AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 114–529

EXAMINING THE OPIOID EPIDEMIC: CHALLENGES AND OPPORTUNITIES

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

FEBRUARY 23, 2016

Printed for the use of the Committee on Finance

U.S. GOVERNMENT PUBLISHING OFFICE

23–291—PDF WASHINGTON : 2017

For sale by the Superintendent of Documents, U.S. Government Publishing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON FINANCE

ORRIN G. HATCH, Utah, *Chairman*

CHUCK GRASSLEY, Iowa
MIKE CRAPO, Idaho
PAT ROBERTS, Kansas
MICHAEL B. ENZI, Wyoming
JOHN CORNYN, Texas
JOHN THUNE, South Dakota
RICHARD BURR, North Carolina
JOHNNY ISAKSON, Georgia
ROB PORTMAN, Ohio
PATRICK J. TOOMEY, Pennsylvania
DANIEL COATS, Indiana
DEAN HELLER, Nevada
TIM SCOTT, South Carolina

RON WYDEN, Oregon
CHARLES E. SCHUMER, New York
DEBBIE STABENOW, Michigan
MARIA CANTWELL, Washington
BILL NELSON, Florida
ROBERT MENENDEZ, New Jersey
THOMAS R. CARPER, Delaware
BENJAMIN L. CARDIN, Maryland
SHERROD BROWN, Ohio
MICHAEL F. BENNET, Colorado
ROBERT P. CASEY, Jr., Pennsylvania
MARK R. WARNER, Virginia

CHRIS CAMPBELL, *Staff Director*
JOSHUA SHEINKMAN, *Democratic Staff Director*

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

WITNESSES

Coukell, Allan, senior director, health programs, The Pew Charitable Trusts, Washington, DC	7
Young, Nancy K., Ph.D., director, Children and Family Futures, Inc., Lake Forest, CA	8
Hart, David, Assistant Attorney-in-Charge, Health Fraud Unit/Consumer Protection Section, Oregon Department of Justice, Salem, OR	10

ALPHABETICAL LISTING AND APPENDIX MATERIAL

Casey, Hon. Robert P., Jr.:	
Prepared statement	35
Coukell, Allan:	
Testimony	7
Prepared statement	36
Responses to questions from committee members	39
Hart, David:	
Testimony	10
Prepared statement	41
Response to a question from Senator Bennet	43
Hatch, Hon. Orrin G.:	
Opening statement	1
Prepared statement	44
Toomey, Hon. Patrick J.:	
Letters submitted for the record	45
Wyden, Hon. Ron:	
Opening statement	4
Prepared statement	55
Letters submitted for the record	57
Young, Nancy K., Ph.D.:	
Testimony	8
Prepared statement	63
Responses to questions from committee members	74

COMMUNICATIONS

American Academy of Pain Management et al.	93
American Academy of PAs (AAPA)	97
American Pharmacists Association (APhA)	101
City of Baltimore, MD	104
DeWine, Mike	111
First Focus State Policy and Advocacy Reform Center (SPARC)	112
National Association of Chain Drug Stores (NACDS)	114
National Community Pharmacists Association (NCPA)	117

EXAMINING THE OPIOID EPIDEMIC: CHALLENGES AND OPPORTUNITIES

TUESDAY, FEBRUARY 23, 2016

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

The hearing was convened, pursuant to notice, at 10:10 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Orrin G. Hatch (chairman of the committee) presiding.

Present: Senators Grassley, Crapo, Thune, Burr, Portman, Toomey, Coats, Scott, Wyden, Schumer, Stabenow, Cantwell, Nelson, Menendez, Carper, Brown, and Bennet.

Also present: Republican Staff: Chris Armstrong, Deputy Chief Oversight Counsel; Brett Baker, Health Policy Advisor; Chris Campbell, Staff Director; and Becky Shipp, Health Policy Advisor. Democratic Staff: David Berick, Chief Investigator; Laura Berntsen, Senior Advisor for Health and Human Services; Anne Dwyer, Health-care Counsel; Michael Evans, General Counsel; Elizabeth Jurinka, Chief Health Advisor; Matt Kazan, Health Policy Advisor; and Joshua Sheinkman, Staff Director.

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

The CHAIRMAN. The committee will come to order. Today, we are here to discuss the very important issue of opioid abuse.

Opioids are a powerful class of drugs prescribed to treat severe pain. When used appropriately, these drugs provide much-needed relief to patients after a surgical procedure or during treatment for cancer. Unfortunately, opioids also have qualities that make them addictive and prone to abuse. The goal of today's hearing is to help us gain a better understanding of why opioid use has risen dramatically in the past 15 years and how we can best curtail abuse.

Put simply, opioid abuse has become an epidemic and a significant public health problem. While it puts serious strains on our health-care system, including Medicare and other Federal programs, the most devastating consequence of opioid abuse is the human impact. Opioid abuse takes a major toll on families and children, often persisting for generations.

The statistics are staggering. Opioids are prescribed in such quantities that every adult in the United States could have a month's supply. Approximately 7,000 people show up in an emergency room each day for treatment of problems associated with prescription opioid abuse. One opioid-related death takes place in our country almost every 30 minutes. My home State of Utah has been

hard hit by this epidemic. In 2014 alone, 289 Utahans died due to opioid abuse, which is more than half of all drug overdose-related deaths in the State. The problem is even worse in other States. I am sure many of my colleagues will not only have numbers to share regarding their States, but have stories about individuals as well.

The good news is that there is wide recognition of the problem and shared interest in trying to find solutions. A few weeks ago, the Senate Judiciary Committee unanimously reported the Comprehensive Addiction and Recovery Act legislation sponsored by Senator Portman. I think it is a good bill. I was pleased to vote for it in committee and hope the full Senate will pass it swiftly and without unnecessary delay. I compliment Senator Portman for his work on that, and others with him.

Today's hearing will focus on another good bill, one that is in the Finance Committee's jurisdiction. As I mentioned, Medicare is not immune from the costs of opioid abuse. The Government Accountability Office, the Medicare Payment Advisory Commission, and others have identified it as a problem. Though only a relatively small number of beneficiaries are at risk, we owe it to those individuals, their families, and the Medicare program to do all we can to address this problem.

Senators Toomey and Portman have a very thoughtful bipartisan bill with Senators Casey and Brown that would provide Medicare with an important tool in the fight against opioid abuse. The bill would allow Medicare Part D prescription drug plans to work with at-risk beneficiaries to identify one physician to prescribe opioids and one pharmacy to fill all the opioid prescriptions. Having opioids prescribed by one physician instead of multiple doctors will result in better patient care and reduced abuse. It will also make it more likely that a beneficiary with a problem gets the help they need. Nearly all Medicaid programs and private payers have such a prescription drug review and restriction or "lock-in" program. I look forward to hearing more today about the success of these programs in Medicaid and how the Toomey-Portman bill would have a similar impact in Medicare.

The Toomey-Portman bill has bipartisan support on the committee, with both Senators Brown and Casey acting as strong proponents. Establishing a lock-in program in Medicare is also supported by President Obama, as it was first proposed in the administration's budget proposal. I applaud Senators Toomey and Portman for their leadership on this legislation, and I hope we can move it very soon.

Of course, the impact of the opioid epidemic stretches far beyond our health-care system, touching on virtually all parts of the social safety net. Today, in addition to discussing the impact on the health-care system, we will hear more about the implications of these substance abuse crises for our child welfare system.

The current opioid epidemic is just the latest manifestation of an ongoing problem in child welfare. Whether it be the crack cocaine epidemic of the 1980s, the methamphetamine epidemic that has plagued many rural areas, or the current opioid crisis, we have seen time and again that the child welfare system is ill-equipped to deal with families struggling with substance abuse. Instead of

finding ways to get families affected by addiction the help and support they need to get and stay sober, the majority of Federal dollars in the child welfare system are spent on removing children from their homes and placing them into foster care, which most have acknowledged is the least-effective and most-expensive outcome.

Children who are raised by the State in foster care face increased risks of substance abuse, homelessness, pregnancy, and other negative outcomes, both while they are in the system and when they transition out as adults. In cases of untreated addiction, the cycle of addiction can persist for generations.

Senator Wyden and I have been working together on bipartisan legislation that would provide the States the flexibility to use Federal child welfare funds to address issues of substance abuse and other risk factors. We are also talking with our colleagues over in the House, and I hope that we will be able to get to a bipartisan, bicameral agreement on a path forward. Children and families are relying on us to take this important step.

Let me conclude by saying that the opioid epidemic is a complex problem that needs a multifaceted solution. We will discuss at least opportunities to make a difference here today—the Toomey-Portman bill dealing with Medicare and our efforts with regard to child welfare.

Of course, these are not the only ideas out there. If there are any others, I would be happy to hear about them and consider any ideas that might be within the Finance Committee's jurisdiction, so long as they are constructive and do not take an overly simplistic view of this serious and complicated problem.

Before I conclude, I want to take a moment and address some concerns that have been shared with the press about the scope of this hearing and the composition of today's panel of witnesses. I have, in keeping with the traditions of this committee, always worked with the ranking member to select witnesses in order to ensure a balanced panel in each committee hearing. Today's hearing is no different. Both Senator Wyden and I agreed and signed off on the witnesses for this panel. I will note, for example, that we have a high-ranking official from the ranking member's home State here with us today.

So it is difficult for me to imagine why anyone would be expressing disappointment over the balance of the witnesses, particularly at this point. We have a very distinguished group of experts before us today, one that I think will shed light on a wide variety of issues.

So I hope that, rather than spending time on lamenting who is and who is not on the panel, my colleagues will focus on the witnesses before us, as well as their own thoughts on how to best address the opioid epidemic.

With that, I would like to thank these witnesses for being here today to discuss this important topic.

I will have to leave shortly to go over and introduce my Governor at the Judiciary Committee hearing, but, at this time, I will turn to Senator Wyden for his opening remarks.

[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. I share your view that this opioid issue is another one where this committee can come together and work in a bipartisan way, and I look forward to working with you in that regard. As the committee that is required to pay for the most important health programs in the Nation, the Finance Committee must step up and do its part to address the opioid crisis.

In the coming years, Medicare and Medicaid are expected to account for over a third of substance abuse-related spending. That amounts to billions and billions of dollars each year. Any solution that is going to stem this tide has to include the Finance Committee and our bedrock health-care programs.

Americans today are paying for a distorted set of priorities. Americans are getting hooked on opioids, there is not enough treatment, and enforcement is falling short. That sounds like a trifecta of misplaced priorities to me, and the Finance Committee has the opportunity, working in a bipartisan way, to develop fresh policies to start righting the ship.

As one listens to the current debate on opioids, there is a sense that somehow policymakers have to line up and choose one of two solutions. One approach is tough enforcement, which means cracking down on pill mills, fraudsters bilking Medicare and Medicaid with unneeded prescriptions, and unscrupulous abusers doctor-shopping for the next bottle of pills. Others want to focus on more social services. My own view is what is needed is a fresh approach that focuses on three areas: better prevention, better treatment, and better and tougher enforcement. Real success is going to require that all three work in tandem.

When it comes to preventing addiction, any discussion has to include how these drugs are prescribed in the first place. In Oregon last week, I discussed with my constituents what I call the prescription pendulum. Where doctors were once criticized for not treating pain aggressively enough, today they are being criticized for prescribing too many opioids to manage pain. So one of our challenges is to have policies that start getting that balance right.

The Centers for Disease Control and Prevention is trying to break new ground with their guidelines for prescribing opioids. Along with better prescribing practices, there need to be more responsible marketing practices by opioid manufacturers.

I am very pleased that we are joined today by David Hart. He is with the Oregon Attorney General's office. He has background in both health care and law enforcement, and I think we are all going to benefit from Mr. Hart's considerable experience in this area.

I am also very troubled about the influence the manufacturers have on medical prescribing practices. I have sent an inquiry to Secretary Burwell to ensure that any potential conflicts of interest as a result of funding received from drug manufacturers have been properly disclosed for members of government panels who are evaluating the Centers for Disease Control guidelines. Doctors ought to have the best information on prescribing these powerful drugs without undue influence from the companies that manufacture them.

In my view, a key piece of the puzzle has to be more prompt and more effective treatment of those who are dealing with an addiction to opioids. A prerequisite for any lasting solution needs to include improving access to addiction treatment and mental health services, and that is especially important for rural and underserved communities. It is no coincidence these areas have some of the highest rates of abuse and overdose in the country.

Mental health and treatment for addiction have also gotten short shrift for far too long, and it is time for changes here as well. For example, the Finance Committee could be taking a look at what is called the IMD exclusion, an out-of-date policy from the 1960s that says services, like rehab or some emergency mental health stays in an inpatient setting, cannot be covered by Medicaid. That is a big policy change. I believe it ought to happen, but I also think we are going to have to be acutely aware of the vast sums that would be needed to pay for these services, and that will be a unique challenge.

So the Congress has some tough choices to make if we are really going to solve this crisis. If prevention and treatment are not addressed up front, the costs will be even higher: pregnant mothers giving birth to opioid-dependent babies, EMTs and emergency rooms dealing with overdose calls every night, county jails taking the place of needed substance abuse treatment, able-bodied adults in the streets instead of working in a family-wage job. America's tax dollars should be spent more wisely, and the Finance Committee has an opportunity to find the right mix.

I am going to close by saying that I believe we already have an opportunity in this committee, in a bipartisan way, to start the reforms that are needed in this area. Our committee has been working for some time on a bipartisan proposal to get parents and kin care providers the kind of help they need to keep children safely out of foster care when addiction strikes a family member. A parent's drug addiction is becoming a growing reason for removing children from their homes and placing them in foster care.

A recent Reuter's investigation found, on average, a baby is born opioid-dependent every 19 minutes. Using hospital records, the reporters found that there were more than 27,000 drug-dependent babies born in 2013. Many of these babies are going to enter the foster care system. In fact, as the committee will hear from Dr. Young, infants made up the largest group of children placed in out-of-home care in 2014, and growth in the share of infants entering care is a trend that has been increasing consistently over the past several years. Protecting these babies and their siblings is, in my view, going to require getting better help and treatment for the moms and dads who are suffering these afflictions.

The chairman and I have engaged in a very active effort to address these daunting challenges. We have been calling it the Family First Act, and it would help prevent unnecessary foster care stays through programs like evidence-based substance abuse treatment, reducing unnecessary congregate care stays, and putting in place stronger protections so that kids in foster care are safe. It is about making sure the system works better for the children.

I thank Chairman Hatch and all my colleagues on both sides of the aisle, because I hope we can pursue these reforms soon.

I spent last week getting to about every corner of my State, from Medford to Eugene to Portland; I was in eastern Oregon and central Oregon. The message whenever anybody asked about opioids was clear: this epidemic is carving a path of destruction through communities in every corner of America.

Oregon has the dubious distinction of ranking fourth worst for abuse and misuse of opioids in the Nation. In my home State, citizens are not going to accept being fourth worst. I know from talking with my colleagues here—Republicans, Democrats—that every State is dealing with this crisis.

Finally, one story of the many I heard was especially devastating, and it illustrates how dramatically this opioid crisis has unfolded across the country. I spoke with a parent who told me about high school athletes struggling with addiction to these medicines.

When I went to school on a basketball scholarship, dreaming of playing in the NBA, there was never any talk in the locker room about opioids. Now, the next generation of young people are getting swept up in a crisis beyond their control.

So I thank all of our witnesses. I think we are going to have a good panel. There are colleagues on the Democratic side, there are colleagues on the Republican side who want to work constructively on these issues.

Finally, special thanks to David Hart. That is a long trek to come and testify. But he has expertise on the health-care side and on the enforcement side. We welcome all three.

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

Senator WYDEN [presiding]. Chairman Hatch is going to have to be away for a few minutes. He asked me to introduce all of our witnesses.

Our first witness will be Allan Coukell. He is with Pew Charitable Trusts. He is the senior director of health programs at Pew, where they do very good work on lots of issues. He focuses on prescription drugs and medical device issues. Prior to joining Pew, he practiced clinical pharmacy in the area of oncology and served as a writer and editor for medical journals and media outlets.

Second, we are happy to have Dr. Nancy Young. She is the director of Children and Family Futures, an organization she founded in 1996. This organization is focused on improving the well-being of those impacted by substance abuse and mental health disorders. While she has been at the organization, she also helped to guide the efforts of government and private entities to achieve optimal outcomes from child welfare programs.

As I indicated, our third witness will be Mr. David Hart. He is an Assistant Attorney General in the Oregon Department of Justice. He has been the lead attorney on health-care fraud and consumer protection issues in our State, focused on marketing practices related to drugs and devices. As I indicated, prior to his work at the Department of Justice, he has been a physical therapist in a variety of patient settings, including hospitals and hospice.

So we are pleased to have all three of you here. We will make your prepared statements a part of the record in their entirety,

and, if you could take 5 minutes or so and summarize your principal views, that would be very helpful.

Welcome.

STATEMENT OF ALLAN COUKELL, SENIOR DIRECTOR, HEALTH PROGRAMS, THE PEW CHARITABLE TRUSTS, WASHINGTON, DC

Mr. COUKELL. Ranking Member Wyden, thank you and Chairman Hatch and the committee for holding this hearing on the opioid epidemic. My name is Allan Coukell. I am a pharmacist and director of health programs at The Pew Charitable Trusts. We are an independent, nonprofit research and policy organization.

We focus on prescription drug abuse, because it is one of the pressing public health problems of our time. You have already outlined some statistics, and suffice it to say that nearly all of us now know someone who has been affected, urban or rural, young or old; 19,000 deaths a year, 50 a day, and that does not even begin to tell the whole story of the toll on people's lives and jobs and families and on the fabric of our communities.

And yet, these deaths and addiction are preventable. It will take a multifaceted approach, and today I will focus on one policy change in Medicare that will improve patient care and reduce the chance of overdose. The approach I am talking about is known as a patient review and restriction program, or PRR. These programs are used in nearly every Medicaid program and by commercial drug plans, but this very same tool is currently prohibited in Medicare.

Fixing that is straightforward. It can be done now by passing S. 1913, the Stopping Medication Abuse and Protecting Seniors Act of 2015. Pew supports this legislation, and I would like to thank Senators Toomey and Brown and Portman and Kaine for their leadership as original cosponsors and the many additional bipartisan cosponsors on this committee.

So what is a PRR program and how would it work? Basically, a PRR identifies people at risk of addiction or overdose and ensures that they get coordinated care through one doctor or one pharmacy. The patient is initially identified using specific criteria, things like multiple prescriptions from multiple doctors in a single month. Other risks include duplicate prescriptions, emergency department visits, and so on.

When these initial criteria are found, a pharmacist or a nurse looks at the patient's profile, and if the high use of opioids is warranted—the patient is in hospice or getting treated for cancer, for example—that is the end of the process. But if there is concern that the patient is doctor-shopping and at risk for overdose, the plan contacts them and works with them to identify just one physician or one pharmacist who will provide the pain medication that they need. That improves care coordination and reduces the risk of multiple prescribers not knowing what else the patient is on.

As I mentioned, these programs are already in widespread use. In Tennessee, for example, individuals who enrolled in the Medicaid PRR had about a 50-percent decrease in controlled substance prescriptions. Minnesota achieved an estimated cost savings of $1.2 million for 245 patients based on reduced prescriptions, but also fewer clinic visits and emergency department visits.

The CDC convened an expert panel that concluded these programs have the potential to save lives and lower health-care costs by reducing opioid use to safer levels. S. 1913 would allow Medicare Part D plans to operate PRRs, something they cannot now do under current law.

We know there are substantial numbers of Medicare patients at risk. A CMS analysis identified about 225,000 beneficiaries who got potentially unsafe doses of opioids for at least 90 consecutive days. A GAO study found 170,000 Part D beneficiaries who obtained the drugs from at least five pharmacies and up to 87 physicians a year.

Pew has worked with a range of stakeholders to develop key principals that should be in any PRR legislation, elements like an appeal process for beneficiaries and patient input into the selection of prescribers and pharmacies to ensure reasonable access. S. 1913 contains these provisions, and there is substantial support to advance the legislation.

A similar proposal has already passed the House with broad bipartisan support. This policy was included in the administration's fiscal year 2016 and 2017 budget requests. The HHS Inspector General has included PRRs as one of 25 quality improvements that should be prioritized and implemented.

So let me conclude by quoting Andy Slavitt, the Acting CMS Administrator. "A PRR proposal for Medicare," he said, "makes every bit of sense in the world and would be very helpful in really taking a practical measure to stem abuse."

I thank you for your work on this important problem, and I welcome your questions.

[The prepared statement of Mr. Coukell appears in the appendix.]

Senator WYDEN. Thank you very much, Mr. Coukell.

Dr. Young?

STATEMENT OF NANCY K. YOUNG, Ph.D., DIRECTOR, CHILDREN AND FAMILY FUTURES, INC., LAKE FOREST, CA

Dr. YOUNG. Chairman Hatch, Ranking Member Wyden, members of the Finance Committee, thank you for conducting this hearing about our Nation's opioid epidemic and specifically your interest in the effects of parents with opioid use disorders on the child welfare system.

There are three points I would like to cover today—they are more fully described in my written statement—first, what the data says; what we know works; and opportunities for systems reform to improve outcomes to reduce our longer-term costs.

For data, I wish I could tell you that there is clear data documenting the effect of parental opioid use disorders on child welfare services. Unfortunately, we have been here before in both the cocaine and the methamphetamine epidemics, and we still do not have reliable data in child welfare systems to monitor alcohol and drug use among parents.

I have provided State-specific data that comes from the AFCARS data set in my written statement. But there are a few things we do know. After a high point in 1999 of over 567,000 children in care, there were about 15 years of decreasing numbers of kids. That trend ended in 2013, and we are now seeing upticks in the

numbers. One of the troubling statistics underlying that trend is the number of babies: 45,000 infants were placed in protective custody in 2013–2014, twice as many as any other age group.

Of course, we then wanted to see, with the States with the high rates of babies coming into care, if they were also the States with high rates of neonatal abstinence syndrome, or NAS. Rates of NAS vary a great deal across the country. Mid-south central States—Kentucky, Tennessee, Mississippi, and Alabama—have the highest rates of NAS, with New England coming in second. These are regions that do also have higher rates of infants coming into care, although the data does not display a consistent pattern in each of the regions across the country. Over the past 5 years, however, drug abuse by a parent as a reason for the child's placement increased by nearly 20 percent, more than any other factor.

My second point is that there is, in fact, some good news. Federal investments during the methamphetamine epidemic and regional partnership grants—we call them RPGs—and OJJDP's and SAMHSA's investment in family drug courts have paid off with increasing our knowledge about how to improve child safety and family outcomes. There are variations from place to place about what these programs look like, but there are seven common practice strategies that communities adopt when they have flexible grant dollars. I detailed those in my written statement.

In the first round of regional partnership grants, over 25,000 children and almost 18,000 parents were served. Five key outcomes emerged. In comparison to standard services, RPG families achieved what we now refer to as the five Rs: recovery, remaining safely at home, reunifying at higher rates, having substantially lower reoccurrence of maltreatment, and having substantially lower rates of reentry to foster care.

These programs were implemented in a different drug epidemic than we are facing today, but they are important lessons for us. Timeliness of treatment access improves child welfare outcomes, and we know for these parents with opioid use disorders, having access to medications is critical.

Yet, I was in Ohio for 3 days last week, in a small county at the border with Kentucky. The child welfare administrator told me that it takes about a month for a family drug court to get a parent into medication treatment. The State official told me that that is when there is a family drug court that is navigating that for a parent. Normally, it is about 3 to 4 months to get into medication treatment.

So this raises some real questions about reasonable efforts. That is the legal standard we ask child welfare to meet, and in Native American communities, we demand that child welfare make active efforts to prevent removing a child and to reunify. When a parent has a life-threatening brain disease, are wait lists of 30 days, 60 days, 90 days reasonable?

There are three critical steps that I see. States are submitting very weak data in most cases, and we cannot solve what we cannot count. States need to be held accountable for counting these children and families better so we can protect them and getting willing parents through the services they need.

It is true that we are in the midst of the largest potential expansion of treatment funding in history through the Parity Act and Medicaid expansion in many States, but constraints on those resources to meet high demand for services mean that very little of that potential is being focused on these children and families.

I was reminded yesterday that in about 1995, I sat with a colleague and made a list of the communities around the country that had put programs in place to address this issue. There were 12 places on that list. The good news is that today there are hundreds, but continuing the idea that pilot programs and demonstrations are needed to show how to improve outcomes for these families, I believe, is misguided.

Every generation of 20-somethings, at least in my professional career, has been impacted by another drug of abuse. It is time that we move from pilots and demonstrations into State system reforms. Solving today's epidemic, as critical as that is, needs to provide the longer-term strategy to support States and communities so that children can stay safely at home and so we prevent future drug epidemics from having such a dramatic impact on our Nation's children.

We have the knowledge. We can no longer say we do not know what to do.

[The prepared statement of Dr. Young appears in the appendix.]

The CHAIRMAN. We will take your testimony, Mr. Hart.

STATEMENT OF DAVID HART, ASSISTANT ATTORNEY-IN-CHARGE, HEALTH FRAUD UNIT/CONSUMER PROTECTION SECTION, OREGON DEPARTMENT OF JUSTICE, SALEM, OR

Mr. HART. Good morning.

The CHAIRMAN. Good morning.

Mr. HART. I would like to thank Chairman Hatch, Ranking Member Senator Ron Wyden from Oregon, and members of the committee for allowing me this opportunity to testify.

My name is David Hart, and I am the Assistant Attorney-in-Charge of the Health Fraud Unit, Consumer Protection Section of the Oregon Department of Justice. For more than 15 years, I have led investigations relating to pharmaceutical marketing and promotion, both for the State of Oregon and for bipartisan, multistate coalitions of State Attorneys General. Under the leadership of Attorney General Ellen Rosenblum, I continue to pursue these cases, especially as they relate to the opioid epidemic.

Prior to graduating from law school and joining the Oregon Department of Justice, I practiced as a physical therapist for 15 years at hospitals, nursing homes, home health agencies, and hospices. Over the years, I have worked with thousands of patients with acute and chronic pain, and that experience informed my investigations of the marketing and promotion of opioids.

The causes of the opioid epidemic are many. While my testimony will focus on the effects of marketing and promotion, I do not want to minimize the existence of other factors that helped cause the epidemic. Because the causes were many, so too will be the solutions.

My testimony today will also cover some of the things we are doing in Oregon to combat the epidemic. In 2007, Oregon was a

member of the executive committee of a coalition of 26 State Attorneys General that reached a settlement with Purdue Pharma resolving allegations that Purdue violated State consumer protection law by misrepresenting OxyContin's risk of addiction and by promoting OxyContin off-label for the long-term treatment of certain chronic pain conditions.*

Before OxyContin was introduced in 1995, opioids were largely used to treat severe, acute pain and cancer pain. Physicians were reluctant to prescribe opioids on a long-term basis for common chronic conditions because of concerns about abuse and addiction. While this inhibition was starting to break down before OxyContin was introduced, afterward the breakdown accelerated greatly, fueled in part by Purdue's aggressive promotion of the drug.

While the 2007 settlement stopped the unlawful promotion, it did not require Purdue to take sufficient remedial action to correct misinformation endemic in the marketplace. At the time of the settlement, I did not fully appreciate the severity of the opioid epidemic and the long-lasting effects of Purdue's promotion. Had I so known, I would have advocated for a settlement with more extensive remedial action.

Since the Purdue settlement, Oregon has remained vigilant to monitor opioid promotion in our State. As part of that effort, we became concerned that Subsys, a sublingual fentanyl spray, many times more powerful than heroin, was being deceptively and unconscionably promoted. Pursuant to Oregon's Unlawful Trade Practices Act, we issued investigative demands to Insys, the manufacturer of Subsys, obtained documents and information from the company, interviewed former sales representatives, and consulted with experts.

After a comprehensive investigation, we issued a formal Notice of Unlawful Trade Practices which alleged that Insys provided improper financial incentives to doctors to increase prescriptions and deceptively promoted Subsys for treatment of chronic back pain, neck pain, mild pain, and even migraine, a condition for which Subsys is contraindicated. I was truly shocked that in 2015, when the scourge of the opioid epidemic was so widely known, that a manufacturer of a Schedule II drug would promote in such an unconscionable and irresponsible way.

To avoid litigating Oregon's allegations, Insys agreed to an Assurance of Voluntary Compliance which prohibited the misconduct identified in our investigation and required payment of more than two times Subsys sales in the State of Oregon. Oregon is the only government entity to have settled with Insys for this alleged misconduct.

Much of the $1.1-million payment Oregon received from the Insys settlement is being used to fund efforts to address the opioid epidemic. This includes regional pain guidance groups that develop opioid prescribing practices and guidelines; facilitating coordination of care across specialties and developing regional action plans; addiction treatment training and addiction treatment tele-medicine consultation services; promoting disposal of used and expired opioids; building a State-wide pain guidance public education web

* *State of Oregon v. Purdue Pharma L.P.,* Case No. O7C14241, 2007.

platform with regional resource pages; and expanding the availability of naloxone, a drug that reverses the lethal effects of an opioid overdose.

It is our hope in Oregon that these programs will save lives. We look forward to working with our Federal congressional delegation on this important issue.

This concludes my testimony. Thank you, Chairman Hatch, Senator Wyden, and the members of the committee, for this opportunity.

[The prepared statement of Mr. Hart appears in the appendix.]

The CHAIRMAN. Thank you. We appreciate your testimony, all three of you.

Let us turn to the prime sponsors of this bill. Let us turn to Senator Toomey first and then we will go to Senator Wyden. He can take my place.

Senator TOOMEY. Mr. Chairman, thank you very much for convening this hearing and for cosponsoring the bill, the Stopping Medication Abuse and Protecting Seniors Act. I want to thank the witnesses as well.

We have all heard an enormous amount of testimony back in our States, as well as here today, about the magnitude of this enormous problem of opioid and particularly prescription drug and heroin abuse and the tragic results. Last October, I did a field hearing with Senator Casey in southwestern Pennsylvania to bring local experts and victims to testify, and I was shocked when there was a standing-room-only crowd in a very large auditorium. That is just how widespread this problem is.

There is no doubt there are many things that we can and should do to try to address this. Senator Portman has outstanding legislation that has just been recently reported out of the Judiciary Committee, is my understanding, which will be very helpful. But there are two specific things that we can do that are the responsibility of this committee, and our bill addresses these things.

Those two specific things are efforts to reduce over-prescribing and an effort to reduce the diversion of these powerful prescribed narcotics. The problem is a very real problem. The GAO has estimated that 170,000 Medicare enrollees have engaged in doctor-shopping, where they go to multiple doctors, who then, typically unknowingly, write duplicative prescriptions, which are then filled at multiple pharmacies for the very same pain killers.

This is fraud. That is what is happening in most of these cases. It is an easy way for people to find commercial-scale quantities of opioids which they can then sell on the black market.

But there is also a subset of Medicare beneficiaries who are innocently getting duplicative opioid prescriptions from multiple doctors and pharmacies because there is insufficient coordination of their care. And that can lead to very, very bad health outcomes, including death, for these innocent seniors.

So the administration has been seeking the authority from Congress to allow Medicare to use the tool that Medicaid already uses, that private health insurers already use, to lock in beneficiaries who are abusing prescription opioids, either intentionally or unintentionally, to a single provider and a single pharmacy, and that is exactly what our bill does. It authorizes Medicare Advantage and

Part D plans to assign one prescriber and one pharmacy to those beneficiaries with a pattern of opioid abuse. As I say, Medicaid and commercial insurers already do this.

This concept, lock-in, as it is called, for Medicare was one of the recommendations made over the weekend by the National Governors Association.

I want to thank Senators Portman, Brown, Casey, and Kaine, whose offices and colleagues and staff met on many occasions with my staff and key stakeholders to get this bill drafted and get it right, and I think we have done that, Mr. Chairman. We have a solid bill that will help opioid-addicted seniors find treatment, will reduce the diversion of powerful narcotics to illegal black markets, will save taxpayer money, and will reduce overspending on opioids.

It is nearly identical to legislation that was already passed in the House in the 21st Century Cures bill, and the bipartisan support that we have is very, very broad. It includes the President's budget. It includes the CMS Acting Administrator, the CDC Director, the White House drug czar, the folks from Pew Trusts—and I appreciate their testimony today—and Physicians for Responsible Opioid Prescribing.

Mr. Chairman, it is a very, very long list of important organizations that have weighed in in support of this legislation. I ask unanimous consent that letters of support from these organizations be included in the record.

The CHAIRMAN. Without objection, we will include them.

[The letters appear in the appendix beginning on p. 45.]

Senator TOOMEY. And I would just say, look, this is overdue, but this is a chance for us to get this done now. There is more in this space that needs to be done. That is not a reason not to do what we can do.

So I would like to just ask a couple of quick questions, starting with Mr. Coukell. The data that I have seen suggests that between 1993 and 2012, the rate of hospitalizations for pain pill overdoses increased fivefold among people 45 to 85. Among people 55 to 64, the increase was sevenfold.

Do you have any idea of why this is happening?

Mr. COUKELL. Thank you for that question, and thank you, again, for your leadership on this important issue.

I think the increase in hospitalizations and deaths that we see associated with opioids closely correlates with the increase in prescribing for the drugs. There is no doubt that there is an epidemic. CDC classifies it as an epidemic, and it peaks in late middle-age but affects all ages and, as you say, has been increasing. And the latest data suggest that it continues to increase.

Senator TOOMEY. The Government Accountability Office and the Office of Inspector General have discovered many, many cases of large-scale fraud. My understanding is, your background is as a pharmacist. I want to read through, very briefly, some of the examples they discovered.

One is a patient who obtained pain killers from 89 different providers in a single year. Another is a beneficiary who received, in 1 year, a 490-day supply of hydrocodone from 22 different prescribers. A Midwestern pharmacy billed Medicare for over 1,000 prescriptions each for two beneficiaries, and one doctor ordered al-

most all the prescriptions for each of these beneficiaries. Another beneficiary received prescriptions for a total of 3,655 oxycodone pills from 58 different prescribers.

In your professional judgment, are these all cases of fraud?

Mr. COUKELL. Well, I cannot comment on specific cases, Senator, but if my math is right, 89 prescriptions a year would be a new one every 4 days, and that would be very, very unusual.

If we look at the whole pattern here of people getting multiple prescriptions——

Senator TOOMEY. And these prescriptions are all for multiple pills, typically 30 days' worth. Every 4 days getting a supply like that strikes me as very likely——

Mr. COUKELL. Clearly, there is some component here that is fraud. I think it is also important to recognize that some of these people are just falling through the cracks in the system and not getting good care. Some of them are trying to get adequate pain relief, and they are going from prescriber to prescriber and whatever the cause, we owe it to them to get them into some kind of coordinated care so they are not at risk of dying or in the case of the elderly—I mean, this does not show up in the statistics, but use of opioids increases very substantially the chances of falling and breaking a hip.

Senator TOOMEY. Right. So just on the front side for a moment—though, you would agree, I think, that the legislation that we are discussing today would dramatically reduce the chances that people could obtain multiple prescriptions from multiple providers and systematically and fraudulently purchase huge quantities.

Mr. COUKELL. Absolutely.

Senator TOOMEY. The last thing is, I know you looked at the specifics in this legislation, and one of the things that we are certainly very concerned about is that people who have a legitimate need for these medicines not be prevented from getting them.

Are you confident that this legislation would not impinge upon a person's legitimate needs for prescription opioids?

Mr. COUKELL. Yes, sir. Again, the first thing to say is, this is not a new idea. Programs like this are already in widespread use in the commercial market and Medicaid. The patient has a number of protections built into this legislation. They get a strong voice in selecting the pharmacy or physician. There are protections for people who have to travel if there is not a supply available at their pharmacy, and so on.

We know from data that people in these programs, while their use of prescription opioids goes down, for example, their use of other prescription drugs is not affected. So that is a sign that it is targeting the problem that we are trying to target.

Senator TOOMEY. Thank you. Thank, you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Wyden?

Senator WYDEN. Thank you very much, Mr. Chairman.

Thank you all. Mr. Hart, great work fighting these manufacturing abuses with my former law school classmate, our Attorney General, Ellen Rosenblum. I am so glad that you are here.

Here is what I want to ask first. When you do the lock-in and you limit access to opioids, it seems to me it is critical at the same time to step up treatment, because the addiction does not go away.

Do any of you disagree with that statement? Let us just go right down the row.

Mr. Coukell, do you disagree with that?

Mr. COUKELL. No. I agree, sir.

Senator WYDEN. Thank you.

Dr. YOUNG. I agree.

Mr. HART. I strongly agree.

Senator WYDEN. I think that is important, because I want that to be a crucial part of this debate. We are going to otherwise separate out into two blocks, some people for enforcement and some people for treatment and prevention. The two areas must go in tandem to be successful, and I appreciate your stating that so specifically.

The second question I want to ask deals with these manufacturers' abuses. I am so glad that you have been pursuing this with Insys and fentanyl in the work that you are doing at home, Mr. Hart.

If you were in our shoes, what would you be pursuing to rein in these kinds of abuses?

Mr. HART. Well, first, I think we have to make sure that these companies disgorge all their ill-gotten gains. We have all heard about these massive settlements with hundreds of millions of dollars paid, but that really represents only a fraction of the profits.

We have to get rid of the incentive. We have to dis-incentivize. We have to create a deterrent, and to do that, you have to get rid of all the profit.

That is why in the Insys matter, we required them to give up two times their total sales in Oregon, and it is with that magnitude of punishment that you will have a truly effective deterrent.

We also have to have more personal accountability of the executives who make these decisions. They cannot walk away with their stock options and their salaries, and, where appropriate, they should be criminally prosecuted.

Finally, we need to have these companies clean up the messes they helped create. Now, in part, that is because there is a lingering effect of the misconduct. Even if you stop the unlawful marketing and promotion, there is a glide effect. Prescribing patterns do not change immediately, and there is a continuing benefit.

So we should have these companies pay to fix the problem they helped create.

Senator WYDEN. That sounds too logical. Go ahead, please. [Laughter.]

Mr. HART. I will leave it at that.

Senator WYDEN. Thank you. I think all three of the suggestions that you have given are certainly worth exploring, and we look forward to working with you.

I have one last question, if I could, for you, Dr. Young, and it goes to the important work the chairman and I are trying to do with all of the committee members dealing with this foster care and child welfare issue.

You pointed out how long families are waiting to access substance abuse treatment, that month-long wait lists for treatment are the norm across the country. You testified, Dr. Young, that these wait times are especially problematic when children's safety and well-being are at stake. Parents need to access treatment much faster than that.

You have also said that parents involved in the child welfare system have a unique set of treatment needs that often do not align particularly well with American health care. In our view, allowing State child welfare programs to have a stronger role in building and paying for substance abuse treatment as a foster care prevention strategy could, in our view, address both of the issues you have been talking about.

What do you think of that? Do you think giving States and counties flexibility to use their foster care dollars to really carve out the most effective substance abuse treatment programs would address both of the issues you are talking about?

Dr. YOUNG. I think it is probably the most important thing that you could do in terms of the child welfare system. Keeping kids at home reduces the trauma to them of the removal.

It makes sense financially. It is much less expensive to serve kids when they are in-home, and we have the demonstrations now that show how to do that.

It is not always an easy population to serve. The engagement has to be pretty intense. But the majority of kids are in in-home cases, not the out-of-home cases, and being able to make sure that those cases get treatment and the other services that they need are the way to be able to prevent them from going into, if you will, the deeper end of the child welfare system.

Senator WYDEN. Very good. Thank you all.

The CHAIRMAN. Thank you.

Senator Portman, we will turn the time over to you.

Senator PORTMAN. Thank you, Mr. Chairman. I want to thank you and Ranking Member Wyden for holding this hearing and for bringing some focus on this issue.

It was mentioned that the Comprehensive Addiction Recovery Act, CARA, was reported out of the Judiciary Committee by a unanimous vote last week. That does not happen often around here. And it did so because, one, it is bipartisan. We have worked on it for several years. We brought in all the experts to make sure that it actually addresses the problem. But also because all of us see this epidemic growing in our States, and we see the human toll.

I have been all around our State. I have met with dozens of recovering addicts, some of whom, by the way, are on Medicare—and this is an issue that, of course, we ought to be addressing.

So this broader bill called CARA does deal, as Senator Wyden talked about, with prevention, treatment, recovery—which is incredibly important—and enforcement. But this legislation that Senator Toomey has proposed is really important, because it says with regard to Medicare, let us be sure that we are not allowing people to do the kind of pharmacy-shopping and doctor-shopping that leads to abuse.

So I thank you for your testimony this morning and talking about that.

I do think that this frequent abuser program also is going to help with regard to identifying people who need treatment. Senator Wyden's question to you was, "Is treatment also important?" Of course, it is. In fact, this very legislation will help people get into treatment, because, once they are identified as a frequent abuser, they actually are given the information and a referral to treatment.

So we need to be sure we are doing all of this, and it is incredibly important. And I thank all my colleagues for joining in this effort and Senator Hatch for being an original cosponsor of the CARA bill, and I am proud to be with Senator Toomey and Senator Brown and others on this legislation.

My Attorney General back home, Mike DeWine, has submitted a letter for the record today that I would ask unanimous consent to include in supporting this legislation. He is on the front lines back there at home, and his point is very simple. This is a strong tool to reduce doctor- and pharmacy-shopping.

But also, we have the National Governors Association, which recently talked about this legislation. They support it. The administration supports it. So I would hope this is one that we could move, and perhaps we can move it along with the CARA legislation.

We have seen in our Medicaid program in Ohio, through this lock-in program, a 41-percent reduction in dosages for certain narcotics. So it works in Medicaid, and it certainly should be in the Medicare program as well.

In your testimony, Mr. Coukell, you talk a lot about this legislation and the fact that it provides a balance. There are some people who have said, "Well, gosh, how can I be sure I can get the drugs that I need?"

Can you briefly tell us, how does it allow beneficiaries to still have a choice in terms of the drugs that they need?

Mr. COUKELL. Thank you for your question, and thank you for your leadership as well on this bill.

The legislation requires patient input into the selection of both the pharmacy and the physician who would be the provider, and so they would be able to get those drugs from the provider, and the provider would ensure that they have adequate pain control.

So that is the essence of the legislation. It allows the individual to appeal if they think that they should not be in the program. It allows them to change pharmacies down the road if they need to.

So there are a number of provisions built in here that help ensure the patient gets the drugs they need.

Senator PORTMAN. Thank you. And thanks for talking about the appeals process. I think that is important.

Just today, we are talking about a lock-in program. I would like to ask your advice, as a pharmacist, on another topic. It is about lock-out rather than lock-in.

Before me here is a pill bottle. It has an inexpensive plastic lock on it. It costs about $1. I am told that the kind of pills that might be inside of this, if they are opioids, might have a street value of $80 a pill.

Do you think it would make sense for pharmacies to offer this as an option? This would allow those seniors we are talking about, if they do need opioids and they are going to this one pharmacy and one prescriber and it is appropriate, to protect their pills from

their grandchildren, their children, their children's friends, their grandchildren's friends accessing them, by a very simple mechanism costing $1 to lock these pill bottles?

This is what I call the lock-out effect. What do you think?

Mr. COUKELL. Having not studied the device or seeing data, Senator, I think I should not comment on it.

Senator PORTMAN. Well, you can see it. It is right here, and it makes a lot of sense. [Laughter.] So I will just say that.

By the way, the CARA legislation also authorizes the Pregnant and Postpartum Women's Program, which creates a pilot grant program specifically for treatment for women who are pregnant or have young babies and are struggling with addiction to deal with the issue, Dr. Young, that you talked about.

So that is in the CARA legislation, but you also talk about CAPTA, the Child Abuse Prevention and Treatment Act, and some of the concerns there.

Can you tell us, because this is something—I have been at hospitals in Cincinnati and Cleveland and in Lima, just in the last couple months, seeing some of these addicted babies, seeing the incredible compassion and care that they are getting, as they take these babies literally through withdrawal.

One question I have asked them—these physicians and nurses and some of these amazing caregivers and some of the mothers—is, what are the long-term impacts? And there are different answers I get.

So I would ask you, as an expert, what research exists on the long-term effects of a child who is born with dependence on a substance like heroin or another opioid?

Dr. YOUNG. I would be happy to follow up and give you the study. There was a meta-analysis that was done just a few years ago that looked at the whole body of research on the long-term effects of opioids.

It is a bit mixed, but we still know that alcohol and tobacco, alcohol in particular, have more neuro-developmental effects than some of the other drugs.

So it is hard to tease out, when you look at what is happening for that child by the time they are in school, was that also the fetal alcohol spectrum disorder, which was not manifested into a full FAS, but had neuro-developmental effects during that prenatal period?

So it is still mixed, but as far as what I have been told, going into the primary grades, there are not effects that are teased out specific to opioids.

Senator PORTMAN. We are seeing a big increase in Ohio and other States of this neonatal abstinence syndrome, and I do hope we can get some better research on that but, in the meantime, of course, do everything we possibly can to aid prevention and treatment to avoid those babies becoming addicted in the first place.

Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Stabenow?

Senator STABENOW. Thank you very much, Mr. Chairman, and thank you to our witnesses. This is an incredibly important issue,

and I hope we are going to move forward. We have strong bipartisan support on this. So I commend everyone who is involved.

I want to specifically focus on one thing. I support all of the things being talked about, certainly from a law enforcement standpoint and so on. But ultimately we have to have treatment in the community.

Dr. Young, you were talking about the fact that we need to get beyond pilots and we need to have systems changed. We have mental health parity, we have substance abuse parity laws now, Medicaid expansion, but we do not have the systems change.

So I want to just urge colleagues and invite colleagues to work with Senator Blunt and me on the next steps in behavioral health care in the community, because whether it is a chemical imbalance from inside the brain or one self-induced because of opioids or some other chemical, it ends up in the same place in terms of treatment for people.

So we have begun the process of a behavioral health clinic status, like Federally Qualified Health Centers. We have now a new quality set of services, 24-hour psychiatric inpatient services, substance abuse detoxification, post-detoxification step-down services, residential services, that are all defined under something we passed a couple of years ago that we are beginning to implement.

Right now, 24 States have stepped up and said, we want to do behavioral health center services. There is funding for eight States to be fully able to do that. We would like very much to have the 24 States that have stepped forward to have the capacity to provide these services. But if we do not, then we are going to still be going, in my judgment, around and around and around with a lot of pieces that are important, but not the core of what happens in the community in terms of individuals asking for help or families being able to get help.

As we know, folks are still going to end up in the emergency room or on the street or in the jail or some other facility. So I wonder if folks might just speak about services. I know one of the most powerful conversations I have had is with the Cook County Sheriff talking about the fact that in his jail, they have a psychiatrist, because at least a third of the people in his jail have mental health or substance abuse disorders. So that is where folks are ending up, and we know that that does not ultimately help anybody.

So when we look at all of this, I wonder if you might just speak to the fact that, when we have identified people—we have drug courts, we have all these other law enforcement provisions—in the end, if we do not have services for what clearly are brain disorders ultimately in addiction, we are not going to truly be able to solve this for the long run.

So I wonder if anyone would want to comment on that. Mr. Hart?

Mr. HART. Treatment is necessary and additional treatment is necessary, and, as you say exactly, it is a brain disorder. It is a disease, and we have to get beyond the stigma associated with it and treat it as a disease.

Among other things, we, for example, are funding additional training for physicians to prescribe buprenorphine, which is a treatment modality. It is a partial opioid agonist. But we have very few physicians who have the DEA waiver necessary to do that. So

providing that type of treatment, behavioral treatment—obviously, the medical treatment—without addressing that, we are not going to solve the problem.

Senator STABENOW. Thank you.

Dr. Young?

Dr. YOUNG. I agree with you. I think one of the trends in the treatment system that needs to happen is the recognition that families are affected and children in particular are affected.

So if there is quality health care, quality substance abuse treatment, we need to have a family focus and make sure that the children perhaps with prenatal substance exposure, but certainly with the post-natal family environment, have their own service—either developmental or mental health services, and clearly parenting that becomes so key.

One of the things that was so important in a grant program operated by SAMHSA, called Children Affected by Methamphetamine, was really understanding what kinds of parenting programs needed to be put in place to really engage parents in treatment, as well as then understanding what were the needs of the children growing up in that environment.

Senator STABENOW. I could not agree more. As co-chair of the Foster Care Caucus with Senator Grassley, I completely agree. I do not know if you might want to just, Mr. Coukell, say something briefly. I know I am out of time.

Mr. COUKELL. Senator, I fully agree with you and with my friends on the panel that solving this will take a multi-factorial or multipronged approach and that all of these things, prevention and treatment, are all part of what we will need.

Senator STABENOW. Thank you, Mr. Coukell.

The CHAIRMAN. Thank you, Senator.

Senator Coats?

Senator COATS. Thank you, Mr. Chairman.

Our State is not exempt from this scourge that is affecting every State across the country. I have, in the last several weeks, been talking to doctors, judges, law enforcement officials, emergency room docs and nurses, grieving parents, friends of loved ones. This clearly is a national crisis, and I share with my colleagues the need to do what we can, realizing that our government does not have a single-bullet solution, but there are some things that we can do in coordination with our States and local communities, with our enforcement people.

But my question really goes to the ability of the drug industry to provide perhaps a better means of pain medication that is not addictive and to the medical device industry.

I know, Mr. Coukell, that the Pew Foundation and you particularly have done some work in this area. I am wondering if you could just bring us up to date here about where the FDA is, where the industry is. Obviously, we have a whole range of treatment, enforcement, and prevention protocols to put in place, but can we get some help from the drug industry with non-addictive drugs? Can we get some help from the medical device industry to address this problem?

Mr. COUKELL. Thank you for that question, Senator.

When I was a clinical pharmacist in oncology, managing pain was part of what we did, and these drugs were a mainstay, and they will continue to be important for the foreseeable future. But we do need research and alternatives to opioids for pain management.

We need to ensure that we are using the drugs we have appropriately.

Senator COATS. Is that going on? Is that research underway?

Mr. COUKELL. I think there is some underway, but I think there is no time soon where we can envision not having opioids as a critical part of pain management.

We also need better abuse deterrent formulations, although it is also important to recognize that most of the people whom we are talking about are swallowing the pills. They are not crushing them and snorting. So the problem is also not solved by better abuse deterrent formulations, although they would be valuable.

Senator COATS. Does anybody else want to comment on that question?

Mr. HART. There are alternatives to opioids for treatment of pain, and historically we would use multidisciplinary approaches. It became quicker and cheaper and easier to prescribe an opioid. But what we need to make sure is that physicians are empowered to use alternative treatment therapies and modalities other than opioids. This is very important for chronic pain.

So, yes, it would be nice to have new treatments and new modalities, but we have to use the ones we already have.

Senator COATS. My wife just went through a surgical procedure for a hip replacement, and I talked to Dr. Cassidy here, my fellow colleague, and said that this is what the doctors have prescribed, and he said, "For how long?" I said, "Well, it was 90 pills, so I guess it is fairly lengthy." I said, "Are there alternatives to that?" My wife was asking that question, also, and he, as a doctor, outlined prescribing a prescription alternative that he thought could manage that pain.

Now, I know that does not apply to everybody, and pain is different in every situation, and chronic pain is particularly an issue here. But it seems to me that we ought to be pursuing every possible alternative given the consequences of what we are facing now.

I do think it is an all-hands-on-deck situation here, with public service announcements and everything else, maybe very graphic ones, that would hopefully scare younger people into not thinking they are immortal and do not need to worry about the consequences of these drugs.

But it is something we have addressed before in other forums, and it is not easy. I appreciate all your help here and giving us some guidance in terms of how we ought to go forward.

Thanks, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Schumer?

Senator SCHUMER. Thank you, Mr. Chairman. I very much thank you for holding this hearing, you and Senator Wyden.

We all know this is now a crisis. It is an epidemic, and we had better get our hands on it quickly. America let crack cocaine get

its tentacles into our people and, unfortunately, nothing was done for years, and it took a decade to get those tentacles out.

Well, prescription drug abuse, heroin abuse, has become an epidemic, and Medicaid and Medicare play a very big role. They are going to provide, by 2020, 33 percent of the total spending on substance abuse.

Just to give you a few quick numbers: 198 deaths from heroin, 884 from prescription opioid drugs in New York State in 2010; 3 years later, 678 heroin deaths, 1,000 deaths due to opioid abuse.

Both are going up, but the heroin abuse is going up more significantly, because the cost of pills is amazing. I mean, my doctors in New York State told me a pill, a Vicodin, an OxyContin, can cost $50 to $80, one pill, on the black market, and that is one of the reasons, we all know, heroin has now raised its ugly head.

The drug dealers, these evil people, these bottom crawlers, realize that they can get kids to take heroin if they cannot afford the Vicodin or the OxyContin, and it is much cheaper.

So there is a lot we have to do here. America has woken up, because this has now affected all corners of America. It has affected poor, middle-class, and rich. It has affected suburban, urban, rural. It has affected black and white and brown. Everybody.

What do we do? The CARA bill, which was passed out of the Judiciary Committee—I am a cosponsor—is a good bill. It certainly does some good things, and I want to support those Senators who have done a very good job there in moving that bill forward. But it is necessary; it is not sufficient. The bottom line is, we need dollars. Sequestration, which my colleagues on the other side of the aisle supported, cut the money available to fight this scourge. Now, we do not have sequestration, so we need to increase the dollars.

Senator Shaheen will introduce an emergency bill, a bill for emergency funding of $600 million, which goes to programs that have already worked—Byrne grants—which give the locality the ability to back up law enforcement and stop the drug dealers from coming in, and separate money for treatment.

I was in Buffalo last week, at one of our best treatment providers, Horizon. The waiting lists are enormous. I have met parents whose kids have killed themselves while they were on a waiting list.

So to say we have enough money for this problem when there are people who are desperate for counselors—and counseling works—we do not have enough money for those counselors, no.

While being fully supportive of the CARA bill, a bipartisan bill, we must at least have an attempt, and hopefully a successful attempt, to add some money here on an emergency basis, as embodied in the Shaheen amendment.

We are certainly open—I spoke with Senator Portman today—to some changes that the other side might want to propose, but this idea of not providing dollars that are needed, if you will, of talking the talk but not walking the walk, is not acceptable, certainly in this crisis.

So my pitch to you is funding. We need funding. I would ask any of you just to comment on the shortage we have of treatment, with the overwhelming needs for treatment.

Dr. Young?

Dr. YOUNG. I misspoke when I said that the county in Ohio last week was the small county on the Kentucky border. It was actually a mid-sized county that told me that it was 30 days to get into medication treatment in Ohio.

The wait lists for residential treatment are, as you know, way too long. But it is not just the dollars when it comes to child welfare. It is critical that you can get treatment access and timely access. But child welfare also needs to have the ability to work with their substance abuse treatment agency and their court in new ways.

Senator SCHUMER. Right. But we have a shortage of counselors right now. That is my point——

Dr. YOUNG. Yes. Yes.

Senator SCHUMER [continuing]. Not what else has to be done, because we need to do other things.

Do you agree, Mr. Coukell, that we have a shortage of counselors and treatment programs?

Mr. COUKELL. I do, Senator. The whole adequacy of treatment and access to evidence-based therapy is something that we are looking at right now.

Senator SCHUMER. How about you, Mr. Hart?

Mr. HART. I agree, and it is particularly acute in rural areas of our State.

Senator SCHUMER. Yes.

Mr. HART. We have treatment available on the I–5 corridor, but not in eastern Oregon. As we know, the scourge is in rural areas as well. That is why we funded tele-medicine addiction training as part of our funding.

Senator SCHUMER. Thank you, Mr. Chairman. My time is up.

The CHAIRMAN. Thank you.

Senator Carper?

Senator CARPER. Thanks, Mr. Chairman.

Welcome, to each of you today.

Several years ago, sitting at the table where you are sitting today was former vice chairman of the Federal Reserve, a fellow named Alan Blinder, who teaches economics at Princeton these days, and we were talking about how to reduce our Nation's budget deficit. And Dr. Blinder said the 800-pound gorilla in the room for deficit reduction was health-care costs. Our health-care costs on a GDP basis, we spend about twice as much for health care as they do in Japan with respect to GDP—health care as a percentage of GDP.

When I asked him what we should do about that, he said, "Find out what works and do more of that." Pretty good advice, and I have used that often in considering the challenges we face in the country.

One of the things we think that works with respect to this particular challenge, opioid addiction, is the lock-in program that we have now in Medicaid. I am told it works reasonably well, not perfectly, but it works reasonably well. It is helpful.

There are those who want to extend that approach, as you heard, to Medicare. There are differences and there are similarities between Medicaid and Medicare, as you know, but my sense is that a lock-in program might work in Medicare Advantage. I am not sure that it works well in fee-for-service.

Mr. Coukell, would you take that on? And anyone else who cares to comment on that, please do so.

Mr. COUKELL. Thank you for that question. I think it is an important question. The first thing to say perhaps is that the commercial drug plans are operating patient review programs now. So that is, in many ways, analogous to a Part D plan. And plans that are operating them have told us that they are confident they will be able to operate.

While fee-for-service does not see or hold both the medical benefit and the drug benefit for the same patient, which Medicare Advantage does, you can still, from a patient's drug profile, get a very good sense of their clinical situation and certainly whether they are getting drugs from multiple sources and then working with the patient to identify a provider and notify that provider.

One of the things that we find is that, once the provider finds out that their patient is getting these drugs from multiple providers—they often do not know that—they sort of become the point for prescribing, then the patient is at reduced risk of getting multiple drugs from multiple providers.

Senator CARPER. Dr. Young, Mr. Hart, is there anything you want to add to that?

Mr. HART. No, Senator. This is not an area of my expertise.

Senator CARPER. Senator Wyden has already asked this question, and some others have asked variations of it. I oftentimes try to drill down on root causes, not just the symptoms or problems.

Lock-in, as good as it is in Medicaid, we are just addressing a symptom of the problem. Root causes—just talk to us a little bit about root causes here and maybe, if you were in our shoes, what you would be doing about addressing the root causes.

Mr. Hart, do you want to lead off?

Mr. HART. Thank you very much for that question. We need to improve prescribing. Most medical schools historically did not cover treatment of pain in their curriculum, and even now most do not. We need to improve prescribing through academic counter-detailing.

Senator CARPER. What does that mean?

Mr. HART. That means, instead of having sales representatives teach doctors how to prescribe, we have pharmacists, we have experts who are independent and unbiased sources of information.

We need to have CME, continuing medical education, that is not industry-funded, and now that is who pays for it. Purdue Pharma paid for 20,000 CMEs, and even if you follow the guidelines, the Accreditation Council for Continuing Medical Education guidelines, and do not have direct control by choosing what is funded and what is not, you are not going to control the message.

So we need independent messaging. I think that is key. We have already talked about addiction treatment—of course, that is important—but also providing alternative treatments to opioids for chronic pain conditions specifically.

Doctors are under a lot of pressures. We need to provide them with clinical guidelines, for example, especially for chronic pain, so that docs who want to do the right thing can have support for their decisions and also to help reduce some of the misinformation out there in the marketplace.

So we need to improve prescribing. We also need to get rid of some of the drugs that are in the marketplace. For example, I know DEA recently changed rules that allowed pharmacies to take back drugs, but few pharmacies actually do so. There is paperwork, there are expenses. So we need to facilitate that process, maybe have the drug companies who sold the drugs pay for their removal when they are not needed anymore.

Senator CARPER. My time has expired. Let me just ask the other witnesses. Do you agree with everything that Mr. Hart has just said?

Dr. YOUNG. That particular aspect is not my area of expertise.

Senator CARPER. So you do not.

Dr. YOUNG. No. I agree with what he said, but I did not have anything to expand on that.

Senator CARPER. Mr. Coukell?

Mr. COUKELL. I agree, Senator, that to address this epidemic, it needs a multipronged approach, which includes reducing the problem before it starts, identifying folks who are at risk, and, once people have a problem, making sure that they get out of that situation and get effective therapy.

Senator CARPER. Our thanks to all three of you.

The CHAIRMAN. Thank you.

Senator Thune?

Senator THUNE. Thank you, Mr. Chairman, for holding this hearing today and examining how we can address this ongoing epidemic.

As Dr. Young noted in her testimony, heroin use has risen at the same time that prescription opioid abuse has, and, as access to prescription opioids is tightened, there is also a concern that this could lead more people toward heroin.

I wanted to, Mr. Hart, ask you, from your experience, what are the most effective ways to ensure that there is coordination between State health officials with law enforcement to ensure that there is not an increased turn toward heroin?

Mr. HART. My area of expertise is not in terms of non-prescription drugs and heroin. So I am sorry, I do not think I can really offer anything on that.

Senator THUNE. Your law enforcement does not coordinate with the State?

Mr. HART. Our law enforcement does coordinate with State officials. I just do not participate in that process and do not have—I would be happy to get back with you——

Senator THUNE. Okay.

Mr. HART [continuing]. Consult with some of our folks and give you a written report on that.

Senator THUNE. That is fine. I would appreciate it, if it is something you are not familiar with.

There are lots of new—I should not say new, but there are, I think, some different proposals for combating the opioid epidemic, and I am wondering—and this would be to anybody on the panel—if there are any current programs that you think are effective in combating opioid abuse and what are the traits of those programs if we were looking for things that we could do? What models exist that are, in your view, effective?

Dr. Young?

Dr. YOUNG. In my area of children who are affected by parents with opioid use disorders, there are a few places that have put in concentrated efforts, one that we wrote a case study about because we were so impressed with what they had done in Burlington, VT with identifying moms with opioid use disorders during the prenatal period: bringing the community together to understand what the family's needs were, making sure that before the baby is born, there is a plan of safe care so that at the time of the birth, there is an understanding about who will have custody of the child, if the child can go home after a period in the hospital, or who will be caring for that child.

The important part, I think, someone said to me is, what we have done by this effort is reduced the crisis at birth, the expense of child welfare, of everyone who comes together, and this crisis mode of "what do we do now?" is eliminated when you have put the effort in to understanding what the family's needs are and what the plan of safe care is for the child before the child is born.

Senator THUNE. Anybody else on that? Mr. Coukell?

Mr. COUKELL. One thing that we are looking at now, Senator, is something that has been shown in numerous, multiple, randomized controlled trials to improve treatment success, which is the use of medication-assisted therapy as an adjunct to counseling and behavioral therapy. And we know that access across the spectrum to MAT is still very low. So that is something that we are looking at now, but clearly it is important in the health-care system and possibly also in corrections.

Senator THUNE. States like South Dakota have permitted properly trained law enforcement officers and first responders to carry naloxone. I am wondering what more can be done at the Federal level to encourage more States to increase access to this life-saving drug.

Mr. Hart?

Mr. HART. Recently, in Oregon, as part of our funding, we funded increased availability of naloxone, and now there is an intranasal variant available on label which should decrease the pricing, making it available in schools. We have made it available to our first responders as well. We have been distributing naloxone in Multnomah County and Clackamas County with needles to the drug abuse community, because they are the ones who are there.

We also have to make sure that there are good Samaritan laws in place so that people are cared for by their fellow abusers who do not run and leave them but can provide that acute assistance.

So you are absolutely correct. Naloxone is a life saver. It is the Lazareth drug, we call it.

Senator THUNE. My time has expired. So thank you all very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Brown?

Senator BROWN. Thank you, Mr. Chairman. And thanks to the witnesses for sitting for a couple of hours listening to questions and sharing your insight and wisdom.

Yesterday I was in Warren, OH, a working-class city north of Youngstown, near the Pennsylvania border, with a group of 25 or so people all concerned about this issue and what it means to this community of high unemployment and high numbers of foreclosures, on top of one thing after another.

They are pretty overwhelmed. They talk in terms of how important it is to have additional resources and a multipronged approach. We need to make sure that health-care providers have the tools they need to manage patients who are being seriously harmed and may even die from addiction.

One woman spoke whose son was 14 and became addicted, in part, because someone in the home had been dying and some morphine was left around. And he has been addicted for 12 years on and off, and she called it a chronic disease, as you would call it.

Patient review and restriction programs, the PRR programs, are one of these tools that are so important. Despite their success in State Medicaid programs and commercial plans, PRR programs are not available in Medicare under current law, as you know. It makes no sense. We have one proven tool that could help patients suffering from addiction, and Medicare is not even allowed to use it.

My colleague, Senator Toomey, and I have been working together, as Mr. Coukell knows, for several years on a legislative proposal to help address the epidemic, the Stopping Medication Abuse and Protecting Seniors Act. Our legislation would allow Medicare to utilize PRR programs by creating a framework for at-risk beneficiaries to get their opioids from one prescriber, reducing the risk, obviously, of overdose. Our legislation incorporates important consumer protections to ensure patients who need pain medications can get them.

Mr. Coukell, describe how these PRR programs balance patients' legitimate need for pain medications and the goal of protecting vulnerable patients from becoming addicted or potentially overdosing, and talk briefly about how the programs have been successful in Medicaid and commercial plans and what their potential could be in Medicare.

Mr. COUKELL. Thank you, Senator, and thank you for your leadership on this bill. S. 1913, the legislation you mention, contains a number of important protections. The first is that, in identifying patients who are at risk, it takes into consideration, are they in hospice, are they in long-term care, are they being treated for cancer, and those patients would not be locked in.

Then someone, a clinician, a nurse, or a pharmacist, looks at their profile and makes a judgment about how much risk they are at, what is the behavior we are seeing there. And then the patient has input into what provider or what pharmacy they will go to. They have the opportunity to appeal their inclusion in the program not once, but twice. If they need to, they can, down the road, change their provider if they need to do that.

So there are a number of protections that are built in here so that we ensure patients get access that they need and that we do not have a false positive.

You also asked about the evidence from Medicaid programs, and I can just touch quickly on a number of States. In Tennessee, we

saw that an assessment looking at patients before and after their enrollment in the program saw a 33-percent decrease in prescribers visited and a 46-percent decrease in the number of controlled substance prescriptions; in Minnesota, very similar data also, with reductions in service utilization found there.

In the Oklahoma PRR program, pharmacies visited fell by more than half, and the number of prescriptions was reduced. In other States, we have seen reduced emergency department and clinic visits and so on. So there is quite a long list, and you probably do not want me to go through the whole thing.

Senator BROWN. Thank you for that. It is clear that implementing a program in Medicare will help, but not solve the problem. It is a small piece in the puzzle.

What we should be focusing on too, Mr. Chairman, is increasing access to treatment for individuals struggling with addiction, ensuring those who need help have community resources. What yesterday in Warren, OH taught me, in part, was how resources are so scarce: not enough providers, not enough treatment homes, if you will.

We have a good group of witnesses. I am thankful and grateful that all three of you are here. But there are significant gaps in expertise. There is no one on today's panel from the administration who could discuss programs in both Medicaid and Medicare that exist to help individuals overcome their addiction or witnesses to speak for additional legislation to improve government programs as needed. There is no one with a background in addiction treatment who can discuss what more we need to do from that side and that standpoint to ensure that beneficiaries who are struggling receive the treatment they need to address their addiction.

That is disappointing, understanding that it costs money, understanding that this is a Congress where most of its members have taken pledges to lobbyists saying they will never come up with any revenues, and it ties our hands and puts too much of a straightjacket on responding to one of the great public health crises of this decade.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Brown.

Well, let me ask you, Dr. Young, just one——

I am sorry. Senator Scott, you go ahead of me.

Senator SCOTT. Thank you, sir. Are you sure?

The CHAIRMAN. Sure.

Senator SCOTT. Sounds good. I always want to follow the chairman and the would-be NBA basketball star down there. [Laughter.]

Mr. Coukell, just a couple questions for you. Senator Brown touched on the topic of the Medicaid success in the lock-in programs.

I know that one of the things that has worked really well in South Carolina is the ability to create 20 criteria that allow for the HHS in South Carolina to figure out who needs to be a part of the program.

How do we make sure that the customization and the flexibility that is necessary and has been successful in South Carolina in Medicaid would also be built into Medicare Part B?

Mr. COUKELL. Thank you, Senator. I think it is an important question, and what we have seen over time is increasing sophistication in how we identify patients who are at risk; so, starting with straight number of prescriptions over a certain number of days, increasingly taking in things like dosage and emergency department visits and other factors which suggest risk.

This legislation I think strikes the appropriate balance between requiring the Secretary to work with the plans to establish criteria, building in some specific exclusions, but still gives the plans the flexibility to identify criteria that are going to work for them and their population and their data.

Senator SCOTT. So you see that as a State-by-State opportunity for Medicare Part D as well?

Mr. COUKELL. As the legislation is written, it would be some Federal guidance, followed by customization by plan rather than by State.

Senator SCOTT. Speaking of the Toomey legislation, those in hospice and long-term care facilities are exempt from these lock-in programs. How do you think the authority to exempt the individuals, which is left to the Secretary, will be exercised, particularly for folks with cancer or rare diseases, like sickle cell, which we have a high incidence of in South Carolina? Which individuals have the State Medicaid programs commonly excluded?

Mr. COUKELL. Thank you for that. It is difficult to generalize across Medicaid programs, because the criteria are various. But some of the categories you have mentioned are ones that should be taken into account, and, under the Federal legislation, the Secretary will work with the stakeholders to identify appropriate exclusions.

Senator SCOTT. As you know, many folks with opioid abuse issues are struggling with mental illness, and in South Carolina, I think it is one out of three seeking treatment, either self-reporting mental illness or doctors determining that the individuals had a mental health problem in addition to their substance abuse problem.

There seems to be a high co-morbidity between mental illness and substance abuse. Given this, when locking patients into one physician for the opioid prescriptions, what can we do to ensure that there is a coordination of care with all of their other doctors, but particularly with the physician treating their mental illness issues, since they are intrinsically related?

Mr. COUKELL. They are, and one thing the legislation does is, it requires that the patient be notified of available services, such as substance abuse treatment and so on, at the point that they are enrolled in the program.

I do not think that is a full solution for the nexus of mental health and substance abuse that you are talking about. It is one thing that I think is valuable in the context of these programs, but it is a bigger issue.

Senator SCOTT. Do you have any specific examples of perhaps positive outcomes from that coordination that we have seen: mental illnesses with the prescriptions?

Mr. COUKELL. I do not have a specific example right now.

Senator SCOTT. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Menendez?

Senator MENENDEZ. Thank you, Mr. Chairman. Thank you to our panelists. I got to read your testimony when I was sitting in the Senate Foreign Relations Committee with Secretary Kerry.

I want to thank you and the ranking member for holding this hearing on the increasing crisis of opioid addiction and death. However, I am troubled, and I hope maybe some future hearings might consider this, by the fact that we do not have any witnesses here today to speak specifically on the issues of addiction treatment and recovery or to the policies this committee should be working on to address the needs of those struggling with an opioid addiction and to be able to help them find and receive the timely, effective help that they need to survive.

As I mentioned when Secretary Burwell was here during a hearing on the President's budget earlier this month, I recently held a listening session with key addiction treatment stakeholders in New Jersey to address this growing crisis. To a person, the issue that came up as the most substantial barrier to addiction treatment was the limitation on a provider's ability to conduct medication-assisted treatment. These limitations include things like restrictions on the number of patients a physician can treat and the number of qualified providers available to treat people seeking treatment to get clean.

So I was pleased that Secretary Burwell committed to taking all possible administrative steps to address these limitations, but I fear that will not be enough, and we have to act to provide the legislative tools necessary to properly address the crisis.

So with that as a preface, Mr. Coukell, would you agree that including expanded access to treatment, including medication-assisted treatment, is a critical component to any comprehensive effort to stem the tide of opioid abuse?

Mr. COUKELL. Senator, this is something that I think is very important, and we have been looking at it as an organization. Now, it is quite clear that medication-assisted treatment is an area where the evidence of effectiveness is very strong and where it is underused really across the board.

So we, I hope, will soon be in a position to make strong recommendations on that. We are looking at it right now.

Senator MENENDEZ. Let me ask anyone else on the panel this question, in a different context. As I think we all know, deaths associated with opioids have quadrupled over the last 12 years to an astounding 78 deaths a day. In addition to the issue of prescription opioids that has been a focus of this and other committees, an increasingly pressing issue is the major increase in heroin use.

This increased heroin issue is, somewhat ironically, in my mind, the result of making access to prescription opioids more difficult. Meanwhile, access to cheap, highly potent heroin on the streets has become, by comparison, very cheap and easy.

In fact, while opioid prescribing per patient in New Jersey is among the lowest in the country, we saw a 160-percent increase in heroin deaths since 2010, and we suffered more than 1,200 overdose-related deaths. These statistics, again, point to the need to provide access to treatment as part of a comprehensive approach to combating the opioid and heroin epidemics.

So I would like to hear from you, if any of you have ideas. What steps can we take to ensure that, as we make illegitimate access to prescription opioids more difficult, we do not just push people to use drugs like heroin?

Mr. Hart?

Mr. HART. If I might, and if I could just back up to your prior question——

Senator MENENDEZ. Sure.

Mr. HART [continuing]. Which had to do with what we could do to improve medication-assisted treatment. I heard earlier mentioned how we are trying to train more physicians in Oregon to use buprenorphine, especially in rural areas where it is not available. It just also strikes me as odd that mid-level providers can prescribe fentanyl, but they cannot prescribe buprenorphine. So that is something to consider, because we have significant shortages in rural areas of medical providers.

Regarding what can be done, while we have been talking about it this morning, one thing to consider is, how can we provide alternatives to opioids for people suffering from chronic pain so then they do not have to turn to opioids and then inadvertently become addicted?

So providing alternative therapies, providing multidisciplinary treatments, where physicians are not just paid for the 15 minutes to write a prescription, could actually create a care plan that would involve behavioral therapists, social workers, psychologists, physical therapists, occupational therapists. That is one proposal I would make.

Senator MENENDEZ. Dr. Young?

Dr. YOUNG. We have been talking about the wait lists, and, from the child welfare perspective, we know that timely access is key. Many of the other funding sources do not necessarily have child safety and child well-being as their outcomes.

So without a funding source that provides treatment for the child welfare system, it is a referral to a wait list in far too many cases.

Mr. COUKELL. Along with what my friends on the panel have said, I think recognizing that, at some point, if a proportion of this population that starts out getting the drugs through the medical system goes out and starts to seek heroin, we have to identify the problem further upstream. So if we can find these folks when they are visiting multiple doctors, multiple pharmacies, and at that point say, "Hey, stop, we need to get you into effective care, we need to manage your pain," before it crosses over from seeking medical treatment into a full-blown addiction, then we will have intervened further upstream.

Senator MENENDEZ. Thank you.

Mr. Chairman, I would just say that a referral to a wait list, to me, is probably a pathway to heroin if that wait list is awfully long. So this is one of the critical elements I hope that the committee under your leadership can look at as we deal with that. Because if I am already, unfortunately, addicted to opioids that I had been prescribed and now I can get, for a fraction of the cost to take care of that addiction, heroin instead of moving to a substance abuse entity that can help me permanently kick the addiction, then the re-

ality is, if that wait list is very long, then we are on a path to a destructive course.

Thank you very much.

The CHAIRMAN. Good point.

Let me just ask one question of you, Dr. Young. That is, as you pointed out, the Congress has acted in response to various substance abuse crises. As you note, in response to the methamphetamine epidemic, Congress enacted the Regional Partnership Grant Program. Additionally, States have access to title IV–B funds and the TANF and Social Services block grant to fund the types of prevention activities you testified about to keep children safely at home.

Do you believe these existing funding streams are sufficient to address the current opioid crisis? Why or why not?

Dr. YOUNG. Regrettably, those funding streams are not sufficient, as we have been talking about with the wait lists and the other priorities that those funding streams have. If you were to take those funding streams and allocate them to paying for treatment for child welfare families, you would just be moving other priorities and other populations from one funding source to this one.

So, it is the fact that there are wait lists that speaks for itself. Only 10 percent of the people in the country who need treatment get into treatment.

In the regional partnership grants, at their peak, there were about 5,000 children in a year, which pales in comparison to the number of children in the child welfare system who need treatment and the number of infants who are born with prenatal substance exposure.

The CHAIRMAN. Well, thank you so much.

Senator Wyden has a question.

Senator WYDEN. Thank you very much, Mr. Chairman.

I wanted to come back, because this has been such an important hearing. We have heard from all our colleagues, and I am walking out of here prepared to make sure that everybody in the Senate understands that when you do the lock-in, when you actually restrict access to opioids, it is absolutely critical, it is crucial that you step up treatment, because everybody in health care is telling us that the addiction is not just automatically going away.

I was very pleased that the three of you all agreed with that proposition, and I can tell you I am just going to be hammering that point away again and again as we talk in the days ahead about how to tackle this. I think the fact that all of you were unanimous in that judgment was just enormously helpful as we try to build a bipartisan coalition for fighting opioid addiction in the right way.

Just one last question, if I might, Mr. Chairman. The Oregon Attorney General, Ellen Rosenblum, and 37 other Attorneys General have written letters to the Centers for Disease Control in support of the CDC's proposal to issue opioid prescribing guidelines.

I would just ask unanimous consent that they be put in the record.

The CHAIRMAN. Without objection.

[The letters appear in the appendix beginning on p. 57.]

Senator WYDEN. And one last question, if I might. Mr. Hart, as I indicated, you all have been doing very good work with your settlement funds—as a result of some of these abuses by the manufacturers—to help Oregon develop prescribing guidelines.

I think it would be helpful for us, as we wrap up, for you to give us your sense of why these sort of prescribing guidelines are so important. You come from a health background, from a law enforcement background, so you give us some special perspective.

Why, in your view, are these prescribing guidelines so important?

The CHAIRMAN. Well, before you answer, I have to leave. So I am going to have Senator Wyden close this down.

I just want to personally express my gratitude to all three of you for being here today, and I want to thank my colleagues for their participation. This is serious stuff, and this hearing has been helpful in shedding light on the serious nature of the opioid problem and providing thoughts on how to move forward.

So we owe it to the individuals, their families, and our programs to tackle these problems.

I would ask that any written questions for the record be submitted by Tuesday, March 8, 2016.

With that, I will turn the remaining time over to you, Senator. Forgive me.

Senator WYDEN [presiding]. Thank you, Mr. Chairman. I look forward to working with you on this.

Our last question then. How appropriate that an Oregonian is going to respond to the last question with respect to why these prescribing guidelines are so important.

Mr. HART. Thank you for the question. In your opening comments, you mentioned how we need to get the balance right for prescribing.

Senator WYDEN. Right.

Mr. HART. Not too much, but we also want to make sure patients who are appropriate get treated, and that is why guidelines are necessary to help get the balance right.

Now, there is misinformation in the marketplace, and they can help correct that, but also, let us remember, most of the prescribing is not being done by specialists. It is primary-care providers.

Frankly, what we recently found is that in Oregon, for the top 50 OxyContin prescribers, they were not even physicians. I mean, half—half of the top 50 OxyContin prescribers were mid-level providers. They were nurse practitioners, they were physician assistants.

So these folks would benefit from guidance. Again, it helps people do the right thing. Doctors and prescribers are under a lot of pressure to prescribe. It is quicker, it is easier. So if you have a guideline, it will help change that.

Finally, it might support alternative treatments, because third-party payers have to pay for what might be initially a more expensive alternative treatment than writing a prescription, and if you have guidelines that support examining and using those alternatives, perhaps we will be more likely to have third-party payers pay for them.

Senator WYDEN. I think it is also important for all who are following this to understand that these are optional guidelines. This

is not the Federal Government coming in with sort of a one-size-fits-all mandate and requirement and the like. These are optional guidelines, and I appreciate what you are talking about.

I will tell you, Mr. Hart, one of the most striking aspects of last week, as I held these forums with Senator Merkley and Congressman Blumenauer and got around the State, was the comments that we got with respect to what I have come to call the prescription pendulum.

It was very clear that 5 to 10 years ago, there was a great deal of hesitancy with respect to prescribing medicine for pain, even when the evidence warranted that was the right thing to do. Now there is a sense that we have gone the other way, that just automatically there is prescribing for pain, and too many pills are made available. Perhaps there ought to be ways in which a person gets a more limited number of pills at the outset and then there is an arrangement to come back as needed.

I think Oregon has really done pioneering work, you and Attorney General Rosenblum and our health specialists, in trying to help right that prescription pendulum. My sense is that this is not an exact science, just as you said. This is a challenge for doctors and patients and health-care providers, but I think we are starting to get a sense of what it is going to take to get the right balance of the pendulum.

So a big thanks to you, Mr. Hart, and your colleagues. You both have, in addition to Mr. Hart, been very, very helpful, and, again, I appreciated the unanimity on this panel, people who have come from different walks of life, in saying that enforcement and treatment and prevention have to go forward in tandem. You have given us an opportunity to get that message out, and I thank you.

With that, the Finance Committee is adjourned.

[Whereupon, at 12 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF HON. ROBERT P. CASEY, JR., A U.S. SENATOR FROM PENNSYLVANIA

Thank you, Chairman Hatch and Ranking Member Wyden, for holding a hearing on heroin and prescription opioid abuse. This hearing is timely, given the way the opioid abuse crisis is engulfing communities throughout the United States, and in my own state of Pennsylvania. According to the Drug Enforcement Agency, Pennsylvania ranks ninth highest for drug overdose deaths in the Nation, at a rate of 18.9 per 100,000 people. According to the Centers for Disease Control and Prevention, more Pennsylvanians now die from drug overdoses than car accidents.

Although it is clear that the opioid abuse epidemic has had a terrible impact on the lives of many adults, we should not overlook the equally tragic impact that it has had on thousands of children. Nationally, the number of children entering care who were removed with parent drug abuse reported as a reason increased 42.5 percent from 2009 through 2014. It is almost certain that opioid addiction played a role. This increase can be particularly challenging for child welfare systems to handle, as the children of adults with a substance abuse problem often stay in the system longer and require extra services and counseling. In Pennsylvania, the number of births covered by Medicaid of children with opioid dependence rose from 883 in 2010 to 1,122 in 2012, according to my state's Department of Public Welfare. These children suffer from a condition known as Neonatal Abstinence Syndrome, which can include seizures, fever, tremors and dehydration. The long-term health effects for these children may not be fully known.

There is no simple solution or law that Congress can pass to fix this problem, but there are commonsense steps that we can take to identify and attack the roots of the opioid crisis in this country, as well as to help mitigate some of its effects. I am pleased to support the Family First Act, bipartisan legislation that is being developed by the Finance Committee to make title IV–E funding available, for a limited time, for family preservation services, including substance abuse treatment. By helping to keep families together, and by expanding access to treatment, this legislation will lead to better outcomes and save the federal government money. I appreciate the efforts that Chairman Hatch and Ranking Member Wyden have put into developing this legislation, and I hope that the Finance Committee will vote on it soon.

I am also a cosponsor of several pieces of legislation that would move us in the right direction, including the TREAT Act, introduced by Senator Markey, that would expand access to Medication Assisted Treatment; the Treatment and Recovery Investment Act, also introduced by Senator Markey, which would increase funding for the Substance Abuse Prevention and Treatment Block Grant; the so-called "heroin supplemental," introduced by Senator Shaheen, which would appropriate $600 million in emergency funding to address the heroin and prescription opioid epidemic; and legislation introduced by Senators Toomey and Brown that would prevent doctor and pharmacy shopping for at-risk Medicare beneficiaries.

Congress has already taken one important step by passing the Protecting Our Infants Act, which I introduced with Senate Majority Leader Mitch McConnell. This legislation, which was signed into law last year, requires the Department of Health and Human Services to develop a strategy to address research and program gaps on prenatal opioid use and Neonatal Abstinence Syndrome. Although passage of this legislation is a critical achievement for helping infants born in withdrawal, I am

also aware of ongoing concerns around states' implementation of Plans of Safe Care for these infants under the Child Abuse Prevention and Treatment Act. I am looking into ways to address this matter.

Far too many of our local communities are struggling against the rising tide of prescription opioid and heroin abuse, and far too many families are being torn apart. I look forward to hearing from the witnesses on how we can combat opioid abuse, protect our children and help keep families together.

PREPARED STATEMENT OF ALLAN COUKELL, SENIOR DIRECTOR, HEALTH PROGRAMS, THE PEW CHARITABLE TRUSTS

Chairman Hatch, Ranking Member Wyden, and members of the Senate Committee on Finance, thank you for holding this hearing on the pressing public health problem of prescription drug abuse. My name is Allan Coukell. I am a pharmacist and I direct health programs for The Pew Charitable Trusts. Pew is an independent nonpartisan research and policy organization that works to develop and support policies that will help reduce the inappropriate use of prescription drugs while ensuring that patients with medical needs have access to effective pain management.

Nearly all of us have been touched by the epidemic of prescription drug abuse or have heard the horrific personal stories of its effects on peoples' lives. It is a problem cities and rural states, of rich and poor, of old and young. This is a public health crisis across the nation, and the statistics are staggering. Almost 19,000 Americans died in 2014 from prescription opioid overdoses. This is the equivalent of 52 people a day, and represents a 16 percent increase in deaths from the year before.[1] What is particularly tragic is that these deaths are preventable.

The epidemic is a public health crisis that requires a multi-faceted response. We need strategies to prevent drug abuse and addiction. We need to identify patients who are at risk. We need to prevent people from overdosing. We need to educate providers about how to prescribe opioids responsibly. And we need to ensure that people who do become addicted get the help they need. We must also not lose sight of the importance of providing adequate pain management to people who need it.

Today, I would like to focus on one policy that will improve patient care and reduce the chance of overdose by ensuring that patients who are at risk of harm from multiple opioid prescriptions get their pain medications from one doctor or one pharmacy. These programs, known as patient review and restriction (PRR) programs, are in wide use in Medicaid and commercial plans. But they are prohibited in Medicare. Senators Toomey, Brown, Portman and Kaine have shown great leadership by introducing the Stopping Medication Abuse and Protecting Seniors Act of 2015, which would allow Medicare to use this important tool to protect seniors. Pew applauds their work on this important legislation.

PATIENT REVIEW AND RESTRICTION PROGRAMS

PRRs are a tool to identify individuals at risk of overdose and other harms, and to ensure they receive coordinated care. PRRs specifically identify patients who are receiving these drugs from multiple healthcare providers, assigning them to designated pharmacies and prescribers to obtain their controlled substance prescriptions. Through this mechanism, PRRs allow plan sponsors and providers to improve care coordination and prevent inappropriate access to medications that are susceptible to abuse.

Let me explain in detail how these programs work. First, potentially at-risk patients are identified based on specific, predetermined criteria, which may include the number of different prescribers and pharmacies visited to obtain controlled substance prescriptions. Other risk criteria may include duplicative therapies, emergency room visits and total daily dosage of the drugs. Once patients have been identified, a clinical review is performed, usually by a medical professional, to determine if the beneficiary's prescription drug use is inappropriate. Patients, such as those in hospice or receiving treatment for certain cancers, are typically excluded from these programs. The beneficiary is then notified of his identification as at risk and his subsequent enrollment in a PRR. The beneficiary is provided the right to appeal the decision and the choice to submit provider preferences.

---

[1] Centers for Disease Control and Prevention (CDC), National Center for Health Statistics. Compressed Mortality File 1999–2014.*http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf.*

Forty-nine Medicaid programs currently operate PRRs, and Pew has researched outcomes from these programs. Tennessee's Medicaid program evaluated patients who were enrolled into the PRR program during the fourth quarter of 2010. An assessment of controlled substance use, which was measured immediately prior to and at least 6 months after PRR enrollment, demonstrated a 51 percent decrease in pharmacies visited, a 33 percent decrease in prescribers visited, and a 46 percent decrease in number of paid prescriptions among those patients enrolled in the PRR (n=96). From a 2014 report, Minnesota's Medicaid PRR estimated cost savings of $1.2 million in the first year of patient enrollment based on reductions in prescriptions, emergency room utilization, and clinic visits that resulted in an average savings of $4,800 per patient (based on projected enrollment of 245). Additional reductions in service utilization and costs were realized during the second year of program enrollment. In 2008, Oklahoma's Medicaid PRR reported decreases pre- and post-enrollment in the mean monthly average for narcotic claims (from 2.16 to 1.32), emergency department visits (from 1.26 to 0.81), number of pharmacies visited (from 2.05 to 0.89), and number of prescribers seen (from 2.48 to 1.63) for PRR patients with at least 1 month of eligibility in both the pre- and post-enrollment periods (n=52).

Outcomes information from commercial plans, including CVS Health and BlueCross BlueShield of Massachusetts, suggest that PRR programs could improve public health. An expert panel convened in 2012 by the Centers for Disease Control and Prevention concluded that these programs have the potential to save lives—and healthcare costs—by reducing opioid usage to safer levels.

PRRS IN MEDICARE

PRRs have shown effectiveness in Medicaid and the private sector, but these programs are currently prohibited in Medicare. A statutory change will be required to authorize their use.

It is clear that substantial numbers of Medicare patients are at risk. A Centers for Medicare and Medicaid Services (CMS) analysis identified approximately 225,000 beneficiaries who received potentially unsafe opioid dosing (the equivalent of 120mg or more of daily morphine for 90 or more consecutive days).[2]

A Medicare Payment Advisory Commission (MedPAC) analysis of 2012 prescription drug event data found that 12.3 million Medicare beneficiaries filled at least one prescription for an opioid, corresponding to about 36 percent of Part D enrollees and ranging from a low of approximately 23 percent in Hawaii to a high of approximately 50 percent in Alabama. Arkansas, Georgia, Kentucky, Louisiana, Oklahoma, and Tennessee were all at 40 percent or higher (see Appendix A). The vast majority of these individuals (87% of the 12.3 million) received the drugs for conditions not associated with cancer treatment or hospice care. In 2012, the beneficiaries with the highest use of opioids filled, on average, 23 opioid prescriptions at a cost of $3,500 per beneficiary.[3]

Medicare beneficiaries are all too often getting opioid prescriptions from multiple providers. According to the same 2012 MedPAC analysis, among the subset of beneficiaries with the highest use of opioids for these indications, 32 percent obtained these prescriptions from four or more prescribers or three or more pharmacies. An evaluation of 2008 claims data conducted by the Government Accountability Office identified 170,000 Medicare Part D beneficiaries who visited at least 5, and as many as 87, medical professionals in a year to obtain prescriptions for opioids or other drugs from 14 classes of abusable drugs.[4]

Data from these evaluations highlight the need for PRR programs as a mechanism to achieve the balance of ensuring access to pain management while preventing overdoses and other harms associated with prescription drug abuse in the Medicare population.

---

[2] Centers for Medicare and Medicaid Services (2013), Supplemental guidance related to improving drug utilization controls. Correspondence from Cynthia G. Tudor, director, Medicare Drug Benefit and C and D Data Group dated Sept. 6, 2012. Available at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf.*

[3] Medicare Payment Advisory Commission (2015). Medicare and the Health Care Delivery System, Report to the Congress. Chapter 5. Available at *http://www.medpac.gov/documents/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0.*

[4] Government Accountability Office (GAO) (2011) Medicare Part D: Instances of questionable access to prescription drugs, Report to Congressional Requesters. Available at *http://www.gao.gov/assets/590/585424.pdf.*

THE STOPPING MEDICATION ABUSE AND PROTECTING SENIORS ACT

In May 2015, Pew, along with health plan sponsors, managed care pharmacy providers and public policy organizations worked together to develop key principles that should be included in PRR legislation to ensure that these proposals provide patient protections while also ensuring that they work as intended to minimize potential harms from prescription drug misuse and abuse.[5] Patients in long-term care and hospice should be excluded from enrollment in a PRR. Beneficiaries should also have the ability to appeal their enrollment in a PRR. In addition, PRR program design should also allow for patient input on the selection of prescribers and pharmacies to ensure reasonable access that considers geographic location, cost-sharing, travel time, and multiple residencies.

Pew supports the Stopping Medication Abuse and Protecting Seniors Act because it includes the key principles described above, to ensure both patient safety and access to care.

This legislation achieves an appropriate balance in allowing identification of doctor shopping and at-risk patients, and providing access to effective pain management. It includes the beneficiary protections outlined above and allows for broad stakeholder input on the development of criteria that will be used to enroll patients. The legislation also requires plan sponsors to contact the beneficiary's physicians prior to patient enrollment to verify whether the prescribed medications are appropriate given the beneficiary's medical condition. Beneficiaries will help select providers. An appeals process is also included. Finally, plans will be required to provide enrollees with information on resources to address prescription drug abuse, such as substance use disorder and addiction treatment services, when possible.

SUPPORT FOR THE LEGISLATION

There is substantial support to advance the Stopping the Medication Abuse and Protecting Seniors Act as an effective tool to decrease opioid abuse and improve patient safety. A similar proposal has already passed the House of Representatives with broad bipartisan support as part of the 21st Century Cures Act, and President Barack Obama proposed this policy in his FY 2016 and 2017 Budget requests for the Department of Health and Human Services.[6] The Office of the Inspector General also included PRRs in the 2015 Compendium of Unimplemented Recommendations as one of 25 quality improvements that should be prioritized and implemented.[7]

We agree with CMS acting administrator, Andy Slavitt, who said a PRR proposal "makes every bit of sense in the world, and we completely agree that that's the kind of authority that would be very helpful in really taking a practical measure to stem abuse."[8] Once again, we thank Senators Toomey, Brown, Portman and Kaine for introducing this legislation, as well as the many cosponsors of the legislation who sit on this Committee. We urge the Senate to help address the nation's prescription drug abuse epidemic by passing the Stopping Medication Abuse and Protecting Seniors Act of 2015, which would expand use of the PRRs to ensure that these programs can be used to prevent prescription drug abuse in Medicare.

---

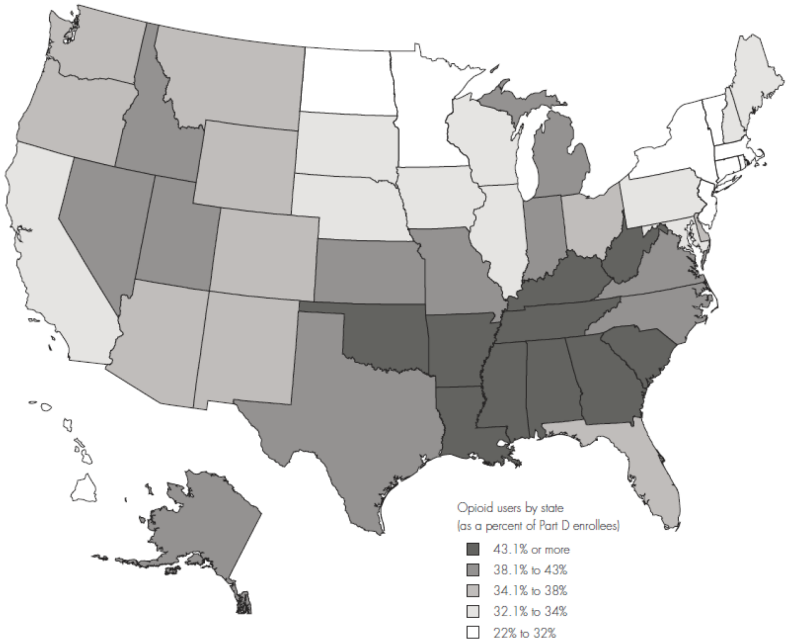
[5] The Pew Charitable Trusts. Pew Urges Congress to Authorize Patient Review and Restriction Programs in Medicare, *http://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2015/05/pew-urges-congress-to-authorize-patient-review-and-restriction-programs-in-medicare.*

[6] 21st Century Cures Act, H.R. 6, 114th Cong. (2015), Prescription Drug Abuse Prevention and Treatment Act of 2015, S. 1431, 114th Cong. (2015); Department of Health and Human Services, "HHS FY 2016 Budget in Brief" (2015), *http://www.hhs.gov/about/budget/budget-in-brief.*

[7] Office of the Inspector General, "Compendium of Unimplemented Recommendations" (2015), *http://oig.hhs.gov/reports-and-publications/compendium/files/compendium2015.pdf.*

[8] Healthcare Co-ops: A Review of the Financial and Oversight Controls. Senate Finance Committee Hearing, (2016)(statement of Andy Slavitt, acting administrator of the Centers for Medicare and Medicaid Services), *http://www.finance.senate.gov/hearings/healthcare-co-ops-a-review-of-the-financial-and-oversight-controls.*

Appendix: Wide variation in use of opioids across states, 2012



Source: MedPAC analysis of Part D denominator and prescription drug event data.

QUESTIONS SUBMITTED FOR THE RECORD TO ALLAN COUKELL

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. You have testified that patient review and restriction programs (PRR) are in wide use in Medicaid and commercial plans. How many Medicaid programs currently operate patient review and restriction programs?

Answer. Based on research conducted by Pew, 48 states and the District of Columbia operate PRR programs for their Medicaid fee-for-service population, managed care population, or both. Twenty-eight states operate PRRs in both Medicaid FFS and managed care environments; 16 states administer PRRs only in Medicaid FFS; and three states administer a PRR only in Medicaid managed care. Two other states also operate a FFS PRR, but we were unable to confirm whether Medicaid managed care plans in these states have active PRRs.

Question. What protections are in place to allow access to needed pain medication for patients with certain medical conditions?

Answer. By coordinating the use of controlled substance prescriptions, PRR programs aim to protect patients from harmful amounts of opioids while also ensuring patients receive needed pain medications. Based on results of a survey Pew conducted of 38 Medicaid fee-for-service PRR programs, PRR staff (typically a pharmacist or registered nurse) perform a clinical review after identification of patients potentially at risk for prescription misuse or diversion. Patients, such as those receiving treatment for certain types of cancer, in hospice, or in long-term care, may be automatically excluded from PRR programs. Further, most programs allow patients to provide input on the selection of their designated providers and to appeal their identification as at-risk and enrollment in a PRR.

The Comprehensive Addiction and Recovery Act, section 705, which passed the Senate on March 10, 2016, would require that the Secretary, in consultation with plan sponsors and other stakeholders, develop screening criteria to identify beneficiaries at risk for prescription drug misuse or diversion. These criteria are to be based on clinical factors indicating misuse of prescription drugs, including dosage, quantity, duration of use, number of prescribers, and number of pharmacies visited to obtain such drugs. Certain patient populations are excluded from PRR enrollment, including individuals receiving hospice care, residents in long-term care facilities, and others that the Secretary elects to treat as exempt. Further, the legislation provides the right for the beneficiary to appeal identification and placement in the PRR program. It also requires that the plan provide the beneficiary an opportunity to submit input on provider selection. Finally, the legislation requires the Comptroller General to conduct a post-program analysis to assess any barriers that may impede access to prescription medications and to evaluate the effectiveness of the reasonable access protections included in the legislation.

Question. In your opinion, is there a need for a patient review and restriction program in Medicare?

Answer. A patient review and restriction program in Medicare would help protect beneficiaries and reduce prescription drug abuse. A Centers for Medicare and Medicaid Services analysis identify approximately 225,000 beneficiaries who received potentially unsafe opioid dosing (the equivalent of 120 mg or more of daily morphine for 90 or more consecutive days) in 2011. An evaluation of 2008 claims data conducted by the Government Accountability Office identified 170,000 Medicare Part D beneficiaries who visited at least 5, and as many as 87, medical professionals in a year to obtain prescriptions for opioids or other drugs from 14 classes of abusable drugs. According to a 2012 Medicare Payment Advisory Commission analysis, among the subset of beneficiaries with the highest use of opioids for conditions not associated with cancer treatment or hospice care, 32 percent obtained these prescriptions from four or more prescribers or three or more pharmacies. Data from these evaluations highlight the need for PRR programs as a mechanism to achieve the balance of ensuring access to pain management while preventing overdoses and other harms associated with prescription drug misuse in the Medicare population.

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

Question. The *Colorado Plan to Reduce Prescription Drug Abuse* is working to educate prescribers and providers. It will also increase public awareness, strengthen the Colorado Prescription Drug Monitoring Program, and expand access to the overdose reversal drug, Naloxone. To date, there are 39,000 fewer Coloradoans who misused prescription drugs since the program was implemented. As we consider policy options to reduce opioid drug abuse, how can the federal government partner with states to advance the work that has been done?

Answer. The Colorado Plan to Reduce Prescription Drug Abuse is working to educate prescribers and providers. It will also increase public awareness, strengthen the Colorado Prescription Drug Monitoring Program, and expand access to the overdose reversal drug, Naloxone. To date, there are 39,000 fewer Coloradoans who misused prescription drugs since the program was implemented. As we consider policy options to reduce opioid drug abuse, how can the federal government partner with states to advance the work that has been done?

The federal government should continue to support states' efforts to curb prescription drug abuse. Federal grants programs, such as the Centers for Disease Control and Prevention (CDC) Prevention for States and the Substance Abuse and Mental Health Services Administration's Medication-Assisted Treatment for Prescription Drug and Opioid Addiction, are examples of programs that have allowed states to enhance prescription drug monitoring programs, support community and health system interventions to prevent abuse, and expand the use of medication-assisted treatment in combination with psychosocial services, recovery support services, and coordination of medical care for HIV and hepatitis C.

Question. In Colorado, drug overdoses are more prevalent in our rural areas. Those areas lack services, treatment, and access to transportation so patients can obtain services. How can we find a solution that takes into account the unique needs of our rural families?

Answer. Individuals in rural areas of Colorado and many other states face substantial barriers in accessing substance use disorder (SUD) treatment. These chal-

lenges include the limited number of healthcare providers who can prescribe buprenorphine, which is an effective therapy for SUD. Use of buprenorphine is especially beneficial in rural areas where opioid treatment programs (OTPs) are scarce. Yet, too few buprenorphine prescribers exist in these areas. A study published by Rosenblatt et al. in *Annals of Family Medicine* in January 2015 found that 10 percent of the U.S. population (30 million people) lives in a county where there are no authorized buprenorphine prescribers. Of these counties with no prescribers, 80 percent are in rural areas. Nurse practitioners and physician assistants may be more readily available in these areas, but legislation is needed to provide these healthcare professionals with the authority to prescribe and manage patients who could benefit from this medication.

Question. Given that over 20% of pregnant women on Medicaid filled a prescription for an opioid during pregnancy, what can we do to aid mothers-to-be and improve outcomes for infants who are born in withdrawal?

Answer. A CDC study published in National Health Statistics Reports in July 2012 found that approximately two in five U.S. pregnancies are unplanned, thus prescribers should assess opioid medication use among all women of reproductive age (15 to 44 years). Women on Medicaid may be at increased risk because of differences in opioid prescribing, differences in coverage of health care services, or differences in the prevalence of underlying health conditions. As recommended by the Association of State and Territorial Health Officials (ASTHO), key strategies for states include: patient education; universal substance use screening; Medicaid reimbursement for substance use screening during preventive care, preconception, and prenatal visits; provider education and training; and access to substance abuse treatment services.

Infants born with neonatal abstinence syndrome (NAS) are at increased risk of complications in the neonatal period, including respiratory complications and seizures. ASTHO recommends that birthing hospitals develop written policies that standardize evaluation and treatment protocol for NAS to decrease biases in screening and testing of mothers-to-be. Infants born with withdrawal respond best when mother-baby bonding is encouraged, and when mothers receive parental support and teaching. To improve outcomes for both mother and baby, mothers may need additional supports (*e.g.,* home-based services; family treatment drug courts) to enhance attachment and reduce the risk of child abuse or neglect.

PREPARED STATEMENT OF DAVID HART, ASSISTANT ATTORNEY-IN-CHARGE, HEALTH FRAUD/CONSUMER PROTECTION SECTION, OREGON DEPARTMENT OF JUSTICE

Good morning. I'd like to begin by thanking Chairman Hatch, Ranking Member Ron Wyden and members of the committee for allowing me the opportunity to testify on this important issue. My name is David Hart, and I am the Assistant Attorney-in-Charge of the Health Fraud Unit/Consumer Protection Section of the Oregon Department of Justice. For more than 15 years I have led investigations relating to pharmaceutical marketing and promotion, both for the State of Oregon, and for bipartisan multistate coalitions of state Attorneys General. Now, under the leadership of Oregon Attorney General Ellen Rosenblum, I pursue cases related to Oregon's growing—and painful—opioid abuse epidemic. Prior to graduating from law school and joining the Oregon Department of Justice, I practiced as a physical therapist for 15 years at hospitals, nursing homes, home health agencies and hospices. In that time period, I worked with thousands of patients with acute and chronic pain. That experience informed my investigations of the marketing and promotion of opioids which is the subject of my testimony this morning.

The causes of the opioid epidemic are many. While my testimony will focus on the effects of opioid marketing and promotion, I do not want to minimize the existence of other factors that helped cause the epidemic. Because the causes are many, so too will be the solutions. My testimony today will also cover some of the things we are doing in Oregon to combat the epidemic that were funded in part with settlement funds from our cases. If the Federal Government wants to take action to stop the opioid abuse, I would urge members of this committee to consider adopting the model approach we have taken in Oregon.

In 2007, Oregon was a member of the Executive Committee of a multistate coalition of state Attorneys General that reached a settlement with Purdue Pharma ("Purdue") to resolve allegations that Purdue violated state consumer protection law by misrepresenting OxyContin's risk of addiction and by promoting OxyContin "off-

label" for long term treatment of certain chronic pain conditions. OxyContin, an extended release formulation of oxycodone, was first introduced in 1995. Until that time, opioids were largely used to treat acute pain and cancer pain. Many physicians were reluctant to prescribe opioids on a long-term basis for common chronic conditions because of concerns about abuse and addiction. However, while this inhibition was already breaking down before OxyContin was introduced, after its introduction, this breakdown accelerated, fueled in part by Purdue Pharma's aggressive marketing and promotion of the drug. Attached as Exhibit 1 to my written testimony is a copy of the complaint the Oregon Department of Justice filed against Purdue in May of 2007. Virtually identical complaints were filed by 26 other state Attorneys General. In short, our complaints alleged that although OxyContin is a Schedule II narcotic with an abuse profile and addictive qualities similar to morphine, Purdue aggressively promoted OxyContin to doctors, nurses and consumers as a first-choice analgesic for treatment of a wide variety of pain symptoms. While it expanded the market for OxyContin, Purdue avoided and minimized the known risks of OxyContin abuse, addiction and diversion. Purdue failed to adequately warn doctors or consumers of OxyContin's significant risks and failed to take reasonable steps to guard against OxyContin abuse and diversion, instead striving to "educate" doctors and consumers that concerns over abuse, addiction and diversion of OxyContin were misplaced. Purdue's aggressive promotion of OxyContin led to a dramatic increase in OxyContin prescriptions which in turn furthered an increase in OxyContin abuse and diversion from legitimate users to illicit use of OxyContin.

The 2007 multistate consumer protection settlement with Purdue required cessation of unlawful promotion, and required Purdue to identify and stop promoting OxyContin to doctors who improperly prescribed opiates. Attached as Exhibit 2 to my written testimony is a copy of the multistate settlement. However, the settlement did not require Purdue to take sufficient remedial action to correct misinformation that was endemic in the marketplace. At the time of the multistate settlement, I did not fully appreciate the severity of the opioid epidemic and the long lasting effects of Purdue's OxyContin promotion. Had I so known, I would have advocated for a settlement which would have required more extensive remedial action by Purdue to correct the inappropriate prescribing patterns for opioids that Purdue's marketing helped create.

Oregon, like the rest of the nation, has continued to struggle with overprescribing and misuse of prescription opioids. Between 2000 and 2013, there were 2,226 deaths in Oregon due to prescription opioid drug overdose. The mortality rate associated with prescription opioid overdose increased 364% between 2000 and 2006, and though it has decreased since then, it remains 2.9 times higher than in 2000.[1] Results from the 2013–2014 National Survey on Drug Use Health tie Oregon for 4th place among all states in non-medical use of prescription pain relievers, down from 1st among all states in the same 2010–2011 survey.[2] In 2013, 3.6 million prescriptions for opioid painkillers were dispensed in Oregon, enough for 925 opioid prescriptions for every 1,000 residents.[3]

To ensure that unlawful drug promotion does not further contribute to this problem, the Oregon Department of Justice has been vigilant to monitor opioid marketing and promotion in our state. As part of that effort, we became concerned about the marketing and promotion of Subsys, a sub-lingual fentanyl spray that is more than 50 times more powerful than heroin and is only approved for breakthrough cancer pain. We believed this powerful drug was being deceptively and unconscionably promoted in Oregon. Pursuant to Oregon's Unlawful Trade Practices Act, we issued Investigative Demands to Insys, the manufacturer of Subsys, obtained documents and information from the company, interviewed former sales representatives and consulted with experts. Our comprehensive investigation revealed several patterns of alleged misconduct, including reports that the company provided improper financial incentives to doctors to increase prescriptions, aggressively promoted Subsys to doctors not qualified to prescribe the drug, and deceptively promoted Subsys for treatment of mild pain. After our investigation, we issued a formal Notice of Unlawful Trade Practices which lays out the allegations. In short, Oregon was the first state in the country to allege that Insys promoted Subsys "off-label" for non-cancer pain such as back pain and neck pain, uses for which Subsys is neither safe nor effective. We also outlined allegations that Insys unconscionably tar-

[1] 4.0 per 100,000 in 2013; 1.4 per 100,000 in 2000.
[2] *http://www.samhsa.gov/data/sites/default/files/NSDUHStateEST2012-2013-p1/ChangeTabs/NSDUsaeShortTermCHG2013.htm.*
[3] Unpublished Oregon PDMP data.

geted problem doctors who misprescribed opiates with aggressive Subsys promotion and that Insys facilitated prescribing of Subsys for contraindicated uses. Not only did Insys target problem opiate prescribers, it hired those doctors to teach other doctors about Subsys. I was truly shocked that in 2015, when the scourge of the opioid epidemic was so widely known, that a manufacturer of a schedule II drug would promote a powerful opioid such as Subsys in such an unconscionable and irresponsible way. Attached to my written testimony as Exhibit 3 is a copy of Notice of Unlawful Trade Practices which describes this conduct in greater detail.

To avoid a lawsuit that would litigate our allegations, Insys agreed to an Assurance of Voluntary Compliance which prohibits the misconduct that we identified in our investigation and required Insys to pay Oregon more than two times the total Subsys sales in the state. Oregon was also the first government entity to settle with Insys for this alleged misconduct. Attached to my written testimony as Exhibit 4 is a copy of the Assurance of Voluntary Compliance.

Fortunately, much of the $1.1 million dollar payment the Oregon Department of Justice received from the Insys settlement is now being used to fund efforts to address the opioid epidemic in Oregon. This includes:

- Funding regional pain guidance groups to develop opioid prescribing practices for their communities and to facilitate coordination of care across specialties;
- Funding development of regional action plans to prevent opioid abuse;
- Funding addiction treatment training to increase the number of Oregon physicians in underserved communities with the waiver necessary to treat opioid dependent individuals with agonist and partial agonist medications in an office based setting;
- Funding to support addiction treatment telemedicine consultation services to expand access to treatment for Oregonians with substance abuse disorders in the communities where they live;
- Funding to promote disposal of unused and expired opioids by helping pharmacies become licensed disposal locations;
- Funding to expand the use of naloxone, a drug that reverses the lethal effects of an opioid overdose; and
- Funding to build a statewide pain guidance public education campaign web platform with regional resource pages to help providers, patients and family members make informed choices.

It is our hope in Oregon that these programs and initiatives will save lives. We also hope that other states, and the Federal government, will consider programs like the one in Oregon that take a holistic—and realistic—approach to fighting our country's opioid epidemic.

This concludes my testimony. Again, thank you Chairman Hatch, Ranking Member Ron Wyden and members of the committee for inviting me today. I am available to answer questions.

QUESTION SUBMITTED FOR THE RECORD TO DAVID HART

QUESTION SUBMITTED BY HON. MICHAEL F. BENNET

Question. In recent months, a Colorado hospital's former employee stole narcotic pain medication and was found to have possibly exposed up to 2,900 patients to viruses including hepatitis B, hepatitis C, and HIV. A similar case occurred in 2009 involving a surgical technician that diverted narcotic pain medication and left behind dirty syringes. In other instances, stolen narcotics have been sold illegally in the community. As we discuss solutions for the opioid epidemic, how can we combat narcotic drug diversion in hospitals that not only adds to the epidemic but may put hospitalized patients at risk of contracting diseases?

Answer. Senator Bennet asks an excellent question. However, I am not the best person to answer it. Diversion of narcotics by addicted health care professionals is a serious problem that can impact thousands of patients. The events in Colorado, where surgical technicians diverted narcotics intended for post-surgical pain relief, was likely the result of insufficient procedures, or a failure to comply with existing procedures. Whether there should have been better screening of the technicians, or more robust monitoring and control of the drugs themselves, is outside of my area of expertise. My suggestion is to consult with groups such as the American Society of Health System Pharmacists, The American Society of Anesthesiologists, and professional licensing boards, who have expertise in this area, for greater insight into

what can be done to prevent diversion of narcotics by health care professionals in the hospital setting.

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 examining the opioid abuse epidemic and its effect on Medicare and the child welfare system:

Today, we are here to discuss the very important issue of opioid abuse. Opioids are a powerful class of drugs prescribed to treat severe pain. When used appropriately, these drugs provide much-needed relief to patients after a surgical procedure or during treatment for cancer.

Unfortunately, opioids also have qualities that make them addictive and prone to abuse. The goal of today's hearing is to help us gain a better understanding of why opioid use has risen dramatically in the past 15 years and how we can best curtail abuse.

Put simply, opioid abuse has become an epidemic and a significant public health problem.

While it puts serious strains on our health care system, including Medicare and other federal programs, the most devastating consequence of opioid abuse is the human impact. Opioid abuse takes a major toll on families and children often persisting for generations.

The statistics are staggering.

Opioids are prescribed in such quantities that every adult in the United States could have a month's supply. Approximately, 7,000 people show up in an emergency room each day for treatment of problems associated with prescription opioid abuse. One opioid-related death takes place in our country almost every 30 minutes.

My home state of Utah has been hard hit by this epidemic. In 2014 alone, 289 Utahns died due to opioid abuse, which was more than half of all drug-overdose related deaths in the state.

The problem is even worse in other states. I am sure many of my colleagues will not only have numbers to share regarding their states, but have stories about individuals as well.

The good news is that there is wide recognition of the problem and shared interest in finding solutions.

A few weeks ago, the Senate Judiciary Committee unanimously reported the Comprehensive Addiction and Recovery Act, legislation sponsored by Senator Portman. It is a good bill. I was pleased to vote for it in Committee and hope the full Senate will pass it swiftly and without unnecessary delay.

Today's hearing will focus on another good bill—one that is in the Finance Committee's jurisdiction.

As I mentioned, Medicare is not immune from the costs of opioid abuse. The Government Accountability Office, the Medicare Payment Advisory Commission, and others have identified it as a problem. Though only a relatively small number of beneficiaries are at risk, we owe it to those individuals, their families, and the Medicare program to do all we can to address this problem.

Senators Toomey and Portman have a very thoughtful bipartisan bill with Senators Casey and Brown that would provide Medicare with an important tool in the fight against opioid abuse. The bill will allow Medicare Part D prescription drug plans to work with at-risk beneficiaries to identify one physician to prescribe opioids and one pharmacy to fill all the opioid prescriptions. Having opioids prescribed by one physician instead of multiple doctors will result in better patient care and reduced abuse. It will also make it more likely that a beneficiary with a problem gets the help they need.

Nearly all Medicaid programs and private payers have such a prescription drug review and restriction, or "lock-in," program. I look forward to hearing more today about the success of these programs in Medicaid and how the Toomey-Portman bill would have a similar impact in Medicare.

The Toomey-Portman bill has bipartisan support on the Committee, with both Senators Brown and Casey acting as strong proponents. Establishing a lock-in program in Medicare is also supported by President Obama as it was proposed in the Administration's budget proposal.

I applaud Senators Toomey and Portman for their leadership on this legislation and I hope we can move it very soon.

Of course, the impact of the opioid epidemic stretches far beyond our health care system, touching on virtually all parts of the social safety net. Today, in addition to discussing the impact on the health care system, we'll hear more about the implications of these substance abuse crises for our child welfare system.

The current opioid epidemic is just the latest manifestation of an ongoing problem in child welfare. Whether it be the crack cocaine epidemic of the 1980s, the methamphetamine epidemic that has plagued many rural areas, or the current opioid crisis, we have seen time and again that the child welfare system is ill-equipped to deal with families struggling with substance abuse.

Instead of finding ways to get families affected by addiction the help and support they need to get and stay sober, the majority of federal dollars in the child welfare system are spent on removing children from their homes and placing them into foster care, which most have acknowledged is the least effective and most expensive outcome.

Children who are raised by the state in foster care face increased risks of substance abuse, homelessness, teen pregnancy, and other negative outcomes both while they're in the system and when they transition out as adults. And, in cases of untreated addiction, the cycle of addiction can persist for generations.

Senator Wyden and I have been working on bipartisan legislation that would provide states the flexibility to use federal child welfare funds to address issues of substance abuse and other risk factors. We're also talking with our colleagues over in the House, and I hope that we'll be able to get to a bipartisan/bicameral agreement on a path forward. Children and families are relying on us to take this important step.

Let me conclude by saying that the opioid epidemic is a complex problem that needs a multi-faceted solution. We will discuss at least opportunities to make a difference here today—the Toomey-Portman bill dealing with Medicare and our efforts with regard to child welfare.

Of course, these are not the only ideas out there. I am would be happy to hear about and consider any other ideas that might be within the Finance Committee's jurisdiction, so long as they are constructive and do not take an overly simplistic view of this serious and complicated problem.

I'd like to thank our witnesses for being here today to discuss this important to topic.

LETTERS SUBMITTED FOR THE RECORD BY HON. PATRICK J. TOOMEY

Supporters of Patient Review and Restriction Programs
Prepared by the Office of Senator Pat Toomey (R-PA)

CMS Acting Administrator Andy Slavitt, Senate Finance Committee Hearing, January 21, 2016.

"Thank you for your leadership on this very challenging issue. I know from work we've done with you, and your office in western Pennsylvania, how personally involved you have been, and of course we are dealing with the effects of this every day as well.

"We think a lock-in proposal makes every bit of sense in the world, and we completely agree that that's the type of authority that would be very helpful in really taking a practical measure to stem abuse."

Statement of Michael P. Botticelli, Director of National Drug Control Policy, HSGAC Field Hearing, September 15, 2015.

Director Botticelli on the President's FY16 budget includes support for a lock-in proposal stating, "The Budget also proposes to establish a program in Medicare Part D to prevent prescription drug abuse by requiring that beneficiaries at risk for pre-

scription drug misuse obtain controlled substances only from specified providers and pharmacies, similar to many state Medicaid programs."

CDC Director Tom Frieden, Press Conference, November 1, 2011.

Dr. Frieden stated in 2011 that, "Prescription pain killers are meant to help people who have severe pain. They are, however, highly addictive. . . . There are specific things that can be done to drastically reduce the number of prescription overdoses, of deaths and people who become addicted. . . . One means of taking that effective action is through patient review and restriction policies which identifies problem patients or patients who have had a problem with drugs and limits them to one doctor to prescribe narcotics and one pharmacy to fill those narcotic prescriptions."

HHS Budget Request

The President's FY 2016 and FY 2017 budget request, "proposes to establish a program in Medicare Part D to prevent prescription drug abuse by requiring that high-risk beneficiaries only obtain controlled substances from specified providers and pharmacies."

Office of Inspector General Reports

In a report issued in August 2014, the Department of Health and Human Services, Office of the Inspector General "has found that Part D is vulnerable to fraud, waste, and abuse" and "found that a number of beneficiaries received . . . drugs from extremely high numbers of pharmacies or prescribers." In order to prevent this abuse of the Part D Program, OIG recommended that "CMS should seek legislative authority, if necessary, to restrict certain beneficiaries to a limited number of pharmacies or to a limited number of prescribers, a practice commonly referred to as 'lock-in.'"

In a report issued in June 2015, HHS OIG stated, "As a means to more appropriately manage prescription drug utilization by beneficiaries, CMS should seek statutory authority to restrict certain beneficiaries to a limited number of pharmacies or prescribers when warranted by excessive or questionable billing patterns. This practice is commonly referred to as 'lock-in' and has been successfully implemented by some State Medicaid programs."

MedPAC

When discussing potential policy options focused on opioids, MedPAC stated on April 2, 2015 that pharmacy and/or prescriber lock-in was an option that had potential to cut down on the opioid epidemic.

Government Accountability Office

In a September 2011 report the GAO recommended, "that the Administrator of CMS . . . consider additional steps such as a restricted recipient program for Medicare Part D that would limit these beneficiaries to one prescriber, one pharmacy, or both for receiving prescriptions. CMS should consider the experiences from Medicaid and private sector use of such restricted recipient programs, including weighing the potential costs and benefits of instituting the control. CMS could consider piloting such a program with a focus on hydrocodone and oxycodone, the two drug classes where [GAO] identified the largest potential doctor shopping activity."

In a July 2015 report the GAO "identified about 16,000 individuals [in the Medicaid program] whose visits to multiple prescribers for antipsychotics and respiratory medications raise questions." To prevent this from occurring, the GAO concluded that, "Lock-in programs are an important tool that can be used to address doctor shopping by locking beneficiaries who have abused the Medicaid program in to one prescriber, one pharmacy, or both for receiving prescriptions."

ACADEMY OF MANAGED CARE PHARMACY

February 22, 2016

The Honorable Orrin G. Hatch
Chairman
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

Re: Senate Finance Committee Hearing—"Examining the Opioid Epidemic: Challenges and Opportunities"

Dear Chairman Hatch and Ranking Member Wyden:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to submit comments for the record on the hearing titled "Examining the Opioid Epidemic: Challenges and Opportunities" scheduled for February 23, 2016. AMCP supports a holistic, comprehensive, and multi-stakeholder approach among health care providers and patients that truly addresses the opioid epidemic.[1] On the federal level, AMCP supports drug management programs for the population of Medicare at-risk beneficiaries. Adoption of federal legislation on this issue is one opportunity to better manage opioid addiction in Medicare and therefore AMCP strongly supports S. 1913—The Stopping Medication Abuse and Protecting Seniors Act that would allow for the expansion of drug management programs to Medicare Part D beneficiaries and allow these patients to benefit positively from these programs.

AMCP is a professional association of pharmacists and other practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 8,000 members develop and provide a diversified range of clinical, educational, medication and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

Rates of prescription drug abuse related to emergency department visits and treatment admissions have reached epidemic levels in the United States. According to the Centers for Disease Control and Prevention (CDC), deaths associated with prescription medications have increased more than 300 percent since 1998, while prescribing rates for these drugs quadrupled between 1999 and 2010. Deaths connected to prescription drug misuse now exceed those from heroin and cocaine combined.[2] Moreover, the economic costs of prescription drug abuse are substantial. The nonmedical use of controlled substances results totals $72 billion in unnecessary costs annually, including lost productivity, costs to the criminal justice system, and health care expenditures.[3]

Managed care organizations have well-established techniques for limiting the abuse or diversion of opiates or other controlled substances for patients who have a history or suspicion of inappropriate utilization, diversion, or abuse of these agents. However, one tool commonly used by the private sector and Medicaid markets that the Medicare Part D program does not permit is the use of a drug management plan (DMP) by prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA–PD) to limit patients with a history of abuse to a single prescriber and/or pharmacy (or chain of pharmacies). Members of Congress, the Centers for Medicare and Medicaid Services (CMS), the Drug Enforcement Administration (DEA), and the Department of Health and Human Services (HHS) Office of Inspector General have all acknowledged the need and expressed support for this type of program.

Forty-six states have successfully implemented DMPs through state Medicaid programs with positive results.[4] An evaluation of state Medicaid DMPs, performed by a CDC expert panel, concluded that these programs have the potential to reduce opioid usage to safer levels and thus save lives and lower health care costs.[5]

- In 2012, the State of North Carolina, announced $5.2 million in savings from their state Medicaid DMP program.[6]

---

[1] Proceedings of the AMCP Partnership Forum: Breaking the Link Between Pain Management and Opioid Use Disorder J Manag Care Spec Pharm 2015 Dec;21(12):1116–1122.

[2] Theresa R.F. Dreyer, Thomas Michalski, and Brent C. Williams. Patient Outcomes in a Medicaid Managed Care Lock-In Program. J Manag Care Spec Pharm, 2015 Nov;21(11):1006–1012.

[3] Centers for Disease Control and Prevention. Prescription painkiller overdoses in the U.S. November 2011. Available at: *http://www.cdc.gov/vitalsigns/painkilleroverdoses/*. Accessed on August 25, 2015.

[4] Roberts A.W., Cockrell Skinner A. Assessing the Present State and Potential of Medicaid Controlled Substance Lock-in Programs. *J. Manag. Care Pharm.* 2014;20(5):439–46.

[5] CDC; National Center for Injury Prevention and Control. Beneficiary review and restriction programs. Lessons learned from state Medicaid programs (2012), *http://www.cdc.gov/homeandrecreationalsafety/pdf/PDO_beneficiary_review_meeting-a.pdf*. Accessed on August 25, 2015.

[6] North Carolina Department of Health and Human Services. 2.3 million pills off the streets, $5.2 million saved by narcotics lock-in. May 14, 2012.

- In 2009, the Oklahoma Medicaid department found that its lock-in program reduced doctor shopping, utilization rates of controlled substances, and emergency room visits with a savings of $600 per person in costs.[7]
- Florida reported 1,315 individuals had been placed into their Medicaid DMP between October 2002 and March 2005. During this time period, cumulative savings for medical and pharmaceutical expenses topped $12.5 million.

A recent study evaluating the clinical outcomes of drug management programs for Medicaid patients found that the proportion of stable patients increased from 31% at 6 months to 78% at 36 months.[8] In addition, a study evaluating the impact of a single-prescriber and single-pharmacy drug management program on health care utilizations and costs within a Medicaid Managed Care Organization in Maryland found that enrollment in a drug management program decreased opioid prescriptions and associated costs among health plan members who exhibited signs of opioid overuse.[9] Therefore, AMCP supports the ability for patients identified as at-risk for opioid overutilization to be entered into a DMP to reduce incidence of doctor or pharmacy shopping.

As noted above, DMPs have successfully been used by state Medicaid programs and commercial plans for years but are currently prohibited under Medicare Part D. Opioid misuse by elderly patients, the primary population covered by the Medicare Part D program, is a growing concern in the United States and it is unfortunate that DMPs, along with other clinical and psychosocial interventions, may not be used to allow these individuals to receive the help they need. Furthermore, Medicare beneficiaries who are disabled and under 65 are at the greatest risk for overutilization or inappropriate utilization of opioids thereby strengthening the need for DMPs under Medicare Part D. In addition, a recent consensus document released by the Johns Hopkins Bloomberg School of Public Health highlights the benefits of DMPs and recommends expansion of the DMPs to Medicare Part D beneficiaries.[10]

Given the success and experience using DMPs, AMCP urges you to support S. 1913. This legislation would allow PDPs and MA–PDs to proactively identify individuals at risk for controlled substance abuse, misuse or improper utilization. Once identified beneficiaries have appeal rights and can submit their preference for a specific DMP prescriber and pharmacy. The use of DMPs may improve continuity of care among at-risk beneficiaries, while ensuring beneficiaries with legitimate medical needs have continued access to effective pain control.

A 2012 CMS study found that less than 1% of beneficiaries would be targeted for a DMP. The study examined the use of potentially unsafe doses of prescription opioids for 90 days. Beneficiaries in hospice or those with a diagnosis of cancer were excluded. The study further found that only 0.7% of Medicare Part D beneficiaries received opioids from at least 4 prescribers and 4 or more pharmacies.[11] Under S. 1913, at-risk beneficiaries are still able to receive non-controlled prescriptions at network pharmacies of their choice.

AMCP appreciates that under your leadership that the Finance Committee is identifying challenges and opportunities on this important issue. AMCP will continue to work on this issue and offers our support to you in your efforts. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703–683–8416 or scantrell@amcp.org.

Sincerely,

---

[7] SoonerCare Pharmacy Lock-in Program Promotes Appropriate Use of Medications. September 9, 2009 [press release]. *http://okhca.org/about.aspx?id=10973.* Accessed on August 25, 2015.

[8] Theresa R.F. Dreyer, Thomas Michalski, and Brent C. Williams. Patient Outcomes in a Medicaid Managed Care Lock-In Program. *Journal of Managed Care and Specialty Pharmacy* 2015 21:11, 1006–1012.

[9] Sarah G. Kachur, Alyson B. Schuster, Yanyan Lu, Elizabeth Patton-LeNoach, Hugh Fatodu, Peter J. Fagan, and Chester W. Schmidt. *Impact of a Single-Provider Lock-In Program for Opiates in a Managed Medicaid Population.* Johns Hopkins University School of Medicine, Baltimore, MD.

[10] Alexander G.C., Frattaroli S., and Gielen A.C., eds. The Prescription Opioid Epidemic: An Evidence-Based Approach. Johns Hopkins Bloomberg School of Public Health, Baltimore, MD: 2015.

[11] Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Centers for Medicare and Medicaid Services, April 2, 2012. Available at *http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=15078.* Accessed September 4, 2015.

Susan A. Cantrell, RPh, CAE
Chief Executive Officer

cc: The Honorable Senator Pat Toomey

AMERICA'S HEALTH INSURANCE PLANS (AHIP)
601 Pennsylvania Avenue, NW
South Building
Suite 500
Washington, DC 20004
202–778–3200

February 19, 2016

The Honorable Patrick Toomey
U.S. Senate
248 Russell Building
Washington, DC 20510

The Honorable Sherrod Brown
U.S. Senate
713 Hart Building
Washington, DC 20510

The Honorable Rob Portman
U.S. Senate
448 Russell Building
Washington, DC 20510

The Honorable Tim Kaine
U.S. Senate
388 Russell Building
Washington, DC 20510

Dear Senators Toomey, Brown, Portman, and Kaine:

On behalf of America's Health Insurance Plans (AHIP), I am writing to thank you for introducing S. 1913, the "Stopping Medication Abuse and Protecting Seniors Act."

Our members appreciate your leadership in proposing thoughtful steps to prevent prescription drug abuse and improve patient safety in the Medicare Part D prescription drug program. Your bill directly addresses concerns about the harmful impact of prescription drug fraud and abuse on the health and well-being of Medicare beneficiaries. Health plans are strongly committed to promoting the safe use of pharmaceuticals among Part D enrollees and the broader population, and have implemented a range of strategies to address this priority. Your bill seeks to add important tools to support fraud prevention. We look forward to working with you to further improve patient safety in this critically important area.

Thank you again for bringing attention to this issue with your bipartisan legislation.

Sincerely,

Marilyn B. Tavenner
President and CEO

BLUE CROSS BLUE SHIELD ASSOCIATION (BCBSA)
1310 G Street, NW
Washington, DC 20005
202–626–4800
www.bcbs.com

February 23, 2016

The Honorable Pat Toomey
Committee on Finance
U.S. Senate
Washington, DC 20510

The Honorable Sherrod Brown
Committee on Finance
U.S. Senate
Washington, DC 20510

The Honorable Rob Portman
Committee on Finance
U.S. Senate
Washington, DC 20510

The Honorable Tim Kaine
Committee on Finance
U.S. Senate
Washington, DC 20510

Dear Senators Toomey, Brown, Portman, and Kaine:

On behalf of the Blue Cross Blue Shield Association (BCBSA), I am writing in support of the Stopping Medication Abuse and Protecting Seniors Act of 2015 (S. 1913).

BCBSA is the national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield companies that collectively provide healthcare coverage for 105 million members. Many Blue Cross and Blue Shield Plans contract with the Centers for Medicare and Medicaid Services (CMS) to sponsor coverage op-

tions in both the MA and Part D programs. We serve more than 4 million members in these 2 important programs.

BCBSA commends your efforts to enable Medicare Advantage and Part D plans to prevent prescription drug abuse and increase patient safety. S. 1913 will help to advance this critical goal by authorizing plans to establish drug utilization management programs that limit beneficiaries who are documented high-risk users of controlled substances to one or more authorized prescriber and one or more designated pharmacy.

Thank you for your bipartisan leadership to address the overutilization of controlled substances which in turn will help combat prescription drug and opioid abuse and addiction. BCBSA and its member Plans look forward to working with you to advance this important public health policy.

Sincerely,

Alissa Fox
Senior Vice President, Office of Policy and Representation
Blue Cross and Blue Shield Association

MAJOR CITIES CHIEFS ASSOCIATION

February 18, 2016

The Honorable Pat Toomey
248 Russell Senate Office Building
Washington, DC 20510

Dear Senator Toomey,

On behalf of the Major Cities Chiefs Association, representing the largest local law enforcement agencies in the Nation, I am writing to voice support for S. 1913, the Stopping Medication Abuse and Protecting Seniors Act.

Our officers see the real life impact of drug abuse everyday as they patrol the streets of the communities we are sworn to protect. Studies show that after marijuana, prescription drugs are the most commonly abused substance by Americans 14 and older. S. 1913 will provide the authority to enact effective fraud prevention and information sharing practices which are important measures in the fight to regulate dangerous medications and prevent prescription drug abuse. By establishing safe pharmacy access programs, the ability to suspend payments pending investigation of fraud allegations, and increased electronic monitoring this legislation will provide strong Nation-wide tools to combat a trend that is destroying lives throughout the country.

We value your leadership in the fight against opioid abuse, and all that you do to support the enforcement of our Nation's laws. We appreciate the chance to be a part of this important conversation and look forward to swift action by your colleagues in the Senate to pass this bill.

Sincerely,

J. Thomas Manger
Chief of Police
Montgomery County Police Department
President, Major Cities Chiefs Association

PENNSYLVANIA STATE CORONERS ASSOCIATION

Secretary/Treasurer
Dennis J. Kwiatkowski
110 Franklin St., Suite 500
Johnstown, PA 15901
(814) 535–6222
(814) 539–9057 Fax

President
Jeffrey R. Conner
Vice President
Charles E. Kiessling Jr.
Assistant Secretary/Treasurer
Kenneth A. Bacha

August 20, 2015

The Honorable Pat Toomey
U.S. Senate
Washington, DC 20510

Dear Senator Toomey:

On behalf of the Pennsylvania State Coroners Association, we are writing this letter in support of S. 1913, Stopping Medication Abuse and Protecting Seniors Act of 2015. According to data collected by the Association nearly seven persons a day are dying in Pennsylvania from drug related deaths. Of those deaths approximately two of those persons daily are over 50 years of age. (A copy of the 2014 Report has been previously sent to your office.)

While we know that many of these drug related deaths can be attributed to the use of illegal drugs, such as heroin and cocaine, many of these deaths are complicated by the use or misuse of prescription drugs. And, even in the absence of prescription drugs in the person's toxicology at the time of death, it has been well-established that the use of prescription drugs may be the gateway to the cheaper substitute of illegal drugs. Many times an individual may have a deadly combination of different opioids, anti-depressants, benzodiazepines, antihistamines, antipsychotics, anti-convulsants, muscle relaxers, barbiturates and hypnotics along with heroin or cocaine used at the same time. Even prescription drugs at therapeutic levels, when combined with other prescription drugs can be deadly.

PSCA has supported the State's passage of a PMP which allows Coroners and Medical Examiners access to prescription data of the deceased as a means of assisting in the investigation into the cause and manner of death. To be sure, the PMP provides other benefits in reducing doctor shopping and reducing a patient's unknowingly accessing incompatible prescription drugs for use.

PSCA supports the legislation's establishment of drug management programs for Medicare recipients. These programs can play an important role in preventing prescription drug abuse and misuse by assigning at risk patients to pre-designated pharmacies and prescribers to obtain these drugs.

If you have any concerns or questions, please feel free to be in further contact with Susan M. Shanaman, Solicitor at 717–412–0002 or shanaman1@comcast.net.

Sincerely,

Jeffrey R. Conner
President

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION (PCMA)
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

February 22, 2016

The Honorable Pat Toomey
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Sherrod Brown
713 Hart Senate Office Building
Washington, DC 20510

The Honorable Rob Portman
448 Russell Senate Office Building
Washington, DC 20510

The Honorable Tim Kaine
231 Russell Senate Office Building
Washington, DC 20510

Dear Senators Toomey, Brown, Portman, and Kaine:

As the Senate Finance Committee investigates ways to stem prescription opioid abuse, PCMA believes that a Medicare Part D "lock-in" pharmacy provision could help curb prescription drug fraud, waste, and abuse.

A pharmacy "lock-in" provision, which would authorize Part D plans to identify at-risk beneficiaries and limit their opioid prescription fills to one or more specific pharmacies, would help prevent inappropriate prescriptions from crossing the pharmacy counter. S. 1913, the Stopping Medication Abuse and Protecting Seniors Act, recognizes that this approach is one step toward addressing the prescription drug abuse epidemic.

The key to stopping "drugstore shopping" is preventing improper prescriptions from being filled in the first place. Currently, Medicare Part D plans are unable to "lock-in" at-risk beneficiaries to a particular pharmacy in order to fill prescriptions for certain controlled substances. This practice is an important and widely used tool in commercial health plans. The creation of this type of program in Medicare Part D would allow health plans and at-risk beneficiaries to agree upon which pharmacy

a beneficiary will use for the dispensing of his or her controlled substance prescriptions.

We appreciate your efforts to promote legislation enabling Medicare Part D plans to establish these types of programs and we look forward to working with you to strengthen the Part D program's ability to combat prescription drug fraud, waste, and abuse.

Sincerely,

Kristin Bass
Senior Vice President—Policy and Federal Affairs

PENNSYLVANIA DISTRICT ATTORNEYS ASSOCIATION
2929 North Front Street
Harrisburg, PA 17110
(717) 238–5416
FAX (717) 231–3912

FOUNDED 1912

February 18, 2016

The Honorable Pat Toomey
U.S. Senate
Washington, DC 20510

Re: Stopping Medication Abuse and Protecting Seniors Act (S. 1913)

Dear Senator Toomey:

Pennsylvania's prosecutors write in support of the Stopping Medication Abuse and Protecting Seniors Act (S. 1913). This legislation comprises a common sense measure in the fight against prescription drug abuse.

Requiring beneficiaries that are known to be abusing prescription opioids to select a single pharmacy for dispensing such drugs will help to control diversion and reduce fraud. The scourge of prescription drug abuse exists in every corner of the Commonwealth and the problem is worsening. With the GAO estimating 170,000 Medicare enrollees diverting medication, this measure will result in improved quality of care and quality of life for seniors.

Authorizing Medicare prescription drug plans to adopt the "lock-in" tool to require an addicted beneficiary to use a single doctor and/or a single pharmacy to get opioids should substantially curtail pharmacy and/or doctor shopping. This expanded use of the "lock-in" tool will provide protections for seniors currently available to those participating in Medicaid or commercial plans.

Our membership recognizes and appreciates the important privacy protections and beneficiary appeal rights included in the bill.

The insidious nature of prescription drug abuse demands a comprehensive strategy in opposition. This act comprises an important piece of such a strategy by helping to limit access to opioids by those most vulnerable. We appreciate the efforts of your fellow members of Congress and you in working to provide the tools to fight prescription drug abuse in Pennsylvania and across the nation. If our association can be of further assistance in this fight please let us know.

Sincerely,

David J. Arnold, Jr.
President

PHYSICIANS FOR RESPONSIBLE OPIOID PRESCRIBING (PROP)
164 West 74th Street
New York, NY 10023
www.supportprop.org
T 347–396–0369
F 347–396–0370

February 19, 2016

The Honorable Pat Toomey
U.S. Senate
Washington, DC 20510

The Honorable Rob Portman
U.S. Senate
Washington, DC 20510

The Honorable Sherrod Brown
U.S. Senate
Washington, DC 20510

The Honorable Tim Kaine
U.S. Senate
Washington, DC 20510

Dear Senators Toomey, Portman, Brown and Kaine,

On behalf of Physicians for Responsible Opioid Prescribing (PROP), I am writing to express our strong support for the Stopping Medication Abuse and Protecting Seniors Act, which authorizes the use of drug management programs in Medicare. PROP represents physicians from diverse specialties including Pain, Addiction, Primary Care, Public Health and Emergency Medicine. Our mission is to reduce morbidity and mortality caused by overprescribing of opioid analgesics.

PROP supports patient review and restriction programs (PRRs) because we understand the important role they play in reducing prescription drug overdose deaths. PRRs allow plan sponsors to better coordinate patient care and prevent inappropriate access to medications that are especially dangerous when prescribed to individuals suffering from a substance use disorder.

Evidence suggests that PRRs in Medicaid programs can effectively reduce opioid-related harms caused by overuse. PRRs are urgently needed in Medicare, where the problem of opioid overuse is especially serious in Medicare Part D beneficiaries. We are supporting the Stopping Medication Abuse and Protecting Seniors Act because it authorizes the use of PRRs in Medicare and will help reduce opioid-related harms while ensuring access to medication for patients with legitimate medical needs. We urge the Senate to appropriately respond to the epidemic of opioid addiction and overdose deaths by passing this legislation.

Your bipartisan efforts to address this urgent public health crisis are greatly appreciated. We look forward to working with you in your efforts to address the opioid addiction epidemic.

Sincerely,

Andrew Kolodny, M.D.

MEDICARE RIGHTS CENTER

February 22, 2016

The Honorable Pat Toomey
U.S. Senate
Washington, DC 20510

The Honorable Rob Portman
U.S. Senate
Washington, DC 20510

The Honorable Sherrod Brown
U.S. Senate
Washington, DC 20510

The Honorable Tim Kaine
U.S. Senate
Washington, DC 20510

Dear Senator Toomey, Senator Brown, Senator Portman, and Senator Kaine:

On behalf of the Medicare Rights Center (Medicare Rights), I am writing to express support for the Stopping Medication Abuse and Protecting Seniors Act of 2015 (S. 1913). Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Our organization provides services and resources to over 2 million beneficiaries, family caregivers, and professionals annually.

This bipartisan legislation would establish a Patient Review and Restriction (PRR) program to identify Medicare beneficiaries at risk for prescription drug misuse. The PRR program would allow Part D plan sponsors to limit enrollees with questionable prescription drug utilization patterns to one prescriber and one pharmacy for a given medication. As this bill and similar legislation was developed in the U.S. House of Representatives, we advised Congress to design PRR programs with adequate consumer protections to ensure no unintended harm comes to those with a legitimate medical need for pain medications or other commonly misused prescriptions.[1]

---

[1] Leadership Council of Aging Organizations (LCAO), "Medicare Part D 'Lock-In' Proposals Must Include Beneficiary Protections," (November 2014), available at: *http://www.lcao.org/files/2014/11/FINAL-LCAO-LockIn-Part-D-Brief.pdf.*

As such, we appreciate that S. 1913 incorporates several critical beneficiary protections, including: a clinically-determined criteria for targeting at-risk beneficiaries; advance, written notification outlining beneficiary rights, resources, and the opportunity to choose a pharmacy and prescriber; exemptions for hospice beneficiaries and those residing in long-term care facilities; required plan audits and monitoring, including a report by the Department of Health and Human Services on opportunities to improve the Part D appeals process; and engagement with diverse stakeholders, including beneficiaries and consumer advocates.

To further strengthen the legislation, we continue to encourage stronger emphasis on provider education, specifically to limit inappropriate prescribing of frequently misused medications, which may lead to addiction and overuse. We look forward to working with you on this issue and other advancements to strengthen Medicare for today's beneficiaries and for future generations. If you have questions, please contact Stacy Sanders, Federal Policy Director, at ssanders@medicarerights.org or 202–637–0961. Thank you.

Sincerely,

Joe Baker
President
Medicare Rights Center

MAJOR COUNTY SHERIFFS' ASSOCIATION (MCSA)

February 23, 2016

The Honorable Pat Toomey
U.S. Senate
248 Russell Senate Office Building
Washington, DC 20510

Dear Senator Toomey,

As Vice President of Government Affairs for the Major County Sheriffs' Association (MCSA), an association of elected sheriffs representing our nation's largest counties with populations of 500,000 people or more serving over 100 million Americans, I write to express our support for S. 1913, the Stopping Medication Abuse and Protecting Seniors Act of 2015.

Prescription drug abuse and diversion have become among the largest contributing factors to crime in our communities and our sheriffs are on the front line combating this growing epidemic and associated crime. According to the National Institute on Drug Abuse, from 2001 to 2014 prescription drug deaths increased 2.8 fold translating to over 25,000 deaths in 2014 alone.

Your legislation would address this problem head on by stopping the epidemic where it starts—at the pharmacy counter. S. 1913 would give Medicare the same authority as Medicaid and the commercial market to prevent prescription drug fraud and abuse. Through fraud prevention, information sharing and increased electronic monitoring measures, thousands of lives will be saved and our communities will be safer.

We appreciate the opportunity to weigh in on this important issue and applaud your commitment to fighting our nation's prescription drug abuse epidemic.

Very Respectfully,

Michael J. Bouchard, Sheriff, Oakland County (MI)
Vice President—Government Affairs, Major County Sheriffs' Association

---

CVS HEALTH

February 22, 2016

The Honorable Pat Toomey
U.S. Senate
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Rob Portman
U.S. Senate

The Honorable Sherrod Brown
U.S. Senate
713 Hart Senate Office Building
Washington, DC 20510

The Honorable Tim Kaine
U.S. Senate

448 Russell Senate Office Building
Washington, DC 20510

388 Russell Senate Office Building
Washington, DC 20510

Dear Senators Toomey, Portman, Brown, and Kaine:

CVS Health applauds your efforts to prevent prescription drug abuse by your work on S. 1913, Stopping Medication Abuse and Protecting Seniors Act of 2015. This bill would permit the use of drug-management programs in Medicare and require patients at risk of drug abuse to utilize designated pharmacies and prescribers to obtain controlled substances.

These drug management programs, which are also known as Patient Review and Restriction programs (PRRs), are a critical tool for addressing the nation's prescription drug abuse epidemic. A Centers for Disease Control and Prevention expert panel evaluation found that PRRs used in state Medicaid programs have reduced narcotic prescriptions, abuse, and visits to multiple doctors and emergency rooms, while also generating cost savings.[1] These programs are used in state Medicaid as well as in commercial plans, but authorization is needed by Congress to permit the use of PRRs in Medicare. The legislation would authorize the use of PRRs in Medicare, potentially improving continuity of care by providing improved drug therapy management while simultaneously ensuring patients with legitimate medical needs continue to have access to effective pain control.

There is support to advance these drug management programs as an effective tool to decrease opioid abuse. The policy has been proposed in the FY 2017 Budget request for the Department of Health and Human Services, and the House of Representatives authorized these programs in the 21st Century Cures Act, which passed the House of Representatives with broad bipartisan support on July 10, 2015. We urge the Senate to join in efforts to address the Nation's ongoing prescription drug abuse epidemic by advancing the Stopping Medication Abuse and Protecting Seniors Act of 2015 to authorize the use of PRRs in Medicare.

Thank you for your careful consideration of this important matter. We welcome the opportunity to work with you to ensure the final legislation brings the proven benefits of PRRs to Medicare beneficiaries. If you have any questions, please feel free to contact Ann Walker at 202–772–3503.

Sincerely,

Melissa Schulman
Senior Vice President, Government Affairs

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

Thank you, Chairman Hatch. As the committee that's required to pay for the most important health programs in the nation, the Finance Committee needs to do its part to address the opioid crisis. In the coming years, Medicare and Medicaid are expected to account for over a third of substance abuse-related spending. That amounts to billions and billions every year. Any solution that's going to stem this tide needs to include the Finance Committee and our bedrock health programs.

Americans today are paying for a distorted set of priorities—people are getting hooked on opioids, there's not enough treatment, and enforcement is falling short. That sounds like a trifecta of misplaced priorities to me, and the Finance Committee has the opportunity to develop fresh policies to start righting the ship.

As one listens to the current debate on opioids, there is a sense that policymakers will have to choose between two solutions. One approach is tough enforcement, which means cracking down on pill mills, fraudsters bilking Medicare and Medicaid with unneeded prescriptions, and unscrupulous abusers doctor-shopping for their next bottle of pills. Others want to focus on more social services. My own view on what's needed is a better approach that includes three things: more prevention, better treatment, and tougher enforcement. True success will require all three to work in tandem.

---

[1] Centers for Disease Control and Prevention; National Center for Injury Prevention and Control. Patient review and restriction programs. Lessons learned from state Medicaid programs (2012). Available at *http://www.cdc.gov/homeandrecreationalsafety/pdf/PDO_patient_review_meeting-a.pdf.*

When it comes to preventing addiction, any discussion has to include how these drugs are prescribed in the first place. In Oregon last week, I heard about the "prescription pendulum"—where doctors were once criticized for not treating pain aggressively enough, and today they are being criticized for prescribing too many opioids to manage pain. So let's look at how to get that balance right.

The Centers for Disease Control and Prevention is trying to break new ground with their guidelines for prescribing opioids. Along with better prescribing practices, there needs to be more responsible marketing practices by opioid manufacturers. I'm pleased that we're joined today by David Hart, with the Oregon Attorney General's office, who will able to discuss his considerable experience in this area.

I am also concerned about the influence the manufacturers have on medical prescribing practices. I've sent an inquiry to Secretary Burwell to ensure any potential conflicts of interest have been properly disclosed for members of government panels who are evaluating CDC's guidelines, as a result of funding they receive from drug manufacturers. Doctors ought to have the best information on prescribing these powerful drugs without undue influence from the companies that are manufacturing them.

In my view, a key piece of the puzzle has to be prompt and effective treatment of those who are dealing with an addiction to opioids. A prerequisite for any lasting solution needs to include improving access to addiction treatment and mental health services—something that's very important for rural and under-served communities. It's no coincidence these areas have some of the highest rates of abuse and overdose in the country.

Mental health and treatment for addiction have gotten short shrift for too long, and it's high time for a change. For example, the Finance Committee could also be taking a look at what's called the IMD exclusion—an out-of-date policy from the 1960s that says services, like rehab or some emergency mental health stays in an inpatient setting, can't be covered by Medicaid. That's a big policy change that should happen, but finding the vast sums needed for these services will be uniquely challenging.

So Congress has to make some tough choices to solve this crisis. If prevention and treatment aren't addressed up front, the costs to come will be even higher: pregnant mothers giving birth to opioid dependent babies. EMTs and emergency rooms dealing with overdose calls every night. County jails taking the place of needed substance abuse treatment. Able-bodied adults in the streets instead of working at a family-wage job. America's tax dollars should be spent more wisely, and it's my hope the Finance Committee can take the lead to find the right mix.

There is an example of how to do this right. The Committee is working in a bipartisan way on a proposal to get parents and kin care providers the kind of help they need to keep children safely out of foster care when addiction strikes a family member.

A parent's drug addiction is becoming a growing reason for removing children from their homes and placing them in foster care. A recent Reuters investigation found that on average, a baby is born opioid-dependent every 19 minutes. Using hospital records, the reporters found there were more than 27,000 drug-dependent babies born in 2013.

Many of these babies will enter the foster care system. In fact, as the Committee will hear from Dr. Young, infants made up the largest group of children placed in out-of-home care in 2014, and growth in the share of infants entering care is a trend that has been consistently increasing over the past several years. Protecting these babies and their siblings is, in part, going to mean getting better help, and treatment, for the moms and dads in these situations.

The Chairman and I are engaged in a very active effort to address these daunting challenges with our Family First Act which would help prevent unnecessary foster care stays through programs like evidence-based substance abuse treatment, reduce unnecessary congregate care stays, and put in place stronger protections to keep kids in foster care safe. It's about making sure the system works better for the children, and I hope the committee is able to act soon.

As I spent the last week travelling around my home state—from Medford to Eugene to Portland, the message on opioids was clear: this epidemic is carving a path of destruction through communities all across the country. Oregon has the dubious distinction of ranking fourth worst for abuse and misuse of opioids in the country.

In my home state, citizens will not accept being fourth worst. And I know from talking with many of my colleagues that every state is dealing with this crisis as well.

One story out of the many I heard was especially devastating. I spoke with a parent who told me about high school athletes struggling with addiction to these medicines. When I played basketball in my younger years, there was never any talk in the locker room about "opioids." Now, the next generation of young people are getting swept up in a crisis beyond their control.

Thank you to our witnesses for coming before the committee today, and in particular I want to thank David Hart for flying all the way out from Oregon to speak about some of the important work he's done to curb improper marketing practices and help establish a comprehensive program to deal with this epidemic in our state.

LETTERS SUBMITTED FOR THE RECORD BY HON. RON WYDEN

ELLEN F. ROSENBLUM
ATTORNEY GENERAL

FREDERICK M. BOSS
DEPUTY ATTORNEY GENERAL

OREGON DEPARTMENT OF JUSTICE
Justice Building
1162 Court Street, NE
Salem, Oregon 97301–4096
Telephone: (503) 378–4400

January 11, 2016

Dr. Debra Houry, M.D., M.P.H.
Director, National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway NE, Mailstop F–63
Atlanta, GA 30341

RE: Docket CDC–2015–0112
Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain

Dear Dr. Houry:

I write in support of the work done by the Centers for Disease Control and Prevention ("CDC") in preparing the draft Guideline for Prescribing Opioids for Chronic Pain ("Guideline"). I urge the CDC to finalize the Guideline as soon as possible.

Oregon has been devastated by the opioid epidemic. Between 2000 and 2013, there were 2,226 deaths in Oregon due to prescription opioid drug overdose. The mortality rated due to prescription opioid overdose increased 364% between 2000 and 2006, and though decreasing since then, remains 2.9 times higher than in 2000 (4.0 per 100,000 in 2013; 1.4 per 100,000 in 2000). Results from the 2012–2013 National Survey on Drug Use Health tie Oregon for 2nd place among all states in nonmedical use of prescription pain relievers, down from 1st among all states in the same 2010–2011 survey.[1] In 2013, 3.6 million prescriptions for opioid painkillers were dispensed in Oregon, enough for 925 opioid prescriptions for every 1,000 residents.[2]

My office is committed to combating this epidemic. For example, in 2015, the Oregon Department of Justice created a nearly $600,000 fund from an Unlawful Trade Practices settlement involving the promotion of a fentanyl product which will be used to fund projects to combat the opioid epidemic throughout Oregon, including distribution of naloxone, disposal of disused prescription drugs, community-based adoption of prescribing guidelines, and improved access to medication assisted treatment for opioid addiction. However, to effectively combat the epidemic, we need highly respected organizations like CDC to provide the health care community with clear guidance for safer opioid prescribing, especially for chronic pain, so health care providers can better meet the needs of their patients while still protecting the health and safety of the community.

---

[1] *http://www.samhsa.gov/data/sites/default/files/NSDUHStateEST2012-2013-p1/Change Tabs/NSDUsaeShortTermCHG2013.htm.*

[2] Unpublished Oregon PDMP data.

Thank you for your work to address this public health crisis. Please do not hesitate to contact my office if we can be of any assistance.

Very truly yours,

Ellen F. Rosenblum
Attorney General

DELAWARE DEPARTMENT OF JUSTICE
820 NORTH FRENCH STREET
WILMINGTON, DELAWARE 19801

MATTHEW P. DENN
ATTORNEY GENERAL

PHONE (302) 577–8400
FAX (302) 577–2610

January 12, 2016

Veronica Kennedy, Acting Executive Secretary
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway NE
Mailstop f–63
Atlanta, GA 30341

Attn: Docket CDC–2015–0112

Re: CDC Guideline for Prescribing Opioids for Chronic Pain—2016

Dear Ms. Kennedy:

I am writing to offer comments on the CDC's Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain.

Delaware has a particularly strong interest in the issue of opioid prescriptions, because empirical evidence suggests that opioids are being prescribed in Delaware at rates that exceed those in most other states, with often tragic results. Delaware's Prescription Drug Advisory Committee found in 2013 that Delaware:

- Had the nation's ninth highest drug overdose rate;
- Had a significantly higher percentage of its residents engaging in non-medical use of prescription opioids than the national average;
- Had the nation's fifth highest overall rate for opioid sales;

More recently, the state's Division of Public Health reported that Delaware's medical providers ranked highest in the country in high-dose opioid pain relievers per 100 people, and second highest in the country in long-acting/extended relief opioid pain relievers per 100 people.

Although real-time statistics are not publicly available and Delaware has been making efforts to address opioid prescription, additional steps are clearly necessary.

Delaware is attempting at the state level to more rigorously regulate the prescription of opioids. The state's Controlled Substance Advisory Committee recently proposed a set of standards for such prescriptions, and my office made a number of suggestions that are under consideration as to how those standards could be further strengthened.

The CDC's Proposed 2016 Guideline covers some of the same areas as the proposed standards issued by Delaware's Controlled Substance Advisory Committee, but in some instances the CDC guidelines are more specific than the proposed state standards. As such, the CDC guidelines are a useful supplement to the state's impending mandatory rules, offering physicians a set of non-mandatory expert guidelines to ensure that opioids are prescribed only when necessary, and only in the amounts necessary, for proper patient care.

The process for adopting these proposed guidelines has, by the CDC's own admission, been an imperfect one. Process is important to reaching a sound medical conclusion, and I am confident that the CDC will review the thousands of comments it has received and make any changes to the proposed guidelines that are reasonably prompted by those comments. The comment deadline does not expire until tomorrow, but to date I have not seen any substantive objections to the proposed guidelines issued by any medical organizations that are not largely funded by the pharmaceutical industry.

I applaud the CDC for taking the initiative to issue these guidelines, and I encourage the CDC to finalize them after thoughtfully reviewing public comments and formally issue them as soon as possible. We have lost too many Delawareans to opioid abuse and the heroin addiction that so often follows it, we cannot delay in employing every tool at our disposal to combat this problem.

Sincerely,

Matthew P. Denn
Attorney General

STATE OF NEW YORK

OFFICE OF THE ATTORNEY GENERAL
120 BROADWAY, NEW YORK, NY 10271 • PHONE (212) 416-6305 • FAX (212) 416-8034 • *www.ag.ny.gov*

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

DIVISION OF SOCIAL JUSTICE
HEALTH CARE BUREAU

January 13, 2016

Dr. Debra Houry, M.D., M.P.H.
Director, National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway NE, Mailstop F–63
Atlanta, Georgia 30341

RE: Docket CDC–2015–0112,
Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain

Dear Dr. Houry:

Thank you for your agency's efforts in developing the draft Guideline for Prescribing Opioids for Chronic Pain (the "Guideline"), which may represent an important tool in battling the epidemic of prescription drug abuse affecting our nation. New York has been a leader in fighting the abuse of prescription opioids, and I strongly encourage CDC to adopt the Guideline.

As you know, drug overdose rates are at a historic high. Most alarming is the rise in heroin and opioid overdoses. As data released last month by CDC data reflects, 18,893 people in the U.S. died from opioid pain reliever overdoses in 2014, a 16% increase from 2013.[1] In New York, from 2003 to 2012, deaths involving opioid analgesics increased four-fold, from 186 deaths in 2003 to 914 deaths in 2012.[2] At the core of this opioid overdose epidemic is the fact that physicians are writing more prescriptions for opioid pain relievers than ever before. As a result, the use of prescription opioids has increased ten-fold over the past 25 years in the United States.[3] The experience in New York mirrors that of the nation as a whole. In New York City, between 2008 and 2011, the number of opioid painkiller prescriptions filled by New York City residents increased by 31%, from approximately 1.6 million to approximately 2.2 million.[4]

The Guideline is addressed to primary care providers treating chronic pain outside of active cancer treatment, thus squarely focusing on an important segment of the medical community. Primary care physicians are the top prescribers of opioid pain medication in the United States. Nevertheless, research suggests that some PCPs may lack a sufficient understanding of how opioid pain medications can result in abuse and addiction. A recent study by the Johns Hopkins Bloomberg School of Public Health suggests that this may be contributing to the ongoing epidemic of pre-

---

[1] National Center for Health Statistics, National Vital Statistics System, Mortality File, at *http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf.*

[2] New York State Department of Health, Poisoning Deaths Involving Opioid Analgesics in New York State, 2003–2012, at *https://www.health.ny.gov/statistics/vital_statistics/docs/poisoning_deaths_opioid_analgesics.pdf.*

[3] Susan Okie, *A Flood of Opioids, a Rising Tide of Deaths,* New England Journal of Medicine (November 18, 2010).

[4] New York City Department of Health and Mental Hygiene, *Health Department Data Show Increase In Opioid Prescription Painkiller Deaths In New York City* (May 14, 2013), at *http://www.nyc.gov/html/doh/html/pr2013/pr013-13.shtml.*

scription opioid abuse and addiction in the United States.[5] Notably, nearly half of the internists, family physicians, and general practitioners surveyed mistakenly believed that "abuse-deterrent" opioid pills were less addictive than their standard counterparts.[6] One-third of these practitioners said they believed that most prescription drug abuse is by means other than swallowing the pills as intended.[7] According to the Food and Drug Administration, however, swallowing capsules or tablets is in fact the most common route of abuse of prescription opioids.[8] Further highlighting the issue, another recent study found that over a median follow-up of 299 days, physicians dispensed opioids to 91% of patients after an overdose, 7% of whom experienced another overdose shortly thereafter.[9] Proper prescribing practice suggests that adverse events, such as overdose, are compelling reasons to cease prescription opioids.[10] Consequently, inconsistencies between proper practice and real-world conduct accentuate the need for health care practitioners to receive more guidance on how to properly prescribe opioid pain medications. While other factors may play a role in the concerning misuse and mismanagement of opioids, health care providers would benefit from stronger and more uniform national guidance on how to properly prescribe opioid pain medication—as set forth in the Guideline.

The nonbinding Guideline is based on solid clinical evidence and contains recommendations that promote the effective treatment of pain and may prevent inappropriate prescribing of opioids, thus saving lives. In particular, Recommendation 9 encourages health care providers to review their patients' history of controlled substance prescriptions using state prescription drug monitoring program ("POMP") data to determine whether the patient is receiving opioid dosages that put him or her at high risk for overdose. Many states have created PDMPs, and some, such as New York, require prescribers to consult the database before prescribing controlled substances. New York's historic Internet System for Tracking Over Prescribing ("I–STOP") legislation was signed into law on August 27, 2012. This law made New York the first state in the nation to ensure every prescription for a controlled substance is tracked in a real-time database accessed by both prescribers and pharmacists. New York's I–STOP program, which became mandatory in 2013, has helped reduce prescription drug abuse, decreasing doctor shopping by almost 75%.[11]

Thank you for the opportunity to comment on the draft Guideline, and for your commitment to the promotion of public health in our state.

Sincerely,

Eric T. Schneiderman
New York Attorney General

THE COMMONWEALTH OF MASSACHUSETTS
OFFICE OF THE ATTORNEY GENERAL
ONE ASHBURTON PLACE
BOSTON, MASSACHUSETTS 02108

MAURA HEALEY
ATTORNEY GENERAL

TEL: (617) 727–2200
www.mass.gov/ago

January 11, 2016

Tom Frieden, M.D., M.P.H.
Director, Centers for Disease Control and Prevention

Debra Houry, M.D., M.P.H.
Director, National Center for Injury Prevention and Control

---

[5] Catherine S. Hwang et al., *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion,* Clinical J. of Pain (Jun. 22, 2015).
[6] *Id.*
[7] *Id.*
[8] Food and Drug Administration, *Abuse-Deterrent Opioids: Evaluation and Labeling Guidance for Industry* (April 2015), at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf.*
[9] Marc R. Larochelle, et al., *Opioid Prescribing After Nonfatal Overdose and Association with Repeated Overdose,* Ann. of Intern. Med. (Jan. 5, 2016).
[10] *Id.*
[11] *https://www.governor.ny.gov/news/governor-cuomo-announces-progress-states-efforts-crackdown-prescription-drug-abuse.*

United States Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329–4027

RE: Docket CDC–2015–0112,
Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain

Dear Drs. Frieden and Houry,

I write to commend the work of the Centers for Disease Control and Prevention ("CDC") in preparing the draft Guideline for Prescribing Opioids for Chronic Pain ("Guideline") and urge the CDC to finalize the Guideline as soon as possible. The Guideline will provide much-needed information to primary care providers across the country about when and how opioids should be prescribed for chronic pain. While there have been various efforts from state officials and other organizations to memorialize best practices for opioid prescribing, the Guideline would provide prescribers with a single, nationwide, evidence-based standard.

The opiate epidemic has had a devastating impact in Massachusetts, as in so many other parts of the country. Deaths from opioid-related overdoses more than doubled in Massachusetts between 2011 and 2014, with more than 1,250 people believed to have died here in 2014.[1] According to SAMHSA, four out of five recent heroin initiates report having previously used a non-medical prescription pain reliever.[2] In Massachusetts alone, there were 4,664,391 prescriptions for Schedule II and III opioids in 2014.[3] That is a prescription for nearly every adult in Massachusetts.

Our national opioid-related overdose deaths are the result of years of overprescribing of prescription pain killers. To significantly impact the trajectory of this epidemic, we need to change this country's culture around opioid prescribing. In the United States, we consume 80% of the world's opioid supply. In 2014, the CDC reported that 18,893 people died from prescription opioid overdoses, a 16% increase from 2013.[4] This is not just a heroin epidemic. There are more than three times as many Americans struggling with prescription opioid dependence or addiction as there are dealing with heroin addiction.

I strongly agree with CDC's conclusion that "[t]o reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity, efforts to improve safer prescribing of prescription opioids must be intensified."[5] The draft Guideline is an important step toward intensifying those efforts. In particular, the Guideline makes clear that opioids should not be the initial treatment for chronic pain and should only be used where their benefits outweigh the risks. See Guideline No. 1. Equally important, the Guideline advises prescribers to evaluate the benefit and harms of opioid treatment within weeks of the initial dose and re-evaluate the patient at least every 3 months. See Guideline No. 7. Furthermore, "there are recent indications that prescription drug overdose deaths are declining in some jurisdictions, for instance Florida and Kentucky , likely due in part to the promulgation and increased use of PDMPs,"[6] as indicated in Guideline No. 9. If finalized, the Guideline will provide much-needed information to prescribers nationwide.

---

[1] Massachusetts Department of Public Health, Data Brief: Fatal Opioid-related Overdoses among Massachusetts Residents (Oct. 2015).

[2] SAMHSA, CBHSQ: Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States (Aug. 2013).

[3] Massachusetts Department of Public Health, Board of Health Care Safety and Quality, Report (Nov. 5, 2015).

[4] CDC/NCHS, National Vital Statistics System, Mortality File, available at *http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf.*

[5] Rose A. Rudd et al., Increases in Drug and Opioid Overdose Deaths—United Sates, 2000–2014, 64 Morb. Mortal. Wkly. Rep. 1 (Dec. 18 2015).

[6] DMP Center of Excellence at Brandeis University, Briefing on PDMP Effectiveness at 3 (Sept. 2014).

Thank you for your continued work to address this public health crisis and help save lives. Please do not hesitate to contact Assistant Attorney General Eric Gold (617–963–2663) in my office if I can provide any additional information.

Very truly ours,

Maura Healey

NATIONAL ASSOCIATION OF ATTORNEYS GENERAL
2030 M Street, NW
Eighth Floor
Washington, DC 20036
Phone: (202) 326–6000
http://www.naag.org/

January 13, 2016

Tom Frieden, M.D., M.P.H.
Dockets Management
Centers for Disease Control and Prevention
United States Department of Health and Human Services
1600 Clifton Road
Atlanta, GA 30329

Re: *Docket No. CDC–2015–0112*
Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain

Dear Dr. Frieden:

As attorneys general whose states and residents have been affected by the epidemic of opioid abuse, addiction, diversion, overdose, and death, we write to urge the speedy adoption of the CDC's Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain (the "Guidelines").

As statewide public officials who work collaboratively with law enforcement, we are regularly confronted with the problems caused by opioid abuse. While some states have reduced the number of deaths due to opioid drug overdose, overall deaths from overdoses continue to rise in our nation. Unfortunately, the opioid overdose deaths and emergency room visits continue to increase in proportion to the increase in prescribed opioids.[1] In order to reduce these deaths and injuries, we must provide clear guidance for prescribers to assess the appropriate balance between the potential harms and benefits of opioid use.

The increase in overdose deaths has made the efforts to improve informed prescribing both a law enforcement and public safety issue. Unfortunately, many prescribers, particularly primary care and family physicians, note they can lack clear and practical guidance in deciding when and how to prescribe opioids. Some are afraid to prescribe opioids at all, for fear that they will jeopardize their patients—or even their licenses. Others provide their patients with opioids when alternative treatments may serve as a more effective long term method of care.

We recognize that the Guidelines are just that. The Guidelines provide a foundation for practice, recognizing that doctors will need to adapt them to meet the individual needs of their patients. But the core message—that many patients can be treated with lower doses or alternative treatment methods, provides much-needed direction to doctors. It gives doctors the knowledge and confidence to prescribe opioids when appropriate, and to more safely manage patients on opioids. The Guidelines also recognize that opioids remain an important tool for responding to extreme or intractable pain.

By better informing and guiding prescribers, these Guidelines will not only provide a strong framework for providers, but they will also improve the access to opioids for patients for whom they are the best choice. For these reasons, we urge the CDC to promptly adopt these Guidelines.

Respectfully submitted,

Pam Bondi
Florida Attorney General

Joseph A. Foster
New Hampshire Attorney General

---

[1] See Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999–2008; Morbidity and Mortality Weekly Report, Nov. 4, 2011.

Leslie Rutledge
Arkansas Attorney General

Samuel S. Olsen
Georgia Attorney General

Lawrence Wasden
Idaho Attorney General

Greg Zoeller
Indiana Attorney General

Jeff Landry
Louisiana Attorney General

Brian Frosh
Maryland Attorney General

Jim Hood
Mississippi Attorney General

Tim Fox
Montana Attorney General

Adam Paul Laxalt
Nevada Attorney General

Hector Balderas
New Mexico Attorney General

Roy Cooper
North Carolina Attorney General

Mike DeWine
Ohio Attorney General

Kathleen Kane
Pennsylvania Attorney General

Alan Wilson
South Carolina Attorney General

Herbert H. Slatery, III
Tennessee Attorney General

Willian H. Sorrell
Vermont Attorney General

Patrick Morrisey
West Virginia Attorney General

Karl A. Racine
District of Columbia Attorney General

Doug Chin
Hawaii Attorney General

Lisa Madigan
Illinois Attorney General

Andy Beshear
Kentucky Attorney General

Janet Mills
Attorney General

Maura Healey
Massachusetts Attorney General

Chris Koster
Missouri Attorney General

Douglas Peterson
Nebraska Attorney General

John Hoffman
New Jersey Attorney General

Eric T. Schneiderman
New York Attorney General

Wayne Stenehjem
North Dakota Attorney General

Scott Pruitt
Oklahoma Attorney General

Peter F. Kilmartin
Rhode Island Attorney General

Marty J. Jackley
South Dakota Attorney General

Sean Reyes
Utah Attorney General

Robert W. Ferguson
Washington Attorney General

Brad Schimel
Wisconsin Attorney General

PREPARED STATEMENT OF NANCY K. YOUNG, PH.D., DIRECTOR, CHILDREN AND FAMILY FUTURES, INC.

Chairman Hatch, Ranking Member Wyden, and Members of the Finance Committee, thank you for conducting this hearing on our nation's opioid epidemic and the effects of opioid and other substance use disorders on our nation's child welfare and foster care system. There are three primary points I would like to emphasize in this statement for the record:

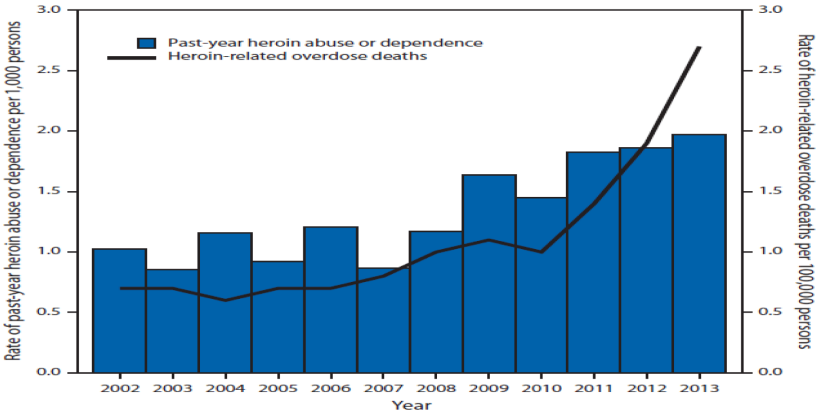
(1) In the past 3 decades, our country has experienced at least three major shifts in substances of abuse that have had dramatic effects on children and families. However, the increase of opioid misuse has been described by longtime child welfare professionals as having the worst effects on child welfare systems that they have seen.

(2) The current environment has at least two major differences from our prior experiences, first that young people are dying at astonishing rates and many states report that infants are coming into protective custody at alarming rates.

(3) Federal investments over the past decade testing strategies to improve outcomes for families in child welfare affected by substance use disorders have generated a knowledge base that allows us to clearly state that we can no longer say we don't know what to do.

BRIEF SUMMARY OF THE DATA

Data from SAMHSA's National Survey on Drug Use and Health show that between 2007 and 2014, the numbers of persons who misuse prescription drugs, new users of heroin and people with heroin dependence increased significantly (SAMHSA, 2014). As shown in this graph, rates of dependence on heroin has doubled and overdose deaths increased 286 percent between 2002 and 2013 (Leonard, 2015).



According to the 2014 National Survey on Drug Use and Health:

- 10.3 million person non-medically used prescription painkillers in 2014 [1]
- Approximately 1.9 million met criteria for prescription painkillers use disorder
- 4.8 million people have used heroin at some point in their lives
- 212,000 people aged 12 or older used heroin for the first time within the prior 12 months
- Approximately 435,000 people were regular (past-month) users of heroin

The pattern of initiating heroin use has changed over the past decade. Approximately three-quarters of persons who use heroin report prior nonmedical use of prescription opioids, as well as current abuse or dependence on additional substances such as stimulants, alcohol and marijuana. Conversely a small percentage, approximately 4 percent, of persons with nonmedical use of prescription drugs become regular users of heroin. However given the 10.3 million persons who reported nonmedical use of prescription drugs in 2014, this small percentage of conversion to heroin generates 200,000 new heroin users in a year and 435,000 regular heroin users (Compton, Jones and Baldwin, 2016).

Among pregnant women, the highest rates of use continues to be the legal substances which have known detrimental effects on the neurodevelopment of the fetus. Among pregnant women aged 15 to 44, 5.4 percent were current illicit drug users based on data averaged across 2012 and 2013. This was lower than the rate among women in this age group who were not pregnant (11.4 percent). In the most recent year for which the data on specific substances are available, among pregnant women in 2011–2012, 18% reported using cigarettes, 9.4% used alcohol and 5% used illicit drugs; heroin use was reported by .2% of pregnant women and .9% non-medically used prescription drugs (SAMHSA, 2012).

There are two aspects of parental opioid use that affect the child welfare system: (1) prenatal opioid and other substance use exposure when it is determined that there are immediate safety factors resulting in the newborn being placed in protec-

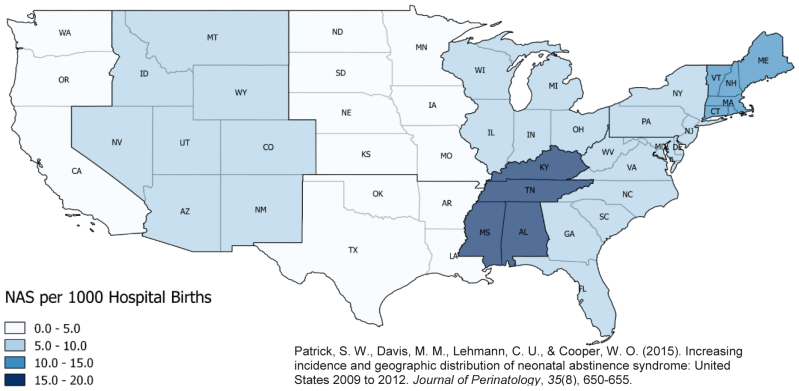
[1] Nonmedical use of prescription drugs includes using medications that are not prescribed for them or using them for the effect or feeling rather than the medical purpose for which they were prescribed.

tive custody and (2) post-natal use that affects parents' ability to safely care for their children.

Congress has been specific that hospital notification of cases of prenatal substance exposure is not substantiated child abuse or neglect.[2] Rather, when these children come to the attention of the child welfare system, assessment of risk and safety are to be conducted and plans of safe care instituted to ensure the newborn's well-being. Unfortunately, as the recent Reuters series made clear, often this is not happening (Wilson and Shiffman, 2015).

Neonatal abstinence syndrome (NAS) occurs in about half of babies with exposure to opioids during pregnancy. At this time, there are not clear data as to why babies do or do not experience the withdrawal syndrome. In a national study on the use of methadone and buprenorphine during pregnancy, researchers found that NAS did not appear to be related to the dose of these medications that are used to treat opioid dependence. But there were data suggesting that experiencing NAS was related to mothers who also smoked during pregnancy (Jones, 2015).

Dr. Stephen Patrick and colleagues (2016) have analyzed Medicaid claims data to monitor the trend of infants who are diagnosed with Neonatal Abstinence Syndrome. There is variation across regions in rates of NAS with the north-east and mid-south central regions experiencing the highest rates of diagnosed cases in Medicaid claims data.

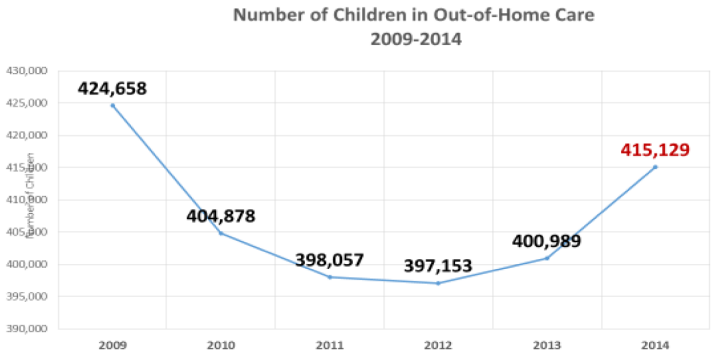


Patrick, S. W., Davis, M. M., Lehmann, C. U., & Cooper, W. O. (2015). Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009 to 2012. *Journal of Perinatology*, *35*(8), 650-655.

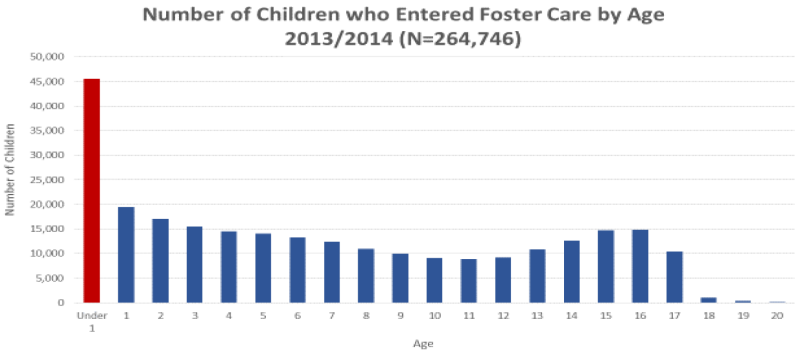
While there is not a clear relationship of rates of NAS and the dramatic increase of infants being placed in protective custody, the trend of younger children in care and particularly the number of infants is alarming. After a decade of decreasing the number of children in out-of-home care, that trend began to reverse in 2012–2013. The total number of children in care are both new intakes as well as children who are remaining longer in care.

Of the nearly 265,000 children who entered care in 2014, the largest group were infants. The data are not available on the percentage of those infants who also experienced prenatal substance exposure, since they are not collected at the federal level nor by the majority of states. One might suggest however, that there are few underlying factors other than a parent's substance use disorder that would disrupt the ability of a parent to care for their infant—particularly in areas of the country that are experiencing a profound opioid epidemic.

[2] The exact language is that ". . . such notification shall not be construed to—(I) establish a definition under Federal law of what constitutes child abuse or neglect; or (II) require prosecution for any illegal action."

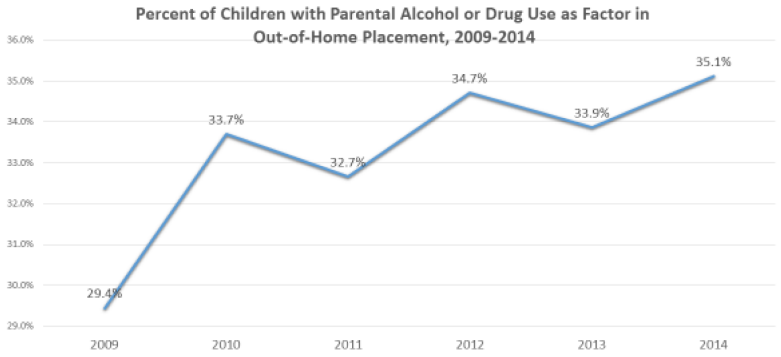


From the all-time high point in 1999 of 567,000 children, there was a steady decline until 2012 when the trend reversed



These trends are resulting in an increasing shift toward younger children making up a larger percentage of children in out-of-home care with children under 6 representing nearly 40% of children in care. These data indicate a short window of time for intervention with these children and families. This alarming rate of young children coming into care is especially troubling, as children ages 0–3 are especially vulnerable. Infancy and toddlerhood is a time of rapid development across all domains of functioning. The brain of a newborn is about one-quarter the size of an adult's and by the age of three, the brain has developed to about 80 percent of its adult size (Nowakowski, 2006). It is imperative that the development of that child take place in a stable environment with a caregiver who fosters mutual attachment with the child.

Unfortunately, I cannot report reliable data that would indicate to what extent parental opioid or other substance use disorders are associated with the number of children in out-of-home care. The nation's data system to monitor these factors does not require collection of parental substance use as factors in child removal, since those are voluntary collection items in the data system. However, our agency has been monitoring the available data for 15 years, and there has been a steady increase in reports of removals due to substance use by parents. The graph on the following page shows that since 2009, states report a 19.4 rate of increase in parental alcohol or drug use as factors in the child's removal.



There has been an increasing trend in the percentage of child placement cases with parental alcohol or drug use as factors in the protective custody placement over the past 15 years. Due to identification and data entry complexities, there is great variability across states with States reporting less than 10% to some reporting more than 60%.

Source: AFCARS Data

However, we have been to all but one state in the country and asked child welfare professionals if they believe these data represent the prevalence of parental substance use in their cases. Not a single state believes these data accurately reflect their experience and tell us that these numbers greatly understate that the vast majority of cases in which a child is placed in protective custody are related to parental substance use disorders.

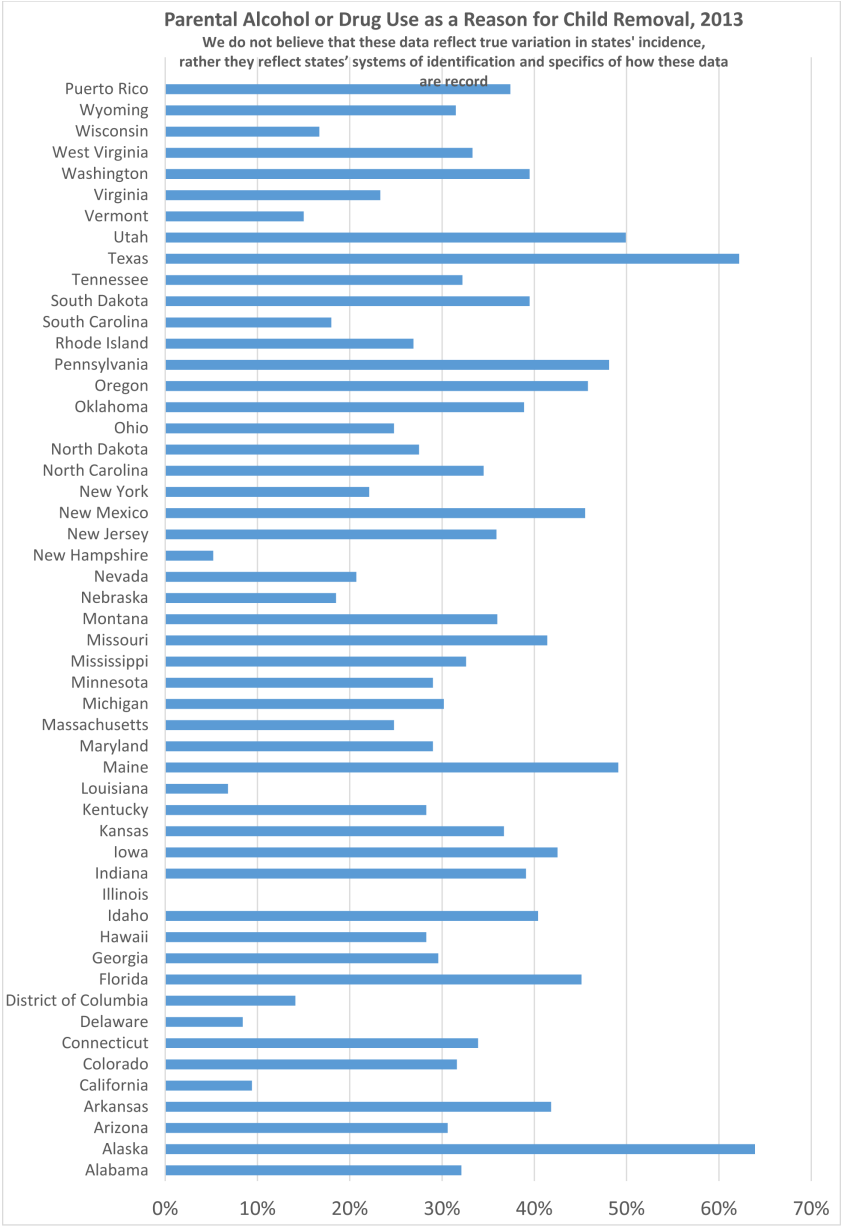
As shown in the graph on the following page, these data vary substantially across states. We do not believe that these data reflect true variation in incidence, rather they reflect states' systems of identification and specifics of how these data are recorded in each state's automated data system. Only a handful of states have a standardized screening tool that is used to detect parental substance use disorders during investigations of child abuse and neglect. Very few states have consistent policy and protocols on how the results of investigations regarding parents' substance use are to be recorded in the automated information system.

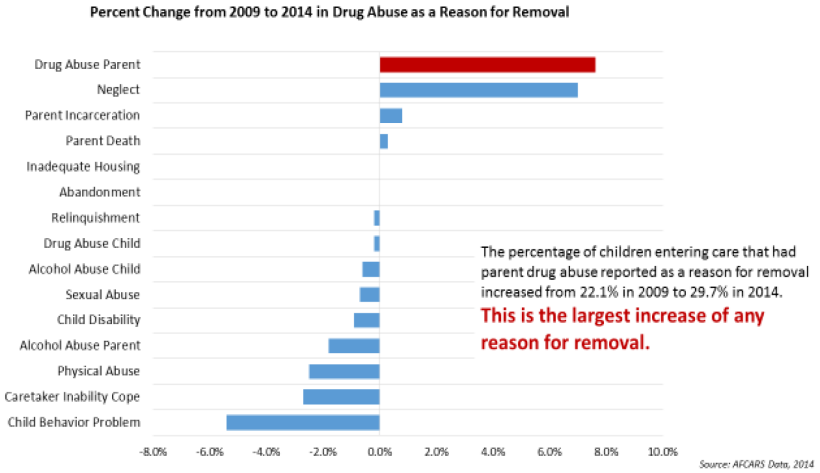
Among all reasons for child removal, drug abuse by parents was the largest rate of increase over the past 5 years. Child welfare professionals often tell us that neglect is the category that is checked in the data system but that neglect is almost always associated with parents' substance use disorder.

These data are reflected in statements by child welfare agency professionals from around the country. Last week I spent 3 days in Ohio. I was told by a child welfare administrator from a county that borders Kentucky that 2015 was the first time ever that there were more children whose parents' rights were terminated than were reunified. That small county had 70 terminations attributed to parents' opioid use disorders. Child welfare officials reported that this trend is evident across the state. They report that over the past 5 years parents with opioid use disorders have increased the number of children placed in care at the same time that overall resources to serve families have decreased.

To summarize

- Infants are the largest age group of children entering foster care, they are at least twice the number of children of other ages.
- Removals of children due to parental substance abuse has increased significantly as reported by the states.


Parental Alcohol or Drug Use as a Reason for Child Removal, 2013
We do not believe that these data reflect true variation in states' incidence, rather they reflect states' systems of identification and specifics of how these data are record
Puerto Rico
Wyoming
Wisconsin
West Virginia
Washington
Virginia
Vermont
Utah
Texas
Tennessee
South Dakota
South Carolina
Rhode Island
Pennsylvania
Oregon
Oklahoma
Ohio
North Dakota
North Carolina
New York
New Mexico
New Jersey
New Hampshire
Nevada
Nebraska
Montana
Missouri
Mississippi
Minnesota
Michigan
Massachusetts
Maryland
Maine
Louisiana
Kentucky
Kansas
Iowa
Indiana
Illinois
Idaho
Hawaii
Georgia
Florida
District of Columbia
Delaware
Connecticut
Colorado
California
Arkansas
Arizona
Alaska
Alabama
0%
10%
20%
30%
40%
50%
60%
70%



- Child welfare professionals across the country, particularly in the north-east and Appalachian states, report that parental opioid use disorders are having a major impact on increasing child removals, preventing reunification and increasing termination of parental rights.

WHAT WORKS FOR FAMILIES AFFECTED BY OPIOID AND OTHER SUBSTANCE USE DISORDERS

Families and child welfare agencies have been affected by multiple drug epidemics over the past several decades—cocaine in the late 1980s, methamphetamine in the early 2000s and now opioids. In the cocaine epidemic, Congress enacted legislation to expand specialty treatment programs for women and their children and required that the Substance Abuse Prevention and Treatment Block Grant prioritize treatment admissions for pregnant and parenting women.

During the methamphetamine epidemic, Congress made the largest ever investment through demonstration grants to find out what works to improve outcomes for these families and ensure child safety, permanency in caregiving relationships, and their well-being. A key shift in policy was that many of the communities that received these grants worked to prevent removal of children by providing services to children and their families while the children remained safely at home. States use different labels to refer to these "in-home" cases—protective supervision for example. But they represent the majority of the caseload of families in child welfare services, often about 70% of the state's caseload.

Across child welfare programs, approximately 85% of children stay home, or go home, or in the case of children who are not reunified, they find home when they age out of foster care or become adults and access their adoption records. These realities make evident the imperative that child welfare service agencies, substance abuse treatment providers, and community partners work together to address the needs of parents to prevent placement, reunify with their children or potentially play another supportive role in their child's life.

The demonstration grants included the Regional Partnership Grant program (RPG) and SAMHSA's Children Affected by Methamphetamine Program (CAM). The RPG and CAM programs documented a set of common ingredients and strategies leading to positive outcomes for families affected by substance use disorders. These strategies include:

1. **Identification:** A system of identifying families in need of substance use disorder treatment.
2. **Timely Access:** Timely access to substance use disorder assessment and treatment services.

3. **Recovery Support Services:** Increased management of recovery services and monitoring compliance with treatment.
4. **Comprehensive Family Services:** Two-generation family-centered services that improve parent-child relationships.
5. **Increased Judicial Oversight**: More frequent contact with parents with a family focus to interventions.
6. **Cross-Systems Response:** Systematic response for participants based on contingency contracting methods.
7. **Collaborative Structures:** Collaborative non-adversarial approach grounded in efficient communication across service systems and the courts.

Implementation of these common strategies for collaborative policy and practice has shown five core outcomes, the 5Rs:

1. **Recovery:** Parental recovery from substance use disorders.
2. **Remain at Home:** More children remain in the care of parents.
3. **Reunification:** Increased number and timeliness of parent-child.
4. **Reoccurrence:** Decreased incidence of repeat maltreatment.
5. **Re-entry:** Decrease number of children re-entering out-of-home care.

REGIONAL PARTNERSHIP GRANTS

The Child and Family Services Improvement Act of 2006 reauthorized the Promoting Safe and Stable Families program and provided a competitive grant program with funding over a 5-year period to implement regional partnerships in states, tribes and communities to improve outcomes for children and families who were affected by parental substance use disorders.

In October 2007, the Administration on Children Youth and Families (ACYF), Children's Bureau (CB) awarded grants to 53 partnerships across the country, including 7 tribes. Family Drug Courts were part of the initiative in 21 of the grantees. The outcomes of the grants were measured in a performance measurement system focused on documenting child safety, permanency, and well-being; systems improvement; and treatment-related outcomes such as timeliness of treatment access, length of stay in treatment, and parents' recovery.

RPG grantee ***OnTrack*** is located in Medford, Oregon. They developed an alternative to children being placed in foster care by creating emergency shelters and residential treatment in which parents and children could stay together. Of families who participated in the program, 98% of kids were reunified with families within 10 months.

After 1 year of program completion, only 6% of families had a subsequent removal, compared 28% of families receiving standard services—comparison group children were four times more likely to experience subsequent removal.

In September 2012, ACYF/CB awarded 17 new RPGs and 2-year extension grants to 8 of the 53 original grantees. This was made possible by Child and Family Services Improvement and Innovation Act (Pub. L. 112–34) signed into law in September 2011. In September 2014, four additional 5-year grants were awarded.

The original 53 grantees served a total of 17,820 adults, 25,541 children and 15,031 families. Key positive outcomes across sites include:

- Parents achieved timely access to substance abuse treatment (36.4% entered treatment within 3 days), stayed in treatment (65.2% stayed in treatment more than 90 days), and reported reduced substance use.
- The majority of children at risk of removal remained in their parent's custody—92.0% of children who were in custody of their parent or caregiver at the time of RPG program enrollment remained at home through RPG program case closure. The percentage of children who remained at home significantly increased through program implementation from 85.1% in Year 1 to 96.4% in Year 5.
- Most children in out-of-home placement achieved timely reunifications with their parent(s).
  - 83.0% of children discharged from foster care were reunified.

- 63.6% reunified within 12 months.
- 17.9% were reunified in less than 3 months.
- 72.7% of infants reunified within 12 months.

- After returning home, very few children re-entered foster care.
  - Only 4.2% of children had a substantiated maltreatment within six months versus 5.8% subsequent maltreatment rate based on state data.

The RPG in the State of Kansas implemented the evidence-based Strengthening Families Program (SFP) with 367 Children and 473 adults. On average, the SFP child participant spent 190 fewer days in out-of-home care than their non-SFP counterparts. For example, at the 360-day point from start of SFP, almost half (45.0 percent) of the SFP children were reunified, compared to 27.0 percent of the comparison children. The evaluation conducted by University of Kansas researchers found that SFP saved approximately $16,340 per child in State and Federal out-of-home care costs (McDonald and Brook, 2013).

CHILDREN AFFECTED BY METHAMPHETAMINE GRANTS

Funded through the Substance Abuse and Mental Health Services Administration (SAMHSA), the Children Affected by Methamphetamine (CAM) Grant Program focused on expanding and enhancing services to children and their families who are affected by methamphetamine and other substance use disorders. The Public Health Service Act of 2000 section 509 provided funding from 2010–2014 to 12 Family Drug Courts to improve the well-being, permanency, and safety outcomes of children, who were in, or at-risk of out-of-home placement as a result of a parental methamphetamine or other substance abuse. The primary focus of the grant program was to provide services directly to the children and to provide supportive services for parents, caregivers, and families.

The ***Sacramento County CAM Project*** (known as Children in Focus) served children and families in the Dependency Drug Court (DDC) and the Early Intervention Family Drug Court (EIFDC). The DDC serves families in which children have been removed from parental care and the EIFDC serves children, primarily infants, who are in the care of their birth parents. The CAM grant supported family-centered services including an evidenced-based specialized parenting program for parents in recovery called Celebrating Families (CF) and the use of Recovery Specialists who conduct active engagement based on motivational interviewing and monitoring activities with parents. The project also linked participants to family resource centers and other community resources to provide recovery support during CF participation and beyond program completion.

Outcome data shows that 97.8% of children who were at home at the time of enrollment remained at home, saving an estimated $34,494 per child in placement costs. Within 6 months of program entry, only 1.5% of children experienced maltreatment reoccurrence. Higher reunification rates and shorter times in out-of-home care compared to standard services saved an estimated $12,254 per child.

Outcome data from across all 12 sites indicated that children enrolled in the CAM program services were kept safe with lower rates of repeat maltreatment than in the general child welfare population. Outcomes included:

- More than 90% of children remained in their home with their parent/caregiver throughout program participation and the majority of children exiting out-of-home care were discharged to reunification.
- Over two-thirds (68.2%) of CAM children were reunified in less than 12 months.
- Less than 6% of reunified children re-entered foster care within 12 months after being returned home. This is about a third of the national average with standard services.

The CAM grantees experience increased our knowledge about the timing and type of parenting classes that should be delivered to parents in early recovery. These grantees experimented with when to start and what type of parenting classes these families need. They found that they could increase retention in treatment when they engaged parents early in their recovery in parenting programs specifically developed for parents with substance use disorders, focusing on teaching effective parenting

skills, and providing opportunities for children and parents to repair their relationship.

The other good news about these projects is that they saved money. Not only in reduced foster care costs, but in keeping parents in treatment long enough for treatment to have a lasting effect. And in the long term, these programs are keeping children out of higher-end, higher-cost mental health, special education, and juvenile justice programs when they get older. These programs proved that they could save millions of dollars, justifying the increase in enhanced services for children and their parents.

Although these grant programs operated in different drug epidemics than the current opioid wave, there is much that can be applied to today's crisis. We do know that access to medication-assisted treatment is imperative for success in today's population. But, as important as access to effective treatment has proven to be in prior eras, access to medication-assisted treatment for this population is not being provided on a timely basis. For example, months of wait lists for treatment are the norm across the country.

In Ohio last week, I was told that in a FDC model that includes facilitating treatment access, it still takes approximately 1 month to get access to medication assisted treatment. Without participation in the specialized drug court docket, it takes at least 3 months to access medications. When children's safety and well-being are at stake, parents need to access treatment much faster than that.

While some states have access to Medicaid funding for some families involved with child welfare, it's important to recognize that the health-related criteria for accessing treatment and the outcomes measured in the health care system may not always relate to the needs of families in child welfare. Medical criteria to access a certain level of care with Medicaid or private insurance does not include the safety or impact on the child as criteria for residential or intensive out-patient levels of care. Similarly, outcomes for substance abuse treatment for adults in the Medicaid or private insurance system do not typically count in their performance measures family safety and child well-being. Rather, these outcomes are the responsibility of the child welfare system in collaboration with substance abuse treatment agencies and courts.

We would suggest that referral to a wait list does not meet child welfare's legal standard of reasonable efforts, and in the case of Native American children the higher standard of active efforts, to prevent placement and to reunify children. Rather, facilitating access to treatment and ensuring treatment availability is needed.

In summary, we can no longer say we don't know what to do. We can build on the track record of dozens of fine, smaller-scale programs in your states and communities. That's a big difference in this epidemic, compared with prior eras. We can take what works into system change approaches, instead of helping only a few families at a time.

OPPORTUNITIES TO TAKE WHAT WORKS INTO SYSTEM-WIDE REFORM

The impact of opioids on children and families in the child welfare system must be placed in context of the history of parental substance use disorders, how to comprehensively address the current epidemic, and to mediate the effects of future shifts in drug use patterns from severely impacting children and their families. The effort should focus on how to build on lessons from prior federal investments, resolve the current gap in timely treatment access, focus on improving data collection and monitoring, and prevent future crises and costs as substance use patterns change over time.

In addition to the key programmatic strategies implemented to prevent child placement, there are system changes that are also needed to effectively monitor effects over time, ensure staff are prepared to work effectively with these families, state-specific financing strategies need to be developed to maximize recent changes in substance use disorder treatment, fill gaps in treatment access for these families, and build collaborative efforts that cross agency boundaries and support communities. Specific system reforms that are needed include:

- **Improve data collection and reporting to monitor the effects of parental substance use disorders on the child welfare system and the outcomes achieved by addressing treatment needs.** This should happen by resolving states' information technology challenges to include alcohol and

drug use factors in case records, require standardized reporting of alcohol and drug use factors in federal child welfare reporting systems and require existing outcome monitoring to report on the differential child welfare outcomes for children and families due to parental substance use disorders.

- **Improve access to quality substance use disorder treatment.** The need for access to substance abuse treatment cannot be over-emphasized. When we refer parents to treatment as a condition of keeping or reunifying with their children, we must make sure that the treatment is state-of-the-art, comprehensive, meets the needs of the entire family, and that treatment, including medications for opioid use disorders, are available and timely.
- **Improve collaborative practice.** This can be achieved through implementation of practical strategies, such as staff development and training programs and cross-systems communication protocols. Ensuring that these strategies include a focus on infants with prenatal substance exposure will develop a workforce that is prepared to work in today's environment. Staff training and communication protocols must provide concrete and pragmatic information, such as guidance in developing comprehensive plans of safe care that keep infants with birth families whenever possible and provide interventions to address the needs of both the infant and mother.

When we ensure timely access to effective treatment, families recover, kids stay safe at home, and we save money. Now we can and must move beyond pilots and demonstration grants and take these lessons to into systemic changes across agencies to help children and families.

REFERENCES

Compton, W.M., Jones, C.M. and Baldwin, G.T. (2016). Relationship between nonmedical prescription-opioid use and heroin use. New England Journal of Medicine, 374(2), 154–163.

Jones, H. (2015). Treatment of Opioid Use Disorder in Pregnancy and Infants Affected by Neonatal Abstinence Syndrome. A Webinar presented for the SAMHSA Women's Health Week. May 15, 2015. Accessed February 20, 2016, *http://www.cffutures.org/files/webinars.*

Leonard, K. (2015). Heroin Use Skyrockets in U.S. *U.S. News and World Report.* July 7, 2015. Accessed February 21, 2016, *http://www.usnews.com/news/blogs/data-mine/2015/07/07/heroin-use-skyrockets-in-us-cdc-says.*

McDonald, T. and Brook, J. (2013). Description of the State of Kansas Regional Partnership Grant and Evaluation Findings. Accessed February 21, 2016, *http://www.cffutures.org/files/rpgprofiles/ArrayofServicesCluster/KansasDepartmentof SocialandRehabilitationServices.pdf.*

Nowakowski, R.S. (2006) *Stable neuron numbers from cradle to grave.* Proceedings of the National Academy of Sciences of the United States of America. 103(33):12219–12220.

Patrick, S.W., Davis, M.M., Lehmann, C.U. and Cooper, W.O. (2015). Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009 to 2012. *Journal of Perinatology,* 35(8): 650–655.

Substance Abuse and Mental Health Services Administration, *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings,* NSDUH Series H–48, HHS Publication No. (SMA) 14–4863. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality (2015). *Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health,* HHS Publication No. SMA 15–4927, NSDUH Series H–50. Retrieved from *http://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf* (accessed February 19, 2016).

Wilson, D. and Shiffman, J. (2015). Helpless and Hooked. *A Reuters Investigation.* December 7, 2015. Accessed February 21, 2016, *http://www.reuters.com/investigates/special-report/baby-opioids/.*

QUESTIONS SUBMITTED FOR THE RECORD TO NANCY K. YOUNG, PH.D.

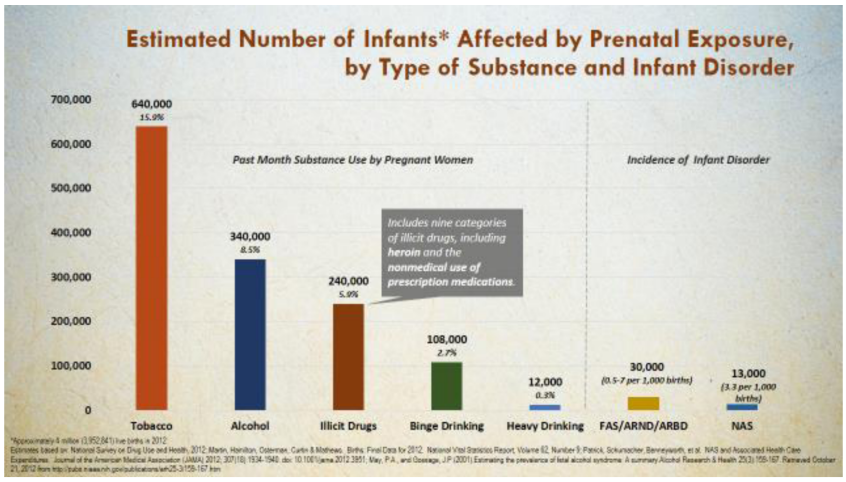
QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

Question. In your testimony, you note that the opioid epidemic is having a worse effect on youth than previous drug abuse epidemics, particularly because young people are dying at a much higher rate and because they are coming into protective custody at a higher rate. Why is the opioid epidemic having a much more substantial impact on young people than previous substance abuse epidemics?

Answer. Prior epidemics did not provide the wide access to over-prescribed prescription drugs that many "pill mills" and unscrupulous physicians provided; fentanyl use and uncertain dosages have worsened effects; and the respiratory effects of opioids have more severe consequences for their users. In addition, many child welfare agencies are not prepared for how to handle families with an infant who goes through a withdrawal syndrome. Too many states, counties and workers make those conditions an automatic placement in foster care rather than understanding family safety and risk factors and how to ensure the infant and family receive best practice.

Question. Your testimony covers some of the policies and programs that were established in response to previous substance abuse epidemics, and how they worked to help adults recover and keep families together. Are there any policies or efforts that did not work, and that should be modified or abandoned as a result?

Answer. Punitive responses that criminalize prenatal use and separate mothers from newborns have not succeeded in achieving recovery or good parenting practices. I would also emphasize the importance of devoting *proportionate* attention to the different substances, rather than over-emphasis on any one substance as we have done in past cycles of increases in specific drugs. The chart bellows shows the proportionate effects on newborns, and makes clear that the legal drugs still have the highest prevalence rates and we know from decades of research create the greater harm for the neurodevelopment of the child.



Question. Thank you for noting the fact that many states do not seem to be in compliance with their Plan of Safe Care requirements under CAPTA. My office has been actively investigating the best course of action to resolve this situation. What, if any, changes do you feel need to be made to CAPTA in order to encourage compliance with this provision? Do you feel there is a danger that some states may begin to turn down CAPTA funding if reporting requirements such as this are enforced?

Answer. The recent passage of the CARA legislation which included changes in CAPTA implementation by improving these provisions, requiring HHS to provide best practice guidance to states on these requirements and ensuring that the caregivers of infants are included in the plan of safe care referenced in CAPTA are critical. I have attached a suggested approach to the plan of safe care that our organization has drafted. As to states that may refuse their CAPTA funding due to these

requirements, if federal agencies annually report on CAPTA numbers and practices for each state, there would be increased accountability for those states that comply with CAPTA reporting-and those that do not. Of course, it is urgent that the Family First Prevention Services Act is passed by the Senate to ensure that families with an infant with prenatal substance exposure can access prevention services including substance use disorder treatment, mental health treatment and in-home parenting supports.

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

Question. Given that over 20% of pregnant women on Medicaid filled a prescription for an opioid during pregnancy, what can we do to aid mothers-to-be and improve outcomes for infants who are born in withdrawal?

Answer. (1) Promote and support strategies that facilitate safe practices in the prescribing of opioids.

- The Centers for Disease Control and Prevention (CDC) *Guideline for Prescribing Opioids for Chronic Pain—United States, 2016* (March 15, 2016) summarizes 12 recommendations. The recommendations include use of non-pharmacologic and non-opioid pharmacologic therapies to manage chronic pain. When opioid medications are necessary, the guidelines provide strategies to identify and address risk factors, such a history of misusing prescription opioids or of a substance use disorder, and strategies to address identified risk factors, such as referral to evidence-based substance use treatment.
- The guidelines include information on prescribing opioids to pregnant women—women should be informed of the potential risks related to opioid use during pregnancy and an assessment of risk and benefit is necessary. During pregnancy, withdrawal from opioids is not recommended, primarily due to the high relapse potential and resultant impact on the fetus. Medication-assisted treatment (MAT) in conjunction with counseling and other behavioral interventions for opioid use disorders is recommended. Pregnant women undergoing MAT should give birth at a hospital prepared and equipped to address the woman's needs and to care for an infant with neonatal abstinence syndrome (NAS).
- Additional information on opioid prescribing guidelines for pregnant women is available on pg. 32 of the Guidelines document.
- On March 22, 2016, the Federal Drug Administration (FDA) announced new requirements for labeling of prescription opioid medications. The requirements include a new warning about the serious risks of misuse, abuse, addiction, overdose and death; and a precaution that chronic maternal use of opioids during pregnancy can result in NAS.

(2) Promote and support strategies that improve early identification of opioid and other substance use disorders during pregnancy and access to, and engagement in, MAT and other evidence-based substance use treatment.

- Approximately half of U.S. births are covered by Medicaid (Markus, et al., 2013; Curtin, et al., 2013).[1] There is wide variation in state Medicaid regulations on whether prenatal care providers are required to screen for opioid and other substance use disorders. Adoption of The American College of Obstetricians and Gynecologists (ACOG) guidelines in universal Medicaid regulations would result in enhanced identification of prenatal exposure to opioids and other substances. The ACOG guidelines state, "Screening for substance abuse is a part of complete obstetric care and should be done in partnership with the pregnant woman. Both before pregnancy and in early pregnancy, all women should be routinely asked about their use of alcohol and drugs, including prescription opioids and other medications used for nonmedical reasons (ACOG, 2012)."
- The ACOG guidelines also state ". . . to optimize care of patients with substance use disorder, obstetrician-gynecologists are encouraged to learn and appropriately use routine screening techniques, clinical laboratory tests, brief interventions and treatment referrals (ACOG, 2015)." Yet, a national study

[1] For state specific information, see: *http://khn.org/news/nearly-half-of-u-s-births-are-covered-by-medicaid-study-finds/*.

found that medical residency programs that require formal training on substance use disorders widely ranges from 31% to 95%, with only 39% of OB/GYN programs including curricula on substance use disorders (Isaacson, et al., 2000). The OB/GYN substance use curricula included an average of 3 hours of training.

- Enhancing training requirements for OB/GYNs and other medical professionals will help address the range of challenges related to identifying opioid and other substance use during pregnancy and in ensuring access to treatment. These challenges include (Terplan, 2015; ACOG 2015):
  - *Screening Tool:* Evidence-based screening tools, such as the 4Ps Plus, are available. Yet there is wide variation in whether prenatal care providers use these evidence-based tools.
  - *Reimbursement:* While Medicaid regulations vary, screening for substance use during pregnancy is a Medicaid reimbursable service.
  - *Referral to Treatment for Opioid and Other Substance Use Disorders:* Prenatal care providers and substance use treatment providers are often in different health networks. A common barrier for obstetricians in screening for substance use during pregnancy is the lack of access to follow-up care should a pregnant women need further assessment and treatment. This can be complicated, since making a referral to a substance use treatment provider outside of the Medicaid managed care network of the obstetrician may require different insurance processes.
  - *Stigma:* Misunderstanding of opioid and other substance use disorders. Fear and concern that identifying substance use during pregnancy will result in criminal prosecution of the woman and automatic removal of the infant with prenatal exposure at the time of birth, without regard for mothers' willingness to enroll in treatment.

(3) Promote and support strategies that encourage evidence-based treatment for infants with NAS.

- According to ACOG, "NAS is an *expected* and *treatable* condition that follows prenatal exposure to opioid agonists (2012)." NAS is the term used to represent the pattern of effects that are associated with opioid withdrawal in newborns (Hudak and Tan, 2012). NAS symptoms are affected by a variety of factors, including:
  - Type of opioid the infant was exposed to;
  - Point in gestation when the mother used the opioid;
  - Genetic factors; and
  - Exposure to multiple substances, particularly tobacco (Wachman, et al., 2013).
- Non-pharmacological treatment (*e.g.,* swaddling, breastfeeding, provision of a calm environment) is the standard of care for an infant with NAS and should begin at birth and continue throughout the infant's hospitalization and beyond (Velez and Jansson, 2008). The goal of both non-pharmacological and pharmacological treatment (*e.g.,* methadone, buprenorphine, morphine) is to soothe the infant's NAS symptoms, while encouraging the mother-infant bond. Other supportive strategies, such as having the mother and infant room together, are also necessary.

(4) Supporting development of partnerships across health networks and other systems involved in the care of pregnant women with opioid and other substance use disorders and their infants.

- Supporting the development of this partnership will facilitate access to:
  - Evidence-based treatment for opioid and other substance use disorders;
  - Evidence-based treatment of NAS; and
  - The range of additional social, health and safe housing services needed by pregnant women and their infants.

(5) Ensure implementation of provisions in the Child Abuse Treatment Act related to hospitals' notification to Child Protective Services of infants identified as affected by illegal substance use, withdrawal symptoms, or a fetal alcohol spectrum disorder and monitor that states and communities are implementing plans of safe care that support the infant and caregiver prior to the infant's and mother's discharge from the hospital.

- We note that the House Education and Labor Committee recently passed out of committee a bipartisan and bicameral bill to improve the CAPTA legisla-

tion in regard to monitoring implementation of these provisions, providing best practice guidance to states on these requirements and ensuring that the caregivers of infants are included in the plan of safe care. We anticipate that the bill will be taken up by the Senate Health, Education, Labor and Pensions (HELP) committee.

In summary, support of the following five approaches are necessary to improve outcomes for pregnant women with opioid and other substance use disorders and their infants:

(1) Safe practices in the prescribing of opioids.
(2) Improving early identification of opioid and other substance use disorders (particularly the co-occurrence of opioid, alcohol and nicotine use disorders) during pregnancy and providing access to and engagement in MAT and other evidence-based substance use treatment.
(3) Improving use of evidence-based treatment including fostering mother-infant bonding and non-pharmacological treatment as well as medication as needed for infants with NAS.
(4) Developing partnerships across health networks and other systems involved in the care of pregnant women with opioid and other substance use disorders and their infants.
(5) Improving provisions in the CAPTA legislation in regard to better monitoring of the implementation of the law and to ensure that plans of safe care are provided to infants and their caregivers.

Question. Thank you for highlighting in your written testimony the importance of keeping children at home and recovery support services for parents who are affected by opioid and substance abuse disorders. Nearly 40% of Colorado children removed from their homes are removed due to parental substance abuse. What do you think is the most immediate step that must be taken to ensure that parents have the help they need and keep children safely in the home?

Answer. (1) Take advantage of the lessons learned from prior federal investments in demonstration programs and title IV–E waivers to ensure child welfare agencies and community partners implement proven strategies to prevent child placement in out-of-home care and improve family outcomes.

After more than a decade of testing strategies to improve outcomes for these families, there are seven key components of services that have been implemented in demonstration grants and Title IV-E waivers that are associated with preventing child removal, decreasing costs, and providing better family outcomes. These strategies are more fully described in my prior written statement submitted to the Finance Committee Hearing in February. In brief, successful communities and interagency collaboratives:

- Implement a system of identifying families in need of substance use disorder prevention and treatment such as establishing standardized screening protocols in child welfare practice and in prenatal care;
- Ensure early access to assessment and treatment services such as securing expert consultation on cases involving substance use disorders, conducting outreach and methods to engage and retain parents in treatment, and provide priority access to assessment and treatment of child welfare-involved families affected by substance use disorders;
- Increase management of treatment and recovery services and monitoring compliance such as co-location of services, specialized recovery case management services; ensuring comprehensive family treatment programs are tailored to individual parent and child needs;
- Ensure access to family-centered services including effective parenting programs focused on enhancing the parent and child relationship and the prevention needs of children;
- Provide appropriate judicial oversight including providing more frequent judicial or administrative reviews of treatment access and compliance with case plans regarding participation in substance use disorder treatment;
- Have a system in place that appropriately responds to participants' behavior such as proven contingency management approaches;
- Improve their collaborative approach across service system and courts including:
  - Cross training of staff;
  - Data collection and information systems capable of monitoring the progress and outcomes of children and families receiving services from the child welfare and treatment systems;

- Arrangements for addressing confidentiality and sharing of information;
- Identification by the State agencies or Indian tribal agencies of funding barriers and how Federal, State, and local resources are being used to sustain programs of these agencies;
- Consultation with community members and persons in recovery to ensure programmatic approaches reflect their consultation and advice; and
- Identifying how infants with prenatal substance exposure are specifically included in the efforts of States or Tribes to monitor and reduce infant fatalities.

As Senator Bennet represents the State of Colorado, we note that efforts are underway in the State of Colorado to implement these strategies. The Office of Juvenile Justice and Delinquency Prevention (OJJDP) provided grant funds to Colorado and four other states in 2014 to conduct cross-system planning and to test methods to implement these strategies in a collaborative effort among the administrative agencies and the juvenile court. Colorado's efforts include pilot testing of universal screening of child welfare-involved families for substance use and mental health issues. There are eight pilot counties that are geographically representative of the State. The first cohort of counties continues to refine and develop practice and protocols through routine information sharing, data collection and analysis to prepare for statewide implementation in the Fall of 2016. Lessons learned from the first cohort are informing the second cohort. Both groups are now testing strategies to ensure that the following are developed into policies and protocols for statewide implementation:

(1) Universal screening for substance use and mental health;
(2) Improved and earlier access to shorten timeframes between screening and assessment for substance use disorder and mental health;
(3) Use of a multidisciplinary team staffing model to integrate substance use disorder and mental health assessments and to consider, simultaneously, the child's safety and risk assessments; and
(4) Compel court's case management to be responsive to treatment needs.

The project has developed a data collection, management and analysis plan that entails development of a shared database to measure the efficacy of the pilots and to ensure continued quality improvement in the statewide implementation. The project has drafted and operationalized shared outcomes across partners in a data dictionary.

(2) The need to improve the identification of families who need assistance and the information systems to better record and monitor the impact of parental substance use and mental disorders on child welfare services.

We understand that the Adoption and Foster Care Analysis and Reporting System (AFCARS) data regarding the prevalence of parental alcohol or drug use are factors in cases of children being placed in protective custody in Colorado. However, under various technical assistance engagements in Colorado over the past dozen years, no one we have interacted with in Colorado believes that the 40% prevalence rate is accurate. They generally believe it is a much higher percentage. In the written statement to the Committee, we detailed some of the reasons for the under-recognition of parental substance use disorders. In addition, as noted by Seay it has been more than a decade since a study on the prevalence of substance use in child welfare agencies has been published (Seay, 2015).

Solutions to the under-reporting of parental substance use and mental health issues as reasons for child removal seem more urgent than ever. As any potential changes in the financing of child welfare services are being discussed, it will be increasingly important to determine the prevalence of substance use. In our view, the mandated Statewide Automated Child Welfare Information System (SACWIS) for child welfare agencies and proposed changes in the AFCARS system reporting on foster care do not adequately address the wide variation among states in reporting removals of children to foster care that involved parental drug and alcohol use. States range from near-zero to the high 50% level, which underscores the under-reporting. Unless reporting on indicators of parental substance use is made mandatory, states will continue to under-report, based on our discussions with state and local officials. States that have done the best job with this reporting could be given incentives to spotlight their efforts as a form of peer-to-peer technical assistance.

In closing, while we now understand "What to Do," based on these strategies, the most urgent need is to change the financing mechanisms in child welfare to support strategies that broaden access to substance use treatment services for child welfare-

involved families so that prevention of child placement becomes a clear priority by providing the substance use treatment and mental health services that are needed by parents and children.

The Role of Plans of Safe Care in Ensuring the Safety and Well-Being of Infants with Prenatal Exposure, Their Mothers and Families

A Discussion Draft in Development of A Technical Assistance White Paper

March 26, 2016

Updated July 27, 2016

Prepared by: Children and Family Futures

Strengthening Partnerships, Improving Family Outcomes

25371 Commercentre Drive
Lake Forest, CA 92692
714–505–3525

This white paper is intended to generate discussion among State and local policymakers and practitioners. The ideas are framed by Children and Family Futures staff and informed by our work with numerous communities across the nation on the public policy issues affecting children of parents with substance use disorders. The views do not reflect the official position or agreement with these ideas from any of the funding organizations of Children and Family Futures.

The Need

More than 500,000 infants are born each year to mothers who used tobacco (13.4 percent), alcohol (9.3 percent), or illicit drugs (5.3 percent) during pregnancy.[1] The number of infants exhibiting the narrower criteria of "affected by illegal substance abuse or withdrawal symptoms or a fetal alcohol spectrum disorder" is unknown. For many of these children, this exposure has lifelong effects.

Many Federal and State programs aim to reduce substance use during pregnancy as well as the potential effects on infants and children, but there is no single Federal agency that is charged with responding to these risk factors or to coordinate a response across the multiple agencies. Legislation and administrative guidelines on risks to infants and young children involve more than a dozen Federal agencies, and dozens more at State and local levels. These agencies and professionals include health care, social services, treatment for substance use disorders, mental health, child welfare, developmental disabilities, home visiting, education, and more.

The Role of the Child Abuse Prevention and Treatment Act (CAPTA) in Meeting the Need

In the child welfare system, the Keeping Children and Families Safe Act of 2003 (amended in 2010) created new conditions for States to receive State grant allocations under the Child Abuse Prevention and Treatment Act (CAPTA). The changes were intended to provide the needed services and supports for infants, their mothers, and their families and to ensure a comprehensive response to the effects of prenatal exposure.

The legislative intent was to improve the likelihood of mothers obtaining treatment for their substance use disorder, not to mandate that prenatal exposure would automatically result in a substantiated case of child abuse or neglect. In referring to needed services, the CAPTA language makes clear that child welfare is only one of the agencies that must be involved. Since child welfare does not have responsibility

---

[1] Substance Abuse and Mental Health Services Administration, *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings,* NSDUH Series H–48, HHS Publication No. (SMA) 14–4863. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014. Retrieved from *http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.pdf.*

for intervening prior to the birth event, other agencies and providers must be responsible for identifying such infants during the prenatal period or at birth and providing mothers the treatment services that are needed.

The committee report on H.R. 14 (2003) the House version of the Keeping Children and Families Safe Act, stated that the requirement was intended to "identify infants at risk of child abuse and neglect so appropriate services can be delivered to the infant and mother to provide for the safety of the child." The authors of this bill called for . . .

> "the development of a safe plan of care for the infant under which consideration may be given to providing the mother with health services (including mental health services), social services, parenting services, and substance abuse prevention and treatment counseling, and to providing the infant with referral to the statewide early intervention program funded under part C of the Individuals with Disabilities Education Act for an evaluation for the need for services provided under part C of such Act.[2]"

Thus, the law intended that the function of Child Protective Services (CPS) is protecting a child who may be at increased risk of maltreatment, regardless of whether the State had determined that the child had been abused or neglected as a result of prenatal exposure.[3]

In 2010, the law was amended again to include the needs of infants born with and identified as being affected by illegal substance abuse or withdrawal symptoms resulting from prenatal drug exposure, or a Fetal Alcohol Spectrum Disorder.[4] Recent attention generated in part by the nation's current prescription drug and opioid epidemic has focused state agencies on the requirement that a Plan of Safe Care be implemented for these infants.[5]

On July 22, 2017, H.R. 4843, Infant Plan of Safe Care was signed into law under Title V, Section 503, of S. 524, Comprehensive Addiction and Treatment Act of 2016. The legislation requires the Plan of Safe Care to address the needs of both the infant and parent(s) while also increasing States' accountability through monitoring by the U.S. Department of Health and Human Services (HHS) to better ensure States are complying with the CAPTA provisions.

The changes in the law are highlighted on page 82.

Defining Drug- and Alcohol-Affected

One of the complicating factors in implementing the CAPTA provisions is that, at present, there is no clear definition of the term "affected by illegal substance abuse." It is certainly easier to make that determination when an infant experiences a withdrawal syndrome. Yet, infants exposed to stimulants or alcohol without the full expression of Fetal Alcohol Syndrome may be "affected by" that exposure as evidenced by impaired growth, prematurity, or subtle neurodevelopmental signs that are more difficult to define in the newborn and infancy stages.

We would suggest that States need to offer clarity on and define through State legislation or administrative policy how they are to define, identify, intervene and ensure the safety of infants and their families with prenatal substance exposure in the immediate post-partum period and through-out infancy.

The language in the CAPTA legislation calls for a response to drug- and alcohol-affected infants, but does not specify how this should be defined. That leaves the definitional task up to States at this point. In the section of this paper on developing a Plan of Safe Care that follows, we reference assessment tools that were created

---

[2] H.R. 14, Keeping Children and Families Safe Act of 2003. Retrieved from *https://www.congress.gov/bill/108th-congress/house-bill/14/text?q=%7B%22search%22%3A%5B%22HR+14+keeping+children+and+families+safe+act+2003%22%5D%7D&resultIndex=4&overview=open#content.* Signed into Public Law (P.L. 108–36; S. 342, Keeping Children and Families Safe Act of 2003) on June 25, 2003. Retrieved from *https://www.congress.gov/bill/108th-congress/senate-bill/342?q=%7B%22search%22%3A%5B%22HR+14+keeping+children+and+families+safe+act+2003%22%5D%7D&resultIndex=5.*

[3] Christian, Steve, *Substance Exposed Newborns: New Federal Law Raises Some Old Issues,* National Conference of State Legislatures: Children's Policy Initiative, September 2004, pg. 3.

[4] Signed into Public Law (P.L. 111–320, CAPTA Reauthorization Act of 2010) on December 20, 2010. Retrieved from *https://www.congress.gov/bill/111th-congress/senate-bill/3817?q=%7B%22search%22%3A%5B%22P.L.+111-320%22%5D%7D&resultIndex=1.*

[5] Wilson, D. and Shiffman, John, "Helpless and Hooked," December 7, 2015, *http://www.reuters.com/investigates/special-report/baby-opioids/.*

in the late 1980s during the cocaine epidemic that are excellent tools to adapt as States define these issues.

We would suggest the following definition for State policymakers' and practitioners to refine:

> An alcohol- or other drug-affected infant is one in which there is any detectable physical, developmental, cognitive, or emotional delay or harm that is associated with parental action involving substance use or abuse.

States may want to consider the use of medical fragility or Medically Fragile Infants when defining this population of infants, as this is consistent with the Maternal and Child Health Bureau definition of children with special health care needs (CSHCN); *children who have or are at increased risk of a chronic physical, developmental, behavioral, or emotional condition and require health care and related services of a type or amount beyond that required by children generally*.[6] Appropriate interventions, including family-centered services and care coordination, should be considered in the context of this definition.

Similar to the current CAPTA language, we do not suggest that this definition is grounds for substantiating child abuse or neglect. Specifically, a mother participating in medication-assisted treatment is not grounds for substantiated child abuse or neglect.

Rather, a definition is warranted to assure that the full spectrum of intervention and supports are provided to ensure the safety of the infant and mother. Further, in the absence of immediate safety concerns, the supports are provided to the mother, infant and family to maintain the mother/infant bond.

We would suggest pediatricians and other medical professionals are consulted for establishing the State's definition. The following factors may be taken into account in developing that definition.[7]

In conjunction with known substance use during pregnancy:

1. Signs of prenatal exposure detectable at birth and early infancy are assessed including:
   a. Facial characteristics of fetal alcohol syndrome[8]
   b. Withdrawal as defined by neonatal abstinence syndrome[9]
   c. Irritability
   d. Irregular and rapid changes in state of arousal
   e. Low birth weight
   f. Prematurity
   g. Difficulties with feeding due to a poor suck
   h. Irregular sleep-wake cycles
   i. Decreased or increased muscle tone
   j. Seizures or tremors
2. Evidence through prenatal screening of mother's substance use including alcohol, tobacco, illegal drugs, prescription drugs used non-medically, or legal use of marijuana in States with legal use, at any time during pregnancy or screening of the mother and infant at the time of birth.
3. Mothers' participation in a treatment program using medications as prescribed for an opioid use disorder or medical marijuana in those States in which medical marijuana is legal (again, inclusion of this group of mothers is to identify infants with possible prenatal substance exposure effects to ensure needed supports are provided to the family, not to classify this group of mothers as perpetrators of child abuse or neglect).

Additional factors, such as previous child welfare history that indicates unresolved substance use issue and other potential risk factors, such as co-occurring mental

---

[6] McPherson M., Arango P., Fox H., et al., A new definition of children with special health care needs. Pediatrics. 1998;102(1 pt 1):137–140 [PubMed].

[7] Many of the characteristics cited in this list are adapted from Messinger, D. and Lester, B., "Prenatal Substance Exposure and Human Development" in Fogel, A. and Shanker, S. (2005) (Eds.), *Human Development in the 21st Century: Visionary Policy Ideas from Systems Scientists.* Council on Human Development, Bethesda, MD.

[8] The Encyclopedia of Children's Health, Fetal Alcohol Syndrome. Accessed March 20, 2016 from: *http://www.healthofchildren.com/E-F/Fetal-Alcohol-Syndrome.html.*

[9] Kocherlakota, P. (2014), Neonatal Abstinence Syndrome. Pediatrics 134(2). Accessed March 25, 2016 from: *http://pediatrics.aappublications.org/content/134/2/e547.*

health concerns, can be considered in developing the Plan of Safe Care. Refer to pg. 16 for additional information.

The bold-face text represents proposed changes from H.R. 4843, "Infant Plan of Safe Care Improvement Act"

Section 103. NATIONAL CLEARINGHOUSE FOR INFORMATION RELATING TO CHILD ABUSE. [42 U.S.C. 5104][10]

a. ESTABLISHMENT.—The Secretary shall through the Department, or by one or more contracts of not less than 3 years duration let through a competition, establish a national clearinghouse for information relating to child abuse and neglect.

b. FUNCTIONS.—The Secretary shall, through the clearinghouse established by subsection (a)—

(5) maintain and disseminate information about the requirements of section 106(b)(2)(B)(iii) and best practices relating to the development of plans of safe care as described in such section for infants born and identified as being affected by illegal substance abuse or withdrawal symptoms, or a Fetal Alcohol Spectrum Disorder.

Section 106. GRANTS TO STATES FOR CHILD ABUSE OR NEGLECTION PREVENTION AND TREATMENT PROGRAMS. [42 U.S.C. 5106a]

A State plan . . . shall contain a description of the activities that the State will carry out using amounts received under the grant to achieve the objectives of this subchapter, including—. . .

(B) an assurance in the form of a certification by the Governor of the State that the State has in effect and is enforcing a State law, or has in effect and is operating a statewide program, relating to child abuse and neglect that includes—

(ii) policies and procedures (including appropriate referrals to child protection service systems and for other appropriate services) to address the needs of infants born with and identified as being affected by illegal substance abuse or withdrawal symptoms resulting from prenatal drug exposure, or a Fetal Alcohol Spectrum Disorder, including a requirement that health care providers involved in the delivery or care of such infants notify the child protective services system of the occurrence of such condition of such infants, except that such notification shall not be construed to—

(I) establish a definition under Federal law of what constitutes child abuse or neglect; or

(II) require prosecution for any illegal action;

(iii) the development of a plan of safe care for the infant born and identified as being affected by illegal substance abuse or withdrawal symptoms, or a Fetal Alcohol Spectrum Disorder **to ensure the safety and well-being of such infant following release from the care of healthcare providers, including through—**

(I) addressing the health and substance use disorder treatment needs of the infant and affected family or caregiver; and

(II) the development and implementation by the State of monitoring systems regarding the implementation of such plans to determine whether and in what manner local entities are providing, in accordance with State requirements, referrals to and delivery of appropriate services for the infant and affected family or caregiver.

(iv) procedures for the immediate screening, risk and safety assessment, and prompt investigation of such reports; . . .

(xxi) provisions and procedures for referral of a child under the age of 3 who is involved in a substantiated case of child abuse or neglect to early intervention services funded under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 *et seq.*); . . .

(d) ANNUAL STATE DATA REPORTS.—Each State to which a grant is made under this section shall annually work with the Secretary to provide, to the maximum extent practicable, a report that includes the following:

[10] Child Abuse Prevention and Treatment Act, Reauthorization Act of 2010: *https://www.acf.hhs.gov/sites/default/files/cb/capta2010.pdf* *https://www.congress.gov/111/plaws/publ320/PLAW-111publ320.pdf.*

(15) The number of children referred to a child protective services system under subsection (b)(2)(B)(ii) [*Note: this section is above related to notification to CPS and referrals to other appropriate services*]

(16) The number of children determined to be eligible for referral, and the number of children referred, under subsection (b)(2)(B)(xxi), to agencies providing early intervention services under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 *et seq.*).

(17)(A) The number of infants identified under subsection (b)(2)(B)(iii).

(B) The number of infants for whom a plan of safe care was developed under subsection (b)(2)(B)(iii);

(C) The number of infants for whom a referral was made for appropriate services, Including services for the affected family or caregiver, as may be necessary under subsection (b)(2)(B)(iii).

Section 114. MONITORING AND OVERSIGHT.

The Secretary shall conduct monitoring to ensure that each State that receives a grant under section 106 is in compliance with the requirements of section 106(b), which—

(1) shall—

(A) be in addition to the review of the State plan upon its submission under section 106(b)(1)(A); and

(B) include monitoring of State policies and procedures required under (ii) and (iii) of section 106(b)(2)(B); and

(2) may include—

(A) a comparison of activities carried out by the State to comply with the requirements of section 106(b) with the State plan most recently approved under section 432 of the Social Security Act;

(B) a review of information available on the Website of the State relating to its compliance with the requirements of section 106(b);

(C) site visits, as may be necessary to carry out such monitoring; and

(D) a review of information available in the State's Annual Progress and Services Report most recently submitted under section 1357.16 of title 45, Code of Federal Regulations (or successor regulations).

The Need for Multi-Agency Support in Implementing CAPTA

It is clear that child welfare agencies cannot be charged with the sole responsibility for responding to prenatal substance exposure and infants who are affected by prenatal substance use. In fact, while data are largely incomplete, only a small percentage of these families are identified and are referred to the child protection system. Child welfare agencies typically cannot intervene until birth, and many do not receive timely notifications of drug- or alcohol-exposed births from hospitals and medical providers. This occurs even though for a State to receive a CAPTA grant, the governor assures that the State is enforcing a complying State law or that the child welfare agency operates a program that ensures that health care professionals notify Child Protective Services when such infants are identified.

A five-stage framework, set forth in a 2009 SAMHSA publication and included in the 2012 White House Office of National Drug Control Policy, specifies five stages which need to be part of comprehensive reform to effectively respond to pregnant women, their families and infants with prenatal exposure:

(1) Pre-pregnancy public education to reduce substance use during pregnancy including tobacco, alcohol, and other drugs;

(2) Prenatal screening and engagement of pregnant women in treatment when indicated;

(3) Universal screening at birth to both deter substance use and to ensure infants who may be at increased risk and their families receive the intervention and supports that are needed to ensure their safety and well-being;

(4) Screening, assessment and intervention during infant and toddler stages (0–3 years) to remediate any developmental concerns and early identification and support for pre-school developmental care and education (3–5); and

(5) Ongoing support and age-appropriate interventions for children and adolescents (5–18) who may have neurodevelopmental or other effects.[11]

There is more than $400 billion of Federal expenditures that benefit children, which is allocated across many agencies.[12] That array of resources underscores the critical roles that could be played by many agencies and providers at all five stages of this framework. Despite these resource allocations and potential expansion of substance use disorder treatment through the Affordable Care Act[13] and parity legislation requiring substance use and mental health treatment benefits on par with medical care provisions,[14] there remains a dramatic gap in substance use disorder treatment,[15] particularly for family-centered care and for medications needed to treat opioid use disorders. Therefore, States need a two-pronged approach to achieve a multi-agency response to prenatal exposure:

(1) A State-level strategic plan that sets forth broad system policies and practices, addresses barriers to multi-agency responses, sets and monitors benchmarks to improve outcomes for these families, and ensures the support of agencies' leadership.
(2) Local-level implementation plans to ensure the necessary policies, practice and communication protocols are in place that ensure a continuum of services, including Plans of Safe Care for infants, their mothers, and their families.

A State-level authority, reporting directly to the governor and charged with convening authority to work across agencies and providers, is needed to develop a strategic, multi-year response to the problems of prenatal substance exposure. The characteristics of that plan have been set forth below: it must be based on shared resources and cross-agency outcomes, rather than the province of a single agency. Its efforts must be monitored by legislative oversight and accountability to the governor's budget authority. Clarifying the role of each participating agency requires measurable outcomes and specific timelines.

At the local government level, a multi-disciplinary approach is needed that draws on professional expertise across agencies and includes an initial response and triage process that assesses risk and protective factors but does not presume child abuse or neglect. This multi-disciplinary approach includes the development of a team comprised of partnering agencies, including, but not limited to, hospitals, private medical providers, maternal and child health, including home visiting, substance abuse and mental health services, and early intervention services.

The development of the Plan of Safe Care for each family must involve an assessment of the strengths of and challenges for the mother, her infant and her family. The plans are based on a preference that infants, mothers, and families can remain together. Reasons for placing an infant in protective custody would be based on immediate risk and safety concerns that are present and not mitigated by sufficient familial protective factors to provide for the infant's safety. If the mother and infant are residing in or enter a residential treatment program, which can mitigate immediate safety concerns, removal of the infant from the mother's care can be avoided. Regardless of the immediate placement decisions, the Plan of Safe Care must include specific follow up plans that support the family and focus on the longer-term well-being of the infant, mother and family.

The following criteria may go beyond provisions in current CAPTA laws. Yet, it is the experience of Children and Family Futures staff and our recommendations that they are needed in developing and implementing Plans of Safe Care. Setting the State's policy context for an approach to families affected by substance use disorders

---

[11] Young, N.K., Gardner, S., Otero, C., Dennis, K., Chang, R., Earle, K., and Amatetti, S. (2009), Substance-Exposed Infants: State Responses to the Problem. HHS Pub. No. (SMA) 09–4369, Rockville, MD: Substance Abuse and Mental Health Services Administration.

[12] Social Policy Report Volume 29, Number 1, 2015, ISSN 1075–7031, *www.srcd.org/publications/social policy-report.*

[13] Mental Health and Substance Abuse Essential Benefits. Accessed March 20, 2016 from *https://www.healthcare.gov/coverage/mental-health-substance-abuse-coverage/*.

[14] Center for Medicaid and Medicare Services. The Mental Health Parity and Addiction Equity Act. Accessed March 24, 2016 from: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/mhpaea_factsheet.html.*

[15] There are several estimates on the gap between treatment need and receipt of treatment; most are in the range that 10–11% of persons who need treatment receive it. State of Health (2014), Despite Obamacare, Big Gap in Substance Abuse Treatment. Accessed March 25, 2016 from: *http://ww2.kqed.org/stateofhealth/2014/04/11/despite-obamacare-big-gap-in-substance-abuse-treatment/*.

is critical in providing guidance to local jurisdictions on the development and implementation of Plans of Safe Care.

State Level Strategic Plans

Charge to the Governor's Council—A Governor's interagency council could be charged with developing a comprehensive State Plan for implementation of Plans of Safe Care (PSC) to focus on reducing prenatal substance exposure and responding effectively to the needs of infants who are affected by prenatal substance exposure, to their mothers with substance use disorders and to their families. The charge of such entity is to develop, coordinate and support the child and family-focused service delivery system, emphasizing prevention, early intervention, and an array of community-based treatment services. The Governor's Council would be tasked with evaluating the State's existing legislation, policies and procedures that govern the State-wide implementation of the CAPTA provisions and determining if changes are needed in State laws or administrative rules. The Council would also be able to issue guidance to local jurisdictions that are charged with developing an effective response and Plan of Safe Care for infants and their families.

Membership of the Governor's Council—This council could include the Departments of Health, including Public Health and Maternal and Child Health (including Home Visiting Division), Substance Use Disorder prevention and treatment, Mental Health, Social Services (Child Abuse Prevention and Protection Services), Early Intervention (IDEA Part C), Developmental Disabilities, Administrative Office of the Courts, State Department of Education, Department of Budget and Finance, the Medicaid Director, as well as representatives from the State Hospital Association, State branches of the American College of Obstetricians and Gynecologists (ACOG) and State branches of the American Academy of Pediatrics (AAP) and the Insurance Commissioner's office who has oversight of private health insurers in the State. Previously existing councils at the state level such as Children's Cabinets or Early Childhood Councils could be tasked with this role if given adequate emphasis and greater priority to the issues of responding to prenatal exposure and its effects.

Tasks of the Governor's Council—At a minimum the plan could include:

Prevention of Infants with Prenatal Substance Exposure

- Strategies for raising awareness about the risks associated with alcohol, tobacco and other substance use during pregnancy. Specific strategies are developed to engage young women of childbearing age, including the adolescent and foster care population.
- Strategies that focus on changing the culture regarding substance use during pregnancy so that women and families are supported to make healthy decisions and to receive appropriate intervention and treatment when needed.

Screening, Assessment and Intervention during Pregnancy, at Birth and Childhood

- Implementing universal screening for substance use during pregnancy using an evidence-based reliable tool.
- Medicaid and private insurer requirements for coverage of screening during pregnancy and the minimum insurance benefit and payment rates (*e.g.,* determining factors such as screening during prenatal care as a billable item in the Medicaid plan and at what rate and who can bill for that service) for treatment in accordance with Federal parity legislation and the Affordable Care Act.
- Demonstrate that policies and protocols for the notification to CPS of an infant with prenatal substance exposure to CPS are developed with hospitals and medical providers responsible for the delivery of such infants.
- A lead agency (*e.g.,* a substance abuse treatment agency or the public health authority) is designated to ensure that multi-disciplinary and comprehensive assessments with the pregnant woman are conducted. However, the Medicaid agency, for example, may be charged with monitoring implementation of the assessments by determining that claims for routine prenatal care include billing codes for substance use disorder screening and assessments.
- A lead agency must also be designated that has the responsibility to ensure that a Plan of Safe Care is implemented for infants identified with prenatal exposure, their mothers and families. While signs and symptoms of neurological effects of prenatal exposure would not be evident during pregnancy or in some cases at birth, the intent of designating which agency is responsible is to ensure that a plan is developed and that follow up with the family occurs to reduce longer-term effects and to foster the child's development.

- A continuum of services for pregnant, post-partum and parenting women that acknowledges women's treatment needs for evidence-based, family-centered and trauma-informed services and addresses barriers to accessing services for pregnant and parenting women. Steps to ensure that continuum include determining gaps in the availability of these services and the development of strategic plans to create such a continuum in States and communities.
- Practice protocols for women in treatment, particularly those receiving medication-assisted treatment, to ensure effective communication between substance use disorder treatment agencies and physicians providing medications.
- Policy and procedures to ensure home visiting or other programs that provide follow up to high risk infants include this population in their services and that all such infants receive those follow up services, regardless of their placement following discharge from the hospital (*e.g.,* with mother and family or an out-of-home care placement).
- A policy for automatic referral to and assessment of need by IDEA Part C providers for infants born affected by substance use disorders as specified by CAPTA for substantiated child welfare cases under the age of 3; exposed to and affected by illegal substance abuse or withdrawal symptoms resulting from prenatal drug exposure, or a fetal alcohol spectrum disorder.
- The provision of evidence-based training to personnel across multiple domains, agencies, and disciplines to educate them on issues related to prenatal alcohol exposure and the diagnosis of fetal alcohol syndrome and the broad spectrum of associated disorders that fall within FASD. Criteria for diagnosing individuals who were exposed to alcohol and have neurodevelopmental deficits without any physical indicators of exposure have been presented in the DSM5 and should be communicated to health care providers.

Data Collection and Monitoring

- Identifying and resolving barriers to data collection and information sharing across agencies and systems;
- Establishing state-wide performance measures and benchmarks with annual monitoring of the numbers, including the data points sufficient to monitor Plan of Safe Care implementation:
  - the prevalence of substance use during pregnancy;
  - pregnant women who screen positive for substance use;
  - the number of treatment admissions for pregnant women;
  - infants born with prenatal substance exposure;
  - notifications to child welfare of infants with prenatal exposure;
  - the number of infants and families with implemented Plans of Safe Care;
  - average hospital stays and costs for infants and mothers;
  - infants with prenatal exposure who remain at home and those placed in custody of the State;
  - the number of families receiving home visiting interventions or other on-going supportive services, including those covered by Plans of Safe Care; and
  - referrals to and receipt of early intervention services through IDEA Part C.
- Assessment of data from hospitals and CPS on the needs of children and families to make appropriate policy updates.
- State policies on the appropriate follow-up time frames for collecting the data needed to monitor child and family benchmarks based upon an agreed-upon set of outcomes and indicators.
- Methods for evaluating costs of the continuum of care involved with Plans of Safe Care, including cost avoidance, in hospitals, child welfare, special education and other agencies.

The Community Level Plan of Safe Care for an Individual Infant, Mother and Family

Charge to the Community Team—A Community's interagency team is charged with implementing the Governor's Interagency Council's decisions by developing a comprehensive practice protocol to focus on reducing prenatal substance exposure and responding effectively to infants who are affected by prenatal substance exposure, to their mothers with substance use disorders and to their families. The charge of such entity is to develop specific practice and communication protocols that coordinate the child and family-focused service delivery system, emphasizing prevention, early intervention, and an array of community-based treatment and support services for infants, children, and their families.

Membership of the Community Team—This team would include, at a minimum, representatives from the Departments of Health, including Public Health and Ma-

ternal and Child Health and Home Visiting Services, Substance Use Disorder Prevention and Treatment, Mental Health, Social Services (Child Abuse Prevention and Protection Services), Early Intervention Services, Developmental Disabilities, Juvenile/Dependency Courts, Office of Education as well as representatives from the Local Hospital Association, local representatives of the American College of Obstetricians and Gynecologists (ACOG) and local representatives of the American Academy of Pediatrics (AAP). These representatives should have decision-making authority to approve or provide needed services to children and families.

Tasks of the Community Team—At a minimum the Community Team would establish community goals that:

(1) Implement an interagency memoranda of agreement that codifies agency roles and responsibilities in reducing prenatal exposure and responding to its effects.
(2) Focus on changing the culture regarding substance use during pregnancy so that women and families are supported to make healthy decisions and to receive appropriate intervention and treatment when needed.
(3) Implement a continuum of care that ensures infants, mothers and families can remain safely together with any needed community supports focused on their well-being.
(4) Ensure appropriate placement for infants who cannot stay in the custody of their birth mother with preference for kin providers when possible.
(5) Ensure coordination and avoid duplication of services for infants, mothers and families.
(6) Identify resources, barriers to care and gaps in services including availability of appropriate resources and the effects of current eligibility criteria.
(7) Identify and address information and data sharing barriers including aggregating, monitoring and changing practice and policies based on the data.

Practice Protocol Specific Tasks Include:

- Developing efficient methods for health care providers to identify and notify specific personnel in the CPS agency in accordance with provisions in CAPTA or the prevailing State's law that implements the CAPTA requirements.
- Ensuring a prompt assessment of families for whom notifications are received by CPS to determine if there are immediate safety concerns and risk of future harm to the infant.
- Determining which infants require a Plan of Safe Care. Options may include those with positive results on the universal implementation of the screening tool during prenatal care and repeating that measure in the month prior to the expected due date and at birth. A Plan of Safe Care should be triggered by positive results on the screen or a positive toxicological screen 30 days prior to birth or at birth, or enrollment of an infant under the age of one year in the substantiated child abuse and neglect caseload who may have not been detected at birth as experiencing prenatal substance exposure.
- Establishing a procedure that assures families are included in the "assessment track" in communities with differential response or methods to assess for immediate safety concerns with the preference for maintaining the infant and mother bond.
- Developing methods for the assessments to be conducted by and coordinated with relevant agencies and service providers. This coordination may take the form of a family team meeting in which multiple disciplines work with the family to ensure a comprehensive assessment of strengths and needs of the infant's and mother's physical, social-emotional health and safety needs.
- Determining whether the community's existing safety and risk assessment and intervention protocols are appropriate and sufficient for this group of families and enhancing those assessment tools and procedures as needed.
- Making determinations on how to support infants and families for whom medication assisted treatment is being used in accordance with the mother's treatment plan.
- Determining the process for and content of an individual Plan of Safe Care which addresses the needs of the infant, mother and other family members identified by the multidisciplinary, comprehensive assessments.
- Ensuring other caregivers receive medical information, training and support to appropriately care for infants with prenatal exposure prior to discharge from the hospital when such infants will not be released to the care of his/her mother and family.
- Determining the appropriate timing for the development of the Plan of Safe Care with a preference that plans are developed with families prior to the infant's birth

so that the family is supported and there is communication among health providers, substance use disorder treatment agencies, child welfare and other community supportive agencies.

- Ensuring Plans of Safe Care are consistent with the individual family support plans that are required for all children accepted by early intervention services under Part C of the Individuals with Disabilities Education Act (IDEA).
- Developing the process for ensuring that families who are determined to have insufficient protective capacity to ensure the safety of the baby with prenatal substance exposure receive prompt investigation services by CPS.
- Implementing policies that ensure the infant's safety plan includes a safety and risk assessment of the home environment, community and family support, mother's recovery status and ongoing treatment needs (including her need and receipt of medication assisted treatment) as well as other health care needs in appropriate medical homes, and infants' health, developmental, well-being and safety needs.

Plans of Safe Care

Specific definition on what was to be included and who was to develop, implement and monitor Plans of Safe Care were not specified in the 2003 and 2010 amendments to CAPTA. While legislative intent in those changes to CAPTA included care for the infant's mother, recognizing that her care and safety of the infant are intertwined, in practice, it does not seem that Plans of Safe Care have been consistently implemented.

Guidance on these questions was provided in the Children's Bureau's Child Welfare Policy Manual, in response to a question that was posed on September 27, 2011. The question states:

> *Which agency is responsible for developing the plan of safe care and what is a plan of safe care, as required by section 106(b)(2)(B)(iii) of the Child Abuse Prevention and Treatment Act (CAPTA)?*
> Answer: The statute does not specify which agency or entity (such as hospitals or community-based organizations) must develop the plan of safe care; therefore, the State may determine which agency will develop it. The plan of safe care should address the needs of the child as well as those of the parent(s), as appropriate, and assure that appropriate services are provided to ensure the infant's safety. There may be Federal confidentiality restrictions for the State to consider when implementing this CAPTA provision.
> (*http://www.acf.hhs.gov/cwpm/programs/cb/laws_policies/laws/cwpm/qacumm.jsp*)
> Legal and Related References*Child Abuse Prevention and Treatment Act (CAPTA), as amended (42 U.S.C. 5101 *et seq.*) section 106(b)(2)(B)(iii).

As proposed in 2016 legislation, Plans of Safe Care are specifically intended to provide the needed services and supports for infants, their mothers, and their families. The 2016 proposed changes to CAPTA specifically state that services for the mother and family are included in the Plan of Safe Care.

At the time of birth, assessing risk to determine if the infant can go home safely is paramount and is a critical component of the comprehensive assessment process (safety factors generally included in CPS investigations are clarified below).

However, the Plan of Safe Care moves beyond seeking information to substantiate allegations of child abuse or neglect. It specifically incorporates the mother's (and potentially the father's) need for treatment for substance use and mental disorders, appropriate care for the infant who may be experiencing neurodevelopmental or physical effects or withdrawal symptoms from prenatal substance exposure, and services and supports that strengthen the parent's capacity to nurture and care for the infant and to ensure the infant's continued safety and well-being. The plan also ensures a process for continued monitoring of the family and accountability of responsible agencies such as substance use disorder treatment, home visiting, public health, health care providers for the infant and mother.

The Plan of Safe Care would:

(1) Be based on the results of a comprehensive, multidisciplinary assessment that is coordinated across disciplines to determine the infant's and mother's

physical, social-emotional health and safety needs, as well as the mother's strengths and parenting capacity.[16]

(2) Assess immediate safety factors and risk of future maltreatment, including:
- *Safety:* Deciding if a child is in danger of being hurt right now (Decision to remove).
- *Risk:* Determining the possibility that a child may be hurt in the future (Decision to open a child welfare investigation case).
- *Strengths:* Assessing the family's positive qualities and resources available to care for the child.
- *Protective Capacities:* Determining if the parent has the ability or support system available to provide an environment that keeps children free from harm. Factors to consider when assessing safety and risk include:
- Mothers' or fathers' child welfare-related history that indicates unresolved substance use disorders related to a prior case of child abuse or neglect:
  - Prior abuse and/or neglect reports related to substance use.
  - Siblings' substance exposure prenatally or in the family environment.
  - Evidence of co-occurring mental health concerns that may affect immediate parenting capacity such as post-partum depression and substance use.
  - Mother's willingness to seek treatment and parenting instruction.
- Family environmental challenges related to parental substance use disorders. Access to sufficient income and resources, employment history, and lack of health access to a medical home can all interact with substance use disorders, and can result in effects on infants in the home, including neglect. It is clear that poverty alone does not connote an immediate safety concern, rather it is the family's access to sufficient resources in combination with substance use disorders that may place an infant at higher risk.

For additional information, see Factors Commonly Included in Assessments Conducted by Child Protective Services on pg. 20.

(3) Be completed when possible prior to the birth of the infant to facilitate engagement of parent(s), and communication among providers; or, when not possible, prior to discharge of the infant from the hospital;
(4) Designate a lead agency responsible for oversight and monitoring of the plan including both needs of the infant and needs of the mother including treatment, mental health and other services;
(5) Be both child- and parent-focused, recognizing that parents' ability to do their part in carrying out such a plan will be as equally important as any role for public or private services;
(6) Specify with whom the child will be discharged and ensure protective capacity of the parents and/or other family members are sufficient to care for the infant;
(7) Include provisions for frequency and the entity responsible for follow up with families including providing home visiting services for all families with a Plan of Safe Care;
(8) Specify a timeline for follow-up and monitoring;
(9) Specify the details of referral of the child to developmental intervention; and
(10) Be available online to relevant agencies with the appropriate privacy safeguards.

Plans of Safe Care should include the provision of services and supports that address the infant's and mother's physical, social-emotional health and safety needs, and foster the mother's and family's capacity to nurture and safely care for the infant. Many of the factors to be included in the plan are identified by various professionals throughout the mothers' pregnancy, at the time of birth and at discharge from the hospital. For example, a mother's post-partum care would typically be included in the hospital discharge plan. It is clear that many of the factors included in assessments, case planning and treatment plans are included in a Plan of Safe Care and are included in processes conducted in communities at present.

Yet, at present there is not sufficient communication among professionals to ensure that families of infants with prenatal substance exposure have sufficient supports and that infants with prenatal substance exposure have follow-up services to ensure

[16] An example of a comprehensive assessment instrument is modeled after the Newborn Assessment developed in Kansas City and adapted by Los Angeles County which can be found at: *http://ican4kids.org/documents/CANProtocol/ap15.Hospital.pdf.* The Kansas City, MO example can be located at: *https://dss.mo.gov/cd/info/cwmanual/section2/ch6/sec2ch6sub2.htm.*

their safety. Thus the plan requires the collaborative effort among community agencies and the family that ensures efficient communication across service systems, agencies and professionals.

Several key aspects differentiate a Plan of Safe Care for an infant with prenatal substance exposure, the mother and family from a typical safety plan developed by child welfare services which assesses for factors that have already occurred in a family and have been brought to the attention of the child welfare agency. Clearly, if it is determined that immediate safety factors are present and protective capacity is not clear to provide for the infant, the family should be moved into the investigation caseload of child protective services. In such instances, it is imperative that the infant's caregivers (*e.g.,* kin, foster parents) also be involved in discharge planning and caring for an infant with any medical concerns, as is likely for infants with Neonatal Abstinence Syndrome or Fetal Alcohol Syndrome.

In the following table, the assessments conducted to develop the Plan of Safe Care are delineated followed by the risk and protective factors that would be considered for families in which the child is not able to safely remain in the family's custody.[17]

COMPONENTS OF PLANS OF SAFE CARE FOR INFANTS, MOTHERS AND FAMILIES AFFECTED BY PRENATAL SUBSTANCE EXPOSURE SERVICES AND SUPPORTS

DOMAINS	
Mother	
Health	• Pregnancy and Post-partum care • Medical home is designated that is consistent with the family's insurance plan and has responsibility for the primary care needs for the mother and family; Medical homes are often designated in States with Medicaid managed care plans • Medication management is assessed and the Medical Home provider has responsibility to oversee including liaison with methadone or other medications used in assisting treatment • Pain management • Contraception and pregnancy prevention • Support with breastfeeding
Substance Use and Mental Disorders Prevention, Intervention and Treatment	• Timely access to treatment is ensured by referrals and appropriate feedback across agencies • Engagement and retention outreach services and on-going recovery supports • Appropriate treatment (gender-specific, family focused, accessible, medication assisted treatment, trauma) • Mental health services including symptoms of depression and anxiety • Intervention for domestic partner and family violence • Substance use and mental health treatment for partner and other family members
Parenting/Family Support	• Coordinated care management • Home visiting follow-up services are provided including infant care, parent/infant bonding, nurturing parenting guidance and skill development, safe sleep practices, and maternal support • Child care in developmentally appropriate programming when needed by the family • Income support and safety net benefits eligibility determination and employment support • Safe and stable housing determinations are made • Need for transportation is assessed
Infant	
Health	• Linkage to a medical home for infant primary health care is provided • Need for high-risk infant follow-up care is determined • Referral to specialty health care as needed

[17] Adapted from the American Humane Association, Breakthrough Series on Risk and Safety. Accessed March 20, 2016 from: *http://www.americanhumane.org/assets/pdfs/children/practice-cards/bsc-defining-safety-and-risk-1.pdf.*

COMPONENTS OF PLANS OF SAFE CARE FOR INFANTS, MOTHERS AND FAMILIES AFFECTED BY PRENATAL SUBSTANCE EXPOSURE SERVICES AND SUPPORTS—Continued

DOMAINS	
Infant	
Development	• Developmental screening and assessment • Referral to developmental pediatrician as needed • Referral to early intervention services for assessment, services and follow up • Early care and education program to ensure developmental intervention and supports are provided by a program with expertise in young children who experienced prenatal substance exposure
Factors Commonly Included in Assessments Conducted by Child Protective Services *	
Immediate Safety Factors	• Physical harm or threat of children in the home • Previous maltreatment of other children • Sexual abuse allegations of other children in the home • Failure to protect older children from harm • Questionable explanation of injuries • Refuses access to monitor the child or threatens to take the child out of the CPS agency's jurisdiction; immediate needs of child not met • Hazardous living conditions • Impairment by substance abuse and parent is not active in treatment or recovery • Domestic violence • Child is danger to self/others • Emotional/developmental/cognitive Impairment
Risk of Child Neglect Factors	• Current complaint includes neglect of other children in home • Prior investigations • Household has previously received CPS • Number of children involved in the child abuse/neglect incident • Age of younger child in household • Primary caretaker provides physical care inconsistent with child needs • Primary caretaker has a past or current untreated mental health problem • Primary caretaker has historic or current alcohol or drug problems and is not actively in treatment or recovery • Characteristics of children in the household • Unsafe housing
Risk of Child Abuse Factors	• Current complaint is for child abuse of other children in the home • Number of prior abuse investigations • Household has previously received CPS • Prior injury to a child resulting from child abuse or neglect • Primary caretaker's assessment of incident • Domestic violence in the household in the past year • Primary caretaker characteristics • Primary caretaker has a history of abuse or neglect as a child • Secondary caretaker has historic or current alcohol or drug problem and is not actively in treatment or recover • Characteristics of children household

*Adapted from the American Humane Association (2016).

COMMUNICATIONS

AMERICAN ACADEMY OF PAIN MANAGEMENT ET AL.
975 Morning Star Dr., Suite A, Sonora, CA 95370
T: 209–533–9744 F: 209–533–9750 E: aapm@aapainmanage.org W: *www.aapainmanage.org*

March 2, 2015
Senate Committee on Finance
Rm. SD–219
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Re: Examining the Opioid Epidemic: Challenges and Opportunities; hearing held February 23, 2016

Dear Chairman Hatch, Ranking Member Wyden, and Honorable Members of the Committee:

On behalf of the American Academy of Pain Management, and with the full support of the undersigned organizations, this letter is in response to the Committee's hearing held on February 23, 2016 entitled "Examining the Opioid Epidemic: Challenges and Opportunities." Collectively, we recognize the challenges involved in addressing two major public health crises, namely, inadequate treatment for pain, and prescription medication abuse, and to that end, have been heavily involved in both national and state-level efforts to address both health concerns. We thank you for addressing these issues, and respectfully offer the following list of possible ways that the Centers for Medicare and Medicaid Services (CMS) could address these dual issues in a balanced and thoughtful approach that aims to improve care for those with pain and other chronic conditions while improving safety for all Americans.

To date, policy solutions to address the opioid crisis have focused on opioid misuse, focusing on prescription practices and treatments for people *after* they have become addicted to opioids. These issues are important and deserve attention; however, a long-term solution to the opioid epidemic will fall short unless policies are broadened to address the underlying public health crisis of chronic pain. Policy solutions to reduce the supply of opioids, will not by themselves end this crisis—we must also address why there is a demand for the use of addictive medications in the treatment of chronic pain at all. This was highlighted in the last month by the President declining to endorse a sweeping proposal by our nation's governors to limit the amount of opioid medication that doctors can prescribe, saying such a policy would be unfair to rural Americans who don't have easy access to integrated pain care or addiction treatment programs.

The country's current state of pain care, research, education and prevention is woefully inadequate, as highlighted by the 2011 Institute of Medicine study, *Relieving Pain in America.* The study found that more than 100 million American adults suffer from chronic pain, at a cost of approximately $600 billion annually in direct medical expenses and lost productivity. Yet, our federal agencies continue to invest poorly in chronic pain research, which averaged just 4 cents per patient in 2015. The result is that the field of chronic pain treatment is "strikingly deficient" of high-quality evidence to assess benefits and risks, according to the Food and Drug Administration, leaving clinicians with little evidence for making informed decisions for effective treatment for patients' chronic pain. It is extremely common for patients to spend months to years consulting multiple clinicians and experimenting with a host of treatments to find solutions that will help to reduce painful symptoms without intolerable side effects.

Prescription medications play a crucial role in treating and curing illness, alleviating pain, and improving quality of life for millions of Americans. Unfortunately, these medications can also be abused—and policies to address this abuse often adversely impact those who truly require these medications in order to live full, healthy, and productive lives. A balance is necessary to ensure that individuals who legitimately need prescription medications for pain and other conditions receive them, but that such medications are not diverted for improper purposes. The following suggestions provide a balanced response to both epidemics: chronic pain and prescription medication abuse.

Opportunities to Reduce Prescription Medication Misuse, Abuse, and Diversion While Improving Care: Eleven Recommendations

1. **In order to provide methods and measures to guide progress towards achieving improved prevention and management of pain in the United States, CMS should fund research that evaluates longitudinal pain outcomes among Medicare, Medicaid, and other beneficiaries.** A core responsibility of public health agencies is assessing the significance of health problems in the population. At present, data are needed on the prevalence, onset, course, impact, and outcomes for most common chronic pain conditions in order to guide policies and initiatives of federal and state governments, and of health care organizations and insurers. Improvement in data methods and measures will (1) guide efforts to reduce the burden of chronic pain through more accurate estimates of the prevalence and impact, (2) provide standard methods for analysis of electronic health care data related to pain treatment, and (3) develop a system of metrics for tracking changes in pain prevalence, impact, treatment, and costs over time that will enable assessment of progress, evaluation of the effectiveness of interventions at the population health level. This is one of the key long-term recommendations of the National Pain Strategy, which was developed by six federal agencies and more than 80 well-respected experts from the medical-scientific, public, private, federal, patient, and advocacy communities, under the direction of the Department of Health and Human Services. If we are to adequately address prescription overdose deaths and substance use disorder in America, we *must not* ignore the millions of people who need better pain care. We *must* develop safer and more effective ways to treat pain. Given the availability of de-identified medical data through electronic medical records, CMS has the opportunity to further this goal by funding longitudinal studies that examine the use of non-pharmacological treatments by Medicare receipts, and the impact of those treatments on subsequent care.

2. **The Center for Medicare and Medicaid Innovation (CMMI) should be required to set aside certain funds to establish demonstration projects related to interdisciplinary and integrated pain care.** An example of a demonstration project highlighting the benefits of integrative care can be found in Colorado. Since 2009, the Colorado Department of Health Care Policy and Financing has been tasked with creating and evaluating a Home and Community Based Services Waiver for the Persons with Spinal Cord Injury (SCI Waiver) Pilot Program. According to the department, there are initial signs of positive trends regarding cost-saving, but without additional research, larger sample sizes, and changes to the evaluation methodology, the evidence remains anecdotal. Personal stories from participants include describing minimal use or complete abstinence from previously used medications for pain, due to the addition of massage, acupuncture, and chiropractic care. The department is in support of the renewal of the SCI Waiver and believes that additional time combined with waiver modifications will significantly improve the data available; further, with additional program experience and some modifications to the evaluation methodology, future reports will provide more insight and actionable recommendations regarding the SCI Waiver program and its benefits.[1] Colorado's legislature agreed to continue support of this promising pilot program with the passage of CO SB 11 (2015), extending the repeal date of the pilot program to 2020. CMMI could greatly improve the outcomes of this study and many more like it, and thus improve health care and cost-savings, by funding additional, and larger, demonstration projects measuring the impact of the type of integrated pain care called for by the 2011 IOM report and the draft National Pain Strategy.

[1] Department of Health Care Policy and Financing. *Summary of the Second Annual Evaluation Report for HCBS–SCI Waiver.* 2014. Print.

3. **CMS should allow a greater number of physical and occupational therapy sessions annually, and should allow patients to access physical and occupational therapy without first acquiring a referral or prior authorization.** Physical and occupational therapies are extraordinarily effective at preventing and treating musculoskeletal pain syndromes, in particular, and chronic pain conditions in general. Medicare's coverage for these therapies is inadequate in terms of the number of sessions covered, and requires that a physician serve as a gatekeeper. Physical and occupational therapists are highly trained professionals who are capable of evaluating a patient's likelihood of benefitting from the treatments they offer. Requiring a gatekeeping appointment with a physician or a prior authorization process only delays a patient's access to treatment and, in some cases, may deny that patient access to an effective and cost-effective treatment that minimizes the need for opioid analgesics. Removing those barriers seems to us to be a logical step.

4. **CMS should provide total reimbursement—and collect long-term efficacy and cost data—for at least the following five non-pharmacologic treatments: chiropractic and osteopathic manipulation, acupuncture, massage therapy, biofeedback, and yoga.** Nearly every recent effort to reduce prescriptions of opioid analgesic medications has been accompanied by a provision which urges the use of alternative treatments to treat pain. However, many people cannot access these treatments due to lack of insurance coverage. This is true for Medicare, which provides only limited coverage for chiropractic and osteopathic manipulations from the list above. These five key treatments are recognized by the Department of Defense and the Veterans Health Administration as effective treatments for chronic pain, are included in the DoD/VHA pain management guidelines, and are covered services in DoD/VHA facilities.

5. **CMS should provide reimbursement to providers of behavioral health services for the prevention, treatment, or management of physical health problems.** As noted above, many efforts to reduce prescriptions of opioid analgesic medications have been accompanied by language that urges the use of alternative treatments to treat pain. Behavioral health care providers are well-equipped to teach patients skills and techniques in how to better manage and cope with pain; however, these practitioners are often not reimbursed for their services when they use proper diagnoses and Current Procedural Terminology (CPT) codes. We urge that CMS be required to reimburse these practitioners for these services utilizing the behavior assessment and intervention reimbursements codes 96150 to 96154, or their successor codes, under the CPT coding system.

6. **Medical residencies funded by Medicare and Medicaid should include adequate content on pain and substance abuse.** Pain consistently ranks as the top reason that people visit a health care provider, and undertreated and mistreated acute pain often causes patients to develop chronic pain. Yet, most health care providers have received little to no formal education in pain management. Substance use disorders also are relatively common, and coverage of that topic in medical training is likewise lacking. The 2011 Institute of Medicine (IOM) report, *Relieving Pain in America,* documented that the median medical school content on pain management is only 9 hours, while a recent survey of medical schools by the Association of American Medical Colleges found a median of only 5 hours dedicated to substance use disorders. Through its support of medical residencies, CMS has the unique opportunity to provide the health care providers of tomorrow with tools that will help them to properly and effectively treat pain and reduce substance abuse and overdose deaths as they treat patients over the course of their careers, producing hugely positive effects on the public welfare.

7. **To improve education for providers already in practice, CMS should require completion of the three hour Risk Evaluation and Mitigation Strategy (REMS) program related to extended release and long-acting opioid analgesic medications as a condition of participation in Medicare.** While the Food and Drug Administration (FDA) mandated that 3 hour REMS courses be offered to prescribers a number of years ago, there was no corresponding mandate for prescribers to take the REMS course. Consequently, completion rates have been low. These REMS courses have the potential to arm health care providers with much needed strategies for preventing and addressing substance abuse, but they cannot do so if no one is taking them. This effort to educate prescribers would be simple to implement for three reasons: (1) the REMS programs have already been developed and implemented; (2) CMS is in

the same department as FDA, which oversees REMS programs; and (3) this requirement could be implemented by a change in rules and regulations, and would not require legislation. The other mechanism that has been discussed as a means of mandating REMS education is linking REMS completion to Drug Enforcement Administration (DEA) registration renewal, but doing that would require legislation and would involve a law enforcement agency in the regulation of medical education, a change that would be unprecedented and, we believe, inappropriate.

8. **Medicare should contact known prescribers and dispensers in the event that a patient overdoses on *any* controlled substance.** It recently came to light that in nearly all cases in which a patient has experienced an opioid-related overdose, patients were, shortly thereafter, given additional prescriptions for opioid analgesic medications. This is due, in large part, to the fact that prescribers were completely unaware that the overdose event had occurred. While overdoses can occur for numerous reasons, some having nothing to do with substance abuse, it is vital that the overdose victim's health care provider is made aware of an overdose to enable completion of a thorough evaluation of the patient and any necessary adjustments to the patient's treatment plan to address the underlying reasons for the overdose event. It would also be important to ascertain the substance(s) that led to the overdose to determine if these were licit or illicit so proper treatment could be determined and initiated. Medicare, by virtue of its coverage of medical services, should be able to identify these events and alert healthcare professionals who are providing care for these patients.

9. **When a prescriber writes a prescription for a controlled substance for a Medicare or Medicaid patient, they should be required to check the prescription monitoring program (PMP) prior to writing the initial prescription and regularly thereafter, at least annually.** We routinely advocate for the regular use of PMPs by prescribers and dispensers, as they have the ability to be extremely valuable healthcare delivery tools. As healthcare delivery tools, PMPs can provide three benefits: (1) Reassurance that patients are using controlled substances as prescribed, allowing providers to prescribe and dispense as needed with less anxiety; (2) Identification of behaviors suggestive of a substance abuse problem, leading providers to more thoroughly assess patients and obtain appropriate treatment where indicated; and (3) Provision of a complete record of a patient's controlled substance prescribing history, enhancing patient safety by enabling a provider to avoid potentially deadly combinations of medications.[2] To best achieve all of these objectives, heath care providers must be provided with an understanding of the full spectrum of controlled substances a patient is taking, as far more medications than just opioid analgesics and benzodiazepines can have serious side effects, potential for abuse, and interactions with one another. If PMPs provide prescribers and dispensers with comprehensive information, and if providers check the PMP upon each initial visit from a patient, they should essentially be able to put a stop to simultaneous prescribing by multiple providers. The periodic checks that we suggest for ongoing patients will help to ensure that patients with legitimate medical needs for controlled substances continue to use their medication safely and effectively and that no medications, potentially prescribed by multiple providers, will negatively interact with one another.

10. **Medicare Part D should consider implementing a policy similar to that proposed in New York Assembly Bill 8601 (2016), which provides that the initial prescription or dispensing of a controlled substance for acute pain shall be limited to a small supply (7 days, for example), but then goes on to prohibit the imposition of an additional health insurance copayment if a subsequent prescription is issued for an aggregate of not more than a 30 day supply of such controlled substance.** Anecdotally, we hear stories about people who only use a few, if any, of their prescribed opioids during an acute pain episode. We believe that in acute pain scenarios, dispensing fewer pills initially, with an option to fill the rest if needed, would allow people with pain to have access to needed medications, while also addressing the problems associated with an abundance of unneeded medications that can be potentially diverted. What's more, in theory, this would save insur-

[2] Twillman, R., PAINS Project. 2013. *Prescription Monitoring Programs.* (Policy brief 2). Retrieved from
http://www.painsproject.org/wp/wp-content/uploads/2014/04/pains_policy_brief_2.pdf.

ers a great deal of money by only providing the number of pills needed to address serious acute pain. However, we admit that this proposal is a bit of a work around, as 21 CFR § 1306.13 does not allow for any partial fills of controlled substance prescriptions, which is why this proposal contemplates two prescriptions. Ideally, we would urge the DEA to change this regulation so as to allow for partial fills of controlled substance prescriptions.

11. **CMS should research post-operative pain and opioid use in order to identify how many pills are actually being used and are needed by this population.** This could be done (1) through direct grants to researchers; or (2) as a part of the scope of work for Medicare Quality Improvement Organizations. As with acute traumatic pain, we often hear of post-operative patients being prescribed large amounts of opioid analgesic medications that they do not, ultimately, end up needing. Unfortunately, we currently have no way of knowing how much medication these patients are taking, and for how long they are needed, after the patients are released from the hospital. Studies would help to determine if post-operative patients, or more specifically, *which* post-operative patients, may be good candidates for smaller initial prescriptions of pain relieving medications.

The undersigned stakeholders view these suggestions as vital components of a comprehensive approach to addressing the intertwined public health crises of undertreated pain and prescription medication abuse.

Sincerely yours,

American Academy of Pain Management
Chronic Pain Research Alliance
Foundation for Peripheral Neuropathy
Global Healthy Living Foundation
International Pain Foundation
Interstitial Cystitis Association
PAINS Project
Reflex Sympathetic Dystrophy Syndrome Association
The Pain Connection
TMJ Association
U.S. Pain Foundation

AMERICAN ACADEMY OF PAS (AAPA)
2318 Mill Road, Suite 1300
Alexandria, Virginia 22314
P 703–836–2272
F 703–684–1924
aapa@aapa.org
www.aapa.org

Statement for the Record

On behalf of the more than 108,500 nationally-certified PAs (physician assistants) represented by the American Academy of PAs (AAPA), we appreciate the Senate Finance Committee's interest in addressing the relationship between the nation's opioid epidemic and the Medicare program, as well as the unique needs of families who are dealing with opioid addiction. AAPA believes combating this crisis will require an "all hands on deck" approach, and we look forward to working with the Committee as it examines these important issues.

Every day, over 60 Americans die from an opioid-related overdose. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), in 2014, 1.9 million Americans over 12 years of age were addicted to prescription painkillers and 586,000 were addicted to heroin. While changes have been made to curb prescription drug abuse at both the healthcare provider and drug manufacturing level, they have had little impact on the overall epidemic. Worse, it appears that limiting the ability to access these drugs has led to a dangerous, unintended consequence: it has become cheaper and easier for many individuals who are dependent on opioids to turn to heroin to achieve similar effects. Yet, it is crucial to remember that there are many Americans who suffer from chronic pain, for whom access to opioids and hydrocodone products are necessary to effectively manage their symptoms. The majority of patients use these drugs without incident. AAPA believes a fine line must be maintained between fighting opioid abuse and ensuring patients who are in need of pain management are able to access it.

Accordingly, AAPA appreciates Congress's work to combat the abuse, diversion, morbidity, and mortality associated with the misuse of opioids that is devastating families and communities across our nation while still ensuring access to these medications. We also support Congress's desire to stop opioid addiction before it starts through the use of safe prescribing practices, patient monitoring, and screening for potential abuse. Unfortunately, federal healthcare programs like Medicare Part D have become targets for fraud and abuse, due in large part to a lack of continuity of care for Part D beneficiaries. In particular, there appears to be a need for better prescription drug monitoring in this population, as well as the establishment of patient review and restriction programs. AAPA believes PAs—who in many communities may be Medicare beneficiaries' sole healthcare provider—must be included in these programs so they may provide the most appropriate care for their patients.

We are also pleased the Committee is examining the effects of opioid abuse on families. AAPA supports the use of medication-assisted treatment for individuals who are struggling with opioid addiction, and we believe early intervention in these situations is vital, particularly when children are involved. However, we also believe the current epidemic will not improve without enlisting the help of additional providers to treat those who are addicted to opioids. In light of the current shortage of providers specializing in addiction medicine, AAPA believes PAs should be part of the solution to this problem.

PA Education and Practice

PAs receive a broad medical education over approximately 27 months which consists of two parts. The didactic phase includes coursework in anatomy, physiology, biochemistry, pharmacology, physical diagnosis, behavioral sciences, and medical ethics. This is followed by the clinical phase, which includes rotations in medical and surgical disciplines such as family medicine, internal medicine, general surgery, pediatrics, obstetrics and gynecology, emergency medicine, and psychiatry. Due to these demanding rotation requirements, PA students will have completed at least 2,000 hours of supervised clinical practice in various settings and locations by graduation.

The majority of PA programs award a master's degree. PAs must pass the Physician Assistant National Certifying Examination and be licensed by a state in order to practice. The PA profession is the only medical profession that requires a practitioner to periodically take and pass a high-stakes comprehensive exam to remain certified, which PAs must do every 10 years. PAs must also complete 100 hours of continuing medical education (CME) every 2 years.

PAs practice and prescribe medication in all 50 states, the District of Columbia, and all U.S. territories with the exception of Puerto Rico. They manage the full scope of patient care, often handling patients with multiple comorbidities. In their normal course of work, PAs conduct physical exams, order and interpret tests, diagnose and treat illnesses, assist in surgery, and counsel on preventative healthcare. The rigorous education and clinical training of PAs enables them to be fully qualified and equipped to manage the treatment of patients with opioid addiction.

PA Prescribing Authority and AAPA Response to the Opioid Epidemic

PAs are currently permitted to prescribe up to Schedule III controlled substances in 48 states and DC; 41 states and DC authorize PAs to prescribe Schedule II drugs. PAs frequently work with patients who struggle with opioid dependency. While some PAs may choose to specialize in addiction medicine, there are also approximately 30,000 PAs practicing as primary care providers on the "front lines" of patient care in hospitals, private practices, community health centers, rural health clinics, non-federally qualified public or community health clinics, prisons, behavioral healthcare facilities, and free clinics, where they commonly encounter patients who present with or are at risk of opioid addiction. This care is especially critical in rural and medically-underserved areas, where PAs may serve as the only primary care clinician or in areas where PAs own their own medical practices.

AAPA has been proactive in ensuring PAs have access to CME and other coursework related to safely prescribing opioid medications, as well as the screening, prevention and management of prescription drug misuse. AAPA is an active partner in the Collaboration of REMS Education (CO*RE) Initiative to Address Extended Release/Long Acting (ER/LA) Opioids. Thousands of PAs have participated in the CO*RE educational activity on safely prescribing ER/LA opioid painkillers, and AAPA is pleased to be a partner among several other provider groups in continuing to create opportunities for inter-professional education in this area. AAPA also

works with the National Institute on Drug Abuse (NIDA) on a CME initiative regarding pediatric substance use and the Hilton Foundation on adolescent substance abuse and the treatment of adolescent opioid addiction. Additionally, AAPA has hosted multiple online and in-person CME courses addressing opioid abuse, pain management, and safe prescribing, and plans to remain active in encouraging PAs to remain up-to-date on current best practices surrounding the responsible prescribing of opioid medications and comprehensive assistance for those who become addicted.

The Role of PAs in Combating Opioid Abuse in Medicare Part D

The Medicare Payment Advisory Commission (MedPAC) has found the majority of Medicare Part D beneficiaries who are prescribed opioid medications are either in treatment for cancer or in hospice care. There is little question most beneficiaries outside of these categories have legitimately been prescribed such medications; yet, the Government Accountability Office (GAO) has estimated as many as 170,000 Medicare enrollees may suffer from opioid addiction. Meanwhile, the Centers for Disease Control and Prevention (CDC) has stated the death rate for individuals who either overdose on opioids or experience a deadly drug interaction involving opioids has more than tripled since 2000. As a result, it is important for all prescribers to have better access to information about what medications their patients have been prescribed, particularly those who see more than one healthcare provider or who are experiencing or at risk of addiction.

One potential solution for this problem is to strengthen prescription drug monitoring programs (PDMPs). Earlier this month, Senators Richard Blumenthal (D–CT) and Dan Coats (R–IN) introduced S. 2479, the Expanding Access to Prescription Drug Monitoring Programs Act, which would encourage state PDMPs to allow PAs and nurse practitioners to view and update their patients' prescription records. While some states allow this access, others do not—even though most states allow these practitioners to prescribe opioid drugs. AAPA supports this legislation, which would ensure PAs have all of the available information to make the best possible determinations about their patients' care and quickly spot potential abuse or diversion issues.

Additionally, Senator Pat Toomey (R–PA) has introduced S. 1913, the Stopping Medication Abuse and Protecting Seniors Act, which would allow prescription drug plans under Part D to establish patient review and restriction programs for beneficiaries who are at risk of misusing or diverting opioid drugs. These programs, which currently exist in nearly every state Medicaid program and a number of private insurance plans, identify beneficiaries with a history of drug abuse and require them to use one main prescriber and pharmacy to access controlled substances as a way to reduce the risk of "provider shopping." AAPA supports coordination of care in this manner; however, it is important for any such efforts to include PAs. While S. 1913 is largely neutral when referring to "prescribers," it includes a provision which requires participating drug plans to contact at-risk beneficiaries' physicians in instances where there may be a question regarding the appropriateness of a prescription. In rural or medically-underserved areas, a PA may be a beneficiary's main healthcare provider. As a result, if a PA is the prescriber, they ought to be the main point of contact to make such a determination and therefore need to be specifically named along with physicians in this provision.

The Role of PAs in Treating Families Affected by Opioid Addiction

Individuals who are struggling with opioid addiction often require personalized treatment plans which take into account a number of factors, including patients' home and family situations, history of criminal behavior, and their likelihood of remaining in treatment over the long term. Typical treatment plans include abstinence, counseling and behavioral therapy; however, the use of medication-assisted treatment (MAT) is also appropriate for many patients.

AAPA supports the use of MAT to assist individuals who are addicted to opioids. Both SAMHSA and the National Institute of Drug Abuse (NIDA) have found that individuals who are addicted to opioids often fare better if they have access to MAT, as well as traditional therapies. These patients have greater overall survival rates and treatment retention, and they show decreased criminal activity, allowing them to become and stay employed. Yet despite these positive outcomes, there is a public perception that MAT simply amounts to replacing one dependency with another. As a result, the stigma associated with these medications has deterred some qualified providers from seeking the ability to prescribe them. At the same time, current federal laws which limit the availability of these drugs and restrict the types of providers who may prescribe and dispense them has led to a severe shortage of pro-

viders to assist patients with an opioid addiction. Additional providers are necessary to combat this growing epidemic, and PAs are part of the solution.

Currently, PAs are authorized to prescribe and dispense three drugs used as part of MAT programs:

- **Methadone:** Methadone is a synthetic opioid used to reduce withdrawal symptoms by blocking pain and reducing cravings. Due to the potential for misuse and dependence, methadone may only be dispensed through a certified opioid treatment program. PAs who are employed at these programs may dispense methadone and participate in the care and treatment of patients who are dependent on opioid drugs.
- **Naltrexone:** Naltrexone blocks the euphoric effects of opioids. While it reportedly reduces cravings for these drugs, it differs from methadone in that it does not mimic the effects of opioid drugs or reduce withdrawal symptoms. Naltrexone is available in settings outside of opioid treatment programs, and it is not a controlled substance. As such, federal laws allow any licensed provider (including PAs) to prescribe and administer this drug.
- **Naloxone:** Naloxone is a fast-acting drug which is used to reverse the effects of an opioid drug overdose. It is typically prescribed to high-risk MAT patients, including those who were taking high doses of opioids for chronic pain, those who are on complicated MAT regimens, and those who have already suffered an overdose. While naloxone is not a controlled substance, states have differing laws regarding the prescribing and dispensing of this drug. Forty eight states currently allow PAs to prescribe naloxone (subject to licensing and educational requirements).

Despite PA presence in MAT programs, the Drug Addiction Treatment Act of 2000 (DATA 2000) prohibits PAs from prescribing one of the most useful MAT drugs—buprenorphine—for the treatment of opioid addiction, even though they are allowed to prescribe this drug in 48 states and DC for pain management purposes. Legislation has been introduced in the Senate (S. 1455, the TREAT Act) which purports to add PAs to the list of providers who may prescribe buprenorphine as part of MAT. But it is problematic because the legislation neglects to recognize PA medical training and attempts to override state prescriptive authority by including only PAs who are "supervised" by physicians, while leaving out those who "collaborate" with them, based on state statute. As a result, the bill would arbitrarily exclude a number of PAs and potentially exclude many more as states update PA practice laws to use the term "collaborate" rather than "supervise." Therefore, the legislation would result in continued lack of access in some of the most high-need areas of the U.S. In light of the shortage of providers who are currently able—and willing—to provide MAT to patients, AAPA recommends referring to state law rather than using terms which have the potential to continue to limit access to PA services to fight the opioid dependency crisis.

AAPA Legislative Recommendations

The opioid addiction epidemic is complicated, and its effects can be seen in myriad populations. Unfortunately, this means there is no one correct solution to cover all of those who are suffering. As such, AAPA offers the following policy recommendations:

(1) **Enact legislation to better allow providers—including PAs—to monitor high-risk Medicare Part D patients and provide them with the most clinically appropriate care.** S. 2479 and S. 1913 represent approaches which allow healthcare practitioners to be fully aware of the medications their patients are taking, and to determine whether they are at risk for drug interaction, abuse, or diversion.

(2) **Support SAMHSA in encouraging state drug courts to allow participants to continue MAT.** MAT is evidence-based treatment which is proven to improve outcomes for individuals who are struggling with opioid drug addiction. Yet, many state-based drug courts serving families in crisis remain resistant to this type of treatment due largely to stigma about how MAT works. AAPA supports the use of MAT, and we encourage the Committee to work with SAMHSA to ensure that individuals—and families—who are working to beat opioid addictions have access to all of the tools necessary to do so.

(3) **Update DATA 2000 to permit PAs to prescribe buprenorphine for the treatment of opioid addiction in any legislation addressing the opioid epidemic.** Currently, federal law does not allow PAs to prescribe buprenorphine—a Schedule III controlled substance—for the treatment of opioid ad-

diction, even though 48 states and D.C. already allow them to prescribe it for pain management purposes. By allowing PAs to prescribe buprenorphine, Congress can help eliminate one of the outdated federal barriers that contribute to the critical shortage of healthcare providers who are willing or able to prescribe MAT to their patients. Legislation like the TREAT Act (S. 1455), which fails to fully engage PAs in fighting opioid addiction also fails patients. Due to the evolving nature of state laws, it is critical federal legislation not qualify the prescribing of buprenorphine on the physician relationship. These types of conditions only serve as a barrier to utilizing all qualified providers to fight this epidemic.

(4) **Include PAs and AAPA in the dialogue surrounding the federal response to the opioid addiction crisis.** PAs are highly-qualified healthcare providers who have a long history of prescribing medications, including opioids. As the Committee works towards solutions to the opioid problem, AAPA stands ready to serve as a resource.

AAPA is committed to working to combat opioid addiction in the U.S., and we look forward to working with the Committee on this important issue. Please do not hesitate to contact Sandy Harding, AAPA Senior Director of Federal Advocacy, at (571) 319–4338 or sharding@aapa.org with any questions.

American Pharmacists Association (APhA)

Improving medication use. Advancing patient care.
2215 Constitution Avenue, NW, • Washington, DC 20037–2985 • 202–628–4410
Fax: 202–783–2351 • *www.pharmacist.com*

February 26, 2016

U.S. Senate Committee on Finance: Examining the Opioid Epidemic: Challenges and Opportunities

On behalf of the American Pharmacists Association (APhA), and our more than 62,000 members, we appreciate the opportunity to provide feedback on S. 1913, "Stopping Medication Abuse and Protecting Seniors Act of 2015" and other efforts to address the opioid abuse epidemic. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA is committed to working with the Committee and other health professionals and stakeholders to identify ways to curb opioid abuse. We believe solutions will take everyone working together, including health care professionals, patients, and federal, state and local governments. As the Committee works toward a solution we urge the Committee to consider the possible effects that any policy change might have on legitimate patient access to prescription drugs. The Institute of Medicine (IOM) estimates that there are 100 million Americans living with chronic pain—a number that does not include the additional 46 million individuals the Centers for Disease Control and Prevention (CDC) estimates suffer from acute pain due to surgery. Given the sheer number of Americans impacted, policy changes that directly or indirectly restrict legitimate patient access to prescription drugs for pain will have far-reaching consequences.

APhA supports education for health care professionals, including pharmacists and student pharmacists, to address issues of pain management, palliative care, and appropriate use of opioid reversal agents in overdose, drug diversion, and substance-related and addictive disorders. APhA proposes the following recommendations regarding S. 1913 and opioid use and abuse.

I. S. 1913: Stopping Medication Abuse and Protecting Seniors Act of 2015

A. Selection Process for Prescribers and Pharmacies

APhA is a long-time advocate for making certain patient choice is included in health care policy. While we appreciate that S. 1913 requires prescription drug plans (PDPs) to ask for and consider beneficiaries' preferences when limiting at-risk

patients to a particular prescriber and pharmacy, APhA remains concerned that the administration of these drug management programs and the final selection of providers is by PDPs. While the legislation provides patient safeguards such as notices and rights to appeal, health care is complex and many patients do not understand the vast array of information that is provided to them.

APhA is a strong supporter of the benefit of patients receiving their prescriptions by a single pharmacy of their choice. Research has demonstrated, and CMS has recognized, that trusted relationships between patients and pharmacists are important, including in mental health-related care.[1] Given the relationship between mental health, chronic pain and substance abuse, being sensitive to the provider preferences of at-risk patient becomes even more important. APhA is concerned that the legislation's section discussing reasonable access may be interpreted to allow PDPs to minimize the importance of patient choice when selecting an at-risk beneficiary's prescriber and pharmacy.[2] This section states that a PDP sponsor's selection take into account "geographic location, beneficiary preference, impact on cost-sharing, and reasonable travel time."

Because PDPs can have a financial interest in steering beneficiaries to certain pharmacies (*e.g.,* better contracted rates, ownership interest), we recommend that choices related to restricting patients to a particular prescriber and pharmacy are not granted to the PDPs. However, if it is decided that PDPs will be the entity to make such decisions, we recommend that patient choice be the default and any deviation from a patient's choice of prescriber and pharmacy must be justified in writing and allowed only upon approval by the Secretary.

B. Pharmacists Role in At-Risk Determinations

APhA is pleased that pharmacists are explicitly included in the list of stakeholders tasked with identifying criteria that will be used to distinguish beneficiaries who are at-risk for prescription drug abuse. While APhA believes the language requiring PDPs to verify with "providers" that the beneficiary is at-risk includes pharmacist, we recommend "including pharmacists" be added to remove any ambiguity. Pharmacists play a unique role in the care continuum as they are medication experts, and often the health care professional that a patient will see most often. Pharmacists advise patients on drug-drug interactions, review medication dosages for appropriateness, and have the ability to more frequently observe behaviors that may be of concern. In addition, the vast majority of states allow providers to engage in collaborative practice agreements with pharmacists for certain services, such as medication therapy management. Some pharmacists in team-based care settings are engaged in pain management with prescribing authority for opioid therapy when working with physicians under collaborative practice agreements. Since pharmacists play such an integral role in pain management, they possess valuable knowledge that can be critical in determining whether a beneficiary is at-risk.

C. Clinical Contact

APhA has concern with the provision of the bill requiring PDPs to contact the at-risk beneficiary's physicians regarding whether prescribed medications are appropriate for the medical condition. Such a requirement without additional criteria related to risk would be overly broad, hinders the health professional's judgement and could cause delay in treatment for patients with a legitimate need.

D. Patient Privacy

APhA is pleased that patient privacy has been addressed in the bill. However, we feel the need to highlight that the Substance Abuse and Mental Health Services Administration (SAMHSA) is currently in the process of modernizing 42 CFR Part 2 which dictates confidentiality of substance use disorder patient records. Generally, 42 CFR Part 2 gives patients who suffer from substance use disorders greater privacy protections than the Health Insurance Portability and Accountability Act. Since PDPs will be exchanging sensitive patient information, we recommend considering adherence to 42 CFR Part 2.

---

[1] Mey, A., Know K., Kelly, F., Davey, A.K., Fowler, J., Hattingh, L., Fejzic, J., McConnell, D. and Wheeler, A.J. (2013). Trust and Safe Spaces: Mental Health Consumers' and Carers' Relationship with Community Pharmacy Staff, *The Patient—Patient-Centered Outcomes Research,* 6(4),281–289.

[2] S. 1913, 114th Cong. Sec. 2(a)(1) adding "(5)(D) Selection of Prescribers" to Section 1860D–4(c) of the Social Security Act.

E. Education

APhA supports comprehensive efforts to educate health care professionals, including prescribers and pharmacists about prescription drug abuse, and mechanisms to prevent it. As drafted, the bill requires the Secretary to provide education only to enrollees and providers regarding the drug management program. Although it is not clear which health care professionals are included in the term "providers," we support improving the training and education of all health professionals related to prescription drug abuse, misuse and treatment and encourage that such efforts incorporate ways to identify patients susceptible to addiction, and behaviors of addiction, abuse, misuse or diversion. In addition, the training should also educate health care professionals on various ways prescription drugs are diverted, and the different ways abusers are manipulating and administering the drugs.

Further, APhA supports incentivized patient education focused on prescription drug abuse beyond education limited to the drug management program. Pharmacists are accessible providers who are able to provide targeted patient education on the risks and benefits associated with taking prescription drugs with a potential for abuse.

II. Alternative Policy Considerations

A. Naloxone

Making naloxone more widely available beyond hospitals/emergency rooms and emergency medical transport is a relatively recent occurrence and precipitated in part by the Substance Abuse and Mental Health Services Administration SAMHSA recommendations (2013–14). Due to the expansion of sites providing naloxone, there needs to be a corresponding growth in training related to the appropriate use and administration of naloxone. State pharmacy associations and other pharmacy stakeholders have already begun to develop naloxone educational programs for pharmacists. We encourage the development, dissemination, and incentivization of naloxone-related education to patients and caregivers as well as to all members of the health care team.

For many patients, cost can be a significant barrier in accessing naloxone. In order to encourage patients and caregivers to obtain naloxone products, it is essential that payer policies allow for coverage of this potentially lifesaving product. Insurance coverage of naloxone varies, but some plans have implemented prior authorization requirements, limiting immediate access even with a prescription. On the supply side, pharmacies that want to stock naloxone may be required to purchase a large quantity of the product—resulting in a large amount of waste if the local demand is low and the excess product expires. Even if naloxone were to be made available over-the-counter, as some stakeholders have suggested, cost would continue to be a potential barrier for patients, especially because many insurers do not cover over-the-counter medications.

Several states have looked to increase patient access to naloxone by allowing pharmacist prescribing of naloxone. Some states have taken the approach of instituting a statewide protocol while others have implemented programs that use existing pharmacist collaborative practice authority. Still others have authorized pharmacists to dispense naloxone without a prescription. It is important to note that changes in scope may not automatically mean patients will have coverage by government and private payers; therefore, while a pharmacist may be able to prescribe or otherwise provide naloxone, a patient's insurance may not cover it. APhA advocates for pharmacists, an important member of the patient's health care team, to be able to furnish opioid reversal agents to help prevent opioid-related deaths and insurance policies that cover naloxone prescriptions, from all providers, for patients and caregivers who need it.

B. Improved Communication and Access to Information

APhA strongly supports better collaboration and communication between pharmacists and physicians to identify potential substance abuse problems. Prescription drug monitoring programs (PDMPs) represent one tool that helps prescribers and pharmacists to identify and prevent drug misuse, abuse, and/or diversion. However, integrated PDMPs that can be accessed by health care professionals' nationwide in a seamless manner with their workflow is necessary. In addition, there needs to be better communication between providers, states and their system so health care pro-

fessionals can have access to real-time information regardless of state lines. Every state should have a PDMP which is interoperable with those of other states.

Expanding electronic prescribing (e-prescribing), which is the secure electronic transmission of prescriptions from prescribers to pharmacies, is also a means to combat prescription drug abuse, misuse, and diversion. The direct transmission of a prescription using electronic prescribing standards and technology reduces the potential for hard copy prescriptions in the patients' possession to be altered, forged, reproduced, or otherwise misused for unlawful purposes. Additionally, the capability for interoperable data exchange of critical clinical information between pharmacists and prescribers is important to having meaningful systems to combat prescription drug abuse and misuse while decreasing heavy administrative burdens on busy health care professionals. Lastly, APhA would like to emphasize the importance of considering the role of pharmacists in policies regarding health information technology, and access to information.

C. Increase Prescription Drug Take Back Programs

APhA suggests increasing the public's access to prescription drug take back opportunities to decrease the likelihood that controlled substances will be used by persons other than the person to whom they were prescribed. According to a Drug Enforcement Agency press release, by May 2014, seven take back days had been organized by DEA and an astonishing 4.1 million pounds (2,123 tons) of unwanted, unused and expired prescription medications had been removed from the public domain.[3] Often an abuser's initial exposure to controlled substance prescription drugs comes from a family member or friend's prescription in their medicine cabinet. If take back programs were more publically accessible, individuals will be more likely to dispose of these unwanted drug products rather than storing them indefinitely. Therefore, we look suggest considering ways to increase participation in and effectiveness of take back programs.

Thank you for your leadership and work on addressing prescription drug abuse. We appreciate the inclusion of pharmacists in several portions of the bill and strongly advocate for continuing to include pharmacists, the medication experts on the patient's health care team, in discussions on ways to help combat prescription drug abuse and misuse. We look forward to supporting your efforts as the legislation moves through the process. If you have any questions please contact our Senior Lobbyist, Michael Spira, by e-mail at mspira@aphanet.org or phone (202) 429–7507.

Sincerely,

Thomas E. Menighan, BSPharm , MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

City of Baltimore, MD
Stephanie Rawlings-Blake, Mayor

Health Department
Leana S. Wen, M.D., M.Sc., FAAEM
Commissioner of Health
1001 E. Fayette St.
Baltimore, MD 21202
health.commissioner@baltimorecity.gov
Tel: 410–396–4387

March 8, 2016

TO: Members of the Senate Finance Committee

FROM: Dr. Leana Wen, Baltimore City Health Commissioner

RE: Comments for the Record: Examining the Opioid Epidemic: Challenges and Opportunities, February 23, 2016

Chairman Hatch, Ranking Member Wyden, and Members of the Committee:

I thank the Committee for holding a hearing to examine the opioid epidemic that is sweeping across our country. Opioid abuse is an epidemic and a public health

[3] Drug Enforcement Agency (May 8, 2014), *DEA's National Prescription Drug Take-Back Days Meet a Growing Need for Americans,* available at: *http://www.dea.gov/divisions/hg/2014/hg050814.shtml,* last accessed: February 24, 2016.

emergency—one that is claiming the lives, the livelihoods, and the souls of our citizens.

As the Health Commissioner of Baltimore City, I work every day with my dedicated staff at the Health Department and partners across our city to change the way we think about and treat opioid use. I appreciate that the Committee hearing focused not just on tougher enforcement, but also on concrete steps for more prevention and better treatment.

Strengthening opioid prescribing best practices is essential to prevent addiction. Nationwide, over-prescribing and inconsistent monitoring of opioid pain medications is a major contributing factor to the overdose epidemic. The "lock-in" model referenced in Mr. Coukell's testimony serves as just one example of effective prescribing practices that prevent addiction and overdose.

While a focus on prevention is critical as we work to combat this epidemic, we must also bolster our treatment efforts for those who suffer from addiction. Dr. Young's testimony on the effects of this epidemic on our foster care system goes to show how a lack of treatment is a burden on both the individual and their families. This hearing also detailed the importance of funding treatment so cities and states can increase access to treatment centers, medications, and innovative programs to meet patients where they are.

I commend the Committee's commitment to addressing the opioid epidemic, and would like to take this opportunity to share how we have addressed this epidemic in Baltimore, with the hope that other jurisdictions can learn from our experience. While many members of the committee noted that there are gaps in treatment available, specific programs and interventions to support treatment were not explicitly addressed. As Senator Stabenow pointed out, we need systems change to create treatment in our communities. We can learn from cities who have taken the lead across the country using innovative approaches to address this national issue; Baltimore City is one such city that is at the cutting edge of addiction prevention and treatment.

The Opioid Problem in Baltimore

With approximately 19,000 active heroin users in Baltimore and far more who misuse and abuse prescription opioid medications, our city cannot be healthy without addressing opioid addiction and overdose. In 2014, 303 people died from drug and alcohol overdose, which is more than the number of people who died from homicide. Drug addiction impacts our entire community and ties into nearly every issue facing our city including crime, unemployment, poverty, and poor health. It claims lives every day and affects those closest to us—our neighbors, our friends, and our family.

To develop our framework to fight addiction and overdose in Baltimore, Mayor Stephanie Rawlings-Blake convened the Heroin Treatment and Prevention Task Force in October of 2014. Understanding that health is not just about physical health, but also behavioral health, the Mayor made this one of her administrations top priorities. She charged the Task Force with developing bold and progressive recommendations that could be implemented to turn the tide against addiction in our city. These recommendations serve as our roadmap and call to action, led by the Baltimore City Health Department, in close collaboration with public and private partners across the city, including our major partner, Behavioral Health System Baltimore, a nonprofit that is the designated behavioral health authority of the city (of which I serve as Chair of the Board).

Baltimore's Response to Addiction and Overdose

Our work in Baltimore is built on three pillars:

- First, we have to prevent deaths from overdose and save the lives of people suffering from addiction.
- Second, we must increase access to quality and effective on-demand treatment and provide long-term recovery support.
- Third, we need to increase addiction education and awareness for the public and for providers, in order to reduce stigma and encourage prevention and treatment.

Our work in each of these areas is multifaceted because addressing a disease like addiction requires a comprehensive approach. We are glad to share these pillars with the Committee and appreciate the greater national public health focus on this issue. The opioid epidemic is affecting every part of our country. We are all in this together, and Baltimore is happy to share our innovations and lessons learned.

1. Preventing Deaths From Overdose

In Baltimore, I have declared *opioid overdose a public health emergency* and led the charge in one of the most aggressive opioid overdose prevention campaigns across the country.

a. The most critical part of the opioid overdose prevention campaign is *expanding access to naloxone*—the lifesaving drug that reverses the effect of an opioid drug overdose. Naloxone is safe, easily administered, not addictive, and nearly 100% effective at reversing an overdose. In my clinical practice as an emergency physician, I have administered naloxone to hundreds of patients and have seen how someone who is unresponsive and about to die will be walking and talking within seconds. Since 2003, Baltimore City has been training drug users on using naloxone through our Staying Alive Program. Last year, we successfully advocated for change in State legislation so that *we can train not only individuals who use drugs, but also their family and friends, and anyone who wishes to learn how to save a life.* This is critical because someone who is overdosing will be unresponsive and friends and family members are most likely to save their life.

   Our naloxone education efforts are extensive. In 2015, *we trained over 8,000 people to use naloxone: in jails, public housing, bus shelters, street corners, and markets.* We were one of the first jurisdictions to *require naloxone training as part of court-mandated time in Drug Treatment Court.* We have *trained state and city legislators* so that they can not only save lives, but also serve as ambassadors and champions to their constituents. We use up-to-date epidemiological data to *target our training to "hotspots,"* taking naloxone directly into the most at risk communities and putting it in the hands of those most in need. This was put into effect earlier this year, when we saw that 39 people died from overdose to the opioid Fentanyl between January and March of 2015. Fentanyl is many times stronger than heroin, and individuals using heroin were not aware that the heroin had been laced with Fentanyl. This data led us to target our messaging so that we could save the lives of those who were at immediate risk.

   Already, our naloxone outreach and trainings are changing the way our frontline officials approach addiction treatment, with a focus on assessment and action. In addition to training paramedics, we have also started to *train police officers.* The initial trainings were met with resistance from the officers who were hesitant to apply medical interventions that some did not see as part of their job description. However, in the first month of carrying naloxone, four police officers used naloxone to save the lives of four citizens. Recently, I attended a training where I asked the officers what they would look for if they were called to the scene for an overdose. In the past, I would have received answers about looking for drug paraphernalia and other evidence. This time, officers answered that their job was to find out what drugs the person might have taken, to call 911 and administer naloxone, because their duty is to save a life. By no means is naloxone training the panacea for repairing police and community relations. However, it is one step in the right direction as we make clear that addiction is a disease and overdose can be deadly. We are changing the conversation so that all of our partners can join in encouraging prevention, education, and treatment.

b. As of October 1, 2015, I have the authority to write blanket prescriptions for naloxone for the roughly 620,000 residents in Baltimore City, under a *"Standing Order"* which was approved by the Maryland State Legislature. This is one of the single largest efforts in the country to achieve citywide naloxone distribution. A Standing Order means that someone can receive a short training (which can be done in less than 5 minutes) and immediately receive a prescription for naloxone, in my name, without having seen me personally as their doctor. In February of 2016, we launched a first of its kind online platform to train Baltimore City residents how to use naloxone. Upon completion, residents will get a Standing Order certification that they can fill immediately at a pharmacy or receive medication from designated individuals, such as overdose response program trainees without a separate doctor's prescription. We also successfully advocated for *Good Samaritan legislation,* which expanded protections for those who assist in the event of an overdose, and malpractice protection for doctors who prescribe naloxone. Finally, our state Medicaid program has agreed to set the *co-pay for naloxone at $1.* While we still struggle with the pricing for naloxone (see below), this has allowed us to provide prescriptions to patients

and others at a greatly reduced cost. We have to get naloxone into the hands of everyone who can save a life—which we believe is each and every one of us.

Some people have the misconception that providing naloxone will only encourage a drug user by providing a safety net. This dangerous myth is not based on science but on stigma. Would we ever say to someone whose throat is closing from an allergic reaction, that they shouldn't get epinephrine because it might encourage them to eat peanuts or shellfish? An Epi-Pen saves lives; so does naloxone, and it should be just as readily available. Our mantra is that we must save a life today in order for there to be a better tomorrow.

2. Increasing Access to On-Demand Treatment and Long-Term Recovery Support

Stopping overdose is only the first step in addressing addiction. To treat people with substance addiction, we must ensure there is adequate access to on-demand treatment. Nationwide, only 11% of patients with addiction get the treatment they need. There is no physical ailment for which this would be acceptable—imagine if only 11% of cancer patients or 11% of patients with diabetes were being treated. If we do not increase access to quality treatment options we are merely treading water, waiting for the person who has overdosed to use drugs and overdose again.

a. In Baltimore, we have started a *24/7 "crisis, information, and referral" phone line* that connects people in need to a variety of services including: immediate consultation with a social worker or addiction counselor; connection with outreach workers who provide emergency services and will visit people in crisis at homes; information about any question relating to mental health and substance addiction; and scheduling of treatment services and information. This line is not just for addiction but for mental health issues, since these issues in behavioral health are so closely related and there is a high degree of co-occurrence. Those who are seeking treatment for behavioral health should be able to easily access the services they need, at any time of day. This 24/7 line has been operational since October 2015; already, there are nearly 1,000 phone calls every week. It is being used not only by individuals seeking assistance, but by family members seeking resources and providers looking to connect their patients to treatment.

b. We have secured $3.6 million in capital funds to build a *"stabilization center"*—also known as a sobering center—for those in need of temporary service related to intoxication. This is the first step in our efforts to start a 24/7 "Urgent Care" for addiction and mental health disorders—a comprehensive, community-based "ER" dedicated to patients presenting with substance abuse and mental health complaints. Just as a patient with a physical complaint can go into an ER any time of the day for treatment, a person suffering from addiction must be able to seek treatment on-demand. This center will enable patients to self-refer or be brought by families, police, or EMS—a "no wrong door" policy ensures that nobody would be turned away. The center would provide full capacity treatment in both intensive inpatient and low-intensity outpatient settings, and connect patients to case management and other necessary services such as housing and job training.

c. We are developing a *real-time treatment dashboard* to obtain data on the number of people with substance use disorders, near-fatal and fatal overdoses, and capacity for treatment. This will enable us to map the availability of our inpatient and outpatient treatment slots and ensure that treatment availability meets the demand. The dashboard will be connected to our 24/7 line that will immediately connect people to the level of treatment that they require—on demand, at the time that they need it.

d. We are expanding our capacity to treat overdose in the community by *hiring community-based peer recovery specialists.* These individuals will be recruited from the same neighborhoods as individuals with addiction, and will be trained as overdose interrupters who can administer overdose treatment and connect patients to treatment and other necessary services.

e. We have implemented the *Screening, Brief Intervention, and Referral to Treatment (SBIRT)* approach, which provides universal screening of patients presenting to ERs and primary care offices. Three of our hospitals are early pioneers in SBIRT; we are looking to expand it to all hospitals and clinics in the city to ensure delivery of early intervention and treatment services for those with or at risk for substance use disorders.

f. We are expanding and promoting *medication-assisted treatment,* which is evidence-based and highly effective method to help people with opioid addiction recover. This combines behavioral therapy with medication, such as methadone or buprenorphine, along with other support. Taking medication for opioid addiction is like taking medication to control heart disease or diabetes. When prescribed properly, medication does not create a new addiction, but rather manages a patient's addiction so that they can successfully achieve recovery. Baltimore has been at the leading edge of innovation for incorporating medication-assisted treatment, including *providing medications in structured clinical settings* through the Baltimore Buprenorphine Initiative. This year, we *expanded access to buprenorphine treatment by offering services in low-barrier settings,* such as recovery centers, emergency shelters, and mental health facilities. Providing access to buprenorphine services in these settings allows us to engage people who are more transient or unstably-housed into much needed treatment.

g. We are working to expand case management and diversion programs across the city so that those who need help get the medical treatment they need. In our city of 620,000, 73,000 people are arrested each year. The majority of these arrests are due to drug offenses. Of the individuals in our jails and prisons, 8 out of 10 use illegal substances and 4 out of 10 have a diagnosed mental illness. Addiction and mental illness are diseases, and we should be providing medical treatment rather than incarcerating those who have an affliction. Baltimore already has *highly effective diversion efforts such as Drug Treatment Courts and Mental Health Treatment Courts.* We are looking to implement a *Law Enforcement Assisted Diversion Program,* a pilot model that has been adopted by a select group of cities, which establishes criteria for police officers to identify eligible users and take them to an intake facility that connects them to necessary services such as drug treatment, peer supports, and housing—rather than to central booking for arrest.

h. Finally, we are increasing our capability for *case management services for every individual leaving jails and prisons.* These individuals are at a highly vulnerable state, and must be connected to medical treatment, psychiatric and substance abuse treatments if appropriate, housing and employment support, and more. Our outreach workers already target a subset of this population; we need to expand capacity to every one of these individuals. Additionally, as mentioned above, we are deploying community health workers in order to reach people where they are in the community as well as provide a credible messenger. In deploying this tactic, we are also excited to bring jobs and opportunities to vulnerable individuals and neighborhoods that otherwise have limited employment opportunities.

3. Providing Education to Reduce Stigma and Prevent Addiction

In addition to treating patients, we must also change the dialogue around substance use disorder. The Baltimore City Health Department is leading a citywide effort to educate the public and providers on the nature of substance addiction: that it is a disease, recovery is possible, and we all must play a role in preventing addiction and saving lives.

a. We have been at the forefront of changing public perception of addiction so those in need are not ashamed to seek treatment. We have *launched a public education campaign "http://dontdie.org/"* to educate citizens that addiction is a chronic disease and to encourage individuals to seek treatment. This was launched with bus ads, billboard ads, a new website, and a targeted door-to-door outreach campaign in churches and with our neighborhood leaders.

We have also launched a concerted effort to *target prevention among our teens and youth entitled "BMore in Control."* We have established *permanent prescription drug drop boxes* at all nine of the city's police stations. This means that anyone can drop-off their unused, unwanted, or unnecessary prescription drugs—no questions asked. Drugs left in the home can end up in the wrong hands—spouses, elderly family members, or even our children. I have treated 2-year olds who were dying from opioid overdose, again underscoring that all of us can be at risk and must play a role.

b. We are targeting our educational efforts to physicians and other prescribers of opioid medications. Nationwide, over-prescribing and inconsistent monitoring of opioid pain medications is a major contributing factor to the overdose epidemic. According to the Centers for Disease Control, there were 259 million prescriptions written for opioids in 2014. That is enough for one opioid prescription for

every adult American. Every day, people overdose or become addicted to their prescription opioids.

To address this, *I have sent "best practice" letters to every doctor in the city* and will also do so for all dentists and pharmacists. The letter addressed the importance of the Prescription Drug Monitoring Program and judicious prescribing of opioids, including not using narcotics as the first line medication for acute pain and emphasizing the risk of addiction and overdose with opioids. Importantly, this best practice *requires co-prescribing of naloxone* for any individual taking opioids or at risk for opioid overdose. Hospitals keep naloxone on hand if patients receive too much intravenous morphine or fentanyl. Patients must also receive a prescription for naloxone if they are to be discharged with opioid medications that can result in overdose.

These best practices were developed through convening ER doctors, hospital CEOs, and other medical professionals in the city. To reach practicing doctors, we have been presenting at Grand Rounds, medical society conferences, and are also about to launch *physician "detailing,"* where we will employ teams of public health outreach workers and people in recovery to visit doctors to talk about best practices for opioid prescribing. We are working with providers to ensure best practices will be used when prescribing opioids and that we all play our part—as providers, patients, and family members—to prevent addiction and overdose.

c. As part of our "best practices" recommendations, we are leading efforts to warn patients and prescribers against combining opioids and benzodiazepines. One in three fatal overdoses is due to this combination—a little known but extremely dangerous phenomenon. In February, I led a group of over 40 City Health Commissioner and State Health Directors across the country urging the FDA to require a "black box warning" on opioids and benzodiazepines that states that current use of the medications increases the risk of fatal overdose. Black box warnings appear on the labels of prescription drugs and call attention to serious or life-threatening risks. We started a *public petition* and have over 3,000 signatures from people showing their support for this public warning.

While we wait for the FDA to require a "black box warning," we are also calling on prescribers to warn patients about the risks of combined opioid and benzodiazepine use. Patients with chronic pain are often prescribed opioids to treat their pain and benzodiazepines to treat their associated symptoms, such as anxiety and sleep disorders. Educating patients about this potentially lethal drug interaction is an important step to reduce the toll of addiction and fatal overdose in communities across the country.

Working With the Federal Government

The Baltimore City Health Department, together with our partners across the city and state, has made significant progress in tackling the opioid epidemic. However, there are some areas where we face continued challenges. Though there is much that can be done on the city and state levels, the federal government plays a critical role in the campaign against addiction and overdose. We appreciate the opportunity to mention four specific areas that can be addressed:

1. Expand Funding and Availability of On-Demand Addiction Treatment Service

We must treat addiction as a disease and not a crime or a moral failing. In order to successfully treat the disease, we need to ensure there are sufficient high-quality treatment options available to those in need.

a. *Federal funding could expand treatment on-demand* including 24/7 dedicated centers for substance addiction and mental health and proven intervention models such as LEAD and expand case management services for vulnerable individuals. These programs will help to ensure that those in need have a path to recovery.

b. *The Senate can push for equitable insurance coverage for addiction services.* Medicare pays for pain medications that can lead to addiction, yet many states do not cover medication-assisted treatment and other evidence-based interventions for addiction recovery. The Senate can ensure that Medicaid, Medicare, and private payers cover on demand treatment for acute care (such as sobering, urgent care, and residential services), as well as ongoing treatment and services like medication-assisted treatment and case management. These *rates should also be equivalent to mental health and physical health care rates*

(which they are not currently, leading to a dearth of providers and inadequate care).

c. *The Senate can remove barriers to prescribing Buprenorphine.* Buprenorphine is a medication-assisted treatment option with a much lower chance of overdose than methadone. Importantly, it can be administered by a primary care provider rather than in a designated drug-treatment clinic. This helps to increase the accurate perception that substance use disorder is a medical condition. Unfortunately, at the moment, only medical doctors can prescribe buprenorphine, and a doctor can only provide Buprenorphine to a maximum of 100 patients. This barrier does not exist for any other medication, and significantly limits the ability of patients to access a life-saving treatment option and leaves many patients with methadone as their only option for medication assisted treatment. Methadone requires administration in a designated treatment clinic, which are often a point of contention within the communities in which they operate due to the stigma associated with drug addiction. We strongly support current efforts underway at the Department of Health and Human Services to revise the limits on buprenorphine prescription in a given year, and urge further support of broadened access to this proven treatment including by requesting the Senate to consider broadening prescription authority of Buprenorphine to Nurse Practitioners and other providers.

2. Provide Cities and States With Opportunity to Innovate Around Addiction Recovery

There are many services not covered by Medicaid, Medicare, or other forms of insurance that are critical to addiction recovery. The Senate can provide funding to local jurisdictions and to States that can give grants and incentives to support innovative, evidence-based programs that do not simply focus on the medical component of addiction but the broader psychosocial components. These include:

a. *New care delivery models.* There is research on new treatment options such as starting buprenorphine from ERs, mobile buprenorphine induction, or telemedicine treatment that would be not eligible for existing reimbursement yet offer much promise. These are examples of delivery models that local and state agencies should have the option of providing grant funding for, with the option of being included in Medicaid formulary after sufficient time and evidence.

b. *Peer recovery specialists.* In Baltimore, we are aiming to provide a peer recovery specialist for every individual who presents for overdose or addiction-related condition to our ERs and other facilities. However, we are limited by the lack of funding for these individuals. There should be opportunities for expanded funding and reimbursement for services rendered by these trained community health workers; grant funding to local and state agencies can be one way to pursue this.

c. *Case management services.* Individuals leaving incarceration or inpatient stays are at very high risk; they must receive wrap-around services that connect them immediately to needed medical and psychiatric assistance. These case management services have inconsistent reimbursement; innovative programs including with telemedicine and use of peer recovery specialists should be encouraged.

d. *Community resources for recovery.* Recovery from addiction involves more than clinical treatment but also support and long-term care. Local and state agencies can also innovate with interventions such as *recovery housing and reentry support;* federal funding can assist in these necessary steps.

e. *Prevention.* Grant support for tailored and targeted prevention support including public education and provider education must also be a critical component.

3. The Senate Can Monitor and Regulate the Price and Availability of Naloxone

Naloxone is a generic medication that is part of the World Health Organization's list of essential medications. Over the last 2 years, the price of naloxone has dramatically increased. In Baltimore, the cost per dose of naloxone has quadrupled—meaning that we can only save a quarter of the lives we could have saved. This is particularly problematic for cities and counties that must purchase naloxone for use by paramedics, police officers, and other front-line workers. Manufacturers have claimed that this price increase is related to increased demand. However, it is unclear why the cost of a generic medication that is available for much lower costs in other countries will be suddenly so expensive. The Senate can join efforts by Sen-

ator Sanders and Congressman Cummings to call for investigation into the reason for the price increase, which would otherwise prohibit us from saving lives at a time that we need to the most.

4. The Senate Can Push for National Stigma-Reduction and Opioid-Awareness Campaign

Many local jurisdictions like Baltimore have launched public education campaigns. There is much more education that must be done in order to encourage people with addiction into care and to disband stigmas that are leading many communities to avoid providing treatment altogether. Local jurisdictions are also limited by funding constraints. The Senate can push for the launch of a national campaign to reduce stigma and to increase awareness of opioid addiction. This national campaign will provide the spotlight this critical issue requires.

Finally, as a part of this campaign, we urge the Senate to pass legislation requiring a "black box warning" on opioids and benzodiazepines. More patients than ever before are being prescribed both opioids and benzodiazepines, and more are running into serious problems from combined use. These warning labels will raise awareness about this dangerous trend that is fueling the overdose epidemic.

Conclusion

While some of the challenges facing Baltimore are unique, we join our counterparts around the country in addressing the epidemic of opioid addiction. According to the Centers for Disease Control, the number of people dying from overdose has quadrupled from 15 years ago. In many states, there are more people dying from overdose than from car accidents or suicide.

There are some who say the opioid problem is too big and too complicated-that it cannot be solved. It is true that treating the opioid epidemic requires many approaches. However, this is an issue that requires our attention. According to the World Health Organization, treating opioid addiction saves society $12 for every $1 spent on treatment. Treatment also impacts communities by reducing excess healthcare utilization, increasing productivity and employment rates, and decreasing poverty and unnecessary cost to the criminal justice system. Furthermore, treating addiction is a moral imperative and a matter of life and death.

Baltimore has been fighting the heroin and opioid epidemic for decades and we continue to make progress with bold ideas and innovative strategies. Our efforts to address opioid addiction seek to change the face of Baltimore from the "heroin capital" to becoming the center of addiction recovery. We are glad to share our lessons with our counterparts around the country and with our national leaders. With dedicated partners like you in the U.S. Senate, we can fight the epidemic, save lives and reclaim people and their families.

On behalf of the Baltimore City Administration, I want to thank you for calling this important hearing. We look forward to working with you to stop the epidemic of opioid addiction in the United States. Please feel free to call on me should you have any questions.

Mike DeWine

OHIO ATTORNEY GENERAL
Administration
30 E. Broad Street, 17th Floor
Columbus, OH 43215
Office 614–728–5458
Fax 614–466–5087
www.OhioAttomeyGeneral.gov

February 23, 2015

The Honorable Orrin Hatch
Chairman
Committee on Finance
U.S. Senate
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance

U.S. Senate
Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden,

Thank you for the opportunity to provide a letter of support for S. 1913.—The Stopping Medication Abuse and Protecting Seniors Act. This legislation will allow Medicare Advantage and Part D plan sponsors to identify and assist beneficiaries with addiction issues, with the added goal of reducing improper diversion of prescription medication.

I share Senator Portman's concern about prescription medication abuse and the opioid epidemic that is plaguing our communities. I have worked with law enforcement and regulatory agencies to crack down on improper prescribing and punish those responsible. My Heroin Unit works with communities to provide awareness about the opioid epidemic and educate the public about issues including naloxone and proper drug disposal.

S. 1913 is a strong tool to help reduce doctor and pharmacy shopping. Diverted and abused prescription medication is strongly correlated with the increased use of illicit drugs nationwide and in Ohio. Reasonable efforts such as S. 1913 that help ensure proper prescribing and limit fraud should be supported.

I applaud Senator Portman's efforts in supporting this important piece of legislation, which will assist those struggling from addiction. Thank you for your leadership and the opportunity to address this vital issue.

Very respectfully yours,

Mike DeWine
Ohio Attorney General

FIRST FOCUS STATE POLICY ADVOCACY AND REFORM CENTER (SPARC)
1110 Vermont Avenue NW, Suite 900 | Washington, DC 20005 | T: 202–657–0670
F: 202–657–0671 | *www.childwelfaresparc.org*

STATEMENT FOR THE RECORD

U.S. SENATE COMMITTEE ON FINANCE

EXAMINING THE OPIOID EPIDEMIC: CHALLENGES AND OPPORTUNITIES

February 23, 2016

Chairman Hatch, Ranking Member Wyden, and Members of the Senate Committee on Finance, we thank you for the opportunity to submit this statement for the record on the hearing focused on addressing the opioid epidemic, currently posing a serious threat to children and families across the United States.

The First Focus State Policy and Advocacy Reform Center (SPARC) is a coalition of state-based advocacy organizations committed to improving the safety, health and well-being of children and families involved in the child welfare system. Many of the SPARC state partners live in communities that are seriously impacted by the opioid crisis and concerned about its impact on children, particularly those at risk of entering the foster care system. The purpose of this statement is to draw the connections between the opioid crisis and challenges faced by state and county child welfare systems that serve as our nation's safety net and offer recommendations on how to ensure better outcomes for families that struggle with substance abuse issues.

Parental substance abuse and opioid use have long been identified as a factor that results in families and children becoming involved in the child welfare system. In 2012, 30.5 percent of child removals—more than one of every four—were due to parental use of alcohol and other drugs. 66 percent of children in foster care have lived with someone with an alcohol or drug problem.[1] In addition, as a recent Reuters series on the crisis highlighted, newborns exposed prenatally to opioids also face significant safety risks. Some are removed at birth, separating families and placing sig-

[1] Gardner, S. (2014) *State-Level Policy Advocacy for Children Affected by Parental Substance Use,* retrieved from: *http://childwelfaresparc.org/wp-content/uploads/2014/08/State-Level-Policy-Advocacy-for-Children-Affected-by-Parental-Substance-Use.pdf.*

nificant strains on the child welfare system, while others may suffer abuse or neglect when they are sent home with parents abusing opioids.[2] The National Institute on Drug Abuse estimates that 21,372 babies were born with neonatal abstinence syndrome (NAS) in 2012, 5 times the number born with NAS in 2000.[3]

States are taking actions to address the opioid crisis. Many states, including Massachusetts, Rhode Island, Indiana, Maryland, Michigan, North Carolina, Virginia, and West Virginia have formed state-level taskforces made up of experts who offer recommendations to the state Governors and Attorney Generals. State Legislatures have also introduced and enacted a significant number of bills to curb the use of opioids in their states. Common threads in these policies include: establishing electronic prescription drug monitoring programs (PDMP) to ensure that patients are not dispensed more medications than necessary; increasing access to naloxone, which counters the effects of opioid overdose; and increasing resources for treatment and services. However, many of these state-wide initiatives fail to draw the connections between the substance abuse and opioid problem and the risk for child abuse and neglect, as well as the impact on the foster care system.

Importantly, there are also some states that are implementing evidence based, evidence informed, and promising programs to ensure better outcomes for both children and their parents who are struggling with opioid use, including:

- Parent-Child Interaction Therapy and Parent-Child Psychotherapy in Nebraska, which promotes positive parenting and attachment between parents and their children;
- Developmental assessments and therapy for prenatally exposed children, including post-natal follow-up services in Illinois; and
- The Engaging Moms Program in Florida, which provides case management by specially trained caseworkers for mothers in treatment programs.

We are pleased that the Family First Act proposal put forth by Chairman Hatch and Ranking Member Wyden recognizes that states need access to reliable federal funds so they can address parental substance use—before children face serious safety threats—to prevent children from entering the child welfare system. The Family First Act would allow states the flexibility to use title IV–E dollars for substance abuse treatment that works so that parents can receive effective services before they present safety concerns that prompt removal of their children from the home.

The Family First Act would be a significant step forward to support and strengthen families who have addiction issues and are involved with the child welfare system.

Additional steps that can be taken at the federal level include: incentives for better cross-agency collaboration between substance abuse, child welfare and mental health systems; enforcement of provisions in the Child Abuse Prevention and Treatment Act (CAPTA) to report babies who are exposed to opioids prenatally to child welfare agencies; uniform practices for states in screening and recording substance abuse as an element of child maltreatment; prioritizing treatment for child welfare involved families; and strengthening family drug court programs to ensure courts are working with families holistically to ensure the safety and best interest of children living in families with substance abuse problems.

We thank you again for the opportunity to submit this written testimony and look forward to working with you to implement policies that prevent children from harm because of substance abuse and opioid use. Should there be any questions regarding this statement, please contact Rricha Mathur, Senior Policy Advisor of Child Welfare and Child Rights at (202) 999–4852 or rricham@firstfocus.org.

---

[2] Wilson, Duff, John, Shiffman. "The Most Vulnerable Victims of America's Opioid Epidemic." *Reuters,* Thompson Reuters, December 7, 2016, retrieved from:
http://www.reuters.com/investigates/special-report/baby-opioids/#article-about-the-series.

[3] Patrick et al., JAMA 2012, Patrick et al., Journal of Perinatology 2015.

NATIONAL ASSOCIATION OF CHAIN DRUG STORES (NACDS)
1776 Wilson Blvd., Suite 200
Arlington, VA 22209
703–549–3001
www.nacds.org

Statement for United States Senate Committee on Finance Hearing on:

"EXAMINING THE OPIOID EPIDEMIC:
CHALLENGES AND OPPORTUNITIES"

February 23, 2016

Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Hatch, Ranking Member Wyden, and members of the Committee on Finance for the opportunity to submit a statement for the hearing on "Examining the Opioid Epidemic: Challenges and Opportunities."

NACDS and the chain pharmacy industry are committed to partnering with law enforcement agencies, policymakers, and others to work on viable strategies to prevent prescription opioid diversion and abuse. Chain pharmacies engage daily in activities with the goal of preventing the diversion and abuse of all prescription drugs. Since chain pharmacies operate in almost every community in the U.S., we support policies and initiatives to combat the prescription drug abuse problem nationwide. We believe that holistic approaches must be implemented at the federal level.

Pharmacists take very seriously their role in helping to ensure safe use of medications—but they cannot do it alone. The time has come to bring about an overarching, collaborative approach to curb prescription opioid abuse and preserve patient access to their medically-necessary pain medications.

We believe that there are a variety of ways to help curb prescription drug diversion, and chain pharmacies actively work on many initiatives to reduce this problem.

Chain Pharmacy Initiatives

Chain pharmacies extensively train their personnel and have strict policies and procedures to prevent prescription drug diversion. Our members rigorously comply with state and federal laws and regulations. Pharmacies and pharmacy personnel are among the most highly regulated industries and professions.

Chain pharmacies have created a variety of extensive and robust loss prevention and internal security systems that are in place from our prescription drug distribution centers right down to the point of dispensing to the patient. We undertake initiatives to ensure that prescription drugs are accounted for every step along the way. We work with law enforcement to see that perpetrators are brought to justice.

Chain pharmacies have zero tolerance for prescription drug diversion. In addition to developing, implementing, and maintaining our own policies and procedures, we support numerous other initiatives to mitigate and reduce the scourge of prescription drug diversion. Chain pharmacies are committed to ensuring that prescription drugs remain under tight control for the purposes of providing care to their patients, and are not diverted for nefarious purposes. Our members' efforts are evidence of this commitment.

DEA Regulations

According to DEA regulations, the responsibility for the proper prescribing and dispensing of controlled substances is on the prescribing practitioner, but a corresponding responsibility also rests with the pharmacist who fills the prescription.

DEA requires pharmacists to take on diverse and sometimes conflicting roles. On the one hand, pharmacists have a strong ethical duty to serve the medical needs of their patients in providing neighborhood care. On the other hand, community pharmacists are also required to be evaluators of the legitimate medical use of controlled substances.

Pharmacies fully understand that controlled substances are subject to abuse by a minority of individuals who improperly obtain controlled substance prescriptions from physicians and other prescribers. Pharmacies strive to help to treat medical conditions and ease patients' pain while simultaneously guarding against the abuse of controlled substances. The key is to guard against abuse while still achieving our primary goal of assisting patients who need pharmacy services.

Legislative Solutions

NACDS and our members are focusing our energies on real, workable solutions that will address the problem of prescription drug abuse while also ensuring that legitimate patients are able to receive their prescription opioid pain medications. In line with this goal, we support H.R. 471/S. 483, the "Ensuring Patient Access and Effective Drug Enforcement Act of 2015." This legislation would promote cooperation among key government agencies, such as DEA and FDA, to jointly identify obstacles to legitimate patient access to controlled substances, issues with diversion of controlled substances, and how collaboration between law enforcement agencies and healthcare stakeholders can benefit patients and prevent diversion and abuse of controlled substances.

This legislation also facilitates open dialogue on issues related to prescription drug diversion and abuse by directing key federal agencies to consult with patient groups; pharmacies; drug manufacturers; common or contract carriers and warehousemen; hospitals, physicians, and other healthcare providers; state attorneys general; federal, state, local, and tribal law enforcement agencies; health insurance providers and entities that provide pharmacy benefit management services on behalf of a health insurance provider; and wholesale drug distributors.

Pharmacy "Lock-In" Proposals

NACDS does have concerns with proposals aimed at "locking in" patients to a certain pharmacy or pharmacies. Any such proposal must ensure that legitimate patient access to needed medications is not impeded. Policies to reduce overutilization must maintain access to prescription medications by the patients who need them most.

We have specific concerns that a lock-in provision may actually be a barrier to care as supply chain issues exist around controlled substance medications that are beyond the pharmacy's control. If a pharmacy is unable to obtain the medication for a lock-in patient, then it creates a barrier that could result in harm to the patient's health. Mechanisms must be developed and executed to allow a pharmacy, in consultation with the prescriber, to fill legitimate prescriptions without needlessly delaying treatment. To minimize any potential harm and address supply issues, a patient should be allowed to use all locations for a pharmacy organization if that pharmacy uses a common database with an integrated patient profile. Additionally, to reduce the potential for further abuse and confusion, claim rejections should occur at the point of sale, otherwise pharmacies will have no way to determine whether a patient is enrolled in a lock-in program.

Controlled Substance Prescription Monitoring Programs

NACDS and chain pharmacies support controlled substance prescription monitoring programs (PMP) to help combat prescription drug diversion. Currently, all but one state have implemented a prescription monitoring program. Recognizing the role these programs have in helping to prevent prescription drug abuse and diversion, chain pharmacies actively support these programs. Pharmacies submit information on the controlled substances they dispense monthly, weekly, and daily depending on the particular state's program requirements. This information includes information on the patient, prescribed drug dosage and quantity, and the prescriber. This information allows the state to conduct confidential reviews to determine any patterns of potential abuse or diversion.

These monitoring programs offer many benefits to aid in curbing prescription drug diversion and abuse at the prescriber, pharmacy, and patient levels. These programs encourage appropriate intervention to determine if a person may have a drug addiction so that treatment may be facilitated.

Yet, to promote continued operation of these programs and enhancements that improve the value of these programs to the healthcare system, law enforcement, and healthcare providers, NACDS encourages federal support for state prescription drug monitoring programs and program enhancements that integrate prescription drug monitoring information into healthcare systems. For example, we ask for federal support of policies that allow agents of pharmacists, prescribers, and other practitioners to access PMP data to assist with the integration of this data into health care delivery, and federal support of policies for increased interoperability of prescription drug monitoring programs across state lines, standardized data elements to harmonize programs, and seamless reporting.

To create more robust public and private prescription monitoring programs, NACDS further supports efforts to accelerate the deployment of e-prescribing of controlled substances, including working with federal and state regulators and stakeholders to

encourage prescribers to issue all controlled substance prescriptions electronically. Encouraging greater use of this technology by practitioners could not only improve the timeliness of prescription monitoring program data, but also reduce the incidence of diversion throughout the country. Electronic prescribing of schedule II–V controlled substance prescriptions is permitted in all 50 states and DC. NACDS would support a policy that would establish a date for all prescribers to be compliant with state and federal e-prescribing laws for controlled substances, and the consideration of a mandate that all controlled substance prescriptions be issued electronically.

Chain pharmacy supports the use of technology to electronically transmit controlled substances prescription information between prescribers and pharmacists. In addition to enhancing patient safety and operational efficiency, this practice serves to reduce prescription fraud. The DEA-approved process for electronic prescribing of controlled substances arguably provides much more protection from diversion than the legacy system of paper and oral prescriptions.

Law Enforcement Authorized Programs for Return and Disposal of Unwanted Prescription Drugs

NACDS supports specific principles for proper return and disposal of consumers' unwanted medications. These include protecting patient health and safety by maintaining a physical separation between pharmacies and locations that take back consumers' unwanted drugs. For example, drug take-back events sponsored by DEA provide for such separation and avoid the potential for returned medications to reenter the drug distribution supply chain. In addition, we support policies where consumers have a reliable and readily available means to return their unwanted medications such as mail back envelope programs. At various locations across the U.S., law enforcement partners with pharmacies to provide drug take-back events to give consumers means to return their unwanted medications.

Until recently, consumers' options for disposal of their prescribed controlled substances were limited. However, now DEA has issued final regulations (effective October 9, 2014) that provide additional options for consumers' disposal of their unwanted prescribed controlled substances. The regulations implement the Secure and Responsible Drug Disposal Act ("Act"). The DEA regulations allow entities, which are DEA registered and authorized by the DEA, to voluntarily set up programs for disposal of consumers' unwanted controlled substances. Both the Act and the DEA regulations expressly state that setting up programs is voluntary. No entity is required to set up a program.

The DEA regulations allow a number of DEA registrants including drug manufacturers, distributors, reverse distributors, retail pharmacies, and hospitals and clinics with onsite pharmacies to set up disposal programs including mail-back and collection receptacles. Law enforcement may set up disposal programs including mail-back, take-back events, and collection receptacles. In short, the DEA regulations allow a voluntary approach with each allowed DEA registrant deciding if and how they want to set up a program.

Federal guidelines recommend consumers mix their unused drugs with undesirable substances such as coffee grounds before placing them in containers for disposal in their household trash. Additionally, various groups operate periodic events to collect consumers' non-controlled unwanted medications. Similarly, DEA has operated a number of periodic collection events over the past several years where they collect both controlled and non-controlled substances from consumers.

It is essential that establishing programs for taking back and disposal of consumers' unwanted prescribed controlled and non-controlled medications be voluntary. Each entity must determine if operating such a program is feasible and workable for their particular setting. For instance, factors for a pharmacy to consider include public health and safety issues that arise if consumers bring their unwanted medications into the pharmacy where drugs are dispensed, patient health care services are provided, and consumers purchase other items such as health care products and food. Pharmacies must consider their space limitations and lack of design to take back consumers' returned drugs. In addition, with pharmacists increasing role in providing healthcare services, such as immunizations and medication therapy management services, they are devoting space to provide these services.

Voluntary drug take back and disposal programs allow the marketplace to determine what works and what does not work. Mandates, although not intended to do so, have the potential to disrupt the efforts to provide disposal programs.

Law Enforcement Initiatives

NACDS and our member pharmacies support the mission and activities of numerous federal and state agencies and law enforcement bodies. NACDS interacts routinely with other state and federal officials to devise strategies to protect Americans from the dangers of prescription drug diversion and abuse. We support the mission and objectives of the National Association of Boards of Pharmacy (NABP), and have worked with them on a number of initiatives over the years, the most recent being the development of a consensus document to alert prescribers and pharmacists about potential "red flags" in the prescribing and dispensing of controlled substances.

Target Illegitimate Internet Drug Sellers

NACDS believes that an important strategy to stop drug diversion and abuse is addressing the problem of illegitimate Internet drug sellers. These illicit online drug sellers have websites that target U.S. consumers with ads to sell drugs often without any prescription required. They operate in clear violation of U.S. state and federal laws and regulations that protect public health and safety. They sell drugs to consumers without the safety precautions of a legitimate prescriber-patient relationship, a valid prescription, or a licensed U.S. pharmacy.

We support targeting illegal Internet drug sellers by enabling entities such as domain name registrars that issue websites, financial entities that handle payment transactions, Internet service providers that show the illegitimate websites on the Internet, and common carriers that provide the mailing services to stop illicit transactions at their point of interaction with these bad actors.

Shutting Down Rogue Pain Clinics

As the number of domestic-based rogue Internet pharmacies has been declining in recent years, there has been an increase in the number of rogue pain clinics. According to DEA, the practitioners in these clinics are responsible for the dispensing of millions of dosage units of oxycodone, a schedule II opioid narcotic. NACDS supports the efforts of states that have enacted legislation to shut down these rogue clinics, such as restricting a physician's ability to dispense oxycodone from a pain clinic.

Conclusion

NACDS and our members are committed to the health and welfare of our patients, as well as all Americans, including ensuring that they do not fall victim to prescription opioid abuse. The prescription drug abuse problem can be successfully curbed. However, chain pharmacy cannot solve this problem alone. There must be a holistic approach. All affected stakeholders must work proactively to tackle and resolve this problem.

National Community Pharmacists Association (NCPA)

Senate Committee on Finance

"Examining the Opioid Epidemic: Challenges and Opportunities"
February 23, 2016

Chairman Hatch, Ranking Member Wyden, and Members of the Committee:

Thank you for conducting this hearing focusing both on the challenges and opportunities that may exist in the ongoing and pervasive opioid epidemic. In this statement, NCPA would like to present our thoughts and suggestions on strategies to curtail prescription drug abuse and address this public health issue. NCPA represents the pharmacist owners, managers and employees of nearly 23,000 independent community pharmacies across the United States. These pharmacies dispense approximately 40 percent of all community pharmacy prescriptions and are typically located in rural or very urban areas.

Recommendations to Address Prescription Drug Abuse

NCPA is committed to working collaboratively with the Department of Justice, DEA, other federal and state agencies, law enforcement personnel, policymakers, and other interested stakeholders in adopting viable solutions to prevent prescription drug abuse and diversion. We believe there are promising policies that could be scalable and have a positive impact on mitigating or preventing abuse, without compromising legitimate patient access to needed pain medications, such as:

- **Expanded Consumer Access to Naloxone:** This is a medication that is used to reverse the effects of opioids, especially in overdose. NCPA has begun work to support and advocate for pharmacists to participate in wider distribution of naloxone under protocols approved by state pharmacy and medical boards.
- **Enhanced Prescription Drug Monitoring Programs (PDMPs):** Creating interoperable and robust electronic databases to track all prescriptions for controlled substances could identify improper prescribing and dispensing behavior as well as individuals at high-risk of overutilization. Making certain that prescribers, pharmacists, and law enforcement personnel have timely access to this information would ensure that drug users and/or seekers could not manipulate the system.
- **Formation of a Prescription Drug Abuse Commission or Working Group:** Several lawmakers have proposed the formation of such a group to bring together the perspectives of law enforcement, health care providers and community advocates to discuss challenges and potential solutions.
- **Increased Health Care Provider Education:** State medical licensing boards could require licensees to obtain continuing education certification on pain management and could also require that all licensees register with a state prescription drug monitoring program in order to obtain their initial license or renewal.
- **Increasing the appropriate use of Risk Evaluation and Mitigation Strategies (REMS):** A REMS is a specialized set of instructions intended for prescribers and dispensers designed to enable professionals to more effectively manage a known or potential serious risk associated with a drug. Increasing more effective use of REMS information can help to decrease abuse, misuse, addiction and overdose death from opioid abuse.

CMS Has Demonstrated Clear Success in Reducing Opioid Overutilization in Medicare Part D

As part of a multifaceted response to address the growing problem of overuse and abuse of opioid analgesics ("opioids") in the Part D program, the Centers for Medicare and Medicaid Services (CMS) adopted a policy in 2013 for Medicare Part D plan sponsors to implement enhanced drug utilization review. CMS is seeing real results from these efforts. From 2011 through 2014, there was a 26% decrease or 7,500 fewer Medicare Part D beneficiaries identified as potential opioid overutilizers. This represents a 39% decrease in the share of beneficiaries using opioids who are identified as potential opioid overutilizers.

In addition, in the recently released Part D "Call Letter"—the annual document that provides guidance to all Part D plan sponsors for the next year—CMS clarified that they will now require all Part D plans to implement "both soft and hard formulary-level cumulative morphine equivalent dose (MED) point of sale edits." This means that Part D plans will have to have certain computer systems in place that will automatically send a message from the Part D plan (payor) to the dispensing pharmacy during the claim adjudication process in the event that a prescription associated with a particular patient or beneficiary would put that patient over a threshold safe dosage of an opioid. Depending on the threshold amount, these edits will in some cases prevent certain prescriptions from being filled or processed.

The success of CMS to date with regard to curbing opioid abuse in the Part D program clearly speaks to the suitability of CMS as the entity that should be tasked with the administration of any "lock-in" or other program designed to curb opioid abuse, given CMS's experience and expertise on the matter.

Concerns With Proposed Medicare Part D "Lock-In" Proposal

NCPA would also like to take this opportunity to share our concerns regarding S. 1913, a proposal that purports to address opioid overutilization in the elderly by requiring that "at-risk" individuals utilize a single prescriber and pharmacy for certain medications. NCPA would like to offer the following recommendations for changes to the proposal to improve oversight of such efforts and maximize beneficiary access to needed medical care and access to medications.

- **CMS, Not Individual Part D Plan Sponsors, Should Administer Any "Lock-In" Program**

  First, for the sake of consistency and to ensure that any such lock-in policy is being applied uniformly across all plan offerings, it is critical that CMS, the regulatory agency currently tasked with oversight of the Part D program, retains oversight over these efforts. In addition, CMS oversight would also ensure that

one entity has access to all of the data generated by "at-risk" individuals and is able to assess the overall success of these efforts across the entire Part D population.

In addition, CMS oversight would eliminate concerns regarding potential PDP "conflicts of interest." As NCPA has articulated in the past, there are multiple PDP sponsors that have existing commercial relationships with large retail pharmacy chains (*i.e.,* Humana-Walmart). The current language of S. 1913 still only refers to the ability of an "at-risk" individual to indicate his or her "preferences" for the single pharmacy and prescriber. In the absence of clear patient "choice," this language establishes the PDP sponsor as the ultimate arbiter of the chosen pharmacy and prescriber.

- **Beneficiaries Must Have the Ability to Choose Their In-Network Prescriber and Pharmacy**

  It must be noted that in virtually all of the 46 Medicaid "lock-in" programs, it is the beneficiary that has the clear ability to choose both the in-network prescriber and pharmacy. These programs all clearly use the word "choice" rather than "preference." In comparison, the current language of S. 1913 would only allow the beneficiary the ability to indicate "preferences for which the beneficiary would prefer the PDP sponsor select."

  In addition, it should be noted that S. 1913 already includes language—that is similar to language that appears in many state Medicaid programs—that would allow the PDP sponsor to change the prescriber or pharmacy if it is determined that either entity is somehow contributing to the potential abuse or diversion. As long as this "fail safe" provision is in place, the beneficiary should be able to choose where and from whom they receive their in-network health care services.

Conclusion

In closing, NCPA stands ready to work with other stakeholders to stem the growing tide of opioid abuse and overdose and strongly believes that there are a number of potential strategies that can be utilized such as increased access to naloxone and enhanced prescription drug monitoring programs to address the problem. Moving forward, we note the success that CMS has had to date in reducing opioid overutilization in the Medicare Part D program and believe that the current "lock-in" proposal would need a number of key edits to ensure that it would be a coordinated and even-handed program. We appreciate the opportunity to provide our thoughts and suggestions.