricately tied to performance-based standards. PBMs and plan sponsors have argued they should have the ability to create programs that are accounted for as DIR to reward pharmacies for achieving contractual, performance-based metrics. However, these retroactive fees are based on a payment methodology that withholds a certain amount with the opportunity for the pharmacy to either "earn back" or

[1] The HHS Office of Inspector General has noted that these catastrophic costs that are driven by retroactive pharmacy DIR fees have tripled in recent years—from $10 billion in 2010 to $33 billion in 2015.

have the retroactive fees decreased based on achieving certain arbitrary quality measures.

Therefore, NCPA requests that the administration or Congress define pharmacy quality within the Medicare Part D program and hold plans accountable for determining performance-based payments. Performance-based payments should be based on standardized, achievable, and proven criteria that measure pharmacy performance, as opposed to criteria that focus on measuring plan performance or criteria which pharmacies have little to no opportunity to influence.

Fiduciary duty for Pharmacy Benefit Managers

NCPA continues to urge policymakers to require PBMs to have a fiduciary duty to the entity for whom they manage pharmaceutical benefits, a move that would shed light on opaque PBM practices, including the PBM's incentive to charge the plan more than the pharmacy is reimbursed and keep the difference as profit. This would force PBMs to put patients' financial interests before their own and would eliminate the loophole of PBMs leveraging their clients' purchasing power.

By way of background, PBMs serve as the "middleman" in all prescription drug transactions in the United States. They are able to leverage the number of beneficiaries in a particular plan in order to negotiate lucrative rebates from pharmaceutical manufacturers. They also formulate pharmacy provider networks that will supply or dispense these drugs to the plans' beneficiaries. What most consumers and plan sponsors alike do not know is that PBMs extract "spread" profits from both these activities.

The amount that the PBM pays the pharmacy for dispensing the drug to the plan beneficiary is rarely the same amount that the PBM "charges" the plan for the same drug. Typically, the PBM "marks up" the cost of the drug, charging the plan more than the pharmacy is reimbursed, keeping the difference as profit for the PBM. It is precisely these hidden spread amounts that are one of many opaque PBM practices that need to be disclosed. Fiduciary status for PBMs would force PBMs to put patients' financial interests before their own.

Federal preemption of contracted pharmacy gag clause laws

NCPA supports this administration's efforts to abolish gag clauses in contracts. The RFI calls for immediate action to prohibit "gag clauses" in Part D contracts. Under some contracts, pharmacists have been unable to inform patients of lower-cost alternatives due to overbroad confidentiality clauses and the pharmacist's inability to disclose the negotiated price to patients. NCPA supports the administration's successful efforts to abolish all pharmacy gag clauses to the extent such clauses were present in Medicare Part D contracts, including CMS' recent letters sent to plan sponsors that state gag clauses in contracts are unacceptable.

However, NCPA remains concerned about the number and scope of other provisions in one-sided PBM contracts that pharmacists are forced to sign, including multiple provisions that in one way or the other prohibit the free flow of information.

Those include overly broad confidentiality provisions, non-disparagement clauses, and requirements that the pharmacy charge insured patients what the PBM tells them to charge. NCPA urges policymakers to examine all contract provisions that prevent the pharmacist from discussing drug costs with patients.

Conclusion

In conclusion, prescription drug prices continue to grow at an alarming rate. There are many factors in the pharmaceutical supply chain and delivery system that may contribute to this growth, including pharmacy benefit manager "middlemen." NCPA stands ready to work with the administration and Congress to implement policies that will lower drug prices at the pharmacy counter.

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