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THE OPIOID CRISIS: REMOVING BARRIERS TO PREVENT AND TREAT OPIOID ABUSE AND DEPENDENCE IN MEDICARE

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

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THE OPIOID CRISIS: REMOVING BARRIERS TO PREVENT AND TREAT OPIOID ABUSE AND DEPENDENCE IN MEDICARE

TUESDAY, FEBRUARY 6, 2018

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to call, at 3:07 p.m., in Room 1100, Longworth House Office Building, Hon. Peter Roskam [Chairman of the Subcommittee] presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
Tuesday, February 6, 2018
HL–03

CONTACT: (202) 225–1721

Chairman Roskam Announces Hearing on The Opioid Crisis: Removing Barriers to Prevent and Treat Opioid Abuse and Dependence in Medicare

House Ways and Means Health Subcommittee Chairman Peter Roskam (R–IL), announced today that the Subcommittee will hold a hearing on "The Opioid Crisis: Removing Barriers to Prevent and Treat Opioid Abuse and Dependence in Medicare." The hearing will discuss the ongoing opioid crisis, and the important role data, addiction prevention, and access to treatment play in addressing the crisis. The hearing will also examine possible legislative solutions to combat opioid abuse. **The hearing will take place on Tuesday, February 6, 2018, in room 1100 of the Longworth House Office Building, beginning at 3:00 p.m.**

In view of the limited time to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit written comments for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, *http://waysandmeans.house.gov*, select "*Hearings*." Select the hearing for which you would like to make a submission, and click on the link entitled, "*Click here to provide a submission for the record*." Once you have followed the online instructions, submit all requested information. ATTACH your submission as a Word document, in compliance with the formatting requirements listed below, **by the close of business on Tuesday, February 20, 2018**. For questions, or if you encounter technical problems, please call (202) 225–3625.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

All submissions and supplementary materials must be submitted in a single document via email, provided in Word format and must not exceed a total of 10 pages. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears. The name, company, address, telephone, and fax numbers of each witness must be included in the body of the email. Please exclude any personal identifiable information in the attached submission.

Failure to follow the formatting requirements may result in the exclusion of a submission. All submissions for the record are final.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TDD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Note: All Committee advisories and news releases are available at *http://www.waysandmeans.house.gov/*

Chairman ROSKAM. The Subcommittee will come to order.

Welcome to the Ways and Means Health Subcommittee hearing on "The Opioid Crisis: Removing Barriers to Prevent and Treat Opioid Abuse and Dependence in Medicare." I am pleased to take on this issue, along with Mr. Levin, as my first hearing as the new Subcommittee Chairman.

This is the second hearing in a series held by the Ways and Means Committee on this crisis. And today we will explore opioid addiction and treatment in our Medicare population and ask the question how Congress can do more to improve detection, education, prevention, et cetera.

Like many States, my home State of Illinois is experiencing an increase in opioid-related overdose deaths. According to the Illinois Department of Public Health, there has been a 44.3-percent increase in drug overdoses from 2013 to 2016. I know this figure is consistent with other States and other experiences. Approximately 80 percent of drug overdose deaths in 2016 were opioid-related. Nationally, more than 42,000 Americans died from opioid-related drug overdoses in 2016, according to the Centers for Disease Control. That is over 115 people a day or the equivalent of over 14 people who would have lost their lives in the course of this upcoming hearing today.

And while those are statistics and the statistics are compelling, we are talking about sons and daughters, brothers and sisters, mothers and fathers, and those who are dear to us who are struggling with this crisis in and around our communities. With 10,000 baby boomers joining Medicare each day, we must harness innovation, technology, and data to get ahead of this problem. Unfortunately, there is a lack of available data regarding the Medicare population and the extent to which opioid abuse, overprescribing, and diversion is an issue for seniors and the disabled. Additionally, gaps in coverage for those that suffer from opioid addiction exist as well.

To help us examine what States are doing to address the opioid epidemic, we have Governor Phil Scott to discuss the tremendous efforts that the State of Vermont has undertaken to battle the crisis through expanded treatment options and substance abuse disorder management. We have representatives from two health plans that serve Medicare beneficiaries to discuss how payers are managing care for those that suffer from substance abuse disorder and the hurdles they face in doing so.

And, finally, to round out our witness panel, we have two representatives from the medical field to discuss both medication-assisted treatment and other intervention pain services.

I think all of us approach this issue with humility. All of us represent constituencies that are being overwhelmed by this crisis, and all of us are looking for solutions. And I think our constituents have sent us here with a disposition to get things done, and I look forward to working with both sides of the aisle to come up with commonsense solutions, to look at the things that work and celebrate them and pursue them, shun the things that don't work, and to do everything that we can to relieve this crisis and bring hope and optimism in a field that is really quite overwhelming.

I am pleased that Mr. Neal, the Ranking Member of the Ways and Means Committee, is here, and I would yield to him for the purposes of an opening statement.

Mr. NEAL. Thank you, Mr. Chairman. Let me congratulate you on your first hearing here. I would remind all that you served with me on the Tax Subcommittee, and it was very clear that you decided your future would lie in the Health Subcommittee after that.

Mr. Chairman, I am pleased that we are holding this hearing to identify solutions to address the opiate abuse and dependence specifically in the Medicare space. Although overdose rates are highest for people 25 to 54, this public health emergency also affects Medicare beneficiaries. Everyone in this room has a family member or knows someone directly impacted by the opiate epidemic. It could be somebody down the street. It could be somebody in the next room. In my home State of Massachusetts, last year, there were 2,094 opiate-related deaths due to abuse. I thank my neighbor to the north, Governor Scott, and his Health Secretary, Al Gobeille, for joining us today. We share a border, and it also means that we share a common challenge in fighting the opiate crisis. Massachusetts Governor Charlie Baker, like Governor Scott, is working to employ all tools in this fight, ranging from expanding Medicaid coverage to provide treatment availability, data analytics, and treating addiction while stabilizing and supporting families.

Opiate abuse and related deaths take a toll on all of our communities and on all of our families. There is no single cause and there certainly is no single solution. Expanding Medicaid under the Affordable Care Act to low-income working Americans who previously could not afford insurance has been the most significant step in recent years to stem the tide of the opiate crisis. Providing access to critical substance abuse and mental health services that previously were prohibitively costly has also worked.

We need to look to Medicare beneficiaries' ability to access treatment as ofttimes providers aren't available to meet the needs. We know there are significant gaps in coverage and access under Medicare. For example, Medicare does not cover outpatient treatment programs that provide comprehensive opiate addiction treatments, nor does Medicare cover methadone for addiction, which is often the treatment of choice for longer term addicts. I recently introduced legislation that would allow methadone to be covered for outpatient services under Medicare.

We also need to work with our partners to identify best practices. Late last week, I sent a letter to the Energy and Commerce Ranking Member Pallone about 14 Medicare plans and asked them to help compile the best practices that they are aware of to address opiate-related disorders. Evidence-based tested activities that are

helping patients turn the corner will help us design sound policy. I look forward to these plans' responses, and I hope Dr. Paz from Aetna today will share his knowledge about what they are doing as well.

We also need to explore how substance abuse is affecting children and families. The epidemic is fueling rising caseloads for children and adult protective services, for foster care, and also for caregivers as they attempt to battle addiction.

I am pleased that our Committee has worked together on this bipartisan basis on legislation to support families and to help them keep children safe who would otherwise be in foster care while they can now remain safely at home with proper monitoring. We hope we can continue this partnership because we have much work to do.

I hope as we move into the following year that we will not endorse or embrace plans to cut efforts that would, in fact, undermine what we are attempting to do here today. For example, the Social Security—Services Block Grant is the largest source of Federal funding for child protective services and the only major source of Federal funding for adult protective services in most States. We have a lot of work to do, and Congress could play a positive role in partnering with the States to provide resources and help to eliminate Federal barriers to treatment and access and support families and law enforcement.

And, Mr. Chairman, to you for holding this hearing, I appreciate it. I also point out something that you and I have talked about a number of times. There are now 2 million people on the sidelines who formerly were in the workplace battling this epidemic. When you look at labor participation rates, it has had a huge impact on what has happened. So this is a very important hearing. Thank you.

Chairman ROSKAM. Thank you, Mr. Neal.

I now recognize Mr. Levin for his opening statement.

Mr. LEVIN. Thank you, Mr. Chairman, and congratulations. We all look forward to working with you. You are surely a very articulate, knowledgeable person. We look forward to it. And thank you for letting us, in essence, make two opening statements. Mr. Neal comes from a State, I think, where there has been a strong wrestling with this issue. The same in Michigan.

Welcome to the witnesses. A son, Matthew, lives in Vermont and is active representing mainly education groups. In the halls, he may have bumped into you.

Mr. Chairman, the opioid epidemic is an enormous societal problem that demands a concerted effort at every level of government. The death toll is astonishing. Ninety-one Americans die every day from an opioid overdose, with five dying every single day in my home State. We have to stop this killer. Despite the urgency of this crisis, it is clear that, although President Trump has declared a public health emergency, to date, the Administration has not taken significant steps to address it.

Last year, President Trump proposed a budget that would radically alter the Medicaid program while slashing its funding by $1.3 trillion. Medicaid is the largest payer for behavioral health services. It funds detoxification, maintenance therapy, medication-

assisted treatment, and other crucial services. We cannot claim we are serious about addressing this crisis on the one hand while gutting one of the country's most important sources of treatment on the other.

These efforts come on the heels of efforts within the Affordable Care Act that would have, I think, if repeal had occurred, undermined these efforts. I will look now to the future and leave those comments for the record.

At this crucial time, the Administration has also undermined the Office of National Drug Control Policy, which for decades has helped fight drug abuse in this country. Last year, we fought against the Administration's efforts to eliminate all funding for the Drug-Free Community Program, an effective multisector community-based drug prevention program that was really started by a fellow Member of this Committee, Rob Portman, when he served, and myself in 1996. There have been thousands of community anti-drug coalitions that have received seed money because of this program. The appropriation level now is $90 million.

This year, we heard once again that the Administration intends to propose undercutting this office by eliminating its oversight of drug control and prevention programs. And I must confess, I was really alarmed, like so many, when the Administration suggested placing a 24-year-old with no relevant experience in the second highest position. Through the Drug-Free Communities Act, we have had so much contact with this office. It needs the most talented personnel effort.

A coordinated Federal response to this crisis is possible, but it will require a dramatic change of course. We must take immediate steps to ensure that we are effectively implementing programs that prevent flooding of our communities with unnecessary prescriptions. In Michigan, a State of less than 10 million, more than 11 million opioid prescriptions are written annually, 11 million. This is more than enough to provide each resident of my home State with a bottle of opioids each year.

Addressing the pervasiveness of this will require a broad-based effort to revise clinical guidelines with the goal of improving provider behavior, leadership at the State and Federal level to monitor for harmful prescriptions and marketing practices, and other immediate steps that will reduce the prevalence.

I just close. We all, Mr. Chairman, encounter this problem every time we go home, do we not? Every time. And we hear of deaths. It is younger people, but also people not so young, people sometimes under immense stress.

And I think with the leadership of this Subcommittee and the entire Ways and Means Committee, Energy and Commerce, and the Congress, we need to do everything to fulfill our obligation. All the answers aren't in Washington, but some of them are.

So we look forward to the testimony of you distinguished members of the public sector. Thank you, Mr. Chair.

Chairman ROSKAM. Thank you, Mr. Levin.

Let me describe how we will move the traffic today. We have two panels. The first panel will be the Governor. And we will have 5 minutes from each of the witnesses. If you are getting a little

lengthy, I will tap my gavel gently. But I think most folks have had an opportunity to read all of the statements.

To give us an introduction of the Governor is the distinguished gentleman and our friend from Vermont, Mr. Welch, who has this distinguishing gift of being able to tell someone to go jump in the lake but with such charm that you kind of look forward to the trip, actually.

So, Mr. Welch, would you——

Mr. LEVIN. And there aren't that many lakes in Vermont, either.

Chairman ROSKAM. Could you introduce the Governor?

Mr. WELCH. I thank the Chairman for that dubious introduction, but I am not here to tell you to jump in a lake. I am here to thank you for having a bipartisan hearing on an incredibly devastating problem. And, as Mr. Levin said, we here in the Federal Government can provide some help, but the hard work is done with first responders, with Mayors, and with Governors.

One distinguishing thing about Vermont is we embraced the challenge on a bipartisan basis. The Democratic Governor, predecessor to Phil Scott, Peter Shumlin, spoke in his entire address in 2014 about the opioid crisis. And I remember talking to some of my colleagues here, saying, "Peter, why would you be advertising that bad news," but then, as we talked, acknowledging that that was a devastating issue in their own communities.

Phil Scott was then Lieutenant Governor. He has taken up the leadership in Vermont now to follow through, and we have this bipartisan approach to try to address the tragic circumstances of opioid addiction.

So I thank all of the Members of this Committee.

Mr. Chairman, thank you for being here.

Ranking Member Neal is here as well. It shows the urgency of this Committee.

And all of us are ready to work with you. Thank you.

And I give you the Governor of the State of Vermont, my friend, former Lieutenant Governor, now Governor Phil Scott, of Middlesex, Vermont.

Chairman ROSKAM. Governor, you are recognized. Thank you for being here.

STATEMENT OF PHILIP B. SCOTT, GOVERNOR, STATE OF VERMONT, ACCOMPANIED BY AL GOBEILLE, SECRETARY OF HUMAN SERVICES

Governor SCOTT. Thank you very much.

And thank you, Congressman Welch. We served together in the Senate not long ago.

Chairman Roskam, Ranking Member Levin—I do know your son. I played hockey with him a few years ago. He is a very good hockey player—and Members of the Subcommittee, I want to thank you for the honor of appearing before you today. My Secretary of Human Services, Al Gobeille; Commissioner of Health, Dr. Mark Levine; and the Director of the Blueprint for Health, Beth Tanzman, are here with me as well.

As was mentioned, in Vermont, the Governor and Lieutenant Governor are elected separately. So, in 2014, when then-Governor

Peter Shumlin, a Democrat, devoted his state of the State address to the opioid epidemic, I was sitting there listening as the Republican Lieutenant Governor. And I must admit, I was more than just a bit skeptical. I was concerned calling so much attention to this problem would damage our image and hurt our State. And sure enough, initially, many at the national level portrayed this as only a Vermont problem. We now know all too well this was and is a national problem.

Governor Shumlin was right to focus our attention on this epidemic, and I have since learned the incredible devastation opioids have had on our State and our people. I have met countless Vermonters impacted by addiction, some in recovery, some still struggling, and some who have had their families torn apart, changing their lives forever.

We have made a lot of progress in Vermont, much of it with support from you and our Federal partners, although, today, I approach you humbly because we have not yet solved this problem. Even with our small population, we see two Vermonters die from a drug overdose every week. And nearly every day a baby is born exposed to opioids, something I have highlighted as one of Vermont's biggest challenges.

We have some of the best access to treatment in the Nation, but too many Vermonters who need treatment have not sought it. And while Vermont's rate of overdose deaths is the lowest in New England, we still lost 106 people in 2016. In 2017, it looks like it will be similar. Tragically, we also experienced high numbers of children under the age of five who come into State custody due to this crisis. And I think we all would agree these kids don't deserve this. They need a better start.

We have focused on what I refer to as the four legs of the stool: prevention, recovery, treatment, and enforcement. My first day in office I established by executive order the Opioid Coordination Council. This Council is made up of a wide range of perspectives, life experience, and different political philosophies. Importantly, this includes those who have suffered from the addiction themselves. I handpicked them and tasked them with providing recommendations to improve Vermont's response to each of the four legs of the stool.

We know that too many Vermonters become addicted through prescription pain medication. Therefore, the State implemented strict prescriber rules around pain management and a prescription monitoring system. So, for the first time, we are beginning to see a reduction in prescribed opioids. Unfortunately, we still prescribe three times as much as we did in 1999.

Vermont has also made Narcan widely available to first responders, law enforcement, people with addiction, and family members of those suffering. We have aggressively used a screening, brief intervention, and referral to treatment model, also known as SBIRT, to prevent the progression of addiction.

Enforcement is another important piece, but we are all in agreement: we can't arrest our way out of this. Our courts, local police, and States attorneys have become important partners in addressing this epidemic, and we address it as a public health issue.

To treat opioid addiction, Vermont operates a medication-assisted treatment, or MAT system, called Hub and Spoke. With the support of our Federal partners, we established a help home for Vermonters with opioid addiction. Through well-coordinated and comprehensive services, we treat opioid addiction like we do any other chronic condition. Our Hubs provide all FDA-approved medications. They also provide critical nursing, counseling, and care management. In our Spokes, primary care offices prescribing buprenorphine are supported by nurses and counselors who offer more complete care. Finally, coordination between Hubs and Spokes assures the patients receive the appropriate level of care as they need it.

Vermont and the Federal Government have been effective partners in tackling healthcare challenges for many years. It is in this collaborative spirit that I offer four areas where together we can improve our response:

First, Medicare needs to treat this as the chronic condition that it is. I have sent a letter to the Secretary of Health and Human Services asking that CMS work with Vermont and engage Medicare in Vermont's Hub and Spoke system. Working with our Federal partners, we hope to develop a path to make this a reality.

Second, we need to make sure that SBIRT is fully supported within the billing system so Vermont can sustain and expand this important work.

Third, we ask you to consider giving States relief from the IMD exclusion, which prohibits using Medicaid funds in mental health or treatment facilities of 16 or more beds.

Finally, our small State could benefit tremendously from nationally supported research in the areas of alternative pain treatment and from expanded coverage for alternative chronic pain management.

In closing, I would like to thank you for the opportunity to address this Committee. We have made great progress over the years, but we have much more to do if we are to improve the health of Vermonters and all Americans to truly end this crisis and this epidemic.

Thank you.

[The prepared statement of Governor Scott follows:]

Vermont Governor Scott Testimony to the House Ways & Means Subcommittee on Health

February 6, 2018

Vermont's Response to the Opioid Epidemic

Chairman Roskam, Ranking Member Levin, Members of the Subcommittee, I want to thank you for the honor of appearing before you today. My Secretary of Human Services Al Gobeille, Commissioner of Health Dr. Mark Levine, and Director of the Blueprint for Health Beth Tanzman join me today.

In 2014, then-Governor Peter Shumlin, a Democrat, devoted his entire State of the State address to the opioid epidemic. Sitting there listening as the then-Lieutenant Governor (an independently-elected Republican), I must admit to being skeptical. I was concerned calling so much attention to this problem would damage our image and hurt our state. And, at first, this was portrayed as a "Vermont Problem." We now know that this was, and is, a national problem. Governor Shumlin was right to focus our attention on this epidemic. Since then, I have learned all too well the impact of opioids on our state and our people. I have met countless Vermonters impacted by addiction. Some who are in recovery, some who are still struggling with addiction, and some who have had their families torn apart, changing their lives forever.

We have made much progress in Vermont, much of it with the support of our federal partners, yet, today, I approach you humbly. We have not solved this problem. Every week, two Vermonters die from a drug overdose. Nearly every day, a baby is born exposed to opioids.

Even though we have some of the best access to treatment in the nation, there are still many Vermonters who need treatment, but have not yet sought it. Vermont's rate of overdose deaths is the lowest in New England, but we still lost 106 people to drug overdoses in 2016. Unfortunately, 2017 looks to be similar. And, tragically, we continue to see high numbers of children under 5, who come into state custody due to opioids. These kids deserve a better start!

What Vermont Has Done

Continued Attention to the Issue

We are focused on what I refer to as the four legs of the stool: Prevention, Recovery, Treatment, and Enforcement. On my first day in office I established, by executive order, the Opioid Coordination Council. This council is made up of a wide range of perspectives and different political philosophies. Importantly, that includes those who have suffered from addiction themselves.

I handpicked them and tasked them with providing recommendations to improve Vermont's response in each of the four legs of the stool.

Prevention

We know too many Vermonters became addicted through prescription pain medication. Therefore, the State implemented guidelines on safer prescribing for acute pain and using the CDC guidelines for chronic pain. We have enhanced our Prescription Monitoring System so that health care providers can see what controlled medications are being prescribed to their patients and avoid prescription drug abuse and dangerous drug-to-drug interactions. For the first time, we are beginning to see the amount of opioid prescriptions decline. It is discouraging to note, however, we still prescribe three times as much as we did in 1999.

Harm Reduction

In Vermont, we make Narcan – the opioid overdose reversal drug – widely available to first responders, law enforcement, people with addiction and their family members. To date, we have successfully reversed over 1,000 overdoses. We also operate needle exchange programs, which not only help prevent the spread of diseases such as Hepatitis, but they also provide an important opportunity to engage people on treatment options.

Early Intervention

The screening, brief intervention, and referral-to-treatment protocol, also known as SBIRT, has been employed in emergency rooms, primary care offices and college health services. It helps people with risky substance use get education and support to prevent the progression to addiction and get them on a better path. The support of the federal Substance Abuse and Mental Health Agency (SAMHSA) has been critical to training and deploying SBIRT in Vermont, and we are now turning our attention to how we can not only sustain, but expand this practice to all emergency departments and primary care offices.

Criminal Justice

Enforcement is an important piece, but we know that we cannot arrest our way out of this epidemic. Our courts, local police, and State's attorneys have become important partners in treating the Opioid epidemic as a public health issue. We use the full force of the law to prosecute dealers, and the full force of our persuasion to divert individuals into treatment.

Treatment

To treat opioid addiction, we operate a medication-assisted treatment (MAT) system called the "Hub & Spoke," one of the most successful treatment systems in the nation. We follow the science, which clearly demonstrates that MAT is the gold standard for treating opioid addiction. Vermonters in treatment are less likely to overdose, have reduced use of acute health care services, and are much more likely to gain stable recovery.

With the support of our federal partners at the Centers for Medicare and Medicaid Services, we amended our state plan to create a "Health Home" for Vermonters with opioid addition. The idea was to treat opioid addiction like we would any other chronic condition with well-coordinated and comprehensive services.

We enhanced the services at our methadone treatment programs to include all the FDA approved medications for opioid addiction (Buprenorphine and Vivitrol), we added nursing, counselors and care management staff. We asked these programs, now called Hubs, to act as regional consulting resources on addiction care to general medical offices.

We supported primary care by adding nurses and counselors to all the general medical offices where Buprenorphine is prescribed – the so-called "Spokes." The nurses and counselors at these sites work directly with prescribers to offer more complete substance use disorder care. The addition of these staff has allowed Vermont's primary care practices to provide comprehensive team-based care, and their relationship to the Hubs helps assure that the patients seen in primary care offices have access to higher levels of care when they need it.

The services at both Hubs and Spokes are supported by payment reforms. At the Hubs, we have implemented a bundled payment that covers methadone and supportive services so important for successful treatment. In addition, the Hubs "buy and bill" for Buprenorphine and Vivitrol. At the Spokes, the nurse and counselor salaries are paid for by a per-member, per-month payment rather than reimbursement for each service they provide.

The new investments we made were primarily in staffing to provide more comprehensive counseling and health services to people with addiction in both Hub and Spoke settings. This program has been incredibly successful, and we have provided advice and assistance to numerous other states who have expressed interest in applying it to their populations. Since its inception, we have tripled the people receiving treatment and almost doubled the number of providers working with these individuals. We also have data indicating that people receiving MAT have fewer visits to the emergency room and admissions to the hospital. We also have indications that this support is beginning to reduce opioid use and overdoses.

Recovery

I have had the privilege of speaking with Vermonters in recovery about what has helped them. They speak of the importance of family, of the dignity of work, and of the support from peers. Vermont's recovery centers and peer recovery coaches help people regain their lives. My administration is very focused on the importance of building the workforce, and we will pursue opportunities to help people in recovery return to gainful employment.

What Vermont Looks to Do Next

Vermont and the federal government have been effective partners in tackling health care challenges for many years. It is in this collaborative spirit, that I offer four areas where, by working together, we can continue to improve our response.

First, Medicare needs to treat addiction as the chronic health condition that it is. I have sent a letter to the Secretary of Health and Human Services asking that CMS work with Vermont and engage Medicare in Vermont's system of care, specifically the Hub & Spoke system. Working with our federal partners, we hope to develop a path to make this a reality. Medicare could also assure that the FDA-approved mediations for opioid addiction are available to beneficiaries.

Second, we need to explore better ways to implement SBIRT so Vermont can sustain and expand this important work. The current billing practices do not seem to fully support this critical early intervention service.

Third, we ask you to consider giving states relief from the IMD exclusion that prohibits the use of Medicaid funds in mental health or treatment facilities of 16 or more beds.

Fourth, our small state could benefit tremendously from nationally-supported research in the areas of alternative treatments for pain and from expanded coverage options for alternatives to opioids to manage chronic pain. Such approaches can help prevent unnecessary and prolonged exposure to opioids and help reduce the rates of addiction.

Closing

In closing, I would like to thank you for the opportunity to address this committee. We have made great progress over the years, but recognize we have a lot more work to do, in partnership with you, to improve the health of Vermonters and all Americans, and to truly end this epidemic.

Chairman ROSKAM. Thank you, Governor. We really appreciate your insight. Don't go anywhere. I am now going to briefly introduce the other panelists for a little bit of a foreshadowing, and then we are going to come back for questions with you.

So for our second panel, we are going to hear from Dr. Ramsin Benyamin, President and Founder of Millennium Pain Center, located in Bloomington, Illinois. We look forward to hearing from him.

For our next few witnesses, I am going to yield to our colleagues. I will now yield to Mr. Thompson for the purpose of an introduction.

Mr. THOMPSON. Thank you, Mr. Chairman, and congratulations on your new Chairmanship and thanks for having this hearing.

Mr. Chairman, thanks for the opportunity to introduce and to welcome to the Committee Dr. Jason Kletter, the President of BayMark Health Services. Dr. Kletter has 20 years of experience in the addiction field and currently serves as President of the Bay Area Addiction Research and Treatment, headquartered in San Francisco in the bay area. His organization operates 20 opioid treatment programs in five States, serving 7,000 patients every day. Dr. Kletter also serves as the President of the California Opioid Maintenance Providers and as a board member of the American Association for the Treatment of Opioid Dependence. He has advised both Federal and State agencies, providing input on accreditation guidelines, physician training, and various State policies.

As part of California's Hub and Spoke program, modeled off the program Governor Scott described earlier, Dr. Kletter's BAART program in Antioch, California, will serve as the Hub to a handful of Spokes that will provide treatment to constituents across my district. And I just learned today he is also a part-time resident of my hometown.

So, Dr. Kletter, thank you for your testimony. I look forward to hearing about your experience in the field and understanding how this Committee can best support your work. Thank you for being here.

Chairman ROSKAM. Thank you, Mr. Thompson.

Mr. Larson.

Mr. LARSON. Thank you, Mr. Chairman. And let me echo the sentiments of the Members of the Committee and congratulate you on your new Chairmanship. And I know how well you work with Mr. Levin, and we thank you for hosting this very important hearing today.

It is my honor to introduce Dr. Harold Paz, who is the Executive Vice President and Chief Medical Officer for Aetna in my home State of Connecticut.

Aetna is blessed that it has probably one of the leading thought leaders around healthcare in the world in Mark Bertolini, and Connecticut as a region is blessed to have an industry that is focused on this, including David Cordani from Cigna as well. But as head of the Aetna's enterprisewide opiate task force, Dr. Paz is responsible for a companywide strategy to prevent the misuse and abuse of medications, something that is critical in this epidemic as it continues to wreck, savage this country of ours.

Under his leadership, we have been able to follow examples and hope that we are able to follow examples that the private sector is setting, find ways to help our public health system, especially Medicare and Medicaid, and effectively and humanely care for those suffering from addiction. Aetna has used its valuable data to help identify what they call super-prescribers and work with hard-hit States to provide training and supplies of lifesaving treatments, like Narcan, as the Governor mentioned early on.

So it is my high honor here today to introduce Dr. Paz. We look forward to your testimony, and we thank you for your leadership and acknowledge it is not just government but the private sector and, in fact, all of us that need to work in collaboration to solve this national epidemic.

Thank you, Dr. Paz.

Chairman ROSKAM. Thank you, Mr. Larson.

And Mr. Buchanan.

Mr. BUCHANAN. Thank you, Mr. Chairman, for holding this important hearing. I also want to congratulate you on your Chairmanship. I am excited about what you are going to be able to do with this Committee.

I am pleased to welcome Laura Hungiville, Chief Pharmacy Officer of WellCare Health Plans based in Tampa, Florida, part of the region that I represent. They do a lot in our region, and throughout the State and the country. In this role, she helps implement programs to prevent opioid abuse, helps members living with chronic pain, and helps members battling addiction.

WellCare insures 4.3 million members nationwide enrolled in Medicare Advantage, Medicare prescription drug plans, and Medicaid. Currently, this does not include mental health counseling, yet according to the HHS, approximately 13 percent of people age 65 and older suffer from mental illness.

And, with that, I yield back.

Chairman ROSKAM. Thank you all.

Now we will turn to make inquiries of the Governor and his team. We are going to break with our normal tradition and, by agreement, we are limiting our Members to 4 minutes.

And, with that, I yield back to Mr. Buchanan to begin the inquiry.

Mr. BUCHANAN. Thank you, Governor, for being here. We also have a Governor Scott in Florida, and I don't know if you are related or not, but if you are nearly as talented as he is, you have to be a heck of a Governor.

Governor SCOTT. If there is any controversy, I usually blame him.

Mr. BUCHANAN. Let me just say, about 7 or 8 years ago, I had a lot of members from Kentucky and Tennessee and other places, and everybody would be coming to Florida. We had 1,300 pill mills that were here, and they had come here because we didn't have a database. And it was a disaster. We were losing 10 people a day. We have shut down a lot of those pill mills, but they have moved over to heroin and fentanyl and other drugs in our community. In fact, my main county is the epicenter of Florida per capita with a lot of these drugs.

But I read something the other day. It just was a shocking statistic from the AARP on deaths from opioids. Of course, being in Florida, we have a lot of seniors. I think 60 percent of my constituents are 60 and older in my area. But deaths from opioids, they have increased seven times for a senior 65 to 74, because you always think sometimes about just younger people, over the past 15 years. This is an absolute tragic thing. And I guess I would be interested in what you have learned from Vermont, in terms of a lot of your seniors. Let's just take that initially, any thoughts that you have on that.

Governor SCOTT. I will start off and then let my Secretary take over from there. But we are seeing—I think a lot of it is the prescription rate amongst seniors across the board that they store in their medicine cabinets and so forth. We have a drug take-back, a prescription drug take-back program, where in the first—what I thought was the first year they collected almost 6,000 pounds in our small State of Vermont. And I thought that was remarkable and that, for the first year, I would expect that with the pent-up reserves. And then they told me that was the third year, and they collected 5,000 the year before and 5,000 the year before that. So that tells me that the prescription rate is abusive and excessive.

So I don't believe we are seeing the deaths of our seniors as we do with our youth, but I will let our Secretary answer that.

Mr. BUCHANAN. Just for time, let me get to another question. I think one of my colleagues had mentioned how everybody is impacted. My family has been impacted. But what are you doing on a little different score? What are you doing in terms of prevention? I had a mother come in the other day, four kids, homeschooled, two of them are addicted.

So the thought to me is, what do we do to prevent this in the first place? Because once they go through that door—she told me, crying, that after 2 weeks of being on these pills, the older brother brought it home and got his sister hooked. In a matter of a couple of weeks, they got addicted. It has been over a year for both of them to be able to get off this stuff, and they might have to deal with this for the rest of their lives.

So the impact and the power of these drugs is incredible, but I have a lot of stories like that. I have had three mothers come in where they have lost their children, and that is what got me initially involved in this effort.

But what is your thought about prevention? Because once they go through that door, in my opinion, it is nice to have all these other things and it is important, but how do we prevent it in the first place? What more can we be doing on the prevention front?

Mr. GOBEILLE. Thank you. My answer to that would be, we need to do a lot more in prevention. Some of the things that we have done is that we have worked with the goal of setting up a prescription monitoring system in our State. We passed a law in 2013. But we had done good work prior to that to try to get a database where we would know what specialties we are prescribing, at what levels, basically so that doctors would know who was prescribing what to their patients so that we could look inside our State, but also, because we are a small State, to our neighboring States and what was happening with our patients, basically, that could go

there for pills. So it is a game of, how do you reduce the impact of the pills, because this is a pill-driven crisis? And so anything that can aid that upstream has a big benefit.

Mr. BUCHANAN. Let me just close out, because I want to yield back.

Chairman ROSKAM. Thank you. Let me just give you a little housekeeping here. I think we as Members have a lot to say. We are going to be well-served if we allow our witnesses to give us input. And so keep the time on your question a little more limited so that they can come back. You know what I am saying? We are varying from our normal procedure.

Mr. Thompson.

Mr. THOMPSON. Thank you, Mr. Chairman.

Governor, thank you for being here. According to the CDC, 42 percent of workers with back injuries got an opioid prescription in the first year after their injury, and then a year later, nearly one in five of those patients are still taking the same drug, despite the fact that the FDA has not approved opioids for long-term use. So, clearly, these people are still suffering serious pain or they are addicted.

So how do we make sure that folks, workers who have been injured on the job and are under the protection of the State workers' comp system are getting appropriate treatment for their injury, and how can we ensure that they have access to treatment if they become addicted?

Mr. GOBEILLE. Thank you. I think that the answer begins with taking a look at the way that pain clinics are formed, and I think you have a witness that will come up and describe it way better than I can. But, basically, there has to be a lot more avenues to treat the pain and to treat the rehabilitation for folks other than just opioids.

So, while opioids may be an answer, there are a lot of other answers that need to—questions that need to be asked and potential remedies other than just simply prescribing long-term opioids.

Mr. THOMPSON. Have you looked at the workers' comp system in your State? I know in my State, I have constituents who become injured and it takes forever to get through the system, and they rely on the opioids to relieve the pain while they are waiting for treatment, sometimes treatment that never comes. And I am just concerned that this may exacerbate the entire program.

Governor SCOTT. I have lived that life. I was three decades in the construction business, so I had numerous of my employees out with injuries and so forth. And we have to be very, very careful. Once we open the door and they are prescribed opioids and the prescription drugs, to just shut them off without proper treatment leads them to other methods of heroin, fentanyl, and so forth. So we are monitoring that. We are taking a look at that as we speak with interest as to what we can do to make sure that we have a pathway for them to recover because, again, we don't want to just shut them off. We want to help them get through it so they can become more productive citizens back into the workforce, which is so important.

And those are some of the opportunities that we see with our Opioid Coordination Council, to look for ways that we can break

down the stigma as well as to appreciate when someone has a problem so that we make sure—again, we want to make sure that we reintegrate them back into the workforce, because we desperately need them in Vermont.

Mr. THOMPSON. Thank you. Some have said that Medicaid expansion is behind the opioid epidemic, but everything that I have read suggests that the expansion happened in 2014, and this has been going on since the nineties.

So, Governor, can you tell us about the role Vermont's Medicaid expansion is playing in your State's efforts to address this epidemic, and just how critical will Medicaid be in the recovery process?

Mr. GOBEILLE. Yes. So, to be clear, we don't believe that Medicaid expansion caused this crisis. And, further, if we believe through fact that this is a chronic illness, then each payer should treat it like the chronic illness it is and be able to pay as a benefit for necessary treatment, counseling, et cetera. This really started in the late nineties, and I think that the evidence is clear.

Mr. THOMPSON. Thank you very much. I yield back.

Chairman ROSKAM. Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman. Thank you to our witnesses for addressing what I think is a large problem across the country, both rural and urban. A lot of folks, as you know, are impacted.

Governor, I am wondering if you think that the type of management and monitoring necessary to successfully guide patients through the process of medication-assisted treatment programs such as yours are possible under the Medicare program. Feel free to answer, either one of you.

Mr. GOBEILLE. We do think they are possible, but the letter that we sent the HHS Secretary was basically a request not that Medicare just simply treat this like a chronic illness and begin to pay for the delivery of services, counseling, or medication-assisted treatment, for example, but to actually participate in Vermont's system of care, which is partially Hub and Spoke but also other treatment modalities.

So it is not enough to just sort of pay the bill. It is about the way in which the services are delivered and organized that we want Medicare to fully participate in like other payers.

Mr. SMITH. Okay. I think you have answered my next question, so I appreciate that. And I think the approach—I would hope that there is the flexibility offered to States to address as they see fit that not often comes from the Federal Government, but hopefully that can be offered in the future, if you will.

Mr. GOBEILLE. Yes, sir. And what I would add is that recovery and healing should be a part of a conversation with your healthcare provider. And Hub and Spoke might be one answer. There might be residential treatment. There might be, you know, other paths to sobriety and getting back to living the life you wanted to live. And so Medicare should participate in all of that, just like we do with other, you know, illnesses.

Mr. SMITH. There are a lot of Nebraskans, especially in the agriculture community, who are buying their health insurance through the individual market. They are telling me that their out-

of-pocket expenses are $30,000 to $40,000 a year, with copays and deductibles contributing to that. That really puts a lot of access out of reach.

And I am wondering if that will ultimately pose a barrier. Certainly, many of our hospitals are even getting stuck with those copays, unpaid copays and deductibles. And I am wondering how we might need to address that at the same time we are looking at these issues.

Mr. GOBEILLE. So just an idea. The way that we treat colonoscopies, the way that we treat primary care services under the Affordable Care Act is that those are included, you know, as a benefit. Services like this could be included and not necessarily go against your deductible.

And so it is a question of, you know, how you want to set up the insurance marketplace so that people actually participate, you know, in different types of prevention alternatives. And, you know, that would be, you know, for others denied, but I would think we would have to take a hard look at that.

Mr. SMITH. Okay, very well.

Thank you. I yield back.

Chairman ROSKAM. Mr. Kind.

Mr. KIND. Thank you, Mr. Chairman, and I welcome you and congratulate you on your new position. I look forward to working with you.

Gentlemen, thank you for being here. And I, in particular, have been paying very close attention to the challenge you face in Vermont. I mean, you have a large rural State. I have a very large rural district in western Wisconsin. We face many of the same issues, and we appreciate your insight on this.

And I also, Governor, appreciate your opening comments, as a former special prosecutor who dealt in the drug world for a long time. I have had a lot of forums, a lot of listening sessions back home, including with law enforcement, and I haven't met anyone yet who thinks we are going to be able to deal with this through the criminal justice system. This has to be a public health approach ultimately to break the cycle of addiction for us to have any fighting chance to get out ahead of that. So I appreciate your insight on that.

Governor, I was wondering if you have been following closely the Trump Administration's Commission on Combating Drug Addiction and the Opioid Crisis, because last November, they did come out with a fairly detailed report and findings and recommendations that were submitted to us here in Congress for our consideration. Have you had a chance to look at that or review that at all?

Governor SCOTT. Yes. Our team has taken a look at that. We, again, have set out on our own course that we think is working. Some of them were replicated within the report. But we are always looking for new information.

And, again, one size doesn't fit all, as we have found out. And there are always new opportunities to do something better. So we are still looking at the report, determining if there is anything that we can use to make better use of our system.

Mr. KIND. Some of the recommendations are kind of commonsense principles that do apply across the board. I mean, increasing

access to substance abuse treatment programs. We are going to hear further testimony today on that. Also, under Federal law, insurers are already required to cover addiction treatment and mental health services. Many of them aren't, and many of them aren't including them within their networks. And it is especially difficult in rural areas, given what is available out there. They also recommended dedicating more money for treatment overall. They are encouraging greater use of alternative and complementary forms of medicine, rather than just a cocktail of prescription drugs that often lead to addiction and then contributing to the opioid epidemic.

One of the recommendations—I am wondering if you had a chance to look at it or have an opinion—is recommending that we give the Department of Labor the authority to start penalizing insurance companies that aren't including it in the network and are not adequately providing coverage for addiction treatment or other mental health services.

Is that something we ought to be considering?

Mr. GOBEILLE. So what I would say is that while they were holding their meetings and writing their report, our Opioid Coordination Council, which I chaired, we were writing a report as well. And we came out almost the same on so many issues. It, you know, really came out right at the same time. And the NGA also has a report. So there is a lot of common sense in all the documents. So I agree with your points.

The last question that you asked, I think that we have to embrace this as a chronic condition. And then, if we do, we should make Medicare, Medicaid, and commercial insurers treat this as an essential health benefit, like we would kidney disease or diabetes or some other chronic condition.

So yes, I would think that would be——

Mr. KIND. The other thing I think we ought to be considering is, since you guys are out front doing a lot of good work and trying to get out, and virtually every State is trying to do the same thing, is some type of national repository of best practices and best evidence medicine, what is working and what isn't, so each State isn't required to, you know, recreate the same wheel over again.

Interesting. Even though we have been going through problems with VA reform lately, we have had some success in a bipartisan fashion implementing certain reforms with the VA Medical Center, especially when it comes to pain management and drug addiction. In fact, in my home area, Tomah, Wisconsin, the VA Center is developing a really interesting model with a tremendous track record of proven results that could become a model of care throughout the country if we do it right. So I would also take a closer look at what the VA has been doing on this front for some time.

Thank you, Mr. Chairman.

Chairman ROSKAM. Hold that thought and kind of weave your answer into an inquiry that is coming from Ms. Jenkins from Kansas.

Ms. JENKINS. Thank you, Mr. Chairman.

And thank you, Governor, for being with us on the Subcommittee. Like Vermont, my home State of Kansas is struggling with a nationwide opioid epidemic. In my view, it is particularly

difficult for rural States to expand access to opioid treatment services, just because of a lack of treatment facilities and trained medical personnel. So Vermont's Hub and Spoke approach may very well be a model for our Nation.

In your written testimony, you mentioned strategies for prevention, harm reduction, early intervention, criminal justice, treatment, and recovery. Your testimony brought to mind just a couple questions I would like to ask.

The first is that it is my understanding that there is a low uptake in the electronic prescribing of controlled substances. Is the State of Vermont doing anything to encourage prescribers to utilize e-prescribing and, if so, can you just talk a little bit about any pushback the State may have received in implementing those proposals?

Mr. GOBEILLE. I had to phone a friend. We use e-prescribing, and according to the smarter people than me behind me, we are good in that area even though we are rural and small. And so we could get you more information and submit that in writing, if that would be okay.

Ms. JENKINS. I would be interested if you had any pushback. Yeah, if you could get back to me, that would be great.

Mr. GOBEILLE. But about the pushback, I think what is interesting, the way the Congressman from Vermont was introduced as somebody who could, you know, politely tell somebody to jump in a snowbank, in Vermont, it is really hard to fight back common sense, because we are so small and we all know each other. And so we don't run into that as much as you might think.

Ms. JENKINS. Okay. I am told that substance abuse community clinics and residential treatment centers still use telephone, paper records, and faxes to communicate with each other and the larger medical systems. I have introduced H.R. 3331 with my friend, Congresswoman Doris Matsui, that would authorize a health IT demonstration for behavioral health providers.

Do you think electronic health records can play a role in States' efforts to combat the opioid crisis? And how is it the State of Vermont is using electronic health records?

Governor SCOTT. The simple answer is yes.

Mr. GOBEILLE. No, the simple answer is that is brilliant. So I am a restaurant owner, got into this, you know, sort of later in life. He was a construction company owner. And we thought we were behind the 8-ball in terms of being modern until we really got to work in healthcare. I mean, I haven't seen a fax machine or a typewriter in a long time, but you can find them in some behavioral health clinics and some doctors' offices.

So the point you are making is right on target. There is not the electronic systems that are necessary to run our community mental health agencies and the like at the level that most people would think they would have, FQHCs as well, et cetera.

Governor SCOTT. I would like to offer as well that when we talk about some of the treatment centers in our rural areas, it does put a burden on many who are seeking treatment. And when you think about in some of our rural sections, we had a waiting list in one area of 700 waiting for treatment. And that doesn't lend itself well

for those seeking treatment when they have to be put on a waiting list.

As well, those who were in treatment at that time, it was so far away that they would spend 2 hours driving to or taking a bus going to a treatment center to receive their treatment on a daily basis, 2 hours one way and then 2 hours back, an hour's worth of treatment. So, for those who were expecting to reintegrate into the workforce and be part of society again, it doesn't lend itself well when you are trying to take care of your family and to find a job where it is flexible enough so you can receive treatment.

So it is something—we did put a Hub in that area. We reduced that level from 700 to zero. We don't have a waiting list in that area anymore, and that is successful. I mean, that was a time when we took a moment to celebrate success because you don't have much success in some months. But that was a time when we said we are doing something fruitful in a positive way.

Chairman ROSKAM. Thank you.

Ms. Sewell.

Ms. SEWELL. I want to thank the Chairman and Ranking Member for hosting today's forum.

As many of us have seen, more Americans died from drug overdoses in 2016 than the number of those lost in the entirety of the Vietnam war. And preliminary data from CDC suggests that 2017 was even worse than 2016.

I want to thank you, Governor Scott, for your leadership on this topic as well as your testimony today. It is my hope that more States, including my own State of Alabama, will realize the successes achieved in Vermont and implement similar strategies to tackle this growing epidemic.

You spoke a little to your administration's focus on the importance of helping people in recovery return to gainful employment. I, like you, Governor Scott, have met with many people who are in recovery who tell me that it is the dignity of a job that keeps them going and that keeps their families going as well. So I think it is really important that we have models that stress the importance of getting gainful employment even when you are still in treatment, as you suggested earlier.

The way we address this public health crisis will serve as a model for decades to come on addiction treatment. I believe we made a terrible mistake in the 1980s as a country in our response to the crack cocaine epidemic, where we are seeing that the response we gave was for more jails and not for more treatment centers.

I am very happy that, with this epidemic, we are seeing that it truly is a public health crisis, and it is a crisis that requires intergovernmental help and lots of wraparound services, and so figuring out how we can get best practices I think is really important.

An issue I worked a lot with in my rural areas is transportation. And so often getting access to treatments has been a big problem in the State of Alabama. In fact, I introduced a bill with Congressman Meehan. It is a bipartisan legislation that would allow Medicare Advantage plans to offer a wider array of supplemental benefits to chronically ill enrollees, such as transportation and nutrition

programs and mental health services. I believe we should implement this type of benefit expansion across Medicare programs.

So I guess my question to you is, Governor Scott, would you recommend expanding coverage for treatment in Medicare, and can you explain why you believe improved Medicare coverage for treatment of opioid abuse is important in fighting this epidemic?

Governor SCOTT. Absolutely. I am going to let our Secretary answer, fill in the gaps, but I did want to mention that is what the beauty is of this Hub and Spoke model, that we can have treatment facilities closer to those who need it. And when we see an area, such as we did, that needed more treatment, we set up another Hub. So it is essential that we react every time that we see an issue.

I would also say, with the introduction and the use of Narcan in our State, I am afraid that the number of deaths that we are seeing, which is almost the same as the previous year, doesn't tell the whole story, because we are preventing a lot of deaths from happening. So that doesn't mean that—just because they are staying the same doesn't mean that we are necessarily making a lot of ground up. So we have to fulfill that.

Stigma is an important part of reintegrating, again, those into the workforce. And I think we have made some positive gains in that respect. A lot of employers we are speaking with, we are making a concerted effort through our Labor Department to try to determine—you know, give those folks a second chance or third chance or fourth chance, because sometimes it is not the first time or the second time; it is the third time.

I had employees of mine that we all are aware, more aware now than we were then, that were addicted, and I didn't know it. And they were great employees. And so we gave them that chance, that opportunity to succeed.

Ms. SEWELL. Thank you.

Chairman ROSKAM. Mr. Marchant.

Mr. MARCHANT. Thank you, Mr. Chairman.

Governor, you spent some time in the legislative branch. Do you think that your State has passed sufficient laws and statutes to give you the tools that you need to combat this? I have three questions. I will ask all three of them.

Second, who in Vermont recognizes this dependency? Is it the State? Is it the doctor? Is it the person themself that recognizes that they are addicted, or is there a definition that the State has?

And the last question is, is most of the acquisition of the opioid legal or illegal?

Mr. GOBEILLE. Sorry, sir?

Mr. MARCHANT. The acquisition of the pills. I mean, are they getting the pills legally, or are they buying them on the black market or from a dealer, as a percentage of the people that are——

Governor SCOTT. I will try to answer some of those and, again, I would ask my Secretary to fill in the gaps. But what we are seeing is a lot of the crime rate is due to obtaining some of the prescription drugs even and some of the unused prescription drugs in medicine cabinets. That is why the take-back program is so necessary. Those who have been utilizing opioids, their kids get in-

volved. They take the drugs. They sell them or utilize them themselves. That is an issue.

I am trying to recall the rest of your question.

Mr. MARCHANT. Has your legislature passed the statutes that you need?

Governor SCOTT. Continually. I think we have a good working relationship. Again, I have served in the Minority, but we have always worked together, trying to do whatever we can, because we recognize this isn't a partisan issue. This is an issue that faces each and every one of us. It doesn't discriminate. Whether you are Republican or Democrat, it doesn't discriminate. It doesn't discriminate from a social standpoint either. So we recognize that, and we have been given many of the tools, and we continually seek resolutions to try to obtain more.

Mr. GOBEILLE. And I think the last question you asked is, what door do you walk through to get treatment in Vermont? And we try to——

Mr. MARCHANT. Who declares that you need treatment? Is it usually self-declared or——

Mr. GOBEILLE. So what I would say is that, for treatment to work, it pretty much has to be self-declared, meaning on a base level, it has to be a recognition that the person has to make.

But, also, through the screening tool that the Governor talked about in his opening remarks that we use in primary care offices, in emergency rooms, and in other healthcare delivery sites in our State, it allows for the conversation to happen with your healthcare provider or a healthcare provider where you may become aware of your behavior to help you get there.

But, also, our Hub and Spoke model, the Hub is actually not just a Hub for treatment. It is a Hub of activity where you can go to receive counseling on your addiction and your options. We also have recovery centers in the State where you can go to basically reach out and get peer support for recovery.

So we have a lot of different doors you can open. We are in the position now of how do we get more people into treatment, because now we can meet the needs of treatment. The Governor articulately went through our waiting list. We just recently in the last 6 months have gotten to the point where we have eliminated the waiting list. So now we are trying to figure out how to get more people into treatment.

Mr. MARCHANT. Thank you.

Chairman ROSKAM. Mr. Blumenauer.

Mr. BLUMENAUER. Thank you very much for joining us. I appreciate your efforts to kind of put a comprehensive picture on the table for us, and I think each and every one of us on an ongoing basis is struck by how complex and interdependent these elements are in our own community.

We are troubled with addiction, homelessness, mental illness, nothing rising probably to the level in terms of the death and destruction of opioids, but there are a whole series of interrelated pieces. And there is lots of blame to go around: the Federal Government was asleep at the switch; problems with the pharmaceutical industry; with the medical profession.

And I appreciate your taking us through your outline of what we could be doing. I was particularly struck by your fourth point: Your small State could benefit tremendously from nationally supported research for areas of alternative treatment for pain. People are driven to opioids often when there are, in fact, cheaper and more effective alternatives, starting with therapy, but I would also point out one that my State has been a pioneer in, and that happens to be medical marijuana.

There is pretty strong evidence that where medical marijuana is available, there are fewer opioid deaths. I think in the State of California, it is a third less than the national average.

And I have had countless people, veterans, tell me what a difference it made for them to be able to have an alternative that was cheaper, less toxic, they played—they felt more comfortable with.

NFL players are suspended routinely, maybe not the wife beaters, but the people who are caught self-medicating with pot because they don't want to get shot up with painkillers, in some cases leading to tragic, tragic consequences.

I am hopeful that this might be an area that we can explore. You just became the first State to have the legislature approve adult use of marijuana, something every other State in the Union, 30 States, have done by a vote of the people who have been ahead of the politicians on this.

And I wonder if you have some thoughts about opportunities to use medical marijuana as an area to expand these treatment options to be able to properly research it, to get rid of the Federal prohibition on robust medical marijuana research and be able to explore this as an alternative to this plague.

Governor SCOTT. We passed medical marijuana when I was in the Senate, and I voted in favor and was one of the few Republicans that did. I was serving with Congressman Welch at the time.

We recognize that one size doesn't fit all, that that is why we need as much flexibility as possible, all different types of treatment on the table so to speak, so that we have everything at our—in our power to confront this.

My wife is an RN. She lives this on a daily basis. She sees it in the office on a daily basis, all the abuse in terms of prescription drugs. But my wife is a runner as well, an athlete. And she has had a number of knee surgeries. She thought her running was over.

And she started using this oil therapy about a year and a half ago, and she is back to running. She did a 10-miler about 2 months ago. So this works for her. My point is we just need everything on the table. We can't allow ourselves to be—put blinders on in terms of what might work for one that might not work for another.

Chairman ROSKAM. Mrs. Black, another RN.

Mrs. BLACK. Yes, and thank you, Mr. Chairman.

And thank you to your wife who is an RN and a runner. So I applaud you for tackling this issue that is a very large problem.

And I want to go to the side, as you would expect an RN to do, and that is, how can we stop this from happening to begin with, because the cost of life, the cost of treatment, and the cost of the illegal activity is certainly very, very large?

And so I am very interested in what you said in your opening statement about the prevention piece of it and how your State is using the prescription monitoring system to help physicians. However, I do see in here, later on, you say that, for the first time, we are beginning to see the amount of opioid prescriptions decline. It is discouraging to note, however, that we still prescribe three times as much as we did in 1999.

So there is a little bit of a contrast there about having a system where we can see what is going on, and yet there still seems to be more of this being prescribed. Can you help me out with that?

Governor SCOTT. Well, again, in 1999, it went—it skyrocketed after that. There was just much more opioid prescription use. So we have seen, since we implemented that policy, we have seen it go down significantly. So—but still, compared to 1999, we are still using three times as much.

Mrs. BLACK. So is this real time for your physicians that they can get into a computer and see whether someone has a prescription filled? And this is real time?

Governor SCOTT. Yeah, I believe it is. Yes, go ahead.

Mrs. BLACK. Okay. So that is very, very helpful.

Mr. GOBEILLE. So it is real time, yeah.

Mrs. BLACK. Okay. Let me go to the second piece, the early intervention and the prevention piece, the screening, the brief intervention referral to the treatment protocol, all of those things that are done in the emergency rooms and primary care.

Is someone coming in that is self-referred, or is this happening when they come in for other kinds of treatment that the practitioner would say, "Maybe this is something I need to address," and talk about how is that actually done?

Governor SCOTT. I think it is all of the above, actually. It could be from many different situations to at least make others aware of the situation.

Mr. GOBEILLE. Yes. So the way we did this was we received a grant and some Federal money to be able to do this in one hospital, and we started there and we have kind of spread out. And we don't do it everywhere in the State yet, but we do it across a large part of—the majority of the State.

And it isn't just if you come in saying you think you have an issue with addiction or substance use disorder. It is literally if you come in for something else, we begin a screening process that sort of—that begins the conversation. And depending on how you answer questions and interactions, we go further and further and further.

Mrs. BLACK. So you do the screening process on every patient that comes in; they answer a screen, and then, from there, you make a determination?

Mr. GOBEILLE. Right.

Mrs. BLACK. Okay. I had one additional question. In many other States, we see doctor shopping. Have you seen that in your State? Do you have pill mills? Do you see that doctor shopping?

And do you also have those pain management facilities that are for cash only? Are you experiencing that in your State?

Governor SCOTT. I don't think we see the pill mills in Vermont, but certainly we see the doctor shopping, and some of this electronic monitoring would help preclude that.

Mr. GOBEILLE. Yeah. So what is interesting is we don't have what you think of as the traditional pill mill, but we certainly had the issues you are describing. Doing the Spokes and having over 200 primary care providers working together to try to basically deal with treatment, it has been really good for communication across the practice, and so it has cut down on doctor shopping.

But also, our prescription monitoring system has improved every year, and it is at the point now where doctors can see that going on through software.

Mrs. BLACK. Thank you. My time is expired.

Thank you, Mr. Chairman.

Governor SCOTT. Keep in mind as well, if I could add—just add——

Chairman ROSKAM. Wow, sliding into home. Nice.

Governor SCOTT. Keep in mind that if you shut someone off from the prescription drug, the opioid, they find another method. They go to heroin or fentanyl. I mean, it is cheaper sometimes, so that is the problem.

Chairman ROSKAM. Mr. Higgins.

Mr. HIGGINS. Thank you, Mr. Chairman. And congratulations as well on your ascension to the Subcommittee Chair.

My community, too, is devastated by the opioid deaths and overdoses. There were 316 in Erie County in New York State. Half of those were in the city of Buffalo. I just want to focus in on fentanyl. Fentanyl is a—it is a powerful artificial opioid, and it accounted for about 60 percent of the deaths in my community of Buffalo and Erie County.

Mexico is a source of much of the illicit fentanyl that is for sale in the United States. Starting in 2015, Canada has seen a massive increase in fentanyl overdoses. You know, we are currently engaged in a renegotiation of the North American Free Trade Agreement.

And I have always believed that the United States and Canada—the United States, a Nation of 323 million people, Canada, a nation of 36 million people—doesn't effectively use its leverage in trade negotiations with a place like Mexico.

You know, Mexico's minimum wage is $4.70, not an hour, a day, which, if you assume it is an 8-hour day, is 57 cents an hour. In free trade, we should be using our leverage to stop this illicit transport, export of fentanyl to the United States and Canada. It is a new twist on a larger problem. I am just curious as to your thoughts about the viability of something like that.

Governor SCOTT. Well, again, we watch with interest the NAFTA negotiation. We share as well a border with Canada, and they are our largest trading partner, essential to the vitality of Vermont's economy.

So we are hopeful that we can get through some of those, but I think that there should be an update to NAFTA, and I believe that we should be trying to do whatever we can to level the playing field, and that may be an area that we should look at.

Mr. HIGGINS. Okay. The President in October declared that the opioid epidemic was a national health emergency. As you know, we

have been kind of stuck in terms of doing a series of continuing resolutions, which is really a failure to do fundamentally what Congress needs to do.

But, obviously, money is a big issue here as it relates to treatment. Have you seen any change, at least in terms of your personal experiences, since that declaration was made in October, or is that something prospective that just hasn't gained traction yet?

Governor SCOTT. I don't believe we have seen any difference since that declaration because we were—have been actively pursuing that. And we have been blessed with having good partners, again, with the Congress as well as with our—the Administration and this previous Administration as well in trying to confront this.

So we have—they have given us some flexibility, and I think that has been essential. And if there is one thing that I can underscore and emphasize it is this: Allow us flexibility, and we will find the pathway forward.

Mr. HIGGINS. I yield back, Mr. Chairman. Thank you.

Chairman ROSKAM. Thank you.

Well, Governor, thank you, and, Mr. Secretary, thank you. I just want to say thank you very much for your time today. We are being called in for votes.

Let me ask you one wrapup question, if I could. Our Subcommittee, and this Committee in particular, is focused on Medicare. The first point that you made in your four points was in particular as it relates to Medicare.

Let me just restate that part to refresh everybody's recollection, and then I just want you to give us a little bit of commentary about what this means. So what you have proposed is Medicare needs to treat addiction as the chronic health condition that it is.

And then you said you sent a letter to the Secretary of Health and Human Services asking that CMS work with Vermont to engage Medicare in Vermont's system of care, specifically the Hub and Spoke system: Working with our Federal partners, we hope to develop a path to make this a reality; Medicare could also assure that the FDA-approved medications for opioid addiction are available for beneficiaries.

I want to sort of go back to Mr. Marchant's inquiry when he was asking about sort of the declaration of who is addicted. Can you just give us a little bit more insight?

Is this a situation where, in order for this to be successful at all, someone has to self-identify as an addict, or does the Hub and Spoke system work for folks that are not acknowledging themselves as addicts but who are clearly addicts? Can you speak to that tension? Maybe it is a question for the Secretary or medical professionals.

Governor SCOTT. Yeah, I am going to let him answer the rest of the question, so to speak. But I would, again, underscore that if they are not ready to admit they have an issue and to seek treatment, it is probably going to fail. And so to force someone into treatment is probably a recipe for failure as well.

Secretary.

Mr. GOBEILLE. Yeah. So what I would say is there is a definition of opioid use disorder, and, you know, they would have to meet

that clinical definition. And so, you know, that is sort of the black-and-white answer.

But I think from a—you know, from a human perspective, when you think about caring for the whole patient or the whole population, to have something that is such a fundamental problem with someone's health and not be able to treat it as basically the illness that it is with the payer that they have sort of distorts the healthcare system.

And so what we are trying to do is work with CMMI and CMS to say we have an all-payer model that we have agreed to with the Federal Government to really take responsibility for what we spend on healthcare. And in order to do that, you have to treat the whole person and the whole population, and this needs to be an integral part of that.

Governor SCOTT. And if you want to break down the stigma, this is one way to do it, to treat them the same.

Chairman ROSKAM. Well, your insights have been really helpful today. And you didn't clear the room, by the way. You didn't clear the dais; it was the fact that we have been called for a vote.

But I just want to let you know how much I appreciate—and I know I speak on behalf of the Ranking Member as well—your willingness to come and share your experience. We appreciate your forthrightness with the strengths and weaknesses, the things that you have learned, and the things that you have struggled with.

And I know that we are going to continue to be interacting on this issue because this is a problem that is very dear to all of us, and I mean literally all of us. And it is an area where there is good work that can be done. And I think people of good will and tenacity willing to give others the benefit of the doubt as we move forward can be really, really significant.

So I sense you have something else to say, Governor, so why don't you respond?

Governor SCOTT. Well, I only wanted to say that we extend an invitation to anyone on your Subcommittee who would like to come up and see it for themselves. We would happily show them what we have done so that they can see it.

Chairman ROSKAM. Thank you.

So the Committee stands in recess subject to the call of the Chair. We are going to go into recess and vote, and we will look forward to hearing from our next panel.

So thank you very much. We will be back shortly.

[Recess.]

Chairman ROSKAM. The Committee will come to order. Thank you, all. I know I speak on behalf of everybody who is reassembling here and thank you for your patience.

As I mentioned, your opening statements are a part of the record, and the Members have had an opportunity to review them. I think that in the interest of time, why don't we begin to proceed. I will recognize each of you for 5 minutes, and we will give you a little bit of guidance in terms of the timing, and then we will open it up for questions from our Members.

So, again, thank you for your patience. We really, really appreciate it. Dr. Benyamin, you are recognized for 5 minutes.

STATEMENT OF RAMSIN M. BENYAMIN, M.D., PRESIDENT AND FOUNDER, MILLENNIUM PAIN CENTER, AND BOARD OF DIRECTORS, AMERICAN BOARD OF INTERVENTIONAL PAIN PHYSICIANS

Dr. BENYAMIN. Chairman Roskam, Ranking Member Levin, and distinguished Members of the Committee, thank you for the opportunity to provide my views on behalf of American Society of Interventional Pain Physicians, known as ASIPP.

I am Dr. Ramsin Benyamin, and I am the Medical Director of Millennium Pain Center in Illinois. I have been practicing interventional pain management for over 20 years. My academic appointments are with the University of Illinois, Illinois Wesleyan University, and A.T. Still University of Missouri.

I serve on the editorial board of several pain management peer-reviewed journals and have over 150 publications, the most recent of which is our society's 2017 guidelines for responsible, safe, and effective prescription of opioids.

In the past, I have served as the President of ASIPP, and I am currently on the board of directors. I am also the President of Illinois' Society of Interventional Pain Physicians.

ASIPP is a not-for-profit professional organization founded in 1998, now comprising over 4,500 members who are dedicated to ensuring safe and appropriate access to pain management services using interventional techniques in addition to medical management.

As an organization, ASIPP has always been cognizant of prescription opioid dangers and began issuing warnings and offering preventive measures in early 2000 with its proposal of a national program known as NASPER, which eventually was signed into law as a State-run prescription drug monitoring program in 2005.

Despite challenges in implementation of the national program, all 50 States now have prescription drug monitoring programs. Many of the common painful ailments, like spine degeneration, disk herniations, spinal stenosis, headache, pathologic fractures, and postsurgical chronic pain, if not managed timely by interventional pain techniques, would result in more invasive and costly procedures, raising the risk of dependency on more or higher doses of opioids.

Currently, one in every three Medicare Part D recipients is on prescription opioids. Based on current data, despite reduction in opioid prescriptions since 2010, the majority of overdose deaths are mainly due to synthetic fentanyl and heroin abuse.

Mr. Chairman, the pill-to-heroin shift has occurred, and that also involves lacing of marijuana with heroin or fentanyl. That is killing many of my fellow citizens in Illinois.

As a result of this disturbing trend, on behalf of ASIPP, I am suggesting legislative reforms to curb opioid abuse and reduce opioid deaths while maintaining appropriate access and promoting nonopioid modalities like interventional techniques.

Unfortunately, reductions and cuts continue to limit access to physical therapy, interventional techniques, and even nonopioid medical therapies while the opioid death rate continues to escalate.

Our proposal includes a three-tier approach. Tier one: An aggressive public education campaign focused on the dangers of illicit

drugs, specifically heroin and fentanyl; a public education campaign relating to the adverse consequences of prescription opioid abuse, particularly in combination with benzodiazepines; and a mandatory 4 hours of continuing education for all prescribers of any amount of opioids or benzodiazepines.

Tier two: Improved access to nonopioid techniques, including physical therapy and interventional techniques, by lowering or eliminating copayments; expanded low-threshold access to buprenorphine for opioid use disorder treatment; enhanced prescription drug monitoring program, including a national program like NASPER, which States having mandated capability to interact with the rest of the States or at least the neighboring States; and mandated review of prescription drug monitoring data by all prescribers prior to prescribing a controlled substance.

Tier three: Buprenorphine must be available for chronic pain management with rescheduling it to a schedule two; and removing methadone from formulary. This medication, despite being only 1 percent of total prescription opioids, results in more than 3,000 deaths every year.

Thank you, again, for allowing our organization the opportunity to testify. I will be glad to answer any questions.

[The prepared statement of Dr. Benyamin follows:]

TESTIMONY OF RAMSIN BENYAMIN, MD, BLOOMINGTON, IL
BEFORE WAYS AND MEANS COMMITTEE
US HOUSE OF REPRESENTATIVES
DATE: TUESDAY, FEBRUARY 6

Chairman Roskam, Ranking Member Levin, and distinguished Members of the Committee:

Thank you for giving ASIPP this opportunity to provide our views on reforming approaches to curb drug overdose deaths and improve care of chronic pain with nonopioid treatments.

I am Dr. Ramsin Benyamin and I am the Medical Director of Millennium Pain Center, a practice with other physicians in Bloomington, IL. I am also Clinical Assistant Professor of Surgery, College of Medicine, at University of Illinois, Urbana-Champaign, IL, and Adjunct Research Professor, Department of Psychology, at Illinois Wesleyan University, Bloomington, IL. I have participated in multiple clinical trials and published over 150 peer-reviewed articles. I also have clinics in Peoria, Decatur, Pekin, Champaign, Libertyville, and Chicago, IL. I have been in the practice of interventional pain management for over 20 years. In the past, I have served as President of the American Society of Interventional Pain Physicians (ASIPP) and I am currently on the Board of Directors of that society. I am the President of the Illinois Society of Interventional Pain Physicians.

The American Society of Interventional Pain Physicians is a not-for-profit professional organization founded in 1998 now comprising of over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States. ASIPP is comprised of 50 affiliated state societies, and the Puerto Rico Society of Interventional Pain Physicians. As an organization, ASIPP began issuing warnings and offering preventive measures in early 2000 with its proposal of a national program --- the National All Schedules Prescription Electronic Reporting Act (NASPER), which eventually was signed into law as a state-run prescription drug monitoring program in 2005. As you know, I am happy to state that all 50 states now have PDMPs. In fact,

mandatory provider review of prescription drug monitoring programs and pain clinic laws have shown to reduce the amounts of opioids prescribed by 8% and prescription opioid overdose death rates by 12%. In addition, it has also been shown that relatively large reductions in heroin overdose death rates after implementation of mandatory prescription drug monitoring programs and pain clinic laws as of 2015.[1] ASIPP also offers extensive educational efforts for pain physicians including a variety of review courses and competency examinations.

Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing sub acute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment.[2]

Interventional pain management techniques are minimally invasive procedures including, percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic discectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain.[3]

Unfortunately, opioid deaths continue to increase at a dramatic pace despite reductions in opioid prescriptions since 2010.[4] No doubt opioid prescriptions are still explosive with the amount of opioids prescribed in the United States continuing to be 3 times higher than in 1999, the year ASIPP developed our idea of the National All Schedules Prescription Electronic Reporting Act (NASPER). Yet, in 2017, the national opioid epidemic continues to show escalation. Drug overdoses accounted for 64,000 deaths in 2016, with over 42,000 of opioid deaths, a 20% increase from 2015 from over 52,000. Increases are greatest for overdoses related to the category including illicitly manufactured fentanyl, which more than doubled, accounting for more than 20,000 overdose deaths in 2016 versus less than 10,000 deaths in 2015. This difference is enough to

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[1] Dowell D, Zhang K, Noonan RK, Hockenberry JM. Mandatory provider review and pain clinic laws reduce the amounts of opioids prescribed and overdose death rates. *Health Aff (Millwood)* 2016; 35:1876-1883.

[2] The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management- 09. www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf

[3] Medicare Payment Advisory Commission. Report to the Congress: Paying for interventional pain services in ambulatory settings. Washington, DC: MedPAC. December. 2001. http://www.medpac.gov/documents/reports/december-2001-report-to-the-congress-paying-for-interventional-pain-services-in-ambulatory-settings.pdf?sfvrsn=0

[4] Guy GP, Zhang K, Bohm MK, et al. Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015. *MMWR Morb Mortal Wkly Rep* 2017; 66:697-704.

account for nearly all increases in drug overdose deaths from 2015 to 2016.[5,6] Consequently, while fentanyl contributed to 20,000 deaths, heroin contributed to 15,000 deaths, whereas prescription drugs contributed to less than 15,000 deaths (Figs. 1-3).[4,7] Deaths due to heroin were up nearly 20% and deaths from other opioids such as hydrocodone and oxycodone were up 14%. Deaths due to methadone declined; however, they still constitute an extremely high percentage with over 3,000 deaths, which is only 1% of prescriptions. As we all realize, things might very well be worse than what is shown in the data. The present problem of overdose deaths is mainly due to illicit fentanyl and heroin use with contributions from prescription opioids. As you may know, Fentanyl is approximately 50 times as potent as heroin. This provides strong economic incentives for drug dealers to mix fentanyl with heroin and other drugs because smaller volumes can provide equally powerful effects at lower costs and easier transport.[5] Ironically, the majority of people who use heroin are not seeking fentanyl and essentially try to avoid it.[8] However, technology has improved so much that it is difficult to identify fentanyl, particularly in white powder form, and heroin is typically sold more in states, east of Mississippi river.[9]

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[5] Dowell D, Noonan RK, Houry D. Underlying Factors in Drug Overdose Deaths. *JAMA* 2017; 318:2295-2296.

[6] US Centers for Disease Control and Prevention. Provisional counts of drug overdose deaths as of August 6, 2017. https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

[7] Ingraham C. CDC releases grim new opioid overdose figures: 'We're talking about more than an exponential increase.' *The Washington Post*, December 21, 2017. https://www.washingtonpost.com/news/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm_term=.f3f893febb8b

[8] Carroll JJ, Marshall BDL, Rich JD, Green TC. Exposure to fentanyl-contaminated heroin and overdose risk among illicit opioid users in Rhode Island. *Int J Drug Policy* 2017; 46:136-145.

[9] Gladden RM, Martinez P, Seth P. Fentanyl law enforcement submissions and increases in synthetic opioid-involved overdose deaths. *MMWR Morb Mortal Wkly Rep* 2016; 65:837-843.

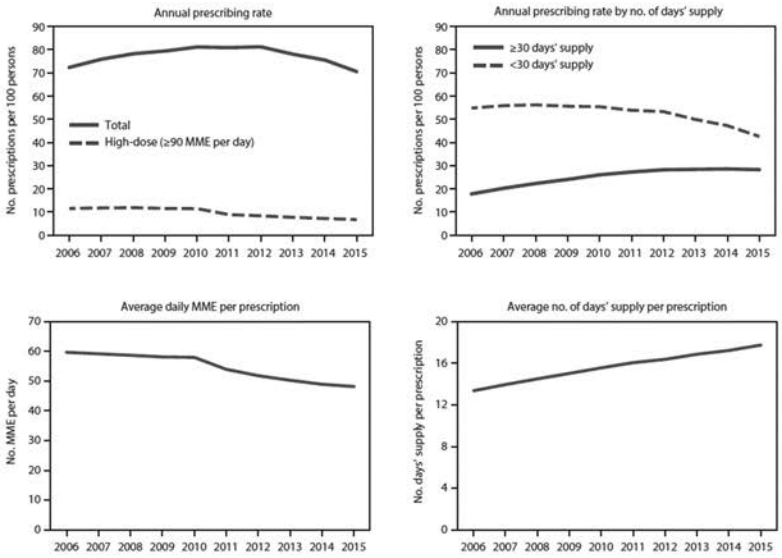

Fig. 1. *Annual opioid prescribing rates, by number of days' supply, average daily morphine milligram equivalent (MME) per prescription, and average number of days' supply per prescription — United States, 2006–2015.*

Source: Guy Jr GP, et al. Vital Signs: Changes in opioid prescribing in the United States, 2006-2015. MMWR Morb Mortal Wkly Rep 2017;66:697-704.[4]

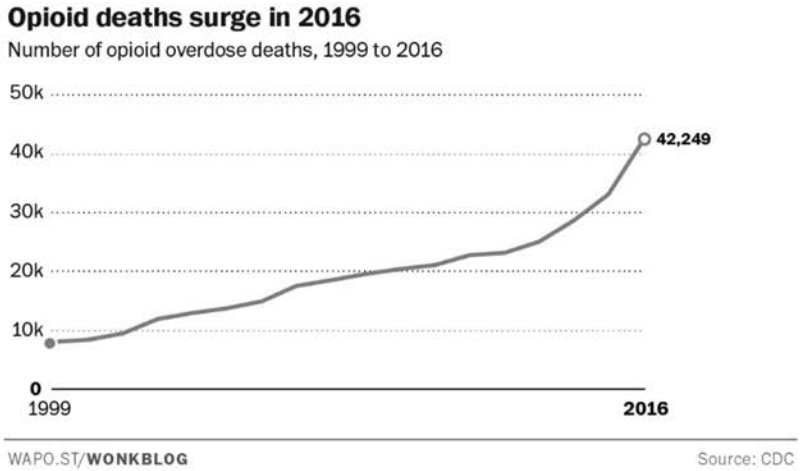

Fig. 2. *Opioid deaths surge in 2016. Number of opioid overdose deaths by category, 1999 to 2016.*

Source: Ingraham C. CDC releases grim new opioid overdose figures: 'We're talking about more than an exponential increase.' *The Washington Post*, December 21, 2017.[7]
https://www.washingtonpost.com/news/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm_term=.f3f893febb8b

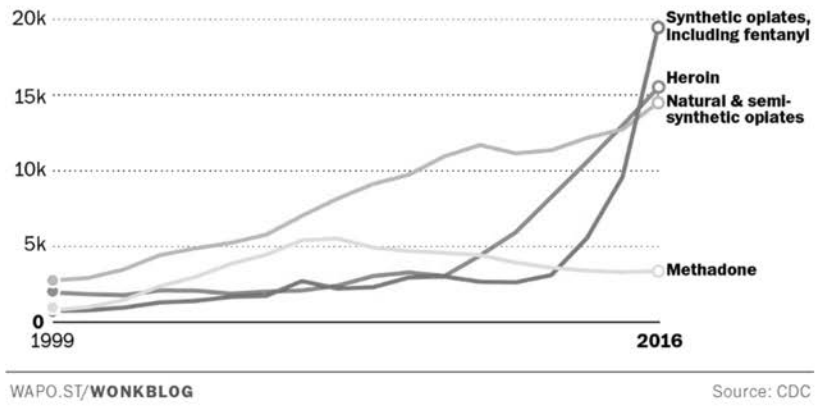

Fig. 3. *Opioid deaths surge in 2016. Number of opioid overdose deaths by category, 1999 to 2016.*

Source: Ingraham C. CDC releases grim new opioid overdose figures: 'We're talking about more than an exponential increase.' *The Washington Post*, December 21, 2017.[7]
https://www.washingtonpost.com/news/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm_term=.f3f893febb8b

In addition, recent data shows that the number of people presenting for opioid treatment with heroin abuse has increased from 8.7% in 2005 to 33.3% in 2015.[10] There also has been an increase in self-reported fentanyl use among the population entering drug treatment from 9% in 2013 to 15% in 2016, referred to as "unknown fentanyl" products.[11] Consequently, the number of prescription opioid admissions is declining and illicit fentanyl and heroin admissions are increasing.

[10] Cicero TJ, Ellis MS, Kasper ZA. Increased use of heroin as an initiating opioid of abuse. Addict Behav 2017; 74:63-66.

[11] Cicero TJ, Ellis MS, Kasper ZA. Increases in self-reported fentanyl use among a population entering drug treatment: The need for systematic surveillance of illicitly manufactured opioids. *Drug Alcohol Depend* 2017; 177:101-103.

Thus far, the effectiveness of numerous interventions to curb opioid epidemic has been limited, including prescription drug monitoring programs, pain clinic laws, treatment of opioid use disorder, guidelines, and numerous other policies.

As a result of this disturbing trend, we, at ASIPP are suggesting more effective legislative efforts to curb opioid abuse and reduce opioid deaths, while maintaining appropriate access, and the promotion of nonopioid modalities including interventional techniques.[12] Consequently, we, at ASIPP propose a 3-tier approach to achieve these goals.

Tier 1 includes the following:

1. An aggressive public education campaign with explicit teaching on the dangers of the use of illicit drugs, specifically heroin and fentanyl.
2. A public education campaign relating to the adverse consequences of opioid abuse in general with emphasis on the adverse consequences in combination with benzodiazepines.
    - A recent survey published in the *New England Journal of Medicine* shows that the public blame the opioid crisis on physicians, pharmacists, and pharmaceutical companies without putting much responsibility on patients. Forty-six percent of the public puts the blame on doctors who inappropriately prescribe medication (33%) and 13% put the blame on pharmaceutical companies that sell prescription medication but only 28% blame people who sell prescription pain killers illegally and 10% put the blame on people who take prescription pain killers.[13]
    - In addition, the public believes that public education and awareness programs are effective in a large proportion of patients.
3. Mandatory physician education for all prescribers of any amount of opioids or benzodiazepines with a mandated requirement of 4 hours of continuing education per year.

[12] Manchikanti L, Kaye AM, Knezevic NN, et al. Responsible, safe, and effective prescription of opioids for chronic non-cancer pain: American Society of Interventional Pain Physicians (ASIPP) guidelines. *Pain Physician* 2017; 20:S3-S92.

[13] Blendon RJ, Benson JM. The public and the opioid-abuse epidemic. *N Engl J Med* 2018; 378:407-411.

4. Mandatory patient education associated with the first prescription of any amount of opioid.

Tier 2 includes the following:

5. Easier access to, and low or no copayments for, nonopioid techniques including physical therapy and interventional techniques which could potentially reduce the medication use and improve patient's functions and outcomes.[12]
   - Ironically, as reimbursement of interventional techniques has decreased with decreasing utilization since 2010, opioid deaths have been escalating.[14]
   - Evidence shows a direct relationship between the decline in utilization of interventional techniques and increase in the number of opioid deaths since 2010 (Figs. 4 and 5).

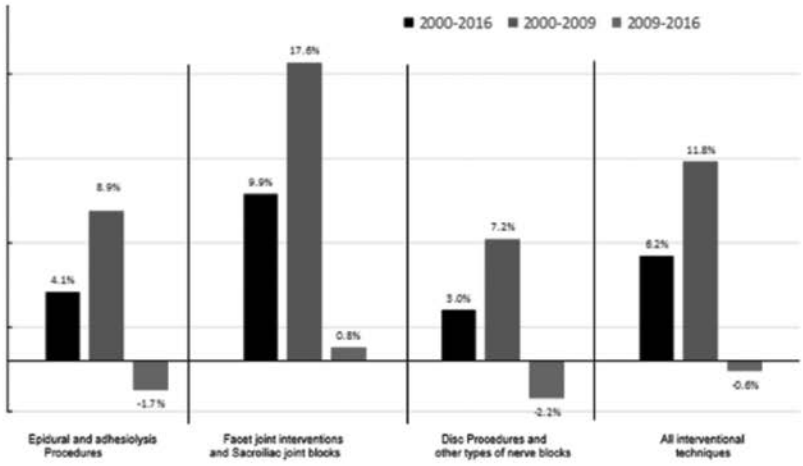

Fig 4. *Comparative analysis of epidural and adhesiolysis procedures, facet joint interventions and sacroiliac joint blocks, disc procedures and other types of nerve blocks, and all interventional techniques.*

[14] Manchikanti L, Soin A, Mann DP, et al. Reversal of growth of utilization of interventional techniques in managing chronic pain in Medicare population post Affordable Care Act. *Pain Physician* 2017; 20:551-567.

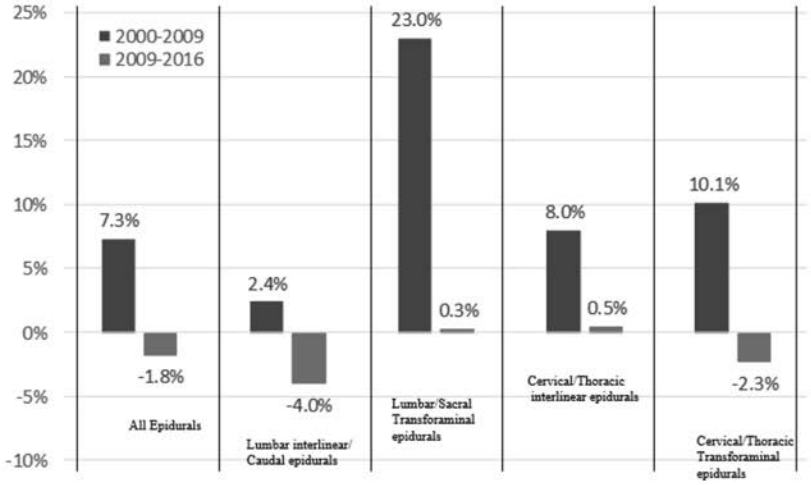

Fig 5. *Frequency of utilization of epidural injections episodes from 2000 to 2009 and 2009 to 2016, in Medicare recipients.*

6. Expand low-threshold access to buprenorphine for opioid use disorder.[5,15,16] It has been shown that a substantial proportion of patients who would benefit from buprenorphine treatment will receive this only if it becomes more attractive and more accessible than either prescription or illicit opioids.[15]

   - Opioid overdose deaths have been shown to decrease 79% over a period of 6 years after widespread prescribing of buprenorphine in France.[16] This will also lead to availability of buprenorphine and its products for chronic pain management.

[15] Kolodny A. Ten steps the federal government should take now to reverse the opioid addiction epidemic. *JAMA* 2017; 318:1537-1538.
[16] Auriacombe M, Fatséas M, Dubernet J, et al. French field experience with buprenorphine. *Am J Addict* 2004; 13:S17-S28.

7. Establishment of enhanced prescription drug monitoring program (PDMP) with National All Schedules Prescription Electronic Reporting Act (NASPER) program, with each state with a mandated capacity to be able to interact with at least all bordering states.
8. Mandated review of PDMP data by all providers, prior to all prescriptions.

Tier 3 includes the following:

9. Buprenorphine must be available for chronic pain management in addition to medication-assisted treatment, with a change of controlled substance scheduling to a Schedule II drug.
10. Remove methadone from formulary, which is responsible for over 3,000 deaths per year with only 1% of total prescriptions.

Finally, it is essential to develop treatment paradigms for patients with true somatic causes of pain. Nonopioid techniques have been recommended by IOM and attorney generals of many states. Yet, these have not been adequately considered. In fact, reductions and cuts continue to make difficulties to being able to utilize physical therapy, interventional techniques, and ironically even nonopioid medical therapy options.[17,18]

Thank you again for providing our organization with the opportunity to testify before Congress and provide our views.

It has been an honor to be here with you today. If you have any questions, I will be happy to answer.

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[17] National Academies of Sciences, Engineering, and Medicine. 2017. *Pain management and the opioid epidemic: Balancing societal and individual benefits and risks of prescription opioid use*. Washington, DC: The National Academies Press.
doi: https://doi.org/10.17226/24781.

[18] Letter to Marilyn Tavenner, from President and CEO, America's Health Insurance Plans from National Association of Attorneys General RE Prescription opioid epidemic. September 18, 2017.

Chairman ROSKAM. Thank you.
Mr. Kletter.

STATEMENT OF JASON KLETTER, PH.D., PRESIDENT, BAYMARK HEALTH SERVICES AND BAY AREA ADDICTION RESEARCH AND TREATMENT (BAART)

Mr. KLETTER. Chairman Roskam, Ranking Member Levin, and Members of the Subcommittee, I appreciate the opportunity to testify today about the opioid epidemic that is ravaging our country and important steps this Committee can take to help address this crisis.

I am Dr. Jason Kletter, President of BayMark Health Services. BayMark provides treatment for opioid use disorder, or OUD, using medication-assisted treatment and outpatient detoxification services in 95 facilities across 26 States, including many of the States you represent. We are the largest organization in the country focused primarily on treatment services for opioid use disorder treating over 33,000 patients each day.

I also serve on the Board of the American Association for the Treatment of Opioid Dependence, and I am also here today on behalf of the OTP consortium, a trade association comprised of more than 300 opioid treatment programs across 37 States. I have 25 years of experience in OUD treatment.

I want to start by highlighting two data points: First, according to the CDC, opioids killed more than 42,000 people in 2016. That is about 115 people every day in our country. These are our friends, our family, our neighbors, our coworkers.

Second, the White House Council of Economic Advisers estimates the economic cost of the opioid crisis was $504 billion in 2015 alone. Of course, these statistics do nothing to describe the devastating effects on our families and communities.

OUD is regarded by experts to be a disease of the brain, not a moral downfall. This concept of OUD as a chronic disease is essential to understanding successful treatment solutions, the most effective of which is medication-assisted treatment.

MAT is the integration of medication and psychosocial services to provide individualized care that will have the greatest likelihood of helping people with OUD transition to recovery and lead healthy, socially productive lives.

There are three federally approved medications for use as part of MAT, methadone, buprenorphine, and naltrexone, all of which must be used in conjunction with psychosocial services to have the greatest likelihood of success.

The benefits of MAT are substantial and have been proven repeatedly through rigorous scientific studies. MAT has been shown to improve patient survival, increase retention in treatment, decrease opioid use and criminal activity, increase patient's ability to gain and maintain employment, and lower person's risk of contracting HIV or hepatitis C.

Those who receive MAT are 75 percent less likely to have an addiction-related death than those who don't. There are roughly 1,500 opioid treatment programs, or OTPs, across the United States providing treatment to approximately 400,000 patients. OTPs are

highly regulated, comprehensive treatment programs that are required by law to provide MAT.

OTPs provide medication, individual and group counseling, random drug testing, and other supportive services, such as case management, primary care, mental health services, HIV, and hepatitis C testing.

Methadone, which is most commonly administered as part of MAT, has been used in OTPs for more than 50 years. It has been rigorously researched and considered to be the gold standard in treatment of opioid dependence. MAT with methadone is highly regulated and can only be dispensed for OUD by clinics that have been certified by SAMHSA, the DEA, and other agencies. It is an excellent medication when used as part of MAT with patients having very high retention and success rates.

Retention in treatment over an extended period of time is essential for positive outcomes. At BayMark, about 61 percent of our patients are retained in treatment for at least 90 days. Furthermore, while 100 percent of our patients are using opioids multiple times each day upon admission, about 50 percent of those folks in treatment less than 30 days are free from illicit opioids. That number jumps to 82 percent for patients in treatment more than 1 year. This is proof that MAT delivered in OTPs is saving hundreds of thousands of lives.

According to CMS, 30 percent of Part D enrollees used prescription opioids in 2015. So we should not be surprised that more than 300,000 Medicare beneficiaries have been diagnosed with opioid use disorder. Moreover, Medicare beneficiaries have the highest and fastest growing rate of OUD.

Unfortunately, Medicare does not cover comprehensive treatment services in OTPs. Instead, Medicare pays for more expensive treatments in less effective settings. This must change.

We respectfully request that Congress pass legislation to provide Medicare beneficiaries with coverage for MAT with all FDA-approved medications to help treat OUD in the OTP setting. We recommend that Medicare adopt a bundled payment methodology where MAT-related services provided in the OTP setting are reimbursed under a capitated rate. This model has proven to be successful in Medicaid and TRICARE and could be quickly implemented by the 1,500 OTPs across the country, rapidly increasing access to lifesaving treatment for Medicare beneficiaries.

While our country is in the throes of a tragic epidemic, the silver lining here is that we have a very effective treatment and a dedicated and compassionate workforce ready and able to save lives and build communities.

Thank you for the opportunity to testify today. I am happy to answer any questions that you have.

[The prepared statement of Mr. Kletter follows:]

The Opioid Crisis: Removing Barriers to Prevent and Treat Opioid Abuse and Dependence in Medicare

Testimony of
Jason Kletter, Ph.D
President
BayMark Health Services

Prepared for the
U.S. House of Representatives
Committee on Ways and Means
Subcommittee on Health
1100 Longworth House Office Building

February 6, 2018

Chairman Roskam, Ranking Member Levin, and members of the subcommittee, I appreciate the opportunity to testify today about the opioid epidemic that is ravaging our country and important steps this committee can take to help address this crisis. I want start by thanking all of you for your interest and attention to this important issue.

I am doctor Jason Kletter, President of Baymark Health Services. BayMark, which is headquartered in Lewisville, TX, currently provides treatment for opioid use disorder (OUD) using medication-assisted treatment (MAT) and outpatient detoxification services in 95 facilities across 26 states – including Alabama, California, Florida, Illinois, Minnesota, Nebraska, Pennsylvania, and Texas. We are the largest organization in the country focused primarily on treatment services for opioid use disorder. We provide treatment services across three modlaities: licensed opioid treatment programs, less-structured office-based services and outpatient detoxification combined with extended recovery support services. Each day, we treat over 33,000 patients in their recovery from opiate dependence and addiction. Our nation faces an unprecedented epidemic of opiate use, and BayMark works hard every day to expand accesst to high-quality, evidence-based services to those who need them.

I currently serve on the board of the American Association for the Treatment of Opioid Dependence (AATOD). I am also the President of the California Opioid Maintenance Providers group, have served as advisor to the California Department of Health Care Services on many committees including the Narcotic Treatment Program Advisory Committee, the California Outcome Management System Workgroup, the Counselor Certification Advisory Committee and the Continuum of Services System Redesign. I have also participated in Federal Center for Substance Abuse Treatment initiatives, advising on accreditation guidelines and evaluating training curricula for opioid treatment program (OTP) physicians. All told, I have 25 years of experience in OUD treatment, including front-line positions such as health worker and counselor and many administrative roles including corrections contract manager and Human Resource Director. I am also here today on behalf of the OTP Consortium, a trade association comprised of more than 300 OTPs across 37 states.

Given that it is impossible to open a newspaper, turn on a TV or check social media and not be overwhelmed with news about our nation's opioid epidemic, I won't spend a lot of time reciting the grim statistics; I know everyone on this Committee is familiar with the scale and scope of this crisis. I will, however, highlight just two data points that I think are among the most shocking: First, according to the Centers for Disease Control and Prevention, opioids (including prescription opioids, heroin, and fentanyl) killed more than 42,000 people in 2016, more than any year on record. That's about 115 people each day in our country – these people are our family, friends, neighbors, and coworkers.

The second data point that warrants special attention is, according to a report from the White House Council of Economic Advisors, in 2015, the economic cost of the opioid crisis was $504.0 billion, or 2.8% of the gross domestic product that year.[1]

So, the data tells us that not only are massive numbers of people being killed by this epidemic, but it is diminishing our nation's resources and costing us very real dollars.

Of course, these shocking statistics do nothing to describe the devastating effects on our families, neighborhoods and communities across the nation.

Opioid Use Disorder is a Disease

I want to be sure that you all are familiar with the current, state-of-the-art science about opioid use disorder. OUD is regarded by experts to be a disease of the brain, not a lack of will power or a moral downfall. Advances in technology over the past several decades have allowed scientists a better understanding of the impacts of drug use and the root cause of the behaviors that manifest from people with OUD. Alan Leshner, a former Director at the National Institute of Drug Abuse (NIDA) wrote in 2001:

> *"A core concept that has been evolving with scientific advances over the past decade is that drug addiction is a brain disease that develops over time as a result of the initially voluntary behavior of using drugs. The consequence is virtually uncontrollable compulsive drug craving, seeking, and use that interferes with, if not destroys, an individual's functioning in the family and in society."*[2]

In addition, NIDA noted, "addiction affects multiple brain circuits, including those involved in reward and motivation, learning and memory, and inhibitory control over behavior."[3]

This concept of OUD as a chronic, relapsing disease is essential to understanding successful treatment solutions.

Medication-Assisted Treatment

The most effective solution we have for treating OUD is medication-assisted treatment (MAT). MAT is the integration of medication and psychosocial services to provide individualized, care that will have the greatest likelihood of helping people with OUD transition to recovery and lead healthy, socially-productive lives. There are three federally-approved medications to treat opioid use disorder, all of which should be used in conjunction with psychosocial services: methadone, buprenorphine, and extended release injectable naltrexone.

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[1] The Underestimated Cost of the Opioid Crisis, Council of Economic Advisors, November 2017.
[2] Leshner, A. I. (2001). Addiction is a brain disease. *Issues in Science and Technology, XVII*, 3. Dallas, TX.
[3] NIDA. (2009). *Drug facts: Treatment approaches for drug addiction*. Retrieved from http://www.drugabuse.gov/publications/drugfacts/treatment-approaches-drug-addiction

Agonist medications like methadone and buprenorphine help to stabilize the patient so that they can effectively participate in counseling, case management and other services that lead to recovery. Naltrexone is an antagonist that blocks the effects of opioids.

However, buprenorphine, methadone, and naltrexone are not proverbial "silver bullets." Despite the claims by some, medication alone generally does not lead to recovery. The medication simply assists the treatment. These patients need counseling and other supportive services to assure successful outcomes.

The benefits of MAT are substantial and have been proven repeatedly through rigorous scientific studies for more than 50 years: MAT has been shown to improve patient survival, increase retention in treatment, decrease opioid use and criminal activity; increase patients' ability to gain and maintain employment, improve birth outcomes among women who have substance use disorders and are pregnant, and lower a person's risk of contracting HIV or hepatitis C by reducing the potential for relapse.[4] Those who receive MAT are 75% less likely to have an addiction-related death than those who do not receive MAT.[5]

Opioid Treatment Programs

There are roughly 1,500 Opioid Treatment Programs or "OTPs" across the United States providing treatment to approximately 400,000 patients. OTPS are highly-regulated, highly-structured, comprehensive treatment programs that provide MAT. More specifically, OTPs provide medication, individual and group counseling, random drug testing and other supportive services such as case management, primary care, mental health services, HIV and Hepatitis C testing and more.

Much of the OTP regulations are intended to prevent diversion of the powerful medications used as part of MAT. For example, our skilled nurses administer the medication to patients each day until patients are able to demonstrate stability and progress in treatment, as measured in part by random drug tests. In this way, we can be certain that the medication is not being sold on the street, unlike other sites of care, where a physician may write a prescription for 30 days and have no ability to ensure the intended person is using the medication as directed. As a result of this highly-regulated structure, diversion from OTPs is very limited. Daily medication administration also has therapeutic value, allowing compassionate, trained medical staff to briefly assess patients daily and provide information and words of encouragement to retain them in treatment.

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[4] https://www.samhsa.gov/medication-assisted-treatment/treatment

[5] Miller, T. and Hendrie, D. Substance Abuse Prevention Dollars and Cents: A Cost-Benefit Analysis. DHHS Pub. No. (SMA) 07-4298. Rockville, MD: Center for Substance Abuse Prevention, SAMHSA, 2008.

At BayMark, about 85% of our 33,000 patients are administered methadone, another 14% are provided buprenorphine, and the remaining 1% receive extended release naltrexone. Which medication each patient receives as part of MAT on their path to recovery is determined on an individual basis as part of the assessment and history of drug use identified during a collaborative process between the patient and his/her physician.

Methadone for Treatment Purposes

Methadone has been used for more than 50 years, has been rigorously researched and is considered to be the "gold standard" in the treatment of opiate dependence. In fact, the American Society of Addiction Medicine states that the efficacy and safety profile of MAT with methadone in the OTP setting "has been solidly and repeatedly established in the clinical outcomes literature since 1965."[6]

Methadone is highly regulated, as it should be, and can only be dispensed for OUD by clinics that have been certified to treat OUD by the Substance Abuse and Mental Health Services Administration, the Drug Enforcement Adminsitration and others. Methadone blocks the effects of heroin and prescription drugs containing opioids while eliminating withdrawal symptoms and relieving drug cravings. It is an excellent medication when used as part of MAT, with patients having very high retention and success rates.

Proven Track Record

As discussed in SAMHSA's TIP 43, research has shown that retention in treatment over an extended period of time is essential for positive outcomes with OUD, just as it is with other chronic diseases such as diabetes, hypertension and asthma.[7]

At BayMark, about 61% of our patients are retained in treatment for at least 90 days. Furthermore, while 100% of our patients are using opioids multiple times each day at admission, about 50% of our patients in treatment less than 30 days are free of opioids. That number jumps to 60% for patients in treatment 3-6 months, 68% for patients in treatment 6-9 months, and 82% for patients in treatment more than one year. This is proof that MAT delivered in an OTP is saving hundreds of thousands of lives.

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[6] https://www.asam.org/docs/default-source/public-policy-statements/1obot-treatment-7-04.pdf?sfvrsn=0

[7] McLellan, A.T.; Lewis, D.C.; O'Brien, C.P.; and Kleber, H.D. Drug dependence, a chronic medical illness: Implications for treatment, insurance, and outcomes evaluation. JAMA 284(13):1689–1695, 2000.

Medicare Coverage Policy is a Barrier to Access

According to CMS, 30% of Part D enrollees used prescription opioids in 2015.[8] So we should not be surprised that more than 300,000 Medicare beneficiaries have been diagnosed with opioid use disorder.[9] Moreover, Medicare beneficiaries have the highest and fastest growing rate of OUD.[10] Alarmingly, Medicare hospitalizations due to complications caused by opioid abuse or misuse increased 10% every year from 1993 to 2012.[11]

While Medicare pays for the pain medications that are contributing to the OUD epidemic, it does not pay for the full range of treatment options necessary to treat beneficiaries' addiction. Specifically, Medicare does not cover comprehensive treatment services in OTP specialty care settings. This would be equivalent to covering insulin for diabetics without covering glucose monitoring or educational services intended to improve diet and other behaviors. Furthermore, no single medication works for all people so having a range of proven treatment options is essential for mitigating the vast harms caused by the current opioid epidemic.

Instead, Medicare will pay for "treatment" with more expensive medications in what are often times less-effective settings. The average reimbursement for MAT in an OTP is roughly $500 per month while average reimbursement for similar treatment in an office-based environment is roughly $800-$1,000 per month, largely because buprenorphine is more expensive than methadone.

Medicaid beneficiaries have OTP coverage. TRICARE beneficiaries have access to treatment in the OTP setting. Yet, Medicare beneficiaries do not, unless they are willing to pay out-of-pocket for treatment. At BayMark, we estimate that between five and seven percent of our patients are Medicare beneficiaries, which is consistent with the rest of the industry.

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[8] CMS Announcement of Calendar Year 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, page 216

[9] Ibid.

[10] https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2535238

[11] Ibid.

What Can Congress Do?

In the 2017 Medicare Advantage and Part D Advance Notice and Call Letter, CMS sought comments about whether Medicare's methadone coverage policy "is a barrier to treatment."[12] In the final rate notice, CMS said "absent a change in law, Medicare is unable to cover methadone for MAT under Medicare Part B or Part D. However, under Part C, [Medicare Advantage] organizations may cover methadone for MAT as a supplemental benefit."[13] More recently, President Trump's Commission on Combating Drug Addiction and the Opioid Crisis recommended that HHS and CMS "remove reimbursement and policy barriers to SUD treatment, including those… that limit access to any forms of FDA-approved medication-assisted treatment."[14]

Given the current public health emergency stemming from opioid addiction, and the rapidly rising number of Medicare beneficiaries suffering from OUD, we respectfully request that Congress pass legislation to provide Medicare beneficiaries with coverage for MAT with all FDA-approved medications to help treat OUD in the OTP setting.

Recommended Medicare Benefit Structure

Congress can look to Medicaid and TRICARE when designing a Medicare OTP benefit. Specifically, BayMark, AATOD, and the OTP Consortium recommend that Medicare adopt a bundled payment methodology where all MAT-related services provided in the OTP setting, in addition to any medications provided, are reimbursed under a unified, fairly reimbursed capitated rate. The bundled model has proven to be successful in Medicaid and TRICARE and could be quickly implemented by the 1,500 OTPs across the country – ensuring timely access to life-saving treatment for Medicare beneficiaries. BayMark, AATOD and the OTP Consortium stand ready to work with this committee and your colleagues in Congress to design, advocate for, and implement this long-overdue coverage option.

Conclusion

In closing, I want to thank you for your concern and your attention to this matter. While our country is in the throes of a tragic epidemic, the silver lining here is that we have very effective treatment and a dedicated and compassionate workforce ready and able to save lives and rebuild communities.

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[12] CMS Advance Notice of Methodological Changes for CY 2017 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter, page 205.

[13] CMS Announcement of Calendar Year 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, page 208

[14] https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf

Chairman ROSKAM. Thank you very much.

Dr. Paz.

STATEMENT OF HAROLD L. PAZ, M.D., M.S., EXECUTIVE VICE PRESIDENT AND CHIEF MEDICAL OFFICER, AETNA, INC.

Dr. PAZ. Thank you, Chairman Roskam, Ranking Member Levin, and Members of the Subcommittee, for holding today's hearing on the opioid abuse epidemic. I appreciate the opportunity to share Aetna's perspective on this critical public health issue.

Aetna is a leading diversified health company that serves over 38 million individuals in the United States and around the world. I currently serve as the company's Executive Vice President and Chief Medical Officer, a role I have held since 2014.

In my capacity as CMO, I lead clinical strategy and policy across Aetna's lines of business and am responsible for driving clinical innovation to improve member experience, quality, and cost. I am also a practicing physician.

The opioid epidemic is the leading public health issue facing our Nation. We have already lost far too many of our friends, family, and neighbors to this unprecedented health crisis. Aetna is taking a holistic approach to addressing the opioid epidemic.

The various segments of Aetna's businesses are all working to help our members struggling with addiction and to prevent future opioid dependency. To that end, Aetna has created an enterprise-wide opioid task force, which I chair, to drive a multifaceted strategy to help stem the tide of overuse.

We have developed a strategy focused on preventing misuse and abuse, intervening when we identify at-risk provider and member behavior, and supporting members by providing access to evidence-based treatments.

I am pleased to share with this Subcommittee three examples of Aetna's efforts to fight the opioid epidemic as well as recommendations for Congress and the Administration. We believe important efforts in our commercial lines of business can inform how CMS regulates Medicare Advantage and Part D plans to allow for similar programs in the Medicare space.

First, within our commercial business, Aetna is leveraging formulary and plan design tools, such as quantity limits and prior authorization, to reduce opioid misuse and encourage evidence-based treatments.

For example, as of January 1, Aetna is limiting initial opioid prescriptions for acute pain to a 7-day supply. These stricter daily and dosage limits are in alignment with CDC guidelines and will help to reduce the potential for abuse and addiction.

Second, effective January 1, Aetna became the first and only national payer to waive copays for Narcan, a lifesaving, highly effective opioid overdose reversal agent, for our fully insured commercial members once their deductible is met. We hope this copay waiver will increase access to remove possible financial barriers to the use of naloxone.

Third, within Aetna's Medicare business, we are striving to be part of the solution. Aetna has taken steps to promote appropriate prescribing and coordination of care for our Medicare members who utilize opiate drug therapies.

Aetna has instituted interventions in its Medicare formularies to assist members in receiving appropriate opioid medication when necessary while preventing inappropriate use and addiction. We also support pharmacists in utilizing opioid controls as well.

Aetna is committed to continuing to work with CMS to highlight areas of opportunity for change to better combat the opioid epidemic. We believe there are three specific areas where Congress and CMS can take additional steps to help remove barriers currently limiting the ability of plans to combat the epidemic itself.

First, while Aetna now limits initial fills of acute opioid prescriptions to a 7-day supply in our commercial business, Medicare Advantage and Part D plans are precluded from unilaterally limiting the duration of a prescription. We are encouraged that CMS in its recently released call letter is proposing significant steps to allow Medicare and Part D plans to take more action to preventing over prescribing.

We strongly encourage CMS to finalize provisions that allow additional point-of-sale edits and supply limits of prescription opioids that limit initial prescribing to a 7-day supply.

Second, we also support CMS' continued efforts to address the opioid epidemic and believe the implementation of CARA and the adoption in Part D of a lock-in mechanism will prevent sponsors with a critical tool to help—will provide sponsors—excuse me—with a critical tool to help curtail the abuse of opioids.

Still, we believe there are several changes CMS should make in implementing the lock-in program to ensure its success, such as allowing Part D sponsors to retain the ability to use point-of-sale claim edits to address other frequently abused drugs and allowing plans to maintain the lock-in status of a member until notified by the applicable provider that the member is no longer at risk.

And, finally, we strongly support modernizing privacy regulations to provide access to a patient's entire medical record, including substance use disorder records, and to ensure that providers and organizations have all the necessary information to provide safe, effective, high-quality treatment and care.

We urge Congress to expeditiously pass the bipartisan legislation introduced in the Senate and here in the House by Representatives Mullin and Blumenauer to align this outdated regulation with already strict HIPAA standards.

In conclusion, Aetna is deeply committed to doing its part to turn the tide on the epidemic. We look forward to continuing to play a productive role in the dialogue with the Subcommittee and with other policymakers to help find solutions to this epidemic.

Thank you, again, for your leadership on this issue and for inviting Aetna to be here today.

[The prepared statement of Dr. Paz follows:]

Statement of

Dr. Hal Paz, M.D., M.S., ***Executive Vice President and Chief Medical Officer***

Aetna, Inc.

United States House Ways and Means Committee

The Opioid Crisis:

Removing Barriers to Prevent and Treat Opioid Abuse and Dependence in Medicare

February 6, 2018

Thank you Chairman Roskam, Ranking Member Levin and members of the Health Subcommittee for holding today's hearing on the opioid abuse epidemic. I appreciate your leadership in bringing a diverse group of stakeholders together to discuss ways we can further our efforts to address the challenges posed by the opioid abuse epidemic facing our nation. I appreciate the opportunity to share Aetna's perspective on this critical public health issue.

Aetna is a leading diversified health company that provides individuals, employers, health care professionals, and others with innovative benefits, products, and services. We serve over 38 million individuals in the United States and around the world.

I currently serve as the company's Executive Vice President and Chief Medical Officer (CMO), a role I have held since 2014. In my capacity as CMO, I lead clinical strategy and policy across Aetna's lines of business and am responsible for driving clinical innovation to improve member experience, quality, and cost in all areas of the health care delivery system. Prior to my role at the company, I served as Chief Executive Officer and Dean of Penn State Hershey Medical Center and Health System. Prior to this, I served as Chief Executive Officer and Dean of the Robert Wood Johnson Medical School. I am an active licensed physician and pulmonologist who still cares for patients at the West Haven VA Hospital.

The opioid epidemic is the leading public health issue facing our nation, negatively impacting the lives of thousands of American families. The Centers for Disease Control and Prevention (CDC) has estimated that in 2016, 64,000 Americans died of drug overdoses—three times the rate in 1999 and up 21% from 2015. Furthermore, America's addiction crisis has led to a two-year consecutive decline in our country's life expectancy, an alarming demographic trend we haven't witnessed since the 1960s.[1]

Aetna understands the importance of fighting the opioid epidemic. Aetna's goal is to help its members who are struggling with addiction return to a productive life free of opioids. Aetna's various business segments are working to support this goal and to prevent future opioid dependency, while aligning with the evolving legal and regulatory guidance surrounding the opioid epidemic. Aetna is also committed to working with state and federal officials to advocate for legislative and regulatory solutions to enable greater public-private partnerships in addressing

[1] Santgaban, Laura. "The opioid crisis is driving down U.S. life expectancy, new data shows." PBS. December 21, 2017.

this epidemic. Furthermore, the Aetna Foundation is, where possible, supporting state and local programs that are aimed at combatting this national crisis.

Aetna is taking a holistic approach to addressing the opioid epidemic. The various segments of Aetna's business—including our Commercial, Medicaid and Medicare product lines—are all striving to help our members struggling with addiction and to prevent future opioid dependency. To that end, Aetna has established an "Enterprise-Wide Opioid Taskforce"—which I chair—with the objective of driving a multi-faceted strategy to help stem the tide of over-use. We have developed a strategy focused on: preventing misuse and abuse; intervening when we identify at-risk provider and member behavior; and supporting members by providing access to evidence-based treatments.

Aetna is focused on helping its members avoid unnecessary opioid use and effectively manage opioid use when needed. In doing so, Aetna is striving—where possible and appropriate—to increase the use of alternative therapies for members' pain relief, such as physical therapy, chiropractic/osteopathic manipulative treatment, massage (in conjunction with physical therapy), cognitive behavioral therapy, and other effective alternative modalities. For members who are dealing with chronic pain, Aetna supports a multi-disciplinary treatment approach, including both outpatient and inpatient treatment programs that consider physical, social, and behavioral factors.

I am pleased to share with the Committee highlights of Aetna's efforts to fight the opioid epidemic. Specifically, we believe our important efforts in our Commercial lines of business, for example, can inform how the Centers for Medicare and Medicaid Services (CMS) regulates Medicare Advantage (MA) and Part D plans to allow for similar programs in the Medicare space.

At Aetna, we are taking a number of steps to address the opioid epidemic. For example, we are leveraging formulary and plan design as tools to reduce opioid misuse and encourage evidence-based treatment. While regulatory and contractual requirements affect the specifics of Aetna's approach by state and product line, Aetna is using these tools to ensure that appropriate prior authorization and quantity limits support the proper use of opioids for pain management and that alternative non-opioid treatments are available. As of January 1, 2018 in our commercial business, Aetna is limiting initial opioid prescriptions for acute pain to a seven day

supply, as well as a limit of 90 milligrams of morphine equivalency per day. These stricter daily and length of coverage limits will help reduce the potential for abuse and risk of addiction.

In our commercial business, Aetna requires prior authorization for all opioids for acute pain beyond the seven day initial fill, and also requires prior authorization for all opioids used for the treatment of chronic pain. These guardrails ensure that additional opioids are used for the shortest possible duration and only when the benefits of use outweigh the risks, aligning with CDC guidelines. The prior authorization requirement ensures that for longer term use in treating chronic pain, the physician and member have a treatment and monitoring plan in place to help prevent excessive side effects and possible future addiction.

Furthermore, Aetna understands the important role that Medication-Assisted Treatment (MAT) plays in treating opioid use disorder. Aetna seeks to support its members who are recovering from opioid dependency and/or are at risk of an opioid overdose. To that end, in its commercial business, Aetna has removed prior authorization requirements on generic drugs that treat opioid addiction, including oral buprenorphine/naloxone and generic dosages of Suboxone and Subutex.

Aetna continues to look for ways to intervene when it identifies at-risk behavior with members. Per CDC, the Substance Abuse and Mental Health Services Administration (SAMHSA), the World Health Organization, and the American Medical Association (AMA) Opioid Task Force recommendations, physicians should consider co-prescribing naloxone—a lifesaving, highly effective opioid overdose reversal agent — to patients who are at an increased risk of an overdose. In light of these recommendations, effective January 1, 2018, Aetna became the first and only national payer to waive copays for Narcan for its fully-insured commercial members once their deductible is met. We hope that this copay waiver will increase access and remove possible financial barriers to the use of naloxone. In order to further increase access in regions particularly hard-hit by the opioid epidemic, Aetna donated 720 doses of Narcan to first responders in the Northern Kentucky and Appalachia regions in August 2017 in support of community efforts to prevent deadly opioid overdoses. Aetna employees also led an educational training event for first responders and community members. And last December, Aetna donated 408 Narcan kits to Howard County, Maryland.

In order to promote prescriber education and prevent potential overprescribing, in 2016, Aetna sent letters to the top 1% of opioid prescribers within their respective specialties, to make them aware of their outlier prescribing patterns. These approximately 1,000 opioid "super-prescribers" were also provided the 2016 CDC guidelines for the use of opioids for the management of chronic pain. Last year, Aetna also sent 480 individualized letters to "super-prescriber" dentists and, in collaboration with the American Association of Oral and Maxillofacial Surgeons, sent 249 letters to "super-prescriber" oral surgeons.

Also, in our commercial business, Aetna is in the process of implementing a pilot program to provide coverage of Exparel—a non-narcotic pain injection used in patients following wisdom teeth extraction (or other dental surgery)—to its fully insured plans in lieu of opioid pills. By providing safer alternatives for pain control, fewer opioids are prescribed, and we can avoid the risk of misuse and diversion of unused pills.

Within Aetna's Medicare business, we have also been taking strides to be part of the opioid solution. Before I turn to specific examples, it's important to consider the structural framework of the Medicare program itself. The Medicare population, including seniors and the qualified disabled, receives their benefits in multiple ways. For example:

1. Some are enrolled in fee-for-service (FFS) Medicare, stand-alone Part D, and have a supplemental policy through an employer or a purchased Medigap plan;
2. Others are enrolled in a Medicare Advantage-Prescription Drug Plan (referred to as an "MA-PD") which combines a Medicare Advantage health plan with an integrated prescription drug plan;
3. Others who are lower income or dual-eligible have both Medicare and Medicaid, and still get their drug benefit through Medicare Part D;
4. Furthermore, certain Medicare retirees obtain coverage through a Medicare employer group waiver plans (EGWP), but often the employers choose another entity to provide the drug benefit.

Aetna believes the best way to manage Medicare beneficiaries' health is through a fully integrated model, such as MA-PD, that coordinates Medicare, Medicaid (if applicable), and drug

benefits. Evidence shows that integrated medical and drug plans are better for the consumer and provide quality service at lower cost.[2] However, structural barriers exist even within MA-PDs that limit Aetna's ability to impose opioid utilization management restrictions (such as requiring non-opioid pain management prior to the use of opioids). And with added flexibility, even more can be done to address beneficiaries' overall healthcare needs, including health, wellness, pain management, addiction, and drug utilization.

As a Medicare Managed Care Organization (MCO), Aetna's Individual Medicare formularies are governed by regulations and guidance from the CMS. CMS's regulatory framework is designed to protect Medicare members' access to prescription drugs, to ensure timely delivery, and to minimize disruption of members' drug therapies. Accordingly, MCOs like Aetna are limited in their ability to make formulary and utilization management changes to limit the use of opioids.

Despite these constraints, Aetna has taken steps to promote appropriate prescribing and coordination of care for its Medicare members who utilize opioid drug therapies. As a general matter, Aetna has instituted, with CMS approval, utilization management tools in its Medicare formularies to assist Aetna's members in receiving appropriate opioid medication when necessary, while preventing inappropriate use and/or addiction. Aetna's Medicare plan system implementation also contains point of sale pharmacy messages to pharmacists in support of opioid use controls, as well as retrospective utilization programs to support physician appropriate prescribing and coordination of care.

As an example, under the point of sale messaging, a dispensing pharmacist will receive an alert when a member has a product like Suboxone in their recent drug history fills and is attempting to fill an opioid prescription. The alert is meant to inform the pharmacist that he or she should assess whether a different non-opioid pain medication would be a more appropriate treatment before filling the prescription.

In addition, Aetna has aligned its targeting criteria—by which it identifies high dose opioid users for potential intervention—in Medicare more closely with CDC guidance on high dose, high risk utilization of opioids. Beginning this year Aetna Medicare's targeting criteria

[2] Smith-McLallen, Aaron. "Effects of Pharmacy Benefit Carve-In on Utilization and Medical Costs: A Three Year Study." Benefits Magazine. February 2012.

decreased from a 120 milligram morphine equivalent dose threshold to 90 milligrams. This change will help target a greater number of at-risk members for potential intervention.

Aetna is committed to continuing to work with Congress and CMS to highlight areas of opportunity for change to better combat opioid abuse. There are a few specific areas where we believe Congress and CMS can make changes:

Limit Initial Opioid Prescriptions to 7-Day Supply

While Aetna now limits initial fills of acute opioid prescriptions to a 7-day supply in our Commercial business, current Medicare rules preclude Part D plans from unilaterally limiting the duration of a prescription (though patients or prescribers may request a shorter fill than prescribed). In other words, in most states that do not have pharmacy-specific rules to this effect, standalone Part D and MA-PD plans cannot limit a prescription fill to only seven days because of safety or potential abuse concerns, without a member or prescriber's request.

We are encouraged that CMS—in its recently released 2019 MA and Part D Advanced Notice and Call Letter—is proposing significant steps to allow MA and Part D plans to take more action to prevent over prescribing of prescription opioids. Specifically, we strongly encourage CMS to finalize provisions that allow additional point-of-sale edits and supply limits of prescription opioids that limit initial prescribing to a 7-day supply, in alignment with CDC guidelines.

Ensure Success of Medicare Part D Lock-in

We support CMS' continued efforts to address the opioid epidemic and believe the implementation of CARA, and the adoption in Part D of a lock-in mechanism (by which a member can be "locked in" to one pharmacy to prevent "pharmacy shopping"), will provide Part D sponsors with a critical tool to help curtail inappropriate abuse of opioids and other medications. However, there are several critical changes CMS should make in implementing the Medicare lock-in program to ensure its success. First, we believe Part D sponsors must retain the ability to use point of sale claims edits to address other frequently abused drugs, including those often used concurrently with opioids. Second, sponsors must also be allowed to continue to apply point of sale edits when a member is identified by their prescriber as potentially at-risk, even if they do not meet the CMS criteria. Third, we also believe plans should be allowed to

maintain the locked-in status of a member until notified by the applicable provider that the member is no longer at risk. Arbitrarily terminating these important limitations after one year without a clinical reason, we believe, unnecessarily puts members at risk of relapsing.

Modernize Privacy Regulations

As a practicing physician, I understand and respect the importance of privacy as it relates to health care. However, I also believe that certain privacy regulations limit the ability for MCOs, like Aetna, and health providers to securely exchange relevant information about a patient's history with substance abuse, addiction, or mental health. We at Aetna believe these barriers warrant further review and updating.

We strongly support modernizing privacy regulations, 42 CFR Part 2, to provide access to a patient's entire medical record, including substance use disorder records and to ensure that providers and organizations have all the information necessary to provide safe, effective, high quality care.

Care coordination for members with a substance use disorder is of utmost importance. The current outdated rule poses a serious safety threat to those with substance use disorders due to risks from drug interactions and co-existing medical problems. In addition, these outdated regulations run counter to new, innovative delivery care models where providers must use patient data and analytics to manage the health of a population and identify patients for targeted outreach.

To this end, Congress should expeditiously pass bipartisan legislation introduced in both chambers by Representatives Mullin and Blumenauer in the House (H.R. 3545) and Senators Manchin and Capito in the Senate (S. 1850) to align this outdated regulation with already strict HIPPA standards.

In conclusion, Aetna is deeply committed to doing its part to reverse the trend of opioid misuse, abuse, and overdoses across the nation. We have already lost far too many of our friends, family, and community members to this unprecedented health crisis. We will continue to enhance our programs to reduce inappropriate opioid prescribing, encourage the use of non-opioid pain treatment modalities, and promote evidence-based recovery for our members struggling with opioid use disorder. We look forward to continuing to play a productive role in

the dialogue with the Committee and with other policymakers to help find solutions to this epidemic. Thank you again for your leadership on this issue and for inviting Aetna to be here today.

Chairman ROSKAM. Thank you very much.
Ms. Hungiville.

STATEMENT OF LAURA HUNGIVILLE, PHARMD, CHIEF PHARMACY OFFICER, WELLCARE HEALTH PLANS, INC.

Ms. HUNGIVILLE. Mr. Chairman, Ranking Member Levin, Members of the Committee, I am Laura Hungiville, Chief Pharmacy Officer for WellCare Health Plans. I want to thank you for your invitation to appear today to share with you our experiences regarding the opioid epidemic and the variety of practices we have employed aimed at curbing the overuse and misuse of prescription opiates.

It is important that the Committee is addressing this vital issue, and managed healthcare companies are equally committed to finding solutions. First, though, let me tell you a little bit about WellCare. Headquartered in Tampa, Florida, WellCare focuses exclusively on provider government-sponsored managed healthcare services through Medicaid, Medicare Advantage, and Medicare prescription drug plans.

WellCare prides itself on managing healthcare services for the underserved and most vulnerable populations. We serve 4.3 million members nationwide with roughly 1 million members relying on WellCare for prescription drug services.

In any given State our beneficiary population ranges from 40 to 50 percent dual eligible. While certainly not the only population at high risk of controlled substance misuse, mental illness and poverty often go hand in hand with substance abuse disorders.

We have spent the last several years investing resources and time into innovative methods for decreasing the misuse of controlled substances among our beneficiaries, culminating most recently in the launch of an opioid task force.

This task force was created to ensure that we are taking an integrated approach to helping our members. Our company has insourced medical, pharmacy, and behavioral departments, a rarity among managed care plans, to ensure that we are looking at the member in a holistic manner.

First and foremost, our goal is to prevent abuse and addiction. Our second goal is to help our members who are battling addiction and often chronic pain to help them manage both conditions. Those members who are at the greatest risk of overdose and death receive the highest attention.

One of our key programs involves monitoring doctor and pharmacy shopping so we can flag high utilizers. WellCare works with patients to enter into medical service agreements, which patients benefit from having a single doctor focused on prolonged pain management therapies to deter opioid misuse.

For several years, WellCare's pharmacy-run opioid overutilization case management program has been using predictive modeling to identify at-risk individuals. As a result, WellCare proactively identified over 200 at-risk members nationally in 2017 based on specific criteria, including prescription dispensing, provider, and emergency department utilization.

We placed these individuals into a lock-in program connected to one pharmacy, one healthcare provider, and a care manager who

helps connect members to needed physical, behavioral, pharmacy, and social services.

In regard to the CMS standard for morphine-equivalent dosage, we have also identified 2,100 additional members who have received prescriptions over the previous CMS standard of 120 milligrams of opioids per day. We intervene with these members through member education on alternative medications, outreach to prescribers, and have begun including integration point with our behavioral health case management team. For our noncancer members, this translated into utilization reduction of over 43 percent between 2015 and 2017.

Since the transition to the lower daily ceiling of 90 milligrams of morphine-equivalent doses, WellCare continues to see increased numbers of members captured through our overutilization case management program.

We also recognize that we must look beyond the treatment of pain to address opioid overuse. Our multifaceted set of interventions includes the creation of the CDC-compliant task force and engaging policy groups at the State level to include prescription drug monitoring program training, and CME for physicians on the training of using opiates.

Some of these partnerships also include working with the YMCA to educate teens on the risk of opioid use, especially in the foster care system. At the organizational level, we are rolling out telehealth programs for use in emergency rooms to help increase medication-assisted treatment.

And, finally, we are also developing incentive programs for physicians to become SAMHSA certified, given the increased demand for addiction specialists.

Much of which I have outlined has been possible because of States like Kentucky where Medicaid regulations allowed us to be aggressive in targeting opioid misuse. In Kentucky, we are able to see a decrease of nearly 50 percent.

We would also like to recommend CMS incentivize other providers to become SAMHSA certified, allow health plans to be empowered to have more restrictive lock-in programs, mandate electronic prescribing of opioids, and address the gaps that create barriers for plans by providing PDP plans with access to medical claims, and allow health plans access to PDMPs as well.

Lastly, Congress, CMS, and the FDA should create educational campaigns similar to the one deployed for tobacco cessation to educate consumers about the dangers of the opioids and remove the stigmatization and encourage people to seek help.

In conclusion, ending this opioid crisis will require a partnership with all stakeholders, and WellCare looks forward to being an active participant as the Committee and Congress work to combat this epidemic. Thank you.

[The prepared statement of Ms. Hungiville follows:]

Comments for the Record

U.S. House Committee on Ways and Means, Subcommittee on Health

Hearing on

The Opioid Crisis: Removing Barriers to Prevent and Treat Opioid Abuse and Dependence in Medicare

Tuesday, February 6, 2018

By Laura Hungiville

Chief Pharmacy Officer

WellCare Health Plans, Inc.

Mr. Chairman, Ranking Member Neal, members of the Committee – I am Laura Hungiville, Chief Pharmacy Officer for WellCare Health Plans. I want to thank you for your invitation to appear today to share with you our experiences regarding the opioid epidemic and the variety of practices we have employed aimed at curbing the overuse and misuse of prescription opiates.

It is important that the Committee is addressing this vital issue, and managed healthcare companies are equally committed to finding solutions. We understand the severity of the epidemic, and applaud the Committee's continued commitment to bringing an end to this crisis, which is exacting a toll on individuals and families across the country.

We would like to use this opportunity to detail some of the key protocols we have implemented to successfully reduce the number of overdoses due to opioid abuse as well as introduce new pain alleviation alternatives.

First though, let me tell you a little bit about WellCare. Headquartered in Tampa, Florida, WellCare focuses exclusively on providing government-sponsored managed healthcare services, primarily through Medicaid, Medicare Advantage, and Medicare Prescription Drug Plans, to members with complex medical needs. WellCare prides itself on managing healthcare services for the underserved and most vulnerable populations. We serve 4.3 million members nationwide, with roughly one million members relying on WellCare for prescription drug coverage.

In any given state, our beneficiary population ranges from 40-50% dual eligible – those beneficiaries that qualify for both Medicare and Medicaid. While certainly not the only population at a high risk of controlled substance misuse, mental illness and poverty often go hand in hand with substance abuse disorders. We have spent the last several years investing resources and time into innovative methods for decreasing misuse of controlled substances among our beneficiaries, culminating most recently in the launch of an Opioid Task Force.

The task force was created to ensure that we are taking an integrated approach to helping our members. Our company has insourced our medical, pharmacy, **and** behavioral departments – a rarity among managed care plans – to ensure that we are looking at the member in a holistic manner. First and foremost, our goal is to prevent abuse and addiction. Our second goal is to help our members who are battling addiction, and often chronic pain, and to also help them manage

both conditions. Those members who are at the greatest risk of overdose and death receive the highest attention.

One of our key programs involves instituting metrics to monitor doctor and pharmacy shopping so we can flag high utilizers and working with patients to enter into medical service agreements. Under a medical service agreement, at-risk patients benefit from having a single doctor focused on prolonged pain management therapies to deter opioid misuse.

Identifying At-Risk Populations

For several years, WellCare's pharmacy-run opioid overutilization case management program has been using predictive modeling to identify at-risk individuals. As a result, WellCare proactively identified over 200 at-risk members nationally, based on specific criteria including prescription dispensing, prescription refills, and provider and emergency department utilization. We placed these individuals in a "lock-in" program connected to one pharmacy, one healthcare provider, and a care manager with specialized training and experience in substance use disorder treatment. Care managers also help connect members to needed physical, behavioral, pharmacy, and social services.

In regard to the CMS standard for morphine equivalent dosage (or MED), we have also identified over 2,100 additional members who have received prescriptions over the previous CMS standard of 120 mg of opioids per day. We intervened with these members through member education on alternative medications, outreach to prescribers, and have begun including an integration point with our behavioral health case management team. For our non-cancer members, this translated into a utilization reduction of over 43% between 2015 and 2017. Since the transition to the lower

daily ceiling of 90 mg MED, WellCare continues to see improvement in the numbers of members captured through our overutilization case management program.

Looking Beyond Narcotic Treatment of Pain

WellCare recognizes that we must look beyond the treatment of pain to address opioid overuse. Our multifaceted set of interventions include the creation of the CDC-compliant task force and engaging policy groups at the state level to include Prescription Drug Monitoring Program (PDMP) training and physician Continuing Medical Education (CME) training on opiates. Some of these partnerships include working with the YMCA to educate teens on the risk of opioid use, especially in the foster care system. At the organizational level, we are rolling out a telehealth program for use in emergency rooms and to help increase access to Medication Assistance Treatment (MAT). And finally, we are also developing an incentive program for physicians to become Substance Abuse and Mental Health Services Administration (SAMHSA) certified, given the increased demand for addiction specialists.

How CMS and Congress Can Take Action

Much of what I outlined above has been possible because of states like Kentucky, whose Medicaid regulations allowed us to be aggressive in targeting opioid misuse. For example, at the conclusion of a recent six-month pilot project, opioid prescription fills by our Kentucky members had decreased by nearly 50%. As a managed care plan that provides services to members in a variety of states, WellCare recognizes the geographic variation in opioid use and resources and believes that federal policymakers would be well-served by applying protocols that have proven successful at the state level to Medicare in light of the current public health emergency.

We would also recommend the following:

- CMS could incentivize other providers to become certified and start treating members with substance use disorders by providing reimbursement to support the additional activities offered under a comprehensive treatment plan, such as counseling, medication assisted treatment, social services, drug screening, and PDMP integration.
- Health plans need to be empowered to have more restrictive lock in programs, with the key being limiting patients to one provider and one pharmacy.
- Congress should mandate electronic prescribing of opioids to prevent prescription tampering, improve security, reduce fraud and limit opioids getting in the wrong hands.
- CMS needs to address data gaps that create barriers for plans by providing PDP plans with access to medical claims data to identify members most at risk for abuse. Additionally, health plans do not have access to PDMPs in most states, and therefore do not have a complete view of the member's utilization of opioids.
- Lastly, Congress, CMS, and FDA should create an educational campaign similar to the one deployed for tobacco cessation, to educate consumers about the dangers of opioids, remove stigmatization and encourage people to seek appropriate help.

In conclusion, ending the current opioid crisis will require a partnership between all stakeholders – Congress and relevant Federal agencies, healthcare payers and providers, as well as patients and their families – in order to continue the successes we have already seen from efforts such as those I outlined today. WellCare looks forward to being an active participant as the Committee and Congress work to combat this epidemic. Thank you again for the opportunity to testify today. I welcome any questions you may have.

Chairman ROSKAM. Thank you very much. You have given us great insight and very valuable perspectives.

We are in a very uncertain time right now in terms of scheduling and the chatter that we are getting about being called back in. Since this has been a two-panel hearing today, I would ask unanimous consent to limit the Members' questions to 3 minutes.

And, without objection, so ordered.

And, with that, we will yield to recognize Mr. Kelly.

Mr. KELLY. Thank you, Mr. Chairman.

Thank you all for being here.

Dr. Benyamin, I was fascinated by your testimony. And I think last year when President Trump talked about this war on drugs, he had talked about nonaddictive painkillers because we are a Nation now of dependence or codependence. I don't think there is any doubt about that.

If you could just go a little bit further into that. I marvel at the fact that we have 50 laboratories around this country that are collecting all this type of data. But your testimony, more than anything, appealed to me because I have been so close to this issue.

Would you expand a little bit more on the fact that we do have a way of keeping pain down? But I think the development of those drugs also had to do with reimbursements, right? If we can keep the pain down and the patient says, "I am not feeling the pain," it is a better result. But it involves an addiction. So please hit the nonaddictive ways of killing pain.

Dr. BENYAMIN. Thank you, Congressman. That's a very good question.

We can divide that into two sections, the medication part and the interventional part. So, on the medication front, we have had challenges as far as funding and research funding for nonaddictive medication, as you know. And we do not have many choices. Our choices are between scheduled prescription drugs and anti-inflammatories. And we all know that anti-inflammatories have their own side effects.

One of the issues is access. Many of the health plans do not cover nonopioid medications. Like, I will give you a good example of a patch that is anti-inflammatory. If you call for a preauthorization, unanimously, they all will deny the patch. They will say to you: Well, we do not cover the anti-inflammatory patch, but we do cover the fentanyl patch. That is the answer that you get. So that tells you part of the problem that we face.

On the nonmedication front, I think we are a young specialty. Interventional pain management is a young specialty. And we have been adding to our tools to treat, as I mentioned, the spinal disorders, like spinal stenosis, and fractures in the spine. These are conditions that, in the past, we did not have any solution for between surgery and opioids. And now we are providing solutions that are minimally invasive techniques that can prevent these patients from getting to the point of becoming dependent on opioids or having all these invasive surgeries and, as a result, becoming dependent on opioids.

Mr. KELLY. Sir, I want to thank you. I am running out of time. I want to thank you all for being here. We have run out of options as a country. We have to get this fixed. So thank you so much for

what you are doing. Please continue your work. We really appreciate you being here. Thanks so much.

I yield back, Mr. Chairman.

Chairman ROSKAM. Mr. Levin.

Mr. LEVIN. Well, I join in our appreciation for all of your efforts.

Just quickly—and then I wanted to ask you another question—why do you think it took us so long to recognize this epidemic? Anybody want to venture? It did take us a long time.

Dr. BENYAMIN. Can I take a shot at that?

Mr. LEVIN. Please.

Dr. BENYAMIN. So I think part of it is a lack of awareness and a lack of knowledge, a lack of public information, and usually we react. You know, we always react, we go from one extreme to the other.

As I said before, this is not just a pill problem anymore. The shift has occurred from the pill to heroin and synthetic fentanyl. And I will be glad if we take some precautionary legislation that will prevent that from happening and reduce the supply of these drugs in our country.

In my community, the rate of death from opioid overdose had tripled in 3 years. And, you know, I would like you to understand that it is very hard for the coroner to determine the exact cause of death. You know, all these data are based on coroners' reports, which is based on what pathologists find in the system.

Now, if you have five, six, seven medications or drugs in the system, who is to say which one of these is the real cause of death? That is why they mark them all as opioid overdose.

Mr. LEVIN. So let me ask you then, in terms of awareness, expanding Medicare treatment, isn't that a very good idea, Doctor?

Mr. KLETTER. So, if I could add to that, I think, to your first question, the reason it has taken so long to recognize is less about not recognizing it and more about the stigma associated with the disease.

People with the disease of addiction are sort of shunned and kept in the shadows and embarrassed and shamed, and treatment has been sort of similarly treated. There hasn't been a lot of attention or focus on treatment services. In fact, physicians are not taught how to treat addiction in medical school generally. They are not taught a lot about opioids and/or addiction.

Mr. LEVIN. So expanding Medicare——

Mr. KLETTER. So how can expanding Medicare help? Well, first of all, making it part of mainstream medicine, helping to sort of acknowledge the disease as just that, as a disease.

We heard Governor Scott of Vermont earlier say we need to do a better job of making—of acknowledging the disease and thinking of it as a disease rather than thinking of it as a lack of will power or a moral downfall.

Mr. LEVIN. Okay. So——

Mr. KLETTER. And so Medicare contributes to that by, you know, legitimizing the treatment that we have as a medical treatment.

Mr. LEVIN. Thank you.

Chairman ROSKAM. Mr. Paulsen.

Mr. PAULSEN. Thank you, Mr. Chairman.

I want to follow up a little bit on some of the perspectives that were offered on the minimally invasive procedures. And, look, I mean, historically, the practice of providers has been to prescribe opioids to patients for years, and it is hard to stray away from that course and then to try new different therapies for pain management.

Now, I also understand that there are about 200 FDA-approved devices for which CMS does reimburse, but it seems that not enough providers or Medicare Advantage plans, for instance, are alerting patients to some very effective and efficient ways to manage pain outside of the risk of addiction.

One example is a spinal cord stimulator that involves a minimally invasive procedure and uses electrical signals to block pain signals from reaching the person's brain. It has about a 50 percent or greater opportunity for reduction in pain, and more than half of the patients don't need to have any pain medication for that management. And it is FDA-approved. It is Medicare reimbursed. It has helped about 500,000 patients.

So I am just curious, maybe Dr. Paz and Ms. Hungiville first, what are your health plans doing in general to ensure that providers are aware and that patients have access to some of these covered nonopioid treatments?

Dr. PAZ. So thank you very much for the question.

So we, as you indicated, cover these types of devices for patients that appropriately fit the criteria. And where we spend a great deal of our emphasis at our opioid-wide task force is really looking at patients with acute pain because that becomes the entry point for them being exposed to opioids in the first place. And that is where alternative types of—my colleagues mentioned, alternative types of treatment come into play, physical therapy, chiropractic, osteopathic, manipulative therapy, different types of approaches, the use of nonsteroidals, SSRIs, for example. These are things that we can do for acute pain. And, frankly, there is data that shows that some of the over-the-counter treatments of pain, acetaminophen even, nonsteroidals, can be equally effective, if not more so, for the treatment of those situations.

When a patient has long-term chronic pain, that is a different matter altogether. And, quite frankly, in those situations, if we think it is appropriate, we will cover opioids because that may be the only treatment that is effective. But, certainly, also if a physician is recommending or prescribing a device, that is something that would be covered as well.

Mr. PAULSEN. Ms. Hungiville, are there any barriers to nonpharmaceutical therapies for chronic pain that currently exist, or can you expand on——

Ms. HUNGIVILLE. It is awareness, and through our case management, we are trying to educate providers as well as our beneficiaries that there are alternatives to the opioid treatment. And so that is one of the interventions that we employ: to make them aware of other alternatives.

Mr. PAULSEN. Good. I mean, this seems to absolutely make sense based on the testimony we are hearing. So I appreciate your perspectives and yield back, Mr. Chairman.

Chairman ROSKAM. Mr. Reed.

Mr. REED. Well, thank you, Mr. Chairman.

And the question I have is for Dr. Benyamin. I am sorry. Is that it?

Dr. BENYAMIN. Benyamin.

Mr. REED. Oh, okay. Thank you. I appreciate that, Doctor.

The question I have for you is, pain, in and of itself, is that a bad thing, from a physician's perspective?

Dr. BENYAMIN. It depends on the condition. If it is acute, it is always an alarming sign that there is something happening.

Mr. REED. So as a physician—and I see two doctors up there—what is a successful outcome of pain management? Is it zero pain? Or is there some level of pain that to me is a natural response of the body telling a doctor, "Hey, there is an issue here"? And are doctors and physicians trained to overmedicate in order to get to an unlikely outcome of zero pain, which is probably not, in my humble opinion, the best outcome that we can anticipate from physicians?

Dr. BENYAMIN. Absolutely, Congressman.

Mr. REED. So could you explain that a little bit?

Dr. BENYAMIN. Yeah. This is how we—part of the reason why we got into this crisis is in all these regulations that we had by the hospitals. If you remember, there was a time they used to call pain the fifth vital sign.

Mr. REED. Uh-huh.

Dr. BENYAMIN. I mean, it cannot be ignored.

Mr. REED. Where do those regulations come from? Government, right?

Dr. BENYAMIN. From government, right.

Mr. REED. We directed you to get to zero pain, did we not?

Dr. BENYAMIN. Right. So that was enforced in the hospitals. All the accredited institutions, health institutions, needed to address—assess and address pain to a point that the pain level will go down to anywhere below four.

Now, as you know, that is a very subjective number. And if you look at Medicare actually, they never talk about regulations. They usually talk about—they never talk about the numbers. They talk about quality and function of the patient.

So I think we need to shift this emphasis toward quality of life and function, and those are the tools that we use in our practice. And we rely much less on that number unless it is required by a lot of insurance companies.

I will give you an example. The Congressman mentioned the spinal cord stimulator. We have this arbitrary number of 50 percent. If the patient's pain didn't go from 8 to 4, well, then, his implant will not be approved, right?

Mr. REED. So, as we learn from that experience going forward and setting policies going forward, could you provide me some insight as to how we would do the new regulations to encourage a better outcome than what we may have, by unintended consequences, made in good faith to limit pain but had an unintended consequence of exacerbating this problem?

Dr. BENYAMIN. Absolutely, unintended consequences. That is what we are facing. And that is why I was mentioning to the Chairman that we need to—if we are looking for a solution, there

is no one magic wand that we are going to wave here and solve this problem. This has many aspects to it.

As the Governor mentioned, I like that four pillars of the treatment on—how to address this issue. And you have to work at the prevention. You have to work on recognizing, what is the disease? Is the patient having a substance use disorder? Treat that, treat the consequences, prevent disasters, and limit the supply. If you look—or, you know, the studies have shown that when you limit the supply, we have less of a prescription writing and less deaths.

Mr. REED. Thank you very much for the input.

Chairman ROSKAM. Mr. Renacci.

Mr. RENACCI. Thank you, Mr. Chairman.

It is interesting what my colleague, Mr. Reed, mentioned, because I was 18 years old in a horrible motorcycle accident and went to school the next day with a bottle of aspirin. It is amazing how government has changed things.

But, anyway, I have introduced legislation with Congressman Mark Meadows that would enact a 7-day limit on opioid prescriptions for acute pain with some exceptions. It was crafted in consultation with over 30 stakeholders to address what studies and researchers have proven time and time again: risk of addiction increases with the length of your opioid prescription.

Dr. Paz, in your testimony, you state that Aetna limits opioid prescribing for acute pain to a 7-day supply. CMS has recently proposed limiting initial limit fills to 7 days. This would apply for all new opioid users in Medicare as well as require plans to implement a hard edit for beneficiaries prescribed more than a 7-day supply of opioids.

Dr. Paz, what research led to Aetna's decision to adopt a stricter threshold before Medicare proposed it?

Dr. PAZ. So this is in our commercial plans, and we base that on the CDC recommendations. Those are the same recommendations that we share with physician and dental superprescribers, who are prescribing large quantities of opioids to our members as well.

We think that is very important guidance. It is something that should be used by the provider community, by physicians and dentists who have prescribing privileges. And we felt the first place to put that in place was in our commercial plans where we could, in fact, do that.

Mr. RENACCI. So do you believe limiting opioid prescriptions for populations other than Medicare beneficiaries—I think you have said this—would have an effect similar to what CMS is hoping to achieve with Medicare beneficiaries?

Dr. PAZ. So I would say that there is one exception to that, Congressman, and that is in individuals that are not suffering from acute pain but in individuals that are terminally ill with cancer, for example, in hospice. There are circumstances where there are very good reasons to have long-term use of opioids. But we are focused here, and most of the situations we are looking at are, in fact, really 35 percent of the population are coming to us with acute pain situations.

Mr. RENACCI. Well, it is interesting. My bill provides exceptions for cancer treatment, hospice care, palliative care, and chronic pain.

The next question is for any of the witnesses: What exceptions would you all recommend for CMS as well as what should Congress consider as a nationwide prescription limit other than those four? You mentioned those. Are there any other exceptions that anyone on the panel thinks we should have?

Okay. I yield back.

Chairman ROSKAM. Mr. Thompson.

Mr. THOMPSON. Thank you, Mr. Chairman.

Dr. Kletter, you heard about the Hub and Spoke program, a program with the Spokes. What can we do or do better at the Federal level to enable the success of this program rather than to impede it?

And I have a county that I represent, Lake County, which is contiguous to your second home, that has a high opioid—a terribly high opioid problem. And what can we do to make sure that they have long-term access to these services, and can you talk a little bit about the barriers in the Medicare program that would prevent treating those patients?

Mr. KLETTER. Sure. So we heard quite a bit about the Hub and Spoke program from Governor Scott. It is a fantastic program. BayMark happens to operate three of the six Hubs in the State of Vermont, so we are very fond of it. And we are developing 4 of the 19 in California.

While Vermont is a very small State, they have created what seems to be a no-brainer. This is one of the most effective approaches to treating the opioid epidemic we have seen in the treatment community.

So what can Congress do? Well, as I said in my testimony, Congress can pass legislation that would allow Medicare to cover treatment services at OTPs. OTPs are the Hubs within this Hub and Spoke program. And the concept is that you get a Hub where all three federally approved medications can be provided and wraparound services, including counseling and drug testing, and other supportive services are provided.

And then patients are admitted at the Hub, they are stabilized there, and then once they are stabilized, they are stepped down to a less-restrictive model of care, level of care, and those are the spokes. Those are primary care physicians generally.

And the reason that the model was created was because, as we know, many primary care physicians have been reticent to prescribe medications to folks with opioid use disorder because it is a complicated disease and requires a lot of attention.

The beauty of the Hub and Spoke system is that the Hub provides services in the form of a MAT team, a nurse, and a counselor, to the Spoke so that the physician has additional resources in dealing with the patients, in helping the patients manage their medications, making sure they are not being diverted, making sure they are taking them on time, making sure they are participating in all the services, like counseling, that are required for effective outcomes.

So coverage in Medicare is important, and we work quite a bit with SAMHSA, who has been helpful in developing more OTPs around the country. The CURES funding that came out of Congress last year or this year has been used in California primarily for developing this Hub and Spoke model. It is being used in other States to develop the Hub and Spoke model.

So we would encourage you to look very closely at how States are using their CURES funding and make sure that they are using it in ways that are evidence-based and are, in fact, intervening in this epidemic and reducing overdose deaths.

Mr. THOMPSON. Thank you. I yield back.

Chairman ROSKAM. Ms. Jenkins.

Ms. JENKINS. Thank you, Mr. Chairman.

And thank you all for being here today.

I have introduced a piece of bipartisan legislation called the Furthering Access to Coordinated Treatment for Seniors Act, or the FACTS Act, which helps to bridge the gap in communication between the clinical setting, where patients are diagnosed and prescribed medication, and the pharmacy setting, where patients receive their medications. In particular, for opioids, having information about hospitalizations due to medication mismanagement can add in another layer of support from the Part D and pharmacy community. This coordination is something that is desperately needed in fee-for-service Medicare, and I really look forward to advancing it here in the House.

With that said, Ms. Hungiville, as I understand, standalone Part D plans cannot review Part A and B claims data. Is that correct?

Ms. HUNGIVILLE. That is correct.

Ms. JENKINS. And Medicare Advantage prescription drug plans can review A and B data plans. What type of challenge does this lack of data present for standalone Part D plans in managing the benefit of a potential opioid abuser, and what could plans do to assist beneficiaries in claims if data were made available?

Ms. HUNGIVILLE. Well, we are limited to identifying those members that are at the greatest risk. For the members in our Medicare Advantage plan, we are looking at their prescription utilization. We are looking at their hospitalizations. We are looking at their ER visits. And we are predicting, sometimes with their first opioid prescription, whether they are at risk for developing into addiction, and we are putting them into our treatment algorithms.

In our standalone Part D plan, we don't have that visibility. So we have to rely on the traditional multiple prescriptions from multiple pharmacies and multiple providers. So we are not able to intervene as quickly as what we would like and hopefully prevent addiction rather than treating addiction.

Ms. JENKINS. Okay.

Thank you, Mr. Chairman. I yield back.

Chairman ROSKAM. Mr. Blumenauer.

Mr. BLUMENAUER. Thank you very much for being with us this afternoon.

There are lots of things to chew on, but, Dr. Paz, I really appreciate your reference to the legislation we have to try to make sure that we take care of this disconnect between people who, in terms of unnecessarily restrictive information, for prescribing physicians

to actually know that somebody has an opioid addiction problem. I think the legislation that we have would help remedy that.

Do you have any sense why this is so hard to remedy? Is this just because any time we are dealing with patient privacy we are in kind of a never-never land, that it hasn't received a high enough priority? Are there examples that you or any of the panelists can help us with to show the disastrous consequences of a physician not having this information?

Dr. PAZ. So, Congressman, thank you for the question. I think there are two parts to the answer. First is the general backdrop of the lack of interoperability of health information in general. We have real challenges in healthcare in terms of connecting data that sits in different places between providers with the patient and often having patient information that is patient-centric that is usable by a patient to make important health decisions. That is a challenge that is historical, longstanding, and, in fact, has become even more complicated with the use of electronic records to record and retain that information. So that is one issue. It is the backdrop for the challenges we have in really improving care in general in terms of wastefulness.

But the other part of it is the part two reform that I mentioned in my testimony. HIPAA was written for many, many good reasons, and, obviously, we are in support of it, as I am sure everybody is, to protect patient health information. But at the same time, we have to have modernization of federalization around health information privacy so that, in certain circumstances like the one we are talking about today, providers, physicians have access to information to know if their patient is abusing or addicted to opioids so that they can make the important decisions they need to make to assist and help their patient. Absent that, they are operating without the useful information they need. And, in fact, that is to the detriment of their patient.

Mr. BLUMENAUER. Mr. Chairman, I think this is just one area, but it speaks to a larger set of challenges. But I am hopeful that, shining a spotlight here, we can help avoid potentially disastrous consequences, but maybe it will guide us toward a broader conversation about some adjustments we can make to protect the confidentiality we all care about but not make it unduly restrictive in terms of people being able to do the job for their patients.

Dr. BENYAMIN. Mr. Chairman, may I interject? Very briefly, this is one of the problems, Congressman, with the prescription monitoring program, in which we have limitations in accessing the private data from addiction management facilities. And those are not reflected in prescription monitoring programs. And a lot of small mom-and-pop types of pharmacies, they are not reporting to the data center.

And, again, this is a State-run program. And, you know, as I mentioned in my testimony, we would like to see a national program so that the States can interact with each other. People who live in, you know, border cities, they can easily cross over and get prescriptions from two different providers and the providers not even know what is going on.

Chairman ROSKAM. Thank you. Mr. Marchant.

Mr. MARCHANT. Dr. Kletter, I see that your company is headquartered in Lewisville, Texas.

Mr. KLETTER. That is correct.

Mr. MARCHANT. That area is the entire northern border of my district. Can you tell me a little bit about the program that you provide to my constituents in Texas? And tell me a little bit about the opioid situation in Texas, specifically north Texas, if you could.

Mr. KLETTER. Sure. I can tell you that the program that we operate in Lewisville in particular is under our AppleGate line of business. And AppleGate is an office-based practice that provides medication-assisted treatment, which is buprenorphine, along with counseling and drug testing. So it is sort of a hybrid between an opiate treatment program, which is a very highly structured program, and a typical office-based practice, which is a primary care physician prescribing medications.

So what we do there is we prescribe medications and counseling and we do counseling and do drug testing to—it is a small number of folks so far. We have been open in Lewisville for just a short time. We have 12 sites in Texas in total. Most of those sites are opiate treatment programs. And, again, opiate treatment programs are the more structured, more regulated programs where we have more intensive services and we provide daily medication administration.

The daily medication administration is part of the Federal regulations that help to prevent diversion of these very powerful medications. So what that means is a patient will come into treatment. They will get a history and physical with a physician. They will be provided a clinical assessment, generally an ASAM assessment, American Society of Addiction Medicine assessment, or an Addiction Severity Index assessment. They will be determined or diagnosed with opioid use disorder, and they will be provided with the appropriate dose—the appropriate type of medication and the appropriate dose of medication, based on a physician's order. And based on that physician's order, they will then participate—they will develop a treatment plan with a counselor, and every 90 days, that treatment plan will be updated so that we can make sure that they are doing well, they are progressing in treatment.

We will do a monthly random drug test to make sure that they are not only taking the medication that we are giving them but that they are also not taking other illicit or prescribed opiates. And they will get their medication from a nurse every day who does sort of a very brief assessment to make sure that the dose is the right dose and that they are progressing well in treatment and getting some words of encouragement to follow their treatment plan.

Mr. MARCHANT. Does Texas have an effective opioid policy, as far as assistance from the State?

Mr. KLETTER. The Medicaid rates for reimbursement for the services that we provide are not good in and of themselves, but they have done a great job in using the STR money out of the CURES grant to supplement that program this year and next, hopefully. So, generally, the regulatory environment in Texas is good. Funding could be improved, but they are working on that, and they are doing better, and we are encouraged that they have been a good partner.

Mr. MARCHANT. Thank you.

Chairman ROSKAM. Mrs. Black.

Mrs. BLACK. Thank you, Mr. Chairman.

And I appreciate you all being here today. As a nurse for over 45 years, I have watched this scourge on our society occur. And I know we talk about chronic pain. We certainly want to take care of people that have chronic pain; there is no doubt about that. They suffer. You can see that by their blood pressures, by their anxiety, by their pulses. But what we did with this, "how bad is your pain," the smiley face system, was not a very good thing for us to do, and I am glad that we have finally stopped doing that.

Thank you, Dr. Benyamin, for what you are doing with the interventional pain management. And I would like at some point in time, and I know we don't have enough time here, to talk with you more about the results that you are getting from that. What percentage of your patients going through that kind of treatment have found success? Is there a number that you could give me on that of the——

Dr. BENYAMIN. I would be glad to provide you with all the data.

Mrs. BLACK. I would really like that.

Dr. Kletter, I want to go to you and talk to you a little bit about—or excuse me, Mr. Kletter—or is it Dr. Paz? Which one of you is doing the program where you are using the medication-assisted treatment?

Mr. KLETTER. We are.

Mrs. BLACK. Dr. Kletter, okay. What percentage of your clients have eventually become drug-free with your medication-assisted treatment? How do you move them to a drug-free situation?

Mr. KLETTER. So, as I said in my testimony, it is important to understand that medication—as we think about medication-assisted treatment, it is important to understand the concept of opioid use as a chronic disease. And so, like any other chronic disease, we know that patients who suffer from opioid use disorder struggle with it in some cases for their entire life. We have very effective treatment, but we don't have a cure for the treatment.

And so, generally, our approach is not to encourage people to get off of treatment immediately. We do encourage folks to stay in treatment at least a year, and in that way, we know that—although science tells us that you must stay in treatment for at least a year to sort of help heal the brain from the changes that have occurred, we know from science that there are changes that have occurred in the brain from overuse of opioids. So we encourage folks to stay in treatment at least a year. I can tell you that 60 percent of our patients are in treatment——

Mrs. BLACK. I know my time is going to run out here in just a second. If I could get more information from you on looking further out and what all the results are, that would be great.

And then, Ms. Hungiville, I would like to ask you about how you are using telehealth, since that is something that I am very interested in.

Ms. HUNGIVILLE. Well, we are piloting a program where, in the ER, we are trying to get patients when they are in crisis, in overdose and/or even drug seeking, and making telehealth avail-

able to them to immediately start with medication-assisted treatment and then get them into counseling and into a program.

Mrs. BLACK. I would love to hear more from you as well.

And, Mr. Chairman, I am asking for a lot of information I guess will be sent back to your office so that you could share with us some of the results of what you are doing. Thank you so much.

Chairman ROSKAM. Thank you. Just a couple questions in kind of summary.

Dr. Kletter, in your testimony and in your statement, you used the phrase "opioid use disorder." Is that a term of art? Is that somehow distinguishing between the word "addiction," and are you communicating something else? I have a brother who is an emergency physician, and I noticed that at one point, the emergency physicians began to speak about the emergency department.

So what is the story behind that phrase, and is there a subtlety that you are communicating there that we need to know about, or are these phrases interchangeable with addiction?

Mr. KLETTER. So opioid use disorder is the term that is used in the Diagnostic and Statistical Manual of Mental Disorders, the DSM, which is sort of the tool that physicians use to diagnose disease, psychological disease generally.

So there is a distinction between addiction and dependence. That is really critical to understand. The difference is, of course, addiction, which is—so opioid use disorder is what you might call an addiction, and it is characterized in the DSM by there being 11 criteria in order to meet the diagnosis of opioid use disorder.

Two of those are physiological; they are tolerance and withdrawal. The other nine are behavioral, things like engaging in behaviors despite negative consequences, compulsive use, using increasing amounts over time even though you don't intend to. So there is an important distinction between opioid use disorder and tolerance—or, sorry, dependence, dependence being simply using a medication consistently—you could be dependent on a medication. For example, I take a statin. I am dependent on that medication to prevent my cholesterol from getting too high and having a heart attack. So I don't know if that answers your question.

Chairman ROSKAM. Yes, it does. But there are some subtleties there that I need to learn more about. So, if you have any insight on the tutorial, I would be grateful.

Mr. KLETTER. Sure. We are happy to tell you more and invite you or Mrs. Black or any of the Members of the Subcommittee to any of our facilities. We are happy to show you around, show you what we do, and how effective our services are.

Chairman ROSKAM. Okay. That would be helpful.

Dr. Paz, in your testimony, you spoke about intervening for those who are at risk. How are at risk individuals, patients or overprescribers identified, and what is the threshold, you know, based on Mr. Blumenauer's observations about the sensitivity around privacy and all that sort of stuff? How do you navigate through identifying someone who is at risk, and how do you walk through that carefully?

Dr. PAZ. Thank you for the question, Mr. Chairman.

So there are several different ways we do this, and one is we have access to our members' claims history, in terms of prescrip-

tions of opioids. And we will find evidence of pharmacy shopping, physician shopping. Right there, that would be a risk factor. We have records of his prior history——

Chairman ROSKAM. So you basically have predictive modeling. I mean, you have that access to those algorithms that say, "Hey, there is a problem here."

Dr. PAZ. And then we would intervene if there are circumstances where that occurs, again, within the boundaries of HIPAA requirements, certainly.

Chairman ROSKAM. What does that intervention look like?

Dr. PAZ. We have case managers, care managers that we actually have that intervene with our member, for example.

Chairman ROSKAM. Is it explicit? I mean, is it a call from a case manager that says, "I think you have a problem"?

Dr. PAZ. Yeah.

Chairman ROSKAM. Okay.

Dr. PAZ. Yeah. We would certainly—our case managers would interface or interact with a member that has a set of conditions that requires some kind of an intervention that we can offer, not as a provider, though, which is key.

We work with providers, and, again, being mindful of HIPAA requirements.

Chairman ROSKAM. Say that again. You were just making an important point, and I didn't quite pick up on it. So the important point that you are making is a distinction between providers and carriers, based on what?

Dr. PAZ. So, in terms of prescribing, a provider would prescribe.

Chairman ROSKAM. Right.

Dr. PAZ. We have access to information that would suggest overprescribing. And I gave a few examples earlier that putting in limits on how many days a prescription can be written for for acute pain, putting in a dosing limit as well. So these are things that we can do.

We have done other things like partnered with a company, Pacira, which has produced a nonopioid pain reliever for oral surgery, post-oral surgery. We have created a partnership with them. It is a value-based contract that we have with them, so it is emphasizing quality outcomes for our members that receive that drug.

But they are now going to receive a nonnarcotic after oral surgery as opposed to a 30-day supply of a narcotic post-oral surgery, which, interestingly, in our review of data and analytics, we find does, sadly, occur. It occurs even after a routine dental visit, unfortunately. So for a wisdom tooth extraction.

So there are a number of different things that we can do including, for example, we have two programs that are noteworthy. One is the work that we are doing with mothers who have neonatal abstinence syndrome. We launched this program in several States. Again, our care managers intervene with mothers who have been identified as being neonatal abstinence, at risk for having children born with neonatal abstinence syndrome, and we put a program in place with ICUs, neonatal ICUs in their communities to address that.

And, certainly, our program where we distribute naloxone and make sure that we are working to train first responders in commu-

nities to help members avoid death associated with overdose and addiction.

Chairman ROSKAM. That is helpful. Thank you.

What is the duration? And this is for the physicians on the panel. What is the duration that somebody can be taking an opioid and they become addicted? We have talked about a 7-day threshold. I have heard that referred to several times.

You know, Doctor, you are shaking your head. There is not a magic number. What is a threshold? What is a range? What is a reasonable expectation?

Dr. BENYAMIN. You know, again, it all depends on who is the patient, what is the pathology behind it, the reason. What is the reason that the patient is taking the medication? Is it a patient who just feels aches and pains all over their body, or is it a patient who has had five low back surgeries and three neck surgeries and two knee replacements? You know, these are all different patients. And, you know, we are human beings at the end of the day. We are not robots. So we react differently to disease, and we react differently to medications for the disease. So we have to allow for individualization of these treatments.

Chairman ROSKAM. In your study and evaluation of this for any of the four of you, is there a spectrum in terms of addiction, or does somebody cross a line and they are addicted?

Dr. PAZ. So, in general, that 7-day number that is in the CDC recommendations is there for a reason, because roughly—and this is, again, depending on the study you look at—about 14 percent of individuals who are exposed to a week of a narcotic will become addicted.

Chairman ROSKAM. Fourteen percent. So, in other words, 14 percent of people who are on it 7 days or more, they are addicted.

Dr. BENYAMIN. And, Mr. Chairman, the psychiatrists will argue that addiction is a disease in the person; it is not in the substance. So this is a continuous saga between one side of this equation and the other.

Chairman ROSKAM. The medical spectrum. Yes, I understand.

Ms. HUNGIVILLE. The dosage is also important, and the CDC guidelines also say that more than 50 morphine-equivalent dosages per day puts you at a higher risk of developing addiction.

Dr. BENYAMIN. Mr. Chairman, if I have to point to one thing that is missing in a lot of medical specialties, we are good at writing prescriptions, at prescribing treatments, but we are not good at monitoring the treatment as far as effect and side effect.

That is why it is very important that when we prescribe, that is what our guidelines say—how you need to monitor the effect and the side effects of medications, that is going to be the key.

Chairman ROSKAM. That is a good summary. So let me ask each of you, in closing, if you had to communicate one thing, not four things, not a handful of things, one thing to this group today, what would it be? Doctor.

Dr. BENYAMIN. Cut the supply of heroin and synthetic fentanyl. That is like a weapon of mass destruction affecting our communities.

Chairman ROSKAM. Got it. Dr. Kletter.

Mr. KLETTER. Increase access to evidence-based treatment services.

Chairman ROSKAM. Dr. Paz.

Dr. PAZ. Ensure education around use of nonopioid pain treatments.

Chairman ROSKAM. Okay. Ms. Hungiville.

Ms. HUNGIVILLE. And I would also add limiting dosages of opioids for acute conditions.

Chairman ROSKAM. Okay. Mr. Thompson.

Mr. THOMPSON. Thank you for indulging me.

I mentioned to the Governor my concern about the treatment delay in the workers' compensation programs leading to opioid problems, and it is something I am very, very interested in.

I have seen a lot of anecdotal evidence that this is true. In my State of California, there is just a long waiting period. Everybody is denied—a lot of people are denied the procedures that the medical profession recommends, so it stretches out the time that they are on painkillers. And I have just seen too many people who, because of this, become addicted.

And I am looking at some different things to try to deal with this. So, if any of you have any information that would help me out in that, would you please send it to me?

Chairman ROSKAM. We have been joined by our former colleague, Ed Whitfield, a great American from Kentucky and former Chairman of our partner Committee, the Energy and Commerce Committee, which has a lot to do with the solutions here. So it is good to have him back.

For the record, Members are advised that they have 2 weeks to submit written questions that can be answered later in writing, and those questions and your answers will be made part of the formal hearing record.

Finally, two things: Number one, thank you for your time. You have been very generous with your time today, and I know it is an adventure to schlepp out here and all that, so thank you for doing that and for the time that you put into your testimony. It was very helpful.

Second, if you think of things subsequent to this, whether you are flying home, driving around, whatever you are doing, in the next several weeks or months, and you think, I wish I had said that or I have this article, and I think those people would benefit from it, send it to us. And I will make sure that it is distributed.

You get the sense of the caliber of these people. These are serious, thoughtful people that are solution-oriented. We are not looking for pen pals, if you know what I am saying. But, things that you think we should be reading, would be very, very helpful.

So, on behalf of the whole Subcommittee, I want to thank you for your time today and look forward to continuing to interact with you in the future. Thank you.

The Committee stands adjourned.

[Whereupon, at 6:31 p.m., the Subcommittee was adjourned.]

[Questions for the Record follow:]

Questions for the Record for Dr. Ramsin Benyamin
Ways and Means Subcommittee Hearing on the Opioid Crisis: Removing Barriers to Prevent and Treat Opioid Abuse and Dependence in Medicare
February 6, 2018

Subcommittee on Health (Majority)

Question: *Diversion and misuse are critical issues with these drugs – what do you think about long-acting treatments, such as injections, that are administered by healthcare professionals and thus are never in the hands of the patient? Could that help alleviate this problem?*

Answer: *Eliminating the handling process of pills and patches by patients will definitely reduce the risk of diversion and misuse. Injectable long acting opioids in the form of intra-thecal pumps have been used for many years and are currently available to Part D recipients. More recently, clinical trials are ongoing to evaluate safety and efficacy of once weekly or monthly subcutaneous injection of a long acting opioid. Once approved by FDA, it may prove to be a great tool to reduce diversion and misuse.*

Question: *We know that often medication combined with behavioral therapy is a critical part of a successful treatment and recovery for individuals with substance use disorders. For this therapy to be successful, many of those will probably be on some form of daily medication. Do you see that act of having to take medication everyday as a barrier? Do you think the patients do? And then, do you think that practitioner-administered treatments that last a week or a month could benefit certain patient populations?*

Answer: *As a matter of principle, the more frequent the treatment, the higher the risk of non-compliance. Having a weekly or monthly opioid administered by practitioners will definitely reduce the risk of non-compliance and maintain a more stable dose of medication in the body, cost permitting.*

Question: *We know that patients who overdose are most vulnerable to having a relapse within a week of that overdose. While behavioral therapy is a critical part of long term treatment and recovery, often times, these individuals are not stable enough to appreciate or ready to enter into therapy right after an overdose. What do you think about medications that last a week and can be administered by a practitioner immediately after an overdose, thus giving those patients more time to become stable and seek permanent treatment?*

Answer: *Currently there is an opioid maintenance therapy in the approval process that's injected once weekly. Once approved by FDA, it will provide a good option to bridge the acute stage into long term treatment plan.*

Questions for the Record for Dr. Harold L. Paz
Ways and Means Subcommittee Hearing on the Opioid Crisis: Removing Barriers to Prevent and Treat Opioid Abuse and Dependence in Medicare
February 6, 2018

Representative A. Smith (R-NE):

Question: *Dr. Paz, can you talk about what Aetna is doing to educate their prescriber network on appropriate prescribing of opioids and other treatment options for chronic pain currently? Is there a difference in how you educate small, independent pharmacies in places rural Nebraska versus some of the larger chain pharmacies? What are some of the challenges you are seeing to providing this type of education to our rural communities?*

Aetna Answer:

Aetna has taken a proactive approach to working with providers to reduce opioid prescribing, misuse, and abuse. We are using our data resources to encourage prescribers to reduce misuse and prevent the diversion of unused pills. Specifically, starting in 2016, Aetna began sending letters to the top 1% of opioid prescribers within their respective specialties to make them aware of their outlier prescribing patterns. These approximately 1,000 opioid "super-prescribers" were also provided the 2016 Centers for Disease Control ("CDC") guidelines for the use of opioids for the management of chronic pain. This program is growing and in 2017, Aetna, in collaboration with the American Association of Oral and Maxillofacial Surgeons, sent separate letters to 480 "super-prescribing" dentists and 249 "super-prescribing" oral surgeons. As part of the "super-prescriber" initiative, Aetna set up a dedicated email address to which prescribers can respond to Aetna's letters and request more information on their own prescribing patterns. The "super-prescriber" initiative is evolving as Aetna continues to explore additional ways to curtail inappropriate opioid prescribing to its members.

In addition to the stigma of opioid use disorder, rural communities in particular face challenges in the availability of multi-disciplinary care teams for chronic pain management and opioid use disorder treatment using medication-assisted treatment ("MAT") and cognitive behavioral therapy. As one example of Aetna's efforts to help combat these challenges, Aetna is exploring ways to increase access to behavioral health telemedicine services, including by supporting research at the University of Alabama Birmingham to study the use of telemedicine to provide MAT to pregnant mothers. Furthermore, the Aetna Foundation recently announced that it will provide grants totaling $6 million over the next two years to fund select projects that state and local leaders have identified as promising, or particularly well-suited to tackle the most critical opioid-related challenges. The Aetna Foundation's initial $1 million grant was recently awarded to the North Carolina Harm Reduction Coalition for its Rural Opioid Overdose Prevention Project.

Representative Chu (D-CA):

***Question**: Dr. Paz and Ms. Hungiville, I'd like to ask if either of Aetna or Wellcare offer plans that cover acupuncture as an alternative to treat pain, and if so, what is the rationale for including such coverage?*

Aetna Answer:

Aetna supports a multi-modal approach to treating pain that includes pharmacologic and non-pharmacologic treatment options. Such options may include acupuncture when medically appropriate, although it varies by plan.

In our Medicare business, in 2018, ten of Aetna's regional MA-PD plans have added a supplemental acupuncture benefit that provides as a covered service between six to twelve visits per year and a member cost share range of $0 to $20. These kinds of added benefits, known as "mandatory supplemental benefits," are part of the product offered in this market and are included in the premium.

Subcommittee on Health (Majority)

***Question**: Diversion and misuse are critical issues with these drugs – what do you think about long-acting treatments, such as injections, that are administered by healthcare professionals and thus are never in the hands of the patient? Could that help alleviate this problem?*

Aetna Answer:

Aetna is continually evolving its management of opioids in the face of the ongoing health crisis and in line with federal and state guidance. Aetna's clinical strategy is generally supportive of long-acting injectable MAT products, which have the potential to address two clinical issues related to proper treatment of addiction: improved treatment adherence and reduced diversion of MAT products. Aetna will determine the appropriate coverage of such products when they are FDA-approved and available on the market. .

***Question**: We know that often medication combined with behavioral therapy is a critical part of a successful treatment and recovery for individuals with substance use disorders. For this therapy to be successful, many of those will probably be on some form of daily medication. Do you see that act of having to take medication everyday as a barrier? Do you think the patients do? And then, do you think that practitioner-administered treatments that last a week or a month could benefit certain patient populations?*

Aetna Answer:

Aetna is continually evolving its management of opioids in the face of the ongoing health crisis and in line with federal and state guidance. Aetna is committed to enhancing access to evidence-based addiction treatment options for its members. One important treatment option available to those with opioid use disorder is medication-assisted treatment ("MAT"), which includes medications such as methadone or buprenorphine. The World Health Organization found the most effective treatment for opioid dependence is a combination of psychosocial support and an opioid agonist (such as methadone or buprenorphine).[1] These medications have shown positive results in interrupting the intoxication withdrawal cycle, significantly reducing drug use, and improving retention in treatment plans.

Aetna continues to evaluate ways to expand its members' access to this treatment option when appropriate. In its commercial business, Aetna has removed prior authorization requirements on generic drugs that treat opioid addiction, including oral buprenorphine/naloxone and generic dosages of Suboxone and Subutex. In addition, these products are now on the Aetna Preventive Medicine List, which helps reduce member cost-sharing. In 2017, and continuing in 2018, Aetna's Medicare formularies offer access to MAT for opioid addiction therapy, as well as reversal agents such as Narcan.

Aetna's clinical strategy is generally supportive of long-acting injectable MAT products, which have the potential to address two clinical issues related to proper treatment of addiction: improved treatment adherence and reduced diversion of MAT products. Aetna

[1] *See, for example, http://www.who.int/substance_abuse/activities/treatment_opioid_dependence/en/*

will determine the appropriate coverage of such products when they are FDA-approved and available on the market.

Question: *We know that patients who overdose are most vulnerable to having a relapse within a week of that overdose. While behavioral therapy is a critical part of long term treatment and recovery, often times, these individuals are not stable enough to appreciate or ready to enter into therapy right after an overdose. What do you think about medications that last a week and can be administered by a practitioner immediately after an overdose, thus giving those patients more time to become stable and seek permanent treatment?*

Aetna Answer:

Aetna's clinical strategy is generally supportive of long-acting injectable MAT products, which have the potential to address two clinical issues related to proper treatment of addiction: improved treatment adherence and reduced diversion of MAT products. Aetna will determine the appropriate coverage of such products when they are FDA-approved and available on the market.

[Submissions for the Record follow:]

Statement for the Record

Pharmaceutical Care Management Association

for the

UNITED STATES HOUSE OF REPRESENTATIVES

COMMITTEE ON WAYS AND MEANS

HEALTH SUBCOMMITTEE

"The Opioid Crisis: Removing Barriers to Prevent and Treat Opioid Abuse and Dependence in Medicare"

February 6, 2018

Introduction

Thank you for the opportunity to submit this statement for the record for the hearing, "The Opioid Crisis: Removing Barriers to Prevent and Treat Opioid Abuse and Dependence in Medicare." PCMA thanks the Subcommittee for its important work to remove policy barriers that may stand in the way of needed changes to help the millions of American families torn apart by the nation's opioid crisis.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million[i] Americans with health coverage provided through self-insured employers, health insurers, labor unions, Medicare, Medicaid, SCHIP, and the Federal Employees Health Benefits Program (FEHBP).

Make E-Prescribing of Mandatory for Controlled Substances: Support H.R. 3528, the Every Prescription Conveyed Securely Act

E-prescribing dramatically reduces medication errors and fraud and PBMs can use claims data to identify at-risk patients and providers with highly unusual prescribing or dispensing patterns. After the DEA allowed e-prescribing for controlled substances in 2010, states followed. Currently all states permit it and a few states actually require its use for controlled substances. By directing a prescription electronically from a specific prescriber to a specific pharmacy, e-prescribing makes it difficult to pharmacy shop and commit. E-prescribing platforms can provide physicians with a patient's medication history among numerous providers. This can be especially important with controlled substances, where patients may engage in doctor shopping to find one or more doctors to write a prescription for a dangerously addictive drug. Congress should require e-prescribing for all controlled substances. H.R. 3528, the Every Prescription Conveyed Securely Act, would require the use of E-prescribing of controlled substances in Medicare. We are appreciative of Congressman Kelly and Higgins for cosponsoring this important legislation.

How PBMs Can Help

PBMs can be an important part of the solution to curbing the nation's opioid crisis. Given their role administering prescription drug benefits in real time, PBMs, through the software systems they use to assess eligibility, determine cost sharing, and adjudicate claims, can see whether patients are using multiple prescribers and pharmacies, are getting a morphine-equivalent dosage well beyond that recommended by the Centers

for Disease Control and Prevention (CDC), and are getting a longer days' supply than necessary.

Increasingly, as health information networks improve and physicians move to e-prescribing controlled substances, PBMs and prescribers will have better information on how, where, and when prescriptions for controlled substances are obtained. Where the law will allow it, PBMs will also be able to reduce coverage for prescriptions exceeding an appropriate days' supply or a morphine-equivalent dosage, and will be able to direct patients at risk to an appropriate pharmacy or pharmacy chain for their controlled substances.

There are significant steps policymakers can take to help private sector efforts to reduce opioid abuse.

Other Common-Sense Policy Solutions to Curb the Opioid Crisis

While the factors driving America's opioid crisis are complex and do not lend themselves to easy solutions, targeted policy changes can help curb prescription opioid abuse and diversion.

Implement Seven-day Fill for Acute-Pain Opioid Users: As recommended by the Centers for Disease Control, prescriptions for acute pain should be limited to prevent patients from getting addicted to pain medication. The CDC specifically mentions that a first fill for acute pain should rarely need to exceed a seven days' supply. The limit would not apply to treatment of cancer or chronic pain, or the use of opioids in treating addiction or for patients in palliative or end-of-life care. Limiting prescriptions to treat acute pain to seven days strikes an appropriate balance between meeting patients' needs for pain relief and helping protect them from potential addiction, and also lessens the danger of diversion.

The Centers for Medicare and Medicaid Services (CMS), in the current Advance Notice of Methodological Changes for Medicare Advantage Capitation Rates and Part D Payment Policies and Draft Call Letter, states that it expects Part D plans to implement a hard safety edit that limits coverage of an initial opioid prescription fill exceeding seven days for the treatment of acute pain. PCMA supports this modification. The Food and Drug Administration (FDA) could also change the labeling for opioids to distinguish appropriate duration of prescriptions for acute users and long-term users of these drugs. Finally, the Drug Enforcement Agency (DEA) should modify its rules to allow pharmacies to dispense less than the full prescription written by a prescriber.

Use Lowest Effective Dose: According to the CDC, "when opioids are started, clinicians should prescribe the lowest effective dosage."[ii] Specifically, the CDC recommends that clinicians "should carefully reassess evidence of individual benefits and risks when increasing dosage to 50 morphine milligram equivalents (MME) or more per day, and should avoid increasing dosage to 90 MME or more per day or carefully justify a decision to move a dosage to 90 MME or more per day."[iii] In addition to considering changes in labeling for the seven-day policy mentioned above, the FDA should add to the label for opioids the information in the CDC guidelines for use of the minimum effective dose.

Improve and Integrate State Prescription Drug Monitoring Program (PDMPs) and Require Prescriber Check: Prescription drug monitoring programs, or PDMPs, are an important tool to help identify and prevent prescription drug abuse. PDMP data should be updated in a timely manner, should be interoperable across state lines, and easily accessible to prescribers and pharmacies. Additionally, prescribers should be required to check state PDMP databases when prescribing opioids, at least until e-prescribing is widely adopted and supplies similar information.

Align Substance Abuse Treatment Privacy Laws with HIPAA to Encourage Better Care Coordination: To help facilitate care coordination for those suffering from substance abuse, the law on substance abuse records should be harmonized with the Health Insurance Portability and Accountability Act (HIPAA). Under current substance abuse treatment privacy laws at 42 CFR Part 2, addiction treatment providers must obtain individual, written consent from patients in order to share any information with non-addiction clinicians — the only exception being for "true emergencies." Obtaining multiple consents from a patient, as required under current law, is challenging and creates barriers to integrated approaches to care that produce the best outcomes for patients. The separate and different treatment in the law of substance abuse disorder patient history creates virtual care silos, hinders good medical care, and perpetuates the unnecessary division between physical and behavioral health and may serve to perpetuate stigma in the contemporary era of electronic health records (EHRs), integrated health care, and HIPAA privacy protections.

Implement Thoughtfully the Comprehensive Addiction and Recovery Act of 2016: PCMA supported the passage of the lock-in provisions in CARA and appreciates CMS for undertaking the process to get the lock-in implemented under Part D. We also support the flexibility to lock a beneficiary into a specific prescriber(s) or specific pharmacy or both, based on the beneficiary's utilization. However, we are very concerned that CMS's proposal in the proposed Part D rule promulgated November 28, 2017, to require a Part D plan sponsor to wait six months from the date the beneficiary

is first identified as potentially at-risk before limiting that beneficiary to a given pharmacy or prescriber for frequently abused drugs is counterproductive. Indeed, a six-month delay works against the goal of CARA and defeats the purpose of the lock-in program, which is to take steps quickly to protect beneficiaries and reduce fraud. Without timely intervention, these beneficiaries will continue to abuse and potentially divert opioids. Furthermore, CMS should preserve the flexibility of the current Drug Utilization Review (DUR) and Overutilization Monitoring System (OMS) programs while also providing flexibility for Part D plan sponsors and their PBMs to develop and implement their lock-in programs.

Conclusion

We thank the Subcommittee for this opportunity to share our views on how common-sense policy proposals can help curb America's opioid crisis. PCMA stands ready to work with the Subcommittee and all Members of Congress to address the rampant overuse of opioids. Should there be any questions, please contact Jonathan Heafitz at jheafitz@pcmanet.org.

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[i] PR Newswire, "PBMs Provide Policy Solutions to Increase Competition, Reduce Rx Costs," Feb 04, 2016.
[ii], Dowell, Op. Cit.
[iii] Dowell, Op. Cit.

PHILIP B. SCOTT
Governor

State of Vermont
OFFICE OF THE GOVERNOR

January 12, 2018

The Honorable Eric Hargan
Acting Secretary of U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Mr. Secretary:

Opioid addiction is devastating communities across our country and in our state of Vermont. As the President's Commission on Combating Drug Addiction and the Opioid Crisis stated in its final report, drug overdoses are now the leading cause of unintentional deaths. In response, the President has declared the opioid crisis a public health emergency. An important step in addressing this crisis, and one supported by the President's Commission, is increasing access to treatment, including medication-assisted treatment (MAT). In that spirit, I am writing you today to ask that we expand our existing state and federal partnership by including Medicare as a participating payer in Vermont's nationally-recognized "Hub and Spoke" opioid addiction system of treatment, as well as for Vermont providers offering complementary prevention, diagnosis, and recovery activities.

The state of Vermont and federal government have been effective partners in health care reform for many years. Vermont has been provided the flexibility and tools to improve the delivery of health care and by extension the health and well-being of Vermonters. Vermont's *Global Commitment to Health* Medicaid 1115 waiver and the *Vermont All-Payer Accountable Care Organization Model Agreement* are examples of how the federal government and a state can design a program that furthers federal goals while being customized for the strengths and needs of an individual State.

Given the urgency of opioid abuse, the state of Vermont would like to further our partnership with CMS by requesting that CMS consider Medicare's participation in Vermont's Hub and Spoke program. This highly praised opioid addiction treatment program has since its launch in 2013 increased access to MAT for thousands of Vermonters. Through coordinated team-based care, it seeks to provide the necessary level of care in the most appropriate settings. Furthermore, MAT is viewed as a gold standard in opioid use disorder treatment and has been associated with reduced medical expenditures in a Medicaid population. Early analysis indicates this pattern could be repeated with Medicare beneficiaries. While Hub and Spoke services to date have been primarily supported by Medicaid, this epidemic does not discriminate against age or socioeconomic status, and Medicare beneficiaries are a growing cohort of Americans overcome by this crisis. Medicare participation in Hub and Spoke would improve Vermont's ability to provide necessary care to the Medicare beneficiaries who need it.

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The Honorable Eric Hargan
January 12, 2018
Page Two

The *Vermont All-Payer Accountable Care Organization Model Agreement* could serve as a platform for the state and CMS to involve Medicare. This novel and forward-thinking model grants Vermont significant flexibility to integrate care across the health care and social services system and across payers. It also holds Vermont accountable to statewide performance targets such as reducing deaths attributed to substance abuse, expanding access to treatment, and improving early intervention.

Vermont is also exploring all-payer approaches to prevention, non-opioid management of chronic pain, and identification of individuals with risky substance use behavior, as well as treatment for opioid use disorder. Many of these efforts are reflected in the recent recommendations by the Opioid Coordination Council I established at the beginning of my administration. As this work matures, additional opportunities for partnership between Vermont and the federal government are likely to arise. Vermont has made great strides in increasing prevention and access to care with Medicaid and state funds; but to truly tackle the opioid crisis, we need an "all hands on deck" approach coordinated across local, state, and federal partners. Together, I believe that we can demonstrate how an effective state and federal collaboration can serve communities torn apart by the opioid crisis.

Thank you in advance for your consideration. Please do not hesitate to contact me or my staff with questions or concerns.

Sincerely,

Philip B. Scott
Governor

PBS/kp

c: Administrator Seema Verma, Centers for Medicare and Medicaid Services

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Impact of Medication-Assisted Treatment for Opioid Addiction on Medicaid Expenditures and Health Services Utilization Rates in Vermont

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ABSTRACT

In the face of increasing rates of overdose deaths, escalating health care costs, and the tremendous social costs of opioid addiction, policy makers are asked to address the questions of whether and how to expand access to treatment services. In response to an upward trend in opioid abuse and adverse outcomes, Vermont is investing in statewide expansion of a medication-assisted therapy program delivered in a network of community practices and specialized treatment centers (Hub & Spoke Program). This study was conducted to test the rationale for these investments and to establish a pre-Hub & Spoke baseline for evaluating the additive impact of the program. Using a serial cross-sectional design from 2008 to 2013 to evaluate medical claims for Vermont Medicaid beneficiaries with opioid dependence or addiction (6158 in the intervention group, 2494 in the control group), this study assesses the treatment and medical service expenditures for those receiving medication-assisted treatment compared to those receiving substance abuse treatment without medication. Results suggest that medication-assisted therapy is associated with reduced general health care expenditures and utilization, such as inpatient hospital admissions and outpatient emergency department visits, for Medicaid beneficiaries with opioid addiction. For state Medicaid leaders facing similar decisions on approaches to opioid addiction, these results provide early support for expanding medication-assisted treatment services rather than relying only on psychosocial, abstinence, or detoxification interventions.

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1. Introduction

1.1. Opioid Epidemic

Opioid addiction continues to grow as a public health problem with significant impacts on morbidity and mortality, health care expenditures, crime, and health outcomes. In 2013, 1.9 million Americans were dependent on pain relievers, and 517,000 were dependent on heroin (Substance Abuse and Mental Health Services Administration (SAMHSA), 2014a) Kolodny et al. estimated that this figure was closer to 5 million when including individuals with active opioid prescriptions who may also have been addicted (Kolodny, Courtwright, Hwang, et al., 2015). While use of prescription opioids has held steady or declined since 2002, heroin use has increased (Substance Abuse and Mental Health Services Administration (SAMHSA). 2014a). The growth in heroin use has carried over to patterns in mortality, which is increasing nationally (Department of Health and Human Services, 2015). In 2010, 3036 deaths resulted from heroin overdoses and 16,651 deaths from opioid pain reliever overdoses. In 2013, heroin overdose deaths more than doubled to 8257 while opioid pain reliever overdose deaths dropped slightly to 16,235 (National Institute on Drug Abuse, 2015). Furthermore evidence associates nonmedical use of pain relievers with subsequent heroin use (Muhuri, Gfroerer, & Davies, 2013), highlighting the link between licit and illicit drug use and the need to address both as a continuum of the same epidemic.

Vermont's experience mirrors the national trend. Nonmedical use of prescription pain relievers among Vermonters age 12 years and older declined between 2012 and 2013 (from 4.6% to 3.7%; p-value <0.01), (Substance Abuse and Mental Health Services Administration (SAMHSA), 2014b) even as opiate-attributed deaths (from 39 to 68 per year) and overdoses (from 1.4 to 2.2 discharges per 10,000 people) increased from 2010 to 2013 (Vermont Department of Health, 2014a). Between 2008 and 2012, the average number of infants exposed to opiates at birth more than doubled, increasing from 17.8 births per 1000 hospital deliveries to 39.8 (Vermont Department of Health, 2014b). One possible explanation for the increase in adverse opioid-related outcomes is an increase in heroin use. The addictions treatment system intake experience appears to support this conclusion. From 2011 to 2013, the number of Vermonters receiving treatment for prescription opiates and heroin increased from 2864 (654 for heroin and 2210 for

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prescription opiates) to 3971 (1375 for heroin and 2596 for prescription opiates) — a 38.6% overall increase, with a 110.2% increase for heroin and a 17.5% increase for prescription opiates (Vermont Department of Health, 2014b).

The combination of increasing overdose deaths, opiate-exposed newborns, and demand for treatment services constituted a public health emergency, and Vermont policymakers determined that a systemic response was needed. However, in a small, rural state, policymakers must consider the cost of expanding access to treatment for opioid addiction and the impact on overall health care and medical service expenditures.

1.2. Treatment for Opioid Abuse or Dependence

Medication-assisted treatment (MAT) is defined by the U.S. Department of Health and Human Services' Center for Substance Abuse Treatment as "the use of medications, in combination with counseling and behavioral therapies to provide a whole patient approach to the treatment of substance use disorders" (Substance Abuse and Mental Health Services Administration (SAMHSA), 2016). The approach involves long-term use of medications and is akin to insulin use among people with diabetes. Evidence has demonstrated that MAT, the combination of medication and counseling, is more effective at treatment retention and reduction of heroin and prescription opiate abuse than using time-limited medication (i.e., opioid detoxification or tapering) or psychosocial and abstinence interventions; the latter approaches are associated with higher rates of relapse (Fullerton, Kim, Thomas, et al., 2014; Thomas, Fullerton, Kim, et al., 2014). Furthermore, maintenance MAT is associated with improved birth outcomes when given to opioid-addicted pregnant women, although neonatal abstinence syndrome remains a concern (Fullerton et al., 2014; Thomas et al., 2014). Both Fullerton et al. and Thomas et al. found mixed results on whether MAT affected the use of other illicit drugs, criminal behavior, and risk factors for human immunodeficiency virus (HIV) or hepatitis C virus (HCV). Other studies, however, do indicate an association between MAT and reduced overall mortality and specifically while in prison, recidivism, and treatment engagement among those recently released from prison (Degenhardt, Larney, Kimber, et al., 2014; Farrell-MacDonald, MacSwain, Cheverie, Tiesmaki, & Fischer, 2014; Larney, Gisev, Farrell, et al., 2014; Zaller et al., 2013).

1.3. Cost of Medication-Assisted Treatment for Opioid Abuse or Dependence

While the effectiveness of maintenance MAT in reducing opioid use has been demonstrated, the treatment itself comes with higher direct costs than tapering, abstinence, or psychosocial interventions. In 2009, $866 million was spent across all payers on substance abuse prescription medicine, 93% of which went towards buprenorphine, one of the drugs used to treat opioid addiction (Substance Abuse and Mental Health Services Administration (SAMHSA), 2013). While the costs of methadone are negligible, the daily dosing and other services provided in opioid treatment programs (OTPs) where methadone is dispensed are relatively high.

However, the question remains as to whether MAT costs can be offset by reductions in other health care expenditures. Relatively few studies have examined the total cost of health care services for opioid addicts. Two studies have looked at data from commercial health insurance claims on the overall health care costs and utilization rates for those using MAT compared to those treated without MAT (Baser, Chalk, Fiellin, & Gastfriend, 2011; McCarty et al., 2010). McCarty et al. found that over a five-year period, members on MAT had 50% lower total annual health plan costs than those who had two or more visits to an addiction treatment department and no methadone and 62% lower than those with zero or one visit for addiction treatment and no methadone (McCarty et al., 2010). Baser et al. found that after a six-month period, those with MAT had significantly lower overall annual health plan costs compared to those with no medication ($10,192 vs. $14,353; p-value <0.0001) (Baser et al., 2011). The difference was driven largely by lower inpatient services and non-opioid-related outpatient services for the group receiving medication (Baser et al., 2011).

McAdam-Marx et al. reported in 2010 that Medicaid beneficiaries with opioid abuse, dependence, or poisoning had nearly triple the total medical costs adjusted for baseline sample characteristics compared to beneficiaries matched by age, gender, and state with no opioid abuse diagnosis ($23,556 vs. $8436; p-value <0.001). The opioid dependence/abuse group also had higher prevalence of comorbidities, such as psychiatric disorders, pain-related diagnoses, and other substance abuse conditions (McAdam-Marx, Roland, Cleveland, & Oderda, 2010). While this study considered overall cost, it did not address MAT costs in particular or any impact treatment may have had on overall cost.

Focusing specifically on a Medicaid population is important for two reasons. First, Medicaid beneficiaries as a population remain at greater risk for substance abuse, including opioid addiction and overdose. Approximately 12% of Medicaid beneficiaries between ages 18 and 64 years has a substance use disorder (Mann, Frieden, Hyde, Volkow, & Koob, 2014). In Washington State, the U.S. Centers for Disease Control and Prevention (CDC) found that between 2004 and 2007, 45.5% of fatal prescription opioid painkiller overdoses involved people enrolled in Medicaid (Coolen, Best, Lima, Sabel, & Paulozzi, 2009). Second, Medicaid's share of all substance abuse expenditures has increased from 9% to 21% between 1986 and 2009 (Substance Abuse and Mental Health Services Administration (SAMHSA), 2013). This equates to Medicaid spending approximately $5 billion in 2009 on substance abuse treatment, an amount that includes federal, state, and local funds. This dollar amount and the findings by McAdam-Marx et al. (2010) indicate that state Medicaid programs have an interest in understanding the potential impact of expanding MAT services on total expenditures and utilization of medical services.

This study examines Vermont's Medicaid expenditures for opioid addiction treatment and other medical and non-medical services, including special Medicaid services (SMS), which are services uniquely reimbursed by Medicaid that target social, economic, and rehabilitative needs (e.g., transportation, home and community-based services, case management, dental, residential treatment, day treatment, mental health facilities, and school-based services). More explicitly, it compares the health care expenditures between two groups with opioid addiction: those receiving MAT ("MAT group"), specifically methadone or buprenorphine, and those receiving non-medication treatment approaches, such as behavioral therapies alone ("non-MAT group"), with the goal of assessing the cost effectiveness of MAT and establishing baseline data against which expanded and enhanced treatment access can be evaluated.

2. Material and Methods

2.1. Data Source and Sample Population

This study reviewed annual medical expenditures and utilization rates (per person) for Vermont Medicaid enrollees from 2008 to 2013 who were identified as having an opioid addiction or dependency. The data source for this study was Vermont's all-payer claims database, the Vermont Health Care Uniform Reporting and Evaluation System (VHCURES). Due to limitations arising from the statutorily-mandated de-identified status of VHCURES, this study could not use a cohort design, but instead relied on annual cross-sectional data for each year in the study period.

The study population included members with Medicaid coverage, ages 18–64 years, who had claims in VHCURES indicating treatment for opioid addiction between the calendar years 2008 and 2013. Within each year, members participating in MAT were compared to members with opioid addiction receiving non-MAT therapies. Expenditures and

Table 1
Summary health & demographics for the study population, unique count of Medicaid patients for the years 2008 to 2013.

Demographic/Health characteristic	MAT		Non-MAT		χ^2
	Member count	%	Member count	%	P-value
N	6158	71.2%	2494	28.8%	
Age (in years), females*					
18–34, female	2450	79.0%	711	64.3%	<0.001
35–44, female	634	20.4%	222	20.1%	
45–64, female	294	9.5%	205	18.6%	
Age (in years), males*					
18–34, male	2259	73.8%	898	64.6%	<0.001
35–44, male	724	23.7%	271	19.5%	
45–64, male	330	10.8%	256	18.4%	
3 M™ Clinical Risk Group (CRG)*					
Opioid-addicted only (CRG category 1)†	644	10.5%	494	19.8%	<0.001
Acute illness or minor chronic disease (CRGs 2–4)	275	4.5%	334	13.4%	
Single dominant or moderate chronic disease (CRG 5)	5350	86.9%	1522	61.0%	
Significant chronic disease, multi-organ system (CRG 6)	1637	26.6%	605	24.3%	
Cancer/Catastrophic condition (CRGs 7–9)	56	0.9%	45	1.8%	
Women with pre- and perinatal care (denominator is females)	962	31.0%	142	12.9%	<0.001
Hepatitis C virus (HCV) diagnosis	1267	20.6%	249	10.0%	<0.001
Medicaid in the prior year	5473	88.9%	2035	81.6%	<0.001
Serious mental health disorder	1328	21.6%	509	20.4%	0.234
Chronic disease					
Asthma	1384	22.5%	448	18.0%	<0.001
Attention deficit hyperactivity disorder (ADHD)	803	13.0%	203	8.1%	<0.001
Coronary heart disease	33	0.5%	19	0.8%	0.218
Chronic obstructive pulmonary disorder (COPD)	137	2.2%	69	2.8%	0.134
Depression	3125	50.7%	1072	43.0%	<0.001
Hypertension	425	6.9%	215	8.6%	0.006
Diabetes	161	2.6%	92	3.7%	0.007

* Since individuals can be in multiple age and clinical risk groups over the span of the study period, the sum of the percentages exceeds 100%.
† Members without additional comorbidities or complicating diagnoses.

selected utilization measures were evaluated for the MAT and non-MAT groups over the six-year period.

The inclusion criteria for the MAT group were based on claims data for the two primary drugs used in MAT: methadone and buprenorphine. Methadone is dispensed only at designated treatment facilities (Opioid Treatment Programs or OTPs). Prior to 2013 in Vermont, buprenorphine was prescribed only in general medical offices by authorized physicians (Office Based Opioid Treatment or OBOT). Members receiving methadone treatment were selected using the Healthcare Common Procedure Coding System (HCPCS) program code H0020 in the claims data. Members receiving buprenorphine treatment were selected using a list of National Drug Codes (NDCs), with the exclusion of any form of buprenorphine when prescribed specifically for pain management. In addition, patients under any treatment for chronic pain were excluded.

The non-MAT comparison group was also identified using claims data. These included members who never received MAT and had at least two opioid addiction diagnoses (i.e., ICD-9 codes 304.00, 304.01, 304.02, 304.70, 304.71, 304.72) on different dates of service, suggesting ongoing addiction. The opioid addiction treatment for the non-MAT population included individual and group outpatient services, intensive outpatient programs, partial hospitalization, detoxification, and residential treatment services identified from the claims data using HCPCS and revenue codes.[i] As in the MAT group, patients under any treatment for chronic pain were excluded.

For each calendar year, MAT and non-MAT members were evaluated using demographics and health status (Table 1). Demographic measures included age, gender, and county of residence. Health status indicators included major mental health disorders (i.e., schizophrenia, major depression, bipolar and other psychoses), selected chronic disease diagnoses (i.e., asthma, attention deficit hyperactivity disorder (ADHD), chronic obstructive pulmonary disorder (COPD), congestive heart failure, coronary heart disease, depression, diabetes, and hypertension), and 3 M™ Clinical Risk Group (CRG) categories, which were used to identify differences in health status for other conditions (e.g., cancer) among the MAT and non-MAT populations. For purposes of ensuring a large enough subsample, the CRG categories were grouped into five categories: opioid-addicted only (which included those addicted or dependent on opioids with no comorbidities or complicating diagnoses); having a history of significant acute disease, a single minor chronic disease, or minor chronic disease in multiple organ systems; having a single dominant or moderate chronic disease; having significant chronic disease in multiple organ systems; and having dominant chronic disease in three or more organ systems, metastatic and complicated malignancies, or catastrophic conditions. Members with claims indicating pre- and perinatal care or HCV positivity were also identified. A measure of continuity of enrollment in Medicaid ("Medicaid in the Prior Year") was assigned for a member who was enrolled in Medicaid during both the study period year and the prior year.

2.2. Statistical Analysis

To reduce the effect of extreme outlier cases, total expenditures were capped at the 99th percentile for each group (Centers for Medicare and Medicaid Services, 2014).

Demographic data for each group was compared with a χ^2 goodness of fit test with the significance level set at 0.05 (Table 1). Multivariable linear regression models were used to evaluate the expenditure and utilization dependent variables that were derived from claims data. Expenditure and utilization measures included those listed in Table 2.

The "Total Expenditures" model included the costs of all medical services and the costs associated with opioid addiction treatments for both the MAT group and the non-MAT group, as described above. The "Total Expenditures without Treatment" model excluded all opioid addiction treatment costs to determine the impact of MAT on medical

[i] HCPCS and Revenue Codes: G0176, G0177, H0001, H0002, H0004, H0005, H0006, H0014, H0016, H0020, H0022, H0028, H0031, H0032, H0036, H0037, H0046, H0047, H2017, H2018, H2019, H2020, H2027, H2033, H2035, H2036, S9475, T1006, T1007, T1011, T1012, 0907, 90,801, 90,802, 90,804, 90,805, 90,806, 90,807, 90,808, 90,809, 90,810, 90,811, 90,812, 90,813, 90,814, 90,815, 90,845, 90,846, 90,847, 90,849, 90,853, 90,857, 90,862, 90,875, 90,876, 90,880, H0015, S9480, T1008, 0905, 0906, H0010, H0011, H0012, H0013, H0018, H0019, T2048, 1002, 90,816, 90,817, 90,818, 90,819, 90,821, 90,822, 90,823, 90,834, 90,826, 90,827, 90,828, 90,829, H0017, H2013, H0008, H0009, H0035, S0201, H2034, 1004

Table 2
Adjusted average annual expenditures and utilization rates[§].

	MAT group	Non-MAT	Difference[‡]	P-value
Expenditures				
Total expenditures	$14,468	$14,880	−$412	0.07
Total expenditures without treatment	$ 8794	$11,203	−$2409	<0.01
Buprenorphine expenditures	$2708	−$47	$2755	<0.01
Total prescription expenditures	$4461	$2166	$2295	<0.01
Inpatient expenditures	$2132	$3757	−$1625	<0.01
Outpatient expenditures	$345	$604	−$259	<0.01
Professional expenditures	$674	$981	−$307	<0.01
SMS expenditures*	$2872	$4160	−$1288	<0.01
Utilization (rate/person)				
Inpatient days	1.54	3.00	−1.46	<0.01
Inpatient discharges	0.30	0.52	−0.22	<0.01
ED visits	1.44	2.48	−1.04	<0.01
Primary care physician visits	15.27	9.81	5.46	<0.01
Advanced imaging	0.29	0.54	−0.25	<0.01
Standard imaging	0.76	1.43	−0.67	<0.01
Colonoscopy	0.01	0.02	−0.01	<0.01
Echography	0.46	0.53	−0.07	0.002
Medical specialist visits	0.49	0.82	−0.33	<0.01
Surgical specialist visits	3.04	1.89	1.15	<0.01

* SMS refers to special Medicaid services and include transportation, home and community-based services, case management, dental, residential treatment, day treatment, mental health facilities, and school-based services.

§ Multivariable regression analysis, adjusted for gender, age, calendar year, clinical risk groups, Medicaid in the prior year, hepatitis C virus (HCV) status, and pre- and perinatal care.

‡ Difference = MAT – non-MAT.

expenditures alone. All expenditure outcomes and utilization rates listed in Table 2 were adjusted for partial enrollment within the calendar year and the independent variables included MAT status, gender, age group, pre- and perinatal status, HCV status, "Medicaid in prior year" status, and health status as measured by CRGs. Chronic diseases and mental health disorders were excluded from the regression because they were encompassed by the CRGs. The independent variable of MAT v. non-MAT was created as a binary (0/1) variable, as were "Women with pre- and perinatal care", HCV, and "Medicaid in the prior year". The remaining were multi-level indicator variables - the model adjusted for age and gender groups using males 18–34 as the reference group, and health status based on CRG groups using "opioid-addicted only" as the reference group.

All statistical analysis was done with SAS version 9.3.

3. Results

3.1. Sample Population and Demographics

Over the period from 2008 to 2013, we identified 6158 unique Medicaid beneficiaries with a diagnosis for opioid misuse and health care claims for MAT, and 2494 unique Medicaid patients with a diagnosis of opioid misuse but no claims for MAT. Table 1 compares the health status and demographics for Medicaid members who received MAT and non-MAT treatment between 2008 and 2013. The MAT group was slightly younger with higher proportion of 18–34 year olds in both genders (79.0% vs. 64.3% for females and 73.8% vs. 64.6% for males). Overall the MAT group was more likely to be female (50.3% vs. 44.3%; p-value <0.001). In line with this trend, MAT members had a higher rate of pre- and perinatal care compared to non-MAT (16% vs 6%). MAT members also had a higher prevalence of known positive tests for HCV (21% vs 10%) and were more likely than non-MAT to have continuity of coverage in Medicaid as indicated by having Medicaid in the prior year (88.9% vs. 81.6%). The prevalence of members with serious mental health disorders (e.g., schizophrenia, major depression, bipolar and other psychoses) in MAT was slightly higher than non-MAT (22% vs. 20%), but the difference was not statistically significant (p-value = 0.23).

Table 1 also compares risks groups and prevalence of select conditions between the two groups. Based on the χ^2 goodness of fit test, there was significant difference in the distribution of the risk groups among the MAT and non-MAT groups. The non-MAT group had higher proportions categorized as opioid-addicted only (i.e., those with opioid addiction or dependency but without comorbidities or complicating diagnoses) or as having acute illness or a minor chronic disease. The MAT group had higher proportions with a single dominant or moderate chronic disease or a significant chronic disease in multiple organ systems. Both groups had low rates of cancer and catastrophic conditions. Of the selected chronic conditions with significant differences between the two groups, MAT had higher prevalence of ADHD, depression, and asthma and a lower prevalence of hypertension and diabetes.

3.2. Multivariable Regression Results

Table 2 shows the adjusted expenditure and utilization rates per person for the MAT and the non-MAT groups and the differences between the two study populations. In all categories of expenditures except prescriptions, members of the MAT group had lower costs. For total medical expenditures, including treatment costs, the MAT group's annual expenditures were $412 less than the non-MAT group's expenditures, although this difference was not significant (p-value: 0.07). When opioid addiction treatment costs for both groups were excluded, the difference in annual expenditures of the MAT group relative to the non-MAT group grew to −$2409 (p-value: <0.01). In each of the four expenditure subcategories (inpatient, outpatient, professional services, and special Medicaid services expenditures) the MAT group's medical expenditures were significantly lower, with the largest difference seen in inpatient expenditures (−$1625). For the utilization categories (Table 2), the MAT group has significantly lower utilization rates per person across all categories except for primary care physician visits and surgical specialist visits.

The expenditure models also found that, independent of MAT status, a positive diagnosis of HCV was associated with significantly higher costs for both models: $3518 (p-value: <0.01) in the "Total Expenditures" model and $2679 (p- value: <0.01) in the "Total Expenditures Without Treatment Costs" model. Conversely, being enrolled in Medicaid in the previous year was associated with lower costs: −$1169 (p-value: <0.01) in the "Total Expenditures" model and −$630 (p-value: 0.01) in the "Total Expenditures without Treatment Costs" model.

4. Discussion

4.1. Findings

The results indicated that the overall difference in annual average expenditures was lower for the MAT group, even with the cost of MAT, but not significantly lower. However, when opioid addiction treatment costs were removed, the MAT group had substantial and statistically significant lower health care costs overall compared to the non-MAT group. This was especially noteworthy given the MAT group's higher rates of pre- and perinatal care, HCV positivity, and more severe health status according to risk groupings (higher proportions of young females and higher rates of pre- and perinatal care were expected because pregnant women were prioritized for MAT treatment, especially in OTPs). Evaluation of the utilization rates suggests that reduction in cost was due, in part, to lower inpatient admissions and outpatient hospital emergency department visits. The higher rate of primary care visits for the MAT group was expected since buprenorphine is prescribed in general medical offices. It may also indicate that MAT may be successfully linking patients with preventive care services. The increased utilization of the surgical specialists and the decreased utilization of imaging services will require additional analysis to identify the reasons for

these trends. Overall, however, this study, in conjunction with the many studies supporting MAT treatment efficacy, suggests that expanding Vermont's MAT services for its Medicaid-enrolled population has the potential to produce better opioid addiction treatment results and lower overall health care costs compared to other approaches to opioid addiction treatment.

The findings also indicate that more continuous enrollment in Medicaid was associated with reduced expenditures independent of the MAT program. One interpretation of this result is that newly insured members tended to have higher initial health care utilization if they had been without it beforehand, and their continued enrollment led to a reduction in health care expenditures. Further study is needed to evaluate this conclusion and its implications on expanding MAT services.

Another point addressed in the results is the prevalence of HCV among the opioid-addicted population. As noted in Table 1, 20.6% of MAT members and 10.0% of non-MAT members were diagnosed with HCV between 2008 and 2013. By comparison, chronic HCV prevalence in the US is approximately 0.8% (Centers for Disease Control and Prevention (CDC), 2016). Further inquiry into the reasons behind this difference should be pursued, such as whether there is increased HCV screening for MAT patients, a possibility supported by another study (Larney, Grebely, Falster, et al., 2015), or greater referral among Medicaid beneficiaries with HCV to MAT services. Additionally, further analysis should evaluate the factors contributing to cost such as severity of HCV-associated disease and treatment-seeking patterns. HCV treatment is expensive, especially the combination therapies involving the relatively new sofosbuvir and ledispasvir approved after the time frame for this study; however, these drugs have significantly reduced side effects and treatment times (6–12 weeks vs. 24–48 weeks) and produce higher cure rates (85%–95% vs. 50%–80%) than the traditional pegylated-interferon with riboviron therapy (Centers for Disease Control and Prevention (CDC), 2016). Should MAT provide a means for improved HCV detection through increased screening, MAT may have the added benefit of reducing HCV transmission (Tsui, Evans, Lum, Hahn, & Page, 2014; White, Dore, Lloyd, Rawlinson, & Maher, 2014) and the medical complications that arise from chronic HCV infection.

4.2. Limitations

While VHCURES data have been validated as a reliable data source (Hoffer & Stein, 2014), they do have some limitations relevant to this study. First, as mentioned above, the de-identified status of VHCURES makes cohort studies difficult; therefore we used annual cross-sectional for each year in the study period.

Second, the dataset did not allow for the estimation of methadone costs in isolation. The HCPCS program code, which is used to identify MAT members receiving methadone and their treatment costs, combines medication and health home services. Furthermore, methadone is not present in pharmacy claims, limiting the ability to find treated members and isolate methadone medication costs.

Third, the data may include some bias due to the influence of outliers. While outliers were capped at the 99th percentile, they could still potentially influence the results given the small sample size. However, since the yearly dollar amounts were consistent (data not shown), this influence is likely minimal.

Finally, a few unmeasurable confounders could also have introduced bias to this study such as unaccounted differences in the severity of opioid addiction between the MAT and non-MAT groups and access to treatment. Additional studies on these factors would improve further evaluations of MAT.

5. Conclusion

Given that total health care expenditures did not differ significantly (p-value: 0.07) even with the higher costs of MAT services and medications, the outlook for a statewide program focused on providing maintenance MAT is favorable. While the total addictions treatment costs were higher for the MAT group, these were offset by much lower health care utilization and expenditures, indicating an insignificant overall cost difference between the MAT and non-MAT groups. While causation cannot be determined in this study, the results, along with strong evidence that maintenance MAT is more effective at achieving treatment retention and reducing opioid use (Fullerton et al., 2014; Thomas et al., 2014), present a persuasive argument for expanding a MAT-centered opiate addiction treatment program throughout the state of Vermont.

Toward the end of this study's time frame (mid-2013), Vermont, through its health care delivery reform program, the Vermont Blueprint for Health, began to roll out a comprehensive services design built on MAT and the opportunity for Health Homes offered under the Affordable Care Act. The goal of this program, also known as Hub (OTPs) and Spoke (OBOT or buprenorphine-prescribing providers), was to expand access to methadone, enhance methadone treatment programs by linking Health Home Services with primary and community services, and providing clinical staff to support and complement primary care providers waivered to prescribe buprenorphine.

The results of this study serve as a strong baseline by which to evaluate Vermont's Hub and Spoke program and to assess whether the reduction in medical costs have continued under the program's service enhancements. Additionally, the methodology employed in this study will be expanded to analyze the impact of MAT beyond health care, such as on incarceration rates, employment rates, and rates of child and family services. These subsequent studies will provide a fuller understanding of the societal costs and savings of opioid addiction and treatment.

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* Flemming et al., 2000, 2002, Gentilello et al., 2005

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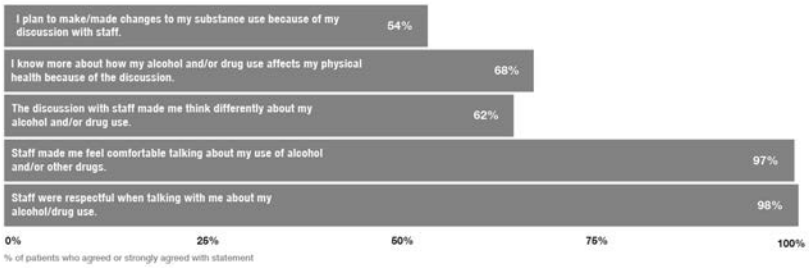
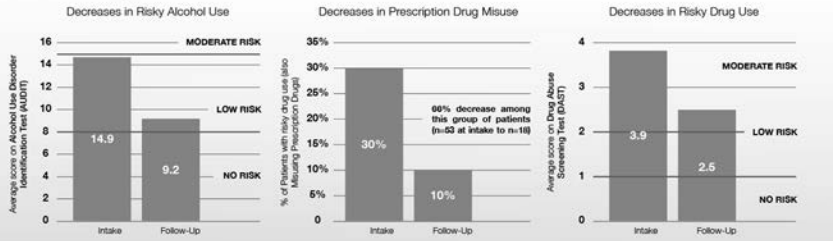
Patients' Rating of Initial Discussion at Six Month Follow-Up Interview



Decrease in Risky Behavior



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