AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 116–455

TREATING SUBSTANCE MISUSE IN AMERICA: SCAMS, SHORTFALLS, AND SOLUTIONS

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

OCTOBER 24, 2019

Printed for the use of the Committee on Finance

U.S. GOVERNMENT PUBLISHING OFFICE
44–731—PDF WASHINGTON : 2021

COMMITTEE ON FINANCE

CHUCK GRASSLEY, Iowa, *Chairman*

MIKE CRAPO, Idaho
PAT ROBERTS, Kansas
MICHAEL B. ENZI, Wyoming
JOHN CORNYN, Texas
JOHN THUNE, South Dakota
RICHARD BURR, North Carolina
JOHNNY ISAKSON, Georgia
ROB PORTMAN, Ohio
PATRICK J. TOOMEY, Pennsylvania
TIM SCOTT, South Carolina
BILL CASSIDY, Louisiana
JAMES LANKFORD, Oklahoma
STEVE DAINES, Montana
TODD YOUNG, Indiana

RON WYDEN, Oregon
DEBBIE STABENOW, Michigan
MARIA CANTWELL, Washington
ROBERT MENENDEZ, New Jersey
THOMAS R. CARPER, Delaware
BENJAMIN L. CARDIN, Maryland
SHERROD BROWN, Ohio
MICHAEL F. BENNET, Colorado
ROBERT P. CASEY, JR., Pennsylvania
MARK R. WARNER, Virginia
SHELDON WHITEHOUSE, Rhode Island
MAGGIE HASSAN, New Hampshire
CATHERINE CORTEZ MASTO, Nevada

KOLAN DAVIS, *Staff Director and Chief Counsel*
JOSHUA SHEINKMAN, *Democratic Staff Director*

CONTENTS

OPENING STATEMENTS

	Page
Grassley, Hon. Chuck, a U.S. Senator from Iowa, chairman, Committee on Finance	1
Wyden, Hon. Ron, a U.S. Senator from Oregon	2

WITNESSES

Adams, Hon. Jerome M., M.D., MPH, Surgeon General, Office of the Secretary, Department of Health and Human Services, Washington, DC	4
Denigan-Macauley, Mary, Ph.D., Director, Health Care, Government Accountability Office, Washington, DC	7
Cantrell, Gary, Deputy Inspector General for Investigations, Office of Inspector General, Department of Health and Human Services, Washington, DC	8
Mendell, Gary, founder and chief executive officer, Shatterproof, New York, NY	10

ALPHABETICAL LISTING AND APPENDIX MATERIAL

Adams, Hon. Jerome M., M.D., MPH:	
Testimony	4
Prepared statement	35
Responses to questions from committee members	53
Cantrell, Gary:	
Testimony	8
Prepared statement	71
Responses to questions from committee members	78
Daines, Hon. Steve:	
Letter from the Federal Law Enforcement Officers Association to Senators Grassley and Wyden, October 24, 2019	88
Denigan-Macauley, Mary, Ph.D.:	
Testimony	7
Prepared statement	89
Responses to questions from committee members	95
Grassley, Hon. Chuck:	
Opening statement	1
Prepared statement	103
Mendell, Gary:	
Testimony	10
Prepared statement	104
Responses to questions from committee members	107
Wyden, Hon. Ron:	
Opening statement	2
Prepared statement	114

COMMUNICATIONS

Association for Behavioral Health and Wellness	117
Avery, Trudy	119
Center for Fiscal Equity	123
Coalition for Office-Based Outpatient Treatment	127
Hazelden Betty Ford Foundation	130
SAFE Project US	132
Voices for Non-Opioid Choices	134

TREATING SUBSTANCE MISUSE IN AMERICA: SCAMS, SHORTFALLS, AND SOLUTIONS

THURSDAY, OCTOBER 24, 2019

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

The hearing was convened, pursuant to notice, at 9 a.m., in Room SD–215, Dirksen Senate Office Building, Hon. Chuck Grassley (chairman of the committee) presiding.

Present: Senators Crapo, Thune, Toomey, Scott, Cassidy, Lankford, Daines, Young, Wyden, Stabenow, Cantwell, Menendez, Cardin, Brown, Bennet, Casey, Warner, Hassan, and Cortez Masto.

Also present: Republican staff: Nicholas Bartine, Detailee; Kolan Davis, Staff Director; Evelyn Fortier, General Counsel for Health and Chief of Special Projects; John Pias, Detailee; and Jeffrey Wrase, Deputy Staff Director and Chief Economist. Democratic staff: David Berick, Chief Investigator; Shana Deitch, Detailee; Anne Dwyer, Senior Health Counsel; Peter Gartrell, Investigator; and Joshua Sheinkman, Staff Director.

OPENING STATEMENT OF HON. CHUCK GRASSLEY, A U.S. SENATOR FROM IOWA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. Good morning. I want to welcome our panelists to today's hearing on the one-year anniversary of the SUPPORT Act. This landmark statute, which many of us had a hand in developing, responded to the opioid epidemic on multiple fronts. That crisis has affected every corner of our Nation, with 130 Americans, on average, dying from an overdose every single day.

We have devoted a lot of Federal resources to tackling this crisis, and I look forward to hearing from the Surgeon General on this administration's efforts to implement the SUPPORT Act over the last year. I also commend Dr. Adams for launching his own unique initiatives to help raise public awareness about the risks of opioid misuse.

Challenges remain, however, because roughly 20 million Americans still struggle with substance abuse disorder. Addiction to other drugs, including meth and heroin, pose an equal, or even greater, challenge for some communities, especially in rural areas.

Another issue is that few battling addiction actually seek or receive treatment. Yet another issue is that even those who do seek help lack the expertise to distinguish the good treatment providers from the bad. Solving that last issue, which is the second focus of our hearing, is easier said than done.

The treatment sector includes not just extremely good and extremely bad providers, but also many others who fall somewhere in the middle. Some, for example, have not updated their methods to incorporate the latest research about what works best for recovering people.

Also, State requirements for addiction counselors and recovery homes vary. For example, some States require licensing of recovery home operators, while others might only use voluntary certification. That is why we have invited two government watchdog agencies and an addiction treatment advocate to our committee to share their expertise with us today.

We welcome back Dr. Denigan-Macauley of the GAO, who testified before this committee last year. We have all seen the media reports about so-called "sober homes" in Florida, Pennsylvania, Massachusetts, and a few other States that exploited recovering addicts with private insurance benefits. We look forward to hearing from her on that subject of GAO's work there.

I also extend a warm welcome to Gary Cantrell, who heads the Inspector General's investigating team. His investigators worked on a recent high-profile case involving a treatment scam in Ohio. That investigation, in partnership with the FBI and law enforcement generally, led to the indictment of six people this year. All six pled guilty to Medicaid fraud.

Some have called for development of more uniform, measurable addiction treatment standards by which the public could evaluate the effectiveness of substance abuse treatment programs.

Our last witness, Gary Mendell, has gone a step further in not only identifying eight core standards he believes are key to any successful program, but also launching a quality rating system. This is an uncharted area in the treatment sector, and we look forward to hearing from him about the progress that has been made there with his nonprofit organization, Shatterproof.

We are here today because too many Americans have lost too many loved ones to addiction and overdose deaths. America's opioid crisis has left a trail of broken hearts and homes across the country. We are here to help communities get on a path towards health and wellness. Millions of Americans are desperately seeking a path forward. Working together, we can save tax dollars and save lives.

Senator Wyden?

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

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

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

Mr. Chairman, I want to thank you because this is an exceptionally important issue, and I think we do need to have our committee tackle it in a bipartisan way. And I also want to thank you for moving this morning's start time to 9 a.m., because we both know there are members who want to attend the memorial service for Chairman Cummings.

Today's hearing is going to spotlight the pitfalls Americans face when they try to find quality treatment for substance use disorder. An American battling this disease is often jostled and pushed

around from one end of the health-care system to the other. The last thing you need when you're suffering from this disease is yet more obstacles, rip-off artists, empty promises, or just out-and-out abuse. The last thing you need is that, when all you want to do is get better.

Too often people travel across the country expecting to arrive at a legitimate treatment facility, only to find that they have fallen prey to a scheme, the goal of which is to drain their bank accounts and just milk their insurance for everything it is worth.

In some instances, unscrupulous operators are working to lure patients by paying for plane tickets and promising free rent. Once the patients arrive, what they end up getting is lousy care, or no care at all. And then the fraudsters just go out and bill the insurance companies for health-care services that may never have even been performed.

One of the biggest problems involves facilities that allegedly treat substance abuse disorders but are actually set up to rip off taxpayers. The fraudsters illegally recruit patients using bribes and kickbacks, and then they bilk the taxpayer by billing the patient's health plan for medically unnecessary drug tests and schemes like this. And we are very pleased to have this really terrific group of witnesses today.

They are going to outline these schemes in detail. And of course these schemes also cost Medicare, Medicaid, and private insurance hundreds of millions of dollars every year. Just this month, six people operating a network of fraudulent treatment centers in Ohio pled guilty to submitting 130,000 Medicaid claims that totaled more than $48 million for medication-assisted treatment and other services that were never legitimately provided.

Part of the reason this type of fraud is so common is because there is no way for a patient and their family to learn about the quality of a treatment facility before they enroll. But today we are going to hear from an organization that is saying, "Hey, wake up, everybody. This has got to change."

Shatterproof is currently developing public databases in multiple States that, if successful, will allow the public to identify, evaluate, and compare substance use treatment programs. This kind of database and transparency is the type of information that American families deserve to have, and they deserve to have it now because it will be a key tool to find quality treatment and avoid sham operators trying to make a quick buck.

One other point that occurred to me as we were preparing for this hearing is, it is particularly important now to set in place the kind of concrete policies to make sure that the programs are not ripping off, and the patients are not taken advantage of. Because when you read the morning newspaper, the fact is that States and communities may now be on the cusp of receiving tens of billions of dollars from the companies that helped feed the epidemic.

I could kind of look down the road, because I have heard about this from virtually all of my colleagues. So if you are talking about a fund of tens of billions of dollars, a sum of that size is going to be a magnet for the fraudsters and the ripoff artists.

This hearing is going to highlight these to make sure that there are rules of the road and vigorous oversight so that those dollars

actually go to help patients get proper care, and all that new money does not just find its way to the ripoff artists.

I thank the witnesses and you, Mr. Chairman, again for your leadership. And we are going to work on this in a bipartisan way, and I look forward to hearing from the witnesses and our colleagues.

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

The CHAIRMAN. The Senator from Maryland is here to introduce the Surgeon General.

Senator CARDIN. Thank you, Mr. Chairman. I thank you for giving me this courtesy.

It is a real pleasure to welcome all of our witnesses today, but particularly I welcome the Surgeon General of the United States, Dr. Jerome Adams. He hails from Mechanicsville, MD, a proud son of Maryland, and has had a glowing career, Mr. Chairman, first winning the prestigious Meyerhoff Scholarship of the University of Maryland, Baltimore County, where he received both a bachelor of science in biochemistry and a bachelor of arts in biopsychology.

I say that because we had a conversation before. Dr. Freeman Hrabowski, who is the president of UMBC, called Dr. Adams his most successful failure. That's because the Meyerhoff Scholarship program is a program that has been extremely successful in African Americans attaining their Ph.D.s and going on to extraordinary, successful lives.

Well, Dr. Adams does not have a Ph.D., but he does have a masters degree and an M.D. degree, and of course has had a very, very successful career.

I want to congratulate him for his leadership in our country, his service to our Nation. He attended Indiana University School of Medicine, an Eli Lilly and Company scholar.

Before serving as the United States Surgeon General, Dr. Adams was appointed as the Indiana State Health Commissioner. As the U.S. Surgeon General, Dr. Adams has spent his time focusing on combating the opioid epidemic.

He has been an advocate on behalf of public health in our country, and we are just very proud of his service, and we are proud to claim him as hailing from our State of Maryland.

The CHAIRMAN. For the other three of you, if you just go through the testimony, I hope you will not feel bad if I do not introduce you because of the time constraints. I talked about all of you in my opening statement.

I want to start with the Surgeon General. So would you start? And then what we will do is go in the order that you are sitting there at the table, and then we will have questions after you all get done.

STATEMENT OF HON. JEROME M. ADAMS, M.D., MPH, SURGEON GENERAL, OFFICE OF THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. ADAMS. Fantastic. Well, good morning, Chairman Grassley. My wife Lacey says to tell Barbara "hi" and that we cannot wait to bring the kids out to the farm. I hope she told you about that. [Laughter.]

The CHAIRMAN. Everybody knows about my wife. Does anybody know about me? [Laughter.]

Dr. ADAMS. Senator Wyden, distinguished members of the committee, if you will allow me just 20 extra seconds, I want to acknowledge the flag flying at half-mast over the Capitol and lift up the example and accomplishments of Representative Cummings.

His life was the very definition of public service, and my condolences go to his family and to all who were blessed to know him.

For my testimony today I would like to begin by thanking all of you and your colleagues, Mr. Chairman, for passing the SUPPORT Act, which has enabled HHS and our country to make progress in its fight against the opioid epidemic. And I am so pleased to be here today on the one-year anniversary.

America's overdose and addiction crisis is one of our most daunting and complex public health challenges ever. Recognizing its scale and scope, HHS launched the five-point strategy in 2017, and under this strategy we are achieving better addiction, prevention, and treatment services; better data; better team management; better targeting of overdose-reversing drugs; and better research.

I have been engaged on this problem as an anesthesiologist involved in acute and chronic pain management and, as you heard from Senator Cardin, as head of a State health department dealing with an unprecedented opioid-fueled HIV outbreak. But my work on the opioid epidemic is also very, very personal.

My younger brother Philip struggled with the disease of addiction. His struggle began with untreated depression, leading to self-medication and opioid misuse. And like many with co-occurring mental health and substance use disorders, my brother has cycled in and out of incarceration. He is currently serving a 10-year prison sentence for crimes committed to support his addiction.

This epidemic is blind to color, geography, and class, as addiction can happen to anyone, even the brother of the United States Surgeon General. And when stigma keeps people in the shadows, it impedes our collective recovery.

To address this opioid epidemic, my office released the "Spotlight on Opioids," a digital postcard which you can find at *surgeongeneral.gov*—and which you have in front of you, Senators—and an advisory on opioid overdose and naloxone.

I want to leave you with five key messages that I detail in these publications.

Number one: early intervention is critical. Evidence-based prevention and intervention programs work, but they need to be initiated early in life. We cannot wait until someone is in high school or in college before we start talking to them about the dangers of opioid misuse.

Number two: treatment is effective, but it must be integrated into mainstream health care. As an example, medication-assisted treatment is the gold standard, but in the course of a year, only one in four people with opioid use disorder received specialty treatment.

Number three: having naloxone can save a life and serve as a bridge to treatment and recovery. And I hope all of you know about this and carry it. I carry it with me everywhere we go. It's literally that easy to save a life. Since my naloxone advisory was published,

almost 3 million two-dose units have been distributed to communities, but too many still needlessly die.

Fourth: comprehensive community-based recovery support services are essential. And I saw this first-hand when Second Lady Pence and I visited Belden Industries in Indiana. Belden developed a unique pilot project called "Pathways to Recovery and Employment" in which potential employees who fail drug tests are offered drug counseling. And participants who stay in the recovery program are then assured jobs. Recovery support services are also vital to Greyston Bakery in New York. And the bakery provides employment and support services without judgment—no resume, no work history, no background check is required. The bakery's motto, which I love, is, "We don't hire people to bake brownies. We bake brownies to hire people." At present, more than 60 percent of Greyston Bakery's employees were formerly incarcerated.

My fifth point is that, when it comes to opioid use disorders, society must continue to move from a criminal justice-based approach to a public health and partnership-based one. Stigma and judgment are keeping people with the disease of addiction, people like my brother, from getting the help they need. And this, in my opinion, is killing more people than overdose.

In conclusion, under this administration and through your support, a historic investment has been made in combating the opioid crisis. By the end of 2019, HHS will have awarded over $9 billion in grants to States, tribes, and local communities to combat addiction. This includes nearly $1 billion across 375 projects in 41 States as part of NIH's Helping to End Addiction Long-term, or HEAL, initiative. It also includes more than $1.8 billion in SAMHSA and CDC funding to States announced last month. These funds expand access to treatment and strengthen data and surveillance.

Since the start of this administration, we have seen the amount of opioids nationally drop 31 percent in terms of prescriptions. We have seen the number of Americans receiving treatment grow. Now nearly 1.27 million Americans are receiving medication-assisted treatment, and we have doubled the number of providers who have their data waiver to prescribe MAT.

Monthly, naloxone prescriptions have risen 378 percent, and provisional drug overdose deaths have dropped by 5 percent, the first drop in over 20 years. We are making progress, but challenges remain, including the resurgence of methamphetamines and the need to increase support for comprehensive syringe service programs and to support emergency department medication-assisted treatment programs with warm hand-off to care.

And we also, finally, must expand the behavioral workforce. And Senator Stabenow and I talked about that before the hearing. I promise you—I promise you—that HHS and my office will continue our commitment and our focus on this critical public health issue.

I thank you for the opportunity to testify, and I look forward to your questions.

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

The CHAIRMAN. Doctor, before you begin, with all your background in animal science, how did you end up at GAO?

Dr. DENIGAN-MACAULEY. Well, as you probably are aware, there is quite a nexus between animal health and public health, and I think GAO recognizes that.

The CHAIRMAN. Okay. Well, I needed that explanation. [Laughter.]

Proceed, please.

STATEMENT OF MARY DENIGAN-MACAULEY, Ph.D., DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, DC

Dr. DENIGAN-MACAULEY. Chairman Grassley, Ranking Member Wyden, and members of the committee, I am pleased to be here today to discuss GAO's recent report on the oversight of recovery homes.

Substance abuse—and illicit drug use—is a persistent problem that has ruined families and taken lives. The DEA reports that, since 2011, drug overdoses alone have been the leading cause of death by injury in the United States, out-numbering deaths by guns, car crashes, suicide, and homicide.

Recovery homes can offer safe and supportive housing. Unfortunately, bad actors have used these homes to take advantage of individuals during their time of need.

Today, I would like to highlight two key findings from our report.

First, GAO found that all five States in our review had received complaints of potential fraud related to recovery homes, and four of the five—Florida, Massachusetts, Ohio, and Utah—had conducted, or were in the process of conducting investigations.

For example, officials told GAO that fraud was extensive in southeastern Florida. A task force found that operators were luring individuals to homes using deceptive marketing techniques, such as promises of free airfare and rent.

Recruiters then brokered these individuals to providers who billed their insurance for hundreds and thousands of dollars in unnecessary drug testing. Home operators were then paid $300 to $500 or more per week for every patient that they referred. At the time of our report, some arrests had been made.

In Massachusetts, the Medicaid Fraud Control Unit found that some laboratories owned recovery homes and were self-referring residents to their own labs for drug testing. Other labs were paying kickbacks to homes for patient referrals for testing that was not medically necessary. And between 2007 and 2015, the State settled with nine labs for more than $40 million in restitution.

At the time of our report, Ohio was investigating fraud at the Braking Point Recovery Center. This month, as Senator Wyden mentioned, the U.S. Attorney's office reported that six people from Braking Point pled guilty to health-care fraud conspiracy for billing Medicaid more than $48 million in drug and alcohol recovery services that were not provided or not medically necessary.

To increase oversight, Florida, Massachusetts, and Utah established either licensure or voluntary certification programs that included incentives for recovery homes to participate. Our other two States, Ohio and Texas, did not have similar programs but were providing resources such as training to recovery homes.

Despite such efforts, though, fraud continues. For example, the Pennsylvania Attorney General and U.S. Attorney's offices recently completed an 18-month investigation looking into insurance fraud in treatment centers. Charges included, once again, kickbacks for unnecessary drug testing and billing insurance companies at exorbitant rates.

Those charged also directed patients to live in company-owned, unlicensed recovery homes where the housing was sometimes unsafe, employees and patients were engaged in sexual relationships, and there were opportunities to relapse. And this is the case of the bad guys getting caught. That's what leads me to my second point.

We do not know the total number of recovery homes, so therefore, we don't know the extent to which this is happening. In addition, no Federal agency oversees the operations of these homes to provide a nationwide perspective.

In closing, when run properly, recovery homes are an important part of a patient's path to sobriety and combating the opioid crisis. Our work on recovery homes is part of GAO's broader work on drug misuse. Recent GAO reports have explored, for example, Federal oversight of opioid prescribing in Medicare. We also have ongoing work identifying barriers Medicaid beneficiaries may face accessing important medications to treat opioid misuse.

Much of our current work is the result of mandates from the SUPPORT Act, which was signed into law 1 year ago from today. We highlight this and other work in our latest high-risk report, where we identify Federal efforts to prevent drug misuse as an issue requiring very close attention.

Thank you, Chairman Grassley, Ranking Member Wyden, and members of the committee, for holding this important hearing and continuing your oversight on this issue. This concludes my remarks. I am happy to respond to any questions you may have.

[The prepared statement of Dr. Denigan-Macauley appears in the appendix.]

The CHAIRMAN. Now, Mr. Cantrell.

STATEMENT OF GARY CANTRELL, DEPUTY INSPECTOR GENERAL FOR INVESTIGATIONS, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. CANTRELL. Good morning, Chairman Grassley, Ranking Member Wyden, and other distinguished members of the committee. I am Gary Cantrell, the Deputy Inspector General for Investigations at HHS OIG. I appreciate the opportunity to appear before you to discuss OIG's efforts to combat the opioid crisis. Our ongoing work is taking a multi-faceted approach, looking at a variety of issues on both the prescribing and treatment dimensions of this crisis.

OIG is addressing the crisis through expanded law enforcement activities, audits, evaluations, and data briefs. Our efforts to combat opioid-related fraud, waste, and abuse while ensuring both substance use disorder treatment and continuity of care continue are a top priority for OIG.

For example, we have expanded enforcement efforts to address the opioid crisis significantly over the past several years, resulting

in an increase of over 100 percent of open investigations at our office from 2015 to 2019. Just this year, the newly launched Appalachian Regional Prescription Opioid Strike Force, a joint initiative between DOJ, OIG, DEA, FBI, and our State Medicaid Fraud Control Unit partners took down 73 individuals, 64 of them medical professionals, for their alleged participation in the illegal prescribing and distribution of opioids and related health-care fraud schemes.

Opioid fraud encompasses a broad range of criminal activities from prescription drug diversion to addiction treatment services and billing schemes. A growing concern is fraud involving medication-assisted treatment, sober homes, and ancillary services such as counseling and urine drug test screening. As the number of treatment facilities and sober homes operating across the Nation continues to increase in conjunction with increased demand and availability of Federal funds to support new services, we have seen the commensurate increase in elicit schemes involving fraudulent billing and diversions.

As our enforcement and oversight efforts to address the opioid crisis have expanded, we have also come to understand the impact our enforcement work can have on the patients that we serve. We recognize that when a clinic whose patients are prescribed opioids or MAT is shut down due to law enforcement efforts, access to care can and will be disrupted. Rather than leaving these patients to potentially turn to another fraudulent provider or street drug to meet their needs, we believe it is vital that they have the access to quality treatment and pain management services with minimal disruption to care.

But this is not something that law enforcement can do alone. Ensuring these patients have continuity of care requires a collaboration with our Federal, State, and local public health service officials. As part of the ARPO Appalachian takedown, OIG and our law enforcement partners worked in close collaboration with HHS's Office of the Assistant Secretary for Health, the Centers for Disease Control and Prevention, the U.S. Public Health Service, and State public health agencies to deploy Federal and State-level strategies and resources to provide assistance to patients impacted by our law-enforcement operations.

OIG will continue to work hand-in-hand with our public health partners to help ensure access to treatment and continuity of care for patients impacted by our efforts.

Beyond our enforcement efforts, OIG continues to grow our robust portfolio of work related to the crisis with new and ongoing work that identifies opportunities to strengthen program integrity and protect at-risk patients across the prescribing and treatment dimensions of this crisis.

OIG currently has several opioid treatment-related audits and evaluations underway, examining issues such as access to medication-assisted treatment and advancement and deployment of oversight of State treatment grants. We look forward to sharing the results of this work with the committee when it is complete.

OIG's recent data brief on opioid prescribing in Medicare shows significant declines in opioid prescribing. At the same time, it also showed that the number of patients receiving buprenorphine and

naloxone in Medicare is increasing. And this is a very positive sign. However, there is still much work to be done to reduce illegal prescribing of opioids and sham treatment schemes, which only detract from the efforts of those who seek to provide the help these patients truly need.

OIG will remain vigilant in identifying and investigating emerging opioid treatment fraud schemes and working to improve HHS's efforts to provide quality treatment services.

Thank you for allowing me the opportunity to discuss this important topic, and I look forward to any questions you have.

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

The CHAIRMAN. Before you start, I realize what little bit I said about you in my opening statement. I need to recognize your success in the private sector, and now, bringing that to the nonprofit organizations, you are able to help us accomplish this goal. I should have said that, and I did not. So proceed.

STATEMENT OF GARY MENDELL, FOUNDER AND CHIEF EXECUTIVE OFFICER, SHATTERPROOF, NEW YORK, NY

Mr. MENDELL. Chairman Grassley, Ranking Member Wyden, and members of the committee, thank you for holding this hearing on treating substance misuse in America. My name is Gary Mendell, and I am the founder and chief executive officer of Shatterproof, a national nonprofit organization dedicated to reversing the addiction crisis in America.

For nearly a decade, my son Brian struggled with substance abuse disorder. Despite our family working tirelessly to find my son the best possible care at eight different treatment programs, on October 20, 2011, we lost my son Brian to the disease of addiction.

In the months that followed, I was destroyed all over again when I learned that research existed proving the types of interventions that would have significantly improved the outcome for Brian and millions of others who were in treatment for addiction, if only we had known what to look for. That is why I founded Shatterproof, the first national nonprofit organization dedicated to reversing the addiction crisis in America.

To accomplish this, we developed a five-point plan to transform the addiction treatment system in the United States.

Number one: a core set of science-based principles for care for treating addiction.

Number two: a quality measurement system.

Number three: payment reform.

Number four: treatment capacity.

And number five: ending stigma.

My remarks today will focus on the second of these five, treatment quality measurement. Addiction is a chronic brain disease. But despite the fact that there are clear clinical best practices, the use of these practices varies widely across the addiction treatment field, and some facilities are still employing tactics based on ineffective and outdated methodologies.

Unlike other health-care services, comprehensive, standardized data on the quality of addiction treatment just simply does not exist. Even worse, because consumers, payers, and State regulators

do not have access to quality measures, market forces have not been aligned to support these best practices.

In 2006, in a landmark report by the Institute of Medicine, it called for the development and dissemination of a common, continuously improving set of measures for the treatment of substance use disorder to drive quality improvement.

Shatterproof is seizing upon this longstanding recommendation to develop a public platform known as ATLAS, with three aims.

Number one: providing patients and family members the information they need to identify evidence-based treatment for their loved ones.

Number two: equipping providers with data to advance the use of evidence-based practices.

And number three: ensuring policy and payment decisions are data-driven.

The tool builds upon our eight national principles of care, which were developed with experts in the field to establish that addiction should be treated like any other chronic illness.

We are currently in phase one of that list and are working with treatment facilities, payers, and other stakeholders in six States: Delaware, Louisiana, North Carolina, West Virginia, Massachusetts, and New York. So far, this phase has included measure identification and refinement through the National Quality Forum expert panel's strategy session and public comment periods, feasibility testing of survey items and claims measures, and a pilot of the Patient Experience Survey across 50 treatment facilities in the State of New York.

Quality data will be collected and triangulated from three sources—claims data, Patient Experience Survey, and Treatment Facility Survey—and reported back to providers, to the public, the payers, and to States. And when I say "the public," I mean the families.

Following evaluation of phase one, Shatterproof will work with other States to bring this resource to serve more than 21 million Americans with a substance use disorder.

ATLAS is part of Shatterproof's strategic goal in transforming the addiction treatment system in the United States to reverse the addiction crisis that has taken such a severe and tragic toll on far too many, and for which the impacts can absolutely be averted for so many others.

Thank you for the opportunity to testify today, and I look forward to your questions. Thank you.

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

The CHAIRMAN. We will have 5-minute rounds of questioning. We will start with the Surgeon General.

First of all, I know and thank you for the top priority you have given as Surgeon General, and even probably as an individual, to addressing opioids and addiction as a top priority. And I also thank the administration for its efforts to prioritize carrying out the enactment of this legislation.

Section 70.31 of the new law calls for the development of best practices. Has the administration appointed working group members to develop such best practices, or identified the factors that

should be used to identify potentially fraudulent recovery housing operators, as required by SUPPORT, and if not, could you give us a timetable when that might happen?

Dr. ADAMS. Thank you for that question, sir, and I want to recognize that Iowa has led the way in the country with a 14.7-percent decrease in overdose rates over the past year that's been recorded. And so we need to share more of what's working in Iowa with the rest of the country, including connecting people with treatment and recovery services.

I will tell you very specifically, in the "Spotlight on Opiods," which I highlighted—this came out last year—there wasn't much fanfare. A lot is going on in DC nowadays, and folks do not always notice when the Surgeon General puts something out. But I highlighted what to look for in a substance use disorder treatment program: personalized diagnosis assessment and treatment planning; long-term disease management.

As we learned in Indiana, it is not just substance use disorders; in many cases it is HIV, it is hepatitis, it is sexually transmitted diseases, it is co-occurring mental illnesses. So, access to FDA-approved medications; effective behavioral interventions; coordinated care for other co-occurring diseases and diagnoses; and recovery support services.

So my role is to help give the public the information they need to make informed decisions. We have put that out. We also have the SAMHSA treatment finder, 1–800–662–HELP. And beyond that, in terms of vetting good from bad, I would turn it over to my friend, Mr. Cantrell, from OIG. I hate to put you on the spot, sir, but——

Mr. CANTRELL. Vetting good from bad is, unfortunately, where we only encounter the bad. And what we see is that our institutions have no intent to provide the services that they are billing for. Individuals do not receive the type of counseling that they are supposed to receive. Sometimes we have seen prescription pads just left behind for staff, nonqualified medical staff at the facility just writing prescriptions as people walk through the door.

There is zero, in most of these cases we are involved in, actual interest in the care of these patients in treatment. So they are not getting the services that they need and deserve, and oftentimes that we are paying for.

The CHAIRMAN. Dr. Denigan-Macauley, I wanted to ask you a question. You referred in your testimony about not knowing how many homes there are, or where those recovery homes are. Do you have any way of telling us what obstacles exist to obtaining this information? Because it seems like we need this information.

Dr. DENIGAN-MACAULEY Yes, it is difficult to obtain this information because, as I mentioned, there is no Federal oversight of these homes. It is left up to the States, and the States have varying practices.

For example, some States require homes to be licensed. Other States offer a voluntary certification. NARR* offers voluntary certifications, and some homes fly under the radar. So there are many

*National Alliance for Recovery Residences.

obstacles to identifying the number of recovery homes that we have.

Dr. ADAMS. Sir, I would highlight—and this ties into your question—today Medicare, CMS, is going to be releasing a substance use disorder data book. And that is a direct request from the SUPPORT Act, which you all passed a year ago, and this will highlight the people and States that are getting recovery and treatment services through Medicaid. And that will be a first important step to figuring out who is getting what, where are they getting it, and will better allow us to then assess the good from the bad.

The CHAIRMAN. Mr. Mendell, obviously we did not—I did not recognize that you lost your son, and obviously that is a terrible loss for you. And I hope you know it is not only your son, but everybody else that we are trying to help in this regard.

So I would like to ask you this question, and this will have to be my last one. Tell us more about what led you to develop the national standards of care.

Mr. MENDELL. Sure. What I saw in the industry was literally about 45 evidence-based practices that treatment programs should be following, each with multiple published articles. Clinical trials showing that they worked—if you do X, the patient does better; you do A, B, C, the patient does better. But there were 45 of these, approximately. And they were not all in one place. They were all in different peer-reviewed medical journals.

There is not a business in America that bonuses anybody on 45 things. Most businesses that are successful narrow it down to less than 10 core things that will really move for success.

So I knew what we needed was less than 10 core principles of care, number one, that could be readily understood. The Surgeon General just mentioned many of those. And our lists are fairly close.

Less than 10 core principles of care, number one, that could be easily understood. But number two, most importantly, able to be measured. You cannot measure 45 things, but you can measure less than 10. And we purposely selected, working with the leading researchers in the field—in fact, many of the researchers who drafted the 2016 Surgeon General's Report, which was followed up on in the "Spotlight"—working with them to draft 8 principles of care that could be easily measured that were the most impactful to treatment, whether it is in-patient, out-patient, opioids, alcohol, adolescent, or adult.

The CHAIRMAN. Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman. This has been an excellent panel. We thank you all for your commitment and compassion to the patients. And let me tell you what is foremost on my mind this morning.

Every morning now, we wake up to these news reports that there is this effort with the States and the communities to work with the pharmaceutical companies to come up with a settlement that deals with the opioid drug addiction and the overdose epidemic that the drug companies contributed mightily to that we are facing in this country.

If these court settlements go forward, it is almost certain that a significant portion of that money is going to go to substance abuse

treatment. And it ought to. But based on the fraud and the ripoffs that you are already describing to us today, it seems to me that this lack of oversight could mean that with a potential influx of more money, we are creating a perfect storm for more fraud.

So I think what I would like you to do, Dr. Denigan-Macauley, is tell us, going forward, what should the Federal Government, working with the States and the private sector, do to make sure that—if that settlement takes place and there are billions of dollars coming in for substance abuse treatment, what should the Federal Government, working with the States and the private sector, do to make sure the dollars go to reputable operators and not more fraud?

Dr. DENIGAN-MACAULEY Thank you. And it is a big question. However, our work would show that the certification programs, the licensing programs, the NARR certifications, the charter houses, have oversight. So it would be good if we could ensure that the funds could at least go to those homes that have some form of oversight.

Senator WYDEN. What are the gaps in those areas? My understanding is, you all have already identified some gaps today in the oversight of some of those key areas.

Dr. DENIGAN-MACAULEY. The gaps are numerous. As I mentioned before, there is no Federal oversight to help us with this program.

Senator WYDEN. So who would you make the point person on the Federal side? Would it be the Centers for Medicare and Medicaid Services? Who would you make the point person, given the fact that you say there is nobody coordinating this?

Dr. DENIGAN-MACAULEY. We did not look at that directly. However, we do know that SAMHSA is providing grant money, and so that could be one way to tie it to what the States are doing.

Senator WYDEN. Would that be the most cost-effective? Based on your work, what would be the most cost-effective way, starting on the Federal side, to fill the gap? So SAMHSA would be better than——

Dr. DENIGAN-MACAULEY. And unfortunately, we have not looked at it all to be able to say which is better. However, clearly CMS and SAMHSA could be involved.

Senator WYDEN. Okay; what are the other gaps?

Dr. DENIGAN-MACAULEY. The other gap is that we just really do not have an understanding. And the States are able to do various things. It is not one-program-fits-all. This is grassroots level. One State that we interviewed did not want to establish State regulations for recovery homes, because they are afraid it would result in fewer recovery homes.

Senator WYDEN. What would be the two most serious gaps? I mean, in other words, we have to start somewhere. We have to have somebody at the Federal level coordinating it, then they are going to say, what are the two most serious gaps that if you do not deal with them, more money is going to get ripped off?

Dr. DENIGAN-MACAULEY. I wish I could answer that, but I do not know the answer to that. I know there are gaps.

Senator WYDEN. Who would? Who would be able to tell us, with all this money coming in, what the biggest gaps are?

Dr. DENIGAN-MACAULEY. I think that is an excellent question, because, when you look at the number of individuals that we had to interview just to get an understanding of the oversight of these homes——

Senator WYDEN. Let me go to Mr. Mendell, because I think you guys have already started us on the way to answering this, because you found some problems with the accrediting organizations and the like. I gather you would say that was a gap?

Mr. MENDELL. Correct. I suspect many in this room would agree that it is difficult for the Federal Government to get down to regulating at the local level. But what the Federal Government can do is condition all the grants it is giving to States on States doing evidence-based practices.

For example, SAMHSA is going to be giving out billions of dollars to States. SAMHSA could—could—condition that money going to States on States doing the following five or six things.

Senator WYDEN. Yes, but my point is, number one—Senator Stabenow has been a leader in working on these kind of behavioral issues right now. We are not talking about the Federal Government taking this over.

Mr. MENDELL. Correct.

Senator WYDEN. We are talking about the fact that the Federal Government—if we are talking about substance abuse, there are significant amounts of dollars that the Federal Government has been involved with, and the Federal Government needs to be a partner with the accrediting organizations and with the States and the private sector and the like.

We will hold the record open—the chairman has had to go—and I would be very interested in hearing from each of you what you think the biggest gaps are right now, and your ideas for helping to fill them. I would also like to throw a bouquet to my seat-mate here for doing good work on this, and being part of the bipartisan coalition that is coming up with an actual plan to deal with it. Thank you.

Dr. ADAMS. Senator Wyden, you asked for two things—and 20 seconds, 20 seconds?

Senator WYDEN. Yes.

Dr. ADAMS. Two big things. One of the HHS pillars is better data. I used to run a State health department. Again, the substance use disorder data book is a big, big deal because it will give States better information about what is going on where, so they can make better choices about who to lift up and who needs to be investigated. So better data is one.

Number two, again, as Gary mentioned, as Mr. Mendell mentioned, we need to let the consumers at the local level know what to look for in a good treatment center. So, please, look at what Shatterpoof has put out. Look at what we have put out. And use your bully pulpit as Senators to push that information out to individuals who are making those decisions, to those parents who are going to treatment center after treatment center after treatment center and do not have a checklist to tell good from bad.

We have those checklists available. We need you to help us push those out.

Senator WYDEN. We will keep the record open, if you can get it to us. The chairman wants to move quickly, within the next 10 days. We would like to have recommendations to make sure that, if we see this influx of money, we are not going to see it used for more fraud.

The CHAIRMAN. I would just like to recognize that this is exactly why we are having this hearing, and this has been a very constructive conversation.

Senator Daines?

Senator DAINES. Thank you, Mr. Chairman. Drug overdose is now the leading cause of death for those under the age of 50 in the United States. We will let that sink in for a moment. It is a sobering fact.

No doubt our country is in the middle of a major opioid and meth crisis, and we absolutely must do more to combat this drug epidemic. In fact, in my home State of Montana, it is meth that destroys families and communities.

In fact, from 2011 to 2017 there was a 415-percent increase in meth cases in Montana, with meth-related deaths rising 375 percent during those same years. And unfortunately in my State of Montana, the meth crisis is disproportionately impacting Native American tribes.

That is why we had a debate up here that included a piece of legislation called "The Mitigating Meth Act." It helped strengthen Indian tribes' ability to combat drug use in the SUPPORT Act, which was signed into law by the President last year.

It was a good first step, but there is a lot more to do. We need to put an end to the tragic stories we are seeing in the news. No more babies being born addicted to meth. No more stories of meth breaking up families, overwhelming our foster care system in Montana. No more stories of individuals being taken advantage of who are desperately seeking substance abuse treatment.

I know I can speak on behalf of Montanans: we have had enough.

Dr. Adams, thanks for being here. First, I would like to invite you and other HHS administration officials to come to Montana to see first-hand how this meth crisis—it is Mexican cartel meth that is affecting our communities.

While the opioid epidemic has certainly been felt in Montana, one of the greatest challenges we are facing, though, is meth use.

Dr. Adams, can you speak to how meth is the next wave of the opioid crisis?

Dr. ADAMS. Thank you for that, sir, and you are right. In Montana, your overdose rates have gone up 26 percent in the last year from all substances, and we know that, while we have seen a 5-percent decrease in opioid overdose rates nationwide, we have seen a 23-percent increase in overdose deaths due to meth and stimulants. So you are exactly right.

And I would loop back to the HHS strategy points: number one, better prevention, treatment, and recovery; and number two, better research on pain and addiction.

I want you to know that about a third of my Commission Corps officers—the Surgeon General heads the Public Health Service Commission Corps—work at IHS facilities, Indian Health Services facilities. We see this firsthand.

I have visited tribes and reservations all over the Nation. And what I want you to know is, this opioid crisis is not a problem so much as it is a symptom. It is a symptom of our failure to recognize untreated behavioral health issues. It is a symptom of our failure to build resilience into communities. It is a failure of our recognition to see that there is massive untreated and under-treated pain in our country, both emotional, mental, and physical.

And so we really need to lean in to truly better prevention, treatment, and recovery services that include all those things. Otherwise, we are just going to keep playing whack-a-mole over and over again. And we will put out the opioid fire, but a meth fire will pop up again in our country. And we are seeing it happen particularly, like you said, in Montana and on the West Coast.

Senator DAINES. And if we look at the meth crisis in Montana, once upon a time the home-grown meth that used to be the source of meth had purity levels of about 25 percent. Today, the Mexican cartel meth has purity levels north of 95 percent. So it is much more potent. The prices have come down because there is so much more being produced, and the distribution has certainly become much more sophisticated, where literally it takes a couple of days from the time it crosses the southern border until it gets to a reservation in Montana. I saw that firsthand.

Dr. ADAMS. I could not agree more, sir. We actually work with ONDCP to bring together public safety and public health. We need to work on the supply side. And you talked a lot about the supply side, but I will tell you, if we do not deal with demand, if we do not deal with people self-medicating away their pain and their mental health issues, there is always going to be a supply.

Senator DAINES. Right.

Dr. ADAMS. Someone is going to find a way.

Senator DAINES. I completely agree with you as well.

Lastly, I do believe we need this multi-faceted approach—you alluded to that, Dr. Adams—to combat this epidemic. And that is why I have been pressing the NIH to develop medication-assisted treatment, or MAT, to treat meth addiction. While MAT exists for opioids, alcohol, and other drugs, there is no MAT for meth.

Dr. Adams, are you familiar with NIH's work to develop MAT for meth?

Dr. ADAMS. I absolutely am. I had about a 10-minute conversation with Dr. Nora Volkow yesterday specifically on this topic. And I will tell you what she told me. Unfortunately, the research out there right now is not promising in terms of developing MAT for meth. They have spent millions of dollars on it, and they will continue to spend more money to try to develop it, but our best solution right now is prevention.

It is trying to get upstream. It is trying to deal with these problems before they turn into the next wave of a meth epidemic. But we still will continue to devote research to trying to find solutions for people who need to recover.

Senator DAINES. Last statement. Would you commit to working with me to advance these efforts to assist Montanans overcoming the meth epidemic?

Dr. ADAMS. Absolutely, sir. Again, the parts of our country where our Native American and tribal folks reside are very, very personal

to me. And it is where I have tried to make a point of getting out and visiting, and I and HHS commit to you that we will not forget about those individuals. They are citizens of our country, and they should not be forgotten.

Senator DAINES. Thank you, Dr. Adams.

Dr. ADAMS. Thank you.

Senator DAINES. I ask unanimous consent to enter a letter from the Federal Law Enforcement Officers Association and others into the record. It helps us to see the devastating effects of substance abuse on our local communities. Without objection, so ordered.

[The letter appears in the appendix on p. 88.]

The CHAIRMAN. Senator Stabenow?

Senator STABENOW. Thank you, Mr. Chairman, for you and the ranking member. Thank you so much for holding this hearing. And to each of you on the panel, thank you very much. This is an incredibly important topic that affects all of us in some way.

And, Mr. Mendell, I am so sorry to hear about your son Brian. And I am sure that is part of the effort that you have put in to moving us forward and making a meaningful difference for so many other families.

I have heard, like everyone else, so many horrifying stories of individuals and families struggling to get substance abuse help, as well as mental health help. Those are very much together. We know many times in mental illness that people are self-medicating with alcohol and drugs, and underneath there is a mental illness as well. So these are very much tied together.

And people are trying to do the right thing to get the best possible treatment, families are, and ultimately, as you have shown, people can be taken advantage of. And unfortunately, I believe that this is happening in part because, structurally, we treat behavioral health, addiction and mental health, differently for reimbursement.

It is the quality standards. It is evidence-based care. But also we predominantly do this in grants rather than reimbursement, like we do for health care. So we have Federally Qualified Health Centers, where we have set high standards, that get full reimbursement if you are a physician, a nurse, and so on. For health centers, we do not yet fully have that on behavioral health, which is what we are working very hard on right now.

So we know right now, based on the eight-State demonstration project, there is a right way to do things, and we can spend Federal dollars much more wisely with high standards. In fact, a couple of years ago—and I am so grateful for Senator Roy Blunt's leadership on this with me as well. But around this table we have people—we have Oklahoma, Oregon, Pennsylvania, Nevada, New Jersey, where we now have 2 years of data of what happens when you have quality standards on addiction treatment and mental health, and then see how it plays out. Are people going to jail? Are more people getting the treatment that they need?

And I want to thank the chairman and ranking member and so many people here for giving us the opportunity now, through additional legislation, to actually take the next step for more services, more States to actually be able to put this in place.

So we have seen in just a short amount of time that this is transformative. We are also grateful this was in the President's budget,

and SAMHSA has been a lead in making sure that we are doing grants to begin to step up these structures.

So, General Adams, Dr. Adams, can you provide an update on the administration's work related to implementation of what we have called "The Excellence in Mental Health and Addiction Treatment Act," as well as the Certified Behavioral Health Center grants that are beginning to move this structure forward?

Dr. ADAMS. Thank you for that question. And again, this is very personal to me. My brother, as I mentioned, sits in jail right now due to crimes he committed to support his addiction. And his pathway started with unrecognized, untreated anxiety and depression.

We know that many of these substance use disorders are co-occurrent with behavioral health issues, and it is a priority for us to make sure that folks who are being treated for substance use disorders are having their behavioral health issues taken into account, but also that we are recognizing them before they turn into substance misuse and self-medication.

You asked for an update. I know you have spoken with Secretary Azar, and he shares your excitement about what is happening. I will tell you that at HRSA, we have Behavioral Health Workforce Education and Training grants, $50 million in 2017. We had mental health and substance use disorder co-occurring treatment expansion, over $550 million distributed to 1,200 health centers across our country, and then the pilot grants that you mentioned.

So far the results look good. So I just want to say, succinctly, that we share your concerns. I want to thank you for your support for this in Michigan. You all have seen a 10-percent decrease in your overdose rates there, and I think it is because you have looked at this as both a mental and behavioral health issue, and a substance use disorder issue, and not separated out the two.

I want to say, quickly, I often tell folks that a long time ago, unfortunately, we cut off the head from the rest of the body. And what I mean by that is, we said, "Anything that happens from here up—oral health, vision health, and mental health—here is a card. Go see somebody. Good luck. Anything that happens from here down, we will take care of it at your primary care visit."

As Surgeon General, I am talking to providers and professional organizations and encouraging them to integrate behavioral health back into primary care and mental health.

Senator STABENOW. Well, thank you. We know that, with the addiction and mental health, it is a brain disease, and so that is a very important part of the body, and we should treat it as we treat every other part of the body. And I know my time is up, so I will just indicate that in the areas now where we have certified community behavioral health centers, we actually have medication-assisted treatment. We have specialists, real trained people with evidence-based treatment options, who are working with people. And in each of these centers is also 24-hour, 7-day-a-week access to services, crisis services.

So folks are not going to jail. They are not going to emergency rooms. They are actually able to talk to someone who is trained to help them.

The CHAIRMAN. Senator Cardin?

Senator CARDIN. Thank you, Mr. Chairman. Again, I thank all of our panelists.

I certainly agree with the points that have been made by Senator Wyden and others that we need more information for consumers, more transparency, in order to prevent fraud. And I also agree that we have to get the metrics for that. And that is not as easy. And we have to narrow it to where consumers can use that information most effectively in making decisions. I do think that Shatterproof does provide some ability to look into these issues.

I want to go on to a point that Dr. Adams made when you talked about the five key messages for addressing the opioid crisis, specifically mentioning recovery support services. In Maryland, we have found that peer support has worked well in our community.

I included a provision in the SUPPORT Act that deals with studying the Medicaid program peer support. In Arundel County, in Garrett County, they are working to increase their capacity for peer support in emergency rooms. In Baltimore County, they are looking at nontraditional hours to make sure that we have peer support programs. In Dorchester County, there are on-call peer support programs that are available.

I would like to get your view as to how effective you think peer-support programs have been, and what we can do to try to encourage more opportunity for peer support, particularly in nontraditional hours and in emergency rooms and things like that.

Dr. ADAMS. So, quickly, I have been all over the country. And the communities I have seen that have been able to turn around their opioid overdose reversal rates have done four key things.

Number one, they have saturated their communities with naloxone, because you cannot get into treatment and recovery if you are dead.

Number two, they have had a warm handoff, usually through some sort of peer recovery type program.

Number three, they have provided medication-assisted treatment, because that is the gold standard.

And number four, they have had strong public safety and public health cooperation, so that again, we can shift from criminalizing the problem to medicalizing the problem.

You asked what we can do. I will tell you that I am very proud of the fact that, during this administration, we have increased the number of Medicaid 1115 waivers substantially; 22 have been approved during this administration, and that has given States the flexibility to pay for things that they feel are appropriate to improve success rates in treatment and recovery, including peer recovery, including housing, including child care, including transportation. We need to provide those wrap-around services, but you are right, Senator. Peer recovery is one of the key tenets in making sure you can stop your overdose reversal rates and get people on the pathway to becoming productive citizens again.

Senator CARDIN. Thank you.

Dr. Denigan-Macauley, some States have implemented peer support under their Medicaid program. Do you have any information as to the effectiveness of the peer support programs under the Medicaid program?

Dr. DENIGAN-MACAULEY. So it is good that you mentioned the SUPPORT Act, because GAO is getting ready to begin a review that is going to look at Medicaid's use of the peer support in States. So I do not have an answer for you now, but we do have work that is beginning that will provide those answers.

Senator CARDIN. Well, I am pleased to see that. If you would keep us informed on that, I would very much appreciate it.

Dr. DENIGAN-MACAULEY. Will do.

Senator CARDIN. I would like to get to one other issue, if I might. In Maryland we are looking at stabilization centers. Two counties have started stabilization centers to get those who are on OD out of the emergency room.

I certainly agree, Dr. Adams: you want them alive. So the medication is important. The emergency services are important. But emergency rooms are not good places for people needing care.

So the current reimbursement structure sort of works against the stabilization center. If you go to the emergency room, the full cost is usually covered. What can we do to encourage that type of care that a person who is stressed needs, usually in nonconventional hours during the middle of the night—and allow for the funding of programs such as stabilization centers in communities?

Dr. ADAMS. Well again, I would highlight giving States the flexibility to fund these types of programs, such as we have done through the 1115 waivers. But this is a good one to kick to Mr. Mendell because he can speak from personal experience about the struggles of bringing his son in over and over and not having a place for him to go that would help him.

Mr. MENDELL. Absolutely. And I think it comes back to quality measures, as far as measuring—defining—through science, what are the most effective methods to treat people and having a transparent set of quality measures where the information is published on a regular basis. We have talked about consumers seeing the information, where they can learn to send their family members. But it is also for payers, for payers to understand which providers are most appropriate in their networks and which ones are not.

And it is also for State regulators. And it is also information that providers can learn from each other. We have talked a little bit here about the unscrupulous providers out there, but there are a lot of good people in the provider community who are not unscrupulous. But they do not have the information about what programs are most effective, and which tactics are most effective.

And if we have transparent, quality information without even having to regulate, they will learn from each other and have the information they need to improve. So it is not just ratings; it is quality measurement. It is quality improvement and providing the resources to do so.

The CHAIRMAN. You brought up, Dr. Adams, my wife, so here is what I found out—— [Laughter.]

Your wife sat beside my wife at the International Club. We had lunch at the Indian Museum, and she was a hostess at the International Club meeting at the Children's Inn at NIH. Is your wife really that active?

Dr. ADAMS. My wife is, and she shared her story. Many of you know this. My wife actually just finished treatment for metastatic

melanoma at the National Institutes of Health, and we are cancer-free based on the last PET scan, but she shared her story. And your wife was so incredibly kind to my wife. She was nervous telling her story. She is not a public speaker, and you can tell I am pretty nervous talking in public too, but she did a great job and appreciated the support from Barbara.

The CHAIRMAN. Well, my wife is a 33-year survivor of breast cancer.

Dr. ADAMS. Exactly. She shared that. Thank you.

The CHAIRMAN. Senator Hassan?

Senator HASSAN. Thank you, Chairman Grassley and Ranking Member Wyden, for holding today's hearing. I want to thank all of our distinguished witnesses for being here today.

But, Dr. Adams and Mr. Mendell, I particularly want to thank you both for sharing your family stories. Because in doing that, you really do help combat the stigma that is such a part of this disease and undermines our capacity to treat it. So thank you.

As many have mentioned today, a year ago today the SUPPORT for Patients and Communities Act was signed into law. The passage of this legislation was a critical step in addressing the opioid crisis. But the crisis did not happen overnight, and we know that it will take a continuous and sustained investment at the Federal level to curb and ultimately reverse the tide of what is truly a horrible epidemic. I look forward to continuing to work on a bipartisan basis to adequately fund the SUPPORT Act, build on the SUPPORT Act, and expand access to prevention, treatment, and recovery services.

I wanted to start with a question to Dr. Adams and Dr. Denigan-Macauley about services, and access for women in particular. The HHS Office on Women's Health estimates that 70 percent of women entering substance use disorder treatment have children. And many residential treatment programs do not allow children to be present when their mother is receiving treatment. This is obviously a real barrier.

We have some good examples of what works. Residential recovery homes that offer services for pregnant and postpartum moms like Hope on Haven Hill in Rochester, NH have proven to be really effective. And data shows that when pregnant women and new moms have access to long-term evidence-based treatment, outcomes improve for the entire family.

Unfortunately, recovery homes like Hope on Haven Hill are few and far between. It is one of only a handful available to women in New Hampshire. Moreover, reporting from news outlets throughout New England, as well as the GAO report we are discussing today, have shown that some recovery homes are scamming patients and they are not using the evidence-based treatments we need them to use.

One of the best means to recovery for many women is residency in an Oxford House, which is an evidence-based recovery home model that addresses addiction. Yet according to the GAO report, only 29 percent of Oxford Houses in the United States provide recovery housing for women.

So, Dr. Adams, what is HHS doing to expand access to long-term evidence-based treatment for moms that allows them to remain

with their children in a safe environment? And how can Congress support those efforts? That is the question I want you to answer.

And then to Dr. Denigan-Macauley, after Dr. Adams, how do we ensure that we are providing access to the increasing number of women in need of treatment and recovery services, especially given the relatively limited number of high-quality recovery homes for women?

Dr. ADAMS. Well, quickly, I have visited New Hampshire many times. Few places have suffered as much from the opioid epidemic, but also few places have had as much success in overcoming the opioid epidemic. You have decreased your overdose rates by 10 percent. And a lot of that has been due to your focus on NAS. I have been to hospitals in New Hampshire and learned about the work they are doing there.

What are we doing? Well, ACL has a Neonatal Abstinence Syndrome national training initiative, listing best practices, including keeping moms and babies together.

I have partnered with Dr. McCance-Katz, the head of SAMHSA, to write an article calling on more OBGYN providers to become trained at MAT so that we are not playing hot potato with a mom who has substance use disorder, and that we can take care of her.

And then two other models I mentioned, very quickly, the Maternal Opioid Misuse Model will increase access to effective substance use disorder treatment through a focus on improving the quality of care for pregnant and postpartum patients.

And then the Integrated Care for Kids Model through CMS is a child-centered service delivery program that again emphasizes providing those supports. So I could not agree with you more, and we are trying to do all we can to provide that flexibility.

New Hampshire also has an 1115 waiver which can provide some flexibility.

Senator HASSAN. Thank you. Dr. Denigan-Macauley?

Dr. DENIGAN-MACAULEY. Thank you. Yes, GAO is similarly concerned, and we have looked at reports on Neonatal Abstinence Syndrome. We also have ongoing work on maternal mortality, which unfortunately does relate to the opioid crisis.

And we have a report that is coming out looking at Medicaid and opioid abuse disorder services for pregnant and postpartum women as a part of the SUPPORT Act. I think it is actually being released today. So there will be some more information there.

Senator HASSAN. Thank you. I know I am running out of time. I will follow up with you, Dr. Adams. Senator Murkowski and I have a bill to remove the waiver necessary right now for physicians to be able to do medication-assisted treatment. I am concerned that people do not understand that it is the gold standard and how important it is. I am concerned about the stigma attached to MAT still. And so I will have a question for the record for you to follow up on that, because we really need to get the word out there how important it is.

Dr. ADAMS. Absolutely. Happy to follow up.

Senator HASSAN. Thank you.

The CHAIRMAN. Senator Menendez, I apologize for passing over you. I forgot.

Senator MENENDEZ. Thank you, Mr. Chairman. Thank you for calling together a very important hearing on a major health crisis in our country.

Dr. Adams, I recently spoke with a constituent whose son is grappling with a substance-based problem, and she mentioned that there is a disconnect between what she has been told by experts is the appropriate time for her son to be in a treatment center, and what her insurance will cover. So now he has cycled through treatment a couple of times—and this is not the first time I have heard this, which drives me to the question: do you think there is a disconnect between what we know are evidence-based best practices for substance use disorder treatment and the coverage of such programs?

Dr. ADAMS. Yes. I cannot say it any plainer than that. We think that, if you put someone in a treatment program, in 4 to 6 weeks they are going to be magically cured. We know that recovery is a lifetime, and it is one of the reasons that HHS is focusing on trying to emphasize treatment and recovery, and provide that flexibility for States to be able to provide those wrap-around services, that transition for recovery moving forward.

Senator MENENDEZ. So what would you recommend to close the gap between what is paid for and what is recommended?

Dr. ADAMS. Well, again I can only speak on best practices, not on regulation or legislation, but I will say that it is important that folks look at the fact that you are not going to solve this problem with a short 4-week, 6-week treatment and that we need to fund that spectrum.

And again, we are trying to use the flexibility we have within CMS through 1115 waivers to give States the ability to do that.

Senator MENENDEZ. Well, it seems to me that this is more consequential, the way it is operating now, more consequential to the life of the individual, more consequential when we rotate people in and out, and then they get paid for different segments of services, instead of having an outcome.

Dr. ADAMS. Certainly not a good practice, Senator.

Senator MENENDEZ. Would an outcome-based payment system for rehab treatment ensure best practices are followed?

Dr. ADAMS. Outcome-based payment is something that we are certainly pushing towards within HHS in a broad array of areas. The whole fee-for-service world, I think, needs to be looked at very closely. We need to make sure we are paying people to actually create health and wellness and not paying people to do procedures or to keep someone as an in-patient until their funding runs out.

And again, HHS is committed to providing that flexibility, but also to incentivizing new payment models. If you look at what we are doing through CMMI, we are trying to help States and local entities figure out what works best for them, but to show proof of concept so that we can scale it up.

Senator MENENDEZ. Mr. Mendell, first of all, you have my deepest sympathy for the loss of your son, and none of this is easy.

You previously stated you do not support heavy Federal regulation but an approach akin to how highway funds are tied to speed-limit changes, for example. What should the Federal Government tie funds to in the addiction space? What laws should all States

have on the books? And what, if any, laws should the Federal Government lead on to ensure national uniformity and protection for individuals in recovery?

Mr. MENDELL. Sure. Before I answer that, let me just add, there is one Federal law that I think is very important, which many members of Congress are working on right now, which is to require, as part of their DEA license, all doctors in the field, and psychiatrists, as part of their DEA license for prescribing controlled substances, to tie it to education.

And if that is done, there will be a huge improvement in the system. Because doctors right now can prescribe Oxycontin, Vicodin, Percocet, all opioids, without having any training. And to have as part of their license to be able to do so, to be trained in basic prevention and treatment of addiction, would be a huge lift to this country. So that is number one what the Federal Government can do.

Then the answer to your question as far as what leverage the government can do, for your example with the 55 mile per hour speed limit, number one, conforming. State medical societies conforming to the CDC prescribing guidelines would be a huge lift. Requiring States to follow a quality measurement system like ours—ours is the only one out there right now, but there could be others, not specific to us.

Tying it to State funding that is coming from the government only going to evidence-based treatment programs, or following evidence-based practices. Again, that relates to a quality measurement system so you can determine which treatment programs are following evidence-based practices.

Requiring medical schools in their States to have basic training on prevention and treatment of addiction. I mean there are three right there that would be significant improvements to the system.

And if I could add one more, Federal legislation to eliminate DATA 2000, which requires any doctor in this country who wants to prescribe buprenorphine to go through a significant process with the DEA: licensing, hours of training, oversight by the DEA.

Doctors can prescribe Oxycontin without any additional training. Why do they have to go through this whole process to prescribe buprenorphine? The result of that is less than 5 percent of the doctors in this country can prescribe buprenorphine. Less than 50 percent of the counties in the United States have even one doctor who can prescribe buprenorphine.

There is legislation in Congress right now to eliminate DATA 2000. I would highly recommend that.

Senator MENENDEZ. Thank you, very much.

The CHAIRMAN. Thank you, Senator Menendez.

Senator Young?

Senator YOUNG. Dr. Adams and other witnesses, welcome.

Dr. Adams, we are really proud of you in the State of Indiana, and we think you are doing the country proud in your current capacity. I was really glad to see you highlight the important work of Belden Industries in Richmond, IN in your testimony. They are really making a difference as well.

Dr. Adams, Dr. Todd Graham, a South Bend physician with over 3 decades of service, was senselessly killed on July 26, 2017, for re-

fusing to prescribe an opioid to a patient. Tragic. And in his memory, I worked with then-Senator Donnelly to pass a provision in the SUPPORT Act that aims to reduce the over-prescribing of opioids by examining ways to expand the use of non-opioid alternatives within the Medicare program.

How is HHS working on increasing the utilization of these non-opioid pain management approaches?

Dr. ADAMS. Well, I have to tell you, this is a major point of emphasis for us. It is part of our five-point strategy of better research on pain and addiction, and it cannot happen fast enough.

What folks do not realize is back 20, 25 years ago, when I was in medical school and they told me pain was a vital sign, it came from a good place. We did and still do have an epidemic of untreated and under-treated pain in this country, and we threw opioids at the problem, foolishly. Now we are pulling them back. We got a significant decrease in opioid prescribing. But what I say to folks is that if we are not also measuring what we are substituting in their place to treat pain, and then folks are going to continue to self-medicate, they are going to continue to be angry when they do not get their pain treated, and we are going to continue to chase our tails and play whack-a-mole.

So the NIH HEAL initiative awarded $945 million in the form of grants, contracts, and collaborative agreements across 41 States to increase research and practices in terms of pain and addiction.

We have also gone around the country and lifted up these different payment mechanisms. CMS has done a lot to make sure we are paying for the right things. And I have actually worked with businesses, because we put a lot on CMS and we have to remember that the other gorilla in the room is the employer-based insurers. We need to make sure they are paying for alternatives and not being the first drug dealer. Many of them will pay for 60 Vicodin but will not pay for one of those alternatives for their covered lives.

Senator YOUNG. Well, thank you. I think that is really important. And there is a lot of emphasis, appropriately so, on increasing access to treatment.

We also need—and I know you agree with this—to make sure that people are in treatment services that are actually working. And this is something I placed great emphasis on during the HELP Committee hearings pertaining to the opioid crisis last Congress.

In your testimony, Dr. Adams, you say we have amassed a mass of evidence on effective prevention, early intervention treatment, and recovery strategies. Can you elaborate on the evidence you are referring to, especially in terms of treatment? Because, as I travel around the great State of Indiana and talk to different service providers, doctors, and others, I have to say there is heterogeneity. There are oftentimes varying perspectives on what works and what does not work.

Dr. ADAMS. You mentioned a couple of things there, and I will work backwards. I highlighted Greyston Bakery and Belden because we need to make sure that, when someone is done with treatment, they can be reintegrated back into society. Stigma is killing more people than overdoses, and it causes people to relapse when they cannot find a job, when they cannot be integrated into society.

So work is a very important part of this, both training and then taking a look at the scarlet letter we attach to people when they come out of a treatment center that prevents them from getting a job.

As far as substance use disorder treatment centers, you are right. There is way too much heterogeneity. And I would actually turn it over to Mr. Mendell to highlight some of the key aspects of what we should look for in a treatment center.

Mr. MENDELL. Absolutely. In a treatment center, we have identified seven principles that every treatment program should have.

Number one, a full and complete assessment not just of addiction issues, but also mental health issues and any physical issues. It needs to be complete with all three, with an evidence-based instrument that is proven to be reliable and valid, delivered by someone who has the credentials to ask the questions in the right way and understand it.

Number two, once you have that assessment, to be continually reassessed and your care adjusted via checking pain and going to the hospital. They will not tell me, based on the first 15 minutes of questions, here is what your treatment is going to look like for the next 28 days. They will tell me what my treatment is going to look like for the next 2 days, or for 1 day, and then they will test me again and readjust it all along the way. Many treatment programs do not do that. So continual reassessment and care adjustment.

Number three, evidence-to-evidence-based medications, not just for opioids but also for alcohol. There are evidence-based medications.

Number four, access to behavioral therapies that are evidence-based. There are only seven that were in the Surgeon General's report, both originally in 2016 and highlighted in the Spotlight, that have randomly controlled trials, are tested and proven to work. They have to have those. I can go on and on, but it is all on our website. But they exist, and they are easily measured.

Senator YOUNG. That is encouraging. And I would also note, it takes 17 years on average for evidence to actually reach the field. That is going to be unacceptable. So I would welcome future dialogue about things we might be able to do at the Federal level to compress that time frame, sir.

Dr. ADAMS. I highlight again, use your bully pulpit to share the Surgeon General's "Spotlight on Opioids," which lists the steps, the criteria to look for in evaluating the treatment center, that we worked with Shatterproof to help develop, but we need you all to help share that.

The CHAIRMAN. Senator Cassidy will be the last one. And will you close the meeting, Senator Cassidy, because I have to go to a meeting in my office? And so I thank all the panel, as chairman of this committee, for this very fruitful meeting.

Senator Cassidy?

Senator CASSIDY. Thank you. And at the outset, the chair will grant himself as much time as is needed. [Laughter.]

Thank you for being here.

First, let me highlight something, Dr. Adams, that HHS has done. You all had a task force on pain management which was

really good, because your statement earlier said that there is still untreated pain, and yet we have people who are dying from addiction. That is the tension. And as you know, Dr. Vanila Singh headed this up. But they differentiated between the patient with chronic pain on stable dose for many years, never escalating, working in society, versus a person who is breaking into a car to steal a purse to buy drugs.

And so there is the distinction we have to make as a physician. Let us not turn our backs, if you will, on the person who has that stable dose who is contributing to society, which includes people in this room, and differentiate that person from those.

Secondly, to my two GAO folks in the middle, you all have been kind of ignored, but I have been thinking about you. I hear that private insurance companies are very capable of looking at pain management, looking longitudinally at the outcomes—okay, who is released and then immediately goes back into a situation requiring more care for addiction versus those who have a sustained response?

And yet, we continue to hear that Medicaid does a poor job of that. Now, it seems like this would be something that could be done with a supercomputer in terms of, if you look at diagnostic codes, okay, if somebody has a billing for admission to a pain management center, and then they had a readmission for something which plausibly is related to drug overdose within a period of time, you compare everybody against everybody and you sort out who is doing a good job, who could perhaps employ science-based methods and improve their work, and who should just be kicked out.

Now what is the obstacle to doing so? Either of you.

Mr. CANTRELL. I will start. From OIG's perspective, we do a lot of analysis similar to what you just described in the Medicare space. We have great access to Medicare claims data.

But on the Medicaid side, we do not have that same level of——

Senator CASSIDY. So let me ask. So we do have the Transform Medicaid Statistical Information System, or TMSIS. Is TMSIS not ready for prime time?

Mr. CANTRELL. Not quite ready for prime time. Improving, but not quite ready for prime time.

Senator CASSIDY. But it is rapidly improving, which makes me think that some States are ahead of the curve, and some States are perhaps still coming on. I think I know that 48 are currently participating, obviously two not. So can we take those as proof of concept that are already submitting adequate data and then create a system which scales as other States come on board?

Mr. CANTRELL. That is something we could explore.

Senator CASSIDY. Well, why not something we do?

Mr. CANTRELL. Well, sir, I work for the Investigations Office, so I do not want to commit our auditors and evaluators yet, but it is something we are very interested in. I will take it back, and we can follow up with you.

Senator CASSIDY. Okay. Ma'am?

Dr. DENIGAN-MACAULEY. So, similarly, the work that we have done that I am familiar with would be related to Medicare, because the data is there.

Senator CASSIDY. By the way, can I insert one thing? I have actually spoken to people who work for clearing houses. And so, when somebody changes a Medicaid plan, they have to do data. And these clearing houses are actually better than TMSIS because they have it all. And it has to be with a unique identifier because it is transmitting, you know, Bill Cassidy's claims data from plan A to plan B.

And so these folks actually have it. I would just point that out as a point of information.

Dr. DENIGAN-MACAULEY. So as GAO, we actually work for you, and we would welcome a conversation to have a discussion about what work we can do in this area.

Senator CASSIDY. Let me ask it one more time, because GAO always does a wonderful job. But roughly in the time it takes you to complete a study, an elephant is born. So it takes a little while.

We actually need something in real time.

So, Dr. Adams, is it possible for HHS to stand up something in real time to do this analysis, maybe getting a system from one of these two folks, but that which you can employ so that we do not have to wait for a year and a half for an excellent study when, by that time, the situation on the ground perhaps has changed?

Dr. ADAMS. Well, that is definitely something I will take back. And you know, sir, that I will follow up with you, and I appreciate your leadership as one of the few physicians in Congress, and I think you bring up a very important question and issue.

Senator CASSIDY. Let me ask you one more thing. I have done a lot of work in jails. You mentioned your brother, and thank you for your openness about that. And I think the statistic I read is that 15 percent of males entering a jail have a mental health issue, 30 percent of females. If you add addiction to that, you are going to be even higher.

Current law is that if you are jailed, even before you were adjudicated, you lose your VA and Medicaid benefits. Okay, so I have been arrested but I am not—you know, sometimes you spend 6 months in jail before you go to court, and I am mentally ill, but I have lost my benefits even though subsequently I am declared to be not guilty, right?

This is a fairly common scenario. I am not making things up. There is a score associated with this, but as a physician I know that, if the formulary in the jail does not include the psychotropics which have stabilized me on Medicaid out in the free world, my care becomes disrupted and my condition may decline.

So I am begging the question, but can you give your thoughts? And maybe I can kick it over to you, sir, as to, whatever the score, the wisdom of allowing Medicaid and VA benefits to continue with someone who is incarcerated in a jail at least prior to the point of being declared guilty or not guilty?

Dr. ADAMS. So you bring up two important points.

Number one, jails and prisons have become our de facto mental health and substance use disorder providers in this country, and we need to flip that script if we are going to dig our way out of this.

And number two, when I saw this first-hand in Scott County, we actually had to work very closely with the jails to solve our HIV

outbreak that was related to prescription opioid misuse—because we know that so many folks who would cycle on, cycle off, cycle on, cycle off, is a significant problem.

Senator CASSIDY. So what you are telling me is that they would be admitted for HIV, and their regime would be disrupted so they develop resistance because they are getting off the one that controlled it and whatever strain was there, et cetera, et cetera, right?

Dr. ADAMS. It is certainly not optimal care, sir. And we need to look at how we can transition that system. But I will also say very plainly and frankly to you, sir, that I learned in Indiana that we did not have a lot of flexibility at the State level. Some of that is because of the law as written currently.

And so we need to take a look at that. We need to take care of the person and the patient, because it has implications beyond that individual and on society.

Senator CASSIDY. Well, I am glad that Senator Brown is here from Ohio, because I am going to need a bipartisan colleague. I think the score is $10 billion over 10 years to allow those Medicaid benefits to continue when someone is, as I have described, put in jail but before they are adjudicated.

Sir?

Mr. MENDELL. Thank you. I would like to add something. Throughout the last hour we have talked about different components of the opioid epidemic and solutions. And as we have talked about each, we have talked about how to remedy each of these individually. But I think it would be really helpful if we could go back to—Surgeon General Adams has mentioned three times in the last hour something else that I do not think has gotten the air time here, which is "stigma," which the Surgeon General has called the biggest killer out there.

He has not talked about any of the specific issues being the biggest killer; it is stigma. And why has he said that? He said that because stigma reaches everything we have been talking about for the last hour.

If there are policies in jail where people lose their insurance, why is that? That is because most people in America think that it is bad people doing bad things who cannot make good decisions—when science shows that is not the case.

Why is our payment policy not equal to other physical diseases? Because we have grown up in a health-care industry that believes it is their fault, that we should not pay for treatment.

Twenty percent of doctors in this country—excuse me, in the State of Massachusetts in a recent study that we did, which I suspect is relevant to the rest of the country—do not want people who are addicted in their waiting rooms. It might affect their practice.

Eighty percent of Americans in a recent poll—80 percent of Americans in a recent poll—said, "I am uncomfortable associating with someone addicted to prescription opioids as my friend, my coworker, or my neighbor."

So let us say that we get through all the hurdles we have been talking about in the last hour, and someone gets to treatment, even though 20 percent of Americans have reported one of the key reasons they do not go to treatment is they do not want anybody to

know. But let us say they get past that hurdle and their parents force them in. They get to treatment.

And then they find a provider, even though there are very few providers that treat it today for the reasons we have been talking about. And then they get to a provider who delivers quality care, through all the hurdles we have heard about today, and they are successfully treated.

But then they enter a society where 80 percent of Americans do not want you working next to them. They do not want you living in their neighborhood. They do not want you to be their friend, do not want you marrying their daughter, or dating their daughter.

I am sure my son did not see those statistics—this is not just opioids—nor did the 20 million Americans who were addicted to drugs or alcohol see that survey, but they feel it. They feel it every day.

Senator CASSIDY. So I thank you and Dr. Adams for being so honest with your experience, because that helps fight that stigma.

Senator Brown?

Senator BROWN. Thank you, Senator Cassidy. Thank you all for being here. And, Mr. Mendell, thank you for coming to my office several months ago. I know there is a lot of pain on this panel and among a lot of us who have had deaths in our families that we think should not have happened, or incarcerations, or just difficult times.

But thank you for making it a mission of your lives to step up and help others so they do not have to experience the pain that some of you, and many of us in this room, have had.

I want to start, Dr. Denigan-Macauley, with a couple of questions for you first. In the course of GAO's work on this report, how many instances—I will ask a couple of questions together—how many instances of substance abuse disorder treatment recovery-related Medicare/Medicaid fraud did you investigate across these five States? And of that total, what percent involved a case where a patient was the perpetrator of that fraud?

Dr. DENIGAN-MACAULEY. Thank you for the question. So we are a little different than the IG. We did not actually do the investigation of any cases. That would be a better question, perhaps, for Mr. Cantrell.

However, we did talk with a sample selection of five States, and we found that all five States had received reports of potential fraud. We spoke with various actors involved, including the Medicaid Fraud Control Units. To our knowledge—and again we did not investigate cases—for example, in Florida, individuals were lured to recovery homes and then brokered to substance use disorder treatment providers.

Senator BROWN. Mr. Cantrell, I want to ask you—and you can respond to that too—based on your work, is it your opinion that individuals with a substance use disorder diagnosis seeking treatment are generally the culprits in these cases of fraud? Or are they more likely the victims?

Mr. CANTRELL. In the cases we see, they are the victims. They are not——

Senator BROWN. Overwhelmingly?

Mr. CANTRELL. Overwhelmingly. Certainly in our fraud schemes, we have some participating patients who are often—you know, maybe they are a patient but they are also a patient broker, where they are trying to solicit other individuals to come into a fraud scheme. But generally speaking, they are the victims of these crimes.

Senator BROWN. Do you both, the two of you, believe that States are doing a good job of addressing fraud, when you say they have in their hands the tools and authorities necessary to police this kind of fraudulent behavior committed much less often by the victim than the perpetrator?

Mr. CANTRELL. Right. I think, you know, certainly on the healthcare fraud space where we have the Medicaid Fraud Control Units, they are very active in this space. Our office is very active.

But where I think there has been maybe a need for additional oversight is not in the law enforcement space but in the oversight of these treatment facilities and quality standards, as we discussed here today, to ensure that there are quality treatment centers that are receiving Federal funding and are delivering the product and the treatment that we all expect.

Senator BROWN. Did you want to add, Dr. Denigan-Macauley?

Dr. DENIGAN-MACAULEY. And clearly we also found that, in our States, that Florida, Massachusetts, and Utah had all started certification or licensure programs. And Texas and Ohio, while they did not have such programs, they were providing training and other services to the operators of the homes. They were concerned and wanted to take steps.

Senator BROWN. Thank you. And this question—I will start with Dr. Adams, but each of you answer, if you would. And I preface it by I think every one of us on this committee in both parties thinks we just simply are not doing enough with prevention education, upscaling treatment, and all that. And I applaud Dr. Cassidy for his interest—and I know Senator Markey and others—on the pretrial incarcerated, to keep them on Medicaid. It is just upside down thinking that you take away their Medicaid when they need it most at that point.

We are clearly not doing enough to provide the kind of treatment options to everyone who needs them. But as we all know, the overall number of non-elderly adults with a substance use disorder who receive treatment is low; we know that those with Medicaid are significantly more likely to receive treatment than those with private coverage.

For instance, thousands of Ohioans are receiving addiction treatment right now because of Medicaid. I was at a substance abuse clinic in Cincinnati, and a man put his hand on his adult daughter's arm and sort of gently said, "My daughter would not be alive if it were not for Medicaid."

We know those stories. So my question for each of you is—and you can answer as close as you can to a "yes" or "no"—are we putting additional burdens on beneficiaries that make it harder for them to access and maintain coverage that could compromise efforts to address the addiction treatment and limit access to substance use disorder? Are those additional burdens helpful, or are they not?

Dr. ADAMS. Well, sir, are you talking about Medicaid?

Senator BROWN. Yes.

Dr. ADAMS. Okay. Well, I would say that we want to make Medicaid as effective and as easy to access as we possibly can, and you frame it as a burden. I do not know which particular provisions you are referring to, but I do believe that we should make Medicaid more available. And we have tried to give States the flexibility through a record number of 1115 waivers to craft their Medicaid programs in a way that works for their citizens and their constituents.

Senator BROWN. Dr. Denigan-Macauley?

Dr. DENIGAN-MACAULEY. So we currently have work looking at beneficiaries of Medicaid and their access to medication-assisted treatment, for example.

Senator BROWN. Mr. Cantrell?

Mr. CANTRELL. We have looked into Medicaid eligibility, but I do not have—I am not the expert in that, so we would have to get back to you on what that work entailed.

Mr. MENDELL. I would completely agree with the comments earlier, of the Surgeon General specifically, that any barriers for those who do not have insurance to get Medicaid, absolutely, create a lot more loss of life and cost to our system—so ER rooms and prisons, et cetera, et cetera. We need to keep as few barriers as possible so more people can be on Medicaid who need it, who are qualified for Medicaid, without the barriers. Absolutely, 100 percent.

Senator BROWN. Thank you. I appreciate the responses of all four of you. I would just close, Senator Cassidy, with this: that the imposition of work requirements in State Medicaid programs will have a chilling effect on access to treatment. This hearing underscores the absolute ludicrousness, if that is a word, and the hard-heartedness of far too many people in this body and the Trump administration who are trying to repeal the Affordable Care Act. They could not do it here. They tried very hard. They could not do it here.

They want to do it through the courts. And it is hard-hearted, it is stupid, and it will mean a lot more people die with this assault on the Affordable Care Act. In my State, 900,000 people have insurance who did not have it before the Affordable Care Act. We know what it means to young people on their parents' plan. We know what it means for the expansion.

We had a Republican Governor in Ohio who showed more courage than most of his party members around the country and expanded Medicaid and saved thousands of lives. And it is just an absolutely cruel and stupid policy to think repealing the Affordable Care Act can possibly be good for our country.

So, thank you.

Dr. ADAMS. Senator Cassidy, can I make one quick comment? I would just very quickly say that I ran the State Department of Health in Indiana when we expanded coverage to several hundred thousand citizens.

As Surgeon General, I want everyone to hear me say that access to quality, affordable health care is critically important. This administration believes that we should give States the flexibility and

the opportunity to do it the way that works best for them, as has occurred in Indiana.

Again, the record number of 1115 waivers shows a commitment to that flexibility, in giving States that flexibility. And in my opening statement, I talked about both Belden Industries and about Greyston Bakery in Indiana and in New York. And I think it is important that when we talk about work, we understand that one of the biggest predictors of whether someone is going to be successful in long-term recovery is whether or not they can get back to work. And so I will be the first to admit that the idea of work requirements is a hot-button political topic, but I do not want us to lose the strong data that says that we need to think about ways that we can help people reintegrate back into society and get a job.

And what I am focused on as Surgeon General is how can we lower the barriers to people getting back to work and help to bring people together so that folks can truly recover?

And thank you so much for the opportunity to testify today. This is a critically important period. And I also want to give you a shout-out, Senator Brown, for the work you all are doing in Ohio. I know you know Sam Quinones. You all have been able to drive down your overdose rates there in that State by over 10 percent. And it is because of the partnerships you brought——

Senator BROWN. Dr. Adams, it is in large part because we expanded Medicaid, and the President of the United States wants to take it away. So I appreciate who appointed you. I appreciate—I do not know your political philosophy, it does not matter—I appreciate your comments on work requirements. But the fact is, the President of the United States wants to wipe off the books the Affordable Care Act with no replacement on Medicaid. And the fact that we have driven down, not very far yet, but driven down the death rate in Ohio and the addiction rate in Ohio is because we have that very, very, very important public health tool.

Senator CASSIDY. Well, with that, that will be the final rule. The chair will thank you all for your testimony. We leave the record open for 2 weeks for submissions of questions for the record. The hearing is now adjourned.

[Whereupon, at 10:45 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF HON. JEROME M. ADAMS, M.D., MPH, SURGEON GENERAL, OFFICE OF THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Thank you, Chairman Grassley, Ranking Member Wyden, and distinguished members of the committee. As the U.S. Surgeon General, it is an honor and privilege to be before you today and have the opportunity to discuss the opioid crisis, the Department of Health and Human Services' (HHS or Department) five-point strategy [1] to address this crisis, and my office's contributions to combating the epidemic. From the start of his administration, President Trump has made addressing the opioid crisis a top priority. The Department and the Office of the Surgeon General share the President's commitment.

On October 26, 2017, at the request of President Trump and consistent with the requirements of the Public Health Service Act, the Acting Secretary of HHS declared a nationwide public health emergency regarding the opioid crisis, and on March 19, 2018 in New Hampshire, the President announced his "Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand." The Department has made addressing the crisis a top clinical priority and is committed to using our full expertise and resources to combat the epidemic. The SUPPORT Act, Pub. L. 115–271 (October 24, 2018) and the Fiscal Year 2019 Consolidated Appropriation Act, which provide HHS new funding to address the opioid epidemic, will allow HHS agencies to continue to invest resources in expanding opportunities for evidence-based prevention, treatment and recovery support services, surveillance and data collection, and research on pain, new non-addictive pain medications, and to enhance our understanding of addiction and overdose.

Over the past 15 years, communities across our Nation have been devastated by increasing prescription and illicit opioid misuse, addiction, and overdose. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health, in 2018, approximately 10.3 million Americans misused opioids; of that population, 9.9 million people misused prescription pain relievers, 808,000 people used heroin, and 2 million people had an opioid use disorder (OUD).[1] While the number of individuals who misused opioids is down 3.7 percent from 2015, almost 400,000 Americans died of an opioid overdose over the past 20 years.[2] Most alarming is the rapid increase in overdose deaths involving illicitly made fentanyl and other highly potent synthetic opioids. According to provisional drug overdose death counts from the Centers for Disease Control and Prevention (CDC), predicted overdose deaths due to synthetic opioids rose approximately

---

[1] Substance Abuse and Mental Health Services Administration. (2019). Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19–5068, NSDUH Series H 54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from *https://www.samhsa.gov/data/*.

[2] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999–2017 on CDC WONDER Online Database, released December, 2018. Data are from the Multiple Cause of Death Files, 1999–2017, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.

10.4 percent between March 2018 and March 2019.[3] OUD and opioid-related overdose and death remain major issues that require a broader understanding of intersecting medical and public health factors.

Between 1999 and 2017, more than 399,000 people have died of overdose involving any opioid, including prescription and illicit opioids, such as heroin and illegally trafficked fentanyl. Overdoses involving opioids killed more than 47,000 people in 2017.[4]

Overall, opioid overdoses appear to plateau when comparing 2017 and 2018 data, which is notable given how aggressively the increases in all prior years over the past decade had been and suggests some success in reducing deaths from synthetic opioids and methadone; the preceding paragraph appropriately calls out illicit fentanyl, given deaths continue to accelerate for this category.

HHS'S FIVE-POINT STRATEGY TO COMBAT THE OPIOID CRISIS

In April 2017, HHS outlined its five-point Opioid Strategy, which provides the overarching framework to leverage the expertise and resources of HHS agencies in a strategic and coordinated manner. The comprehensive, evidence-based Opioid Strategy aims to:

- Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction and to help individuals to achieve long-term recovery;
- Target the availability and distribution of overdose-reversing medications to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations;
- Strengthen public health data collection and reporting to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves;
- Support cutting-edge research that advances our understanding of pain and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms; and
- Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

To date, the Department has taken significant steps to advance the goals of our Opioid Strategy. This statement addresses my personal commitment to address the opioid epidemic, and the unique role that the Office of the Surgeon General serves in combating this crisis. In order to provide a more comprehensive overview of the Department's coordinated strategy, it also highlights efforts within the Centers for Medicare and Medicaid Services (CMS) and across HHS.

MY WORK IS PERSONAL

In the case of substance use disorders (SUDs) and OUD, my office's work is quite personal as my family and I are among the millions of Americans affected by it. My younger brother, Philip, has struggled with this disease, which started with untreated depression and led to opioid misuse. Like many with co-occurring mental health and SUDs, my brother has cycled in and out of incarceration. Philip is currently serving a 10-year prison sentence for crimes committed to support his addiction. I share his story to illustrate that addiction can happen to anyone—even the brother of the U.S. Surgeon General.

Just as the opioid crisis has touched my life, it has also touched the lives of most Americans. This epidemic is blind to color, geography, or class and has affected every corner of our country. Quite simply, this crisis affects all of us.

---

[3] Ahmad FB, Escobedo LA, Rossen LM, Spencer MR, Warner M, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2019. Designed by LM Rossen, A Lipphardt, FB Ahmad, JM Keralis, and Y Chong: National Center for Health Statistics. *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

[4] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999–2017 on CDC WONDER Online Database, released December, 2018. Data are from the Multiple Cause of Death Files, 1999–2017, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.

TACKLING OPIOID USE DISORDER AND OTHER SUBSTANCE USE DISORDERS

While the opioid epidemic continues to be our most pressing public health crisis, there is evidence that the administration's commitment to the epidemic and HHS's five-point response strategy have had a substantial effect.

1. First, we have experienced a **nationwide decrease in opioid prescribing and use.** From January 2017 to June 2019, we've seen a **31-percent reduction in the total morphine milligram equivalents dispensed monthly** by retail and mail order pharmacies.[5] We've seen a **52.4-percent decrease in the number of first-time heroin users** from 2016 to 2017.[6] And, between 2017 and 2018, approximately **1 million fewer Americans reported misusing opioids in the preceding year.**[7]
2. There is also evidence of **fewer drug overdose deaths.** As of March 2019, the 12-month rolling count of predicted overdose deaths **remained below 70,000** for fourth month in a row. This represents a **decrease of approximately 2 percent** from the corresponding 12-month period. During that period, **28 States reported a reduction in drug overdose deaths** and many experienced substantially larger decreases than the national average. For example, between February 2018 and February 2019, **there was a 14.7-percent reduction in Iowa, a 12.4-percent reduction in Ohio, an 11.5-percent reduction in Pennsylvania, an 8.2-percent reduction in Kentucky, and a 9.7-percent reduction in New Hampshire.**[8]
3. Furthermore, we have seen progress in making both **medication-assisted treatment (MAT) and overdose-reversing medications more available.** From January 2017 to June 2019, the number of **patients receiving buprenorphine and naltrexone monthly increased by 28 percent and 55 percent, respectively.**[9] Availability of naloxone, an opioid antagonist that is used to temporarily reverse the effects of an opioid overdose, has increased dramatically, as evidenced by a 378 percent increase in the number of prescriptions dispensed monthly by **retail and mail order pharmacies since 2017.**
4. **Consensus has now been achieved reached on how to best address pain.** In May 2019, the **Pain Management Best Practices Inter-Agency Task Force released its final report,** which provides a best practices roadmap for managing acute and chronic pain.

Of course, these indicators are only a fraction of the available statistics that illustrate our progress.

OFFICE OF THE SURGEON GENERAL'S RESPONSE TO THE CRISIS

The Office of the Surgeon General has been fully engaged in the Department's response and has made important contributions to the achievements I have described. In 2018 alone, the office released the "Spotlight on Opioids,"[2] a digital postcard[3] showing the five actions everyone can take to prevent opioid misuse, and a Surgeon General's Advisory on Naloxone and Opioid Overdose.[4] These publications convey effective strategies to prevent and treat OUD and support the successful recovery of

---

[5] IQVIA National Prescription Audit. Retrieved October 2018 and August 2019. Note: These data are for the retail and mail service channels only and do not include the long-term care channel.

[6] Substance Abuse and Mental Health Services Administration. (2018). Key substance use and mental health indicators in the United States: Results from the 2017 National Survey on Drug Use and Health (HHS Publication No. SMA 18–5068, NSDUH Series H–53). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from *https://www.samhsa.gov/data/*.

[7] Substance Abuse and Mental Health Services Administration. (2019). Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19–5068, NSDUH Series H–54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from *https://www.samhsa.gov/data/*.

[8] Ahmad FB, Escobedo LA, Rossen LM, Spencer MR, Warner M, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2019.

Designed by LM Rossen, A Lipphardt, FB Ahmad, JM Keralis, and Y Chong: National Center for Health Statistics. *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

[9] IQVIA National Prescription Audit. Retrieved October 2018 and August 2019. Note: These data are for the retail and mail service channels only and do not include the long-term care channel.

those affected. I want to leave you with five key messages based on this scientific information:

1. First, **prevention, screening, and early intervention are critical.** Evidence-based prevention, screening, and intervention programs are effective and need to be initiated early in life. Traumatic experiences in childhood, sometimes referred to as adverse childhood experiences (ACEs), have been repeatedly linked to increased risk of substance misuse and SUD. So interventions must begin during childhood and continue throughout the lifespan to prevent or delay the initiation of substance use and stop the progression to SUD. To support these early interventions, the Administration for Children and Families (ACF) is working on implementation of the Family First Prevention Services Act, which provides Federal funding for services to help families remain safely together, preventing the need for foster care. As Surgeon General, I am committed to preventing opioid addiction before it starts by promoting: (1) safe prescribing practices according to the CDC Guideline for Prescribing Opioids for Chronic Pain, (2) the benefits of opioid alternatives, and (3) safe storage and disposal.

2. Second, **treatment is effective but must be integrated into mainstream health care.** Addiction is a chronic disease of the brain, which must be treated with skill, compassion, and urgency. And as with other chronic diseases, we have evidence-based treatment that works, and we know that recovery is possible. Medications can successfully treat the chronic disease of addiction. MAT, the combination of FDA-approved medications for the treatment of OUD with psychosocial therapies and community-based recovery supports, is the gold standard for treating opioid addiction; yet, in the course of a year, only one in four people with OUD receives any treatment at all. For this reason, care models that integrate SUD services using medications and MAT into primary care hold tremendous promise and have the potential to greatly expand access to effective, evidence based OUD care.

3. Third, **knowing how to use naloxone and keeping it within reach can save a life and serve as a bridge to treatment and recovery.** As described in my advisory, increasing the awareness, availability, and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths. Since the advisory was published, more than 2.7 million 2-unit doses of naloxone have been distributed to States and local communities.[10] As the Surgeon General, I am focused on putting naloxone in the hands of first responders and community members.

4. Fourth, there are **many pathways to recovery**—a term that is expansive and goes beyond the remission of symptoms to include a positive change in the whole person. Recovery support services include mutual aid groups, housing, childcare, recovery coaches, and community services that provide continuing emotional and practical support.

   I saw the benefits of these services, first-hand, when I visited Belden Industries in Richmond, IN. Belden has developed a unique pilot project—called Pathways to Employment—in response to community needs and the labor market. Specifically, in collaboration with its local health department and community colleges, the technology company offers potential employees who fail drug tests opportunities to participate in drug counseling. Participants who stay in the recovery program are assured jobs. Belden is connecting those suffering from drug addiction to care with the goal of helping them become employment-ready.

   Recovery support services are also vital to Greyston Bakery's workforce development strategy. The bakery, which is located in Yonkers, NY, began its Open Hiring model in 1982. Under this model, Greyston provides employment opportunities without judging applicants or asking questions—no resume, work history, or background check are required—while providing a range of social support services including case management, life-skill building, and workforce training. This approach creates jobs for people who have traditionally been marginalized and considered "unemployable"— people with past felony convictions, persons who are homeless or have disabilities, and people with addiction. The bakery's motto is, "We don't hire people to bake brownies; we bake brownies to hire people." At present, more than 60 percent of Greyston's bakers were formerly incarcerated.

[10] Data provided by Emergent BioSolutions.

I applaud these companies and others that are investing in their communities to improve health and create economic opportunities. While people will choose their own recovery pathway based on their cultural values, psychological and behavioral needs, and life circumstances, community-based recovery support services like those embraced by these innovative companies are instrumental in helping individuals resist relapse and rebuild their lives.

5. Fifth, when it comes to addiction, society is **moving from a primarily criminal justice-based model to a more balanced approach that better accounts for public health.** I believe that this shift cannot happen quickly enough. I'll return to my own family. Had my brother's addiction been treated like a disease rather than a moral failing, he might be significantly closer to recovery than he is today. The stigma associated with SUDs keeps many sufferers from speaking about their troubles and seeking help. Nowhere is stigma more prevalent than in the communities of color. The way we as a society view and address OUD and other SUDs must change; individual lives and the health of our Nation depend on it.

CMS ROLE IN ADDRESSING THE OPIOID CRISIS

As a payer, CMS plays an important part in HHS efforts by working to make sure clinicians are providing the right services to the right people at the right time. Medicare, Medicaid, and CHIP beneficiaries are CMS's top priority across all of its programs, and CMS works hard to protect their safety and put them in the driver's seat of their care. CMS is keenly focused on three areas—preventing and reducing OUD by supporting access to pain management using a safe and effective range of treatment options that rely less on prescription opioids, including non-pharmacological approaches; increasing access to evidence-based treatment for OUD; and leveraging data to target prevention and treatment efforts and to support fraud, waste, and abuse detection.

Preventing Overprescribing and Misuse of Opioids

CMS is taking a number of steps to identify and stop inappropriate prescribing to help prevent the development of new cases of OUD that originate from opioid prescriptions while balancing the need for continued access to prescription opioids to support appropriate, individualized pain management. To ensure that balance is maintained, CMS will provide quality improvement technical assistance to those communities hit hardest by the opioid epidemic, particularly small, rural communities' physician practices and hospitals.

- *Improved Opioid Safety Reviews in Medicare Part D.* Due to the structure of the Medicare Part D program, Medicare Advantage Organizations (MAOs) and Medicare Part D sponsors have a primary role in detecting and preventing potential misuse of opioids. CMS's job is to oversee Medicare Part D plans to ensure that they are in compliance with requirements that protect beneficiaries, ensure access to opioids when needed, and can help prevent and address opioid overutilization. Medicare Part D plans are expected to use multiple tools, including better formulary management, case management with beneficiaries' clinicians and pharmacists for coordinated care, and safety edits at the point of dispensing.

  Medicare Part D sponsors are required to have concurrent drug utilization review (DUR) systems in place to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point of sale (POS). Since 2013, CMS has incrementally adopted successful opioid policies in the Part D program to appropriately address opioid overutilization, while preventing interruption of medically necessary drug therapy. These policies incorporate prescriber involvement through pharmacist and payer efforts to give providers additional clinical information to better coordinate care.[11]

  CMS recently finalized a series of additional changes in 2019 to further the goal of preventing OUD. Part D sponsors are now expected to implement improved opioid safety edits at the POS that alert a pharmacist of possible overutilization.[12] In real time, the alerts can flag for a pharmacist that they

[11] CY 2020 Final Call Letter, p. 225.

[12] CMS, Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (April 2, 2018), avail-

Continued

should conduct additional review and/or consultation with the plan sponsor or prescriber to ensure that a prescription is appropriate.

Second, to reduce the potential for chronic opioid use or misuse, beginning in 2019, CMS expects all Part D sponsors to limit initial opioid prescription fills for the treatment of acute pain to no more than a seven days' supply.[13] This policy change is consistent with the CDC Guideline for Prescribing Opioids for Chronic Pain that States that opioids prescribed for acute pain in primary care settings and outside post-surgical pain should be limited to the minimal dose and amount necessary and, as a rule, three days or fewer unless otherwise clinically indicated.

Beginning in 2019, CMS also expects all sponsors to implement an opioid care coordination safety edit.[14] This new edit alerts pharmacists when a beneficiary's average daily opioid dose reaches high levels. When this occurs, plan sponsors are expected to direct pharmacists to consult with the prescriber to confirm their intent. If the pharmacy cannot fill the prescription as written, the pharmacist will give the beneficiary a notice explaining how the beneficiary or their prescriber can call or write to the Medicare drug plan to ask for a coverage decision, including an exception, about a drug they think should be covered. If their health condition requires, beneficiaries have the right to ask their plan for a fast decision or a decision even before they get the prescription filled at the pharmacy. The prescriber only needs to attest to the Medicare drug plan that the cumulative level or days' supply is the intended and medically necessary amount for their patient.

- *Non-Opioid Pain Relief Options in Medicaid.* Pursuant to section 1010 of the SUPPORT Act, CMS issued an Informational Bulletin in February of 2019 about Medicaid Strategies for Non-Opioid Pharmacologic and Non-Pharmacologic Chronic Pain Management. The Bulletin expands on earlier guidance issued by CMS by providing information to States seeking to promote non-opioid options for chronic pain management. In addition to meeting the requirements of the SUPPORT Act, this Bulletin supports the goal of reducing the use of opioids in pain management included in the President's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand and is consistent with the HHS Five-Point Strategy to Combat the Opioid Crisis.
- *Additional State Reporting.* Additionally, pursuant to section 1004 of the SUPPORT Act, CMS issued an Informational Bulletin in August 2019 that States will be required to report on their policies related to reducing opioid-related misuse and abuse in Medicaid. Implementation of these provisions includes requirements regarding opioid prescription claim reviews at the POS and retrospective reviews; the monitoring and management of antipsychotic medication in children; identification of processes to detect fraud and abuse; and mandatory DUR report updates; as well as requirements for Medicaid MCOs. In order to comply with these new requirements, States must submit a State Plan Amendment by December 31, 2019.
- *Drug Management Programs for Medicare and Medicaid.* For years, States have been establishing and augmenting effective "lock-in" programs that require Medicaid enrollees who are "at-risk" for opioid misuse or addiction to use only one pharmacy and/or get prescriptions from only one medical office. The Comprehensive Addiction and Recovery Act of 2016 (CARA), Pub. L. 114–198, provided CMS with the authority to allow Medicare Part D plans to implement similar programs. For both Medicaid programs and Medicare Part D plans, these programs provide additional tools to promote better coordination between providers and for beneficiaries who meet the guidelines for lock-in.

  Under current law, States are able to implement lock-in requirements for enrollees who have utilized Medicaid services at a frequency or amount that is not medically necessary, according to guidelines established by the State. These limitations may be imposed for "a reasonable period of time." Almost all Medicaid agencies have a Lock-In or Patient Review and Restriction Program in which the State identifies potential fraud or misuse of controlled drugs by a beneficiary.

---

able at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.*

[13] *Id.* at p. 237.

[14] *Id.* at p. 235–236.

In April 2018, as required by CARA, CMS finalized the framework under which Part D plan sponsors may adopt drug management programs (DMPs) beginning with plan year 2019.[15] DMPs allow Part D sponsors to limit certain beneficiaries to a specific opioid prescriber and/or dispensing pharmacy within their prescription drug benefit plan. The final rule incorporated input gathered from various stakeholders, including beneficiary advocates, clinicians, pharmacists, pharmacy benefit managers, and plan sponsors.[16] The rule also incorporated and codified many aspects of the prior retrospective DUR Policy and the Overutilization Monitoring System (OMS), which identifies and reports beneficiaries who are potentially at risk of misusing or abusing opioids to Part D plan sponsors. These beneficiaries meet OMS criteria established under the final rule, which take into account the beneficiary's use of multiple opioid prescribers and dispensing pharmacies and their level of opioid use. Part D sponsors also have some leeway to identify additional potential at-risk beneficiaries in their plans.

Under DMPs, after case management with the beneficiary's prescribers and written notice to the beneficiary, Part D plan sponsors may determine that a beneficiary is an at-risk beneficiary and limit the beneficiary's access to coverage of opioids and/or benzodiazepines. To ensure care coordination, and depending on the specific coverage limitation the sponsor puts in place, at-risk beneficiaries receive their opioid medications from a specific prescriber and/or pharmacy that the beneficiaries may generally select. At-risk beneficiaries may also be subject to individualized POS claim edits that limit their coverage of opioids. Sponsors report to CMS the outcome of their case management review for each case, including whether the sponsor implemented a coverage limitation or not. It is important to note that most OMS cases are managed without a sponsor implementing a coverage limitation, which CMS views as the more desirable result for providers, their patients and Part D plans. Also important is that beneficiaries, and their prescribers on their behalf, also have the right to appeal these decisions.

Furthermore, provisions in the SUPPORT Act of 2018 provided CMS with the authority to implement additional policies in Medicare Part D to address the opioid epidemic. Section 2004 of the SUPPORT Act requires all Part D sponsors to have a drug management program for plan years beginning on or after January 1, 2022, although CMS notes that the majority of sponsors have already adopted DMPs in 2019. In addition, section 2006 requires that Part D enrollees with a history of opioid-related overdose, as defined by the Secretary, be included as potential at-risk beneficiaries under Part D drug management programs beginning on or after January 1, 2021.

The Medicare Part D opioid policies have been designed to promote improved communication between the pharmacy, doctor, and Medicare drug plan, and give providers additional tools to safely manage their patients' opioid use. The Medicare Part D opioid safety edits and DMPs generally do not apply to patients with cancer, patients receiving hospice, palliative, or end-of-life care, or patients who live in a long-term care facility. They also should not impact patient access to medication-assisted treatment (MAT) for OUD, such as buprenorphine.

- *Tools for State Medicaid Agencies.* While the Federal Government establishes general guidelines for Medicaid, States design, implement and administer their own programs. CMS takes this partnership seriously and, because Medicaid is the single largest payer for behavioral health services, has been working under the current statutory framework to ensure that States have the tools they need and to share best practices to improve care for individuals with mental illnesses or SUD.

  To reduce opioid misuse while ensuring access to treatment for acute and chronic pain, Medicaid programs can utilize medical management techniques such as step therapy, quantity limits, and morphine milligram equivalent (MME) limitations. Additionally, to increase oversight of certain prescription opioids, States have the option of amending their Preferred Drug Lists and Non-Preferred Drug Lists to require prior authorization for certain opioids.

---

[15] CMS, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 Fed. Reg. 16440, 16440 (April 16, 2018).

[16] *Id.*

States have long been required to develop a DUR program aimed, in part, at reducing inappropriate prescribing of outpatient prescription drugs covered under the State's Medicaid Program. Medicaid DUR is a structured, ongoing program that interprets patterns of drug use in Medicaid programs and includes prospective drug review, retrospective drug use review, data assessment of drug use against predetermined standards, and ongoing educational outreach activities conducted by Medicaid State agencies, managed health care systems, pharmacy benefit managers (PBMs), academic institutions and/or other applicable stakeholders. The Medicaid DUR Program promotes patient safety through State-administered utilization management tools and systems that interface with the claims processing systems. Additionally, CMS requires any MCO that includes covered outpatient drugs to operate a DUR program that is as comprehensive as the States fee-for-service (FFS) program.

Ensuring Access to Evidence-Based Treatment

A critical part of tackling this epidemic is making sure that beneficiaries with OUD have access to effective treatment options. Through its networks of health quality experts and clinicians, CMS advocates sharing best practices for pain management and substance use disorders, including OUD.

Medicare Parts A and B cover substance use disorder services in multiple ways. Inpatient treatment in a hospital is covered if reasonable and necessary; treatment in a partial hospitalization program, such as an intensive outpatient psychiatric day treatment program, may also be covered when the services are furnished through hospital outpatient departments and Medicare-certified community mental health centers. Medicare currently pays for substance use disorder treatment services provided by physicians and other practitioners on a service-by-service basis under the Medicare Physician Fee Schedule (PFS), such as counseling services provided by a psychiatrist or other Medicare practitioners and an annual depression screening. Medicare Part B pays for medications used in physician offices or other outpatient settings that require a physician/practitioner to administer, including injections like extended-release formulations of naltrexone or buprenorphine or implants of drugs like buprenorphine used in medication-assisted treatment. CMS recently made changes to the Medicare PFS that help support the fight against the opioid epidemic, such as establishing separate coding and payment for the insertion and removal of buprenorphine implants, a key drug used in treatment for OUD, and improving payment for office-based behavioral health services. For 2020, CMS also proposed to create new coding and payment under the PFS for a bundled episode of care for management and counseling for OUD. The new proposed codes describe a monthly bundle of services for the treatment of OUD that includes overall management, care coordination, individual and group psychotherapy, and substance use counseling.

- *Medication-Assisted Treatment (MAT).* MAT is the use of FDA-approved medications, in combination with counseling and behavioral therapies, to treat SUDs, including OUD. MAT is a valuable intervention that has been proven to be the most effective treatment for OUD, particularly because it helps sustain long-term recovery and has been shown to reduce morbidity and mortality.[17]

  To increase access to MAT, CMS requires that Medicare Part D formularies include covered Medicare Part D drugs used for MAT. In addition, CMS issued guidance on best practices in Medicaid for covering MAT in a joint informational bulletin with SAMHSA, the CDC, and the National Institute on Drug Abuse. CMS also released an informational bulletin with SAMHSA on coverage of treatment services for youth with SUD and guidance on the coprescribing of opioids and benzodiazepines.

  While Medicaid programs vary greatly by State, all 50 States currently offer some form of MAT. Section 1006(b) of the SUPPORT Act requires State Medicaid programs to provide coverage for MAT for OUD beginning October 1, 2020, and ending September 30, 2025. In addition, section 5022 of the SUPPORT Act makes behavioral health coverage a mandatory benefit for children and pregnant women covered under the Children's Health Insurance Program (CHIP) and requires that child health and pregnancy related assistance "include coverage of mental health services (including behavioral health) nec-

[17] Sordo, L, Barrio, G, Bravo, MJ, Indave, BI, Degenhardt, L, Wiessing, L, . . . Pastor-Barriuso, R. (2017). Mortality risk during and after opioid substitution treatment: Systematic review and meta-analysis of cohort studies. *BMJ,* 357. *https://doi.org/10.1136/bmj.j1550.*

essary to prevent, diagnose, and treat a broad range of mental health symptoms and disorders, including substance use disorders."

Additionally, section 2005 of the SUPPORT Act established a new Medicare Part B benefit for OUD treatment services, including MAT utilizing methadone, which can only be furnished by opioid treatment programs. CMS proposed to implement this new benefit for 2020 with flexibility to deliver the counseling and therapy services furnished as part of OUD treatment services via two-way interactive audio-video communication technology as clinically appropriate and zero beneficiary copayment for a time limited duration.

- *Increasing the Use of Naloxone to Reverse Opioid Overdose.* CMS is promoting improved access to the opioid overdose reversal drug naloxone by requiring that it appear on all Medicare Part D formularies. CMS is also encouraging sponsors to include at least one naloxone product on a generic or Select Care tier beginning in 2020.[18] The percentage of Part D plans that included at least one naloxone product on a non-branded tier for each of the past three plan years are: 42.4 percent for Calendar Years (CYs) 2018 and 2019 and 99.4 percent for CY 2020. Of all naloxone products on formulary, the percentage of products included on non-branded tiers are: 27.5 percent for CY 2018; 28.4 percent for CY 2019 and 63.3 percent for CY 2020. CMS recognizes that it is very important for Medicare beneficiaries and those who care for them to understand that these options are available to them under Medicare, so CMS is also working to educate clinicians, health plans, pharmacy benefit managers, and other providers and suppliers on services covered by Medicare to treat beneficiaries with OUD. In a number of cases, this includes education on naloxone products.

  In addition, all Medicaid programs include forms of naloxone on their Medicaid Preferred Drug Lists. Many State Medicaid programs also have pharmacist protocols for dispensing naloxone through collaborative practice agreements, standing orders, or other predetermined guidelines. CMS has also issued guidance to States on improving access to naloxone.[19] States can offer training in overdose prevention and response for providers and members of the community, including family members and friends of opioid users.

- *SUD Treatment and Demonstrations in Medicaid.* Under section 1115 of the Social Security Act, the Secretary of HHS may approve experimental, pilot, or demonstration projects that, in the judgment of the Secretary, are likely to assist in promoting the objectives of certain programs under the Act, including Medicaid. In November 2017, CMS announced that it was using this authority to provide a streamlined process for States interested in increased access to treatment for individuals who are primarily receiving treatment or withdrawal management services for SUD. This opportunity allows coverage services to beneficiaries who are short-term residents in that meet the definition of an institution for mental diseases (IMD), provided that coverage is part of a State's comprehensive OUD/SUD strategy as long as the State is working to improve access to OUD and other SUD treatment in outpatient settings as well. In addition, States are expected to take certain steps to improve the quality of care for individuals with SUD, including OUD, particularly in residential treatment settings, including by requiring these settings to offer MAT as a treatment choice onsite or facilitating access offsite.

  This initiative offers a more flexible, streamlined approach to accelerate States' ability to respond to the national opioid crisis while enhancing States' monitoring and reporting of the impact of any changes implemented through these demonstrations. In addition to being budget neutral, demonstrations must include a rigorous evaluation based on goals and milestones established by CMS. Information on the progress and outcomes of these demonstrations and evaluations will be made public in a timely and readily accessible manner on *Medicaid.gov* so that other States can learn from these programs; this cycle of evaluation and reporting will be critical to informing our evolving response to the national opioid crisis. To date, CMS has approved these section 1115 demonstrations in more than in 25 States.

---

[18] CMS, Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (April 1, 2019), available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

[19] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf* and *https://www.medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf.*

The Medicaid Innovation Accelerator Program (IAP), a project of the Center for Medicare and Medicaid Innovation, provides technical assistance to Medicaid agencies across a variety of topics, including SUD, aimed at moving forward Medicaid delivery and payment reforms. IAP works with States on designing, planning, and implementing strategies that improve their SUD delivery systems through technical assistance in areas such as: creating data dashboards; identifying individuals with an SUD; understanding which options are available to expand coverage for effective SUD treatment; and designing payment mechanisms for SUD services that incentivize better outcomes.

Another tool States have to improve access to treatment through their Medicaid programs is the implementation of a health home benefit focused on improving treatment for beneficiaries with opioid use disorder. Health homes are an optional Medicaid benefit through which States can improve care coordination and care management for individuals with chronic conditions, including substance use disorders. States can receive 90-percent Federal matching funds for their expenditures on Medicaid health home services for the first 8 fiscal year quarters that the health home State plan amendment is in effect. Under the SUPPORT Act, States with a SUD-focused health home State plan amendment approved on or after October 1, 2018, may request that the Secretary extend the enhanced Federal match period beyond the first 8 fiscal year quarters, for the subsequent two fiscal year quarters, for a total of 10 fiscal year quarters from the effective date of the State plan amendment.

- *Improving Access to Coordinated Care for Vulnerable Populations.* CMS announced a funding opportunity for a 5-year model that is designed to address fragmentation in the care of pregnant and postpartum Medicaid beneficiaries with opioid use disorder. The primary goals of the Maternal Opioid Misuse (MOM) Model are to improve quality of care and reduce costs for pregnant and postpartum women with OUD and their infants; expand access, service-delivery capacity, and infrastructure; and create sustainable coverage and payment strategies that support ongoing coordination and integration of care. Up to $64.5 million will be provided to up to 12 State Medicaid agencies who will collaborate with local care-delivery partners, which could include health systems, hospital systems, or payers, such as a Medicaid managed care plans, to transform the care-delivery system for affected mothers and their infants. The MOM model will require awardees and their care-delivery partners to provide integrated physical and behavioral healthcare services, such as MAT, maternity care, relevant primary care services, and mental health services, as well as wraparound services like coordination, engagement and referrals to community and social supports. Primary care centers can be integrated into this care model in a number of ways including as an MAT prescribing site. States and care-delivery partners will have the flexibility to develop the care delivery structure that best fits their local context.

Leveraging Data to Enhance Prevention and Treatment Efforts

Data are a powerful tool and CMS is utilizing the vast amounts of data at our disposal to better understand and address the opioid crisis. CMS is working with its partners to ensure that they have the data and information they need to make changes and improvements to help address the crisis.

- *Utilizing Medicare Data to Address Overutilization.* Through the OMS referred to above, CMS identifies and reports potential at-risk beneficiaries to Part D sponsors that have DMPs, and sponsors report to CMS the outcome of their case management review for each case. Starting this year, beneficiaries are identified as potentially at-risk and reported to plans if, in the most recent 6 months, their daily dose of opioids exceeds 90 MME; and if they have received opioids from three or more opioid prescribers and three or more opioid dispensing pharmacies, or from five or more than five prescribers, regardless of the number of opioid dispensing pharmacies.

  These criteria are called the minimum OMS criteria. Part D sponsors also have the flexibility to apply supplemental OMS criteria to identify potential at-risk beneficiaries with any level of opioids and received opioids from seven or more opioid prescribers and/or opioid dispensing pharmacies.

  In the 2019 Final Call Letter, CMS finalized additional enhancements to the OMS including revised metrics to track high opioid overuse and to provide additional information to sponsors about beneficiaries who take opioids and "potentiator" drugs, such as benzodiazepines, (which when taken with an

opioid increase the risk of an adverse health event).[20] To help identify and prevent opioid users from taking duplicate or key "potentiator" drugs, in 2019 CMS also expects sponsors to implement additional safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.

CMS utilizes the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) to conduct data analysis that is shared with plan sponsors to help them identify outlier prescribers or pharmacies. For example, plans receive Quarterly Outlier Prescriber Schedule II Controlled Substances Reports, which provide a peer comparison of prescribers of Schedule II controlled substances. This report now provides a separate analysis of just Schedule II opioids. Plans also receive quarterly pharmacy risk assessment reports, which contain a list of pharmacies identified by CMS as high risk; plan sponsors can use this information to initiate new investigations, conduct audits, and potentially terminate pharmacies from their network, if appropriate. CMS has also sent letters to prescribers that include educational information and comparative prescribing data to, and held a webinar, for prescribers whose opioid prescribing patterns were different as compared with their peers on both a specialty and/or national level.

In May, CMS sent letters to providers of opioid-naive beneficiaries that received one or more selected procedures. Providers received the letters if 10 or more of their patients' average daily MME were in the 90th percentile or higher when compared to their peers, for a given procedure. CMS will monitor the prescribing patterns of those surgeons/prescribers who are in the subsequent 10 percentiles of prescribers as a comparison group. In addition, CMS intends to evaluate the prescribing of the two groups approximately 12 months after the issuance of the letters.

The SUPPORT Act includes further measures designed to address overprescribing and misuse of opioids. Section 6065 of the Act requires annual notification of outlier prescribers of opioids. Currently, CMS is deciding on the method for selecting outliers. CMS expects to mail the first set of letters in January 2020. Section 6063 of the Act requires the Secretary to establish a secure Internet website portal to enable the sharing of data and referrals of "substantiated or suspicious activities" related to fraud, waste, and abuse between plan sponsors, CMS and CMS's program integrity contractors. It also requires plan sponsors to submit information on the corrective actions taken against those identified as over-prescribers. This would include information on investigations and any credible evidence of suspicious activities in plan sponsors' possession as well as information on other actions taken by plan sponsors related to inappropriate prescribing of opioids.

To assist clinicians in assessing their own opioid-prescribing practices while continuing to ensure patients have access to effective acute and chronic pain treatment, CMS released two interactive online mapping tools that display the Medicare Part D opioid prescribing rate and the Medicaid opioid prescribing rate for 2017. The Medicare Part D Opioid Prescription Mapping Tool[21] allows users to quickly compare Part D opioid prescribing rates in urban and rural areas at the State, county and ZIP code levels. The Medicaid Mapping Tool[22] allows users to review Medicaid opioid prescribing rates at the State level and compare prescribing rates in fee-for-service and managed care. The mapping tools also offer spatial analyses to identify "hot spots" or clusters in order to better understand how this critical issue impacts communities nationwide.

CMS is working with the National Quality Forum, the HHS Secretary's consensus-based entity, to review quality measures and measure concepts related to opioids and opioid use disorders. NQF's technical expert panel will review quality measures in this area, summarize and prioritize gaps in measurement, provide for revision of existing measures, address the need for development of new measures, and make recommendations for measure inclusion

---

[20] CMS, Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, at p. 235 (April 2, 2018).

[21] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap_Medicare_PartD.html.*

[22] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap_Medicaid_State.html.*

in certain health-care quality-based programs. Measures of opioid use and disorder from State and Federal surveys vary considerably and are often drawn from questions asked in clinical or diagnostic settings, raising concerns regarding the accuracy and comparability of the information and resulting estimates. As part of an ongoing effort to develop a standardized battery of opioid questions, NCHS has conducted cognitive testing and evaluation of opioid measures for use on national population health surveys and surveillance systems to inform measurement strategies for use in different settings and populations.

In response to recommendations from the President's Commission on Combating Drug Addiction and the Opioid Crisis, and in compliance with the SUPPORT Act and to avoid any potential unintended consequences, CMS has updated the Hospital Consumer Assessment of Healthcare Providers and Systems patient experience of care survey by removing three pain communication questions, removing the quality measure based on these questions, and no longer publicly reporting on this measure on the Hospital Compare Internet website.

- *Modernizing Medicaid Data Collection.* CMS has been working with States to implement changes to the way in which administrative data are collected by moving from the Medicaid Statistical Information System (MSIS) to the Transformed-MSIS (T–MSIS). More robust, timely, and accurate data via T–MSIS will strengthen program monitoring, policy implementation, and oversight of Medicaid and CHIP programs. CMS had transitioned all States to T–MSIS as of 2018. Together with our partners in all 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, CMS has made tremendous progress in preparing T–MSIS data for program oversight, evaluation, research, and program integrity. CMS continues to work with States to improve the quality of their data and to stay current with T–MSIS data submissions.

  CMS is now using T–MSIS data for program integrity and other purposes and used T–MSIS data to prepare a Substance Use Disorder data book, as required by the SUPPORT Act. The data book will be published this fall and will present nationwide T–MSIS data for the first time. CMS has begun to develop tools for T–MSIS users, as well as work with States to improve the quality of data submitted. For example, CMS is developing data quality information, which aggregates data quality findings in topical areas as well as by State. This information will help users of the T–MSIS data, which CMS plans to use for program oversight efforts. T–MSIS includes data on prescription opioids, and CMS looks forward to working with States to fully utilize this data in innovative ways that will augment efforts to combat opioid misuse.

THE ROLE OF ACF, SAMHSA, CDC, NIH, FDA, AND HRSA IN ADDRESSING THE OPIOID CRISIS

ACF

The Regional Partnership Grant Program:

Since 2007, the Regional Partnership Grant (RPG) Program has been a cornerstone to the ACF Children's Bureau's efforts to improve outcomes for children and families affected by parental substance use. The intent of the RPG program, authorized under sections 436 and 437 of the Social Security Act as part of the Promoting Safe and Stable Families program, is to increase the well-being, improve permanency outcomes, and enhance the safety of children and families in the child welfare system who are affected by parental substance use. The grants are funded to build system-level capacity to support families through collaborative partnerships among child welfare, substance use disorder treatment, court systems, and other family support systems and organizations to implement evidence-based, evidence-informed and promising programs and strategies with children and families. To date, there have been five rounds of RPG projects, consisting of 101 grants, in 36 States. The RPG Program was reauthorized in February 2018. Under this reauthorization, ACF anticipates awarding RPG Round 6, consisting of eight grants in eight States, awarded in September 2019.

Regional Partnership Grants Round 2 (2012–2017) Interim Findings

The RPG national cross-site evaluation has resulted in several significant, interim findings from RPG Round 2 that will be formally shared in a forthcoming Report to Congress. These interim findings represent the work of RPG Round 2 projects

that operated from September 2012 to September 2017. Findings from RPG Round 3 projects, will be identified and disseminated following the conclusion of their grants this September, and the completion of data analysis by the national cross-site evaluator. In June 2019, the national cross-site evaluation for RPG projects in Round 4 and 5 was officially launched and findings from this evaluation will be shared at appropriate intervals in the future.

From October 2012 to April 2017, the 17 RPG Round 2 grantees enrolled 11,416 adults and children—55 percent of whom were children, the majority under 5 years old. The strategies and services provided by the RPGs included: expanded and timely access to comprehensive family-centered treatment; creation or expansion of family treatment drug courts; in-home services; case management and case conferencing; and use of evidence-based and evidence-informed practice approaches, such as recovery coaches, mental health, and trauma-informed services; parent-child interventions; and strengthening of cross-system collaboration. Most RPG Round 2 families received at least one evidence-based program.

Interim findings demonstrate many adult and child outcomes improved significantly following entry into RPG. These findings include a significant decrease in adult drug and alcohol use between program entry and exit, and adult mental health and parenting attitudes improved significantly with fewer attitudes about parenting that placed their children at risk of maltreatment. Additionally, there was a significant reduction in rates of substantiated maltreatment. Thirty-six percent of children in RPG had an instance of substantiated maltreatment in the year before RPG, and this decreased to just seven percent of children in the year after RPG enrollment. Removals of children from the home were also less common: 29 percent of children experienced a removal in the year before RPG enrollment, and only 6 percent of children were removed from the home after entering RPG. Reunifications with the family of origin or other permanent placements were also more common in the year after RPG entry than in the year before. The cross-site evaluation also completed analysis of the adults in RPG Round 2 that indicated at program entry they were opioid users. As a result of participation in RPG program, opioid use in particular appears to be an area of significant improvement. Approximately 16 percent of adults were recent prescription opioid users at program entry, and only four percent of adults indicated at program exit that they were recent prescription opiate users.

National Center on Substance Abuse and Child Welfare's (NCSACW) Work to Address the Impact on the Opioid Crisis on the Child Welfare System

The National Center on Substance Abuse and Child Welfare (NCSACW) is a HHS initiative jointly funded by SAMHSA's Center for Substance Abuse Treatment and the Administration for Children and Families' Children's Bureau and administered by SAMHSA. The mission of the NCSACW is to improve family recovery, safety, and stability by advancing practices and collaboration among agencies, organizations and courts working with families affected by substance use and co-occurring mental health disorders and child abuse or neglect. The NCSACW provides training and technical assistance (TA) to families affected by substance use disorders, including opioid use disorders, and involved with the child welfare system. The NCSACW saw a dramatic and sizable increase in TA responses related to opioids from 2009 to 2018. Since that time, the most common technical assistance topics continue to be related to the opioid epidemic, and more specifically have been on the Child Abuse Prevention and Treatment Act (CAPTA) Plans of Safe Care, working with pregnant and parenting women, and infants with prenatal substance exposure. TA responses included sharing of information on related topics such as best practices in the treatment of opioid use disorders during pregnancy and collaboration to support infants with prenatal substance exposure and their families. The NCSACW also creates written materials that support communities in addressing the opioid epidemic. In 2016, the NCSACW released A Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorders. This publication continues to be one of the most-downloaded resource from the NCSACW website. Web-based tutorials are also provided to train substance use disorder treatment, child welfare, and court professionals. The content of these tutorials includes information on opioid use disorders, CAPTA, and Plans of Safe Care. The website receives approximately 60,000 visitors per year. Additionally, in September 2019, the NCSACW released their updated Child Welfare Training Toolkit, which includes specific training modules on considerations for families in the child welfare system affected by opioids, methamphetamines, and understanding prenatal substance exposure and child welfare implications.

NCSACW also provides a limited amount of in-depth TA to State, tribal, and local agencies to assist in developing cross-system partnerships and the implementation of best practices to address the needs of this population. The NCSCAW's Infants with Prenatal Substance-Exposure In-Depth Technical Assistance (IPSE–IDTA) program continues working to advance the capacity of agencies to improve the safety, health, permanency, and well-being of infants with prenatal substance exposure and the recovery of pregnant and parenting women and their families.

SAMHSA

As HHS's lead agency for behavioral health, SAMHSA's core mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA supports a portfolio of activities that address all five prongs of HHS's Opioid Strategy.

SAMHSA administers the State Opioid Response (SOR) grants to provide flexible funding to State governments to increase access to medication-assisted treatment using medications approved by the Food and Drug Administration (FDA), reduce unmet treatment needs, and reduce opioid overdose related deaths through the provision of prevention, treatment and recovery activities for Opioid Use Disorder in the ways that meet the needs of their State.

In FY 2018, a total of $930,000,000 (including a 15 percent set-aside for the 10 States with the highest mortality rate related to drug overdose deaths) was awarded among all 50 States and seven territories. In FY 2019 SAMHSA awarded an additional total of $1.4 billion in supplemental and continuation funds. Other funding, including $50 million for tribal communities under the Tribal Opioid Response (TOR) grant program, has been awarded separately.

Previously, SAMHSA awarded $485 million to States and U.S. territories in FY 2017 and an additional $485 million in FY 2018 through the Opioid State Targeted Response (STR) grants, a 2-year program authorized by the 21st Century Cures Act (Pub. L. 114–255). This program allows States to focus on areas of greatest need, including increasing access to treatment, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of the full range of prevention, treatment and recovery services for opioid use disorder. SAMHSA also has several initiatives aimed specifically at advancing the utilization of medication-assisted treatment (MAT) for opioid use disorder, which is proven effective but is highly underutilized. SAMHSA's Medication Assisted Treatment for Prescription Drug and Opioid Addiction (MAT–PDOA) program expands MAT access by providing grants to States with the highest rates of treatment admissions for opioid addiction. Twenty-two States are currently funded by MAT–PDOA, and in September 2017, SAMHSA awarded $35 million dollars over 3 years in additional MAT–PDOA grants to six States.

SAMHSA is also implementing section 3201 of the SUPPORT Act, which broadened the eligibility requirements needed to prescribe buprenorphine, and thus should result in greater access to treatment for individuals with opioid use disorder.

CDC

As the Nation's public health and prevention agency, CDC is applying scientific expertise to understand the epidemic, conduct surveillance, and use data to inform evidence-based interventions to prevent further harms, including the spread of infectious disease, neonatal abstinence syndrome, and overdose death. CDC continues to be committed to the comprehensive priorities outlined in the HHS strategy and to saving the lives of those touched by this epidemic. CDC's work falls into five key strategies to address opioid overdose and other opioid-related harms: (1) conducting surveillance and research; (2) building State, local, and tribal capacity; (3) supporting providers, health systems, and payers; (4) partnering with public safety; and (5) empowering consumers to make safe choices.

CDC tracks and analyzes data to improve our understanding of this epidemic. According to the most recent provisional data, there were 69,096 drug overdose deaths predicted in the 12-month period ending March 2019. This is a slight decrease from 70,924 drug overdose deaths when compared to the 12-month period ending in March 2018.[23] CDC's data indicate that the epidemic continues to be driven by synthetic opioids, including illicitly manufactured fentanyl. Additionally, in March 2019, there were approximately 145,000 predicted drug overdose deaths involving cocaine, representing an increase from March 2018, and nearly 14,000 drug over-

[23] *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

dose deaths involving psychostimulants, a 24-percent increase from March 2018.[24] Given the evolving nature of this epidemic, it is essential that we continue to track and analyze data to target prevention efforts.

Data are crucial in driving public health action. Timely, high-quality data can help public health, public safety, and mental health experts better understand the problem, focus resources where they are needed most, and evaluate the success of prevention and response efforts. With the passage of the SUPPORT Act and continued support from the Administration and Congress, CDC is investing in strengthening the capacity of States to monitor the opioid overdose epidemic and target their prevention activities. CDC's Overdose Data to Action (OD2A) is a 3-year cooperative agreement that began in September 2019 and focuses on the complex and changing nature of the drug overdose epidemic and highlights the need for an interdisciplinary, comprehensive, and cohesive public health approach. CDC has awarded $301 million in new funding for the first year of a 3-year cooperative agreement to Washington, DC, 16 localities, and two territories to advance the understanding of the opioid overdose epidemic and to scale-up prevention and response activities. These funds will support State, territorial, county, and city health departments in obtaining high quality, more comprehensive, and timelier data on overdose morbidity and mortality and using those data to inform prevention and response efforts. This cooperative agreement builds upon CDC's OPIS Initiative and the OPIS Surge Support emergency funding.

Over 3 years, recipients will gather and rapidly report data that includes the substances, circumstances, and locations leading to overdoses and deaths. In addition, recipients will work to strengthen prescription drug monitoring programs, improve State-local integration, establish links to care, and improve provider and health system support.

CDC is also collaborating with SAMSHA on an evaluation of MAT to improve the evidence base, with the intent of scaling up MAT to achieve population-level impact. The purpose of this effort is to assess the type of MAT and the contextual, provider, and individual factors that influence implementation and improved patient well-being. CDC will be following 3,500 patients over the next 2 years. This evaluation will address the gaps that currently exist about MAT treatment, including:

- What are the features of programs that make MAT work?
- Who does it work for and which MAT works best for whom?
- What are the long-term risks and benefits associated with the different types of MAT medications?

Finally, CDC developed the CDC Training Series Applying CDC's Guideline for Prescribing Opioids, a web-based training to help providers gain a deeper understanding of the CDC Guideline for Prescribing Opioids for Chronic Pain and implement it into primary care practice. One of the trainings, "Assessing and Addressing Opioid Use Disorder" provides education to providers on methods for assessing and addressing an opioid use disorder when it is suspected.

Following the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain in 2016, the medical and health policy communities have largely embraced its recommendations.[25]

CDC is also taking the lead in preventing opioid-related harms such as the spread of infectious disease and the impact of opioids on mothers and babies. The number of new hepatitis C infections has more than tripled since 2010, with an estimated 44,000 people newly infected and 17,253 associated deaths in 2017. One of the greatest successes in HIV prevention has been among people who injection drugs, with an 80-percent decrease in injection drug use associated infections over time. Since 2011, our progress preventing new infections has stalled, and we are at risk of reversing our success, as seen by multiple outbreaks of injection drug use associated with HIV throughout the country just in the last year. In 2015, the rate of hepatitis C among U.S. women giving birth was more than five times higher than it was 15 years prior (in 2000).[26] Further, both new infections and deaths associated

---

[24] *https://www.cdc.gov/mmwr/volumes/68/wr/mm6817a3.htm?s—cid=mm6817a3_e.*

[25] *https://www.nejm.org/doi/full/10.1056/NEJMp1904190.* Tamara M. Haegerich, Christopher M. Jones, Pierre-Olivier Cote, Amber Robinson, Lindsey Ross. (2019) Evidence for State, community and systems-level prevention strategies to address the opioid crisis. *Drug and Alcohol Dependence* **204,** 107563.

[26] *https://www.cdc.gov/mmwr/volumes/68/wr/mm6839a1.htm?s_cid=mm6839a1_e&deliveryName=USCDC_921-DM10135.*

with hepatitis C and hepatitis B are largely underreported. Infectious disease surveillance is essential in order to understand epidemics and facilitate more effective State and local responses. Moreover, evidence-based, prevention programs such as syringe services programs—sometimes referred to as needle exchanges—are proven effective in preventing infectious disease among people who use drugs. People who access syringe service programs are three times more likely to stop injecting drugs. In addition to access to and disposal of sterile syringes and injection equipment, syringe service programs can provide a range of services or referrals to services such as substance use disorder treatment, including medication assisted therapy; testing, and linkage to care for infectious diseases; Naloxone distribution to prevent overdose; and vaccination for hepatitis A and B.

National Institutes of Health (NIH)

NIH is the lead HHS agency providing support for cutting-edge research on addiction, mental health, pain and opioid misuse, opioid use disorder, and overdose. Drug addiction and pain are complex neurological conditions, driven by many biological, environmental, social, and developmental factors. Continued research will be key to understanding the opioid crisis, informing future efforts, and developing more effective, safer, and less addictive pain treatments.

Over the last year, NIH has continued its work with stakeholders and experts across scientific disciplines and sectors to identify areas of opportunity for research to combat the opioid crisis. These discussions have centered on ways to reduce the over prescription of opioids, accelerate development of effective non-opioid therapies for pain, and provide more flexible options for treating opioid addiction. The result of these discussions is the awarding of over 375 grants, contracts and cooperative agreements across 41 States for a total of $945 million in FY 2019 funding for the second year of the NIH Helping to End Addiction Long-term (HEAL) Initiative. The Trans-NIH research initiative aims to improve treatments of opioid misuse and addiction and to enhance pain management. The six specific areas of focus this year are (1) translation of research to practice for the treatment of opioid addiction, (2) new strategies to prevent and treat opioid addiction, (3) novel medication for opioid use disorder, (4) enhanced outcomes for infants and children exposed to opioids, (5) clinical research in pain management, and (6) preclinical and translational research in pain management.

The HEAL Initiative will also prevent addiction through enhanced pain management. A longitudinal study will explore the transition from acute to chronic pain, non-addictive pain medications development efforts will be enhanced by data sharing, and a clinical trials network for pain therapeutics development will be developed. Best practices for pain management will be further explored, including nondrug and integrated therapies. Finally, innovative neurotechnologies will be used to identify potential new targets for the treatment of chronic pain, and biomarkers that can be used to predict individual treatment response will be explored and validated.

The NIH HEAL Initiative will build on extensive, well-established NIH research that has led to successes such as the development of the nasal form of naloxone, the most commonly used nasal spray for reversing an opioid overdose; the development of buprenorphine for the treatment of opioid use disorder; and the use of nondrug and mind/body techniques to help patients control and manage pain, such as yoga, tai chi, acupuncture, and mindfulness meditation.

Advances that NIH is working to promote may occur rapidly, such as improved formulations of existing medications, longer-acting overdose-reversing drugs, and repurposing of medications approved for other conditions to treat pain and addiction. Others may take longer, such as novel overdose-reversal medications, identifying biomarkers to measure pain in patients, and new non- addictive pain medications.

A large component of the HEAL Initiative with the potential for rapid impact is the HEALing Communities Study, a multisite implementation study testing an integrated set of evidence-based practices across health care, behavioral health, justice, and other community-based settings. The goal of the study is to reduce opioid-related overdose deaths by 40 percent over the course of 3 years in communities highly affected by the opioid crisis. Sixty-seven such communities are partnering with research sites in four States to measure the impact of these efforts.

Finally, NIH is engaged in efforts to advance the HHS Opioid Strategy pillar of advancing the practice of pain management. NIH worked with HHS and agencies across government to develop the National Pain Strategy, the government's first

broad-ranging effort to improve how pain is perceived, assessed, and treated, and is now working with other Departments and Agencies and external stakeholders to implement this Strategy. NIH is also involved in implementing the Federal Pain Research Strategy, a long-term strategic plan developed by the Interagency Pain Research Coordinating Committee (IPRCC) and the National Institutes of Health to advance the Federal pain research agenda.

FDA

Reducing the number of Americans who are addicted to opioids and cutting the rate of new addiction is one of the FDA's highest priorities. This may be achieved by ensuring that only appropriately indicated patients are prescribed opioids and that the prescriptions are for durations and doses that properly match the clinical reason for which the drug is being prescribed in the first place. FDA's efforts to address the opioid crisis are focused on encouraging "right size" prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids. The SUPPORT Act, enacted by Congress in 2018, allows FDA to require special packaging for opioids and other drugs that pose a risk of abuse or overdose. Earlier this year, FDA opened a public docket to solicit feedback on potential use of this new authority to require that certain immediate-release opioid analgesics be made available in fixed-quantity, unit-of-use blister packaging. The availability of these new packaging configurations could help prescribers to more carefully consider the amount of opioid pain medication they prescribe. Reducing the amount of unnecessary opioid pain medication prescribed will lead to fewer pills left in medicine cabinets that could be inappropriately accessed by family members or visitors, including children, and could potentially lower the rate of new opioid addiction.

Opioid analgesics present unique challenges: they have benefits when used as prescribed yet have very serious risks and can cause enormous harm when misused and abused. Our goal has been to ensure product approval and withdrawal decisions are science-based and that the agency's benefit-risk framework considers not only the outcomes of prescription opioids when used as prescribed but also the public health effects of inappropriate use. The agency recently issued a new draft guidance which describes the application of the benefit-risk assessment framework that the agency uses in evaluating applications for opioid analgesic drugs and summarizes the information that can be supplied by opioid analgesic drug applicants to assist the agency with its benefit-risk assessment, including considerations about the broader public health effects of these products in the context of this crisis. In addition, FDA held a public meeting to further discuss the agency's benefit-risk assessment of opioid analgesics, including the manner in which risks of misuse and abuse of these products factor into the benefit-risk assessment and whether an applicant for a new opioid analgesic should be required to demonstrate that its product has an advantage over existing drugs in order to be approved.

Given the scale of the opioid crisis, with millions of Americans already affected, prevention is not enough. We must do everything possible to address the human toll caused by opioid use disorder and help those suffering from addiction by expanding access to lifesaving treatment. FDA is supporting the treatment of those with opioid use disorder and promoting the development of improved, as well as lower cost, forms of medication-assisted treatment. FDA is also working to increase availability of all forms of naloxone, an emergency opioid overdose reversal treatment. Among other actions, FDA has approved the first generic naloxone hydrochloride nasal spray, granted priority review to all generic applications for products that can be used as emergency treatment of known or suspected opioid overdose, and for the first time proactively developed and tested a Drug Facts label to support development of over-the-counter naloxone products.

FDA plays an important enforcement role when it comes to the illicit market for diverted opioids and illegal drugs. One of those roles is collaborating with U.S. Customs and Border Protection (CBP) on interdiction work on drugs being shipped through the mail. Earlier this year, FDA implemented new authority granted by Congress to treat imported articles as drugs when they meet certain requirements, even in the absence of certain evidence of intended use. This allows FDA to more efficiently apply its existing authorities to appropriately detain, refuse, and/or administratively destroy these articles if they present significant public health concern. FDA also signed a Letter of Intent with CBP that addresses information sharing, operational coordination for better targeting of higher risk parcels, and collaborative strategies more specific to each agency's respective regulatory enforcement requirements. In addition, FDA continues to target illegal sales of opioids online and

work with Internet stakeholders to advance a proactive approach to cracking down on Internet traffic in illicit drugs to address this public health emergency.

Health Resources and Services Administration (HRSA)

HRSA investments in community health centers, rural communities, and workforce programs establish and expand access to opioid and other substance use disorder (OUD/SUD) services. These programs work toward integrating behavioral health services into primary care to better meet the needs of communities across the country.

In FY 2019, through the Integrated Behavioral Health Services (IBHS) Program, HRSA awarded more than $200 million to 1,208 health centers across the Nation to increase access to high quality, integrated behavioral health services, including the prevention and treatment of OUD/SUD. Health centers are using this funding to hire behavioral health providers, train health center staff to support the delivery of OUD/SUD and mental health services in primary care settings, deliver OUD/SUD and mental health services via telehealth, and improve awareness of and facilitate access to services through outreach, partnerships, and community integration efforts.

This new funding builds on the success of HRSA health center program investments in recent years. In FY 2017 and FY 2018, HRSA awarded more than $550 million to expand behavioral health services and increase access to critical OUD/SUD treatment. The impact of these programs is evident in the expansion of MAT in primary health care settings. Overall, the number of health center providers eligible to provide MAT increased nearly 190 percent (from 1,700 in 2016 to 4,897 in 2018) and the number of patients receiving MAT increased 142 percent (from 39,075 in 2016 to 94,528 in 2018).

In FY 2018, HRSA launched the multi-year Rural Communities Opioid Response Program (RCORP) to support OUD/SUD prevention, treatment, and recovery services in high-risk rural communities. Through RCORP, in FY 2018 and FY 2019, HRSA awarded $43 million to 215 rural grantees to establish partnerships with stakeholders and develop plans for addressing the treatment and recovery needs in their communities. In August 2019, HRSA awarded $111 million to 96 rural organizations across 37 States to implement comprehensive OUD/SUD programs, and expand access to MAT in eligible hospitals, health clinics, or tribal organizations in high-risk rural communities. HRSA also established three Centers of Excellence on Substance Use Disorders to identify and disseminate evidence-based best practices.

HRSA workforce programs expand and enhance the OUD/SUD treatment and recovery workforce. In FY 2019, HRSA awarded over $87 million in funding for programs that, over the course of the 3-year project period, will add approximately 7,860 behavioral health professionals and paraprofessionals working in the provision of OUD/SUD prevention treatment and recovery services. These workforce investments support training across the behavioral health provider spectrum including community health workers, social workers, psychology interns and post-doctoral residents. Central to these programs is an approach to training that builds on academic and community partnerships, enabling clinicians to provide integrated behavioral health care and treatment services in underserved communities.

HRSA also supports the National Health Service Corps (NHSC) which awards scholarships and loan repayment to primary care providers to pay off their student loan debt in exchange for service to underserved communities. In FY 2019, HRSA established the NHSC Substance Use Disorder Workforce Loan Repayment Program to improve recruitment and retention of providers and expand access to quality opioid and substance use treatment in underserved areas nationwide. This new initiative broadened the NHSC to include SUD counselors, pharmacists, and registered nurses, and approximately 1,100 awards were made. Also in FY 2019, as part of the new NHSC Rural Community Loan Repayment Program, an additional 100 awards were made to providers working to combat the opioid epidemic in the Nation's rural communities. In addition to these new programs, the NHSC now offers $5,000 incentive awards to practitioners who obtain DATA 2000 Waivers and demonstrate that they provide MAT at NHSC-approved clinical sites. Nearly 200 providers received these incentive awards when they continued their service in 2019.

FUTURE DIRECTIONS AND CONCLUSION

As my testimony has highlighted, there is cause for optimism in addressing OUD. Under this administration, an historic investment has been made in combating the crisis. For example, as mentioned previously, the NIH recently awarded nearly $1

billion across 375 projects in 41 States as part of its HEAL Initiative, to support research in key areas where we need better tools to treat or prevent opioid addiction. In fact, between FYs 2016–2019, HHS has awarded over $9 billion in grants to States, tribes, and local communities to address this public health issue.

We have amassed a wealth of evidence on effective prevention, early intervention, treatment, and recovery strategies. Implementation of HHS's five-point strategy, along with the efforts of other Federal Government agencies, has resulted in reductions in opioid use and drug overdose deaths , increased access to medication assisted treatment, and increased the availability and distribution of overdose-reversing medications.

Even so, challenges remain. To that end, HHS's immediate priorities include addressing the surge of methamphetamine use and overdose, the introduction of new and highly lethal fentanyl analogues and other synthetic opioid analogues, and improving, demonstrating, and expanding the integration of Federal, State, local, and non-governmental efforts at the community level. Among these initiatives are comprehensive syringe services programs, Emergency Department MAT programs with warm hand-offs following overdose, and efforts to expand the behavioral health workforce. Ultimately, we need to pay attention not just to addiction, but also to mental health, ACEs, and the social determinants that exist in all communities.

Although we are making tremendous progress in our fight against the opioid epidemic, no one is declaring victory at this time. Indeed, we have only begun the public health fight against SUDs in our country. The Department will continue to devote its resources to solving this critical public health issue. And, as U.S. Surgeon General, I echo that pledge.

Thank you for the opportunity to testify on this important issue.

References

1. HHS Opioid Five-Point Strategy. *https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf.*

2. Surgeon General's Spotlight on Opioids. *https://addiction.surgeongeneral.gov/sites/default/files/OC_SpotlightOnOpioids.pdf.*

3. Digital Postcard. *https://addiction.surgeongeneral.gov/sites/default/files/SG-Postcard.jpg.*

4. Surgeon General's Advisory on Naloxone and Opioid Overdose.

QUESTIONS SUBMITTED FOR THE RECORD TO HON. JEROME M. ADAMS, M.D., MPH

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. Medication-Assisted Treatment (MAT) for opioid addiction typically involves regular use of methadone, buprenorphine or naltrexone (accompanied by individualized counseling). In addition, a monthly buprenorphine injection for the treatment of opioid addiction was approved by the Food and Drug Administration 2 years ago. What challenges exist for patients in accessing these products, and what strategies might we adopt in this area?

Answer. Chapter 5 of the recent National Academies consensus study report, *Medications for Opioid Use Disorder Save Lives,* noted several barriers to use of medications for treating OUD.[1] The report concluded that high levels of misunderstanding and stigma toward drug addiction, individuals with OUD, and OUD medications contribute to their underutilization. One study cited in the report that found that high levels of stigma were associated with greater public support for more punitive policy responses to the opioid epidemic and lower support for public health-oriented policy responses. Lack of provider training was also identified as a barrier, with "few among the broad range of providers who may treat patients with addiction . . . trained in or knowledgeable about evidence-based practices in addiction prevention and treatment," as well as inconsistent treatment approaches for patients. A lack of supporting infrastructure also contributes to the underutilization of OUD treatment. The National Academies report pointed to the lack of integration of OUD treatment with other medical care, gaps in insurance coverage for OUD medications, and regulatory barriers related to the prescribing of methadone and

[1] *https://www.nap.edu/read/25310/chapter/7.*

buprenorphine such as waiver policies, patient limits, and restrictions on settings where medications are available. Despite these challenges, we cannot keep losing people from avoidable deaths and instead, we must work together to mitigate these challenges.

As I have mentioned previously, although Medicaid programs differ by State, all States currently offer some form of MAT. Overall, although there is need for continued progress, approximately 1.28 million individuals are now receiving MAT, increased 39 percent from 2016. This represents significant progress we have made in advancing evidence-based treatment.

Question. To what extent has the Department of Health and Human Services (HHS) recently updated its programs and policies to reflect the latest brain and other research on what works best with those struggling with addiction? For example, are there certain performance measures or addiction treatment standards that HHS incentivizes through its grant making policies? What other programs or policies has HHS embraced to ensure the government is allocating its resources to support access to the most effective products and treatment services available?

Answer. HHS continues to support research on understanding opioid misuse and addiction to further inform our programs and policies. Through the NIH HEAL (Helping to End Addiction Long-term℠) Initiative, NIH awarded $945 million in Fiscal Year (FY) 2019 to institutions across 41 States. By leveraging expertise from almost every NIH institute and center to approach the crisis from all angles and disciplines, this research effort aims to improve treatments for chronic pain, curb the rates of opioid use disorder (OUD) and overdose and achieve long-term recovery from opioid addiction. The Initiative has six overarching research priorities: (1) translation of research to practice for the treatment of opioid addiction, (2) new strategies to prevent and treat opioid addiction, (3) enhanced outcomes for infants and children exposed to opioids, (4) novel medication options for opioid use disorder and overdose, (5) clinical research in pain management, and (6) preclinical and translational research in pain management.

As part of the NIH HEAL Initiative,℠ NIH and SAMHSA have awarded grants to four academic institutions working in partnership with 67 communities highly affected by the opioid crisis to conduct research as part of the HEALing Communities Study. The awards, totaling approximately $354.1 million, will support research on the effectiveness of a comprehensive, data-driven, community-engaged intervention designed to increase the adoption of an integrated set of evidence-based practices to reduce opioid-related overdose deaths and associated outcomes.

The State Opioid Response (SOR) program aims to increase access to MAT using the three FDA-approved medications for the treatment of opioid use disorder, reduce unmet treatment need, and reduce opioid overdose related deaths through the provision of prevention, treatment and recovery activities for opioid use disorder (OUD) (including prescription opioids, heroin, and illicit fentanyl and fentanyl analogs). Grants were awarded to States and territories via formula based on overdose death rates and treatment need. The program also includes a 15 percent set-aside for the 10 States with the highest mortality rate related to drug overdose deaths.

Grantees are required to develop and implement comprehensive systems of prevention, treatment, and recovery support services to address the opioid crisis. The SOR Program specifically emphasized the use of MAT as a requirement of the program. Grantees are required to ensure that FDA-approved medications are coupled with clinical psychosocial interventions and community recovery supports to address opioid use disorder. Currently, there are 57 active SOR grants funded for a total of $933 million per year for up to 2 years. SOR was funded at $1.5 billion in FY 2019.

In addition to the grant program, SAMHSA supported a robust technical assistance and training effort to enhance education across the country to address the opioid crisis. This $12 million effort is premised on the concept that the opioid crisis will best be addressed if local needs are addressed in a tailored fashion. As such, SAMHSA has placed local teams of experts on the ground in every State. These teams are comprised of clinicians, preventionists, and recovery specialists to provide training and education not just to practitioners but also to individuals and families.

SAMHSA has encouraged drug court and reentry program grantees for the past several years to provide MAT as it is an evidence-based practice and an important part of a comprehensive treatment plan. FY 2018 and FY 2019 grantees were encouraged to use up to 35 percent of their annual grant award to pay for FDA-approved medications (*e.g.,* methadone, buprenorphine, naltrexone, disulfiram,

acamprosate calcium) when the client has no other source of funds to do so. MAT is an evidence-based SUD treatment protocol for alcohol and opioid use disorders and SAMHSA supports the right of individuals to have access to FDA-approved medications. Drug court grantees must affirm that they will not deny access to the program to any eligible client for his/her use of FDA-approved medications for SUD treatment. Any providers of substance use disorder services who are eligible by law to obtain what is commonly referred to as a Drug Addiction Treatment Act (DATA) waiver and receiving funding from this grant program must obtain the DATA waiver and certify their willingness to provide, when clinically indicated, FDA-approved medications on Schedule III, IV or V to treat opioid use disorder.

In all cases that MAT is utilized, MAT must be permitted to be continued for as long as the prescriber determines that the medication is clinically beneficial. Recipients must assure that a drug court client will not be compelled to no longer use MAT as part of the conditions of the drug court if such a mandate is inconsistent with a licensed prescriber's recommendation or valid prescription. Under no circumstances may a drug court judge, other judicial official, correctional supervision officer, or any other staff connected to the identified drug court deny the use of these medications when made available to the client under the care of a properly authorized prescriber and pursuant to regulations within an opioid treatment program (OTP) or through a valid prescription by an authorized Buprenorphine prescriber and under the conditions described above. A judge, however, retains judicial discretion to mitigate or reduce the risk of misuse or diversion of these medications.

SAMHSA's services grants are intended to fund services or practices that have a demonstrated evidence base and that are appropriate for the population(s) of focus. An evidence-based practice (EBP) refers to approaches to prevention or treatment that are validated by some form of documented research evidence. Both researchers and practitioners recognize that EBPs are essential to improving the effectiveness of treatment and prevention services in the behavioral health field. While SAMHSA realizes that EBPs have not been developed for all populations and/or service settings, application reviewers closely examine proposed interventions for evidence base and appropriateness for the population to be served. If an EBP(s) exists for the types of problems or disorders being addressed, the expectation is that EBP(s) will be utilized.

SAMHSA has created the "Evidence-Based Practices Resource Center" to provide communities, clinicians, policy-makers and others with the information and tools to incorporate evidence-based practices into their communities or clinical settings. It can be accessed at: *https://www.samhsa.gov/ebp-resource-center*.

SAMHSA's Medication-Assisted Treatment for Prescription Drug and Opioid Addiction (MAT–DOA) program addresses treatment needs of individuals who have an opioid use disorder (OUD) by expanding and enhancing treatment system capacity to provide accessible, effective, comprehensive, coordinated, integrated, and evidence-based MAT and recovery support services.

MAT refers to the use of the FDA-approved pharmacotherapies (*i.e.,* buprenorphine products, methadone, and naltrexone products) in combination with evidence-based psychosocial interventions for treatment of OUD. MAT is a safe and effective strategy for decreasing the frequency and quantity of opioid misuse and reducing the risk of overdose and death. Recovery support services include linking patients and families to social, legal, housing, and other supports to improve retention in MAT to increase the probability of positive outcomes.

In FY 2017, SAMHSA funded five multi-year State grants and funded one new annual State grant, 23 continuations and one continuing technical assistance contract. In FY 2018 SAMHSA funded 11 continuation MAT–PDOA State grants; and in FY 2019 funded 6 continuations. In FY 2018, SAMHSA expanded its funding (TI–18–009) to States, political subdivisions in States, nonprofit organizations within States, and tribes by funding 128 new MAT–PDOA grants, 20 of which were tribes, to support program implementation and provided supplemental funding for direct technical assistance to the new FY 2018 grantees. SAMHSA's services grants are intended to fund services or practices that have a demonstrated evidence base and that are appropriate for the population(s) of focus. In selecting an EBP, the grantee must be mindful of how the choice of an EBP or practice may impact disparities in service access, use, and outcomes for the population(s) of focus. While this is important in providing services to all populations, it is especially critical for those working with underserved and minority populations.

HRSA also recently awarded $20 million to three Rural Centers of Excellence on SUD through its Rural Communities Opioid Response Program (RCORP). This program supports practitioners in rural communities across the country to find and implement evidence-based interventions that work best for rural populations. RCORP-Rural Centers of Excellence will facilitate access to the most effective products and treatment services available in communities often disproportionately affected by the opioid crisis.

Question. Engaging overdose survivors in the hospital, when they are at their most vulnerable, and therefore inclined to commit to addiction treatment, is a strategy that some communities across the country have pursued. Is there research to suggest the effectiveness of emergency room initiated support services, and if so, what more could we do to promote greater awareness of this approach?

Answer. Emergency Departments (ED) can play an important role in preventing overdose and treating engaging persons with opioid use disorder. EDs can provide naloxone to everyone who presents with an overdose or risk for an overdose. An additional important, evidence-based intervention is the initiation of MAT in the ED, with linkage to follow up services. CMS has recently proposed additional payments to incentivize both MAT initiation and linkage to care directly from the ED.

Additionally, a growing body of research supports the initiation of treatment with buprenorphine in the emergency department for opioid overdose survivors and other emergency department patients with opioid use disorder. Research is also beginning to suggest that peer workers, individuals who are in recovery from addiction themselves and have received specialized training, can be effective in engaging overdose survivors and other patients with opioid use disorder or other substance use disorder in emergency departments, distributing naloxone, linking with specialty treatment, providing ongoing support, and improving outcomes.[2]

HHS recognizes this as an important strategy for connecting persons with opioid use disorder to treatment services and will continue to invest in research (*e.g.,* through SAMHSA's Drug Abuse Warning Network and studies within the National Institute on Drug Abuse's (NIDA's) Clinical Trials Network, including the Emergency Department Connection to Care with Buprenorphine for Opioid Use Disorder (ED–CONNECT) trial and the Emergency Department-INitiated bupreNOrphine and VAlidaTIOn Network (ED–INNOVATION) trial) which aims to better understand this area.

In 2018, CDC released its resource "Evidence-Based Strategies for Preventing Opioid Overdose: What's Working in the United States." This resource consolidates the best evidence currently available for opioid overdose prevention strategies with demonstrated feasibility in the United States. It offers community leaders, local and regional organizers, non-profit groups, law enforcement, public health, and members of the public relevant research and examples of use in the field. One of the strategies included in this resource is initiating buprenorphine-based MAT in emergency departments.

In 2019, CDC also funded 47 States, Washington, D.C., Puerto Rico, Northern Mariana Islands, and 16 localities under its Overdose Data to Action (OD2A) funding opportunity, which builds on the previous Overdose Prevention in States (OPIS) work. Funded jurisdictions will work to collect high quality, more comprehensive, and timelier data on overdose morbidity and mortality and use those data to inform prevention and response activities. A required strategy under OD2A is linkage to care, under which all funded jurisdictions must implement activities to ensure a systems-level approach to link individuals in need of care to providers. Potential activities can include emergency department based buprenorphine induction, peer naviga-

---

[2] Carey, C.W., Jones, R., Yarborough, H., Kahler, Z., Moschella, P., and Lommel, K.M. (2018). 366 Peer-to-Peer Addiction Counseling Initiated in the Emergency Department Leads to High Initial Opioid Recovery Rates. Annals of Emergency Medicine, 72(4), S143–S144. doi:10.1016/j.annemergmed.2018.08.371.

Samuels, E.A., Baird, J., Yang, E.S., and Mello, M.J. (2019). Adoption and Utilization of an Emergency Department Naloxone Distribution and Peer Recovery Coach Consultation Program. Academic Emergency Medicine, 26(2), 160–173. doi:10.1111/acem.13545.

Waye, K.M., Goyer, J., Dettor, D., Mahoney, L., Samuels, E.A., Yedinak, J.L., and Marshall, B.D.L. (2019). Implementing peer recovery services for overdose prevention in Rhode Island: An examination of two outreach-based approaches. Addictive Behaviors, 89, 85–91. doi:https://doi.org/10.1016/j.addbeh.2018.09.027.

Welch, A.E., Jeffers, A., Allen, B., Paone, D., and Kunins, H.V. (2019). Relay: A Peer-Delivered Emergency Department-Based Response to Nonfatal Opioid Overdose. Am J Public Health, 109(10), 1392–1395. doi:10.2105/ajph.2019.305202.

tors, warm hand-offs, pre-arrest diversion, and community health workers, all of which can help to increase awareness of and help connect persons with OUD to care.

Further, because trained peer workers with lived experience with substance use and recovery can effectively build a rapport with people presenting in the ED with substance use issues, HRSA is working to expand the number of peer support specialists trained and available to be placed in the ED setting. These trained support specialists can help bridge patients to SUD treatment. HRSA recently awarded grants for training paraprofessionals. First, HRSA's Behavioral Health Workforce Education and Training (BHWET) Program increases access to treatment by increasing the number of professionals and paraprofessionals trained to deliver integrated behavioral health and primary care services in interprofessional teams. Second, HRSA's Opioid Workforce Expansion Program (OWEP) offers community-based experiential training for students preparing to become behavioral health paraprofessionals with a focus on opioid use disorder (OUD) and other SUD prevention, treatment, and recovery services. HRSA expects to train 4,309 paraprofessionals over the 3 years of the grants which began September 1, 2019.

Question. Are there sufficient mechanisms in place to ensure a coordinated, cohesive approach to treatment of pregnant women with substance use disorders? Or do barriers still exist for pregnant women in accessing affordable prevention and treatment services and interventions? If so, what steps do you recommend to eliminate such barriers?

Answer. Progress is being made in ensuring such an approach to treatment of pregnant women with SUD. HHS is addressing the 39 recommendations in the HHS Protecting Our Infants Act (POIA) strategy, per the HHS Status Report on POIA Implementation Plan.[3] CMS announced a funding opportunity for a 5-year model that is designed to address fragmentation in the care of pregnant and postpartum Medicaid beneficiaries with opioid use disorder (OUD).[4] The primary goals of the Maternal Opioid Misuse (MOM) Model are to improve quality of care and reduce costs for pregnant and postpartum women with OUD and their infants; expand access, service-delivery capacity, and infrastructure; and create sustainable coverage and payment strategies that support ongoing coordination and integration of care. On December 19, 2019, CMS awarded MOM Model funding to 10 States to collaborate with local care-delivery partners, which could include health systems, hospital systems, or payers, such as a Medicaid managed care plans, to transform the care-delivery system for affected mothers and their infants. The MOM Model has a 5-year period of performance, which began on January 1, 2020, and three different types of funding, approximately $50 million in total.[5]

The Child Abuse Prevention and Treatment Act requires that providers report illicit substance use including RX misuse by mothers to child welfare authorities if a State defines such use to constitute child abuse or neglect. This, as well as ongoing judicial and prosecutorial bias against MAT, and the lack of facilities willing to treat pregnant women (or who believe they can treat them safely) are among the major barriers to the treatment of pregnant women that HHS and DOJ need to overcome if pregnant women are going to get into prenatal care and SUD treatment in a timely manner.

Since 2018, the HHS Office on Women's Health and HRSA have collaborated on the Regional Opioids Coordination Initiative, which is developing a family-centered care coordination model for women who misuse opioids who are served by HRSA-funded care settings. In 2018 OWH and HRSA hosted three regional stakeholder consultations (in Regions III, VII, and IX), which brought together a diverse group of public and private sector stakeholders to identify best practices for care and treatment coordination in diverse clinical and social service settings. One of these meetings (in Region VII) specifically focused on the needs of pregnant women. The project will conclude in late 2020 with the development and release of a toolkit that will include resources for providers, and will feature a section focused specifically on the needs of pregnant women.

HHS established an implementation plan in response to the Protecting Our Infants Act strategy that is focused on preventing prenatal opioid exposure, providing

---

[3] *https://aspe.hhs.gov/system/files/pdf/260891/POIA.pdf.*

[4] *https://www.cms.gov/newsroom/press-releases/cms-model-addresses-opioid-misuse-among-expectant-and-new-mothers.*

[5] *https://www.cms.gov/newsroom/press-releases/cms-awards-funding-combat-opioid-misuse-among-expectant-mothers-and-improve-care-children-impacted.*

evidence-based treatment for both mother and infant, increasing the accessibility of family-friendly services for pregnant and parenting women with OUD, supporting continuing education for healthcare providers, and determining optimal family and developmental support services for children who have experienced prenatal opioid exposure. Reporting to Congress about this is ongoing.[6]

The SUPPORT Act contains more than 20 Medicaid-related provisions, and CMS is working expeditiously to implement this law. Two such provisions are sections 1012, Help for Moms and Babies, and 1007, Caring Recovery for Infants and Babies. Section 1012 creates a limited exception to the Institutions for Mental Diseases (IMDs) payment exclusion in Medicaid, and allows payments to States for medical care provided outside IMDs to pregnant or postpartum women receiving treatment for SUD in IMDs. Section 1007 permits States to include residential pediatric recovery centers (RPRCs) as providers in their Medicaid programs for infants with Neonatal Abstinence Syndrome (NAS), permits payments for room and board to RPRCs for treating such infants, and permits RPRCs to offer certain services to mothers and other appropriate family members and caretakers that are for the benefit of such infants, including counseling or referrals for services, activities to encourage caregiver-infant bonding, and training on caring for infants with NAS. CMS issued guidance to States on these provisions on July 26, 2019.

Moreover, in November 2017, CMS launched an opportunity through section 1115 demonstration projects for States to demonstrate and test certain Medicaid flexibilities to improve the continuum of care for beneficiaries with SUD. CMS has approved more than 25 States' SUD demonstrations to date.

The National Center on Substance Abuse and Child Welfare (NCSACW) is an HHS initiative to improve family recovery, safety and stability for those affected by substance use. This initiative also creates written materials that help those impacted by opioid epidemic. NCSACW developed publications and web-based tutorials to train professionals and the site receives 60,000+ visits per year.

HRSA/MCHB's *State Legislation on Substance Use During Pregnancy Guide*[7] developed by the Healthy Start Technical Assistance Center, highlights the following barriers adapted from an American College of Obstetricians and Gynecologists (ACOG) toolkit.

Policies that penalize pregnant or parenting women for substance use leads to adverse consequences for both mother and baby. Research shows that State laws and policies that penalize women for substance use during pregnancy lead to a host of negative consequences including:

- Deterring women from seeking the care they need to reduce their substance use.
- Discouraging women from disclosing substance use to health-care providers who could help them access treatment and care.
- Pressuring women to end their pregnancies in order to avoid arrest if they do not feel they can successfully stop using substances.
- Limiting health-care providers' ability to provide the best possible care to women, including providing appropriate treatment for pain or substance use disorders.

Regarding *barriers for pregnant women in accessing affordable prevention and treatment services and interventions,* adapted from ACOG's toolkit: (1) Health experts agree that substance use during pregnancy is best addressed through preventative measures and treatment. Every leading medical and public health organization that has addressed this issue has concluded that education, prevention, and community-based treatment are the best methods for reducing substance use during pregnancy; (2) Staying connected to the healthcare system is key to improving birth outcomes. The evidence shows that getting prenatal care, staying connected to the healthcare system, and maintaining open communication channels with physicians and healthcare providers about substance use helps improve birth outcomes, regardless of whether a woman can successfully stop using substances.

Question. What steps has HHS taken to promote development and use of alternative, non-opioid medications to treat acute pain, and what more could the Department do in this area?

---

[6] *https://aspe.hhs.gov/report/status-report-protecting-our-infants-act-implementation-plan.*
[7] *https://www.healthystartepic.org/wp-content/uploads/2019/05/JSI-SU-and-Pregnancy-Resource-Guide.pdf.*

Answer. HHS has implemented multiple initiatives to promote awareness regarding risks of prescription opioid misuse and promote conversations about effective pain management with their health-care providers. CDC launched the Rx Awareness communication campaign that features testimonials from those recovering from opioid use disorder and of people who have lost loves ones to opioid overdose. The CDC has also developed promotional materials including a piece titled *Non-opioid Treatment for Chronic Pain* that lists options of non-opioid medications as well as non-pharmacological therapies. We will continue to promote these options, but I would like to note, there is no "one-size-fits-all" approach to treating pain.

In May 2019, HHS also released a report informed by Pain Management Task Force meetings, including review and analysis of over 9,000 public comments and testimonials from patients dealing with chronic pain. Over 165 medical organizations submitted feedback on this report as well. This report examines best practices for acute and chronic pain management and is available publicly online.

In addition, a major focus of the NIH HEAL Initiative℠, is to accelerate the discovery and development of innovative treatments for pain including non-opioid pain medications and devices. To learn more about HEAL Initiative efforts to manage pain, I refer you to: *https://heal.nih.gov/research.*

Question. What incentives exist for State governments to adopt programs that offer a continuum of care for addicts and prioritize use of evidence-based behavioral treatments and medications? Could we do more to incentivize such programs (*e.g.,* by making eligibility for certain HHS grants contingent on the adoption of additional policies that integrate care for mental health and substance abuse disorders)?

Answer. Of note, to avoid perpetuating stigma and to ensure clear, consistent, science-based language that aligns with the terminology and "people-first" framing used to refer to people with other chronic conditions or disabilities, HHS refers to *people with substance use disorder.* Terms such as "addict," "alcoholic," or "user" assign an implicit identity to those they designate and de-emphasize their full personhood. Stigma, misunderstanding, and negative attitudes toward individuals with substance use disorder are still pervasive and even affect the quality of health care patients with substance use disorder receive and their health outcomes.[8] HHS prioritizes evidence-based treatments and medications among State governments through the design of our programs. SAMHSA's State Opioid Response Grants require State agencies to utilize evidence-based implementation strategies to rapidly and adequately address the gaps in their systems of care and deliver evidence-based treatment interventions that include FDA-approved medications.

In 2019, CDC also funded 47 States, Washington, DC, Puerto Rico, Northern Mariana Islands, and 16 localities under its Overdose Data to Action (OD2A) funding opportunity, which builds on the previous Overdose Prevention in States (OPIS) work. Funded jurisdictions will work to collect high quality, more comprehensive, and timelier data on overdose morbidity and mortality and use those data to inform prevention and response activities. A required strategy under OD2A is linkage to care, under which all funded jurisdictions must implement activities to ensure a systems-level approach to link individuals in need of care to providers. Potential activities include peer navigators, warm handoffs, pre-arrest diversion, and community health workers, all of which can help to increase awareness of and help connect persons with OUD to care. HHS also promotes the integration of mental health and substance use disorder care services through several programs and innovative payment models. Through HRSA's Health Center Program, 1,208 health centers across the Nation, which provide comprehensive primary health services to medically underserved communities and populations, received funding in FY 2019 to increase access to high quality, integrated behavioral health services, including the prevention or treatment of mental health conditions and/or substance use disorders, including opioid use disorder. Additionally, in FY 2019, HRSA awarded 80 grants to rural communities through its Rural Communities Opioid Response Program (RCORP)-Implementation. This program requires award recipients to implement a set of required activities that span the care continuum, including increasing the number of providers who can provide MAT, supporting integrated treatment and recovery, and enhancing individuals' abilities to find, access, and navigate evidence-based and/or best practices for affordable treatment and recovery support services for SUD/OUD.

[8] van Boekel, L.C., Brouwers, E.P.M., van Weeghel, J., and Garretsen, H.F.L. (2013). Stigma among health professionals towards patients with substance use disorders and its consequences for healthcare delivery: Systematic review. Drug and Alcohol Dependence, 131(1), 23–35. doi:https://doi.org/10.1016/j.drugalcdep.2013.02.018

On December 19, 2019, the CMS Center for Medicare and Medicaid Innovation (Innovation Center) announced the awarding of Maternal Opioid Misuse (MOM) Model funding to 10 States address fragmentation in the care of pregnant and postpartum Medicaid beneficiaries with opioid use disorder through State-driven transformation of the delivery system surrounding this vulnerable population.[9] By supporting the coordination of clinical care and the integration of other services critical for health, well-being, and recovery, the MOM Model has the potential to improve quality of care and reduce costs for mothers and infants. Additionally, the Innovation Center announced that it had issued eight cooperative agreements for the Integrated Care for Kids (InCK) Model across seven States, which is a child-centered local service delivery and State payment model that aims to reduce Medicaid expenditures and improve the quality of care for children under 21 years of age enrolled in Medicaid/CHIP through prevention, early identification, and treatment of behavioral and physical health needs.

HHS recognizes that there is still more work to be done to further address the changing landscape of the drug overdose crisis.

Question. To what extent do we have reason to be concerned about respiratory depression in patients who receive post-operative intravenous opioid medications, and under what circumstances, if any, should such hospital patients be closely (or continuously) monitored?

Answer. Opioids have been the cornerstone therapy used for the management of post-operative moderate and severe pain. But as with all medications, they are accompanied by potential complications or adverse reactions. It is well accepted that opioids increase the risk of post-operative respiratory depression in certain populations (*e.g.,* those who are obese, or have sleep apnea), but more health-care and training institutions are promoting opioid sparing anesthesia and analgesia as a way to reduce complications—including respiratory depression—for all populations.

This current reality restates the importance of finding different treatment alternatives to intravenous opioid medications that have lower risk of complications.

In 2014, CMS issued a Survey and Certification Memorandum to update guidance for hospital medication administration requirements which reflect the need for patient risk assessment and appropriate monitoring during and after medication administration, particularly for post- operative patient receiving intravenous (IV) opioid medications, to prevent adverse events. The guidance states that hospitals are expected to address monitoring for over-sedation and respiratory depression related to IV opioids for post-operative patients. Hospitals must have policies and procedures related to the use of high-alert medications, such as IV opioids for post- operative patients, that include the process for patient risk assessment, including who conducts the assessments, and, based on the results of the assessment, monitoring frequency and duration, what is to be monitored, and monitoring methods. If surveyors find that a hospital does not have adequate policies and procedures on the use and monitoring of high-alert medication, the hospital could be cited for a deficiency under the survey, and the hospital would be required to address this deficiency.

QUESTIONS SUBMITTED BY HON. JOHN THUNE

Question. Your testimony acknowledged continued challenges with methamphetamine use, which is a problem in South Dakota. What trends are you seeing nationwide compared to opioids, and what can the Department and policymakers do to ensure this does not grow to the size of the opioid crisis?

Answer. As Assistant Secretary Giroir has termed it, methamphetamine abuse is now the fourth wave of America's overdose crisis. Deaths associated with psychostimulants with abuse potential now outnumber deaths from natural and semi-synthetic opioids; and in 14 States (of 37 which report monthly by category), methamphetamines are involved in more overdose deaths than are synthetic opioids like fentanyl.

Methamphetamine is readily available throughout the United States, and availability is highest in the West and Midwest. It is a significant problem in American Indian/Alaska Native (AI/AN) communities. It is increasing in prevalence in new

[9] *https://www.cms.gov/newsroom/press-releases/cms-awards-funding-combat-opioid-misuse-among-expectant-mothers-and-improve-care-children-impacted.*

markets, such as the Northeast, as prices continue to decline throughout the United States. Meth mixed with fentanyl and fentanyl-related substances has been seized and is increasingly reported on death certificates.

CDC has provisional mortality data on methamphetamine- and cocaine-related overdose in 18 States. Methamphetamine and cocaine use are captured in CDC ESOOS data if ED visits or overdose deaths also involve opioids.

Today's cohort of methamphetamine users is different from the population using methamphetamine in the early-mid 2000s in the following ways:

- More co-use of opioids.
- Larger percent injecting (including both injection of methamphetamine and opioids).
- More geographically diffuse—some of the largest increases in treatment admissions and deaths are occurring in the Northeast, Midwest, and South; the West has always had higher rates and has increased, but not to the same degree as other areas of the country. This geographic diffusion correlates highly with methamphetamine supply data from the Drug Enforcement Administration and others in law enforcement.
- More racial/ethnic distribution—in the treatment admission data—all race/ethnicity groups have experienced significant increases in the past decade. Consistent with historical patterns, AI/AN populations have significantly higher rates, but some of the largest increases have occurred among populations that historically have not had much involvement with methamphetamine, especially non-Hispanic blacks.
- All age groups are impacted—treatment data indicate significant increases across all age groups—both for any methamphetamine at treatment admission, primary methamphetamine treatment admission, and heroin treatment admissions also reporting methamphetamine abuse.

SUBSTANCE USE PATTERNS AMONG PEOPLE USING METHAMPHETAMINE

Poly-substance use is the rule rather than exception among people using methamphetamine in a number of ways:

- Among individuals reporting past-year methamphetamine use in the National Survey on Drug Use and Health (NSDUH) in 2015–2017, more than 95 percent reported lifetime use of tobacco, alcohol, and cannabis use, 84 percent reported lifetime cocaine use, and 36.7 percent reported lifetime heroin use.
- Among past-year users of methamphetamine in 2017, past-year use of other substances is common: 70.2 percent used cannabis, 37.9 percent misused prescription opioids, 32.3 percent used cocaine, 28.8 percent misused prescription sedatives/tranquilizers, 28.0 percent misused prescription stimulants, and 19.0 percent used heroin. In addition, 42.9 percent had past-month nicotine dependence and 40 percent reported binge drinking in the past month.
- Among past-year methamphetamine users in 2015–2017, the average age of initiation for methamphetamine use was 21.9. On average, among the past-year methamphetamine users reporting lifetime use of cigarettes, alcohol, cannabis, cocaine, and heroin, the average age of initiation was earlier for alcohol (14.0 years), cigarettes (14.1 years), cannabis (14.7 years), and cocaine (19.5 years). Average age of initiation for heroin was later than methamphetamine (25.5 years).
- Among past year methamphetamine users who also misused prescription opioids in the past year in 2015–2017, the average age of first methamphetamine use was 21.6 years and the average age of first misuse of prescription opioids was 22.3 years.
- Among past year methamphetamine users who also misused prescription stimulants in the past year in 2015–2017, the average age of first methamphetamine use was 21.5 years and the average age of first misuse of prescription stimulants was 24.1 years.
- Among past year methamphetamine users who also misused prescription tranquilizers in the past year in 2015–2017, the average age of first methamphetamine use was 22.2 years and the average age of first misuse of prescription tranquilizers was 27.1 years.
- Among past year methamphetamine users who also misused prescription sedatives in the past year in 2015–2017, the average age of first methamphetamine use was 21.2 years and the average age of first misuse of prescription sedatives was 26.2 years.

- In the 2015–2017 NSDUH, among past-year methamphetamine users, 24.7 percent reported past-year injection drug use, 22.7 percent reported methamphetamine injection, 22.1 percent reported heroin injection, and 4.8 percent reported past year cocaine injection.
- These findings are consistent with other studies in the literature using different data sources.
- Females are experiencing significant burden.
- In addition to co-use of opioids; there is also significant polysubstance use—this is consistent across the NSDUH and treatment data.

In the mortality data, there are differences among age and race/ethnicity populations with respect to opioid-involvement in psychostimulant-related overdose deaths, with younger age groups more likely to have opioids involved and non-Hispanic AI/AN, non-Hispanic black, and Hispanic populations less likely to have opioids involved in psychostimulant overdose deaths.

There are administration-wide efforts to support prevention, treatment, recovery, and law enforcement against cartels. We are also working closely with State, local, and non-government programs as we expand the healthcare workforce and implement comprehensive services following overdose.

QUESTIONS SUBMITTED BY HON. PATRICK J. TOOMEY

Question. How far along is the Department of Health and Human Services in implementing mandatory electronic prescribing of controlled substances?

Answer. Section 2003 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271), signed into Federal law in October of 2018, includes an electronic prescribing requirement for all controlled substance prescriptions under Medicare part D. The Centers for Medicare and Medicaid Services is working on the implementation of this provision.

Following the Federal mandate, many States have put forth legislation with similar laws. Today, more than 20 States have EPCS (electronic prescribing of controlled substances) mandates. Over 15 States have future effective dates. In addition to working toward all States requiring e-prescribing of controlled substances, we will keep working with these local, State and Federal departments to find ways to halt the over-prescription of prescribed opioids and diversion via forgery of paper prescriptions.

Question. Do any of the States stand out as high performers when it comes to oversight and regulation of addiction treatment centers? Please provide examples.

Answer. In general, all States license inpatient and outpatient addiction treatment centers. State licensure includes a measure of regulatory oversight and enforcement by the designated State agency. Two States in particular, have been identified to demonstrate robust oversight of Medication-Assisted Treatment (MAT) within their respective jurisdictions. Vermont has been a leader in the field by creating the Hub and Spoke model, along with creating oversight requirements for Office Based Opioid Treatment. Connecticut has incorporated MAT into criminal justice settings and has been a leader in this area.

Additionally, 26 States, of their own accord have established certification of addiction recovery residences through formal affiliation with the National Alliance of Recovery Residences (NARR). Certification serves to assure adherence to national operating standards established by NARR. The 26 NARR Affiliates are: CA, IL, PA, GA, FL, TX, OH, IN, MI, CT, SC, NC, VA, MN, NJ, RI, UT, CO, MO, TN, MD, ME, WA, VT, and AZ. According to NARR, six States are also in the process of establishing affiliated certification programs, these are: OR, DE, NH, WV, NY, and WI. NARR Certification closely aligns with SAMHSA's newly published Best Practices and Suggested Guidelines for Recovery Residences (2019), and serves to counter the emergence of, and potential acquiescence by some to, fraudulent and substandard practices in the addiction treatment community.

Question. How much money do Federal insurance programs (FEHB, TRICARE, Medicare, Medicaid, etc.) spend on drug treatment and how much of it is suspected of being fraud? What, if any, are the challenges in quantifying this?

Answer. Medicare fee-for-service makes payments for covered items and services that could be used for drug treatment, such as partial hospitalization program services and physician services. Beginning January 1, 2020, Medicare will pay for opioid

use disorder treatment services furnished by Medicare-enrolled Opioid Treatment Programs. Data on Medicare fee-for-service expenditures can be found at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research-Statistics-Data-and-Systems.* States make payments for items and services covered by Medicaid; the Centers for Medicare and Medicaid Services (CMS) pays States the Federal share of those payments.

CMS cannot make legal determinations of fraud and thus does not estimate fraud. CMS refers any suspicious behaviors to law enforcement partners for determining fraud. CMS annually estimates improper payments for Medicare and Medicaid. Improper payments are not necessarily indicative, or measures, of fraud but rather are payments that did not meet statutory, regulatory, administrative, or other legally applicable requirements, and which may be overpayments or underpayments. CMS's most recent improper payment estimates can be found in the FY 2019 HHS Agency Financial Report.[10]

QUESTIONS SUBMITTED BY HON. TIM SCOTT

Question. I am grateful to the chairman and ranking member for holding a hearing on the important and challenging topic. We have taken significant steps over the past few years, both through this committee and through the HELP Committee, to try to reverse the trends of this epidemic, and I have no doubt that the myriad bipartisan provisions that we have seen enacted will continue to aid efforts across the Nation on this front. That said, while it is too early to assess the impact of much of our Federal legislation in this area, there are always opportunities for additional initiatives, and opioids persist in posing a massive threat to our public health, our workforce, and our society. In South Carolina, we saw 816 opioid overdose deaths last year, which marked a 9-percent increase over the year before. In one county, the increase in opioid-related fatalities was as high as 80 percent. Looking specifically at fentanyl, we saw a 27-percent increase across the State over the same period.

This is a complex epidemic that unquestionably requires a wide range of solutions. That being said, given that roughly one quarter of patients who are prescribed opioids for chronic pain ultimately misuse them, and that around one in ten develop an opioid use disorder, ensuring access to viable alternatives for pain management is clearly one key part of the solution. Fortunately, we are seeing some groundbreaking work on this front.

In August, Nephron Pharmaceuticals, which is based in South Carolina, announced a partnership with Infutronix to provide an affordable alternative to opioids that combines an easy-to-use pain pump with a non-narcotic, pre-mixed bag of medications. Moreover, in order to effectively scale up operations on treatments like these ones, Nephron has also launched partnerships with USC and Clemson to work alongside faculty and students to enhance advanced manufacturing capabilities. For patients dealing with chronic pain, these efforts could be a game-changer.

We are also seeing significant progress when it comes to developing new non-opioid alternatives to pain relief. Just last month, MUSC announced an NIH grant worth more than $830,000 through the agency's HEAL Initiative. This will give MUSC team members across disciplines the opportunity to engage with networks of front-line researchers across the Nation to enhance and accelerate clinical trials for innovative alternatives to opioids. We are seeing similar efforts across research institutions, as well as industry.

From your perspective, what role can efforts like these play in combating the opioid epidemic?

Answer. Efforts like these are essential. We need to continue to fund research, specifically in the development of new and effective diagnostic, preventive and therapeutic approaches for patients. We must also work together to implement these novel approaches effectively in health systems and communities.

Question. What remaining barriers do you see when it comes to ensuring broad patient access to non-opioid alternatives to pain management, and what can we do to mitigate those barriers?

---

[10] *https://www.hhs.gov/sites/default/files/fy2019-hhs-agency-financial-report.pdf.*

Answer. Fifty million adults in the United States have chronic daily pain, with 19.6 million adults experiencing high-impact chronic pain that interferes with daily life or work activities. Many of these patients face significant access to care barriers (*i.e.,* stigma, poor dialogue with providers, not enough research on effective pain management approaches, shortages of behavioral pain management specialists, lack of insurance coverage for pain management services, etc.) and these need to be addressed in order to optimize the management of acute and chronic pain. We need to enable patients and physicians to utilize clinically indicated treatment modalities (opioid and non-opioid, restorative therapies, interventional approaches or behavioral approaches) to ensure that patients receive the assistance they need.

QUESTION SUBMITTED BY HON. BILL CASSIDY

Question. This hearing highlighted some of the challenges that families affected by substance use disorder face when trying to find properly certified treatment centers that use appropriate, science-based methods. One way that families could be helped is by having access to an app which directs them to certified treatment centers in their area. Generally speaking, how has HHS considered ways to direct families to treatment centers that are certified and use science-based methods? If not such an app exists, could HHS put forth a challenge grant to help one be created?

Answer. HHS now offers several mechanisms to find opioid treatment programs. When a person enters their zip code (anonymously), they will be taken to the Substance Abuse and Mental Health Services Administration (SAMHSA) facility finding map. Another option is *https://findtreatment.gov,* which also includes treatment types, distance from location and payments accepted. I will continue to work with my office, and HHS as a whole to improve access to families impacted by OUD.

QUESTIONS SUBMITTED BY HON. JAMES LANKFORD

Question. How can treatment plans (particularly MAT plans) ween addicts off opioid dependence without completely replacing their addiction with an MAT drug? Can it be standardized to have an end-goal of no drug intake instead of a different drug intake?

Answer. There is no one-size-fits-all situation when it comes to combating opioid addiction, but we know that MAT works. A common misconception associated with MAT is that it substitutes one drug for another. Instead, these medications relieve the withdrawal symptoms and psychological cravings caused by chemical imbalances in the body and changes to brain circuitry caused by opioid addiction. MAT programs provide a safe and controlled level of medication to overcome the use of a misused opioid. When provided at the proper dose, medications used in MAT should not affect a person's mental capability or employability for most jobs.

Research is underway to determine if and when it may be appropriate to taper patients off of medications used to treat OUD. Current evidence clearly shows that rates of relapse increase when medications are discontinued; relapse where highly potent synthetic opioids are prominent put patients at especially high risk of fatal overdose and therefore cessation of these medications should not be a treatment priority.

Evidence-based strategies such as employing psychosocial supports, community recovery services and MAT using medicines approved by the FDA (buprenorphine, extended release naltrexone, and methadone) constitute the gold standard of treatment for opioid use disorders. HHS has invested significantly (through SAMHSA and HRSA funding) in efforts to increase access to MAT in communities across the Nation. It also a critical component of the Department's 5 point strategy for combating opioid addiction.

Question. How can we increase access to non-addictive opioid alternatives?

Answer. In answering this question, it is important to distinguish addiction (substance use disorder) from physical dependence. Any individual who takes a sufficient dose of opioids over a sufficient period of time will become physically dependent on them, meaning that individual will experience withdrawal if they discontinue or significantly reduce their use of opioids. This does not mean that this individual has become addicted to opioids. Addiction is characterized by "uncontrollable, compulsive drug seeking and use, and that persists even in spite of negative health and social consequences. These behaviors are much more difficult to control than the

physical dependence that underlies withdrawal symptom." A patient being treated for opioid use disorder with buprenorphine or methadone is physically dependent on the medication, but not addicted to it. Moreover, treatment that includes one of three FDA-approved medications is the standard of care for opioid use disorder. Therefore, medication should be part of the front-line response, just as it is for high blood pressure, diabetes, or high cholesterol. Medications for the treatment of opioid use disorder can be more effective when used in combination with behavioral and/or psychosocial interventions. This combination of medication and psychosocial interventions is known as medication-assisted treatment (MAT).

While it is not desirable to reduce the use of medication for the treatment of opioid use disorder, it is important to complement medication with behavioral treatment that utilizes evidence-based approaches, such as cognitive behavioral therapy. In addition, it is critically important to support the use of non-addictive medications and non-pharmacological interventions for the management of pain and to support continued research and development in relation to non-addictive medication. One way HHS is working to make pain management safer is by pushing for insurance to cover opioid alternatives whether they are for pain treatment or for addiction treatment (*e.g.,* extended release naltrexone).

One of the barriers to use of extended release naltrexone is the medical requirement for abstinence from opioids for 7–10 days prior to initiation of the naltrexone injection. Many people simply drop out prior to starting this medicine for opioid relapse prevention. Coverage for inpatient detoxification services can help but they must be followed by ongoing treatment. Additionally, FDA approved lofexidine to help people endure the withdrawal period so they can initiate extended-release naltrexone. More payors need to cover lofexidine to enable more patients the opportunity to start extended release naltrexone.

Question. How can we ensure that early intervention in addiction treatment is a part of mainstream health care?

Answer. The HHS Five-Point Strategy to combat opioid misuse, addiction, and overdose supports early intervention. One of the activities detailed under the first strategy "Better Addiction Prevention, Treatment, and Recovery Services" is: "Identify individuals who are at risk of opioid use disorder and make available prevention and early intervention services and other supportive services to minimize the potential for the development of opioid use disorder (OUD)."

It is essential to advocate and support evidence-based practices with the aim of prevention and early intervention and to promote screening, assessment, and treatment as part of mainstream health care.

Question. In medical marijuana States, marijuana advocates promote replacing opioids with marijuana to alleviate opioid addiction. Would you suggest those with opioid dependence use marijuana as a substitute for or as a type of MAT?

Answer. HHS would not suggest marijuana as a substitute for FDA-approved medications for the treatment of opioid use disorder. While some States have legalized the use of marijuana for recreational or medicinal purposes, the FDA has not approved marijuana containing THC as medicine to treat opioid use disorder.

No, marijuana should not be promoted as a replacement treatment for opioid use disorder. Few scientific studies have addressed whether marijuana may be an effective or safe treatment for this purpose and those that have been done have significant limitations. Marijuana use, particularly long term, has been associated with harmful effects specifically in adolescents and during pregnancy. Medication-Assisted Treatments, in combination with behavioral therapies, are strongly recommended for patients with opioid use disorder given the robust base of evidence for their safety and effectiveness.

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. The lack of access to safe, effective treatment for addiction is its own health-care crisis. The examples that the Government Accountability Office has provided are just the tip of the iceberg when it comes to scam artists trying to take advantage of those who are desperate for help. You are an accomplished doctor and public health professional. There are many families like yours who have loved ones struggling with substance use disorders but they do *not* have the same medical expertise or financial resources that you had. For them, the job is even tougher. How do they find good treatment? What red flags should they avoid? What should the

Finance Committee be doing to make sure those seeking treatment have access to the high-quality care they deserve?

There are a variety of factors involved with accessing safe and effective health care. It's important to have open dialogue with physicians and other health professionals so they are aware of past opioid use and whether they should be looking for alternative treatment options for their patient's pain. When it comes to finding treatment, HHS now offers several mechanisms to find opioid treatment programs. When a person enters their zip code (anonymously), they will be taken to the Substance Abuse and Mental Health Services Administration (SAMHSA) facility finding map.[11] Another option is *https://findtreatment.gov,* which also includes treatment types, distance from location and payments accepted. Information on the signs of quality treatment that patients and their families should be looking can be found in Finding Quality Treatment for Substance Use Disorders.[12] NIDA also provides guidance to help individuals seeking treatment know what to ask at Seeking Drug Abuse Treatment: Know What to Ask.[13] NIAAA provides guidance on identifying quality alcohol treatment providers at *Find Your Way to Alcohol Treatment.*[14] Additionally, most specialty substance use disorder treatment facilities treat both alcohol and other drug use disorders. I will continue to work with my office, and HHS as a whole to improve access to families impacted by OUD.

Stigma plays a huge role in this realm and is a major barrier to treatment and to recovery. We must help people to not only feel comfortable having a conversation about addiction, but empower them to take action when they notice family members are misusing prescribed medicines or involved with illicit drugs. That's why I am so open about my family's addiction struggles, and it's why I asked all the Senators to share my opioid postcard, which lists the steps everyone can take to better understand, and respond to the opioid epidemic. Additionally, one of my priorities is to ensure that everyone carries naloxone and knows how to use it. It only takes a few moments to save a life, and I ask that you and the other Senators share my naloxone advisory, and learn about and carry naloxone yourselves.

In FY 2017, HRSA established the Substance Abuse Treatment Telehealth Network Grant Program, a 3-year pilot program that uses telehealth networks to improve access to substance use treatment services in rural, frontier, and underserved communities. In FY 2017 and FY 2018, HRSA awarded approximately $675,000 to three recipients. Additionally, HRSA's Evidence-Based Tele-Behavioral Health Network Program increases access to behavioral health-care services in rural and frontier communities. Through this program, in FY 2018, HRSA awarded $524,000 to two recipients that are primarily focused on using telehealth services for OUD treatment. Support to these programs continues in 2019.

QUESTION SUBMITTED BY HON. BENJAMIN L. CARDIN

Question. Do you know if Federal agencies are collaborating with State and local governments to inform consumers of the dangers of sober homes and patient brokering practices?

If not, what could the Federal Government do to educate consumers about quality treatment programs for their loved ones and how to identify patient brokering scams?

Answer. In response to the questions above: It is important to promote and educate the public on the evidence-based practices supported by HHS and the strategies listed in the HHS 5 point strategy to combat opioid abuse, misuse, and overdose. One tool that can be used by the public to find quality treatment is *findtreatment.gov;* this website provides the public treatment options close by these individuals. Some of the publications developed by HHS to help individuals find quality treatment include: *https://store.samhsa.gov/system/files/pep18-treatment-loc.pdf; https://www.drugabuse.gov/publications/seeking-drug-abuse-treatment-know-what-to-ask/introduction* and *https://alcoholtreatment.niaaa.nih.gov/*.

While not a form of treatment, recovery (sober) housing is a critical component of the service continuum. Therefore it is important to be able to differentiate quality

---

[11] *https://findtreatment.samhsa.gov/locator.*
[12] *https://store.samhsa.gov/system/files/pep18-treatment-loc.pdf.*
[13] *https://www.drugabuse.gov/publications/seeking-drug-abuse-treatment-know-what-to-ask/introduction.*
[14] *https://alcoholtreatment.niaaa.nih.gov/*.

recovery residences from those that that exploit patients and payers. Subtitle D of the SUPPORT Act, Ensuring Access to Quality Sober Living, required the HHS Secretary to identify or facilitate the development of best practices for operating recovery housing. In response to this requirement, SAMHSA released recovery housing best practices and suggested guidelines that can be found here: *https://www.samhsa.gov/sites/default/files/housing-best-practices-100819.pdf.* Building on existing standards, this guidance can help establish criteria for quality recovery residences. Elimination of fraudulent sober homes and patient brokering practices will require coordinated action involving funders, regulators, and law enforcement at the Federal, State, and local levels.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

NON-OPIOID ALTERNATIVES TO PAIN TREATMENT

Question. Congress has taken several steps over the past few years to provide additional tools, resources, and authority to the administration to support and promote the development of non-addictive pain treatments. Emphasizing the use of non-opioid alternatives should be a critical part of the Trump administration's strategy to confront this devastating public health crisis. Senator Young focused on this issue as part of his remarks during the hearing.

Can you please provide an update on the administration's efforts thus far to support the development and prioritization of these new products that help prevent addiction in the first place? Please specify what each agency tasked with doing more in this space has worked on (including, at the very least, CDC, FDA, CMS, NIH, DoD, VA).

Answer. While we would be pleased to provide an update on the activities of HHS agencies and their work with non-HHS departments/agencies, including DoD and VA, it would not be appropriate for HHS to comment on other Departments' efforts in this domain as HHS does not oversee those activities. The Office of National Drug Control Policy coordinates relevant activities across the departments and agencies have a role in the Nation's response to drug use and its consequences.

Two tenets of the HHS Five-Point Strategy to address the opioid crisis support the development and prioritization of non-opioid alternatives. These strategies are better pain management and better research. One example of the promotion of non-opioid alternatives in treating pain was The Pain Management Best Practices Interagency Taskforce Report. This report was the culmination of a Federal advisory group that was comprised of 29 private-sector and Federal members overseen by HHS in cooperation with the Department of Veterans Affairs (VA) and the Department of Defense (DoD). Another example of the promotion of non-opioid alternatives is CMS's proposal to cover acupuncture for Medicare patients with chronic low back pain in clinical trials supported by the NIH or in CMS-approved studies. In response to the President's Commission on Combating Drug Addiction and the Opioid Crisis recommendation as well as stakeholder requests and peer-reviewed evidence, CMS finalized beginning in 2019 to pay separately for non-opioid pain management drugs that function as a supply when used in a covered surgical procedure performed in the ambulatory surgical center setting. CMS is also continuing to analyze the issue of access to non-opioid alternatives in the hospital outpatient department and the ambulatory surgical center settings for which our payment policy should be revised to allow separate payment as appropriate. In addition, CMS provided guidance to States seeking to promote non-opioid options for chronic pain management,[15] and encourages Medicare Advantage plans to consider benefit designs for supplemental benefits that address medically-approved non-opioid pain management and complementary and integrative treatments.[16] CMS also implemented Section 6021 of the SUPPORT Act, by including information on non-opioid pain management in the 2020 Medicare and You Handbook.

The agency for Health Research and Quality (AHRQ) released a systematic review on the non-pharmacological treatments for chronic pain. This review examined many common chronic pain classifications and non-pharmacologic treatments for them. The NIH HEAL Initiative is another program that, in part, aims to accelerate

---

[15] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib022219.pdf.*
[16] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

the discovery and pre-clinical development of non-addictive pain treatments, and advance new non-addictive pain treatments through the clinical pipeline.

The NIH Helping to End Addiction Long-term (HEAL) Initiative is a broad effort to address the opioid crisis through evidence-based strategies. It significantly expands research to discover and accelerate development of non-addictive pharmacological and non-pharmacological pain treatments. Through the HEAL initiative, NIH supports programs to discover and accelerate development of new medications and devices to treat pain. HEAL established preclinical screening platforms to test for potential new non-addictive pain treatments. The platforms will use animal-based and human cell-based models such as neural tissue chips for rapid screening of molecules or devices for analgesic relevant biological and behavioral activity. Through HEAL, NIH also is partnering with academia and industry to bring in promising new drugs and devices for early phase human testing of novel therapeutics in the newly established Early Phase Pain Investigation Clinical research network (EPPIC–NET). Trials in this network will test the safety and efficacy of novel drugs and devices and support discovery research on a wide range of pain conditions. NIH also established the Pain Management Effectiveness Research Network to support phase 3 effectiveness trials which will support a range of trials on pharmacological and nonpharmacological therapies for many different pain conditions. Implementation research to evaluate and embed effective pain management strategies into large health care systems also are supported by HEAL.

Under section 3001 of the SUPPORT Act (clarifying FDA regulation of non-addictive pain products), FDA has taken the following actions to date. In November 2018, FDA held an advisory committee meeting to discuss the assessment of opioid analgesic sparing outcomes in clinical trials of acute pain. Opioid analgesic sparing is when non-opioid drugs are used to provide analgesia that would otherwise be provided with opioids. This can reduce patient exposure to opioids as well as the number of leftover opioids available for abuse or misuse in the community. FDA issued a June 2019 draft guidance, *Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework,* which describes the benefit-risk assessment framework that the agency uses in evaluating applications for opioid analgesic drugs and summarizes the information that can be supplied by opioid analgesic drug applicants to assist the agency with its benefit-risk assessment, including considerations about the broader public health effects of these products in the context of the opioid crisis. In September 2019, FDA held a Part 15 hearing to gain feedback on and further discuss the agency's benefit-risk assessment of opioid analgesics, including the manner in which risks of misuse and abuse of these products factor into that assessment. The agency also requested input on potential new preapproval incentives aimed at fostering the development of new therapeutics to treat pain or addiction.

Question. Can we count on you to work with your partners across the Federal Government to make non-addictive alternatives to pain management a priority?

Answer. Yes. Throughout my time as U.S. Surgeon General, I have prioritized the opioid crisis and what we can do to change and eventually eliminate this issue. In my travels around the country, I have engaged key stakeholders and gathered experts, community leaders, and families deeply impacted by opioid use. I issued evidence-based guidance on opioid treatment and continue to disseminate a digital postcard detailing five key actions to prevent opioid misuse. I also emphasize the importance of alternatives to opioids, as well as reducing barriers to treatment, the need for increased funding, and the importance of addressing stigma.

The Pain Management Best Practices Interagency Task Force Final Report was issued in May 2019. This report discussed acute and chronic pain management best practices and emphasized a balanced, individualized, patient-centered approach. This Task Force was a Federal advisory group comprised of 29 Federal and private-sector members overseen by HHS in cooperation with VA and DoD.

The 2016 CDC Opioid Prescribing Guideline for Chronic Pain, States that clinicians should ensure that patients are aware of potential benefits of, harms of, and alternatives, to opioids before starting or continuing opioid therapy.

THE METHAMPHETAMINE CRISIS

Question. During the hearing, Senator Daines spoke about the methamphetamine crisis he has seen in his home State of Montana and especially within Native American tribes. We are seeing a similar challenge with methamphetamine in the State of Ohio, and there is a need to do more. In responding to questions from Senator Daines, you mentioned that there are no options available to help treat meth addic-

tion (that are comparable to medication-assisted treatment for opioid use disorder), so our focus should be on the supply side of this crisis.

Most experts agree that we need a multi-solution approach for the addiction crisis. We will never tackle supply if we do not first tackle demand. What would your strategy be to help prevent addiction in the first place as a way to address the growing methamphetamine crisis?

Answer. We must continue to get "upstream" by recognizing and addressing the root causes of addiction. These include learning about, screening for, and addressing Adverse Childhood Experiences (ACEs), social determinants of health, mental illness, and other challenges that may lead people to seek relief through illicit drugs. I have spoken about stigma in relation to drug use but it also operates to prevent those who are suffering from mental health conditions from speaking out and seeking care.

A complex interplay exists between supply and demand. Without efforts to reduce supply, our prevention programs continue to be challenged. It is critical to have effective prevention and reduction efforts working simultaneously to make headway against the addiction crisis.

MEDICAID COVERAGE FOR THOSE INCARCERATED PRETRIAL

Question. During the hearing, Senator Cassidy raised an issue I have been working on with Senator Markey for several years—the fact that Medicaid coverage is revoked when an individual is incarcerated pretrial. According to the National Association of Counties, local jails admitted 10.6 million individuals in 2017. Approximately 65 percent of these inmates are in pretrial status, meaning that they are awaiting disposition of charges and have yet to be convicted of any crime. Some individuals in pretrial status are able to return to the community while they wait for disposition of their charges. Others may remain in custody if, for example, they are unable to post bail.

Because of the Medicaid inmate exclusion, Medicaid will not cover health-care services for a pretrial detainee because the individual is in custody. But Medicaid would cover the same health-care services for the same individual in pretrial status if that person awaited trial outside of custody.

In this country, the law states that you are innocent until proven guilty. However, the Medicaid inmate exclusion results in the loss of health insurance coverage before any court makes a determination on whether or not the individual is guilty. Do you agree that we should be doing more to remove barriers to care for all individuals, including justice-involved populations?

Answer. HHS agrees that it is important to prioritize removing barriers to care for all individuals, including justice-involved populations. A longstanding provision of the Medicaid statute excludes Medicaid payment for services provided to inmates of public institutions. It is an important responsibility of the appropriate State or local government to provide health-care services to inmates who are in their custody and HHS would be concerned about simply shifting financial responsibility of State or local inmates' health care to Federal taxpayers. HHS maintains its commitment to these populations and important work is happening in the Department to implement sections 1001 and 5032 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271) to better support inmates leaving jails and prisons and connect them to health care, including Medicaid coverage when they are eligible, more quickly and seamlessly upon release.

Question. Will you commit to working with your colleagues across the administration to solve the Medicaid inmate exclusion and ensure continuation of coverage for pretrial detainees?

Answer. As previously stated, it is a longstanding provision of the Medicaid statute that excludes Medicaid payment for services provided to inmates of public institutions. HHS maintains its commitment to these populations; however, the Department would be concerned about simply shifting financial responsibility of State or local inmates' health care to Federal taxpayers.

QUESTIONS SUBMITTED BY HON. MAGGIE HASSAN

Question. I am greatly appreciative of your support for expanded access to evidence-based treatments, including medication-assisted treatment, for those suffering from opioid use disorder.

Earlier this year I joined with Senator Murkowski to introduce legislation that would eliminate the waiver requirement that keeps many health care providers from prescribing buprenorphine.

Can you please identify the clinical benefits of medication-assisted treatment, and list any specific policies being considered by Department of Health and Human Services that would address the barriers that limit access to medication-assisted treatment?

Answer. Medicines involved in medication-assisted treatment (buprenorphine, naltrexone, and methadone) operate to normalize brain chemistry, block the euphoric effects of opioids, relieve cravings and normalize body functions without the negative effects of the misused drug. These medications have been approved by the FDA and the overarching MAT programs are clinically driven to meet each patient's needs.

The law allows coverage and payment for opioid use disorder treatment and services in a range of settings including in an Opioid Treatment Program accredited and certified by SAMHSA. Buprenorphine and naltrexone can also be prescribed in office-based settings. It is important that health-care providers receive effective training to safely provide their patients with the best options available, but unfortunately most clinicians have received little to no training on addiction. That's why I have co-written a number of articles and visited numerous clinician training programs calling on ALL providers to receive training in addiction prevention, diagnosis, and treatment.

To that extent, for example, SAMHSA continues to provide education and training to providers on MAT through webinars, workshops, publications, and research, as well as buprenorphine and opioid prescribing courses for physicians.

HHS continues to work internally to identify policies and strategies that can help remove barriers to care for individuals struggling with addiction. For example, two of our priorities moving forward include exploring opportunities to enhance emergency room MAT and warm hand-offs following an overdose, as well as working to improve MAT during transitions into, and our of, the criminal justice system.

Finally, my office continues to emphasize the importance of eliminating stigma, a major impediment to seeking treatment and support. By acknowledging that addiction is a disease and not a moral failing, we can begin to open up pathways to recovery for millions of Americans.

Question. A recent report by the Centers for Disease Control and Prevention illustrates the growing public health threat caused by the dramatic increase in sexually transmitted diseases and infections across the United States.

Cases of syphilis, gonorrhea, and chlamydia have reached all-time high records. Since 2014, primary and secondary syphilis cases have increased by 71 percent, and cases of gonorrhea have increased by 63 percent.[17]

Even New Hampshire—a State with historically low rates of sexually transmitted diseases and infections—has experienced an outbreak of gonorrhea in recent years. In 2016 alone, the New Hampshire Department of Health and Human Services saw a 250-percent increase in cases of gonorrhea.[18]

Data from the Centers for Disease Control and Prevention suggests that drug use may be a risk factor for contracting sexually transmitted diseases and infections.

Please identify the steps that the Department of Health and Human Services is taking to reduce the rate of sexually transmitted diseases and infections among individuals suffering from substance use disorder, including what resources the Department is providing to these individuals.

Answer. Unfortunately, yes, the CDC estimates that 20 million new STI cases are seen a year and the 2018 report released on October 8, 2019 indicated that chlamydia, gonorrhea, and syphilis have all increased for the fifth consecutive year.

---

[17] *https://www.cdc.gov/std/stats18/default.htm.*
[18] *https://www.dhhs.nh.gov/media/pr/2017/01192017gonorrhea.htm.*

HHS, specifically the Office of the Assistant Secretary of Health's Office of Infectious Disease Policy, will be releasing the first ever STI Federal Action Plan in 2020. This plan includes ways to prevent new STIs, improve the health of people (reduce adverse outcomes of STIs), reduce STI health disparities and integrate Federal program efforts to address STI epidemics.

HHS is also supporting research aimed at reducing at the spread of sexually transmitted infections associated with drug use. For example, NIDA partnered with the Appalachian Regional Commission (ARC), CDC, and SAMHSA to issue eight grants to help rural communities develop comprehensive approaches to prevent and treat consequences of opioid injection, including HIV, hepatitis C viral (HCV) infections, and syphilis. Funded in FY 2017 and continuing into FY 2022, investigators will work with State and local communities to develop best practices that can be implemented by public health systems in these regions and rural areas in other parts of the country. NIDA is also supporting a separate study aimed at increasing access to treatment for HCV in a rural Appalachian community in Kentucky and a project studying the effects of linking treatment for HIV, HCV, and opioid addiction in a community in rural northern New England. The spread of STI among people who use methamphetamine is also a concern and area of research focus for HHS. For example, NIDA is testing the use of mobile applications to help men who have sex with men reduce methamphetamine use and risky sexual behavior and to increase adherence to HIV pre-exposure prophylaxis among men who use methamphetamine.

A common theme deeply rooted within STIs and opioid misuse is stigma and this needs to be addressed in both instances. Increasing and normalizing these conversations will help health care providers give their patients safe and effective treatments.

PREPARED STATEMENT OF GARY CANTRELL, DEPUTY INSPECTOR GENERAL FOR INVESTIGATIONS, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning, Chairman Grassley, Ranking Member Wyden, and distinguished members of the committee. I am Gary Cantrell, Deputy Inspector General for Investigations with the Department of Health and Human Services (HHS) Office of Inspector General (OIG).

I appreciate the opportunity to appear before you to discuss OIG's enforcement efforts and other work to address the prescribing and treatment dimensions of the opioid crisis.

OIG is charged with overseeing all HHS programs and operations. We combat fraud, waste, and abuse in those programs; promote their efficiency, economy, and effectiveness; and protect the beneficiaries they serve. To accomplish this, OIG employs tools such as data analysis, audits, evaluations, and investigations. We are a multidisciplinary organization comprising investigators, auditors, evaluators, analysts, clinicians, and attorneys. We depend on our strong public and private partnerships to ensure coordinated enforcement success.

The Office of Investigations is the component of OIG that investigates fraud and abuse involving HHS programs. Our special agents have full law enforcement authority and effect a broad range of actions, including the execution of search warrants and arrests. We use traditional as well as state-of-the art investigative techniques and innovative data analysis to fulfill our mission. Our office has investigators covering every State, the District of Columbia, Puerto Rico, and other U.S. territories. We collaborate with other Federal, State, tribal, and local law enforcement authorities to maximize our impact.

INTRODUCTION

OIG has, for several years, identified curbing the opioid crisis as one of the Department's Top Management and Performance Challenges, as well as one of OIG's four priority focus areas.[1] Key components of that challenge include addressing in-

[1] The other three priority areas are: (1) promoting patient safety and accuracy of payments for services furnished in home and community settings, (2) strengthening Medicaid protections against fraud and abuse, and (3) ensuring health and safety of children served by grant-funded programs. For each priority focus area, OIG executives and senior-level staff develop strategies,

Continued

appropriate prescribing of opioids, improving access to treatment, and stopping the misuse of grant funds. In addition, combating fraud issues, such as drug diversion and billing for medically unnecessary prescriptions or services not actually rendered by providers, presents a significant challenge for the Department. OIG's ongoing opioids-related work is taking a multifaceted approach, looking at a variety of issues on both the prescribing and treatment dimensions of the crisis.

OIG has a longstanding and extensive history of enforcement and oversight work focused on prescription drug fraud, drug diversion, pill mills, medical identity theft, and other schemes that harm patients and waste taxpayer money. For years, OIG has been acting to address a rise in fraud schemes involving opioids, as well as associated potentiator and treatment drugs and ancillary services. In addition to increasing our investigative efforts to combat prescription drug abuse, we have responded to the growing severity of the opioid crisis by focusing on work that identifies opportunities to strengthen program integrity and protect at-risk beneficiaries. OIG uses advanced data analytics tools to put timely, actionable data about prescribing, billing, and utilization trends and patterns in the hands of investigators, auditors, evaluators, and government partners. Our goal is to identify opportunities to improve HHS prescription drug programs to reduce opioid addiction, share data and educate the public, and identify and hold accountable perpetrators of opioid-related fraud.

Today, I will highlight how OIG addresses both the prescribing and treatment dimensions of the opioid crisis through expanding law enforcement activities, led by my Office of Investigations, as well as new OIG work such as audits, evaluations, and data briefs, to combat opioid-related fraud, waste, and abuse while ensuring that both substance use disorder treatment and beneficiary continuity-of-care needs are met.

OIG'S EFFORTS TO ADDRESS THE OPIOID CRISIS ARE INCREASING THROUGH EXPANDING LAW ENFORCEMENT PARTNERSHIPS

Over the past 2 years, through expansion of Medicare Fraud Strike Force districts, establishment of the Opioid Fraud and Abuse Detection Unit Initiative, and establishment of the Appalachian Regional Prescription Opioid (ARPO) Strike Force, OIG's enforcement efforts to address the opioid crisis have increased significantly. For example, we have seen an increase of more than 100 percent in open opioid-related cases from 2015 to 2019.

Medicare Fraud Strike Force

The Strike Force effort began in Miami, FL in March 2007 and has expanded to now include a total of 12 districts. Strike Force teams effectively harness the efforts of OIG and the Department of Justice (DOJ), including Main Justice, U.S. Attorneys' Offices, the Federal Bureau of Investigation (FBI), and the Drug Enforcement Administration (DEA), as well as State and local law enforcement, to fight health-care fraud in geographic hot spots.

Strike Force partnerships between HHS–OIG, DOJ, U.S. Attorney's Offices, the FBI, and the DEA are a force multiplier that utilize data proactively to identify high-risk districts to target the worst offenders involved in criminal conduct or fraud associated with the improper prescription, distribution, possession, and use of opioids. This coordinated and data-driven approach to identifying, investigating, and prosecuting fraud has produced record-breaking results, including the June 2018 National Health Care Fraud Takedown, the 2019 Appalachian Regional Prescription Opioid Strike Force Takedowns, and most recently, the 2019 Regional Health Care Fraud and Genetic Testing Takedowns.

Appalachian Regional Prescription Opioid Strike Force

In October 2018, DOJ, in partnership with HHS–OIG, FBI, and DEA, launched the ARPO Strike Force. The mission of the ARPO Strike Force is to identify and investigate health-care fraud schemes in the Appalachian region and surrounding areas, and to effectively and efficiently prosecute medical professionals and others involved in the illegal prescription and distribution of opioids. This new Strike Force is operating out of two hubs based in the Cincinnati-Northern Kentucky and Nashville, TN areas, and supports the six States and 10 districts that make up the ARPO

---

drive action, unleash organizational creativity, and measure impact to provide solutions and improve outcomes for HHS programs and beneficiaries. OIG's current priority focus areas were selected based on past and ongoing work, top challenges facing HHS as identified annually by OIG, ability to collect data, and ability to influence outcomes.

Strike Force region: eastern, middle, and western districts of Tennessee; northern district of Alabama; eastern and western districts of Kentucky; northern and southern districts of West Virginia; southern district of Ohio; and most recently, western district of Virginia. The ARPO Strike Force has spearheaded takedowns in April and September 2019, resulting in charges against 73 individuals, including 64 medical professionals.

Collaboration With Public Health Partners

As part of the ARPO takedowns, OIG and our law enforcement partners worked in close collaboration with HHS's Office of the Assistant Secretary for Health (OASH), the Centers for Disease Control and Prevention (CDC), the Commissioned Corps of the U.S. Public Health Service, and the States' respective Departments of Health to deploy Federal and State-level strategies and resources to provide assistance to patients impacted by the law enforcement operations with additional information regarding available treatment programs and where they can turn for quality assistance. I will further discuss this new effort to ensure continuity of care and prevent patient harm later in my testimony.

In addition, OIG also implemented a pilot program providing OIG special agents in the ARPO region with a nasal spray version of naloxone—a drug that reverses the effects of an opioid overdose. The special agents were equipped and trained to treat any law enforcement officer who came into accidental contact with an opioid or any individual in medical distress caused by an opioid overdose encountered as part of the operations. OIG has expanded this program nation-wide to ensure that we are prepared to address agent and public needs that could arise as we engage in enforcement efforts.

Health-care Fraud Takedowns

Over the month of September, along with our Medicare Fraud Strike Force, several U.S. Attorney's Offices, and various other Federal, State, and local law enforcement agencies, OIG participated in a series of health-care fraud takedowns across the country. In total, these coordinated law enforcement activities resulted in charges against over 380 individuals, including 178 medical professionals and 105 defendants for opioid-related offenses, who allegedly billed Federal health-care programs for more than $3 billion and allegedly prescribed or dispensed approximately 50 million controlled substance pills.

Overall, the 2018 National and 2019 Regional and Appalachian Regional takedown efforts demonstrate OIG's commitment to rooting out fraud in HHS's opioid prescribing and treatment programs, helping to protect patients from harmful prescribing and worthless treatment services.

OIG'S OPIOID FRAUD ENFORCEMENT EFFORTS

Opioid fraud encompasses a broad range of criminal activity from prescription drug diversion to addiction treatment schemes. Many of these schemes are elaborate, involving multiple co-conspirators including healthcare professionals such as physicians, nonphysician providers, and pharmacists, and sometimes even beneficiaries or patients themselves. These investigations can be complex and often involve the use of informants, undercover operations, and surveillance.

Of particular concern is fraud involving medication-assisted treatment (MAT), sober homes, and ancillary services such as drug screening and urinalysis. Through our oversight of opioid treatment facilities, we have seen a recent increase in MAT-related prescription fraud cases, particularly those involving buprenorphine.

Case Examples

The following examples highlight common schemes involving prescription and treatment opioid-related fraud:

Prescription Fraud

In Maryland, OIG recently worked a joint case with Federal, State, and several local law enforcement agencies to investigate allegations that Starlife Wellness Center was operating as a pill mill, charging patients $400 or more in cash for each office visit in exchange for unlawful prescriptions for large quantities of narcotics. Patient deaths were attributed to the prescribing practices of Dr. Kofi Shaw-Taylor and Starlife owner/general manager Tormarco Harris. Ultimately, Dr. Shaw-Taylor and eight co-conspirators were all indicted and charged with a variety of crimes, pled guilty, and sentenced to prison. Harris was found guilty at trial and sentenced to 20 years incarceration without the possibility of parole, 5 years probation, and a $10,000 fine.

Treatment-Related Fraud

Dr. Rajaa Nebbari and Dr. Chethan Byadgi, owners/operators of a medical practice in Pennsylvania that operated as an urgent-care medical clinic and a Suboxone treatment facility, both pled guilty to one count each of Medicaid Fraud, Theft by Deception and Insurance Fraud. Dr. Nebbari and Dr. Byadgi admitted to defrauding Medicaid, Medicare Part D, Medicare Part B, and various private health insurers of between $100,000 and $500,000. The doctors admitted to directing unlicensed "Suboxone coordinators" to see, treat, counsel and prescribe Suboxone to opioid-addicted patients. As part of the scheme, the doctors provided the Suboxone coordinators with pre-signed prescription pads and let the Suboxone coordinators use Google to find information on how to treat drug-addicted patients with Suboxone and how to determine the dosage of Suboxone for the prescription. Both doctors were sentenced to 9–23 months imprisonment, 7 years probation, and 1,000 hours of community service to be directed toward those impacted by drug addiction. Additionally, both doctors were ordered to pay $198,189.06 in restitution to the Medical Assistance program, the Medicare Part B and D programs, and various private health insurance companies.

Enforcement Actions Against Manufacturers

Since first taking action against executives with Purdue Pharma in 2007, OIG has been at the forefront of enforcement efforts to hold opioid manufacturers accountable for the illegal marketing and distribution of opioids. Notably, OIG has been heavily involved with investigation of Insys Therapeutics, which in June of this year agreed to a global resolution to settle the government's separate criminal and civil investigations. Both the criminal and civil investigations, as well as the conviction of seven former executives (including the company's billionaire founder and CEO) in May, stemmed from Insys's payment of kickbacks and other unlawful marketing practices to illegally promote sales of Subsys, a sublingual fentanyl spray that is only approved by the Food and Drug Administration for the treatment of persistent breakthrough pain in adult cancer patients who are already receiving, and tolerant to, around-the-clock opioid therapy. Many of these kickbacks allegedly took the form of sham speaker programs designed to reward high-prescribing physicians with jobs for the prescribers' relatives and friends, and lavish meals and entertainment. Insys also is alleged to have improperly encouraged physicians to prescribe Subsys for patients who did not have cancer and lied to insurers about patients' diagnoses to obtain reimbursement for Subsys prescriptions that had been written for Medicare and TRICARE beneficiaries. This was the first successful prosecution of top pharmaceutical executives for crimes related to the prescribing of opioids.

Sentencing for the executives and the plea hearing for the global resolution have been set for next January. As part of the criminal resolution, Insys will agree to a detailed statement of facts outlining its criminal conduct and pay a $2 million fine and forfeiture of $28 million, while its operating subsidiary will plead guilty to five counts of mail fraud. As part of the civil resolution, Insys agreed to pay $195 million to settle allegations that it violated the False Claims Act. Insys also has entered into an unprecented 5-year Corporate Integrity Agreement and Conditional Exclusion Release with OIG.[2]

OIG has been heavily involved with the indictment of pharmaceutical company Indivior and subsequent resolution with its former parent company,[3] Reckitt Benckiser Group plc (RB Group) this year. In April 2019, a Federal grand jury indicted Indivior for allegedly engaging in an illicit nation-wide scheme to increase prescriptions of Suboxone. According to the indictment, Indivior—including during the time when it was a subsidiary of RB Group—promoted the film version of Suboxone (Suboxone Film) to physicians, pharmacists, Medicaid administrators, and others across the country as less divertible and less abusable and safer around children, families, and communities than other buprenorphine drugs, even though such

[2] Because of the extensive cooperation provided by Insys in the prosecution of culpable individuals and its agreement to enhanced CIA requirements, OIG elected not to pursue exclusion of Insys at this time. The CIA includes several novel provisions, including enhanced material breach provisions, designed to protect Federal health-care programs and beneficiaries. In addition, Insys admitted to a Statement of Facts and acknowledged that the facts provide a basis for permissive exclusion. OIG did not release its permissive exclusion authority, as it generally does for CIA parties in False Claims Act settlements. Instead, OIG will provide such a release only after Insys satisfies its obligations under the CIA *(https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal).*

[3] In December 2014, RB Group spun off Indivior Inc., and the two companies are no longer affiliated.

claims have never been established. The indictment further alleges that Indivior touted its "Here to Help" Internet and telephone program as a resource for opioid-addicted patients. Instead, however, Indivior used the program, in part, to connect patients to doctors it knew were prescribing Suboxone and other opioids to more patients than allowed by Federal law, at high doses, and in a careless and clinically unwarranted manner. The United States' criminal trial against Indivior is scheduled to begin in May 2020.

In the meantime, in July 2019 RB Group has agreed to pay $1.4 billion to resolve its potential criminal and civil liability related to a Federal investigation of the marketing of the opioid addiction treatment drug Suboxone. The resolution—the largest recovery by the United States in a case concerning an opioid drug—includes the forfeiture of proceeds totaling $647 million, civil settlements with the Federal Government and the States totaling $700 million, and an administrative resolution with the Federal Trade Commission for $50 million. The $700 million settlement amount includes $500 million to the Federal Government and up to $200 million to States that opt to participate in the agreement. As I said at the time of the resolution in July, with the Nation continuing to battle the opioid crisis, the availability of quality addiction treatment options is critical. When treatment medications are used, it is essential that they are prescribed carefully, legally, and based on accurate information, to protect the health and safety of patients in Federal health care programs.

Exclusions Actions

OIG protects federally funded health care programs by excluding certain dangerous or unscrupulous individuals and entities. Excluded providers cannot receive payment from Federal health-care programs for any items or services they furnish, order, or prescribe. OIG's criminal law enforcement efforts are complemented by its efforts to exclude problem providers from participating in Federal health-care programs. From the start of fiscal year 2018 through the end of fiscal year 2019, OIG has issued exclusion notices to 1,348 individuals (doctors, nurses, other providers, business owners/employees, etc.)—including 161 physicians, 896 nurses, and 87 pharmacists/technicians—and 15 entities (physicians' practices and other businesses) because of conduct related to opioid diversion and abuse.

OIG'S EFFORTS TO COMBAT THE OPIOID CRISIS GO BEYOND ENFORCEMENT

OIG continues to augment its robust portfolio of work related to the opioid crisis, with new and ongoing work that identifies opportunities to strengthen program integrity and protect at-risk beneficiaries across both the prescribing and treatment dimensions of the crisis. OIG currently has numerous opioid-related audits and evaluations underway covering multiple departmental programs, including questionable opioid prescribing patterns in Medicaid and Medicare; characteristics of Part D beneficiaries at serious risk of opioid misuse or overdose; beneficiary access to MAT through SAMHSA's Buprenorphine Waiver Program; SAMHSA's awarding of Opioid State Targeted Response (STR) grants; and opioid prescribing practices in the Indian Health Service.

Prescribing Oversight

In a series of reviews targeting provider oversight, OIG examined actions that selected States have taken using CDC and SAMHSA funds for enhancing prescription drug monitoring plans (PDMPs) to achieve program goals toward improving safe prescribing practices and preventing prescription drug abuse and misuse. In another series of reviews, OIG identified actions that selected States took related to their oversight of opioid prescribing and their monitoring of opioid use. Specifically, OIG reviewed the States' policies and procedures, data analytics, programs, outreach, and other efforts.

Treatment Oversight

SAMHSA estimates that 2 million people have an opioid use disorder related to prescription pain relievers and/or heroin. MAT provided by opioid treatment programs (OTPs) is a significant component of the treatment protocols for opioid use disorder (OUD) and plays a large role in combating the opioid crisis in the United States. SAMHSA issued final regulations to establish an oversight system for the treatment of substance use disorders with MAT. These regulations (42 CFR part 8) established procedures for an entity to become an approved accreditation body, which evaluates OTPs and ensures that SAMHSA's opioid dependency treatment standards are met. OIG has an ongoing review that examines whether SAMHSA's oversight of accreditation bodies complied with Federal requirements.

Separately, OIG is reviewing potential geographic disparities in access to MAT through SAMSHA's Buprenorphine Waiver Program, which enables patients to access MAT through regular doctor's offices—instead of limiting this service to OTPs. In this review, we are determining how many providers have received waivers to prescribe buprenorphine for MAT and whether they are located in counties likely to have high needs for opioid treatment services.

In July 2019, building on our extensive body of work related to the opioid crisis, which includes annual data briefs on opioid prescribing in Medicare Part D, OIG released a data brief on the 2018 Part D data, *Opioid Use Decreased in Medicare Part D, While Medication-Assisted Treatment Increased.* We found that nearly three in 10 Medicare Part D beneficiaries received an opioid in 2018, a significant decrease from the previous 2 years. At the same time, the number of beneficiaries receiving Part D drugs for MAT for OUD and the number of beneficiaries receiving prescriptions through Part D for naloxone both increased. The number of beneficiaries at serious risk of opioid misuse or overdose also decreased, along with the number of prescribers with questionable opioid prescribing for these beneficiaries. Despite this seeming progress, concerns remain. About 354,000 beneficiaries received high amounts of opioids in 2018, with almost 49,000 of them at serious risk of opioid misuse or overdose. Further, about 200 prescribers had questionable opioid prescribing for the beneficiaries at serious risk.

The data briefs help OIG and OIG's law enforcement partners investigate high prescribers for possible fraud. We are also referring actionable information with program integrity partners including the Centers for Medicare and Medicaid Services (CMS), States, and the Healthcare Fraud Prevention Partnership (HFPP), so that they can use tools at their disposal to address high-risk beneficiaries and prescribers that have questionable billing.

Data Analysis to Identify Questionable Prescribing, Dispensing, and Utilization of Opioids

OIG uses data analytics to detect and investigate healthcare fraud, waste, and abuse. We analyze billions of data points and claims information to identify trends that may indicate fraud, geographical hot spots, emerging schemes, and individual providers of concern. At the macro level, OIG analyzes data patterns to assess fraud risks across Medicare services, provider types, and geographic locations to prioritize and deploy our resources. At the micro level, OIG uses data analytics, including near-real-time data, to identify potential fraud suspects for a more in-depth analysis and efficiently target investigations.

Although OIG's increased utilization of data analytics enhances our enforcement and oversight efforts, there are still areas where we lack access to reliable data that hinders our work. For example, historically, Medicaid data have not been complete, accurate, and timely, and have not been adequate for national analysis and oversight. In August 2018, CMS announced that all States were submitting data to the national Medicaid database, known as the Transformed Medicaid Statistical Information System (T–MSIS), and that it was prioritizing T–MSIS data quality. OIG has a history of advocating for complete and accurate Medicaid data and is now monitoring whether the quality of T–MSIS is suitable for program enforcement and oversight activities. In fact, we have recently completed work assessing the completeness of variables needed to monitor national opioid prescribing in Medicaid. Complete and accurate T–MSIS data are critical for effective monitoring of the opioid crisis in Medicaid, as well as general program integrity efforts.

OIG MAXIMIZES IMPACT THROUGH STRONG COLLABORATION WITH PUBLIC AND PRIVATE PARTNERS

In addition to the Strike Force Operations and Opioid Fraud and Abuse Detection Unit law enforcement collaborations addressed earlier, OIG works closely with several HHS agencies on initiatives to prevent prescription drug and opioid-related fraud and abuse covering both the prescribing and treatment dimensions of the opioid crisis.

Collaboration With CDC on Opioid Rapid Response Teams

As our enforcement and oversight efforts to address the opioid crisis have expanded, we have come to understand the impact our enforcement work can have on the beneficiaries we serve. We recognize that when a clinic whose patients are prescribed opioids is shut down, access to care for patients, including many suffering from substance use disorders, can be disrupted. Rather than leaving these patients to potentially turn to another fraudulent provider or street drugs to meet their

needs, we believe that it is vital that those struggling with substance use disorder have access to treatment and that patients who need pain treatment do not see their care disrupted. The potential dangers of abrupt opioid withdrawal are well established and thoughtful dose tapering may help patients discontinue opioid use safely.

Ensuring that these patients have continuity of care requires a collaborative approach with our Federal, State, and local partners, which has led OIG to work closely with CDC on standing up their new Opioid Rapid Response Teams (ORRTs). The mission of this team is to work alongside law enforcement partners to address disruptions in care after a clinic closure by providing support to State, local, and tribal jurisdictions; providing clinicians with resources; conducting targeted outreach; expanding access to MAT; and building response capacity. OIG worked closely with CDC in the planning and development of the ORRTs. We advised them on protocols, connected them with other law enforcement partners, prepared data and support/educational materials, and continue to coordinate with them on deployment preparations to help focus their efforts to maximize impact. As part of the recent ARPO takedowns, OIG and our law enforcement partners coordinated closely with the CDC to make sure they were able to share their technical expertise with State and local officials and ensure that all impacted jurisdictions had sufficient response capacity to address the impact of takedown operations. OIG will continue to work hand in hand with our public health partners at the CDC to ensure access to treatment and continuity of care for beneficiaries impacted by our opioid-related law enforcement efforts moving forward.

Other Collaboration With the Department

OIG collaborates with a number of other HHS agencies, including CMS and the Agency for Community Living (ACL), on fraud and opioid-related initiatives. OIG collaborates with CMS and ACL to educate providers, the industry, and beneficiaries on the role each one plays in the prevention of prescription drug and opioid-related fraud and abuse. We share our analytic methods and data analysis with CMS and work together to identify mitigation strategies and develop follow-up approaches to deal with the prescribers and at-risk beneficiaries identified. OIG engages ACL's Senior Medicare Patrol and State Health Insurance Assistance Program through presentations on the prevention of fraud, waste, and abuse.

Additionally, in June 2018 OIG published a data analysis toolkit that our Federal, State, and private insurance partners can use to translate opioid prescriptions into a morphine equivalent does (MED) and identify patients who are at risk of opioid misuse or overdose. The CDC posted the toolkit to its public website aimed at researchers and analysts.

The Healthcare Fraud Prevention Partnership and the National Healthcare Anti-Fraud Association

OIG also engages with private-sector stakeholders to enhance the relevance and impact of our work to combat health-care fraud. The HFPP and NHCAA are public-private partnerships that address health-care fraud by sharing data and information for the purposes of detecting and combating fraud and abuse in health-care programs. OIG is an active partner in these organizations and frequently shares information about prescription-drug fraud schemes, trends, and other matters related to health-care fraud. We also share our expertise in data analytics, including the aforementioned toolkit and specific data resulting from takedown operations. Through our partnership in the HFPP and collaboration with the NHCAA, OIG strives to educate and empower private-sector insurers to best leverage data analytics and intelligence from the field to protect their own insured customer population. Likewise, OIG benefits from hearing directly from private and public partners about schemes and techniques used by other payers to combat healthcare fraud.

CONCLUSION

OIG has made combating the opioid crisis a top enforcement and oversight priority. We will continue to leverage our analytic, investigative, and oversight tools, as well as our partnerships with law enforcement, the program integrity community, and the Department to maximize our efforts to address both the prescribing and treatment dimensions of the crisis. OIG will remain vigilant in identifying and investigating emerging opioid fraud trends, especially schemes involving patient harm and abuse.

Thank you for affording me the opportunity to discuss this important topic with you.

QUESTIONS SUBMITTED FOR THE RECORD TO GARY CANTRELL

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. What policies does your office recommend that Federal, State, and local policymakers adopt to help reduce future scams in addiction treatment and recovery housing?

Answer. The Office of Inspector General (OIG) has not conducted audits or evaluations that specifically address how to reduce scams in addiction treatment and recovery housing, and as such we do not have formal recommendations to offer at this time. However, as we continue to carry out enforcement actions and identify vulnerabilities in this space, we will follow up to offer you and your staff a briefing.

Question. I understand that the OIG currently is assessing the effectiveness of States' efforts to monitor opioid treatment programs' services and medications in accordance with the Federal guidelines for opioid treatment programs. Can you share any preliminary findings or emerging trends that you have observed to date?

Answer. In March 2019, OIG published an audit report (A–02–17–02009) in which we found that New York failed to trace Substance Abuse Prevention and Treatment Block Grant (SABG) funds to a level of expenditure adequate to establish that the funds were used for their program's intended purpose. Specifically, New York used estimated expenditure data to advance SABG funds to providers and subsequently reported these payments as expenditures to the Substance Abuse and Mental Health Services Administration (SAMHSA). In addition, New York did not record information (*e.g.,* provider names) needed to effectively account for or trace the payments to SABG expenditures. By not implementing procedures for reporting actual expenditures and tracing payments, New York may have retained unexpended funds and hindered its ability to ensure that substance abuse prevention and treatment programs received the funds needed to provide timely interventions to people at risk for and suffering from substance use disorders. We also found that New York does not have procedures in place to determine whether providers accurately report Medicaid revenues. Specifically, the one opioid treatment provider we reviewed received more than $1.8 million in excess SABG funding from New York because the provider underreported Medicaid revenue on its fiscal report. This excess funding occurred because State agency staff who reconciled providers' fiscal reports did not have access to necessary data.

OIG also reviewed States' oversight of opioid prescribing and monitoring of opioid use. OIG published State fact sheets and a July 2019 audit report (A–09–18–01005) based on this work. The fact sheets list actions that States took in five categories: policies and procedures, data analytics, outreach, programs, and other efforts. The audit report contains State-by-State comparisons of actions that the initial eight States took related to the five categories, including opioid prescribing limits compared with the Centers for Disease and Control and Prevention's (CDC's) Guidelines for Prescribing Opioids for Chronic Pain.

QUESTIONS SUBMITTED BY HON. JOHN THUNE

Question. This summer, the Department's Inspector General issued a report on opioid dispensing at Indian Health Service (IHS) facilities. The report found that IHS hospitals did not always follow agency established prescribing and dispensing protocols and had IT vulnerabilities that could affect patient outcomes.

These problems included failure to complete agency established treatment follow up and drug testing for opioid patients, and failure to check medical records before dispensing opioids prescribed by non-IHS providers.

Can the IG project how widely these problems may be spread outside of the five facilities studied?

Answer. Our observations were specific to the five IHS-operated facilities that we visited, although some of our observations could apply more broadly because they were identified in all five hospitals. Therefore, we have recommendations for IHS to implement controls, including policies and procedures that will affect all IHS Federal facilities.

Question. When will the IG follow up to ensure the recommendations IHS agreed to are implemented?

Answer. In resolving Federal audit recommendations, IHS must comply with Office of Management and Budget Circular A–50, which requires "prompt resolution and corrective actions on audit recommendations. Resolution shall be made within a maximum of 6 months after issuance of a final report." As a result, IHS is required to prepare an OIG Clearance Document (OCD) and provide it to OIG within 6 months of the final report. The OCD is due to the OIG by January 16, 2020. The OCD will contain IHS's concurrence or non-concurrence decision, along with any action taken, for each recommendation. Once IHS submits the OCD, OIG will assess the actions taken, conduct any follow-up, and monitor the resolution of the recommendations.

QUESTIONS SUBMITTED BY HON. PATRICK J. TOOMEY

Question. How can the Federal Government coordinate and communicate better with private health plans in Medicare and Medicaid to ensure actions are being taken swiftly to root out the fraudulent behaviors of these addiction treatment facilities?

Answer. The Federal Government can better coordinate and communicate with private health plans through leveraging relationships with public-private program integrity partners such as the Healthcare Fraud Prevention Partnership (HFPP) and the National Healthcare Anti-Fraud Association (NHCAA).

HFPP and NHCAA are public-private partnerships that address health-care fraud by sharing data and information for the purposes of detecting and combating fraud and abuse in health-care programs. OIG is an active partner in these organizations and frequently shares information about prescription-drug fraud schemes, trends, and other matters related to health-care fraud. We also share our data analytics expertise as well as specific data resulting from takedown operations. Through our partnership in the HFPP and collaboration with the NHCAA, OIG strives to educate and empower private-sector insurers to best leverage data analytics and intelligence from the field to protect their own insured customer population. Likewise, OIG benefits from hearing directly from private and public partners about schemes and techniques used by other payers to combat health-care fraud.

We also note the new authorities granted under sections 2008 and 6063 of the SUPPORT [Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities] Act, which will enhance the ability of CMS and plan sponsors to share data and information regarding bad actors, take swift action based on such data and information, and enhance the means for more effective law enforcement referrals based on plan sponsor reporting.

Question. What impact is illicit fentanyl having on our country compared to illicit opioids?

Answer. OIG does not specifically investigate illicitly manufactured fentanyl, such as some types of "street" fentanyl that were illegally imported or smuggled into the United States, and so we would refer you to the Surgeon General, CDC, and SAMHSA for HHS information on this issue. OIG does, however, investigate allegations of fraud and abuse involving prescription fentanyl products that are legitimate Food and Drug Administration-approved medications, but then become "illicit" when they are prescribed without medical necessity or diverted from the normal chain of commerce through Federal health-care programs. For example, our investigators and attorneys have been heavily involved with the recent criminal and civil investigations of Insys Therapeutics over allegations involving the unlawful marketing of Subsys, a sublingual fentanyl spray. In May 2019, seven of Insys Therapeutics' former executives were convicted. In June 2019, the company agreed to a global resolution to settle the government's separate criminal and civil investigations. As part of the criminal resolution, Insys will agree to a detailed statement of facts outlining its criminal conduct and pay a $2 million fine and forfeiture of $28 million, while its operating subsidiary will plead guilty to five counts of mail fraud. As part of the civil resolution, Insys agreed to pay $195 million to settle allegations that it violated the False Claims Act.

Additionally, at an operational level, the spread of illicit fentanyl poses unique safety risks. Given fentanyl's lethality even in very small doses, OIG now equips our agents in the field with naloxone, a drug that can be administered to reverse opioid overdoses.

Question. If a drug treatment facility does not have to be certified, how do consumers, States and the Federal Government and other payers ensure it is providing the resources it advertises?

Answer. Although we have no ongoing work related to facilities that have not been certified, we currently have ongoing work on SAMHSA's Oversight of Accreditation Bodies for Opioid Treatment Programs (W–00–18–59035). SAMHSA issued final regulations to establish an oversight system for the treatment of substance use disorders with MAT. These regulations (42 CFR part 8) established procedures for an entity to become an approved accreditation body, which evaluates Opioid Treatment Programs and ensures that SAMHSA's opioid dependency treatment standards are met. Our objective is to determine whether SAMHSA's oversight of accreditation bodies complied with Federal requirements. We will reach out to your office to offer a briefing for you or your staff as soon as we have findings we can share.

Question. Do any of the States stand out as high performers when it comes to oversight and regulation of addiction treatment centers? Please provide examples.

Answer. OIG has no work looking at this specific issue.

Question. How much money do Federal insurance programs (FEHB, TRICARE, Medicare, Medicaid, etc.) spend on drug treatment and how much of it is suspected of being fraud? What, if any, are the challenges in quantifying this?

Answer. OIG has no work looking at this specific issue.

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. Prior to the hearing, the Office of Inspector General (OIG) told my staff that there were numerous examples of drug treatment providers that OIG had investigated. Your written testimony furthermore stated that "[o]f particular concern is fraud involving medication-assisted treatment (MAT), sober homes, and ancillary services such as drug screening and urinalysis. Through our oversight of opioid treatment facilities, we have seen a recent increase in MAT-related prescription fraud cases, particularly those involving buprenorphine." However, your testimony only cited one specific example of such fraud and provided no statistics to substantiate the claim of increased MAT-related fraud. In order to gain a more comprehensive understanding of the changing scope of MAT-related fraud:

Please provide data regarding the OIG's MAT-related caseload on an annual basis since 2013 that substantiates the "recent increase in MAT-related prescription fraud cases," referred to in your testimony. Examples of such data are the number of arrests, convictions, settlements and convictions related specifically to MAT fraud; the dollar value of MAT-related fraud schemes; and the dollar value of restitution paid in relation to settlements and convictions.

Answer. Please find our response to this QFR on the following page.

National Opioid Addiction Treatment Cases

	CY 2013	CY 2014	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	Totals
Complaints Received	6	7	6	14	23	37	34	5	132
Cases Opened	5	5	6	14	20	33	36	7	126
Indictments	0	0	2	9	13	34	47	6	111
Criminal Actions	0	0	0	0	8	9	26	10	53
Civil/CMPL Actions	0	0	5	6	2	5	7	0	25
Expected Receivables	$–	$–	$12,871,210	$13,039,631	$1,906,052	$20,470,279	$1,430,579,113	$31,400,254	$1,510,266,539

Important Points to Note Regarding This Data:

- This data includes all cases where substance use disorder treatment was a primary focus of the investigation. Our criteria for inclusion incorporate a wide variety of fraud schemes, including medication-assisted treatment (MAT)-related prescription fraud cases, sober homes, false behavioral health service claims, fraud in ancillary services such as drug screening and urinalysis, and other illicit conduct.
- However, it is important to note that since many MAT medications (*i.e.,* buprenorphine) are opioids, OI cases where MAT diversion is present but secondary to a larger opioid diversion scheme are not captured above and are aggregated under our broader drug-related statistics. For this reason, we have also included a table providing data for the last 4 fiscal years of our drug related cases below.

OI Drug-Related Stats CY 2016–CY 2020

(using allegations 387-Drug Controlled Substances, 393-Drug Diversion, 320-Drug Trafficking)

	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	5-Year Total
Complaints Received	280	404	480	348	58	1,570
Cases Opened	214	325	389	337	30	1,295
Cases Closed	171	177	215	269	71	903
Indictments	153	201	335	271	17	977
Criminal Actions	144	118	139	235	39	675
Civil/CMPL Actions	2	11	19	5	1	38
Total Money	$383,816,380	$30,259,188	$37,346,644	$56,026,597	$12,827,072	$520,275,881
Cases Worked Jointly With DEA	308	382	544	596	463	2,293

Question. My staff gathered the following examples of fraudulent substance use disorder treatment schemes. Please confirm whether the examples gather by my staff are consistent with the types of "MAT-related prescription fraud" referred to in your testimony. Please provide additional examples of such schemes.

2015

Massachusetts—A physician was sentenced to serve 11 months in prison and ordered to pay $9.3 million in restitution for providing kickbacks from Medicaid reimbursements, filing false Medicaid claims, and larceny. The physician owned 29 medical branches throughout Massachusetts and engaged in a complex scheme to pay bribes and kickbacks to sober home owners to have their residents use his labs for urine drug screenings, even though these residents were never treated by any of the provider's offices. The physician billed tens of thousands of urine drug tests to the Massachusetts Medicaid program (MassHealth), which generally reimburses providers $100 to $200 per test.

2016

Virginia—Owners of a lab and an addiction treatment practice were sentenced to 3 years in prison and ordered to pay more than $1.4 million in restitution for billing the Virginia and Tennessee Medicaid programs, Medicare, and other insurers between $120 and $1,800 for medically unnecessary urine drug screenings. Insurance programs were billed for these tests twice a week for each patient, and tests were not used to direct patient care.

2017

Pennsylvania—Two physicians were sentenced to 9 to 23 months each in county prison and ordered to pay $200,000 in restitution for felony conspiracy to commit unentitled reimbursement, theft by deception, and insurance fraud; their medical licenses were also suspended for 3 years. The physicians directed untrained, non-physician, staff members to write prescriptions for Suboxone and submitted false claims to Medicaid, Medicare, and private insurance showing that the physicians performed these services.

Florida—A total of 124 defendants were charged with offenses relating to their alleged participation in various fraud schemes involving over $337 million in false billings of Medicaid, Medicare, and other Federal health-care programs for services including substance abuse treatment and lab testing fraud, among other charges, as part of the annual Federal National Healthcare Fraud Takedown. The defendants allegedly participated in schemes to submit claims to Medicare, Medicaid, TRICARE, and private insurance companies for treatments that were medically unnecessary and often never provided. In many cases, patient recruiters, beneficiaries, and other co-conspirators were allegedly paid cash

kickbacks in return for supplying beneficiary information to providers, so that the providers could then submit fraudulent bills to Medicare for services that were medically unnecessary or never performed. Collectively, the doctors, nurses, licensed medical professionals, health care company owners and others charged are accused of submitting a total of over $2 billion in fraudulent claims.

2018

Pennsylvania—Four doctors were sentenced to 24 to 48 months in prison and ordered to pay more than $4.6 million in restitution for conspiracy to distribute controlled substances, distribution of controlled substances, and health-care fraud. The physician owner of a medical clinic and employed physicians prescribed large doses of Suboxone and Klonopin together to patients regardless of medical need in exchange for large cash payments. Expert opinion is that these two medications should never be prescribed together except in rare cases when medically necessary. The physician owner also helped his customers to pay for these illegally prescribed drugs by providing false information to health insurance companies.

2019

Pennsylvania—A physician operating as the medical director of a network of addiction treatment centers was sentenced to 37 months in prison and ordered to pay $2,484,864 in restitution. The sentencing included health-care fraud, signing blank prescription forms and patient orders and ordering medically unnecessary testing for patients he never saw. Two other individuals were also charged in connection with this health-care fraud scheme. A State grand jury investigation also found that employees of these treatment centers signed up vulnerable patients for "platinum" insurance policies and paid their premiums in order to bill private insurance companies about $17 million between July 2015 and early 2018 for treatment that was substandard, medically unnecessary, or not rendered. Employees also directed patents to live at facility-owned, unlicensed sober homes, where they were not permitted to come and go freely, were subjected to residents' use of drugs and alcohol, making them susceptible to relapse (and overdose), and subject to sexual harassment and abuse.

Ohio—A recovery center owner and five employees pleaded guilty in Federal court to crimes related to a health care fraud conspiracy. Between January 2015 and October 18, 2017, the defendants submitted billing to Medicaid for drug and alcohol services that were coded to reflect a service more costly than was actually provided without proper documentation or valid diagnoses, billing for patients whose records did not contain a physician diagnosis, billing for case management services that were not provided (clients were working out at the recovery center owner's gym, and billing for inpatient detox and drug treatment services that were provided in an outpatient setting), among other violations. The recovery center submitted over 100,000 claims to Medicaid for more than $48.5 million in services it claimed to provide between May 2015 and October 2017, which resulted in Medicaid reimbursements of more than $31 million.

Answer. The following are additional examples compiled by HHS OIG:

- **Addiction Specialist, Inc.**—A doctor and his wife owned a behavioral health center through which they fabricated mental health treatment records for payment and falsified patient names to get Medicaid to pay for Suboxone. Mental health "therapy" was provided to patients by unqualified employees who had no training in behavioral health. Suboxone and methadone accounting/control on site was poor, and individuals who were not actual patients were given prescriptions.
  https://www.justice.gov/usao-wdpa/pr/health-care-fraud-charge-filed-fayette-county-addiction-specialists-inc-case
- **Mt. Holly Family Practice, Inc.**—A North Carolina physician who owned, managed, and was sole practitioner of an office-based opioid treatment practice, treated a large volume of Medicaid patients for substance abuse and pain management issues. He coerced patients into sexual encounters in exchange for controlled substance prescriptions and also fraudulently billed these sexual encounters as office visits to Federal health-care programs.
  https://www.justice.gov/usao-wdnc/pr/former-north-carolina-physician-pleads-guilty-drug-distribution-health-care-fraud-and
- **LabTox, LLC**—This Kentucky lab billed for urine drug screens that they could not have possibly run because they did not have the necessary equip-

ment. These services were billed to Medicare and Medicaid. LabTox agreed to pay $2.1M.

https://www.justice.gov/usao-edky/pr/lexington-laboratory-agrees-pay-21-million-resolve-allegations-false-claims-urine-drug

- **Redirections Treatment Advocates, LLC**—The owner, operations manager, and several doctors practicing at Redirections Treatment Advocates, LLC, a buprenorphine clinic with offices in Pennsylvania and West Virginia, received various sentences for conspiring together to create and submit unlawful prescriptions for buprenorphine and then unlawfully dispensed those controlled substances to the clinic's patients. Doctors at Redirections would routinely pre-sign blank prescriptions for buprenorphine, which were then given to other medically unlicensed employees at Redirections who completed the prescription and provided it to the patients in exchange for cash. On numerous occasions, the doctors were not physically present at Redirections and did not exam their patients when prescriptions bearing their names were issued.

  https://www.justice.gov/usao-wdpa/pr/contracted-physician-operations-manager-redirections-treatment-advocates-sentenced

  https://www.justice.gov/usao-wdpa/pr/former-suboxone-clinic-doctor-sentenced-illegal-prescribing-and-health-care-fraud

  https://www.justice.gov/usao-wdpa/pr/opioid-treatment-practice-owner-sentenced-illegal-distribution-buprenorphine-and-health

  https://www.justice.gov/usao-ndwv/pr/pennsylvania-physician-sentenced-drug-charge

- **Health and Wellness Medical Center and Health and Wellness Pharmacy**—The owners and managers of Health and Wellness Medical Center, a Suboxone clinic, and affiliated Health and Wellness Pharmacy, along with a doctor employed by the center, conspired to commit a health-care fraud scheme that included billing Medicaid for compound creams that were not provided or were not medically necessary, prescribing and distributing Suboxone without medical necessity, and submitting fraudulent claims to Medicaid for psychotherapy services that were never rendered to patients.

  https://www.justice.gov/usao-sdoh/pr/jury-convicts-doctor-health-care-fraud-distributing-controlled-substances-through-pain

  https://www.justice.gov/usao-sdoh/pr/husband-and-wife-sentenced-prison-health-care-fraud

- **Cherry Way**—The owner/operator and medical director of Cherry Way, a suboxone clinic, conspired together to create and submit unlawful prescriptions for Suboxone, Adderall, and Percocet, and then unlawfully dispensed those controlled substances.

  https://www.justice.gov/usao-wdpa/pr/medical-director-bridgeville-suboxone-clinic-pleads-guilty-unlawfully-distributing

- **SKS Associates**—A prescribing physician with SKS Associates, an opioid treatment facility in Johnstown, PA, pled guilty to creating and submitting unlawful prescriptions for buprenorphine, and then unlawfully dispensing those controlled substances to other persons. This doctor also committed health-care fraud by submitting fraudulent claims to Medicare for payments to cover the costs of the unlawfully prescribed buprenorphine.

  https://www.justice.gov/usao-wdpa/pr/suboxone-clinic-doctor-pleads-guilty-unlawfully-dispensing-controlled-substances-health

- **Family Medicine Doctor**—A doctor operated an addiction-medicine practice out of offices in Greensburg and Connellsville, PA, through which he pled guilty to unlawfully prescribing buprenorphine to undercover law enforcement officers, billing Medicare and Medicaid to cover the costs of fraudulent buprenorphine prescriptions that he wrote for his patients—even though he did not accept insurance/required his patients to pay in cash, and money laundering of cash proceeds from his illicit prescribing at a casino.

  https://www.justice.gov/usao-wdpa/pr/greensburg-physician-pleads-guilty-drug-distribution-health-care-fraud-and-money.

- **Advance Healthcare, Inc.**—The co-owner of Advance Healthcare, Inc., a drug treatment center in Weirton, WV, conspired with two physicians and other employees to illegally sell/distribute controlled substances, including Suboxone.

https://www.justice.gov/usao-ndwv/pr/two-west-virginia-physicians-and-business-partner-indicted-illegally-distributing-drugs

https://www.justice.gov/usao-ndwv/pr/hancock-county-addiction-center-co-owner-admits-illegally-selling-suboxone

https://www.justice.gov/usao-ndwv/pr/west-virginia-physician-convicted-illegal-opioid-distribution-patients

https://www.justice.gov/usao-ndwv/pr/west-virginia-physician-sentenced-illegal-opioid-distribution-patients

https://www.justice.gov/usao-ndwv/pr/west-virginia-physician-found-guilty-illegally-distributing-drugs

https://www.justice.gov/usao-ndwv/pr/west-virginia-physician-sentenced-illegally-distributing-drugs

- **Indivior**—In April 2019, a Federal grand jury indicted Indivior for allegedly engaging in an illicit nation-wide scheme to increase prescriptions of Suboxone. According to the indictment, Indivior—including during the time when it was a subsidiary of Reckitt Benckiser Group plc (RB Group)—promoted the film version of Suboxone (Suboxone Film) to physicians, pharmacists, Medicaid administrators, and others across the country as less divertible and less abusable and safer around children, families, and communities than other buprenorphine drugs, even though such claims have never been established. The indictment further alleges that Indivior touted its "Here to Help" Internet and telephone program as a resource for opioid-addicted patients. Instead, however, Indivior used the program, in part, to connect patients to doctors it knew were prescribing Suboxone and other opioids to more patients than allowed by Federal law, at high doses, and in a careless and clinically unwarranted manner. The United States' criminal trial against Indivior is scheduled to begin in May 2020.

  https://www.justice.gov/usao-wdva/pr/indivior-inc-indicted-fraudulently-marketing-prescription-opioid

- **RB Group Settlement**—In July 2019 RB Group agreed to pay $1.4 billion to resolve its potential criminal and civil liability related to a Federal investigation of the marketing of the opioid addiction treatment drug Suboxone. The resolution—the largest recovery by the United States in a case concerning an opioid drug—includes the forfeiture of proceeds totaling $647 million, civil settlements with the Federal Government and the States totaling $700 million, and an administrative resolution with the Federal Trade Commission for $50 million. The $700 million settlement amount includes $500 million to the Federal Government and up to $200 million to States that opt to participate in the agreement.

  https://www.justice.gov/opa/pr/justice-department-obtains-14-billion-reckitt-benckiser-group-largest-recovery-case

- As a matter of general policy, HHS Office of Investigations does not discuss ongoing investigations. Accordingly, it is important to note that many of our germane case examples are still open matters that have not been adjudicated so we cannot discuss any of these in detail at this time. That being said, our active investigations also touch upon the following types of schemes:

  A sober home flying in patients after being told they "won" a scholarship for treatment and then, once there, patients being encouraged to abuse drugs on the condition of submitting to multiple drug tests and mental health therapy sessions per week. This type of scheme can also involve kickbacks being paid and false billing to patients' insurance plans. Patients in such schemes are often allowed to stay as long as they allowed billing to occur and are given access to high levels of controlled substances, buprenorphine products, and benzodiazepines. Patient files in such cases also typically lack continuity of care and reflect insurance billings for services like urine drug screens, despite absence of documentation for such testing in the medical record.

  A lab company stealing the practice identity of legitimate medical providers and then using the stolen identities to order medically unnecessary urine drug tests.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

STATE TARGETED RESPONSE TO OPIOID CRISIS GRANTS

Question. Much like the rest of the country, Maryland has been impacted by the opioid epidemic. In 2017, there were almost 2,000 overdose deaths involving opioids, and Maryland ranks in the top five States for opioid-related overdose rates.

To help States address the opioid crisis, the Federal Government created the State Targeted Response to Opioid Crisis Grants. This is a 2-year grant program that helps States supplement their existing opioid prevention and treatment programs and recovery support activities with Federal dollars. For Fiscal Year 2019, Maryland received over $32.9 million from this Federal grant program. As you know, States are able to use this grant funding for treatment programs and recovery housing like sober homes.

Since some of the sober homes could receive Federal funding under the State Targeted Grant Program, are there any guardrails in place to certify grant recipients who are recovery programs or other treatment programs are effective and safe for patients? If not, what should Congress consider in ensuring Federal funding for opioid treatment programs do not unintentionally fund bad actors like these sober homes?

Answer. Although we have no ongoing work related to sober home facilities, we currently have ongoing work on SAMHSA's Oversight of Accreditation Bodies for Opioid Treatment Programs (W–00–18–59035). SAMHSA issued final regulations to establish an oversight system for the treatment of substance use disorders with MAT. These regulations (42 CFR part 8) established procedures for an entity to become an approved accreditation body, which evaluates Opioid Treatment Programs and ensures that SAMHSA's opioid dependency treatment standards are met. Our objective is to determine whether SAMHSA's oversight of accreditation bodies complied with Federal requirements. We would be happy to brief your staff as soon as we have findings we can share.

INVESTIGATING PATIENT BROKERING AND EDUCATING CONSUMERS

Question. Ms. Donna Johnson, a mother of four from Frederick, detailed in a *Baltimore Sun* article how her then 21-year-old son was caught in the sober home cycle scam. Over a 4-year period, her son cycled through more than two dozen sober homes and treatment facilities, receiving little actual therapy. It all began with a patient broker who lured her son to South Florida with the promise of treatment, and resulted in tens of thousands of dollars in fraudulent charges to her insurance company for drug testing that her son never received.

GAO's 2018 report pointed to unnecessary or fraudulent testing as central to sober home scams; in one instance, an insurance provider was billed close to $700,000 for urine testing in a 7-month period.

In my State, State representatives from Frederick, MD are reportedly drafting a bill that would outlaw the practice of patient brokering for substance use disorder treatment. Also, the SUPPORT for Patients and Communities Act included a provision based on a Rubio/Klobuchar bill making patient brokering illegal and subjects those found guilty to a fine of up to $200,000 or 10 years in prison, or both.

Since the SUPPORT Act was enacted, have Federal prosecutors been able to curb patient brokering with the threat of fines and prison terms?

Has the Department of Justice brought forth an increased number of cases to prosecute instances of patient brokering?

Are there additional authorities needed to investigate and prosecute patient brokering?

Answer. Under the Inspector General Act and Health Insurance Portability and Accountability Act, OIG has authority to conduct investigations relating to HHS programs and operations, including fraud relating to the Medicare and Medicaid programs. Although the Affordable Care Act does provide OIG with the authority for limited oversight of private insurers (largely those participating in exchanges), HHS OIG does not have the authority to conduct oversight of private insurance companies or their executives or for billings by their providers and suppliers, for example. We refer you to the Federal Bureau of Investigation and Department of Justice to obtain information about the investigation and prosecution of cases of private insurance fraud when such schemes constitute Federal criminal violations under the

Eliminating Kickbacks in Recovery Act of 2018 (EKRA) (18 U.S.C. 220) or another Federal statute.

Question. Do you know if Federal agencies are collaborating with State and local governments to inform consumers of the dangers of sober homes and patient brokering practices? If not, what could the Federal Government do to educate consumers about quality treatment programs for their loved ones and how to identify patient brokering scams?

Answer. OIG does not have any work specific to this question.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

STATE CAPACITY TO ADDRESS FRAUD

Question. Testimony from both the Government Accountability Office (GAO) and the Office of the Inspector General (OIG) presented during this hearing detailed examples of several States that have rigorously investigated and taken action against fraudulent providers in their States.

In your experience investigating substance use disorder (SUD)-related fraud, do you both believe States are doing a good job of addressing fraud, and would you say they maintain the tools and authority necessary to police this fraudulent behavior? What more tools should Congress consider creating to ensure any fraud is addressed?

Answer. OIG notes that the Federal Government relies on our partnerships with States in addressing substance use disorder (SUD), and that State oversight of SUD treatment services varies across the country. This variance will continue to be a factor in our assessment of the issues surrounding SUD treatment services to beneficiaries with SUD, including SUD-related fraud. Although we recognize that States will vary in their approaches, we recognize the value in strong, consistent oversight at the State level. A pertinent cautionary example of this—and a topic raised by Senator Cassidy's question at the hearing about the Transformed Medicaid Statistical Information System—is the lack of complete, accurate, and timely national Medicaid data, which has hampered the ability to combat Medicaid provider fraud at a national level. Although OIG and the other witnesses on the panel at the hearing did testify about the challenges in finding a one-size-fits-all solution, OIG continues to assess these issues to determine where there is an appropriate link or opportunity for the OIG to look at Medicaid providers, owners, and affiliations who are offering SUD treatment services to beneficiaries with SUD (*e.g.,* those who reside in sober homes) to determine OIG's role in this area.

PERPETRATORS OF FRAUD

Question. During the hearing, I asked both you and Dr. Denigan-Macauley about who tends to be the perpetrator of fraud in the situations you have investigated. As you both testified, in the vast majority of cases, it is treatment providers who are engaging in troublesome practices at the expense of patients. More often, patients are the victim.

Do you believe that going after patients as if they are scam artists is an effective method of preventing this type of fraud?

Answer. In most cases, we do not investigate patients, as they are most often the victims of such schemes. However, if we uncover evidence that a patient is diverting drugs or conspiring to commit health-care fraud, we would pursue an investigation of such conduct as circumstances warrant.

Question. Given that the culprits in these scenarios are providers/schemers and the victims are the patients they broker/fail to provide quality treatment to, would you agree that regulations that may restrict patient access to addiction treatment is not the appropriate way to tackle fraud in this space?

Answer. With the caveat that our response should not be interpreted as commenting on any pending legislation, regulation, or policy proposal, we recognize the importance of ensuring that beneficiaries receive appropriate care and note that restricting patient access to treatment may negatively impact those suffering from SUD. We support ensuring patients have access to addiction treatment in conjunction with appropriate oversight to ensure quality of services and prevent fraud.

SUBMITTED BY HON. STEVE DAINES,
A U.S. SENATOR FROM MONTANA

FEDERAL LAW ENFORCEMENT OFFICERS ASSOCIATION
7945 MacArthur Blvd., Suite 201
Cabin John, MD 20818
Phone: 202–870–5503
https://www.fleoa.org/

October 24, 2019

The Honorable Chuck Grassley
Chairman
U.S. Senate
Committee on Finance
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
U.S. Senate
Committee on Finance
Washington, DC 20510

Dear Mr. Chairman and Ranking Member Wyden,

The Federal Law Enforcement Officers Association *(www.fleoa.org)* is the Nation's largest non-partisan professional association representing Federal law enforcement officers. With over 27,000 members from across all 65 Federal law enforcement agencies, FLEOA's members are on the front lines of protecting and defending America. As America's experts on Federal law enforcement, we request this letter be included in the official hearing record.

The committee's hearing today titled "Treating Substance Misuse in America: Scams, Shortfalls, and Solutions" is aptly titled. Within the ranks of American law enforcement, one theme is constant and that is, many drug treatment centers fail at their mission and often have an inverse effect of creating better addicts and expanding a local drug distribution network. The end result is often individuals that go in looking for help, leave and return to a life of addiction and crime.

Federal law enforcement officers across America see these tragic results every day. They do a tremendous job working to stop the flow of illicit drugs into America, responding to substance abuse infused incidents and are often the backstop when treatment fails and these individuals fall into the criminal justice system. Unfortunately, as law enforcement professionals we know that addiction is a problem that can't solve by just arrest and incarceration. It needs to be solved with proven and validated programs that address an addicts issues and help that individual become a productive member of society.

FLEOA believes that this is due in large part to a non-existent Federal regulatory structure, no certification requirements for these facilities and a patchwork of State licensing requirements that often fail to even mandate that a facility is actually conducting treatment for substance abuse.

Within the ranks of FLEOA, it is hard to find an individual whose family has not been touched by substance abuse. Our new Executive Director Donald Mihalek lost his sister Denise in July of this year due to an accidental overdose. The story of his sister Denise is the same as many American families, in and out of drug abuse treatment centers—all failing to provide the treatment they advertised. This widespread fraud is being perpetrated against some of the most vulnerable among us—those dealing with substance abuse and their families looking for help.

In our profession, we've identified some key areas that we feel if focused on, could change the dynamic of substance abuse treatment in America.

First, there is no clear Federal standard for a substance abuse treatment center. To date, the States are allowed to self-regulate what a treatment center looks like. This has created a patchwork where a treatment center in one State looks markedly different than in another. Having a clear Federal standard would help States and treatment centers be able to know exactly what they should be providing. It would also allow easier cross State treatment as individuals would know, like a hospital, that they would receive the same standard of treatment wherever they go.

Second, unlike other medical establishments such as hospitals, rehabilitation facilities, and nursing homes, there is no certification requirement for a substance abuse

treatment center. Treatment centers around our Nation are allowed to exist with no mandate of certification. Every law enforcement agency in our Nation must undergo a certification process, every hospital and school must—how are we allowing substance abuse treatment facilities to exist without having to go through a certification process?

Third, America is paying for inadequate, ineffective, and often failure-ridden substance abuse treatment. The rate of relapse is high for substance abuse, arguably because real treatment is not occurring in many facilities yet they take our insurance dollars as payment. Many articles have been written about the "substance abuse treatment for profit" situation that exists throughout the country, yet the Federal Government, the Nation's largest health insurer, is paying for it.

Every Federal insurance plan, from FEHB, TRICARE, Medicaid, Medicare to all others that are paid for by the Federal Government should be prohibited from paying for treatment at facilities that don't work. This one step may fundamentally change treatment in America.

The Congress has an important role to play in reframing the nature of substance abuse treatment in America. The failure, fraud and farce must stop and should be addressed in a holistic way that stops this fraud being perpetrated against people desperate for help and drive substance abuse treatment to a better place.

We look forward to working with the committee to address this dangerous issue, support our law enforcement officers and ensure that in every way, America provides the resources necessary to address the substance abuse issue that if tackled, can only make America stronger and better.

We are always available to provide our subject matter expertise on this issue.

Sincerely,

Larry Cosme
National President

PREPARED STATEMENT OF MARY DENIGAN-MACAULEY, PH.D., DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE

SUBSTANCE USE DISORDER: PREVALENCE OF RECOVERY HOMES, AND SELECTED STATES' INVESTIGATIONS AND OVERSIGHT

Why GAO Did This Study

Substance abuse and illicit drug use, including the use of heroin and the misuse of alcohol and prescription opioids, is a growing problem in the United States. Individuals with a substance use disorder may face challenges in remaining drug- and alcohol-free. Recovery homes can offer safe, supportive, drug- and alcohol-free housing to help these individuals maintain their sobriety and can be an important resource for recovering individuals. However, as GAO reported in March 2018, some States have conducted investigations of potentially fraudulent practices in some recovery homes.

This statement describes (1) what is known about the prevalence of recovery homes across the United States; and (2) investigations and actions selected States have undertaken to oversee such homes. It is largely based on GAO's March 2018 report (GAO–18–315). For that report, GAO reviewed national and State data, among other things, and interviewed officials from the Department of Health and Human Services, national associations, and five States—Florida, Massachusetts, Ohio, Texas, and Utah. GAO selected these States based on their rates of opioid overdose deaths, their rates of dependence or abuse of alcohol and other drugs, and other criteria.

What GAO Found

In March 2018, GAO found that the prevalence of recovery homes (*i.e.,* peer-run or peer-managed drug- and alcohol-free supportive homes for individuals in recovery from substance use disorder) was unknown. Complete data on the prevalence of recovery homes were not available, and there was no Federal agency responsible for overseeing recovery homes that would compile such data. However, two national organizations collected data on the prevalence of recovery homes for a subset of these homes.

- The National Alliance for Recovery Residences (NARR), a national nonprofit and recovery community organization that promotes quality standards for recovery homes, collected data only on recovery homes that sought certification by some of its State affiliates. As of January 2018, NARR told us that its affiliates had certified almost 2,000 recovery homes, which had the capacity to provide housing to over 25,000 individuals.
- Oxford House, Inc. collected data on the number of individual recovery homes it charters. In its 2018 annual report, Oxford House, Inc. reported that there were 2,542 Oxford Houses in 45 States.

The number of recovery homes that were not affiliated with these organizations was unknown.

In March 2018, GAO also found that four of the five States in its review—Florida, Massachusetts, Ohio, and Utah—had conducted, or were in the process of conducting, investigations of potentially fraudulent recovery home activities in their States. Activities identified by State investigators included schemes in which recovery home operators recruited individuals with substance use disorder to specific recovery homes and treatment providers, and then billed those individuals' insurance for extensive and unnecessary drug testing for the purposes of profit. For example, officials from the Florida State attorney's office told GAO that, in some instances, substance use disorder treatment providers were paying $300 to $500 or more per week to recovery home operators for every individual the operators referred for treatment. Then, in one of these instances, the provider billed an individual's insurance for hundreds of thousands of dollars in unnecessary drug testing over the course of several months. Further, these officials told GAO that as a result of these investigations at least 13 individuals were convicted and fined or sentenced to jail time.

To increase oversight, officials from three of the five States—Florida, Massachusetts, and Utah—said they had established State certification or licensure programs for recovery homes in 2014 and 2015. Officials from the other two States—Ohio and Texas—had not established such programs, but were providing training and technical assistance to recovery homes.

Chairman Grassley, Ranking Member Wyden, and members of the committee:

I am pleased to be here today to discuss our recent report on recovery homes. Substance abuse and illicit drug use, including the use of heroin and the misuse of alcohol and prescription opioids, is a growing problem in the United States. Individuals recovering from substance use disorder (SUD) face challenges remaining alcohol or drug free. Recovery homes can offer safe, supportive, stable living environments to help individuals recovering from SUD maintain an alcohol- and drug-free lifestyle. The Substance Abuse and Mental Health Services Administration (SAMHSA) within the Department of Health and Human Services (HHS) is responsible for promoting SUD prevention, treatment, and recovery services to reduce the impact of SUD on communities, which includes some activities to support recovery homes.[1]

We have a growing body of work examining policies and oversight of SUD-related services, including recovery homes. We reported in March 2018 that some States have conducted criminal investigations into recovery home operators and associated SUD treatment providers within their States who have engaged in potential health insurance fraud and exploited residents for the purpose of profit. These investigations included potential fraud that involved Medicaid—which is one of the largest payers of SUD treatment in the United States.[2]

My testimony today focuses on

1. What is known about the prevalence of recovery homes across the United States; and

---

[1] SAMHSA activities include issuing best practices and suggested guidelines, and making some funds available to States for recovery homes.

[2] Medicaid is a joint Federal-State program that funded medical and other health-care-related services for an estimated 75 million low-income and medically needy individuals in fiscal year 2018. According to SAMHSA, in 2015, total spending on SUD treatment across the United States was $56 billion, and Medicaid spending on SUD treatment accounted for 25 percent of this total. See SAMHSA, *Behavioral Health Spending and Use Accounts 2006–2015,* HHS Pub. No. (SMA) 19–5095 (Rockville, MD: 2019). While recovery homes are not eligible providers for the purposes of billing Medicaid, SUD treatment providers may enroll and bill Medicaid.

2. Investigations and actions selected States have undertaken to oversee recovery homes.

My statement today is largely based on our March 2018 report describing information on recovery homes.[3] For the report, we reviewed available Federal and State information and interviewed officials from national organizations that provide or have missions related to recovery homes as well as Federal agencies, including SAMHSA and the Centers for Medicare and Medicaid Services—the agency within HHS that is responsible for overseeing Medicaid. For our March 2018 report, we selected a non-generalizable sample of five States for review: Florida, Massachusetts, Ohio, Texas, and Utah. We selected these States based on a variety of criteria, such as the rates of opioid overdose deaths and rates of dependence on or abuse of illicit drugs and alcohol, among others. In each State, we interviewed officials from the State substance abuse agency, State Medicaid agency, State Medicaid Fraud Control Unit, State insurance department, and others.[4] Our March 2018 report includes a full description or our scope and methodology. Further, this statement reflects the most recent publicly available data on recovery homes from two national nonprofits dedicated to recovery homes—the National Alliance for Recovery Residences (NARR) and Oxford House, Inc.[5] We conducted the work on which this statement is based in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our finding and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

BACKGROUND

SAMHSA and other organizations recognize recovery homes—peer-run and peer-managed supportive homes—as an important step in SUD treatment and recovery. Definitions of and terms for recovery homes can vary, and recovery homes may differ in the types of services offered and resident requirements. Alcohol- and drug-free homes for individuals recovering from SUD may be referred to as "recovery residences," "sober homes," or other terms. For the purposes of our March 2018 report, we used the term "recovery homes" to refer to peer-run, nonclinical living environments for individuals recovering from SUD in general.

Recovery homes generally are not considered to be residential treatment centers, are not eligible to be licensed providers for the purposes of billing private insurance or public programs—such as Medicaid—and residents typically have to pay rent and other home expenses themselves. Recovery home residents may separately undergo outpatient clinical SUD treatment, which is typically covered by health insurance. In addition, recovery homes may encourage residents to participate in mutual aid or self-help groups (*e.g.,* 12-step programs such as Alcoholics Anonymous) and may require residents to submit to drug screening to verify their sobriety. Residents may be referred to recovery homes by treatment providers, the criminal justice system, or may voluntarily seek out such living environments.

NATIONWIDE PREVALENCE OF RECOVERY HOMES WAS UNKNOWN

In our March 2018 report, we found that the prevalence of recovery homes nationwide was unknown, because complete data were not available. We found these data are not collected at the Federal level to provide a nationwide picture, in part, because there was no Federal agency responsible for overseeing them. However, as we reported in March 2018, two national organizations with missions dedicated to recovery homes collect data on the prevalence and characteristics for a sub-set of recovery homes and the number of homes that were not affiliated with these organizations was unknown.

---

[3] *See* GAO, *Substance Use Disorder: Information on Recovery Housing Prevalence, Selected States' Oversight, and Funding,* GAO–18–315 (Washington, DC: March 22, 2018).

[4] Medicaid Fraud Control Units investigate and prosecute Medicaid provider fraud, as well as patient abuse or neglect in health-care and related facilities.

[5] NARR is a national nonprofit and recovery community organization that aims to support individuals in recovery by improving their access to quality recovery residences through standards, supportive services, placement, education, research, and advocacy. Oxford House, Inc. is a national nonprofit corporation that serves as an umbrella organization to connect individual Oxford Houses.

- NARR collected data on recovery homes that sought certification by one of its 15 State affiliates that actively certify homes.[6] As we previously reported, as of January 2018, NARR told us that its affiliates had certified almost 2,000 recovery homes, which had the capacity to provide housing to over 25,000 individuals.[7]
- Oxford House, Inc. collected data on the prevalence and characteristics of its individual recovery homes (known as Oxford Houses).[8] In its 2018 annual report, Oxford House, Inc. reported that there were 2,542 Oxford Houses in 45 States.[9]

MOST SELECTED STATES HAD INVESTIGATED POTENTIAL FRAUD RELATED TO RECOVERY HOMES AND TAKEN STEPS TO ENHANCE OVERSIGHT

Four of Five Selected States Had Conducted Investigations of Recovery Homes

Officials from four of the five selected States we reviewed for our March 2018 report (Florida, Massachusetts, Ohio, and Utah) told us that since 2007, State agencies had conducted, or were in the process of conducting, law enforcement investigations of unscrupulous behavior and potential insurance fraud related to recovery homes.[10] According to the State officials, the outcomes of some of these investigations included criminal charges and changes to health insurance policies.

Across the four States, officials told us that the potential insurance fraud may have relied on unscrupulous relationships between SUD treatment providers (including laboratories that perform tests to check for substance use) and recovery home operators. Officials explained that recovery home operators establish these relationships, because they cannot directly bill health insurance themselves due to the fact that recovery homes are not considered eligible providers for the purposes of billing health insurance. For example, treatment providers may form relationships with recovery home operators who then recruit individuals with SUD in order to refer or require residents to see the specific SUD treatment providers. This practice is known as patient brokering, for which recovery home operators receive kickbacks, such as cash or other remuneration from the treatment provider, in exchange for patient referrals. The extent of potential fraud differed across the four States, as discussed below.

Florida

Officials from several State agencies and related entities described investigations into fraud related to recovery homes in southeastern Florida as extensive, although the scope of the fraud within the industry is unknown. In 2016, the State attorney for the 15th judicial circuit (Palm Beach County) convened a task force composed of law enforcement officials tasked with investigating and prosecuting individuals engaged in fraud and abuse in the SUD treatment and recovery home industries. The task force found that unscrupulous recovery home operators or associated SUD treatment providers were luring individuals into recovery homes using deceptive marketing practices. These practices included online or other materials that will-

---

[6] As of January 2018, NARR's membership comprised 27 State affiliates that work to promote and support NARR's quality standard for recovery housing and other activities in their States. The remaining 12 affiliates support recovery homes in their States by providing information about recovery homes to the public and hearing complaints.

[7] NARR-certified recovery homes include recovery homes across all four NARR levels. NARR level I and II residences are primarily self-funded, peer-run, single-family homes where residents have an open-ended length of stay. Level II residences typically have a paid house manager or senior resident who oversees the house and its residents. Level III and IV residences are structured or semi-structured living environments with paid facility staff, such as case managers, to assist residents in developing treatment plans and may be licensed by the State if they offer clinical services (such as level IV residential treatment centers). Residential treatment centers were outside the scope of our study; however, the activities of some States in our review may have included more structured facilities (*i.e.,* levels III and IV).

[8] Oxford Houses operate under charters granted by Oxford House, Inc. and are democratically run, self-supporting homes. According to the Oxford House Inc. manual and related documents, all Oxford Houses are rentals and residents are responsible for sharing expenses, paying bills, and immediately evicting residents who drink or use illicit drugs while living in the house.

[9] Of the total number of Oxford Houses in 2018, 69 percent served men and 31 percent served women. The average Oxford House resident age was 39 years, and the average length of stay was about 9 months. *See* Oxford House, Inc., *Annual Report, FY 2018* (Silver Spring, MD: January 30, 2019).

[10] An official from the fifth State, Texas, told us that the State had not conducted any recent law enforcement investigations related to recovery homes. This official told us that the Texas Department of Insurance received two fraud reports in 2014 and 2016 related to recovery homes and that the State was unable to sufficiently corroborate the reports to begin investigations.

fully misdirected individuals or their family members to recruiters with the goal of sending these individuals to specific treatment providers so that the recruiters could receive payments from those treatment providers for each referral. According to officials from the Florida State attorney's office, these individuals—often from out of State—were lured with promises of free airfare, rent, and other amenities to recover in southern Florida's beach climate. Recruiters brokered these individuals to SUD treatment providers, who then billed their private insurance plans for extensive and medically unnecessary urine drug testing and other services. Officials from the Florida State attorney's office told us that SUD treatment providers were paying $300 to $500 or more per week to recovery home operators or their staff members for every individual they referred for treatment. In addition, these officials cited one case in which a SUD treatment provider billed an individual's insurance for close to $700,000 for urine drug testing over a 7-month period. Officials from the State attorney's office noted that the recovery homes that the task force investigated were not shared homes in the traditional, supportive sense, but rather existed as "warehouses" intended to exploit vulnerable individuals.

As a result of these investigations, as of December 2017, law enforcement agencies had charged more than 40 individuals primarily with patient brokering, with at least 13 of those charged being convicted and fined or sentenced to jail time, according to the State attorney's office. In addition, the State enacted a law that strengthened penalties under Florida's patient brokering statute and gave the Florida Office of Statewide Prosecution, within the Florida Attorney General's Office, authority to investigate and prosecute patient brokering.

Massachusetts

An official from the Massachusetts Medicaid Fraud Control Unit told us that the unit began investigating cases of Medicaid fraud in the State on the part of independent clinical laboratories associated with recovery homes in 2007. The unit found that, in some cases, the laboratories owned recovery homes and were self-referring residents for urine drug testing. In other cases, the laboratories were paying kickbacks to recovery homes for referrals for urine drug testing that was not medically necessary. According to the Medicaid Fraud Control Unit official, as a result of these investigations, the State settled with nine laboratories between 2007 and 2015 for more than $40 million in restitution. In addition, the State enacted a law in 2014 prohibiting clinical laboratory self-referrals and revised its Medicaid regulations in 2013 to prohibit coverage of urine drug testing for the purposes of residential monitoring.

Ohio

At the time of our March 2018 report, Ohio had begun to investigate an instance of potential insurance fraud related to recovery homes, including patient brokering and excessive billing for urine drug testing. Officials from the Ohio Medicaid Fraud Control Unit told us that the unit began investigating a Medicaid SUD treatment provider for paying kickbacks to recovery homes in exchange for patient referrals, excessive billing for urine drug testing, and billing for services not rendered, based on an allegation the unit received in September 2016. Officials from other State agencies and related State entities, such as the State's substance abuse agency and NARR affiliate, were not aware of any investigations of potential fraud on the part of recovery home operators or associated treatment providers when we interviewed with them. According to these State officials, this type of fraud was not widespread across the State.

Utah

In our March 2018 report, we reported that officials from the Utah Insurance Department told us that the department was conducting ongoing investigations of private insurance fraud similar to the activities occurring in Florida, as a result of a large influx of complaints and referrals the department had received in 2015. These officials told us that the department had received complaints and allegations that SUD treatment providers were

- Paying recruiters to bring individuals with SUD who were being released from jail to treatment facilities or recovery homes;
- Billing private insurance for therapeutic services, such as group or equine therapy, that were not being provided, in addition to billing frequently for urine drug testing; and
- Encouraging individuals to use drugs prior to admission to qualify them and bill their insurance for more intensive treatment.

In addition, insurance department officials told us that they believed providers were enrolling individuals in private insurance plans without telling them and paying their premiums and copays. According to these officials, when doing so, providers may lie about the individuals' income status in order to qualify them for more generous insurance plans. Officials found that providers were billing individuals' insurance $15,000 to $20,000 a month for urine drug testing and other services. Officials noted that they suspect that the alleged fraud was primarily being carried out by SUD treatment providers and treatment facilities that also own recovery homes. The officials said the department had not been able to file charges against any treatment providers, because it had been unable to collect the necessary evidence to do so. However, according to the officials, the State enacted legislation in 2016 that gave insurers and State regulatory agencies, such as the State's insurance department and licensing office, the authority to review patient records and investigate providers that bill insurers. As we noted in our March 2018 report, this authority may help the insurance department and other Utah regulatory agencies better conduct investigations in the future.

Three Selected States Have Established Oversight Programs, and Two Selected States Are Taking Other Steps to Support Recovery Homes

In addition to actions taken in response to State investigations, our March 2018 report described steps taken by three of the five selected States (Florida, Massachusetts, and Utah) to formally increase oversight of recovery homes by establishing State certification or licensure programs. Florida enacted legislation in 2015 and Massachusetts enacted legislation in 2014 that established voluntary certification programs for recovery homes. Further, Florida established a two-part program for both recovery homes and recovery home administrators (*i.e.,* individuals acting as recovery home managers or operators). According to officials from the Florida State attorney's office and Massachusetts Medicaid Fraud Control Unit, their States established these programs, in part, as a result of State law enforcement investigations. Utah enacted legislation in 2014 to establish a mandatory licensure program for recovery homes. According to officials from the Utah substance abuse agency and the State licensing office, Utah established its licensure program, in part, to protect residents' safety and prevent their exploitation and abuse.

In our March 2018 report, we found that although State recovery home programs in Florida and Massachusetts are voluntary, there are incentives for homes to become certified under these States' programs, as well as incentives to become licensed under Utah's programs. Specifically, all three States require that certain providers refer patients only to recovery homes certified or licensed by their State program; therefore, uncertified and unlicensed homes in the three States are ineligible to receive patient referrals from certain treatment providers.[11] Further, State officials told us that State agencies are taking steps to ensure providers are making appropriate referrals. For example, according to officials from the Florida substance abuse agency, treatment providers may refer individuals to certified recovery homes managed by certified recovery home administrators only and must keep referral records.

To become State-certified or licensed, recovery homes in Florida, Massachusetts, and Utah must meet certain program requirements, including training staff, submitting documentation (such as housing policies and a code of ethics), and participating in onsite inspections to demonstrate compliance with program standards. However, specific requirements differ across the three States. For example, while all three State programs require recovery home operators or staff to complete training, the number of hours and training topics differ. In addition, for recovery homes to be considered certified in Florida, they must have a certified recovery home administrator. Similar to Florida's certification program for the homes, individuals seeking administrator certification must meet certain program requirements, such as receiving training on recovery home operations and administration, as well as training on their legal, professional, and ethical responsibilities. Features of the State-established oversight programs also differ across the three States, including program type, type of home eligible for certification or licensure, certifying or licensing body, and initial fees.

As we noted in our March 2018 report, the State-established oversight programs in Florida, Massachusetts, and Utah also include processes to monitor certified or licensed recovery homes, and take action when homes do not comply with program

[11] In Massachusetts, this requirement applies to referrals from State agencies and State-funded providers only. In Utah, this requirement applies to referrals from the criminal justice system, such as drug courts.

standards. For example, an official from the Florida Association of Recovery Residences—the organization designated by the State to certify recovery homes—told us that the entity conducts random inspections to ensure that recovery homes maintain compliance with program standards. State-established oversight programs in the three States also have processes for investigating grievances filed against certified or licensed recovery homes. Further, officials from certifying or licensing bodies in all three States told us their organizations may take a range of actions when they receive complaints or identify homes that do not comply with program standards, from issuing recommendations for bringing homes into compliance to revoking certificates or licenses. According to officials from Florida's certifying body, the entity has revoked certificates of recovery homes that have acted egregiously or have been nonresponsive to corrective action plans. Officials from the certifying and licensing bodies in Massachusetts and Utah told us that they had not revoked certificates or licenses, but had possibly assisted homes with coming into compliance with certification standards or licensure requirements.

Officials from Ohio and Texas told us that their States had not established State oversight programs like those in Florida, Massachusetts, and Utah, but said their States had provided technical assistance and other resources to recovery homes in an effort to increase consistency, accountability, and quality.

- Officials from the Ohio substance abuse agency told us that since 2013 the State has revised its regulatory code to define recovery homes and minimum requirements for such homes. Officials also told us that the agency did not have authority to establish a State certification or licensure program for recovery homes. According to these officials, the State legislature wanted to ensure that Ohio's recovery homes community maintained its grassroots efforts and did not want a certification or licensure program to serve as a roadblock to establishing additional homes. However, officials from the Ohio substance abuse agency told us that the agency encourages recovery homes to seek certification by the State's NARR affiliate—Ohio Recovery Housing—to demonstrate quality. In addition, these officials told us that the State substance abuse agency also provided start-up funds for Ohio Recovery Housing, as well as continued funding for the affiliate to provide training and technical assistance, and to continue certifying recovery homes. According to officials from Ohio Recovery Housing, the NARR affiliate regularly provides the State's substance abuse agency with a list of newly certified recovery homes, as well as updates on previously certified homes as part of ongoing efforts to develop a recovery home locator, under its contract with the agency.
- Officials from the Texas substance abuse agency told us that establishing a voluntary certification program would be beneficial. However, the State legislature had not enacted legislation establishing such a program at the time of our review. At the time of our report, the agency was in the process of developing guidance for providers on where and how to refer their patients to recovery housing, which includes a recommendation to send patients to homes certified by the Texas NARR affiliate.

Chairman Grassley, Ranking Member Wyden, and members of the committee, this concludes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

QUESTIONS SUBMITTED FOR THE RECORD TO MARY DENIGAN-MACAULEY, PH.D.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. Officials in two States that were the subject of the GAO's study on fraudulent treatment providers indicated that they could not obtain sufficient evidence to initiate investigations or file charges against these fraudulent providers. What specific barriers exist to obtaining such evidence and what options exist for States to overcome these barriers?

Answer. Recovery homes—peer-run, nonclinical living residences for individuals recovering from substance use disorder (SUD)—are generally not considered to be residential treatment centers, and are not eligible to be licensed providers for the purposes of billing private insurance or public programs, such as Medicaid. Potential insurance fraud related to recovery homes has typically relied on unscrupulous relationships between SUD treatment providers, such as laboratories, and recovery home operators. As we reported in March 2018, officials from two of the five States

in our review told us they faced barriers collecting information to investigate or file charges against providers for potential fraud related to recovery homes.[1]

- An official from the Texas Department of Insurance told us that the department received two fraud reports in 2014 and 2016 related to recovery homes, but the State was unable to collect information to corroborate the reports.
- Officials from the Utah Insurance Department told us that they faced barriers collecting necessary evidence to file charges against providers.

We also reported in March 2018 that officials from two of the five States in our review told us their State had enacted legislation that may help them to conduct future investigations of fraud related to recovery homes. Officials from Utah told us that the State legislature enacted legislation in 2016 that gives insurers and State regulatory agencies, such as the State insurance department and State licensing office, the authority to review patient records and investigate providers that bill insurers. Similarly, Florida enacted a law that gives the Florida Attorney General's Office the authority to investigate and prosecute patient brokering. This law also strengthened penalties for patient brokering.

Question. What other policies do you recommend that Federal, State, and local policymakers consider adopting to help reduce future scams in addiction treatment and recovery housing?

Answer. The Substance Abuse and Mental Health Services Administration (SAMHSA)—the agency within the Department of Health and Human Services (HHS) responsible for promoting SUD prevention, treatment, and recovery—maintains certain resources for locating treatment providers and understanding the resources available for treating SUD. In response to the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patient and Communities Act (SUPPORT Act), SAMHSA published best practices and suggested guidelines for recovery housing.[2] We also reported in March 2018 that national organizations with missions dedicated to recovery homes, such as the National Alliance for Recovery Residences (NARR) and Oxford House, Inc., provide support and guidance for recovery home operators.[3] Such information could inform policymakers' efforts to develop safeguards to help prevent or reduce abuses in addiction treatment and recovery homes.

Question. Use of evidence-based interventions can reduce the health-care costs and criminal justice costs associated with substance abuse, according to a Surgeon General's report. Is the government allocating funding in a way that best promotes evidence-based interventions, or is there room for improvement in this area? Please explain.

Answer. Our work on recovery homes did not examine whether the government is allocating funding in a way that best promotes evidence-based interventions. However, we previously reported that in an effort to reduce the prevalence of opioid misuse and the fatalities associated with it, HHS established a goal to expand access to medication-assisted treatment (MAT).[4] MAT is an evidence-based approach that combines behavioral therapy and the use of certain medications, such as methadone and buprenorphine. We also have ongoing work examining the Office of National Drug Control Policy, including its responsibility to assess and certify Federal agencies' drug control budgets to determine if they are adequate to meet the goals and objectives of the National Drug Control strategy—which includes expanding access to evidence-based treatment. We anticipate issuing our report later this month.

Question. To what extent is professional education on evidence-based treatment of substance use disorders widely available for health professionals?

Answer. As we noted in our March 2018 report, recovery homes are generally not staffed by treatment providers, but are intended to provide drug- and alcohol-free housing to help individuals recovering from SUD.[5] While we did not review the education of treatment providers in our work on recovery homes, our other work has

---

[1] *See* GAO, "Substance Use Disorder: Information on Recovery Housing Prevalence, Selected States' Oversight, and Funding," GAO–18–315 (Washington, DC: March 22, 2018).

[2] Pub. L. No. 115–271, § 7031, 132 Stat. 3894, 4014–16 (October 24, 2018). SAMHSA, "Recovery Housing: Best Practices and Suggested Guidelines" (Rockville, MD: 2018).

[3] *See* GAO–18–315.

[4] *See* GAO, "Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment," GAO–18–44 (Washington, DC: October 31, 2017); and GAO, "Opioid Addiction: Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access," GAO–16–833 (Washington, DC: September 27, 2016).

[5] *See* GAO–18–315.

found that some Federal grant programs support education on evidence-based practices for health-care providers. For example, in October 2017, we reported that HHS had four grant programs that focused on expanding the use of MAT for opioid use disorders, and grant recipients could use funds for a range of activities, including training providers and supporting treatment involving MAT.[6]

QUESTIONS SUBMITTED BY HON. PATRICK J. TOOMEY

Question. If a drug treatment facility does not have to be certified, how do consumers, States and the Federal Government, and other payers ensure it is providing the resources it advertises?

Answer. In our March 2018 report, we identified actions that States are taking to oversee recovery homes.[7] We found that three of the five selected States (Florida, Massachusetts, and Utah) had established voluntary certification or mandatory licensure programs to increase oversight. Recovery homes seeking State certification or licensure must demonstrate compliance with State program standards. For example, all three States require recovery home operators or staff to complete training. Further, State-established oversight programs in Florida, Massachusetts, and Utah also include processes for monitoring certified or licensed recovery homes and actions when homes do not comply with program standards. While participation in state oversight programs cannot guarantee consumers, the Federal Government, or others that recovery homes are providing resources as advertised, it can indicate that homes have met standards.

Our other work has described the laws and restrictions that apply to drug treatment facilities that administer medication-assisted treatment (MAT).[8]

- Methadone—one medication used for MAT—may generally only be administered or dispensed within an opioid treatment program (OTP), as prescriptions for methadone cannot be issued when used for opioid addiction treatment. As we reported in September 2016, under the Controlled Substances Act, OTPs must be certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and registered by the Drug Enforcement Administration. To be eligible for full certification, an OTP must first be accredited by a SAMHSA-approved accrediting organization. Accreditation is a peer-review process in which an accrediting organization evaluates an OTP by making site visits and reviewing policies, procedures, and practices. Once accredited, SAMHSA may certify an OTP if it determines that the OTP conforms with Federal regulations governing opioid treatment standards. Among other things, Federal opioid treatment standards set forth patient admission criteria, record-keeping guidelines, and required services, such as counseling. Once certified by SAMHSA, the OTP must apply for a separate registration from the Drug Enforcement Administration.
- Buprenorphine—another medication used for MAT—may be administered or dispensed within an OTP and may also be prescribed by a qualifying practitioner who has received a waiver from SAMHSA. Practitioners who received this waiver are limited in the number of patients they may treat for opioid addiction.

Question. Do any of the States stand out as high performers when it comes to oversight and regulation of addiction treatment centers? Please provide examples.

Answer. Our March 2018 report focused on recovery homes, which are different from addiction treatment centers.[9] Recovery homes are peer-run, drug- and alcohol-free supportive homes for individuals in recovery from substance use disorder (SUD). As noted in our report, three of the five States in our review—Florida, Massachusetts, and Utah—had established certification or licensure programs for recovery homes in 2014 and 2015. Officials from the other two States in our review—Ohio and Texas—said they had not established such programs, but they were providing training and technical assistance to recovery homes. We did not evaluate these efforts.

---

[6] *See* GAO–18–44.
[7] *See* GAO–18–315.
[8] *See* GAO–16–833.
[9] *See* GAO–18–315.

Question. How much money do Federal insurance programs (FEHB, TRICARE, Medicare, Medicaid, etc.) spend on drug treatment and how much of it is suspected of being fraud? What, if any, are the challenges in quantifying this?

Answer. SAMHSA reported that total spending on SUD treatment was $56 billion in 2015, and public spending accounted for 57 percent of total spending.[10] Among Federal programs, Medicaid accounted for 25 percent of total spending. Other Federal spending accounted for 11 percent of the total. This included SUD block grants from SAMHSA, which accounted for 2.5 percent of all SUD spending, and Medicare, which accounted for less than 5 percent. Other State and local government spending accounted for 17 percent of the total.

Our work on recovery homes did not examine the portion of SUD treatment spending that is suspected of being fraud. We have reported in the past that there are no reliable estimates of the extent of fraud in the health-care industry but fraud continues to be a concern because Federal health-care programs remain vulnerable.[11] By its very nature, fraud is difficult to detect, as those involved are engaged in intentional deception. For example, a provider submitting a fraudulent claim may include false documentation to substantiate a service not provided, and thus the claim may appear valid on its face. Fraud may also involve payments made to beneficiaries to obtain information for fraudulent billing purposes.

QUESTION SUBMITTED BY HON. BILL CASSIDY

Question. This hearing highlighted some of the challenges that families affected by substance use disorder face when trying to find properly certified treatment centers that use appropriate, science-based methods. One way that families could be helped is by having access to an app which directs them to certified treatment centers in their area. Generally speaking, how has HHS considered ways to direct families to treatment centers that are certified and use science-based methods? If not such an app exists, could HHS put forth a challenge grant to help one be created?

Answer. Our March 2018 report on recovery homes did not examine ways HHS can direct families to treatment that is certified and uses science-based methods, or possible grants to assist in this. Rather, our report examined the Substance Abuse and Mental Health Services Administration's (SAMHSA) funding and how selected States have used this funding for housing.[12] As noted in our report, SAMHSA administers two Federal health-care grants for substance use disorder (SUD) prevention and treatment that States may use to establish recovery homes and for related activities. Two of the five States in our review used a portion of their grant funds for recovery homes. Further, we reported that SAMHSA was undertaking initiatives related to recovery homes, including a needs assessment for certifying recovery homes in the future and holding two meetings to discuss emerging best practices and other topics on recovery homes.

SAMHSA maintains certain resources for locating treatment facilities and understanding the resources available for SUD treatment. According to the SAMHSA website, the agency collects information on thousands of State-licensed providers who specialize in treating SUD, addiction, and mental illness. On SAMHSA's website, individuals seeking SUD treatment or their family members can find treatment facilities, including recovery homes, and learn about

- Finding quality treatment, the different types of treatment, and what to expect when starting treatment;
- The cost of treatment and payment options; and
- Addiction and mental health illness.

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. The Government Accountability Office found problems around the country of programs that claim to be providing housing and health-care services for people in recovery, but in reality these programs don't come close to making good on

[10] Substance Abuse and Mental Health Services Administration, "Behavioral Health Spending and Use Accounts 2006–2015," HHS Pub. No. (SMA) 19–5095 (Rockville, MD: 2019).

[11] *See* GAO, "Medicare Fraud: Progress Made, but More Action Needed to Address Medicare Fraud, Waste, and Abuse," GAO–14–560T (Washington, DC: April 30, 2014).

[12] *See* GAO–18–315.

their promises. In many instances, these recovery home operators are just out-and-out crooks who are conspiring with treatment providers and drug testing companies to defraud patients and their families, Federal programs like Medicaid, and even private insurers. What are the warning signs that patients and their families should look out for in order to avoid these types of fraudulent programs? How can we ensure that essential government programs like Medicaid aren't being defrauded?

Answer. Recovery homes can offer safe, supportive, stable living environments to help individuals recovering from substance use disorder (SUD) maintain an alcohol and drug-free lifestyle. However, as we reported in March 2018, four of the five States in our review conducted law enforcement investigations of unscrupulous behavior and potential fraud related to recovery housing.[13] State officials told us that instances of fraud may have relied on relationships between providers, including laboratories, and recovery home operators who exploit residents for the purpose of profit. State investigations of unscrupulous behavior and potential fraud included:

- Luring individuals into recovery homes using deceptive marketing practices, such as promising free airfare or rent;
- Billing insurance plans for services not rendered; and
- Requiring residents to get frequent and medically unnecessary drug tests in order to excessively bill insurance plans.[14]

We also reported that, in response to investigations, three of the five States in our review established oversight programs for recovery homes to avoid potential fraud. We found that homes that participate in State oversight programs must meet certain requirements. Further, we noted that two national recovery home organizations—the National Alliance for Recovery Residences (NARR) and Oxford House Inc.—maintain standards for recovery homes. Recovery homes that are certified by a NARR affiliate or operate under an Oxford House charter must also meet certain standards, potentially reducing the risk of fraud.[15]

We have a body of work examining fraud in Federal programs, including some programs that pay for SUD treatment, such as Medicaid. As part of this work, we developed the Fraud Risk Framework, which is a comprehensive set of key components and leading practices that serve as a guide for agency managers to use when developing efforts to combat fraud in a strategic, risk-based way.[16] In 2017, we made three recommendations to the Centers for Medicare and Medicaid Services (CMS) to better align its efforts with the four components of the Fraud Risk Framework: commit, assess, design and implement, and evaluate and adapt.[17] Specifically, we recommended that CMS (1) provide and require fraud-awareness training to it employees; (2) conduct fraud risk assessments; and (3) create an antifraud strategy for Medicare and Medicaid, including an approach for evaluation. The agency agreed with these three recommendations and has taken some steps to implement them, such as initiating the fraud risk assessment for some programs in Medicare. However, additional actions are needed to fully address these three recommendations and, as of November 2019, they remain open.

Question. During the hearing, you noted that there is no Federal oversight of so-called sober homes. What other regulatory gaps has the Government Accountability Office identified in this industry?

---

[13] *See* GAO–18–315.

[14] According to the American Society of Addiction Medicine's April 2017 consensus statement on appropriate use of drug testing in clinical addiction treatment, drug testing should be tailored to individual patients' needs and stages of addiction and recovery. For purposes of verifying or ensuring that residents in recovery housing remain free from alcohol and illicit drugs, the consensus statement states that weekly testing may be appropriate using presumptive testing—that is, lower sensitivity tests, such as using drug tests that can be purchased over the counter. The statement notes that more frequent or more sensitive testing (*i.e.,* testing that takes place in a laboratory) is inappropriate and does not fit in the standard of care.

[15] NARR promotes standards for recovery housing, and provides training and education to recovery home operators and others, among other activities. NARR's membership is composed of State affiliates that work to promote NARR's quality standards for recovery housing and other activities in their State. As of January 2018, NARR had 27 State affiliates, 15 of which were actively certifying recovery homes. Oxford Houses operate independently, but must follow procedures laid out in the Oxford House manual and adhere to charter conditions.

[16] GAO, "A Framework for Managing Fraud Risk in Federal Programs," GAO–15–593SP (Washington, DC: July 28, 2015).

[17] GAO, "Medicare and Medicaid: CMS Needs to Fully Align its Antifraud Efforts With the Fraud Risk Framework," GAO–18–88 (Washington, DC: December 5, 2017).

Answer. In March 2018, we reported that there was no Federal oversight and limited State oversight of recovery homes at the time we did our work.[18] We also reported that some States are beginning to increase their oversight of recovery homes operating in their States. For example, we reported that three of the five States in our review—Florida, Massachusetts, and Utah—said they had established certification or licensure programs for recovery homes in 2014 and 2015. Officials from the other two States in our review—Ohio and Texas—said they had not established such programs, but said that they were providing training and technical assistance to recovery homes.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

STATE TARGETED RESPONSE TO OPIOID CRISIS GRANTS

Question. Much like the rest of the country, Maryland has been impacted by the opioid epidemic. In 2017, there were almost 2,000 overdose deaths involving opioids, and Maryland ranks in the top five States for opioid-related overdose rates.

To help States address the opioid crisis, the Federal Government created the State Targeted Response to Opioid Crisis Grants. This is a 2-year grant program that helps States supplement their existing opioid prevention and treatment programs and recovery support activities with Federal dollars. For Fiscal Year 2019, Maryland received over $32.9 million from this Federal grant program.

As you know, States are able to use this grant funding for treatment programs and recovery housing like sober homes.

Since some of the sober homes could receive Federal funding under the State Targeted Grant Program, are there any guardrails in place to certify grant recipients who are recovery programs or other treatment programs are effective and safe for patients?

If not, what should Congress consider in ensuring Federal funding for opioid treatment programs do not unintentionally fund bad actors like these sober homes?

Answer. In 2015, we reviewed aspects of the Substance Abuse and Mental Health Services Administration's (SAMHSA) grant oversight and its efforts to ensure that grant funds are spent as intended.[19] This review did not cover the State Targeted Response (STR) to the Opioid Crisis Grant Program. However, similar to the grants covered by our review, STR has specific requirements intended to make sure grantees use the funds as they were intended. As we reported in March 2018, the STR grant is intended to supplement States' existing opioid prevention, treatment, and recovery support activities.[20] SAMHSA requires most grant funding to be used for opioid use disorder treatment services, such as expanding access to clinically appropriate, evidence-based treatment. States may also use a portion of their opioid grant funding for recovery homes and recovery support services—which SAMHSA recognizes as part of the continuum of care—such as establishing recovery homes and providing peer mentoring.

Our 2015 work resulted in a recommendation to SAMHSA to take steps, such as developing additional program-specific guidance, to ensure that it consistently and completely documents both the application of criteria when awarding grants to grantees, and its ongoing oversight of grantees once grants are awarded. In response, SAMHSA developed program-specific guidance, including standard operating procedures and additional program specific guidance. SAMHSA incorporated this guidance into an updated Government Project Officer handbook, which was finalized in October 2015. SAMHSA's continued adherence to its guidance for grantee oversight should assist it in ensuring that SAMHSA grant funds are used appropriately.

DEVELOPMENT OF SOBER HOME STANDARDS

*Question.*GAO's 2018 report noted, "the nationwide prevalence of recovery housing is unknown because there was no Federal agency responsible for overseeing recovery homes that would compile such data." However, there are two national nonprofit

---

[18] *See* GAO–18–315.

[19] GAO, "Mental Health: Better Documentation Needed to Oversee Substance Abuse and Mental Health Services Administration Grantees," GAO–15–405 (Washington, DC: May 12, 2015).

[20] *See* GAO–18–315.

organizations, the National Alliance for Recovery Residences (NARR) and Oxford House, which have been dedicated to collecting data on the prevalence of recovery housing.

In fact, NARR promotes standards for recovery housing. In addition, Shatterproof, has developed Atlas, a web- and app-based platform that will allow any individual searching for high-quality addiction treatment to locate and compare facilities.

As 3.8 million Americans received substance use treatment at any facility in the past year, it seems prudent and necessary that we have some standards in place for the health and safety of patients and to ensure that taxpayer dollars are being appropriately spent.

In the review of the standards that NARR uses to certify recovery homes, did GAO find a consistent set of quality standards that might be adopted at the Federal level?

Answer. Our report examined investigations and actions that five selected States had undertaken to oversee recovery homes.[21] We found that three of the selected States had enacted licensure or voluntary certification programs to enhance oversight. These programs require recovery homes to meet certain requirements, including staff training, documentation submissions, and onsite inspections. However, specific requirements varied across States. In addition, we identified two national nonprofit organizations that have missions dedicated to recovery homes that maintain standards for recovery homes—NARR and Oxford House, Inc.—which you cite above. We included information from these organizations in our review.

SAMHSA issued best practices and suggested guidelines for recovery homes.[22] According to SAMHSA, the agency identified 10 specific areas, or guiding principles, to assist States and Federal policy-makers in defining and understanding what comprises safe, effective, and legal recovery homes. SAMHSA recommends following these Ten Guiding Principles to guide recovery home operators, stakeholders, and states in enacting laws designed to provide the greatest level of resident care and safety possible. These principles include, among other things, having a clear operational definition, recognizing that a substance use disorder is a chronic condition requiring a range of recovery supports, and recognizing that co-occurring mental disorders often accompany substance use disorders.

INVESTIGATING PATIENT BROKERING AND EDUCATING CONSUMERS

Question. Ms. Donna Johnson, a mother of four from Frederick, detailed in a *Baltimore Sun* article how her then 21-year-old son was caught in the sober home cycle scam. Over a 4-year period, her son cycled through more than two dozen sober homes and treatment facilities, receiving little actual therapy. It all began with a patient broker who lured her son to South Florida with the promise of treatment, and resulted in tens of thousands of dollars in fraudulent charges to her insurance company for drug testing that her son never received.

GAO's 2018 report pointed to unnecessary or fraudulent testing as central to sober home scams; in one instance, an insurance provider was billed close to $700,000 for urine testing in a 7-month period.

In my State, State representatives from Frederick, MD are reportedly drafting a bill that would outlaw the practice of patient brokering for substance use disorder treatment. Also, the SUPPORT for Patients and Communities Act included a provision based on a Rubio/Klobuchar bill making patient brokering illegal and subjects those found guilty to a fine of up to $200,000 or 10 years in prison, or both.

Since the SUPPORT Act was enacted, have Federal prosecutors been able to curb patient brokering with the threat of fines and prison terms?

Has the Department of Justice brought forth an increased number of cases to prosecute instances of patient brokering?

Are there additional authorities needed to investigate and prosecute patient brokering?

Answer. We have not conducted any work on investigating and prosecuting patient brokering since the SUPPORT Act. We would be happy to work with your staff to explore potential future work for GAO.

---

[21] *See* GAO–18–315.

[22] SAMHSA, "Recovery Housing: Best Practices and Suggested Guidelines" (Rockville, MD: 2018).

Question. Do you know if Federal agencies are collaborating with State and local governments to inform consumers of the dangers of sober homes and patient brokering practices?

Answer. In March 2018, we reported that SAMHSA was undertaking initiatives related to recovery homes, including a needs assessment for certifying recovery homes in the future. In 2017, SAMHSA held two recovery homes meetings that covered such topics as research on emerging best practices, State recovery housing programs, and challenges that State entities have experienced regulating recovery homes in their States. Further, SAMHSA contracted with NARR at the end of fiscal year 2017 to provide training to recovery homes organizations, managers, and State officials.

We also reported that SAMHSA administers two Federal health-care grants for substance use disorder (SUD) prevention and treatment that States may use to establish recovery homes and related activities, and two of the five States in our review—Texas and Ohio—used a portion of their SAMHSA grant funds for recovery homes. For example, Texas used funds to increase the number Oxford Houses in the State and hire outreach workers who assist individuals in finding recovery homes, negotiating leases, and helping individuals or groups that want to open new homes apply for Oxford House charters.

Since our report, SAMHSA published best practices and suggested guidelines for recovery homes. According to SAMHSA, the agency identified 10 specific areas, or guiding principles, to assist States, among other policy-makers, in defining and understanding what comprises safe, effective, and legal recovery homes.

Question. If not, what could the Federal Government do to educate consumers about quality treatment programs for their loved ones and how to identify patient brokering scams?

Answer. While our work on recovery homes did not examine how to educate consumers on quality treatment programs and how to identify patient brokering, SAMHSA's website includes information on finding SUD treatment, including a blog post and a fact sheet on finding quality treatment for SUD. Further, SAMHSA maintains web-based tools to help consumers find State-licensed SUD treatment providers.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

MANDATORY LICENSING AND CERTIFICATION REQUIREMENTS

Question. One of the States GAO interviewed in putting together its report was Utah, which has mandatory licensing and certification requirements for recovery homes.

Do you believe that these requirements have stifled the growth of substance use disorder treatment facilities in the State of Utah?

Answer. Utah enacted legislation in 2014 to establish a mandatory licensure program for recovery homes.[23] According to officials from the Utah substance abuse agency and the State licensing office, Utah established its licensure program, in part, to protect residents' safety and prevent their exploitation and abuse. We did not evaluate the growth of sober homes or substance use disorder treatment facilities, which were beyond the scope of our report, following the enactment of the legislation in 2014.

PEER SUPPORT

Question. During the hearing, you mentioned that the Government Accountability Office (GAO) is planning a few additional reports in this space—one report is focused on doing a review of peer support programs across the Medicaid programs of a few States, and another on Medicaid and treatment of pregnant and postpartum women (which came out after the hearing adjourned).

What is GAO's timeline for the peer support program report? Are you planning to do any other work in this space that wasn't mentioned during the hearing?

---

[23] *See* GAO–18–315.

Answer. We plan on reporting on peer support services in Medicaid on or before the mandated reporting date in the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patient and Communities Act (SUPPORT Act), October 24, 2020. We have other ongoing work examining a range of topics related to substance use disorder (SUD) treatment, including possible barriers in Medicaid to substance use treatment, Medicare mental and behavioral health services, and substance use treatment capacity and access. We anticipate issuing these reports throughout 2020.

PERPETRATORS OF FRAUD

Question. During the hearing, I asked both you and Mr. Cantrell about who tends to be the perpetrator of fraud in the situations you have investigated. As you both testified, in the vast majority of cases, it is treatment providers who are engaging in troublesome practices at the expense of patients. More often, patients are the victim.

Do you believe that going after patients as if they are scam artists is an effective method of preventing this type of fraud?

Answer. We have not examined the effectiveness of investigating patients as a method for preventing fraud. Our work on combating fraud has centered on the Fraud Risk Framework, which encompasses activities in which payers can engage to prevent, detect, and respond to fraud, with an emphasis on prevention and structural and environmental factors that influence or help managers achieve their objective to mitigate fraud.[24]

Question. Given that the culprits in these scenarios are providers/schemers and the victims are the patients they broker/fail to provide quality treatment to, would you agree that regulations that may restrict patient access to addiction treatment is not the appropriate way to tackle fraud in this space?

Answer. Our work on recovery homes has not examined the impact of regulations on access to SUD treatment, including regulating recovery homes, which are included in the continuum of care. We would be happy to meet with your staff to discuss your concerns about this and the potential for future work.

PREPARED STATEMENT OF HON. CHUCK GRASSLEY,
A U.S. SENATOR FROM IOWA

Good morning. I want to welcome our panelists to today's hearing on the 1-year anniversary of the SUPPORT Act. This landmark statute, which many of us had a hand in developing, responded to the opioid epidemic on multiple fronts. That crisis has affected every corner of our Nation, with 130 Americans, on average, dying from an overdose every single day.

We've devoted a lot of Federal resources to tackling this crisis, and I look forward to hearing from the Surgeon General on this administration's efforts to implement the SUPPORT Act over the last year. I also commend Dr. Adams for launching his own unique initiatives to help raise public awareness about the risks of opioid misuse.

Challenges remain, however, because roughly 20 million Americans still struggle with substance abuse disorder. Addiction to other drugs, including meth and heroin, pose an equal or even greater challenge for some communities, especially in rural areas. Another issue is that few battling addiction actually seek or receive treatment. Yet another issue is that even those who do seek help lack the expertise to distinguish the good treatment providers from the bad. Solving that last issue, which is the second focus of our hearing, is easier said than done.

The treatment sector includes not just extremely good and extremely bad providers but also many others who fall somewhere in the middle. Some, for example, haven't updated their methods to incorporate the latest research about what works best with recovering addicts.

Also, State requirements for addiction counselors and recovery homes vary. For example, some States require licensing of recovery home operators, while others might only use voluntary certification programs. That is why we have invited two

[24] *See* GAO–15–593SP.

government watchdog agencies and an addiction treatment advocate to our committee to share their expertise with us today.

First, I want to welcome back to the committee Dr. Deagan-Macauley of the Government Accountability Office, who testified before this committee last year. We've all seen the media reports about so-called "sober homes" in Florida, Pennsylvania, Massachusetts, and other States that exploited recovering addicts with private insurance benefits. We look forward to hearing from her about GAO's oversight of recovery housing.

I also extend a warm welcome to Gary Cantrell, who leads the Inspector General's investigations team. His investigators worked on a recent high-profile case involving an addiction treatment scam in Ohio. That investigation, in partnership with the FBI and other law enforcement entities, led to the indictment of six people this year. All six pled guilty to Medicaid fraud this month.

Some have called for development of more uniform, measurable addiction treatment standards, by which the public could evaluate the effectiveness of substance use disorder treatment programs. Our last witness, Gary Mendell, has gone a step further, not only identifying eight core standards he believes are key to any successful treatment program, but also launching a treatment quality rating system. This is an uncharted area in the treatment sector, and I look forward to hearing from him about the progress he's made since founding his nonprofit, Shatterproof, the obstacles he's faced along the way, and the challenges that remain to the successful use of such a rating system.

We're here today because too many Americans have lost too many loved ones to addiction and overdose deaths. America's opioid crisis has left a trail of broken hearts and homes across the country. We're here to help communities get on the path towards health and wellness. Millions of Americans are desperately seeking a path forward. Working together, we can save tax dollars and save lives. Thank you to our witnesses today for helping us examine best practices and take a look at what works—and what doesn't work—to help get Americans on the road to recovery.

PREPARED STATEMENT OF GARY MENDELL,
FOUNDER AND CHIEF EXECUTIVE OFFICER, SHATTERPROOF

Chairman Grassley, Ranking Member Wyden, and members of the committee, thank you for holding this hearing on the important topic of solutions for treating substance misuse in America. My name is Gary Mendell, and I am the founder and chief executive officer of Shatterproof, a national nonprofit organization dedicated to reversing the addiction crisis in this country.

For nearly a decade, my son Brian suffered with a substance use disorder. During this time, our family worked tirelessly to find Brian the best possible care, and he went to eight different treatment programs. Brian and my family took the advice of supposed experts on how to support him. On October 20, 2011, we lost Brian to the disease of addiction. In the months that followed, I learned that in the decades prior to my son's death, the Federal Government had provided grants of tens of billions to dollars to researchers all across our country, and those researchers had successfully created a body of knowledge that had proven to be able to significantly improve outcomes for those in treatment. But shockingly, all this information was sitting in peer-reviewed medical journals, and hardly any of it was being used. It broke my heart to realize that there were options that could have helped Brian, if only we had known what to look for and who to trust. It haunted me knowing how many families were being shattered every day by this disease and how much devastation could be easily prevented by ensuring research is implemented into practice. This is why I founded Shatterproof, the first national nonprofit organization dedicated to reversing the addiction epidemic in America.

To accomplish this, we developed a plan to transform the addiction treatment system in the United States. This plan includes five components:

1. A core set of science-based principles of care for treating addiction.
2. Treatment quality measurement.
3. Payment reform.
4. Treatment capacity.
5. Stigma reduction.

For the purpose of this hearing, I will focus my remarks on treatment quality and share how Shatterproof is currently implementing the first phase of ATLAS, an ad-

diction treatment locator, analysis, and standards tool, in six States. I commend the other witnesses today for their critical work of uncovering fraud and abuse in the substance use disorder treatment space. I hope that I complement that testimony by addressing the problem of slow adoption of evidence-based practices, which are essential to improving patient outcomes and reversing the nation's staggering overdose rates. ATLAS seeks to spur transformation in this space, and quickly.

Addiction is a well-researched chronic brain disease, but despite the fact that there are clear clinical best practices with demonstrated efficacy the use of these practices varies widely across the addiction treatment field, even in the wake of an opioid epidemic. While some addiction treatment facilities offer clinically effective medical treatment, others employ tactics based on ineffective and outdated methodologies that may be harmful to patients. Using the information currently available, Americans with substance use disorders and their loved ones find it almost impossible to sort through misinformation and identify the most appropriate level of addiction care, and, evidence-based care, Even worse, some addiction treatment facilities capitalize on the fact that addiction impacts the part of the brain that regulates decision-making, problem-solving, and stress, making people with substance use disorders susceptible to schemes like patient-brokering. Unlike other health-care services, comprehensive, standardized, accurate data on the quality of addiction treatment does not exist. Even worse, market forces have not been aligned to support best practices. This must change. And this can change.

WHAT IS ATLAS?

ATLAS is a web- and app-based platform with a triple aim: (1) empower and educate patients and family members looking for addiction treatment with reliable information on the use of evidenced-based best practices by treatment facilities, (2) equip addiction treatment providers with data to inform their quality improvement initiatives and advance the use of best practices, and (3) ensure policy and payment decisions are data-driven, such as the deployment of technical assistance resources and modified payment models.

Measurement systems for health-care quality have been used to drive improvements and reduce costs for decades.[1] Fueled by increased consumerism, this trend has grown in scope and sophistication since the early 1990s, and early supporting research shows that health-care rating systems positively impact provider quality and patient outcomes. Hospitals with publicly reported quality metrics have significantly more quality improvement activities[2] than those without such metrics. These systems also bring the power of market forces to incentivize improvements in the quality of care by informing consumer and payer decisions that impact the market share of treatment providers.[3] With regard to addiction treatment, I would like to highlight that this approach is consistent with recommendations[4] made by the Institute of Medicine in 2006, calling for the development and dissemination of a common, continuously improving set of measures for the treatment of SUD to drive quality improvement and the public reporting of the delivery of this care.

ATLAS will allow the public searching for high-quality addiction treatment to locate and compare facilities, including trustworthy, standardized quality data on the services available at addiction treatment facilities, and to review feedback on the services reported by other patients. ATLAS fulfills Shatterproof's goal of leveraging healthcare quality measures to increase transparency in and encourage improvements to addiction treatment. It is based upon Shatterproof's National Principles of Care©:

1. Routine screenings in every medical setting.
2. Rapid access to care.
3. A personalized plan for every patient.

---

[1] McIntyre, Rogers, and Heier, "Overview, History, and Objectives of Performance Measurement," *Health Care Financing Review,* Spring 2001, available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4194707/*.

[2] Hibbard, Stockard, and Tusler, "Does Publicizing Hospital Performance Stimulate Quality Improvement Efforts?", *Health Affairs,* March/April 2003, available at: *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.22.2.84.*

[3] Werner, Konetzka, and Polsky, "Changes in Consumer Demand Following Public Reporting of Summary Quality Ratings: An Evaluation in Nursing Homes," *Health Services Research Journal,* June 2016, available at: *https://www.ncbi.nlm.nih.gov/pubmed/26868034.*

[4] Institute of Medicine Committee on Crossing the Quality Chasm: Adaptation to Mental Health and Addictive Disorders, "Improving the Quality of Health Care for Mental and Substance-Use Conditions," *National Academies Press, 2006,* available at: *https://www.ncbi.nlm.nih.gov/books/NBK19830/*.

4. Long-term disease management.
5. Coordinated care for all behavioral and physical health conditions.
6. The use of evidence-based behavioral therapies by trained professionals.
7. Access to FDA-approved medications for addiction treatment.
8. Access to recovery support services, including peer and community services.

ATLAS will collect facility-level data from three sources: insurance claims, patient experience surveys, and a validated treatment facility survey. Data from these sources will be available at the addiction treatment facility level in a free online dashboard that allows for easy comparisons among facilities. Individuals may filter searches based upon facility features that are important to them, such as location and insurance coverage. Facilities that do not respond to the survey will still be listed on the public-facing website with an indication that quality data was not disclosed. This approach creates a source of trusted information, preventing people looking for care from falling prey to call centers and fraudulent schemes.

Additionally, ATLAS will promote quality improvement by offering portals for facilities, payers, and States to view and use the data to drive innovations such as internal facility improvements, rewards for facility performance, and data-driven State initiatives such as addiction treatment technical assistance and policy reform. Without this system, we are concerned that the funneling of needed resources to the addiction treatment space may only further support questionable treatment practices. Instead, with ATLAS, responses can be targeted and ensure that State and Federal dollars are only being used to support the delivery of evidence-backed care.

CURRENT STATUS

Phase 1 of ATLAS is currently being implemented in select states—Delaware, Louisiana, Massachusetts, New York, North Carolina, and West Virginia—over 2 years. States were selected based upon various criteria, including capacity for successful implementation and demonstrated potential to scale ATLAS in the future. Shatterproof is working closely with many addiction treatment stakeholders, including provider and medical organizations, payers, and recovery advocates, to ensure a successful and collaborative implementation.

Shatterproof is working with RTI International (RTI), an independent research institute with national expertise in quality measurement and substance use disorders, to support ATLAS analytics. RTI currently supports five national health quality reporting efforts and one large private rating system and has developed and obtained National Quality Forum (NQF) endorsements for over 40 quality measures. RTI leads large-scale quality measure collection efforts with health-care providers including supporting over 3,000 providers in reporting measures for the Centers for Medicare and Medicaid Services' (CMS's) Comprehensive Primary Care Plus (CPC+) project.

Shatterproof received $5 million in funding for the ATLAS pilot, with majority funding coming from Arnold Ventures and the Robert Wood Johnson Foundation and the remainder coming from a group of national health insurance companies.

PROGRESS TO DATE

Thus far, the pilot has included measure identification and refinement through an NQF Expert Panel Strategy Session and public comment period, feasibility testing of survey items and claims measures, and a pilot of the patient experience survey approach across 50 facilities in one State. Data collection for the pilot phase is underway from mid-October to mid-December 2019 from three sources: insurance claims, treatment facility surveys, and patient experience of care. Facilities will have the opportunity to review the display of their quality measure data before public launch.

Claims Data. The four claims-based measures address the concepts of care continuity, overdose after treatment, evidence of opioid use disorder (OUD) medication use, and continuity of pharmacotherapy for OUD. The measures are currently being calculated by participating Medicaid agencies and commercial health plans across the six phase 1 States.

Patient Experience Survey. The Patient Experience Survey, which includes questions related to treatment quality, access, patient improvement in functioning, and facility staff support that are based on the Agency for Healthcare Research and Quality's (AHRQ) CAHPS survey, was recently piloted at 50 facilities in New York State with promising findings. Twenty responses per facility will be needed to report reliable data to the public. Data collection is now underway across all of the phase

1 States. Upon the launch of ATLAS, the public will be able to complete these surveys to leave feedback on facilities directly on the ATLAS site.

Treatment Facility Survey. Shatterproof and RTI have conducted an iterative process for finalizing the Treatment Facility Survey questions based on the result of the NQF Expert Panel. This has included feasibility testing and formal input processes with treatment providers, State partners, and the public. Validation measures and protocol, used to ensure the accuracy of survey data collected, have also been finalized. The Treatment Facility Survey was distributed to all 2,444 facilities across the six phase1 States via an online portal on October 14, 2019. More than 15percent of the facilities have already submitted a response or are in the process of doing so.

Quality data will be triangulated from these three sources and reported through the ATLAS site back to providers, to the public, and to payers and States. Importantly, facility-level composite scores such as a letter grade or star rating will not be generated during this pilot; instead, descriptive and quality information will be displayed as objectively as possible with lay-friendly educational content. ATLAS is slated to be launched as early as May 2020.

FUTURE OF ATLAS

Following the implementation and evaluation of the ATLAS pilot, Shatterproof will lead the sustained implementation and scale-up of this resource to serve people with substance use disorders and their loved ones nationally. Lessons learned from phase 1 will inform further refinement of the quality measures and improve data collection techniques for future phases to ensure ATLAS is providing comprehensive, useful information on addiction treatment and driving overall quality improvement.

Shatterproof remains committed to using data-based indicators to catalyze long-term systems- and policy-level changes in addiction treatment. This is part of our strategic goal of transforming the addiction treatment system in the United States in order to reverse the addiction crisis that has had a severe and tragic toll on too many, and for which the impact can be averted for so many more.

Thank you for the opportunity to testify today, and I look forward to your questions.

QUESTIONS SUBMITTED FOR THE RECORD TO GARY MENDELL

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. Research suggests that a low percentage of those struggling with addiction actually seek treatment. Could you comment on how peer support services can reduce the stigma associated with seeking treatment for behavioral health conditions?

Answer. This is not an issue we have focused on at Shatterproof, but we would be happy to work with you and your staff on it. We do know that some States have started to pay for peer supports and this is a signal that there is some basis for their benefit.

Question. Please tell us more about your efforts to partner with State government agencies to offer guidance on different approaches to expand evidence-based treatment options for those struggling with addiction.

Answer. In the absence of a national standard of care for addiction treatment, Shatterproof, in partnership with a multi-stakeholder collaborative, released its National Principles of Care. The use of these evidence-based best practices is known to improve patient outcomes. Recognizing the gap in transparent information on the quality of addiction treatment facilities, along with a plethora of misinformation in this space, Shatterproof then created ATLAS to help families looking for high-quality addiction treatment. ATLAS helps people searching for treatment by displaying trustworthy quality information using multiple data sources. This quality information will be available on treatment facility profiles along with educational information to help guide treatment decisions by individuals and family members.

Having established standards of care, it was incumbent on us to work with States to remove barriers to that care. Prior authorization (PA) before receiving medication for addiction treatment (MAT) is one such barrier. Despite the evidence supporting MAT, treatment use remains low among individuals with an opioid use disorder

(OUD): only 25 percent of the 2.1 million individuals with an OUD are treated with MAT. Utilization management practices applied to MAT by public and private health insurers or payors contribute to this gap. PA requirements and annual limits are associated with decreased MAT availability.[1] Providers also rate PA requirements as a significant barrier to MAT prescribing.[2] Despite evidence suggesting that PA reduces MAT use, these policies remain prevalent across public and private markets. In the 2019 Medicaid managed care organization market, 42 percent of plan sponsors or pharmacy benefit managers imposed a PA or step therapy requirement on generic MAT products; 53 percent imposed a requirement on brand products.[3] Among 2017 marketplace plans, 36.1 percent of plans applied PA to a buprenorphine formulation.

We, along with leading organizations like the American Society of Addiction Medicine (ASAM) and the American Medical Association (AMA), have worked in several States to end the practice of requiring PA before accessing MAT. We are making significant progress with many States banning the use of prior authorization for MAT. Missouri, Colorado and Texas each passed laws this year ending that practice to varying degrees. This followed several other States, including Massachusetts and Pennsylvania, that had already done so.

Another issue is ensuring that States require quality treatment as part of their licensure of treatment facilities. We worked in California to ensure that residential treatment facilities have quality standards and are hopeful that they will require the same for outpatient treatment.

Question. Engaging overdose survivors in the hospital, when they are most vulnerable, and therefore inclined to commit to treatment for addiction, is a strategy that some communities have embraced. Do emergency room initiated support services work, in your opinion, and if so, under what circumstances are they most likely to succeed? What else might we do to promote awareness of additional strategies to encourage addiction treatment?

Answer. According to Dr. Nora Volkow, Director of the National Institute on Drug Abuse, emergency department (EDs) represent a critical opportunity for overdose prevention and engagement in treatment. Those who have overdosed on heroin are four to five times more likely to suffer a subsequent overdose event and are at higher risk of death from opioid overdose.[4] A recent report from the Delaware Drug Overdose Fatality Review Commission found that half of the people in Delaware who died of an overdose during the second half of 2018 had suffered a previous nonfatal overdose. More than half of these deaths occurred within 3 months of an ED visit. The report recommended that patients who visit EDs with signs of OUD be linked to treatment.[5]

Studies show that the time period immediately following an overdose is a critical time to transition an individual into treatment. Individuals who are treated for a nonfatal overdose in the ED are at the highest risk for mortality in the first month, and in particular, the first two days after the overdose.[6] Yet, a recent study found that patients with OUD who were treated with buprenorphine in the ED were twice as likely to be in treatment after 30 days when compared to patients who were only given referrals to addiction treatment specialists.[7]

These studies and anecdotal evidence we hear from States and medical practices suggest this is an area that needs urgent attention.

Further, Shatterproof supported the section 7081 "Preventing Overdoses While in Emergency Rooms" provision of the SUPPORT Act to support coordination and continuation of care for drug overdose patients. The grant program will support implementation of voluntary programs for care and treatment of individuals after a drug

---

[1] Andrews CM, Abraham AJ, Grogan CM, Westlake MA, Pollack HA, Friedmann PD. "Impact of Medicaid Restrictions on Availability of Buprenorphine in Addiction Treatment Programs." *American Journal of Public Health.* 2019;109(3):434–436. doi:10.2105/AJPH.2018.304856.

[2] Kermack A, Flannery M, Tofighi B, McNeely J, Lee JD. "Buprenorphine prescribing practice trends and attitudes among New York providers." *Journal of Substance Abuse Treatment.* 2017;74:1–6. doi:10.1016/j.jsat.2016.10.005.

[3] Avalere Health PlanScape. 2019.

[4] *https://www.acep.org/how-we-serve/sections/trauma--injury-prevention/news/june-2015/opioid-overdose-prevention-and-response/.*

[5] *https://www.drugabuse.gov/about-nida/noras-blog/2019/08/emergency-departments-can-help-prevent-opioid-overdoses.*

[6] *https://www.ncbi.nlm.nih.gov/pubmed/31229387.*

[7] *https://jamanetwork.com/journals/jama/fullarticle/2279713.*

overdose based on best practices to be defined by the Secretary of the Department of Health and Human Services, including on the use of recovery coaches, better coordination and continuation of care, and the prescribing of overdose reversal medication. We look forward to the Secretary's report on long-term health outcomes of the population served by grantees and remain supportive of providing immediate care continuation and treatment options after a non-fatal overdose.

QUESTION SUBMITTED BY HON. PATRICK J. TOOMEY

Question. Do any of the States stand out as high performers when it comes to oversight and regulation of addiction treatment centers? Please provide examples.

Answer. Of the States we work with, Massachusetts in particular stands out as a leader on addressing addiction issues in a comprehensive way. The State's licensing for addiction facilities incorporates the highest level of rigor. They have also led the way on integrating data systems to expand the knowledge base around opioid use disorder and overdose deaths with their chapter 55 data. This in turn allows for more targeted interventions. Lastly, they have been a leader on increasing education around addiction and treatment among future healthcare professionals.

QUESTION SUBMITTED BY HON. BILL CASSIDY

Question. This hearing highlighted some of the challenges that families affected by substance use disorder face when trying to find properly certified treatment centers that use appropriate, science-based methods. One way that families could be helped is by having access to an app which directs them to certified treatment centers in their area. Generally speaking, how has HHS considered ways to direct families to treatment centers that are certified and use science-based methods? If not such an app exists, could HHS put forth a challenge grant to help one be created?

Answer. Recognizing the gap in transparent information on the quality of addiction treatment facilities, along with a plethora of misinformation in this space, Shatterproof created ATLAS to help families looking for high- quality addiction treatment. ATLAS helps people searching for treatment by displaying trustworthy quality information. In the absence of a national standard of care for addiction treatment, Shatterproof, in partnership with a multi-stakeholder collaborative, released its National Principles of Care. The use of these evidence-based best practices known to improve patient outcomes are then assessed using multiple data sources. This quality information will be available on treatment facility profiles along with educational information to help guide treatment decisions by individuals and family members.

There may be an opportunity to build upon the current quality measures and learn from the first round of data collection to implement a certification-type of program in partnership with the Department of Health and Human Services (HHS). Additionally, if HHS were to implement a certification program, that distinction could easily be mobilized in the ATLAS system to make the information available to families. ATLAS uses best practices in website design and user experience to maximize the ease of use for consumers and is poised to integrate additional metrics to help people locate the best quality care.

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. Recent press reports have been critical of accrediting organizations and State licensing agencies for failing to weed out bad actors lurking in the substance use disorder rehabilitation industry. For example, the magazine Mother Jones reported earlier this year on a chain of substance use disorder rehabilitation facilities in Florida that had been accredited by the Joint Commission up until the day they were raided by law enforcement agencies. The owner of the fraudulent Florida facilities went on to be sentenced to 27 years in jail on charges of committing healthcare fraud and coercing patients into prostitution. In your view, what should accrediting agencies be doing differently than they are now to avoid these types of shortfalls? What should the Federal Government's role be in oversight of the drug treatment industry?

Answer. States have a critical role to play in improving the quality of treatment by addressing the licensing requirements for treatment facilities in their State. At the April 2019 National Academy of Medicine's Action Collaborative meeting, it was discussed that many State licensing laws have not been reviewed for decades. It is critical that this be done to ensure that licensing requirements account for the evidentiary base that has been developed more recently, specifically the use of medication-assisted treatment (MAT). For example, Shatterproof has worked with California to ensure its residential treatment facilities are licensed with current evidence-based standards and we expect to continue that effort with the State's outpatient facilities in the coming year.

While State accrediting agencies play an important role in ensuring the safety and legitimacy of a facility, they provide little transparency into the quality of the facility to the average consumer. A facility's use of best practices may vary based on the services and, without more nuanced information, it may provide a false sense of quality for an individual seeking care. Shatterproof's ATLAS tool will display earned accreditations for facilities that participate, as well as additional transparency around the use of a multitude of best practices and patient reviews.

On the Federal level, important steps have been taken which include the requirement that State Opioid Response grants be spent on expanding MAT capacity. However, much more should be done such as incentivizing quality care through adequate payment models and oversight.

Finally, ongoing oversight by the Senate Committee on Finance, the Government Accountability Office and the HHS Officer of Inspector General will be essential to ending this crisis of quality treatment.

Question. The Government Accountability Office stated during its testimony that there is no Federal oversight of so-called "sober homes." Please provide examples of regulatory gaps in the sober home industry, or the substance use treatment industry, in general, where the Federal Government should play a greater role.

Answer. ATLAS does not currently include evaluation of or information about sober homes, but we agree that this is an area in need of better oversight and transparency. We are aware of some licensing groups at the State level for sober homes, including the Massachusetts Alliance for Sober Housing (MASH).

Question. As we have heard during the hearing, it's a real challenge for people seeking treatment to find good programs. Your organization is running a pilot program to try to document how well treatment programs actually perform for both inpatient and out-patient facilities that Shatterproof is piloting in Delaware, North Carolina, Louisiana, New York, West Virginia, and Massachusetts. According to your testimony, these six States have more than 2,400 treatment facilities. What is the cost of standing up and running these databases? What is the penetration rate (*i.e.,* how many facilities you expect to have participate in the pilot program)? What are barriers to getting the databases off the ground? How do you expect to expand the program to other States? What steps can the Finance Committee consider taking to facilitate an expansion of the program if its pilot proves successful?

Answer. The cost of standing up ATLAS in each State is roughly $350,000, with some variation based on State size. This includes costs to engage addiction treatment providers, raise awareness, deploy and manage the data collection tools, analyze the data, and build and manage the ATLAS website. Efficiencies to reduce costs for maintenance of the system will be realized in subsequent years resulting in cost savings for running the system once launched. In addition to the cost of building, launching, and maintaining ATLAS, there is further opportunity to deploy technical assistance to support provider improvement and adoption of best practices if funding allows.

During the first phase of ATLAS, we expect roughly one third of facilities to participate across all six States; however, we expect the participation rate to range from 20–50 percent by State based on factors related to engagement in the project and incentives for participation. Facilities participate by completing the Treatment Facility Survey, or submitting information on the practices, processes, and services available at their site. Importantly, even if facilities do not participate in the Treatment Facility Survey, their site will still be listed on the ATLAS website and it will clearly indicate that they did not disclose quality data. If data on quality is available from the other data sources (*e.g.,* claims-based measures or patient experience surveys), we anticipate that information will still be displayed.

Shatterproof has worked to overcome barriers to ensure ATLAS is successful. The level of provider engagement has varied greatly across Phase 1 States. In some cases, providers have been hesitant or unwilling to collaborate on ATLAS, given facilities are being assessed on the quality of their services. Shatterproof has worked diligently alongside State partners to understand provider concerns and build trust in the Phase 1 States through frequent provider roundtables, advisory committees, and other engagement efforts. These efforts have been worthwhile as engagement has improved in recent months and survey response rates are on target.

Shatterproof is also revolutionizing the use of claims measures for addiction treatment—working with health insurers to identify a feasible strategy to incorporate these data into ATLAS. This novel approach has proven difficult to implement due to data differences across States and organizations, but Shatterproof is continuing to troubleshoot and refine the data collection and analytics processes with participating insurers and State Medicaid agencies to determine the best approach.

Despite these challenges, we have seen early successes in Phase 1 and are preparing to scale ATLAS to the remaining 44 States and the District of Columbia. Lessons learned from Phase 1 will allow for increased efficiencies, reduced costs, and the delivery of a responsive and useful product to users across the country. At this point in time, we are exploring phased expansion of ATLAS to other States based on available funding. We welcome conversations with the committee to determine the best path to reach national expansion and sustained implementation of ATLAS. Our research has indicated an annual cost of approximately $15M to run the program once it is launched. We are exploring philanthropic support to facilitate expanding nationally as quickly as possible and are also exploring possible revenue streams to sustain implementation. We would welcome conversations with the committee on other sources of funding and strategies to expand and sustain ATLAS.

Question. During the hearing, you stated that the Federal government could condition treatment-related grants to States on them funding evidence-based treatment practices. What other steps should the Finance Committee consider taking to help people connect with good treatment programs?

Answer. Encouraging States to use Federal grant funding for treatment quality measurement would be an effective way to incentivize States to support ATLAS implementation and ongoing management. This would also be an effective mechanism to ensure that Federal and State dollars spent on addiction treatment are directed to providers using evidence-based best practices and supporting the adoption of these practices, as well as helping families and people with substance use disorders navigate this complex system.

Question. The lack of access to safe, effective treatment for addiction is its own health-care crisis. The examples that the Government Accountability Office has provided are just the tip of the iceberg when it comes to scam artists trying to take advantage of those who are desperate for help. Mr. Mendell, you are a successful businessman. There are many families like yours who have loved ones struggling with substance use disorders but they do *not* have the same resources that you had. For them, the job is even tougher. How do they find good treatment? What red flags should they avoid? What should the Finance Committee be doing to make sure they have access to the high-quality care they deserve?

Answer. For people with substance use disorders and their loved ones, it is difficult to discern between high-quality addiction care and inadequate or even fraudulent providers based on the information currently available. Unlike other health-care services, comprehensive, accurate, and lay-friendly data on addiction treatment quality does not exist. In the absence of a system like ATLAS to provide trustworthy and reliable information on the quality of facilities, patients and family members should be on the lookout for some red flags, including treatment providers that offer incentives to begin treatment at their facilities, such as free flights, money, and even cigarettes. Patients should expect to receive an individual bio-psycho-social examination that informs their treatment plan resulting in patient-specific care and should be concerned if a treatment program funnels patients through a one-size-fits-all program. It is a red flag if facilities do not assess and monitor each individual patient. Other red flags include dehumanizing practices and an unnecessary degree of restriction on personal freedoms, blanket policies prohibiting the use of medication, policies that kick someone out of a program for relapsing rather than providing support and re-engaging to the appropriate level of care, programs without any trained medical staff, and programs boasting of unrealistic or unsubstantiated outcomes such as 80 percent or higher “success rates.” People looking for addiction

treatment can use Shatterproof's National Principles of Care to identify what elements of care should be included in every treatment program.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

Question. Shatterproof has launched a pilot called ATLAS to develop a platform for individuals to search for and find high-quality addiction treatment facilities on the web or through an app.

Could you discuss how HHS or CMS could possibly use the standardized quality data gathered by ATLAS to aid in oversight of recovery homes?

Answer. ATLAS does not currently include evaluation of or information about recovery homes, but we agree that this is an area in need of better oversight and transparency. We are aware of some licensing groups at the State level for recovery housing, including the Massachusetts Alliance for Sober Housing (MASH).

Question. Do you know if Federal agencies are collaborating with State and local governments to inform consumers of the dangers of sober homes and patient brokering practices?

Answer. ATLAS does not currently include evaluation of or information about recovery or sober homes, but we agree that this is an area in need of better oversight and transparency. We would be happy to work with you and your staff to raise awareness about the dangers of patient brokering practices. We also submitted comments to the House Energy and Commerce Committee's effort to continue its ongoing investigation into patient brokering and other challenges, failures, fraud, and abuse within the substance use disorder treatment industry.

Question. If not, what could the Federal Government do to educate consumers about quality treatment programs for their loved ones and how to identify patient brokering scams?

Answer. ATLAS will educate consumers on the best practices in addiction treatment and report facilities' use of these practices. Encouraging States and providers to participate in ATLAS and promoting the website *(https://www.shatterproof.org/atlas)* to those looking for addiction treatment will not only help people avoid potentially harmful or fraudulent providers, it will realign market forces with the delivery of high-quality care.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

MANDATORY LICENSING AND CERTIFICATION REQUIREMENTS

Question. During the hearing, we heard how it can be difficult for individuals and their families to obtain information on the quality of sober homes and treatment facilities because there are no Federal requirements on these facilities that they provide information relevant to the public to aid in evaluating potential treatment options. You expressed support for putting conditions on Federal funding to incentivize States to establish better quality metrics and reporting to help improve access to useful information that folks can use when evaluating treatment options.

In its report, GAO commented that some States have chosen not establish mandatory licensing standards or certification requirements for treatment facilities out of fear it would be a "roadblock" to establishing additional sober homes. Do you believe that these facilities should be required to pass a basic certification/licensing requirement so consumers have access to basic information regarding the quality of the facility?

Answer. Licensing requirements are critical and should be consistent with a reputable evidence-based standard, such as the ASAM criteria. At the April 2019 National Academy of Medicine's Action Collaborative meeting, it was discussed that many State licensing laws have not been reviewed for decades. It is critical that this be done to ensure that licensing requirements account for the evidentiary base that has been developed more recently, specifically the use of medication-assisted treatment (MAT). With regard to how these licensing standards influence the availability of sober homes, this is not a core area of expertise for Shatterproof at this time. However, one concern we should have relates to anecdotes about those in recovery who are not allowed to take their medications for addiction in a sober home or other

recovery setting. This is an issue that needs to be considered as the licensing and quality conversation continues.

Question. What would you say to somebody who argues that minimum standards, quality metrics, and licensure requirements for sober homes are not worth it because they might create barriers to the existence of these types of facilities?

Answer. Shatterproof is supportive of ensuring individuals have access to the appropriate level of quality addiction treatment and other supportive services. Barriers to access should be taken into consideration when weighing any new policy decisions, but we also must find ways to encourage or incentivize treatment providers to meet basic standards for quality, evidence-based treatment and for other recovery support services.

ATLAS

Question. In lieu of any standardized Federal accreditation/certification system, we appreciate Shatterproof's efforts to create a standardized rating system for treatment facilities to give individuals and their families more information and power as they compare treatment options.

What criteria does Shatterproof use to compile ratings for its ATLAS program?

Answer. ATLAS will allow the public searching for high-quality addiction treatment to locate and compare facilities, including trustworthy, standardized quality data on the services available at addiction treatment facilities, and to review feedback on the services reported by other patients. ATLAS fulfills Shatterproof's goal of leveraging health-care quality measures to increase transparency in and encourage improvements to addiction treatment. It is based upon Shatterproof's National Principles of Care©:

1. Routine screenings in every medical setting.
2. Rapid access to care.
3. A personalized plan for every patient.
4. Long-term disease management.
5. Coordinated care for all behavioral and physical health conditions.
6. The use of evidence-based behavioral therapies by trained professionals.
7. Access to FDA-approved medications for addiction treatment.
8. Access to recovery support services, including peer and community services.

ATLAS will collect facility-level data from three sources: insurance claims, patient experience surveys, and a validated treatment facility survey. Data from these sources will be available at the addiction treatment facility, or location-based, level in a free online dashboard that allows for easy comparisons among facilities. Individuals may filter searches based upon facility features that are important to them, such as location and insurance coverage. Facilities that do not respond to the survey will still be listed on the public-facing website with an indication that quality data was not disclosed. This approach creates a source of trusted information, preventing people looking for care from falling prey to call centers and fraudulent schemes.

Additionally, ATLAS will promote quality improvement by offering portals for facilities, payers, and States to view and use the data to drive innovations such as: internal facility improvements, rewards for facility performance, and data-driven State initiatives such as addiction treatment technical assistance and policy reform. Without this system, we are concerned that the funneling of needed resources to the addiction treatment space may only further support questionable treatment practices. Instead, with ATLAS, responses can be targeted and ensure that State and Federal dollars are only being used to provide evidence-backed care.

Our website will be regularly updated as Phase 1 progresses and next steps are announced: *https://www.shatterproof.org/atlas.*

Question. Based on the information your organization has gathered, are there common characteristics that are shared among recovery homes that ATLAS considers to be high quality? Are there trends across low-performing facilities?

Answer. ATLAS does not currently include evaluation of or information about recovery homes, but this is an area in need of better oversight and transparency. We are aware of some licensing groups at the State level for recovery housing, including the Massachusetts Alliance for Sober Housing (MASH).

QUESTION SUBMITTED BY HON. MAGGIE HASSAN

Question. Thank you for sharing your story as a witness during the Senate Finance Committee hearing on "Treating Substance Misuse in America." And thank you for the incredible work that you are doing in your son's memory to improve the lives of so many people.

I am grateful for your work to expand access to information about recovery homes, including the quality and types of treatment available at these homes. It is critical that individuals and their families have this information in order to make informed decisions about their treatment and recovery options.

But, as you know, stigma can limit access to medication-assisted treatment, and can also raise individual privacy concerns, including the risk of employment discrimination, for those in recovery housing.

How does Shatterproof work to address the stigma associated with medication-assisted treatment and recovery housing, and how can Congress help?

Answer. Shatterproof has identified nine commonly cited drivers of the epidemic: overprescribing, increased access to substances, social isolation, lack of help-seeking, insufficient treatment capacity, insurance coverage disparities, lack of evidence-based treatment, criminalization of SUD, and social and structural barriers to recovery. **Seven of these nine drivers are either partially or entirely driven by stigma.**

There are three types of stigma: public, structural, and self. Public stigma is society's negative attitudes towards a group of people, creating an environment where those with an addiction are discredited, feared, rejected, discriminated against, and socially isolated. In a recent survey, fewer than 20 percent of Americans said they were willing to associate closely with someone who is addicted to prescription drugs as a friend, colleague, or neighbor.

Recognizing this gap, Shatterproof, McKinsey and Company, and The Public Good Projects studied 11 analogous social change movements (*i.e.,* tobacco, HIV/AIDS, etc.) to determine whether stigma could be significantly reduced and, if so, the most effective ways to do so. Our research identified six factors from previous movements that helped reduce stigma and that we believe will be most impactful in reducing the stigma associated with addiction:

- A well-funded, central actor can coordinate rapid change.
- Specific actions included educating, changing policies, and altering language.
- Educational initiatives used contact-based strategies (messaging between people with OUD and those without OUD) to humanize the disease and emphasize treatment is effective.
- Sequencing can help a movement activate influential institutions who can trigger broader adoption, ensure sustainable momentum, and reach a tipping point for mass adoption.
- Positive and negative incentives were employed for the most impactful stakeholders.
- Action was mobilized at both the "grassroots" and "grasstops."

Our research concluded that the stigma related to OUD can be significantly reduced. Shatterproof and our partners will be releasing a plan in the coming months to achieve this.

Congress can and should play a pivotal role in addressing the stigma associated with addiction. We invite you to join us to help launch and implement this national initiative and significantly reduce the devastation of the addiction crisis in our country.

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

Today's hearing will spotlight the pitfalls people face when they try to find quality treatment for a substance use disorder. A person battling this disease is often jostled around from one end of the health-care system to the other. The last thing they need is another obstacle—rip-off artists, empty promises, or outright abuse—when they are just trying to get better.

Too often, people travel across the country expecting to arrive at a legitimate treatment facility only to find that they have fallen prey to a scheme whose goal

is to drain their bank account and bilk their insurance for everything it's worth. In some instances, these unscrupulous operators lure would-be patients by paying for plane tickets and promising free rent. Once they arrive, these patients may receive sub-standard care or no care at all. But the fraudsters are still billing insurers for health-care services that may have never been performed.

One of the biggest problems involves facilities that allegedly treat substance use disorders but are actually set up to defraud taxpayers. These fraudsters illegally recruit patients using bribes and kickbacks, and then bilk taxpayers by billing the patient's health plan for medically unnecessary drug tests. Schemes like these, which our witnesses will detail this morning, cost Medicare, Medicaid and private insurance hundreds of millions every year.

Just this month, six people operating a network of fraudulent treatment centers in Ohio pled guilty to submitting 130,000 Medicaid claims that totaled more than $48 million for medication-assisted treatment and other services that were never legitimately provided.

Part of the reason this type of fraud is so common is because there is no way for a patient or their family to learn about the quality of a treatment facility before they enroll. Today the committee will hear from an organization that is working to change that. Shatterproof is currently developing public databases in multiple States that, if successful, will allow the public to identify, evaluate, and compare substance use treatment programs. This kind of database and transparency is the type of information families need to find quality treatment and avoid sham operators trying to make a quick buck.

One final point. The recent court settlements in multiple States with drug makers and wholesale distributors demonstrate that States and communities may be on the cusp of receiving tens of billions of dollars from the companies that helped seed this epidemic. A sum of that size will almost certainly be a magnet for fraud. This hearing will highlight the need to make sure rules of the road and vigorous oversight are in place to ensure those dollars go to proper care that will help heal this national crisis.

I thank the witnesses for joining the committee this morning. This is an opportunity for bipartisan progress on health care, so let's get to work.

COMMUNICATIONS

ASSOCIATION FOR BEHAVIORAL HEALTH AND WELLNESS
1325 G Street, NW, Suite 500
Washington DC, 20005
202–449–7660
https://abhw.org/

November 5, 2019

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

October 24, 2019: "Treating Substance Misuse in America: Scams, Shortfalls, and Solutions"

Dear Ranking Member Wyden:

The Association for Behavioral Health and Wellness (ABHW) appreciates the opportunity to respond to your comments requesting information about substance use disorder (SUD) treatment during the Finance Committee's October 24th hearing, "Treating Substance Misuse in America: Scams, Shortfalls, and Solutions."

ABHW is the national voice for payers that manage behavioral health insurance benefits. ABHW member companies provide coverage to approximately 200 million people in both the public and private sectors to treat mental health, SUDs, and other behaviors that impact health and wellness.

ABHW members have witnessed firsthand the fraud in some SUD treatment facilities in areas of licensure, accreditation, administrative and billing practices, quality, and enrollment. Our comments below outline the problems ABHW members have experienced with fraud and abuse as well as offer ideas to improve the quality of SUD treatment. These fraudulent activities usually occur in out-of-network SUD facilities and the inappropriate care they provide can have dire, and sometimes fatal outcomes.

Recovery Homes

ABHW supports the notion that recovery housing should have a clear operational definition that accurately delineates the type of services offered. While recently released guidelines by the Substance Abuse and Mental Health Services Administration (SAMHSA) encourage this, we believe additional oversight needs to be identified to truly hold unethical treatment centers accountable.

Efforts to address this issue should explicitly state that recovery homes are not treatment programs and individuals do not receive treatment at a recovery home. Additionally, it should be made clear that recovery homes can be a component of an individual's treatment and recovery and that any necessary treatment will be accessed in other settings and that all services should be coordinated. This level of specificity is critical so that recovery homes can be evaluated by consumers, providers, accrediting bodies, government, and payers. A clear delineation will help everyone know what to expect.

Licensure and Accreditation

While licensing is a function under state and other local jurisdictions, efforts are needed to ensure that all facilities are licensed and fully accredited to provide SUD treatment. ABHW members have found that some facilities do not have a valid license, a license does not exist at the address provided, a license is not for services

being advertised, and/or the facility may be providing services for which they are not licensed.

Additionally, it is critical that facilities adopt quality standards and be held accountable to those standards through accreditation. Standards should take into account that there are several levels of care within the recovery housing model, each with different oversight needs.

Administration and Billing Practices

As more funding is directed toward treating SUDs it has drawn the interest of private equity and other profit driven providers. Several important clinical and billing issues need to be addressed. ABHW members have identified that fraudulent facilities may bill for the same diagnosis, same procedures, same units for every member, every day. Additionally, there is often misrepresentation of billed services such as an inpatient/hospital bill, but the facility is residential or intensive outpatient. These providers are often unable to substantiate billed services and lack adherence to federal and state regulations, policies, and/or procedures.

Quality

ABHW member companies continue to grapple with fraudulent claims and identifying deceptive practices. While there are efforts to roll back prior authorization, these and other utilization review tools are important to help ensure that patients aren't being preyed upon by fraudulent providers. These managed care techniques help provide checks and balances to ensure quality treatment and patient protections. ABHW member companies have identified improper practices sue as, treatment not being rendered by a medical professional, in appropriate medical supervision of SUD treatment programs, clinical information provided during prior authorization is unclear or vague, excessive use of medically unnecessary services, unlicensed personnel rendering services, and facilities billing for levels of care that they are not licensed to perform.

Quality standards, best practices, and model policies need to be identified and widely disseminated and adopted to ensure individuals have appropriate and accurate information to make treatment decisions. Additionally, this will give payers a full picture of the medically necessary services rendered under appropriately licensed medical professionals. This will ensure the appropriate level of care and treatment needed to produce positive health outcomes and protect patients struggling with SUDs.

Enrollment

Patient brokering continues to be a part of fraudulent practices in pockets of the SUD treatment industry. This activity often results in kickback payments and targeting patients through deceptive marketing and advertising practices with paid travel and incentives to enroll in treatment, often outside of their state of residence and out-of-network. Once an individual is enrolled, facilities often bill for treatments, tests, and other services or procedures that may or may not be clinically appropriate and may not even be provided. We encourage efforts to identify this fraudulent behavior and procedures for law enforcement to address it in a timely manner.

ABHW is committed to working with Congress, the Administration, health care providers, and other stakeholders to shed light on this issue, prevent fraud, and protect patient lives.

Additional SUD Policies

ABHW is fully committed to addressing SUDs. In particular we are interested in curbing the opioid epidemic and supporting a continuum of evidence-based, person-centered care to treat individuals with an opioid use disorder (OUD), including medication assisted treatment (MAT). Our members work to identify and prevent addiction where they can; and where they cannot, they help individuals get treatment so that they can recover and lead full, productive lives in the community. As you continue your work to address SUDs, we encourage you to consider the following additional policy and legislative proposals.

42 CFR Part 2

ABHW is committed to aligning 42 CFR Part 2 (Part 2) with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of treatment, payment and health care operations (TPO) to allow appropriate access to patient information that is essential for providing whole-person care while protecting patient privacy.

The Protecting Jessica Grubb's Legacy Act, S. 1012, promotes coordinated care and expanded access to treatment. As you continue your work to address SUDs, we high-

light the importance of including S. 1012 in any legislative health package that is considered on the Senate floor this year. This legislation would align Part 2 with HIPAA to allow for the transmission of SUD records for the purpose of TPO as well as enhance patient privacy and anti-discrimination protections. Only then can we promote integrated care and heightened patient safety, while providing health care providers with one federal privacy standard for all of medicine.

The recent Confidentiality of Substance Use Disorder Patient Records Notice of Proposed Rulemaking, issued by SAMHSA, proposed some helpful changes to patient consent, and clarified the ability of non-Part 2 providers to segregate any patient records received from Part 2 programs in order to avoid subjecting their own records to Part 2. The proposed rule did not address aligning Part 2 with HIPAA for the purposed of TPO. As a result, it remains important for you to consider S. 1012.

Expanding Access to Care and Addressing Workforce Shortages

We thank you again for your leadership and efforts to ensure a sustainable workforce to meet the behavioral health needs in communities across the country. Expanding access to care by addressing workforce shortages and barriers that limit available providers to treat addiction can improve health outcomes, overcome stigma, and reduce costs. Given that approximately 1 in 5 adults have a mental illness and 1 in 12 have a SUD, and the fact that there is a growing shortage of behavioral health providers to respond to this significant need for services, addressing these barriers is vital to help address this growing need for ready and timely access to necessary treatment. Increasing the number of mental health professionals in communities will help confront the behavioral health workforce shortage that hinders so many individuals and families from accessing care.

ABHW recommends eliminating the DEA X waiver to prescribe buprenorphine. It is important to remove regulatory hurdles to help reduce unmet needs for addiction treatment. In many areas1our members find it hard to locate a provider willing to provide treatment to the consumers they serve. Addressing this barrier would allow more providers to prescribe medication for opioid use disorder and help individuals overcome addiction.

ABHW also advocates expanding access to treatment by addressing workforce shortage issues. In particular, we propose expanding the number of residency positions to treat addiction, increasing access to a wide variety of behavioral health providers such as licensed counselors and marriage and family therapists, and incentivizing mental health professionals to serve in workforce shortage areas. These steps will improve SUD treatment and help curb the opioid epidemic.

Thank you for the opportunity to comment on this import ant issue. We look forward to working with you to identify solutions and ensure quality, evidence-based SUD treatment in communities across our nation. Please feel free to contact Maeghan Gilmore, Director of Government Affairs at gilmore@abhw.org or 202–449–7658 with any questions.

Sincerely,

Pamela Greenberg, MPP
President and CEO

LETTER SUBMITTED BY TRUDY AVERY

October 23, 2019

U.S. Senate
Committee on Finance
Dirksen Senate Office Building
Washington, DC 20510

RE: "Treating Substance Misuse in America: Scams, Shortfalls, and Solutions"

To Whom it May Concern:

I am writing this letter on the eve of the Committee's hearing on "Treating Substance Misuse in America: Scams, Shortfalls and Solutions"; thus you will be receiving this after the fact.

I was just made aware of this hearing this morning, but still felt it imperative to write to the committee. I am the mother of an adult son, Corey, now 32, who is in

long-term recovery from IV heroin use. He struggled since the age of 14 and got sober at age 28, after four in-patient programs.

I am enclosing a *Cape Cod Times* article from 2013 reflecting on my lawsuit with Blue Cross of Massachusetts, which took place 10 years ago. I wish I could say that access to treatment has improved, but unfortunately it has not. Even with legislation on many state and federal books, such as the 2-week requirement that Massachusetts insurers must pay. I appreciate all the hard work over the years in addressing this crisis; however, as I continue to testify (as I have done so for over 15 years), the single most important factor missing from strategies is to take the decision-making process of the *medical necessity* out of insurer's hands, and place it into the hands of the primary care physician, of which the insurers cannot override. The medical necessity piece is the loophole that still allows insurers to get out from payment and access.

I will continue advocating on behalf of so many in this country who needs that access. Corey originally received 60 in-patient days through my lawsuit, which was written into my husband's employer's health contract, and two more additional 60-day programs with his relapses. He ultimately attended Caron Treatment Centers for five months back in 2016, which gave him the desperately needed time that launched him into sobriety.

Thank you.

Trudy Avery

From *Cape Cod Times,* April 8, 2013

INSURANCE COMPANIES PUSHED TO COVER ADDICTION TREATMENT

By K.C. Myers

Blue Cross Blue Shield of Massachusetts didn't know what it was up against when it refused to cover the son of Sandwich resident Trudy Avery for extended treatment for opiate addiction in 2008.

SANDWICH—Trudy Avery's life changed completely when her son became addicted to opiates while at Sandwich High School.

In 4 years, the mother of four grown sons has joined a host of volunteer committees related to addiction and spoken on Beacon Hill. She went from a job fundraising at Massachusetts Maritime Academy to fundraising for Caron Treatment Centers, which operates in several states.

But first, Avery learned how to fight insurance companies.

Blue Cross Blue Shield of Massachusetts didn't know what it was up against when it refused to cover her son Corey's extended treatment for opiate addiction at the Florida Center for Recovery in 2008.

Corey began abusing oxycodone while in high school.

At 18, he sought treatment for the first time at Gosnold on Cape Cod's detox hospital in Falmouth. After a 5-day stay, paid for by the family's Blue Cross Blue Shield policy, he "begged to be transferred to a 30-day program," Avery said.

But insurance wouldn't cover it.

As Avery soon learned, the insurance policy stated it would allow up to "60 inpatient days per member per calendar year in a mental hospital or substance abuse facility."

But the stays had to be pre-approved by the insurance company. And the approval came down to whether the insurance company deemed the treatment "medically necessary," Avery said.

Three years after Corey's first detox treatment, when he was 21, he overdosed while living with his grandmother in Connecticut in September 2008.

"It was an absolute heartbreak to our family, but I can now look back at it as our blessing in disguise," Trudy Avery said. "Corey now had the 'medical necessity' for the addiction treatment he had been seeking all those long years."

The insurance company approved a 14-day stay at the Florida Center for Recovery in Fort Pierce. Corey moved next to outpatient treatment at the Transformations Treatment Center in Delray Beach.

But Blue Cross Blue Shield denied his $23,000 claim for the outpatient treatment, saying his benefits were used up.

Avery didn't give up.

"My son had a medical overdose and was entitled to those 60 days stated in our contract," she said. Avery appealed the denial. She contacted Massachusetts Attorney General Martha Coakley, and in the meantime, told her story publicly to the state's former OxyContin and Heroin Commission, a group formed to hear testimony from those affected by opiate addiction and to craft legislation to fight opiate abuse.

In September 2009, she testified at the Statehouse.

After she spoke, state Sen. Steven Tolman, D–Brighton, who was then chairman of the heroin commission, called a meeting with the president of Blue Cross Blue Shield of Massachusetts and Avery in his office.

The meeting never happened because "lo and behold, I got paid in full," Avery said.

"I think they were afraid of the publicity," she said. "I think the insurance companies hope that the majority of people will accept their 'no' without question, or just give up."

A Blue Cross Blue Shield representative would not talk about the Avery case because of patient privacy laws.

The Avery family is hardly alone in its fight to have addiction treatment covered by private health insurance.

In 2011, only 64 percent of substance abuse treatment facilities accepted private health insurance, according to the federally funded Substance Abuse and Mental Health Services Administration.

Private insurance payments were accepted at 85 percent of facilities with a primary focus on mental health services, the report found. At facilities that treated mainly substance abuse, only 56 percent accepted private insurance.

For members of Parents Supporting Parents, the Cape self-help group for parents of addicts, this isn't news. Many parents have paid $20,000 to $60,000 at a time to put their children into long-term treatment or reputable inpatient facilities that don't accept insurance at all.

When parents ask how they can pay for addiction treatment, Mashpee mother Lisa Murphy, who founded the support group, says, "Take your children off your private plan, and tell them to go on MassHealth."

It's true that MassHealth—publicly funded insurance—pays for a lot of addiction programs. But that adds a burden to taxpayers and the treatment centers since MassHealth payments cover only 70 percent of the cost of services, said Gosnold on Cape Cod President and CEO Raymond Tamasi.

Gosnold tries to have a mix of patients paying privately, on MassHealth or receiving free care.

"We have to pay close attention to our 'pair mix,'" Tamasi said.

With the wave of young opiate addicts that followed the U.S. Food and Drug Administration's approval of OxyContin in 1995, Tamasi hears the Avery story quite often.

Families read "60 days" in their policies, he said. But they soon discover the insurance company won't approve that much treatment, particularly for someone seeking help for the first time.

"It's a fail-first policy," Tamasi said. "You have to fail at a lesser level of care first. . . . It's the worst part of this field."

Laws in 43 states require commercial group health insurance plans to provide some level of treatment for alcohol or other drug addiction, according to Deb Beck, president of Drug and Alcohol Services Providers of Pennsylvania and a consultant with the National Alliance for Model State Drug Laws, which was created and funded by a bipartisan act of Congress.

But many insurance companies and managed-care firms continue to work to find ways around the laws, she said.

"This is the hidden part of the war on drugs," Beck said. "Everyone says, 'We want to treat addiction.' But the insurance companies make it very difficult to access the treatment required by law."

In 2008, Congress passed the Mental Health Parity and Addiction Equity Act. It requires group insurance plans that already offer mental health and substance abuse treatment to offer the coverage at the same level as other medical benefits.

But the equity act hasn't improved coverage, Tamasi said.

In theory, the bill was a victory for treatment because it placed the disease of addiction on the same plane with physical ailments, he said.

"But the guidelines on how it is implemented and interpreted is a miasma of confusion," he said. "And we still don't have full implementation."

Tamasi has seen insurance coverage become more selective about what it approves and more restrictive since the 1970s, he said.

Twenty years ago insurance typically approved a 28-day inpatient treatment stay. Now it's much less, often just a week.

Gosnold has five full-time employees whose sole job is to call insurance companies arguing for a few more days of treatment for patients, he said.

As Avery learned last year, the equity act wasn't exactly the answer to her prayers.

After 3 years of sobriety, Corey relapsed briefly in February 2012 with prescription stimulants and alcohol while starting his new recovery-focused business called *sobernation.com.*

Corey, 25 and still on his family's insurance plan, got himself back into a treatment program within 2 months of his relapse, he said.

Avery called Blue Cross Blue Shield, seeking coverage again.

This time, the insurance policy couldn't put an annual time limit on the treatment because of the new requirements of the equity act, she said.

But everything else about fighting for Corey's treatment was familiar.

Eventually the insurance company paid for about one month of inpatient treatment, Avery said. That treatment was approved in 5- to 7-day increments.

"They still strive to give the least treatment necessary," she said.

As before, the treatments had to be deemed "medically necessary" by the insurance company, she said. "I think the parity bill is helping, but not much," Avery said.

Dr. Jan Cook, a medical director at Blue Cross Blue Shield, said the definition of "medical necessity" is broad. She said the actual degree of treatment that gets approved is determined on a case-by-case basis after a "conversation" between the patient's doctor and the insurance company's medical staff.

The insurance company, however, does not have to agree with the doctor or treatment specialist. And the appeals process is incredibly time-consuming and costly, Tamasi said.

Blue Cross Blue Shield receives more claims for substance abuse treatment now, but not because of the equity act, said Sharon Torgerson, the company's Massachusetts director of public relations.

Inpatient substance abuse treatment for Blue Cross Blue Shield clients rose by 7.6 percent in 2012 and by 5 percent in 2011 because of a rise in addiction nationally and in Massachusetts, she said.

As Beck says, laws alone don't force change, unless those laws also come with enforcement.

"States need to move forward to monitor and measure compliance by the insurance companies," Beck said. "Right now, accountability tools available to the states are not being used, don't exist or are too complicated for the average person to decipher."

Beck said her home state of Pennsylvania has done a lot of work on ways to hold insurance companies accountable.

In 2009, Pennsylvania's Supreme Court upheld one of the strongest laws in the nation that requires insurance companies to cover addiction treatment. The law states

that a managed-care plan does not have the authority to overrule a referral by a doctor or psychologist.

Beck said Pennsylvania's addiction treatment law has been on the books since 1986. But when managed care came to the state in the early 1990s, many people were "unable to access the treatment required under law," she said.

In 2004, the insurance companies mounted a legal challenge to Pennsylvania's addiction treatment law that went all the way up to the Pennsylvania Supreme Court. Five years later, the court upheld the state's enforcement efforts, Beck said.

"And Pennsylvanians' access to lifesaving addiction treatment required under law improved dramatically," Beck said.

Before Tolman resigned from the Massachusetts Senate in 2011, he sponsored a bill modeled on Pennsylvania's that would allow the doctor, not the insurance company, to determine the type and duration of treatment.

The bill—House 936, An Act to Further Define Adverse Determinations by Insurers—was refiled this year by state Rep. Kay Khan, D–Newton.

CENTER FOR FISCAL EQUITY
14448 Parkvale Road, Suite 6
Rockville, Maryland 20853
fiscalequitycenter@yahoo.com

Statement of Michael G. Bindner

Chairman Grassley and Ranking Member Wyden, thank you for the opportunity to submit these comments for the record to the Committee on Finance. The name is quite apt. I am assuming that this has to do with both Prescription Drug pricing and Opioids. I will rely on the Administration witnesses to outline the current case.

Opioids

This national pandemic has been gaining strength for a long time, starting in rural America and expanding nationally. Any family can be victimized by this scourge. It is now magnified by the ability to get even stronger versions through the Internet from Chinese suppliers.

Recent information lays the blame for much of the opioid crisis on the manufacturer and its owners. I am sure we all hope that the bankruptcy judge assigned to the Purdue Pharmaceutical case can find a way to claw back the funds looted from the company prior to expected legal actions.

Bankruptcy Law

Bankruptcy should not be used to reward the guilty. Allow me to provide a scenario from comments to the Ways and Means Subcommittee on Oversight on how the tax code subsidizes hate crimes, held on September 19, 2019.

While the First Amendment precludes content regulation, that does not prevent the Southern Poverty Law Center from suing them into obscurity. The problem is that the same characters simply pop up on YouTube (sometimes literally), overnight. One solution is to change bankruptcy law to make obligations follow successor companies. This would also be helpful in labor and tort cases (especially the extant case against Purdue Pharma).

Mandating Treatment

Treatment modalities need to be improved to fight this crisis. They should have been long ago. Access to both initial and continuing treatment is vital to both addition and mental health care, as addiction can often uncover pre-existing psychiatric conditions. Even for non-alcoholics, once addiction has been turned on by opioids, the patient can never drink safely again and even moderate or heavy drinking previously will have to end, along with any medicinal effect it had.

For initial treatment, the question is not just access for willing patients, but mandated treatment for the unwilling. The liberalization of commitment laws in the 1970s has likely gone too far. Our first clue was mental patients, especially veterans, living on the street. Even when forced into treatment, taking a sober breath in a few days, treatment plan or no, resulted in release and resumption of the previous lifestyle. This is not freedom or health.

State laws or one overarching federal standard must make it easier for families, police, doctors and social service agencies to begin mandatory treatment, with the out-

come being assignment to medical care if required and housing beyond shelter space if not already possessed. While some will not need the latter, those who do, especially our nation's seniors, disabled and veterans, should not be sent back to the cold.

Early addiction after-care with an HMO provided two sessions a week after partial hospitalization. Medicare and Medicaid should as well. If relapse is detected during this period, the addiction specialist should be empowered (and the patient funded) to go back into treatment, possibly in a more intense setting than originally. The therapist should be similarly empowered, even with patients with long-term sobriety.

Synergies Provided by Employee Ownership

Companies who hire their own doctors and pharmacists, whether as part of a cooperative purchase program or as an offset to a single-payer program (whether it is Single Payer Catastrophic or Medicare for All) have an advantage in providing treatment. Their health plans would be much less likely to prescribe their employees into drug misuse and could more effectively monitor abuse when it occurred. This purchasing and monitoring would also include franchise and 1099 employees brought into employee status. Community is the best solution to recovery. The community most important to most is work. Please see Attachment One for more on tax reform and Attachment Two for more on Employee Ownership.

Thank you for the opportunity to address the committee. We are, of course, available for direct testimony or to answer questions by members and staff.

Attachment One—Tax Reform, Center for Fiscal Equity, September 13, 2019

Individual payroll taxes. These are optional taxes for Old-Age and Survivors Insurance after age 60 (or 62). The collection of these taxes occurs if an income sensitive retirement income is deemed necessary for program acceptance. The ceiling should be lowered to $75,000 reduce benefits paid to wealthier individuals and a floor should be established so that Earned Income Tax Credits are no longer needed. Subsidies for single workers should be abandoned in favor of radically higher minimum wages.

Income Surtaxes. Individual income taxes on salaries, which exclude business taxes, above an individual standard deduction of $75,000 per year. It will range from 6% to 36%. This tax will fund net interest on the debt (which will no longer be rolled over into new borrowing), redemption of the Social Security Trust Fund, strategic, sea and non-continental U.S. military deployments, veterans' health benefits as the result of battlefield injuries, including mental health and addiction and eventual debt reduction.

Asset Value-Added Tax (A–VAT). A replacement for capital gains taxes, dividend taxes, and the estate tax. It will apply to asset sales, dividend distributions, exercised options, rental income, inherited and gifted assets and the profits from short sales. Tax payments for option exercises and inherited assets will be reset, with prior tax payments for that asset eliminated so that the seller gets no benefit from them. In this perspective, it is the owner's increase in value that is taxed. As with any sale of liquid or real assets, sales to a qualified broad-based Employee Stock Ownership Plan will be tax free. These taxes will fund the same spending items as income or S–VAT surtaxes. This tax will end Tax Gap issues owed by high income individuals. A 24% rate is between the GOP 20% rate and the Democratic 28% rate. It's time to quit playing football with tax rates to attract side bets.

Subtraction Value-Added Tax (S–VAT). These are employer paid Net Business Receipts Taxes that allow multiple rates for higher incomes, rather than collection of income surtaxes. They are also used as a vehicle for tax expenditures including healthcare (if a private coverage option is maintained), veterans' health care for non-battlefield injuries, educational costs borne by employers in lieu of taxes as either contributors, for employee children or for workers (including ESL and remedial skills) and an expanded child tax credit.

The last allows ending state administered subsidy programs and discourages abortions, and as such enactment must be scored as a must pass in voting rankings by pro-life organizations (and feminist organizations as well). An inflation adjustable credit should reflect the cost of raising a child through the completion of junior college or technical training. To assure child subsidies are distributed, S–VAT will not be border adjustable.

The S–VAT is also used for personal accounts in Social Security, provided that these accounts are insured through an insurance fund for all such accounts, that accounts

go toward employee ownership rather than for a subsidy for the investment industry. Both employers and employees must consent to a shift to these accounts, which will occur if corporate democracy in existing ESOPs is given a thorough test. So far it has not.

S–VAT funded retirement accounts will be equal dollar credited for every worker. They also has the advantage of drawing on both payroll and profit, making it less regressive.

A multi-tier S–VAT could replace income surtaxes in the same range. Some will use corporations to avoid these taxes, but that corporation would then pay all invoice and subtraction VAT payments (which would distribute tax benefits). Distributions from such corporations will be considered salary, not dividends.

Invoice Value-Added Tax (I–VAT) Border adjustable taxes will appear on purchase invoices. The rate varies according to what is being financed. If Medicare for All does not contain offsets for employers who fund their own medical personnel or for personal retirement accounts, both of which would otherwise be funded by an S–VAT, then they would be funded by the I–VAT to take advantage of border adjustability. I–VAT also forces everyone, from the working poor to the beneficiaries of inherited wealth, to pay taxes and share in the cost of government. Enactment of both the A–VAT and I–VAT ends the need for capital gains and inheritance taxes (apart from any initial payout). This tax would take care of the low income Tax Gap.

I–VAT will fund domestic discretionary spending, equal dollar employee OASI contributions, and non-nuclear, non-deployed military spending, possibly on a regional basis. Regional I–VAT would both require a constitutional amendment to change the requirement that all excises be national and to discourage unnecessary spending, especially when allocated for electoral reasons rather than program needs.

As part of enactment, gross wages will be reduced to take into account the shift to S–VAT and I–VAT, however net income will be increased by the same percentage as the I–VAT. Adoption of S–VAT and I–VAT will replace pass-through and proprietary business and corporate income taxes.

Carbon Value-Added Tax (C–VAT). A Carbon tax with receipt visibility, which allows comparison shopping based on carbon content, even if it means a more expensive item with lower carbon is purchased. C–VAT would also replace fuel taxes. It will fund transportation costs, including mass transit, and research into alternative fuels (including fusion). This tax would not be border adjustable.

Attachment Two

A. Employee Ownership, March 7, 2019

Employee ownership is the ultimate protection for worker wages. Our proposal for expanding it involves diverting an ever-increasing portion of the employer contribution to the Old-Age and Survivors fund to a combination of employer voting stock and an insurance fund holding the stock of all similar companies. At some point, these companies will be run democratically, including CEO pay, and workers will be safe from predatory management practices. Increasing the number of employee-owned firms also decreases the incentive to lower tax rates and bid up asset markets with the proceeds.

Establishing personal retirement accounts holding index funds for Wall Street to play with will not help. Accounts holding voting and preferred stock in the employer and an insurance fund holding the stocks of all such firms will, in time, reduce inequality and provide local constituencies for infrastructure improvements and the funds to carry them out.

ESOP loans and distribution of a portion of the Social Security Trust Fund could also speed the adoption of such accounts. Our Income and Inheritance Surtax (where cash from estates and the sale of estate assets are normal income) would fund reimbursements to the Fund.

At some point, these companies will be run democratically, including CEO pay, and workers will be safe from predatory management practices. This is only possible if the Majority quits using fighting it as a partisan cudgel and embraces it to empower the professional and working classes.

The dignity of ownership is much more than the dignity of work as a cog in a machine.

B. Hearing on the 2016 Social Security Trustees Report

In the January 2003 issue of *Labor and Corporate Governance,* we proposed that Congress should equalize the employer contribution based on average income rather than personal income. It should also increase or eliminate the capon contributions. The higher the income cap is raised, the more likely it is that personal retirement accounts are necessary. A major strength of Social Security is its income redistribution function. We suspect that much of the support for personal accounts is to subvert that function—so any proposal for such accounts must move redistribution to account accumulation by equalizing the employer contribution.

We propose directing personal account investments to employer voting stock, rather than an index funds or any fund managed by outside brokers. There are no Index Fund billionaires (except those who operate them). People become rich by owning and controlling their own companies. Additionally, keeping funds in-house is the cheapest option administratively. I suspect it is even cheaper than the Social Security system—which operates at a much lower administrative cost than any defined contribution plan in existence.

If employer voting stock is used, the Net Business Receipts Tax/Subtraction VAT would fund it. If there are no personal accounts, then the employer contribution would be VAT funded.

Safety is, of course, a concern with personal accounts. Rather than diversifying through investment, however, we propose diversifying through insurance. A portion of the employer stock purchased would be traded to an insurance fund holding shares from all such employers. Additionally, any personal retirement accounts shifted from employee payroll taxes or from payroll taxes from non-corporate employers would go to this fund.

The insurance fund will save as a safeguard against bad management. If a third of shares were held by the insurance fund than dissident employees holding 25.1% of the employee-held shares (16.7% of the total) could combine with the insurance fund held shares to fire management if the insurance fund agreed there was cause to do so. Such a fund would make sure no one loses money should their employer fail and would serve as a sword of Damocles to keep management in line. This is in contrast to the Cato/PCSSS approach, which would continue the trend of management accountable to no one. The other part of my proposal that does so is representative voting by occupation on corporate boards, with either professional or union personnel providing such representation.

The suggestions made here are much less complicated than the current mix of proposals to change bend points and make OASI more of a needs-based program. If the personal account provisions are adopted, there is no need to address the question of the retirement age. Workers will retire when their dividend income is adequate to meet their retirement income needs, with or even without a separate Social Security program.

No other proposal for personal retirement accounts is appropriate. Personal accounts should not be used to develop a new income stream for investment advisors and stock traders. It should certainly not result in more "trust fund socialism" with management that is accountable to no cause but short-term gain. Such management often ignores the long-term interests of American workers and leaves CEOs both over-paid and unaccountable to anyone but themselves.

If funding comes through a Subtraction VAT, there need not be any income cap on employer contributions, which can be set high enough to fund current retirees and the establishing of personal accounts. Again, these contributions should be credited to employees regardless of their salary level.

Conceivably a firm could reduce their S–VAT liability if they made all former workers and retirees whole with the equity they would have otherwise received if they had started their careers under a reformed system. Using Employee Stock Ownership Programs can further accelerate that transition. This would be welcome if ESOPs became more democratic than they are currently, with open auction for management and executive positions and an expansion of cooperative consumption arrangements to meet the needs of the new owners.

———

COALITION FOR OFFICE-BASED OUTPATIENT TREATMENT

October 24, 2019

Senator Charles E. Grassley
Chairman
Senator Ron Wyden
Ranking Member
U.S. Senate
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510–6200

Dear Chairman Grassley and Ranking Member Wyden:

We applaud the Senate Finance Committee for holding today's hearing entitled "Treating Substance Misuse in America: Scams, Shortfalls, and Solutions." We appreciate the Committee's work to help stem the opioid crisis nationally and welcome the opportunity to submit these comments for the official hearing record. We are glad for the opportunity to share more information about who we are and the important role that outpatient addiction treatment programs play in the addiction treatment landscape. We hope that in sharing this information we can begin to engage more effectively with lawmakers and key decision makers as they develop strategies to further mitigate the damage the opioid crisis has inflicted on our great nation.

The Coalition for Office-Based Outpatient Treatment ("Coalition") is an advocacy group dedicated to promoting the role of Office-Based Outpatient Treatment providers ("OBOTs") in the fight against addiction in America. Coalition medical practitioners are all specially trained and licensed to prescribe buprenorphine (most often Suboxone) under DATA 2000 waivers administered by the Drug Enforcement Agency ("DEA"). Coalition outpatient centers focus primarily on treating patients suffering from opioid use disorder ("OUD") by deploying an individualized mix of medication and counseling, but also treat other substance use disorders ("SUDs") by similar methods.

Chairman Grassley (R–IA) has expressed concern that the patchwork of State and Federal enforcement regimes has left holes and opportunities for fraud and abuse to arise in the treatment space. We appreciate the concern that exists around how to best distinguish between quality treatment and the "fraudsters," as Ranking Member Senator Wyden (D–OR) referred to those who prey on the most vulnerable. We share these concerns and feel that we are uniquely qualified to demonstrate what works for patients and for the payors. We believe that our method of treating patients embodies the quality and value that so many legislators, policymakers, and patients are seeking.

Medication-Assisted Treatment ("MAT") is the standard of care for treatment of OUD. We believe that any OUD treatment program that does not utilize MAT is not meeting the standard of care for addiction treatment as defined by the American Medical Association.[1] MAT in an outpatient setting, properly applied and managed, is both effective at treating addiction and cost efficient for payors.

During the hearing, and in response to a question from Senator Cardin (D–MD), the Honorable Jerome Adams, M.D., MPH, Surgeon General, Department of Health and Human Services, pointed out that successful communities that have turned around overdose rates have done the following four things: (1) increased naloxone availability; (2) ensured a warm handoff from hospital emergency departments; (3) provided MAT; and (4) received cooperation from public safety officials to prevent criminalizing addiction. Integration of all of these critical components is fundamental to the addiction treatment provided by OBOTs.

Our comments are intended to provide more detail on the role of OBOTs in the fight against addiction and why our model offers a powerful combination of treatment effectiveness and cost efficiency.

What is an OBOT?

The American Society of Addiction Medicine ("ASAM") defined OBOT in 2004:

> OBOT refers to models of opioid agonist treatment that seek to integrate the treatment of opioid addiction into the general medical and psychiatric care of the patient. The foundation of OBOT is the conceptualization of

[1] *https://www.end-opioid-epidemic.org/wp-content/uploads/2018/02/180221-AMA-MAT-One-Pager_National-FINAL3.pdf.*

opioid addiction as a chronic medical condition with similarity to many other chronic conditions.[2]

While the concept of OBOT was defined 15 years ago, there is still confusion as to how practitioners working within OBOTs and prescribing buprenorphine in outpatient offices are distinguished from Opioid Treatment Programs (OTPs), which dispense Methadone. The distinction, however, is simple and clear-given the relative safety of buprenorphine, DATA 2000 certified practitioners can prescribe buprenorphine in an office-based setting and patients can pick up their prescription at a pharmacy convenient for them. *Unlike OTPs, OBOTs do not dispense medication.*

When the initial DATA 2000 regulations were promulgated, OBOTs were expected to be primary care physicians who would integrate addiction treatment into their practices. Many primary care practices have done so, but treatment in mainstream practices has proven to be more challenging than originally imagined. It has now become clear that there is strong patient demand for specialized outpatient addiction treatment which is not otherwise being met.

What is the role for OBOTs?

OBOTs can provide high quality, effective, and cost-efficient treatment in an outpatient environment. We believe that high quality OBOTs should be a central feature of any national treatment policy and are eager to participate in a process that helps to set the standards for outpatient addition treatment.

The needs of patients suffering from substance use disorders are extensive and while many patients' struggles pre-date their addiction, others are caused and/or exacerbated by addiction. Below are a few important characteristics of much of the population suffering from substance use disorders:

1. **Poverty**—If people with an addiction were not struggling financially before they became addicted, almost all are impoverished by the time they reach out for treatment;
2. **Co-Occurring Mental Health Disorders**—Multiple studies have shown that at least 50% of those with substance use disorder also have at least one diagnosable mental illness;[3] and
3. **Polysubstance Use**—Most patients with OUD are also dependent on other illicit substances (*e.g.,* cocaine, methamphetamine, etc.) and/or prescription pharmaceuticals (*e.g.,* benzodiazepines).

Patients in the active throws of addiction require an extreme amount of attention and effort across a wide spectrum of services. For every office visit, OBOTs typically receive an average of three times more incoming phone calls and electronic messages from patients. Moreover, while 70 percent of OBOT patients are stable enough to visit with a practitioner just once a month, who those patients are changes regularly. Unfortunately, relapse is a pervasive part of the disease of addiction.

Often, as one patient is stabilized another may relapse and require intensive intervention. To address this challenging patient population, larger scale OBOTs have built specialty outpatient addiction practices that we believe represent the most cost-effective method for treating the majority of people suffering from OUD. Coalition practices are designed to address the broad needs of this population.

How Coalition practices manage the various phases of addiction treatment:

Induction—Depending on the severity of how a patient presents at their first appointment, patients visit with a medical practitioner between one and three times in their first week of treatment;

Stabilization—As patients stabilize over the first months, the frequency of visits is reduced;

Maintenance—Once a patient is abstinent from illicit and unprescribed substances and positive for buprenorphine, the frequency of appointments is typically decreased to monthly visit s, allowing patients to live more independent lives;

Relapse—In cases of relapse, patients are asked to come back more frequently until they are stabilized again. Higher levels of care may be required in some cases and patients will often leave an OBOT to receive more intensive treatment than an

[2] ASAM: Public Policy Statement on Office-based Opioid Agonist Treatment (OBOT), 2004.
[3] NIDA: Common Comorbidities with Substance Use Disorders, 2017.

OBOT can offer. Patients are always welcome back to Coalition practices once they have become stabilized; and

Tapering—As patients get their lives back, as evidenced by successful functioning in the workforce and their family lives, many are eager to wean themselves off medications. This is a period of elevated relapse risk and appointment frequency is often increased until patients are able to work toward tapering entirely off their medication.

Best practices for drug screening:

Urine drug testing has been abused by many bad actors in the addiction treatment space and all practitioners need to be aware of the costs associated with unnecessary testing. It is critical, however, to appreciate how central routine urine drug toxicology is to providing high quality and effective treatment. ASAM released a Consensus Statement in 2017 defining the Appropriate Use of Drug Testing in Clinical Addiction Medicine [4] and all Coalition practitioners follow the ASAM guidelines.

Responsible practitioners only test for substances that will impact treatment decisions. High quality toxicology is the only way to assess patient compliance in a comprehensive way and also acts as an early warning system for OBOTs as different drugs ebb and flow in popularity. As a result, toxicology is central to treatment and is typically administered in two stages:

- **Screening**—Either through the use of instant point of care testing or through more accurate immunoassay screening, these initial tests identify what tests need to be run for definitive confirmation; and
- **Definitive Testing**—Depending on screening results, confirmation labs use highly accurate methods to quantitatively report the levels of drugs and metabolites in a patient's system.

Key components of staffing an OBOT:

- **Medical Oversight**—Provided by a physician with extensive clinical addiction treatment experience. Medical Directors are often board certified in addiction psychiatry or addiction medicine.
- **Medical Practitioners**—DATA 2000 certified Physicians, Nurse Practitioners and Physician Assistants focus on the pharmaceutical needs of the patients. Prescriptions can include medications to treat addiction including buprenorphine and naltrexone as well as psychiatric drugs if the practice has qualified psychiatric practitioners.
- **Mental Health Practitioners**—Substance use and mental health counselors, whether in house or referred, work with patients one-on-one and in groups to help them rebuild their lives.
- **Case Managers/Care Coordinators**—Many patients at varying times in their recovery need additional services or higher levels of care. Care coordination is necessary to help patients find outside social services such as housing and psychiatric services. In circumstances where outpatient treatment is insufficient in its intensity, staff will work with patients to find higher levels of care, including inpatient services.
- **Front-line staff**—Often overlooked, this is the group that interacts with patients most regularly, whether at the front desk, on the phone, or via other electronic messaging. Front-line staff must be well-trained and knowledgeable about how to escalate a wide range of challenging interactions.

During the hearing and in response to a question from Senator Ben Cardin (D–MD), Gary Mendell, Founder and CEO of Shatterproof, suggested that transparent quality measures would allow payers to better evaluate value for payments. We are in total agreement and welcome the opportunity to share the quality measures that our members have developed internally to improve patient care.

The Coalition is focused on not only addressing each patient's individual needs but also on evaluating the impact our treatment has on the broader patient population. Patient and data-centric management efforts give great insight into what elements of treatment protocols are effective and what are less so. Well managed practices are always adjusting aspects of their protocol to adapt to changes that they see in their patient population.

---

[4] *https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-(7).pdf?sfvrsn=2.*

We welcome the opportunity to engage with legislators and the Administration as we work together to combat this crisis and treat patients most effectively and cost efficiently.

Sincerely,

Enrique Oviedo, M.D.
Board Certified Addiction Psychiatrist

HAZELDEN BETTY FORD FOUNDATION

Statement of Nick Motu, Vice President and Chief External Affairs Officer

Chairman Grassley, Ranking Member Wyden, and members, my name is Nick Motu, and I serve as Vice President and Chief External Affairs Officer for the Hazelden Betty Ford Foundation ("Hazelden Betty Ford"). Hazelden Betty Ford, with its headquarters located at 15251 Pleasant Valley Road, Center City, Minnesota 55012, has long advocated for patients who suffer from substance use disorders, including in support of measures before Congress and within states to ensure that patients and their families can access quality treatment services.

Since Hazelden Betty Ford CEO Mark Mishek testified last Congress alongside our partner Marv Ventrell, CEO of the National Association of Addiction Treatment Providers (NAATP), and the subsequent passage of the SUPPORT Act, we have seen incremental improvements to addiction treatment industry practices across the country. This is due in part to nationwide implementation of NAATP's Code of Ethics, additional scrutiny by online search engines, and states making concerted efforts to crack down on predatory behavior. And more needs to be done. Below are summaries of the priority issues we see—often through patients at our doorstep—and recommendations for action by Congress.

1. **Patient brokering continues to plague the addiction treatment industry, and the most vulnerable patients and their families suffer the most severe consequences.**

The ongoing brokering of vulnerable people for financial gain remains a grave concern and a tremendous risk to patients and their families who are seeking help in their most desperate time of crisis. We see this practice .across the country, both through solicitation of Hazelden Betty Ford by those seeking payment for referrals, and through patients and their families who have fallen victim to these predatory practices and who seek our care following their exploitation. Virtually every day, Hazelden Betty Ford receives materials peddling patient referrals from third-party "bed brokers" pursuing our organization as a "partner." Additionally, our patients continue to fall victim to call aggregators and other deceptive marketing practices.

We also continue to hear stories from our clinicians of unethical providers seeking out uninsured patients through third-party scouts who are trolling support meetings for those in the most desperate state, "assisting" their enrollment in insurance, admitting them into care, and then discharging them immediately upon exhaustion of benefits—regardless of their clinical need—often in an extraordinarily vulnerable state. Although sometimes this practice can be as blatant as providing a patient with a gift card for relapsing, often it is more nuanced—although just as damaging—such as paying a person's rent as long as they stay under the care of a subpar provider so that their insurance benefits can be tapped. Both in its most blatant and more nuanced forms, this brokering of people as commodities is egregious and is particularly common across all levels of care in states where a sound and comprehensive regulatory structure does not exist.

To address ongoing concerns with patient brokering, Congress must take further action. Funding the Department of Justice's Eliminating Kickbacks in Recovery Act (EKRA) enforcement activities specifically focused on the addition treatment industry, as well as expanding the penalties to include civil monetary enforcement, would have a chilling effect on these predatory activities. Additionally, publishing guidelines related to anti-kickback and patient brokering issues-perhaps in the form of Special Fraud Alerts or otherwise—would provide valuable guidance to providers and to state legislatures as they shape public policy to enforce the intent of EKRA's expansion found in the SUPPORT Act, in part through enhanced state regulatory oversight, both criminally and civilly.

2. **States lack comprehensive, quality-based regulatory oversight of the addiction treatment industry and are not adequately incented to prioritize adoption of necessary reforms.**

As a national system of care, Hazelden Betty Ford sees wide variations in regulatory oversight requirements at the facility, program, and individual-practitioner levels. We also see the related consequences suffered by people with substance use disorders. In no other area of healthcare is regulatory compliance so frequently accepted as voluntary, so disconnected from basic quality standards, and so outsourced to non-governmental, non-transparent entities. We see wholly unregulated programs purporting to provide the most intense levels of care in buildings that have not been fire coded, without utilization of any evidence-based practices, and with care delivered by individuals with no training or experience as professional clinicians.

The federal government has taken steps to not only highlight these issues but also to provide some limited guidance to states about quality. Additionally, pending legislation that incents state adoption of quality standards through contingent grant funding, if passed, would require states to prioritize reforms, using access to federal funding as a powerful incentive. Any guidance related to quality standards, and legislation requiring those standards to be tied to federal funding streams, would benefit state legislatures, several of which are actively pursuing quality-based industry licensing reforms. Quality-based regulatory guidance should include incentivizing accreditation from entities such as the Joint Commission or the Commission on Accreditation of Rehabilitation Facilities, requiring a qualified workforce, ensuring evidence-based practices, and supporting treatment for co-occurring disorders. Additionally, efforts to incentivize professional training and education—not only of addiction counselors, but also clinicians in other areas of healthcare—on addiction medicine and treatment best practices will continue to be instrumental to reforming the industry and ensuring better outcomes for patients across the country.

3. **42 CFR Part 2 providers lack the regulatory alignment necessary to facilitate integration and to effectuate true and complete parity for patients. Separate privacy laws and regulations foster an environment that is not conducive to quality, coordinated care for patients and foment "otherness," extending the historical subordination and stigmatization of the addiction treatment industry versus other areas of healthcare.**

Hazelden Betty Ford has long advocated for alignment of federal privacy standards as a key component to increasing acceptable standards of care for the addiction treatment industry. Alignment of the federal regulations found within 42 CFR Part 2 (Part 2), privacy regulations which can negatively affect a patient's access to integrated care in certain settings, with those of the Health Insurance Portability and Accountability Act (HIPPA), which apply to all health care providers, would facilitate optimal care while protecting patient confidentiality. Such alignment is crucial to holding the addiction treatment industry to the standards we expect of all healthcare providers.

Some of the most challenging issues related to quality of treatment relate to the lack of care integration and coordination for patients of substance use treatment providers. Part 2 essentially codifies subpar care. For example, providers like Hazelden Betty Ford are prevented from electronic prescribing, limited in implementing available electronic-health-record capabilities, and, in some cases, statutorily prevented from being able to collaborate with other providers and process claims. To facilitate standards that align with the rest of healthcare, thus improving industry practices and ultimately the quality of the treatment patients receive, privacy regulations must support integrated, person-centered care for those suffering from substance use disorders. Without this alignment, the institutional quality barriers that have risked compromising care for patients suffering from substance use disorders across the country will continue.

4. **A lack of industry-wide quality standards enables some insurance carriers to justify practices that prevent the effectuation of full parity for patients who suffer from substance use disorders.**

Since the passage of the Mental Health Parity and Addiction Equity Act and the subsequent expansion of coverage found within the Affordable Care Act, effectuating true parity for those suffering from substance use disorder has been challenging for a variety of reasons. Most significantly, a lack of nationally accepted standards of practice upon which state insurance regulators are able to test legal parity compliance against has resulted in a wide variation of what is appropriate management

of care. As a provider, we see this in widely variable medical necessity criteria, discriminatory prior authorization protocols, and other improper approaches to managing care for people seeking substance use disorder services versus services for other healthcare conditions. This practice harms our patients and patients seeking help across the country, and has the effect of giving payers a free pass to create their own thresholds for what they deem to be "enough" treatment for purposes of complying with parity's requirements.

A more robust set of guidelines for comprehensive and quality treatment for what is widely recognized as a chronic disease condition would incent payers to appropriately manage care for people they insure. Without agreed-upon national standards, payers will continue to circumvent parity's intent, and state insurance regulators will be left in the dark-without guidance to rely on when assessing whether people seeking treatment for their substance use disorder or other mental health conditions are appropriately benefiting from insurance coverage that holds true to the intent of these important federal laws.

In closing, Hazelden Betty Ford stands ready to provide any additional information and assistance your committee needs to continue to advance this important work on behalf of the millions of people with substance use disorders and their families across the country. Thank you.

SAFE PROJECT US
3118 Washington Blvd., Box 101734
Arlington, VA 22201–9998

Statement of James and Mary Winnefeld, Co-Founders

Recovery housing is a part of the larger continuum of housing and continuum of care options available to individuals in recovery from the disease of addiction, otherwise referred to as substance dependency. Recovery houses are a critical and often necessary step in the recovery process and a positive transition for people back into the community from a residential treatment program. They allow individuals to learn how to live sober in society, while having a shared supportive environment in which safe and effective recovery can be fostered if the right house and environment is chosen.

Recovery housing ranges from independent, peer-run homes to staff-managed residences where clinical services are provided. These environments create supportive and connected communities within the house and within the external community, where individuals achieve a safe place to improve their overall wellness. In these environments, additional skills and resources are available for a person in long-term recovery to sustain it.

These facilities should offer individuals suffering from substance use disorders a greater chance of achieving long-term recovery because of the community that exists within the home. Good recovery housing has been associated with numerous positive outcomes, including decreased substance use, reduced probability of relapse/reoccurrence, lower rates of incarceration, higher income, increased employment, and improved family functioning.

Addiction treatment has become a billion-dollar industry, which has opened the industry up to abuse. Stories have emerged of recovery houses with substandard living conditions (including no electricity or running water). All too often, too many residents are packed in one room. In some cases, gambling or prostitution rings are allowed access to the home, and house managers or owners kick people out onto the streets with no warning. In other cases, residents are kept in the home by allowing them to relapse in order to maintain relapse insurance payouts. For many, access to a recovery house and a recovery community is a matter of life or death.

A misconception exists among some communities that, like treatment facilities, recovery houses are accredited, closely monitored, operate equally, and have the best interest of the residents in mind. Unfortunately, this is often far from the truth. Without oversight and accountability, unscrupulous businesses will continue to make money on this disease. In most states, anyone can open up a recovery house; there is no requirement that the proprietor be in recovery, or work in the addiction treatment field. There is no national unification of regulations or standards for these types of homes because they are not considered "treatment" (a license to operate is only required for facilities providing treatment). While there are some states and municipalities that have adopted National Association of Recovery Residences

(NARR) standards, these are challenging to enforce since they are voluntary certifications. Federal laws or regulations do not exist to regulate how these houses operate.

Moreover, unlike treatment facilities, data on which are captured by the Substance Abuse and Mental Health Services Agency (SAMHSA), there is no database or registry for recovery housing. Although some organizations, such as NARR and Oxford Houses, collect data on the prevalence and characteristics of recovery housing, the data is only used for their recovery homes. As such, it is extremely challenging for individuals seeking recovery housing to find a place that suits their needs.

Stigma is another challenge for recovery housing. A recent Harris Poll, SAFE Project Opioid Report, confirms that most Americans believe that more treatment and recovery resources are needed in order to address this epidemic, but they do not want them in their back yards. Unfortunately, a perception has been created that a local recovery home will devalue a neighborhood and bring in crime. For example, the Not in My Backyard Movement (NIMBY) has resulted in neighbors putting up anti-recovery housing signs, knocking on recovery housing doors with unwelcoming words, and standing up at town halls fighting for their perceived safety.

In short, the recovery housing landscape resembles the Wild Wild West, with a soup of ethical recovery homes battling for space to exist in neighborhoods of need, rogue houses that are only accessible through word-of-mouth, and no protection available for the individual in recovery.

Several solutions will help enhance the ability of recovery housing to better support those on the journey of substance abuse recovery.

First, nationwide collaboration is essential in addressing the challenges listed above. As such, SAFE Project, a national nonprofit fighting to stop the addiction epidemic, hopes to bring together a group of experts through the Recovery Housing Collective. Through the collective, SAFE Project will have the ability to access key information to address the complex issues of recovery housing throughout the nation.

Second, federal regulations requiring recovery houses be permitted will establish a strong foundation for recovery resources, ensure a safe and healthy environment for residents, and prevent abuse of the system. This is desperately needed. We believe that SAMHSA should be empowered to drive this forward, with the support of the Recovery Housing Collective.

Third, a trackable database for recovery housing would allow states to determine what recovery houses exist in their state, accredit and monitor those houses, and provide better access to recovery housing for the individual seeking recovery housing. We believe SAMHSA should be resourced to establish such a database. Such a database would also allow states to track the "spin cycle" of addiction treatment-to recovery housing kickbacks or insurance fraud that often exist within communities.

Fourth, recovery residences should be celebrated in all neighborhoods, including college campuses, cities, townships, and even military bases. We need recovery houses that meet the needs of the broad diversity of the populations seeking recovery assistance, including LGBTQ, people of color, differently abled persons, and those suffering with co-occurring mental health disorders.

Fifth, although living in a recovery home costs money, it is cheaper than a relapse. Providing financial support for those in such housing on an as-needed basis and in a way that enforces ethical behavior, either directly or through requiring the insurance industry to step up, would be a cost-effective way of contributing to the attenuation of the opioid epidemic.

In conclusion, recovery houses should exist to assist those who have transitioned away from self-destructive demoralizing behaviors to become responsible thriving members of society, who want to be of service, who have examined their lives to become a better person, and who are developing the resiliency required for long-term recovery. Access to quality recovery housing means less time in treatment, less likelihood of relapse, and more time for a person to recover within their own environment. More support and oversight are desperately needed to bring this critical aspect of reversing the epidemic up to the capability and promise it provides.

VOICES FOR NON-OPIOID CHOICES

October 24, 2019

Senator Chuck Grassley
Chairman
Senator Ron Wyden
Ranking Member
U.S. Senator
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510–6200

Dear Chairman Grassley and Ranking Member Wyden,

On behalf of Voices for Non-Opioid Choices, we are pleased to submit this statement for the record of the hearing to be held October 24, 2019, entitled "Treating Substance Misuse in America: Scams, Shortfalls, and Solutions." We applaud the Senate Finance Committee for further addressing the epidemic of substance use in the United States. While we look forward to the focus on high-quality treatment options for those struggling with substance use disorder, we believe no discussion of substance use, and the commensurate Congressional response, is sufficient without including methods of prevention. Congress, along with the Trump Administration, must tackle the problem of substance abuse with downstream treatment options as well as upstream preventive efforts.

Voices for Non-Opioid Choices is a nonpartisan coalition dedicated to one proven method of preventing substance misuse—ensuring patient and provider access to safe and effective non-opioid pain management therapies. Our 30 members include licensed healthcare professionals such as physicians, nurses, dentists, therapists and related associations as well as patient advocacy groups, students, individuals in recovery and retirees. We are united in our belief that it is crucial to prevent addiction before it starts by increasing the availability and utilization of non-opioid approaches through responsible policy changes.

The over-prescription of opioids following an acute pain incident is a significant contributing factor to the current U.S. opioid epidemic. On average, patients receive 80 opioid pills to manage pain following a surgical procedure, which is typically well above what is necessary to help these patients adequately control their symptoms.[1] Every year in our country, three million Americans become persistent opioid users following surgery.[2] Unfortunately, some of these users will go on to develop substance use disorder and never recover.

Leading practitioners, researchers and health care experts know how to reverse this trend without sacrificing quality pain management. Increased use of non-opioids has been proven in peer-reviewed studies to reduce unnecessary opioid use after surgery,[3] and research on the benefits of multimodal approaches to pain management, which prioritize non-opioid use and minimize opioids, shows that such approaches provide better patient outcomes than patients receiving opioids following surgery.[4]

We have made progress on many fronts combatting the opioid epidemic, including slight decreases in overdose deaths and some modest reductions in opioid prescribing rates in certain populations. Without additional action to prevent substance misuse, however, we are at risk of stalling this progress.Medicare policy continues to prioritize less expensive opioids over the life-saving potential of nonopioids in the surgical setting.

We look to Congress and the Administration to act to prevent opioid misuse by promoting broad use of non-opioid treatments as a first-line therapy for acute pain across all treatment settings.

---

[1] Bicket M., et al. Prescription opioid oversupply following surgery. *Journal of American Pain Society* 2017.

[2] Brummett C.M., Waljee J.F., Goesling J., et al. New Persistent Opioid Use After Minor and Major Surgical Procedures in U.S. Adults. *JAMA Surg.* Published online June 1, 2017, 152(6):e170504, doi:10.1001/jamasurg.2017.0504

[3] Mont M.A., Beaver W.B., Dysart S.H., Barrington J.W., Del Gaizo D.J. Local infiltration analgesia with liposomal bupivacaine improves pain scores and reduces opioid use after total knee arthroplasty: results of a randomized controlled trial. *J Arthroplasty,* 2018;33(1):90–96.

[4] Wang M.Y., Chang H.K., Grossman J. Reduced Acute Care Costs With the ERAS® Minimally Invasive Transforaminal Lumbar Interbody Fusion Compared With Conventional Minimally Invasive Transforaminal Lumber Interbody Fusion. *Neurosurgery,* 2017. [epub ahead of print]

Last year, the Centers for Medicare and Medicaid Services (CMS) wisely adopted a policy change that would provide separate reimbursement for non-opioid pain management approaches provided during surgery to patients treated in an Ambulatory Surgery Center (ASC). This was a welcomed change that appropriately incentivizes the utilization of non-opioid therapies. Unfortunately, because most surgeries performed in the United States every year occur in a hospital outpatient department (HOPD) setting, CMS has not yet taken sufficient action to ensure that these patients can access available pharmacologic and non-pharmacologic non-opioid approaches to alleviate their acute pain. For example, many common orthopedic procedures take place in the HOPD setting and are not eligible to be performed in the ASC. The estimated 8 million Medicare patients who undergo these procedures every year are therefore unable to reasonably access non-opioid pain management approaches.

Given that most of these procedures—and associated opioid prescribing—take place in the HOPD setting, we urge Congress to work with the Administration to adopt reimbursement policies that better incentivize the utilization of non-opioid approaches for pain management. We believe that, in doing so, federal leaders will have the opportunity to safely and effectively alleviate pain with optimal opioid stewardship and provide all patients with the necessary access to the plethora of available pharmacologic and non-pharmacologic non-opioid approaches and therapies.

Congress and the Administration must continue to work hand-in-hand to solve the substance abuse emergency currently taking place in the United States, and specifically the issues around opioids. We hope that commonsense solutions and changes to outdated policies can help increase access to nonopioid approaches to pain management and therefore prevent opioid addiction or dependence from ever occurring after an acute pain incident such as a surgical intervention.

We look forward to your continued work on solving the crisis and stand available to answer any questions.

Sincerely,

Chris Fox
Executive Director