COMBATING THE OPIOID CRISIS: IMPROVING THE ABILITY OF MEDICARE AND MEDICAID TO PROVIDE CARE FOR PATIENTS

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED FOURTEENTH CONGRESS
SECOND SESSION
APRIL 11 & 12, 2018
Serial No. 115–116

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov
COMBATING THE OPIOID CRISIS: IMPROVING THE ABILITY OF MEDICARE AND MEDICAID TO PROVIDE CARE FOR PATIENTS
## CONTENTS

### April 11, 2018

<table>
<thead>
<tr>
<th>Witness</th>
<th>Opening Statement</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hon. Michael C. Burgess</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Hon. Gene Green</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Hon. Greg Walden</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Hon. Frank Pallone, Jr.</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Kimberly Brandt, Principal Deputy Administrator</td>
<td>11</td>
<td></td>
</tr>
</tbody>
</table>

### WITNESSES

<table>
<thead>
<tr>
<th>Witness</th>
<th>Prepared Statement</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kimberly Brandt</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Toby Douglas, Senior Vice President</td>
<td>68</td>
<td></td>
</tr>
<tr>
<td>David C. Guth, Jr.</td>
<td>81</td>
<td></td>
</tr>
<tr>
<td>John M. Kravitz, Chief Information Officer</td>
<td>95</td>
<td></td>
</tr>
<tr>
<td>Sam K. Srivastava, Chief Executive Officer</td>
<td>103</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Witness</th>
<th>Answers to Submitted Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kimberly Brandt</td>
<td>432</td>
</tr>
<tr>
<td>Toby Douglas</td>
<td>437</td>
</tr>
<tr>
<td>David C. Guth</td>
<td>443</td>
</tr>
<tr>
<td>John M. Kravitz</td>
<td>454</td>
</tr>
<tr>
<td>Sam K. Srivastava</td>
<td>458</td>
</tr>
</tbody>
</table>

### SUBMITTED MATERIAL

- Article entitled, “Medicare is cracking down on opioids. Doctors fear pain patients will suffer,” New York Times, April 6, 2018  174
- Statements of various pharmacy associations  177
- Statement of the Washington State Pharmacy Association  198
- CMCS Informational Bulletin  200
- Statement of the National Association of Counties  215
- Statement of the American Medical Association  217
- Statement of the American Society of Addiction Medicine  218
- Statement of the American Psychiatric Association  220
- Statement of the Community Resources for Justice  222
- Statement of the International Community Corrections Association  223
<table>
<thead>
<tr>
<th>Statement</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statement of the National Commission on Correctional Healthcare</td>
<td>225</td>
</tr>
<tr>
<td>Statement of the American College of Obstetricians and Gynecologists</td>
<td>226</td>
</tr>
<tr>
<td>Statement of telehealth and technology stakeholders</td>
<td>234</td>
</tr>
<tr>
<td>Statement of treatment providers in support of the access to telehealth</td>
<td>236</td>
</tr>
<tr>
<td>services for their opioid and use disorders</td>
<td></td>
</tr>
<tr>
<td>Statement of Members of Congress supporting the Pharmacy and Medically</td>
<td>238</td>
</tr>
<tr>
<td>Underserved Areas Enhancement Act</td>
<td></td>
</tr>
<tr>
<td>Statement of Walgreens supporting the Pharmacy and Medically Underserved</td>
<td>241</td>
</tr>
<tr>
<td>Areas Enhancement Act</td>
<td></td>
</tr>
<tr>
<td>Statement of the American Association of Oral and Maxillofacial Surgeons</td>
<td>243</td>
</tr>
<tr>
<td>the Association for Behavioral Health and Wellness</td>
<td>246</td>
</tr>
<tr>
<td>Statement of AdvaMed</td>
<td>248</td>
</tr>
<tr>
<td>Statement of the American Hospital Association</td>
<td>251</td>
</tr>
<tr>
<td>Statement of the American Psychological Association</td>
<td>253</td>
</tr>
<tr>
<td>Statement of the American Society of Health-System Pharmacists</td>
<td>257</td>
</tr>
<tr>
<td>Statement of the Association for Community Affiliated Plans</td>
<td>259</td>
</tr>
<tr>
<td>Statement of the College of Healthcare Information Management Executives</td>
<td>264</td>
</tr>
<tr>
<td>Statement of the ePrescribing Coalition</td>
<td>268</td>
</tr>
<tr>
<td>Statement of the National Association for Behavioral Healthcare</td>
<td>270</td>
</tr>
<tr>
<td>Statement of the National Association of Chain Drug Stores</td>
<td>274</td>
</tr>
<tr>
<td>Statement of the National Association of Medicaid Directors</td>
<td>287</td>
</tr>
<tr>
<td>Statement of the National Indian Health Board</td>
<td>290</td>
</tr>
<tr>
<td>Statement of the Oregon Community Health Information Network</td>
<td>297</td>
</tr>
<tr>
<td>Statement of the Partnership to Amend 42 CFR Part 2</td>
<td>298</td>
</tr>
<tr>
<td>Statement of the Pharmaceutical Care Management Association</td>
<td>301</td>
</tr>
<tr>
<td>Statement of the Property Casualty Insurers Association of America</td>
<td>309</td>
</tr>
<tr>
<td>Statement of Shatterproof</td>
<td>311</td>
</tr>
<tr>
<td>Statement of Imprivata</td>
<td>315</td>
</tr>
<tr>
<td>Statement of the Pharmacy Coalition</td>
<td>317</td>
</tr>
<tr>
<td>Statement of the National Association of Counties</td>
<td>319</td>
</tr>
<tr>
<td>Statement of Trinity Health</td>
<td>321</td>
</tr>
<tr>
<td>Statement of the Infectious Disease Society, the HIV Medicine Association,</td>
<td>328</td>
</tr>
<tr>
<td>and the Pediatric Infectious Disease Society</td>
<td></td>
</tr>
<tr>
<td>Study entitled, “States With Prescription Drug Monitoring Mandates Saw</td>
<td>332</td>
</tr>
<tr>
<td>a Reduction in Opioids Prescribed to Medicaid Enrollees,” Health Affairs,</td>
<td></td>
</tr>
<tr>
<td>April 1, 2017</td>
<td></td>
</tr>
<tr>
<td>Study entitled, “Medicaid Drug Utilization Review State Comparison/Sum-</td>
<td>348</td>
</tr>
<tr>
<td>mary Report FFY 2016 Annual Report,” Centers for Medicare &amp; Medicaid</td>
<td></td>
</tr>
<tr>
<td>Services, October 2017</td>
<td></td>
</tr>
</tbody>
</table>
OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. The Subcommittee on Health will now come to order. The chair will recognize himself 5 minutes for the purposes of an opening statement.

This afternoon the Health Subcommittee marks its third in a series of hearings this spring on legislation addressing the opioid epidemic. By the end of this week’s hearing we will have considered a total of 67 opiate-related bills. In our last hearing we discussed 25 public health and prevention-focused bills over the course of 2 days. Today the subcommittee will be breaking a record by exam-
ining 34 bills centered around improving Medicaid and Medicare programs at the Center for Medicare and Medicaid Services.

While committee members on both sides of this dias have put in a lot of time and thought in developing these bills, a majority are still in discussion draft form. And this is a feature not a bug. It is intentional. We seek to explore promising ideas while collecting important feedback from Members, providers, plans, patients, and other stakeholders. Some of these bills challenge the status quo for some practices within Medicaid and Medicare. But with more than 110 Americans dying daily from an opiate overdose, we must be willing to ask hard questions and seek solutions.

With the crisis devastating our country and eroding our economic productivity, all of us must be willing to take a fresh and fair look at each of the policies presented today. We should think creatively about how to help strengthen Medicaid and Medicare’s ability to combat this scourge of opiate abuse because without adequate tools and accountability our largest public players will be unable to handle the challenge that is before them.

So today we are joined by Kimberly Brandt, who has been charged to lead the efforts addressing the opiate crisis at the Center for Medicaid and Medicare Services. Ms. Brandt, thank you for being here testifying before us and providing your insights on ways that we can partner together to turn the tide in this fight.

Tomorrow we will hear from individuals representing healthcare providers, health plans, behavioral health specialists who provide the critical treatment to Americans with opiate addiction and substance use disorder. It is my expectation that our conversations will help us adopt effective policies that have a meaningful impact.

One issue that has repeatedly come up is our physician workforce. Congress can pass bills to increase access to evidence-based treatment, but if we do not have enough physicians equipped with proper tools and training we will not have the sufficient capacity to provide treatments for individuals suffering from this disorder.

To this end, I have worked on draft legislation that will provide Congress with more robust transparency about how graduate medical education dollars under current law are helping equip the next generation of doctors to better identify and treat patients with substance use disorder.

Prescription drug monitoring programs are important informational tools that help track prescriptions and identify patients at risk of overdosing on opiates. The Medicaid Partnership Act would require State Medicaid programs to integrate these monitoring programs into Medicaid providers’ and pharmacists’ clinical workflows while establishing basic criteria for qualified prescription drug monitoring programs. I think it is common sense to ask one of our largest payers to access one of our most powerful data tools to care for some of our most at-risk patients.

Another useful tool already in place in many State Medicaid programs are pharmaceutical homes. The Medicaid Pharmacy Home Act would codify the commonsense idea of requiring States to have provider and pharmacy assignment programs that identify at-risk Medicaid beneficiaries and set reasonable limits on the number of prescribers and dispensers that they can utilize. Given what we
know, it is good medicine for all of us to ensure that States are using this effective approach to identify at-risk beneficiaries.

We certainly have much to consider, but we are building on years of previous bipartisan efforts, and we know our work is important to our families and our communities and our constituents affected by this epidemic.

Before I close, I want to touch on the growing fear that I am hearing from many patients suffering from a chronic pain condition who have actually been successfully managed by long-term opiate administration, especially when these drugs are drugs of last resort. I anticipate some discussion on the recent CMS rule to limit the amount and length of opiate prescriptions. Our effort to overcome this crisis is vital, but I want us to keep these patients in mind and not, as we say down south, overtorque the bolt. I have a submission from The New York Times that I would like to add to the record for this.

[The information appears at the conclusion of the hearing.]

Mr. BURGESS. Again, I want to thank our witness for testifying today and our witnesses tomorrow. I look forward to learning from your insights.

And I want to yield time to the vice chairman of the Health Subcommittee, Mr. Guthrie of Kentucky, for his statement.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF MICHAEL C. BURGESS

This afternoon, the Health Subcommittee marks its third in a series of hearings this spring on legislation addressing the opioid epidemic. By the end of this week's hearing, we will have considered a total of 67 opioid-related bills. In our last hearing, we discussed 25 public health and prevention-focused bills over the course of two days. And today the subcommittee will be breaking a record by examining 34 bills, centered around improving Medicaid and Medicare programs at the Center for Medicare and Medicaid Services (CMS).

While committee members on both sides of the aisle have put a lot of time and thought into developing these bills, a majority are still in discussion draft form. This is intentional, as we seek to explore promising ideas, while collecting important feedback from members, providers, plans, and other key stakeholders. Some of these bills challenge the status quo for some practices within Medicaid and Medicare, but with more than 110 Americans dying daily from opioid overdoses, we must be willing to ask hard questions and find solutions.

With the opioid crisis devastating our country and eroding our economic productivity, all of us must be willing to take a fresh and fair look at each of the policies presented today. We should think creatively about how to help strengthen Medicaid and Medicare's ability to combat the scourge of opioid abuse—because without adequate tools and accountability, our largest public payers will be unable to handle the challenge before them.

Today, we are joined by Kimberly Brandt, who has been charged to lead the efforts addressing the opioid crisis at CMS. Ms. Brandt, thank you being testifying before us and providing your insights on ways we can partner together and turn the tide in our fight.

Tomorrow, we will hear from individuals representing health care providers, health plans, and behavioral health specialists who provide critical treatment to Americans with opioid addiction and substance use disorder. It is my expectation our conversations will help us adopt effective policies that have meaningful impact.

One issue area that repeatedly comes up is our physician workforce. Congress can pass bills that increase access to evidence-based treatment, but if we do not have enough physicians equipped with proper tools and training, we will not have sufficient capacity to provide effective treatments for individuals suffering from substance use disorder.

To this end, I have authored draft legislation that will provide Congress with more robust transparency about how graduate medical education dollars under cur-
rent law are helping equip the next generation of doctors to better identify and treat patients with substance use disorder.

Prescription Drug Monitoring Programs (PDMPs) are important informational tools that help track prescriptions and identify patients at risk of abusing or overdosing on opioids. The Medicaid PARTNERSHIP Act would require the state Medicaid programs to integrate PDMP usage into Medicaid providers’ and pharmacists’ clinical workflow while establishing basic criteria for qualified PDMPs. As a physician, I think it’s common sense to ask one of our largest payers to access one of our most powerful data tools to care for some of our most at-risk patients.

Another useful tool already in place in many state Medicaid programs are pharmaceutical homes. The Medicaid Pharmacy Home Act would codify the common-sense idea of requiring states to have a provider and pharmacy assignment program that identifies at-risk Medicaid beneficiaries and sets reasonable limits on the number of prescribers and dispensers they can utilize. Given what we know, it’s good medicine for us to ensure all states are using this effective approach to identify at-risk beneficiaries and improve care.

We certainly have much to consider. But, we are building on years of previous bipartisan efforts, and we all know our work is important to the families and communities—our constituents—affecting by the opioid epidemic.

Before I close, I would like to touch upon the growing fear of many patients suffering from chronic pain who have been successfully managed by opioids, especially when these drugs are the last resort. I anticipate some discussions on the recent CMS rule to limit the amount and length of opioid prescriptions. Our effort to overcome this crisis is vital, but I want us to keep these patients in mind and not “over-torque the bolt.”

I again thank our witnesses for testifying today and tomorrow, and I look forward to learning your insights on making improvements in the Medicare and Medicaid system.

I would like to yield the balance of my time to the Vice Chairman of the Health Subcommittee, Mr. Guthrie of Kentucky, for a statement.

Mr. Guthrie. Thank you, Mr. Chairman.

I appreciate the chairman’s diligent efforts to ensure our committee responds quickly and meaningfully to our Nation’s opioid crisis. Just last week I heard another awful story about how the destructive path of the opioid crisis harmed a family in Cecilia, Kentucky, all caused because of a motorcycle accident that led to back surgery that led to addiction.

I would like to ask unanimous consent to submit a number of letters in the record on how pharmacists and the Pharmacy and Medically Underserved Areas Enhancement Act can help address these in the opioid epidemic.

Mr. Burgess. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

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

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from Texas, Mr. Green, the ranking member of the subcommittee, 5 minutes for an opening statement, please.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. Green. Thank you, Mr. Chairman.

This is the third in a series of hearings on the opioid epidemic and its impact on individuals, families, and communities in our nation. Our committee has heard from Federal agencies and stakeholders on the terrible cost of opioid abuse, which takes the lives of 115 Americans each day and is estimated to cost our national economy over $78 billion annually.
Today’s hearing will focus on the role that Medicaid and Medicare play in providing health coverage for Americans in need of comprehensive treatment and recovery services. Medicaid is the largest payer for behavioral health services, mental health, and substance use disorder, or SUD, in the United States. Medicaid delivers care to 4 of 10 nonelderly adults with opioid use disorder.

Nearly 12 percent of adults enrolled in Medicaid have SUD. Adults on Medicaid are more likely than other adults to receive substance use disorder treatment.

Medicaid plays a critical role for children either suffering from substance use disorder or born with neonatal abstinence syndrome, NAS. Medicaid covers more than 80 percent of the NAS babies nationwide.

Medicaid expansion provided under the Affordable Care Act has played a critical role in providing comprehensive coverage for Americans suffering from substance abuse disorder who live in 31 States that have expanded.

Data recently published by the Center for Budget and Policy Priorities found that under Medicaid expansion the uninsured rate among people with opioid-related hospitalizations fell dramatically in States that expanded, from 13.4 percent in 2013, the year before the expansion took effect, to just 2.9 percent 2 years later.

For example, after Kentucky expanded Medicaid in 2014, Medicaid beneficiaries’ use of substance use treatment services in the State rose by 700 percent. My home State of Texas and 18 other States continue to refuse to expand Medicaid, denying millions of Americans the comprehensive services and continuum of care necessary to treat and recover from opioid addiction and other substance use disorders. Medicaid expansion includes substance use services as mandatory benefit.

The reality is that if folks want to save lives of these individuals, we have got to focus first on getting those people health insurance so they can access treatment. Continuity of comprehensive health insurance makes the difference between life and death.

Two weeks ago the Texas Department of State Health Services released a report that found opioid overdoses as the leading cause of death for new mothers in our State, with the most occurring after a pregnant woman’s Medicaid benefits end 60 days after delivery.

Last year, I introduced the Incentivizing Medicaid Expansion Act, H.R. 2688, in order to incentivize States to provide critical Medicaid coverage for Americans in need and to avoid the kinds of tragedies that have led to the rising rate of maternal mortality in our home State. My legislation would guarantee that the Federal Government covers 100 percent of expansion costs for States that have not yet expanded and no less than 90 percent afterwards.

Medicare also plays an important role in the opioid crisis. According to SAMHSA, more than one million seniors suffered from substance use disorders in 2014. While Medicare part B and part D provide SUD treatment services, there are significant gaps in Medicare’s benefits, including no coverage for substance abuse treatment at opioid treatment programs or methadone clinics.
We also need to ensure that Americans on Medicaid or Medicare are not overprescribed opioids. HHS’ Office of Inspector General found that more than 500,000 part D beneficiaries received high amounts of opioids in 2016, with the average dose far exceeding the manufacturers’ recommended amount. Additionally, nearly one-third of the beneficiaries in Medicare part D or C had an opioid prescription in 2016.

Before closing, I would like to voice my concern over the number of bills and discussions drafts being considered at the hearing, 34 in total. Never in my time on Energy and Commerce have we had legislative hearings on so many bills and drafts. Combined with the bills and discussion drafts from the two previous opioid hearings, we are looking at over 70 pieces of legislation. I am concerned that the majority is planning to mark up legislation later this month, and that has not been fully vetted by our staffs, stakeholders, and the appropriate Federal agencies.

The opioid crisis is hitting communities throughout America regardless of location or political affiliation. We can and must advance opioid legislation in a bipartisan manner that the American people deserve. I ask for the majority to work with us and provide the necessary time to vet legislation being considered and ensure the anticipated markup will not become a partisan exercise.

Thank you, and I yield the balance of my time.

Mr. BURGESS. The chair thanks the gentleman.

The chair would just observe that the gentleman has never served with the current chairman before. And you may have recognized by now you do have a very active and an activist chairman and that will continue for the balance of the year.

Mr. GREEN. Well, I like activism, Mr. Chairman, but I also like substance.

Mr. BURGESS. There is substance, I guarantee you, with these 34 bills.

The chair recognizes the chairman of the full committee, Mr. Walden, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. With these 34 on top of the other 24 on top of the other 6 or 7, we are going to have our hands full of good legislation, because today marks our third and final legislative hearing this spring aimed at advancing targeted, timely, and bipartisan legislative solutions to help combat the opioid crisis.

This committee has already been instrumental in working in a bipartisan manner to devote a record—let me underscore record—amount of Federal resources toward the opioid epidemic, namely through passage of the CARA and 21st Century Cures Act last Congress. My colleague here, Fred Upton, led the effort with Diana DeGette to get that done. This hearing continues the work to address the crisis that has impacted virtually every neighborhood, every community, and so many families across our country.

At roundtables I have done in my district, across Oregon, most recently in Pendleton and Madras, I have met with people on the front lines of this fight and with those who have lost a friend, lost a child, lost a sister, lost a loved one, lost a neighbor. These meet-
ings have been crucial to my efforts to put forth concrete solutions to stem the tide and save lives, and I am not alone doing these roundtables around the country.

With more than 100 Americans estimated to die every day from opioid overdoses, we simply have to do everything within our power. We must continue to push forward. And I would respectfully ask everyone involved, stakeholders and Members of Congress alike, to push beyond our comfort zones and think creatively and boldly about how we can help, because the status quo is simply not acceptable. The unprecedented scope of this crisis requires an unprecedented response, and that is what we are able to provide at the Energy and Commerce Committee.

To that end, over the span of 2 days, we will consider 34 bills from Members on both sides of the aisle. These bills have a common theme: They seek to improve the roles Medicaid and Medicare can play in helping combat this crisis. This marks the largest numbers of bills noticed in a legislative hearing before this committee. But the number and scope of the bills helps underscore how important this topic is to all of us and how many good ideas there are to help patients. While considering this many bills does require some extra work on behalf of the staff and our members, I think we should see this as not an inconvenience, but rather as an opportunity.

Just look at how many promising ideas there are to help patients who are served by these two programs who represent roughly one in three Americans. Certainly both programs play key roles in identifying at-risk beneficiaries, providing treatment, and decreasing overdose deaths.

The bills we will consider today cover a range of important issues, including provisions to remove barriers to treatment, improve data to identify and help at-risk patients, provide incentives for greater care coordination and enhanced care. Many of the bills before us build on efforts in Medicaid and Medicare that are already yielding positive benefits for patients and reducing dependency or misuse of opioids.

As we move forward, we look forward to stakeholders and others providing feedback on these proposals. The input of the Congressional Budget Office will also help shape our decisionmaking on several pieces of legislation before us today. But our aim remains the same: moving through committee in regular order to advance legislation to the House floor before the Memorial Day recess. That is our goal.

We have seen announcements in sister committees recently as they are also developing and advancing legislation, and we look forward to continuing our work with them to get a robust bipartisan package of proposals to the White House for signature of the President in the coming months.

The urgency of the crisis demands an urgent response, and the challenges facing our communities demand action now.

So I would like to thank our witnesses for taking time to share their expertise with us today and tomorrow and for Members on both sides of the aisle for making this fight a top priority.

With that, I would yield the balance of my time to my friend and colleague from Tennessee, Mrs. Blackburn.
Today marks our third and final legislative hearing this spring aimed at advancing targeted, timely, and bipartisan legislative solutions to help combat the opioid crisis.

This committee has already been instrumental in working in a bipartisan manner to devote a record amount of Federal resources towards the opioid epidemic, namely through the passage of CARA and 21st Century Cures last Congress. This hearing continues our work to address a crisis that has impacted virtually every neighborhood across our country.

At roundtables throughout Oregon, most recently in Pendleton and Madras, I’ve met with the people on the frontlines of this fight and with those who have lost a friend or loved one to this epidemic. These meetings are crucial to our efforts to put forth concrete solutions to stem the tide and save lives. With more than 100 Americans estimated to die each day from opioid overdoses, we simply must do more.

We must continue to push forward, and I would respectfully ask everyone involved—stakeholders and members alike—to push beyond their comfort zones and think creatively and boldly about how we can help. The status quo is not acceptable. The unprecedented scope of the opioid crisis requires an unprecedented response.

To that end, over the span of 2 days, we will consider 34 bills from members on both sides of the aisle. These bills have a common theme—they seek improve the roles Medicaid and Medicare can play in helping combat the crisis.

This marks the largest number of bills noticed in a legislative hearing before this committee. But the number and scope of bills helps underscore how important this topic is to all of us and how many good ideas there are to help patients. While considering this many bills requires some extra work from members and staff, I think we should see this not as an inconvenience, but as an opportunity.

Just look at how many promising ideas there are to help patients who are served by these two programs—who represent roughly one in three Americans. Certainly, both programs play key roles in identifying at-risk beneficiaries, providing treatment, and decreasing overdose deaths. The bills we will consider today cover a range of important issues— including provisions to: remove barriers to treatment, improve data to identify and help at-risk patients, provide incentives for greater care coordination and enhanced care.

Many of the bills before us build on efforts in Medicaid and Medicare that are already yielding positive benefits for patients and reducing dependency or misuse of opioids.

As we move forward, we look forward to stakeholders and others providing feedback on the proposals before us. The input of the Congressional Budget Office will also help shape our decision-making on several pieces of legislation before us today.

But our aim remains the same—moving through committee in regular order to advance legislation on the House Floor before the Memorial Day recess. We have seen announcements in sister committees recently as they are also developing and advancing legislation, and we look forward to continuing our work with them to get a robust, bipartisan package of proposals to the White House for signature in the coming months. The urgency of the crisis demands our response, and the challenges facing our communities demands action.

I’d like to thank our witnesses for taking the time to share their expertise with us today and tomorrow, and for our members—on both sides of the aisle—for making this fight a top priority.

Mrs. Blackburn. Thank you, Mr. Chairman, and thank you, Dr. Burgess, for the hearing on these issues.

There are two components that I am looking forward to. And I will tell you, Ms. Brandt, I appreciate the work of the administration to support the State Medicaid programs in their efforts to examine combat these programs.

Tennessee’s TennCare program recently implemented some new policies, and I had some good discussion this past weekend with some of our State legislators and some physicians who are hard at work on that with a 5-day limit on the prescriptions, prior authorization for any refills, a robust buyback program.
And I am looking forward also to discussing with you the IMD exclusion. Some of those that treat substance abuse have talked about this as a barrier to getting individuals into beds, into the treatment that they need.

So we really appreciate the work that you all are doing and look forward to getting the legislation across the finish line.

I yield back.

Mr. BURGESS. The gentlelady yields back. The chair thanks the gentlelady.

The chair yields to the gentleman from, New Jersey, Mr. Pallone, ranking member of the full committee, 5 minutes for an opening statement, please.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

Today's hearing is the third in a series to address the opioid and substance abuse crisis that is ravaging communities across the country, and our focus today is on the role of the two largest public health insurance programs, Medicaid and Medicare.

A lot needs to be done to address this epidemic, but we should focus our time on what is most meaningful and impactful. While I support addressing this crisis through a bipartisan process, I am concerned that the sheer quantity of bills before the committee today and the chairman's extremely ambitious timeframe will not leave us much time to get these policies right.

Today we will discuss 34 bills in one 2-day hearing, the vast majority of which the members of the committee have seen for less than a week. So I am concerned that many of the proposals have not been introduced. Most have not had the benefit of technical assistance or a CBO score. In fact, CMS' own testimony today I don't believe discusses any of the bills under consideration.

So at times to me this process feels more like an opioids media blitz than a thoughtful discussion about our national public health crisis, and this is not the deliberative process that the members of this committee and the American people deserve.

But with that important caveat aside, I will say that many of the proposals we are examining today have merit and strive to address a number of policy problems that Medicaid and Medicare face in combating the opioids epidemic. In Medicaid, we are considering legislation that would strengthen the continuity of coverage that people receive, particularly vulnerable populations, like adults and children leaving the justice system and former foster youth. And I know that the best way to combat the opioids crisis is for people to have access to strong and consistent health coverage that provides the treatment they need.

You also will hear about policies that invest in our providers on the ground, and our State Medicaid infrastructure helps States to build on what works, like Medicaid health homes, and promote new models of care to expand treatment capacity of providers.

We are also looking at complex issues related to how our Medicaid programs track and dispense prescribing of opioids and relieving barriers to lifesaving treatment, like naloxone and MAT. And
I think we could do even more in this area. There are bills to improve quality and data on how this crisis impacts Medicaid that will also be important to know in the coming years.

In addition, Mr. Chairman, there is legislation related to repealing the so-called IMD exclusion for a 5-year period. Medicaid IMDs are one very important piece of the treatment puzzle that States are incorporating into their delivery systems already through Medicaid's special Substance Use waivers. This is an example of a bill that needs a very thoughtful approach so we do not hurt the efforts that are already occurring in States today.

And we are also considering legislation regarding the role of Medicare parts B and D to address the rising epidemic of opioid overprescription and misuse among seniors. For example, we will discuss legislation under Medicare part B to expand opioid disorder treatment options through telehealth and also legislation under part D to ensure e-prescribing is utilized when prescribing controlled substances. And we will also discuss legislation to create an alternative payment model to incentivize the delivery of high-quality, evidence-based opioid treatment service for Medicare beneficiaries.

These bills are important because evidence suggests that opioid use among older adults is a significant and growing problem. According to the OIG, more than 500,000 part D beneficiaries received high amounts of opioids in 2016, with the average dose far exceeding the manufacturers' recommended amount.

So I want to be clear, this committee must focus on meaningful proposals that will address the opioid crisis. I intend to oppose any bill that has nothing to do with opioids, that makes the problem worse, or that is simply not ready and vetted in the time that we have allotted. Our policy goal should always be to first do no harm, and without the proper time to vet the legislation before us I can't be sure that we are meeting that goal.

For instance, I have significant concerns regarding one of the discussion drafts to add a pain assessment to the Welcome to Medicare physical. While well intentioned, I am concerned that this bill could actually exacerbate our opioid crisis.

I have heard from numerous stakeholders in the medical community that a similar approach adopted by the Joint Commission in 2001 to treat pain as a fifth vital sign actually contributed to the opioid epidemic, because by requiring healthcare providers to ask every patient about their pain and incentivizing aggressive management of pain these measures may have resulted in the overprescribing of opioids.

So finally, Mr. Chairman, I hope to work with my colleagues to address these concerns so that we can all support concrete and thoughtful legislation that will actually help address the crisis. And thank you again. I yield back.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman.

That concludes member opening statements. The chair reminds members that, pursuant to committee rules, all members’ opening statements will be made part of the record.
And we do want to thank our witness for being here this afternoon, staying with us through the previous full committee hearing, taking the time to testify before the subcommittee.

Today our witness will have the opportunity to give an opening statement, followed then by questions from members. The panel today, of course, will be Dr. Kimberly Brandt, the Principal Deputy Administrator for Operations for the United States Centers for Medicare and Medicaid Services.

We appreciate you being here today, Dr. Brandt, and you are recognized for 5 minutes to summarize your opening statement, please.

STATEMENT OF KIMBERLY BRANDT, PRINCIPAL DEPUTY ADMINISTRATOR FOR OPERATIONS, U.S. CENTERS FOR MEDICARE AND MEDICAID SERVICES

Ms. Brandt. Chairman Burgess, Ranking Member Green, and members of the subcommittee, thank you for inviting me to discuss CMS’ work to address the opioid epidemic.

CMS understands the magnitude and impact the opioid epidemic has had on our communities and is committed to a comprehensive and multipronged strategy to combat this public health emergency.

As the principal deputy administrator for operations at CMS, I am charged with addressing cross-cutting issues that affect our programs, with the efforts to fight the opioid epidemic being one of our agency’s and the administration’s top priorities.

Over 130 million people receive health coverage through CMS programs, and the opioid epidemic affects every single one of them, as a patient, family member, caregiver, or community member. This theme has been repeated throughout multiple stakeholder listening sessions that CMS has facilitated to discuss best practices and brainstorming solutions.

As a payer, CMS plays an important role by incentivizing providers to provide the right services to the right patients at the right time. Our work at CMS is focused mainly on three areas: prevention, treatment, and data. Due to the structure of our programs, Medicare part D plan sponsors in State Medicaid programs are well positioned to prevent improper opioid utilization by working with prescribing physicians. Our job at CMS is to oversee these efforts and to make sure that plan sponsors in States have the tools they need to be effective.

Beginning in 2019, CMS expects all part D sponsors to limit initial opioid prescription fills for acute pain to no more than 7 days’ supply, which is consistent with the guidelines set by the Centers for Disease Control and Prevention. Additionally, we expect all sponsors to implement a new care coordination safety edit that would create an alert for pharmacists when a beneficiary’s daily opioid usage reaches high levels. Pharmacists would then consult with the prescriber to confirm intent.

Thanks to recent action taken by Congress, CMS now has the authority to allow part D plan sponsors to implement lock-in policies that limit certain beneficiaries to specific pharmacies and prescribers. We recently finalized a proposal to integrate lock-in with our Overutilization Monitoring System, or OMS, to improve coordi-
nation of care. The administration also has put forth legislation to require plan sponsors to implement lock-in policies.

These new tools will add on to existing innovative approaches in part D to track high-risk beneficiaries through OMS and to work with plan sponsors to address outlier prescribers and pharmacies. We have seen a 76 percent decline in the number of beneficiaries meeting the OMS high-risk criteria from when we started this in 2011 through 2017, even at the same time that part D enrollment was increasing.

We also support State efforts to reduce opioid misuse. Medicaid programs can utilize medical management techniques such as step therapy, prior authorization, and quantity limits for opioids. In this year’s President’s budget, CMS proposed establishing minimum standards for the Medicaid Drug Utilization Review program, a tool that we use to oversee State activities in this area.

In addition to our prevention measures, ensuring that Medicaid and Medicare beneficiaries with substance use disorder have access to treatment is also a critical component to addressing the epidemic. Our aim is to ensure the right treatment for the right beneficiary in the right setting, and we are working to increase access to medication assisted treatment, or MAT, as well as naloxone.

The President’s budget also includes a proposal to conduct a demonstration to cover comprehensive substance abuse treatment in Medicare through a bundled payment for methadone treatment or similar MAT. Because current statute limits CMS’ ability to pay for methadone, we are focused on ensuring access to other evidence-based MAT.

The administration is also committed to increasing treatment access for Medicaid beneficiaries as well through our 1115 waiver authority. CMS recently announced a streamlined process last November providing more flexibility for States seeking to expand access to treatment. Already we have approved five State demonstrations, which include services provided to Medicaid enrollees in residential treatment facilities.

As this committee knows, ordinarily residential treatment services are not eligible for Federal Medicaid reimbursement due to the statutory exclusion related to institutions for mental disease or IMDs. Combined with the full spectrum of treatment services, we believe the new residential treatment flexibility is a powerful tool for States, and we look forward to reviewing more requests.

Finally, CMS is utilizing the vast amount of data that we have at our disposal to better understand and address the opioid crisis to share with our partners and to ensure program integrity. This includes active monitoring of trends, sharing prescribing patterns publicly through heat maps, and various other efforts to ensure the effectiveness of prevention and treatment policies.

While CMS has taken numerous steps in the areas of prevention, treatment, and data to address this national epidemic, we know there is more we can do. We appreciate the work that your subcommittee has already done to highlight the importance of addressing this crisis, and we look forward to engaging with you on the legislative solutions that you are developing.

Thank you for your interest in our efforts to protect our beneficiaries, and I look forward to answering your questions.
[The prepared statement of Ms. Brandt follows:]

STATEMENT OF

KIMBERLY BRANDT
PRINCIPAL DEPUTY ADMINISTRATOR FOR OPERATIONS
CENTER FOR MEDICARE & MEDICAID SERVICES

ON

COMBATING THE OPIOID CRISIS: IMPROVING THE ABILITY OF MEDICARE
AND MEDICAID TO PROVIDE CARE FOR PATIENTS

BEFORE THE
U.S. HOUSE COMMITTEE ON ENERGY & COMMERCE
SUBCOMMITTEE ON HEALTH

April 11, 2018
Chairman Burgess, Ranking Member Green, and members of the Subcommittee, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services’s (CMS’s) work addressing the misuse of opioids by some providers and beneficiaries in our programs. The Administration is aggressively fighting the opioid epidemic on all fronts. We understand the magnitude and impact the opioid misuse epidemic has had on our communities and are committed to a comprehensive and multi-pronged strategy to combat this public health emergency.

The number of Americans who are struggling with an opioid use disorder (OUD), is staggering. In 2016 alone, nearly 64,000 Americans died from drug overdoses, the majority (over 42,000) of them involved opioids. On average, 116 Americans die every day from an overdose involving opioids.1 Opioid addiction is deeply affecting communities, families, and individuals across the nation. The estimated cost of the lost lives and worsened health of Americans due to the opioid crisis exceeded $500 billion in 2015.2

At the request of President Trump and consistent with the requirements of the Public Health Service Act, the Secretary of the Department of Health and Human Services (HHS) declared a nationwide public health emergency regarding the opioid crisis. The President also directed that executive agencies use all appropriate emergency authorities and other relevant authorities to respond to America’s deadly opioid crisis. Last month, President Trump further highlighted the Administration’s commitment to tackling the opioid crisis by announcing a goal of cutting the number of legal opioid prescriptions by one-third within three years.

For this reason, combating the opioid epidemic is a top priority for the Department of Health and Human Services (HHS) and the Administration as a whole. The President’s Fiscal Year (FY) 2019 Budget proposes a number of legislative and administrative policy changes within

1https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf
Medicare and Medicaid to combat the opioid epidemic and address serious mental illness and provides a historic level of new resources across HHS — $10 billion – to build upon the work started under the 21st Century Cures Act. The Budget’s targeted investments advance HHS’s five part strategy, which involves:

- Improving access to prevention, treatment, and recovery services, including medication assisted therapies;
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health data and reporting;
- Supporting cutting edge research on pain and addiction; and
- Advancing better practices for pain management.

As a payor, CMS plays an important part in this plan by working to make sure providers are providing the right services to the right patients at the right time. Beneficiaries are our top priority across all of our programs, and we work 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 OUDs by promoting CDC guidelines for opioid prescriptions and and encouraging non-opioid pain treatments; 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 efforts.

Preventing Overprescribing and Misuse of Opioids

CMS is taking a number of steps to reduce overprescribing in order to help prevent the development of new OUDs that originate from opioid prescriptions while balancing the need for continued access to prescription opioids for certain medical conditions and pain management. 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. All Medicare Part D sponsors are expected to have a documented, written strategy for addressing overutilization of prescription opioids given the public health crisis. Our job at CMS is to oversee Medicare Part D plans to ensure that they are in compliance with requirements that protect beneficiaries 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 aimed at coordinated care, and safety edits at the point of dispensing.

CMS recently finalized a series of additional changes for 2019 to further the goal of preventing OUD. 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. This policy change is consistent with the Centers for Disease Control and Prevention's (CDC) Guideline for Prescribing Opioids for Chronic Pain that states that opioids prescribed for acute pain in most cases should be limited to three days or fewer, and that more than a seven-day supply is rarely necessary.

Safety edits alert a pharmacist of possible overutilization at the point of sale. In real-time they can flag for a pharmacist that they should conduct additional review and/or consultation with the plan sponsor or prescriber to ensure that a prescription is appropriate. In 2018, all plan sponsors are utilizing these safety edits. Beginning in 2019, we expect all sponsors to implement a new opioid care coordination safety-edit. This new edit would create an alert for pharmacists when a beneficiary’s daily opioid usage reaches high levels. When this occurs, plan sponsors are expected to direct pharmacists to consult with the prescriber to confirm their intent. This new policy aims to strike a balance between addressing opioid overuse without a negative impact on the patient-doctor relationship, preserving access to medically necessary drug regimens, and reducing the potential for unintended consequences.

**Lock-In Authority**

For years, states have been establishing and augmenting effective “lock-in” programs that require Medicaid enrollees who are “at-risk” for misusing or abusing opioids to use only one pharmacy and/or get prescriptions from only one medical office. The Comprehensive Addiction and Recovery Act of 2016 (CARA) provides CMS with the authority to allow Medicare Part D plans to implement similar pharmacy and prescriber lock-in programs. For both Medicaid

---


4 See [https://www.cdc.gov/drugoverdose/prescribing/guideline.html](https://www.cdc.gov/drugoverdose/prescribing/guideline.html)
programs and Medicare Part D plans, lock-in programs are an additional tool to promote better coordination between providers and beneficiaries who meet the guidelines for lock-in.

Under current law\(^3\), 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.

CMS recently implemented the new CARA lock-in requirements in Part D to provide an important additional tool to combat the growing opioid epidemic that is devastating families and communities across the nation.\(^6\) CARA requires CMS to establish through regulation a framework that allows Part D sponsors to implement drug management programs. Our policy incorporated input gathered from various stakeholders, including beneficiary advocates, clinicians, pharmacists, pharmacy benefit managers, and plan sponsors. With a focus on addressing opioid misuse, the proposal would integrate our new “lock-in” authority with our current programs aimed at curbing the opioid epidemic. For example, Part D plan sponsors implementing a drug management program could limit an at-risk beneficiary’s access to coverage of frequently abused drugs beginning in 2019 through a beneficiary-specific Point of Sale (POS) claim edit and/or by requiring the beneficiary to obtain frequently abused drugs from a selected pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary. In addition, the President’s FY 2019 Budget\(^7\) includes a proposal that would provide the HHS Secretary with the authority to require plan participation in a prescriber and/or pharmacy lock-in program to prevent prescription drug abuse in Medicare Part D; this proposal would save an estimated $100 million over ten years.

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

\(^3\) 42 CFR 431.54(e)
because Medicaid is the single largest payer for behavioral health services, we have been working under our 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 substance use disorders (SUD).

To reduce opioid misuse without restricting access to legitimate services, Medicaid programs can utilize medical management techniques such as step therapy, prior authorization, and quantity limits. For example, Vermont implemented prior authorization criteria which involves step therapy for methadone as a treatment of pain, requiring that patients must have documented side effects, allergies, or treatment failure to a preferred, long-acting opioid before being prescribed methadone for pain. Virginia implemented prior authorization criteria which involves additional documentation by both providers and beneficiaries before long-acting opioids can be approved for managing chronic, nonmalignant pain. As of FY 2016, thirty-seven states have edits in place to limit the quantity of short-acting opioids that will be covered for a beneficiary and thirty-nine states have similar edits in place to limit the quantity of long-acting opioids. 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.

States are required to report on their providers’ prescribing patterns, including prescription opioids, as part of the Medicaid Drug Utilization Review (DUR) program. This is a two-phase process that is conducted by the state Medicaid agencies. During the first phase, (prospective DUR), the state agency’s electronic monitoring system screens prescription drug claims to identify problems such as therapeutic duplication, contraindications, incorrect dosage, and clinical misuse or abuse. The second phase (retrospective DUR) involves ongoing and periodic examination of claims to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care.

The President’s FY 2019 Budget includes a proposal that would establish minimum standards for Medicaid Drug Utilization Review programs. Currently, CMS does not set minimum requirements for these programs, and there is substantial variation in how states approach this issue. Establishing minimum standards would not only help increase oversight of opioid
prescriptions and dispensing in Medicaid, but would save the program an estimated $245 million over 10 years.

**Ensuring Access to Evidence-Based Treatment**

A critical part of tackling this epidemic is making sure that beneficiaries grappling with OUD have access to the most effective treatment options. Through its networks of health quality experts and clinicians, CMS advocates the sharing of best practices for OUD screening and treatment.

Medicare Parts A and B cover and pay for substance abuse 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, is also covered when the services are furnished through hospital outpatient departments and Medicare-certified community mental health centers. Medicare pays for substance abuse treatment services provided by physicians and other practitioners on a service-by-service basis under the Medicare Physician Fee Schedule, such as counseling services provided by a psychiatrist. Medicare Part B pays for medications used in physician offices or other outpatient settings that require a physician/practitioner to administer, including injections like naltrexone or implants of drugs like buprenorphine used in medication-assisted treatment. In addition, CMS recently made changes to the Medicare Physician Fee Schedule 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 medication-assisted treatment for opioid addiction, and improving payment for office-based behavioral health services.

*Medication-Assisted Treatment (MAT)*

Medication-Assisted Treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to treat SUDs, including OUDs. MAT is a valuable intervention that has been proven to be the most effective treatment for OUD, particularly because it sustains long-term recovery and has been shown to reduce opioid-related morbidity.
and mortality. To increase access to MAT, CMS requires that Medicare Part D formularies include covered Medicare Part D drugs used for MAT and mandates Medicare Part C coverage of the behavioral health element of MAT services. In addition, CMS issued guidance on best practices in Medicaid for covering MAT in a joint informational bulletin with the Substance Abuse and Mental Health Services Administration (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.

While Medicaid programs vary greatly by state, all 50 states currently offer some form of MAT. In addition, the President’s FY 2019 Budget includes a proposal that would require state Medicaid programs to cover all FDA-approved MAT for OUD, including associated counseling and other costs. These up-front investments in expanded MAT treatment are expected to reduce total Medicaid expenditures over time as more individuals recover from OUD; this provision would result in an estimated $865 million in savings over ten years.

Under an additional proposal in the President’s FY 2019 Budget, CMS would conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare. This demonstration could be expanded nation-wide if successful in key metrics, such as reducing opioid-related deaths among beneficiaries, reducing hospitalization for opioid poisoning, and reducing emergency room utilization for opioid-related issues. Through this proposal, Medicare would provide bundled reimbursement on a per-week-per-patient basis to providers for methadone treatment or similar MAT and would recognize opioid treatment programs and substance abuse treatment facilities as independent provider types; outpatient counseling would be billed separately as clinically necessary. The model would be allowed to target beneficiaries determined to be at-risk, as defined by the Overutilization Monitoring System, to voluntarily receive comprehensive substance abuse treatment, including MAT and SUD counseling.

Increasing the Use of Naloxone to Reverse Opioid Overdose

CMS is also promoting improved access to the opioid overdose reversal drug naloxone by requiring that it appear on all Medicare Part D formularies.¹¹ We recognize 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.¹²

In addition, Medicaid programs in a number of states include forms of naloxone on their Medicaid Preferred Drug Lists. CMS has also issued guidance to states on improving access to naloxone.¹³ States can offer training in overdose prevention and response for providers and members of the community, including family members and friends of opioid users.

Substance Use Disorder (SUD) Treatment and Demonstrations in Medicaid

Under the demonstration authority granted by section 1115 of the Social Security Act, CMS can waive certain federal requirements so that states can test new or existing ways to deliver and pay for health care services in Medicaid. Last November, we announced that we were using this authority to provide for a streamlined process for states interested in designing demonstration projects that increase access to treatment for OUDs and other SUDs by permitting services to be covered in an institution for mental diseases (IMD) as part of a state’s comprehensive OUD/SUD strategy. Current law prohibits Medicaid from making payments to IMDs for services rendered to Medicaid beneficiaries ages 21 to 64. Previously, states seeking to cover services otherwise subject to the exclusion of coverage for IMD patients had been required to meet rigid CMS standards concerning operational details for implementation before Medicaid demonstration approvals could be granted. The new policy will allow states to begin to provide better treatment options more quickly while improving the continuum of care over time.

We are encouraging states to apply for CMS approval of a five-year demonstration allowing them to receive federal financial participation for services to treat addiction to opioids or other

substances, including services provided to Medicaid beneficiaries residing in IMDs, as these states work to improve access to treatment in outpatient settings as well. In addition, we are working with states that operate these demonstrations to establish strong quality of care standards, particularly for residential treatment settings.

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. States must also make available on Medicaid.gov information on the progress and outcomes of these demonstrations and evaluations 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, we have approved these waivers for five states – Louisiana, New Jersey, Utah, Indiana, and Kentucky.

To further support this initiative, throughout 2018, the Medicaid Innovation Accelerator Program (IAP) will be available to states that would benefit from strategic design support related to improving their treatment delivery systems. The IAP provides states with access to national learning opportunities and technical expert resources, including strategic design support to states planning targeted addiction treatment delivery system reforms and developing 1115 proposals. In addition, CMS is available to provide technical assistance to states on how to meet federal transparency requirements as well as to preview states’ draft 1115 proposals and public notice documentation to help ensure states successfully meet federal requirements.

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 benefit for which states can receive 90 percent federal match for the first two years to improve care coordination and care management for individuals with chronic conditions including substance use disorders.\footnote{Four states currently focus health home benefits on improving treatment for opioid use disorders: VT, MD, RI, and ME.}
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. We are also working with our 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

CMS uses the Overutilization Monitoring System (OMS) to help CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of certain prescribed medications, including opioid pain medications. CMS has continued to refine and improve the criteria used in OMS. OMS identifies and reports on beneficiaries with a high risk of misusing opioids and plan sponsors can then use these reports generated by OMS to conduct case management and beneficiary-specific edits. Starting this year, beneficiaries are now identified as at-risk and reported to plans if, in the most recent six months, their daily dose of opioids exceeds 90 morphine milligram equivalent (MME); and if they have received opioids from more than three prescribers and more than three pharmacies, or from more than five prescribers, regardless of the number of opioid dispensing pharmacies.\(^\text{15}\)

In the 2019 Final Call Letter\(^\text{16}\), CMS finalized additional enhancements to the OMS including revised metrics to track high opioid overuse and to provide additional information to sponsors about high risk beneficiaries who take opioids and “potentiator” drugs, such as benzodiazepines, (which when taken with an opioid increase the risk of an adverse event). To help identify and prevent opioid users from taking duplicate or key “potentiator” drugs, in 2019 we also expect 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

\(^{15}\) [Link]
\(^{16}\) [Link]
substances. This report now provides a separate analysis of just opioids. Plans also receive quarterly pharmacy risk assessment reports, which contain a list of pharmacies identified by CMS as high risk and provide plan sponsors with 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 billing data to, and held webinars\textsuperscript{17} for prescribers whose opioid prescribing patterns were different as compared with their peers on both a specialty and/or national level.

To assist clinicians, nurses, and other health care providers to assess opioid-prescribing habits while continuing to ensure patients have access to the most effective pain treatment, CMS released an interactive online mapping tool. The mapping tool allows the user to see both the number and percentage of opioid claims at the local level and offers spatial analyses to identify "hot spots" or clusters in order to better understand how this critical issue impacts communities nationwide.\textsuperscript{18}

The CMS' Quality Innovation Network Quality Improvement organization (QIN-QIOs) program, consisting of 14 quality contractors, works to improve healthcare quality and safety for Medicare beneficiaries. The QIN-QIO program\textsuperscript{19} has established a methodology using CMS claims data to identify adverse events, hospital admissions, readmissions, emergency visits, and observation stays for high-risk Medicare beneficiaries who have taken an opioid medication in the outpatient setting. QIN-QIOs collaborate with providers and other community coalitions, using their reports to support local and national efforts to address the opioid epidemic and increase surveillance of adverse events.

\textit{Modernizing Medicaid Data Collection}

CMS has been working with states to implement changes to the way in which administrative data is 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

\textsuperscript{17} \url{https://www.chisinfocentre.org/ehs202101-webinar}

\textsuperscript{18} \url{https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html}

\textsuperscript{19} \url{http://qioprogram.org/about/why-cms-has-qios}
programs. CMS is working to transition all states to T-MSIS and has made significant progress. As of March 8, 2018, 49 states plus the District of Columbia and Puerto Rico have begun submitting T-MSIS data. These entities represent 98 percent of the Medicaid and CHIP population. CMS continues to work with the remaining states to help them submit data and expects all states to report T-MSIS data.20

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 a data quality assessment for users, which aggregates data quality findings in a user-friendly tool. These efforts will help states report complete and comparable 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 President’s FY 2019 Budget also includes a proposal to require states to monitor high-risk billing activity to identify and remediate prescribing and utilization patterns that may indicate abuse or excessive utilization of certain prescription drugs in the Medicaid program. States are currently authorized to implement prescription drug monitoring activities, but not all states have adopted such activities. States would have flexibility to choose one or more drug classes and must develop or review and update their care plans to reduce utilization and remediate any preventable episodes to improve Medicaid integrity and beneficiary quality of care.

Conclusion

CMS is actively engaged in addressing the opioid epidemic and is committed to implementing effective tools across our programs. CMS will continue to work with beneficiary and advocacy groups, health plans, states, our federal and state partners, and other interested stakeholders to address this devastating epidemic. This epidemic is devastating families and communities, and CMS is committed to using all the tools at its disposal to take meaningful action to stem this tide. We look forward to working with this Committee and the Congress on these efforts.

Mr. BURGESS. Thank you, Dr. Brandt. Thank you for your testimony. Thank you for being here today.

We will move on to the question portion of the hearing, and I would like to first recognize the vice chairman of the committee of the Health Subcommittee, Mr. Guthrie, 5 minutes for your questions, please.

Mr. GUTHRIE. Thank you very much.

Thank you, Ms. Brandt.

Thank you, Mr. Chairman, for the time.

Thank you for being here, Ms. Brandt.

As you know, there is a lot of interest in the committee on more timely, accurate, and complete Medicaid data, whether it is the Transformed Medicaid Statistical Information System, otherwise known as T-MSIS, or basic Medicaid expenditure data. I think having more timely data is important in the opioid fight for targeting, funding, and understanding how the program is evolving.

One of the bills before the Committee would amend the law to allow States only 1 year instead of 2 to submit claims for Federal matching. This deadline does not include adjustments to prior year spending, and the Secretary is allowed to waive the requirement if needed. The requirement in current law was added by Senator Moynihan in 1980. Yet today nearly 99 percent of Medicaid claims are submitted within 1 year.

Ms. Brandt, can you talk about why we would have providers in 2018 that are still taking up to 2 years to submit claims?

Ms. BRANDT. Thank you for the question, sir.

As you noted, the T-MSIS system is one of our big priorities at CMS. Moving to get more accurate and timely data from the States is one of the Administrator’s top priorities. We are pleased at this point that we have 49 States, the District of Columbia, and recently, just as of a week ago, Puerto Rico now reporting in. So we have 98 percent of Medicaid data now being reported in.

We share your goal in working to make sure that data is as timely as possible, and one of our challenges right now is ensuring that we have good quality data. As much as the timeliness of the data is an issue, we want to make sure that it is good quality data, as well.

So now that we have the data being reported in, we are working to scrub the data and try to make it as good a quality of data as possible, and we are focusing particularly on the pharmacy files from the data so that we can begin to get information that will particularly help us with the opioid issue because of the State data that they report.

Mr. GUTHRIE. You said 49 States plus District of Columbia, Puerto Rico, are you using the system. They report within 1 year?

Ms. BRANDT. It is the most recent data that they have. It is not all within 1 year, and that is something we are working on with them. It is as timely as the States have the ability to report it.

Mr. GUTHRIE. But I guess my question is States should be able to do that within 1 year. I know that is one of the bills that we are looking at.

Ms. BRANDT. We are working with them to try and get them to transmit it as timely as possible.

Mr. GUTHRIE. OK. I want to transition then.
According to NIH, every 25 minutes a baby is born suffering from opioid withdrawal. These are the most vulnerable victims of the opioid epidemic. I, along with Congressman Luján, plan to introduce a bill on this important issue later this week.

Do you believe that we should facilitate public-private partnerships to provide additional information in support to women, children, and those tasked with their care?

Ms. BRANDT. Yes. In fact, CMS is very much dedicated to committing resources to help mothers and their infants struggling with opioid addiction, and we actually approved a State plan amendment for West Virginia back in February to provide additional treatment services and additional resources to help target just that issue.

Mr. GUTHRIE. OK. And my final question, as you know, in November of 2017 the President’s Commission on Combating Drug Addiction and the Opioid Crisis recommended that CMS revise reimbursement policies that limit patient access to non-opioid drugs used to treat post-surgical pain. Would you please provide the committee an update on where CMS is on the report and specifically on this issue?

Ms. BRANDT. I am sorry, can you repeat the part of the question?

Mr. GUTHRIE. Yes. The President’s Commission revised reimbursement policies that limit patient access to non-opioid drugs used to treat post-surgical pain.

Ms. BRANDT. So we are committed to working to make sure that we get the right treatment in the right setting, and that certainly includes making sure that we explore non-opioid alternatives to treat pain, and it is something that we are continuing to look at as an agency to determine how we can best address it from a reimbursement perspective.

Mr. GUTHRIE. Thank you.

Mr. Chairman, in the spirit of today, I used 4 minutes. So I will yield back a minute.

Mr. BURGESS. The chair thanks the gentleman.

The chair recognizes the gentleman from Texas, Mr. Green, 5 minutes for your questions, please.

Mr. GREEN. Thank you, Mr. Chairman.

Ms. Brandt, thank you for being here.

For years, States and the Federal Government have under-invested in building the necessary infrastructure for provider treatment capacity, workforce development, and wraparound services needed to help Americans suffering from opioid abuse.

Do you agree that the administration should work with States to strengthen the Medicaid coverage and infrastructure and remove the barriers for coverage for people that need the treatment?

Ms. BRANDT. Yes. In fact, that is the whole point. As I mentioned in my testimony, we have already been working to give States as much flexibility as possible. We have, as of last November, since then approved five States to have more flexibility through our 1115 waiver authority and are very much committed to continuing to work with States to give them the flexibilities they need so that they can determine the right types of coverage to address the opioid crisis.
Mr. GREEN. Well, let me ask another question. I just see that CMS is finalizing a rule allowing more State options in the essential health benefits package. Is that essential benefit package going to include mental and substance abuse?

Ms. BRANDT. I can’t speak specifically to what was just included in the recent benefits package, but I can say that as a whole we have been committed to trying to work with States to allow more support for behavioral health services and those types of support services.

Mr. GREEN. Well, in the Affordable Care Act there was essential benefits package, and substance abuse and mental health was included in there. We didn’t get as much as we should. I know a lot of folks wanted parity, and I support it, but we just couldn’t afford it.

But my concern is that we can pass all 70 of the bills, and if we limit States to making sure that they don’t cover substance abuse all this paperwork is not going to be worth it. So that is the issue, whether it is through Medicaid or through an insurance policy bought through the ACA. That is my concern, and particularly with the cutting in cost-sharing reduction payments last year.

Do you think CMS plans to continue these efforts to sabotage the ACA marketplaces and endanger healthcare coverage of the millions of Americans? Because, again, if CMS is not making sure that that essential benefits package covers mental health and also substance abuse, it doesn’t do us any good to have you and to have these hearings.

If you would take that back.

Ms. BRANDT. I will take that back certainly, sir.

Mr. GREEN. OK. And I appreciate it.

The other concern, I think, when Congress did recently authorize $6 billion in Federal grants for opioids for 2018 and 2019, this additional funding still falls short of the treatment for Americans struggling with opioid use. Even more troubling is the uncertainty for the new funding stream for 2019. This uncertainty may keep States from fully spending the funds without a commitment of long-term stable funding.

Will CMS urge the Department of Health and Human Services to request increased block grant funding for opioid abuse and other substance use disorders beyond 2019?

Ms. BRANDT. Well, as you are probably aware, sir, the President’s budget does advocate for block grants to States for more flexibility, and we believe that that is appropriate because that gives States the right to decide the right type of coverage that they need for the opioid crisis and to address their own individual needs.

Mr. GREEN. Well, and again, one of the reasons we have on the ACA side the essential benefits package, and, frankly, even in Medicaid. Medicaid is the predominant server for mental health and for substance abuse, and if we don’t fund those programs, like I said, we can pass all the bills we want, it just won’t help us with people being treated out in the street.

And so I appreciate you being here.

And thank you, Mr. Chairman.

Ms. BRANDT. Thank you.

Mr. BURGESS. The chair thanks the gentleman.
The chair recognizes the gentleman from Michigan, 5 minutes for your questions, please.

Mr. UPTON. Thank you, Mr. Chairman.

Ms. Brandt, welcome.

Last week I—actually it was this week, Monday—Debbie Dingell, my colleague, we were in west Michigan, and we sat down with a good number of our local mental health providers in my district to talk about pressing issues facing them, how we can be of more help. And I want to flag one of those issues for you and ask that you might be able to work with us on resolving it.

As part of an 1115 waiver, our providers were told that they had to adopt a universal assessment tool called GAIN, G-A-I-N. It is a 77-page assessment tool that takes more than a couple of hours to complete. It is completely duplicative, as every agency already does a comprehensive assessment for each beneficiary. Our providers were told by the Michigan PIHPs that it has to do with the Federal 1115 waiver requirement and that the reason for completing the tool is that we have to do this, we are only the messenger.

And they read some of the questions they are going to actually provide with me later on. Again, I didn't realize this hearing was already scheduled when we sat down Monday afternoon. They are going to share with me that document. But it seems, as they said, they want to practice medicine, often this document turns people away from even continuing the process.

And I just wonder if you can work with us and see if this is really the right approach for them to look at. I know it came, the regs, I think, were written before, but they have been finalized, and it is just something else.

Ms. BRANDT. Well, certainly we welcome if you could provide us with the information and the tool I will take it back.

Mr. UPTON. I will. I will get it to you next week.

Ms. BRANDT. But I will say that one of the Administrator's top priorities has been patients over paperwork, which has been an effort that I know that she has talked to many of you about, to reduce regulatory burden and to try and put patients first over paperwork, hence the name. So it is something that we certainly will go back and look at and appreciate you flagging for us.

Mr. UPTON. Great. I will follow up with you on that next week.

The last question I have is a 2018 report notes that psychotherapeutic drugs might account for up to 4 in 10 drugs prescribed to kids in Medicaid. HHS' Office of the IG has recommended that CMS work with the State Medicaid programs to perform utilization reviews on the use of second-generation antipsychotic drugs prescribed to kids.

The Medicaid Drug Improvement Act seeks to codify that recommendation by requiring that every State have a program to protect kids from unnecessary utilization of these powerful drugs, which could place them at a greater risk for substance abuse.

Do you think that such a requirement on States could help CMS better monitor how States are providing care for kids in their State programs?

Ms. BRANDT. Well, we have read the OIG report and are familiar with their recommendations and are committed to working with them to see how we can reduce the high number of drugs that kids
would be potentially subject to. We are committed to making sure that kids get the right treatment in the right setting, and we will work with the OIG and with you all to see what we can do to address that.

Mr. UPTON. Great. Thank you.

I yield back.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from Oregon, 5 minutes, for your questions, please.

Mr. SCHRADER. Thank you, Mr. Chairman.

Thank you very much, Ms. Brandt, for all the work you are doing at CMS to help deal with the opioid prescription issues. At least I think that we are seemingly getting somewhere. A recent Post article indicated some substantial reduction.

Our medical and dental colleagues are getting on board with prescribing less long-term doses, seems like much in line, might be some incentivized by CMS, but in any case helping drive down the prescription drug abuse problem. And I think that is huge. We work together both in your office and here, frankly, at the practice level. I think that is a big deal.

Are you getting any pushback with regard to some of the guidelines you are putting out there? It seems to be in line with what I am hearing from my medical colleagues.

Ms. BRANDT. I think that the biggest thing we got comments on when we put out the proposals that we codified in our call letter in our proposed regs was making sure that we were striking the right balance.

And that is something that I have heard several of you as well mention today, and that is making sure that the people who have a chronic illness or cancer or a real need for these types of drugs are able to have the access to them while still making sure that we put the safeguards in place on our side to ensure that those who maybe are just taking it for acute pain or maybe should not be having it at the full level are not at risk of getting addicted.

And I think that is a balance we are striking to get, and that is really where I wouldn't say it is pushback, I think it has just been a constructive dialogue that we have been having with the community on that issue.

Mr. SCHRADER. It is a work in progress as we work through this. There is some recent evidence that even for chronic pain you can manage—depending on the person and the situation—chronic pain with modest anti-inflammatories as opposed to having to go to the narcotic.

Ms. BRANDT. Correct. And that is why we are looking at other types of MAT and other solutions to be able to work that and try and provide as much flexibility on that as possible.

Mr. SCHRADER. Would you comment at all on the other, the flip side of this, unfortunately, is that creative people, unfortunately, find alternate ways to satisfy their habits, and there has been a huge rise in the deaths with regard to synthetic opioids and fentanyl, very dangerous, tainted products out there in the market.

What does CMS or how is CMS responding to that and what might we want to help you do.
Ms. BRANDT. Well, it certainly is a real risk, and it is something we have taken several steps to address. I mentioned our Overutilization Monitoring System that we have, OMS. That allows us to put alerts in place to tell us when we see a high number of beneficiaries that are using drugs.

So, for instance, if a beneficiary has 90 morphine milligram equivalents or higher for a sustained period of time, say 6 months, and has been using either three or more providers or three or more pharmacies during that time, it puts an alert in place.

I mentioned the 76 percent reduction that we have been able to see as a result of some of those alerts on the part D side, and we are very encouraged by that. But we are really working to put additional edits in place. These are really checks, if you will, that allow it so that the pharmacist, who is obviously a big part of the care team, can work with the provider to ensure that the beneficiary is getting what they need.

I mentioned we have the new 7-day initial fill limit for acute pain. That is, again, intended to make it so that it is part of a discussion. If there is a need to have something more than that, great, but if not, that really would stop that supply because really, as the CDC has pointed out, there is no need to go beyond that. So we have got that.

We are also looking at prescribers. Unfortunately, while most providers are good, upstanding individuals, we do have a number of people who are overprescribers. And so, we work with our MEDIC, who is our sort of fraud integrity contractor, to really look at identifying the outliers.

They provide reports on who those outliers are. And we rely on our plans to really be able to monitor for that. And then, obviously, States use their PDMPs and other things to help them identify where they see outliers, as well. It is really a multipronged approach.

Mr. SCHRADE. Yes, we have that issue in my part of the profession, also. There are a few outliers, unfortunately, that give the rest of us grief and lead to sometimes more overregulation.

I certainly appreciate your approach and CMS’ approach to work with the providers to come up with that right balance to get good results, and it looks like we are getting there.

Ms. BRANDT. Slow but sure. We still have a ways to go.

Mr. SCHRADE. I yield back, Mr. Chairman.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentlelady from Tennessee, 5 minutes, for questions, please.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

I have two questions that I wanted to talk with you about. The Medicaid Drug Improvement Act, which is going to look at the States’ drug utilization review or the DUR programs and would put in place the minimum standards for the States while giving them some flexibility to determine what is and isn’t going to work.

But they would have to have a minimum standard for the limitations in place for the opioid refills, monitor concurrent prescribing of opioids and other drugs, monitor the antipsychotic prescribing
for children, and have at least one of the naloxone-buprenorphine combination drugs on their formulary.

And as I mentioned in my opening statement, TennCare has already put in place some of these limitations, but as we have seen the growth of Medicaid and with the Medicaid expansion, I wanted you just to talk a little bit about what you think putting these guidelines in place, passing this legislation, what that would do to help with clinical care and the health outcomes for our Medicaid enrollees.

Ms. BRANDT. Thank you. It is a great question. And as you may be aware, actually in the fiscal year 2019 budget there is a proposal to establish minimum standards for Medicaid drug utilization review programs, and that is something that we think is an important first step.

We have already seen that States have been using many tools to address this. We get reports through our DUR report each year that let us know this, and States have been using a lot of medical management techniques like step therapy, prior authorization——

Mrs. BLACKBURN. What are the outcomes when they report them to you?

Ms. BRANDT. I think thus far, from what we have seen in some of the initial outcomes that we have gotten from our DUR reports, is that it seems to be going well, that these things are making a difference and it is starting to make an impact.

Mrs. BLACKBURN. How many States are doing this, electing to do this, to move forward with it?

Ms. BRANDT. Well, right at the moment we have 37 States that limit the short-acting opioids, and we have 39 States that limit the quantity of long-acting opioids.

Mrs. BLACKBURN. So we have got different components that are being implemented in different States?

Ms. BRANDT. Correct.

Mrs. BLACKBURN. Would it be helpful if you had the benchmarks that they had to hit across the board?

Ms. BRANDT. Well, I think that is one of the reasons that the President’s budget proposal advocates for minimum standards, so that there would be something unified across the board.

Mrs. BLACKBURN. OK. That is great.

Let’s talk about the IMD exclusion, because this comes up in nearly every provider meeting that I have, and in my district in Tennessee I have constituents who are so involved in the delivery of substance abuse and mental health programs. And so the IMD exclusion comes up a good bit.

So if you will elaborate on your efforts there. I know that Ms. Verma is working on this issue. She has mentioned that she is. But we want to ensure that Medicaid enrollees are going to be able to get access to the needed care.

Ms. BRANDT. Well, as I mentioned in my testimony, our goal is to make sure there is the right treatment in the right setting for the right individual, and a big part of that is allowing flexibilities for IMD.

So as I mentioned, since last November we have implemented some new demonstration projects in five States—Louisiana, New Jersey, Utah, Indiana, and Kentucky—all of which have flexibility
to be able to waive IMD requirements and allow them to have
greater residential flexibility.
We have gotten a lot of interest from other States and we are
talking with them about giving similar flexibilities, and look for-
ward to working with you all as a committee to determine how we
can address this from a statutory perspective.
Mrs. BLACKBURN. Thank you. I yield back.
Mr. BURGESS. The chair thanks the gentlelady.
The chair recognizes the gentlelady from California, Ms. Eshoo,
5 minutes for your questions.
Ms. ESHOO. Thank you, Mr. Chairman.
And thank you, Ms. Brandt, for your testimony and your work
at CMS.
Ms. BRANDT. Thank you.
Ms. ESHOO. I have several questions.
Do you know how much we spend today, what the Federal Govern-
ment spends on services related to opioids?
Ms. BRANDT. I do not have an exact number for you.
Ms. ESHOO. Approximate?
Ms. BRANDT. I would say that it is definitely in the hundreds of
millions, but I couldn’t give you an exact number. I am happy to
get back to you.
Ms. ESHOO. I think it would be helpful because the committee
staff doesn’t have it either.
Ms. BRANDT. We are happy to look from our perspective.
Ms. ESHOO. But at any rate, it comes from different places, and
I understand that, and there are grants and all of that.
I believe the majority of it is funded through Medicaid, though,
correct?
Ms. BRANDT. Medicaid is certainly a part of it. There are mul-
tiple funding streams in the Federal Government, including NIH,
CDC, SAMHSA, FDA. So there are multiple components.
Ms. ESHOO. But I do think that Medicaid is the single largest
payer both of mental health services and substance abuse, or a
major player in it.
Ms. BRANDT. It definitely is for behavioral health, yes.
Ms. ESHOO. All right.
Now, this is a little bit of a tough question, but the agency I am
sure had done some kind of analysis of this. The President’s fiscal
year 2019 budget proposal slashes $1.4 trillion from Medicaid. So
have you done an analysis of that and the impact it will have on
the very issue that we have 35 bills on in this committee, on
opioids?
Ms. BRANDT. I think that the challenges with the opioid epidemic
is it is not something that we can necessarily spend our way out
of. We want to make sure that—
Ms. ESHOO. Well, that is not what I am asking you. I am not
asking you that.
Ms. BRANDT. We have not done an analysis, specifically.
Ms. ESHOO. Money provides access to fill in the blank. This is not
a partisan issue, Member after Member has spoken to the needs
of people in their communities, the needs for access to a variety of
services, one of the most important being treatment for this after
people are hooked, after they are addicted. So there is a direct correlation between dollars and services.

So maybe you haven't done an analysis, you can tell me that, but I think that it is important to put this on the table. Otherwise this is an extraordinarily serious issue that is plaguing the country, and we are going to reduce it, diminish it to next to nothing if, in fact, this $1.4 trillion is cut from Medicaid. I mean, this is reality. That is the proposal, the President's budget.

So I would like to hear back from the agency as to what your analysis is to the impact of Medicaid and the issue of opioids, otherwise we are just fooling ourselves here.

I mean, it is important to have the discussion, but if, in fact, there is going to be a balanced budget amendment that comes up on Friday, what is contained in that? How is it going to affect this issue? There is a linkage between all of these. And I think unless and until we acknowledge that, that we are really not being straight up.

Now, I am very proud that Stanford University is in the heart of my congressional district. I think they are doing great work in the telemedicine space, specifically for opioid and pain management treatment. They have told me that there are barriers to Medicare and Medicaid reimbursing telemedicine, such as originating site requirements.

Does telemedicine, do you think, save the Federal Government money compared to in-person medicine?

Ms. BRANDT. We absolutely——

Ms. ESHOO. That is such a softball question. So there is the softball.

Ms. BRANDT. We appreciate the question, and it is one of the top priorities of the current CMS Administrator.

Ms. ESHOO. That is not what I asked you. I asked you if you believe——

Ms. BRANDT. And she does believe it has money-saving possibilities, and it is something we are pursuing as part of our proposed payment rules for this next year.

Ms. ESHOO. Do you think the patients, whether they are in a rural setting or an urban setting, should be able to access telemedicine if it is appropriate, obviously, for them?

Ms. BRANDT. We absolutely believe it is a very critical tool, particularly for the rural areas and for underserved communities.

Ms. ESHOO. Has CMS identified any barriers that providers face when trying to use non-opioid treatments for pain?

Ms. BRANDT. We have been working with the providers to discuss how we can eliminate some of the barriers for treatment and are trying to work with them on solutions.

Ms. ESHOO. Well, that is pretty broad. What steps has the agency taken to reduce the barriers?

She can answer. I won't ask anymore.

Ms. BRANDT. We have had a number of stakeholder sessions, as I said, and have been engaged in lots of discussions with the industry to figure out where the barriers are and how best to address them.

Ms. ESHOO. Thank you.
Mr. Burgess. The chair thanks the gentlelady. The gentlelady yields back.
The chair recognizes the gentleman from Ohio, Mr. Latta, 5 minutes for your questions, please.
Mr. Latta. Thanks, Mr. Chairman, and thank you very much for holding today’s hearing.
Again, the opioid epidemic is a scourge on this country. And in the State of Ohio, I am sure, Ms. Brandt, you are aware, that we are about the third hardest hit State. We had 5,232 people lose their lives because of it by the end of the fiscal year of June 30 of last year.
But in 2015, six newborns a day were admitted to Ohio hospitals for neonatal abstinence syndrome, NAS, because of drug use by their mothers, and the cost to Medicaid is $133 million. The State of Ohio has been diligently working to address this issue and helping to improve health outcomes for the moms and the babies out there.
Could you point to any CMS efforts to prevent and treat neonatal abstinence syndrome? For example, States may also include funding for facilities that provide care for infants with NAS to an 1115 demonstration waiver. That is correct, I believe.
Ms. Brandt. Certainly. Certainly this is an issue that we know is very important not only in Ohio, but lots of other States. And we have been working to commit resources to really help mothers and their infants that are struggling with opioid addiction.
One of the ways that we have been doing it is through the Early and Periodic Screening, Diagnostic, and Testing services, or EPSDT. We are requiring States to provide a comprehensive array of prevention, diagnostic, and treatment services for low-income infants, children, and adolescents under age 21. This would include providing treatment services for conditions such as neonatal abstinence.
I mentioned earlier, but in February we approved a State plan amendment for West Virginia to provide additional treatment services for neonatal abstinence syndrome in NAS treatment centers. This would allow West Virginia to reimburse all medically necessary NAS services through an all-exclusive bundled cost per diem rate based on a prospective payment methodology. And it also would allow them to fund things like nursing salaries, supportive counseling, and case management, which are important wrap-around services.
Mr. Latta. Thank you.
And last week in my district I held a roundtable with pharmacists also to talk about the opioid crisis in Ohio, and most of the pharmacists agree that we need to have non-opioid alternatives for pain treatment and management; furthermore, that payments need to be expanded to alternative drugs and therapies outside of opioids.
Should CMS be taking the lead in setting the example to private payers by encouraging non-opioid alternatives for pain management?
Ms. Brandt. Absolutely. As I mentioned in my oral testimony, we are looking very aggressively at MAT and how we can provide that, including things such as naloxone, to be able to have other
non-opioid treatment alternatives to be able to address the problem.

Mr. LATTA. How do you get that information out to everybody out in the real world who are treating folks and saying that we need to make sure we are using non-opioids? How are you doing that? How are you getting that information out?

Ms. BRANDT. We have a variety of methods that we use. We have Medicare Learning Network, MLN, which allows us to get information out. We have open door forums. We have our plan sponsors communicate directly with their providers, and we communicate directly with Medicare providers through various listserves and emails and other things.

We have also partnered with the Centers for Disease Control and other Federal partners to try and get the word out. But we can always work with you all to do more and to try and figure out how to do that more effectively.

Mr. LATTA. OK. And also there is often a lot of discussion about developing new drugs for pain treatment, but also new medical devices have also shown promise in effectively managing pain.

What has CMS done to make sure that medical devices are included in CMS’ efforts to address this crisis?

Ms. BRANDT. That is actually a big area. I can tell you during our stakeholder sessions and during the meetings that myself and other members of the CMS team have had we have had probably hundreds of people come in with various alternatives and other things.

And we have been working very closely with the FDA, who is our partner in this, to be able to figure out a parallel track process so that as they are approving new alternatives we can simultaneously be looking at coverage and reimbursement for them to help get those alternatives in the system as quickly as possible.

Mr. LATTA. Well, thank you very much.

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

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from California, Mr. Cárdenas, 5 minutes for questions.

Mr. CÁRDENAS. Thank you very much, Mr. Chairman. I am glad we have an opportunity once again to speak about this very, very important issue that is crushing our communities and individuals and families.

Ms. Brandt, what is your current title?

Ms. BRANDT. Principal Deputy for Operations.

Mr. CÁRDENAS. OK. And do you report to somebody who is a permanent person in that position or are you reporting to somebody who is actually temporary as you go up the ladder?

Ms. BRANDT. Well, I report directly to the Administrator for CMS, who is appointed by the President.

Mr. CÁRDENAS. OK. All right. Thank you. Many times when we have these hearings there are a lot of vacancies in and around the people who are testifying. I am glad to hear that they have a permanent person in that position.

Ms. BRANDT. I am, too.
Mr. CÁRDENAS. I want to point something out and then ask you a question. And what I want to point out is that often when we talk about healthcare we never mention how it interacts with the justice system, and when we talk about improving the justice system we leave out healthcare for children. Even if we do talk about both of them at the same time once again, with the children we tend to leave them out of the dialogue.

My bill, which is in our committee, which is being discussed today, the At-Risk Youth Medicaid Protection Act, does just that. This bipartisan bill, which I was proud to work on with Congressman Morgan Griffith of western Virginia, keeps the government from kicking at-risk youth off of Medicaid if they come into contact with the justice system.

With this bill, when a child returns home she would immediately be able to see a doctor again and have access to any physical, mental health, and addiction treatments that she may need. Right now children are left out in the cold to battle with the bureaucracy on their own because many States are automatically kicking them off.

The opioid epidemic has grown in a way that the country was not ready for. According to a June 2017 MACPAC report, the opioid epidemic disproportionately affects Medicaid beneficiaries, and thus, State Medicaid programs are taking the lead in identifying and tailoring strategies to prevent and treat opioid use disorders.

It does not matter whether it is on the streets of Los Angeles or the hills of Appalachia; opioid addiction can cripple communities and destroy families. But among those affected the most are our most vulnerable, which is our youth.

Kids suffering from addiction need to be able to see a doctor and get better quick. In some States, when a child comes in contact with the justice system, her access to Medicare is permanently terminated.

Imagine her leaving the facility without family support, wanting to get better, and trying to figure out how to continue with her recovery, manage her mental health issues though she has no ability to refill her medication, get back into school, and find housing.

On top of all that, do we really expect her to have to fill out a bunch of Federal forms and wait until she can get the support that she deserves and needs so badly? The bill that I am talking about does, in fact, fix that.

The need for continuous access to healthcare goes beyond the opioid crisis and not just benefits to children, but also their families, their communities, and the society they will continue to be successful as adults in.

This bill will ensure that children do not fall through the cracks because of red tape that adults created. The legislation has broad support in the law enforcement, healthcare, and social justice communities. I appreciate the ability to discuss this bill and look forward to seeing it advance through the legislative process.

Ms. Brandt, currently Federal law prohibits States from receiving Federal financial participation for individuals covered by Medicaid while they are incarcerated. It does not, however, specify how each State should handle the Medicaid enrollment of these individuals once they get back in the community.
While some States are beginning to suspend instead of terminating Medicaid enrollment of incarcerated individuals, 19 States still permanently terminate healthcare coverage of incarcerated individuals.

Therefore, I ask you, do you agree that these policies limit the ability of most incarcerated children who are covered by Medicaid to access treatment for substance use disorders once they are back in their community?

Ms. BRANDT. Well, I am not familiar entirely with the policies that you are describing, but as I said before, we are committed to working with States to be able to provide flexibility so that they can get the right treatment to the right people, whether that is juveniles, infants, or others.

And so, we are happy to work with you to provide technical assistance and work with the issues. I can’t speak specifically beyond that, because I am not familiar, but we are committed to providing the right treatment and the right setting to the right people.

Mr. CA´RDENAS. Well, I am familiar with that one point that is affecting so many young people in our country. And the point here is that we can and hopefully will clarify in the law that the States do have that option right now to continue to remove them—right now they have the option to remove them once they come in contact with the justice system.

But what should be happening, they should be suspended, because they are going to get out. And for a person with any medical need, mental or otherwise, shouldn’t have to go a month, 2, 3, 4, 5, 6, without the care that has already been identified for them, and that is the rub and that is the part that we are trying to fix. So hopefully we will do that and then you will be able to follow suit.

Ms. BRANDT. Very good. Happy to follow.

Mr. CA´RDENAS. Thank you. I yield back.

Mr. BURGESS. The chair thanks the gentleman.

The chair would observe we have a series of votes that have been called on the floor. We will entertain questions from Mr. Shimkus, and which we will then recess until after the vote series.

Mr. Shimkus, you are recognized for 5 minutes, please.

Mr. SHIMKUS. Thank you, Mr. Chairman.

So Dr. Burgess, and also, really, Dr. Schrader, mentioned the concern on the chronic pain end of these folks. And I have been trying to carry that message, because they are different, right? They are not addicted. They need it to just live normal lives.

Having said that, could you—because I get a lot of questions on this issue of the editing process that you have. Can you briefly explain that. I know that there is a soft edit, hard edit, and that is milligram based, and what the purpose is and why we do it that way.

Ms. BRANDT. Sure. So the whole purpose, again, of the edits is to make sure that if you see folks who are potentially over-utilizers, for instance, someone, as I mentioned before, who would be receiving maybe 90 morphine milligram equivalents or higher on a sustained basis for up to 6 months or more, maybe getting prescriptions from three or more providers, three or more pharmacies, peo-
ple who look like they really are not someone who maybe has a dedicated physician, a dedicated care issue. The whole point is that the pharmacist works with the provider to be able to have a discussion about whether or not that pain treatment is right for that individual. The whole point of the edits is to serve as a flag, if you will, to be able to highlight it so that if you have something that looks like an aberrancy, we can stop it early.

The 76 percent number that I keep going back to, I think, is an important example of this, because by using those types of edits, we have been able to really reduce those numbers by over 25,000 individuals, and that is a significant step forward in that program. So the point of the edits is more to ensure that there is the right treatment being provided to the right person, and to have that discussion among the care team about what that is.

Mr. Shimkus. So are we seeing any response by the chronic pain community that this is inhibiting their ability and slowing up the process of prescriptions for them?

Ms. Brandt. Well, as I said, that is something that we have had a very active dialogue with the community on. We got a lot of comments on that back in response to our call letter. And we have really been working with them to try and make sure that we are striking that right balance.

That is one of the reasons in the call letter that we went to a 7-day initial fill for acute pain, and to make it so that there was the ability to have that conversation between the pharmacist and the provider about the needs of the individual so that hopefully someone who has cancer or some other disease that requires them to need these drugs would be able to get them and to keep getting them as appropriate.

Mr. Shimkus. And Illinois is an 1115 waiver State. Can you explain some of the issues with applying for that? I think it is going to end up being a big discussion within the committee about, if it is working, then we need to make sure that that is working and why versus other responses to this issue that we may hear from some of our other colleagues.

Ms. Brandt. Well, again, the whole goal of our waiver process is to allow States more flexibility, and it is to allow them more flexibility to be able to utilize their resources to treat the opioid crisis in their State as best fits the needs of their State.

Each State is very unique and has different populations and different needs and different resource constraints, so the idea is to be able to work with the States to give them the flexibility.

Mr. Shimkus. And how many States do we have in that process right now?

Ms. Brandt. Well, as I mentioned, since we started the new process in November, we have gotten five States that have gotten substance use disorder waivers. I can’t speak to the total number because there were waivers before that, but since we sort of began the new process, there are five States that have been approved. And we have discussions ongoing with several others.

Mr. Shimkus. And I would just like to end on the—obviously in the coding issue and reimbursement on nonopioid pain management treatments. Obviously, you have heard the concern that if we
Ms. BRANDT. Certainly. Again, that is an area where we are having an ongoing dialogue with the provider community to determine what the right levels are there in terms of coding and how we can work with them to make sure to balance the burden with the appropriate targeting of treatment and codes for that.

Mr. SHIMKUS. I appreciate you being here. Thank you for your time.

And, Mr. Chairman, I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

And once again, the chair observes we have a series of three votes on the floor of the House. The Committee is going to briefly recess while we record those votes over the in the House Chamber, and we will reconvene immediately after the last vote.

I thank the witness for the forbearance during that time.

Ms. BRANDT. Thank you.

Mr. BURGESS. The committee stands in recess.

[Recess.]

Mr. BURGESS. I call the subcommittee back to order. I want to thank everyone for their forbearance while the vote series occurred.

At this point, I would like to recognize for 5 minutes the vice chairwoman of the conference, Cathy McMorris Rodgers, 5 minutes for your questions, please.

Mrs. MCMORRIS RODGERS. Thank you, Chairman, Ms. Brandt.

I want to first applaud CMS for clarifying in the final part D rule that MTM programs will fall under quality improvement activities when calculating the medical loss ratio requirements. This should encourage plan sponsors to expand access to MTM programs, which will ensure a greater number of patients can benefit.

Given the important role pharmacists can play in addressing the opioid epidemic, we are considering legislation today to add patients at risk for prescription drug abuse to the list of eligible beneficiaries for MTM under Medicare Part D. Can you please give us your thoughts on utilizing pharmacists to help address the opioid epidemic?

Ms. BRANDT. Thank you.

We think that pharmacists are a very important part of the care coordination. As I mentioned in several of my answers today, pharmacists play a vital role and are on the frontline in helping work with providers to address this. And we think the MTM treatments, in particular, have been very beneficial to beneficiaries, and we look forward to working with you to expand that.

Mrs. MCMORRIS RODGERS. And while we are on the topic of MTM, can you provide us with a quick update on where CMS is ensuring sufficient retail pharmacy representation in the CMMI enhanced MTM model demonstration project?

Ms. BRANDT. I can't speak specifically to that, but I am happy to get back to you with some more information about how that is going. I am sorry, I am just not familiar with that particular one.

Mrs. MCMORRIS RODGERS. OK. That would be great.
I am interested in how existing dollars can be leveraged in the effort to help educate providers providing care for patients with substance abuse disorder. When we spend more than $2 billion in Medicaid-funded GME programs each year, it is just common sense for Congress to better understand how these programs are helping to train providers on pain management and substance use disorder.

For example, the University of South Carolina implemented a program into their medical school curriculum to address the opioid crisis using case studies, panel discussions, and group work.

By the end of medical school, all USC-trained medical students will be able to recognize patients that are at risk for substance abuse, and have solutions for treatment. I think that this is a great model for other medical schools.

Do you think that it is appropriate use of GME dollars, particularly since Medicaid beneficiaries represent a disproportionately large share of those with substance abuse disorder?

Ms. BRANDT. Well, we certainly agree that education is an important component. And we agree that we want to continue, as we have been doing, to work with States in the accrediting organizations to make sure that GME dollars are put towards education to help make sure that that is targeted in the appropriate way.

Mrs. MCMORRIS RODGERS. Thank you.

I would also like to take this opportunity to submit for the record from the Washington State Pharmacy Association, pharmacists play a unique role in patient care and are frequently the healthcare professional that a patient sees the most, especially in our rural communities.

Authorizing pharmacists clinical services under Medicare Part B, which H.R. 529 accomplishes, will go a long way to empower pharmacists and give them an opportunity to help address prescription drug misuse and abuse.

So I would like to submit this letter for the record, Mr. Chairman, and with that, I will yield back.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. BURGESS. The chair thanks the gentlelady. The gentlelady yields back.

The chair recognizes the gentleman from Massachusetts, Mr. Kennedy, 5 minutes for your questions, please.

Mr. KENNEDY. Thank you, Mr. Chairman. I appreciate the opportunity to have this hearing.

Thank you, Ms. Brandt, for being here as well, answering our questions.

Mr. Chairman, I would like to start just by submitting or requesting an opportunity to submit for the record a letter of support from about 2 dozen or so organizations in support of our mental health parity bill, if you would be so kind.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. KENNEDY. Thank you, sir.

Ms. Brandt, I wanted to drill down a little bit your understanding and the administration’s understanding about the current status of Medicaid with regard to the two areas of focus, substance abuse and mental illness, with regards to some of the policies that
I think have been put forth from a couple of States that you mentioned earlier.

Do you have any information or data that indicates how long it takes the average patient to recover from a substance use disorder?

Ms. BRANDT. I don't know exactly the amount of time, but I can get back to you with any information that we have.

Mr. KENNEDY. Yes. And I would imagine that it obviously is going to vary quite a bit individual to individual.

Ms. BRANDT. Yes. I think it depends on the type of person, the type of treatment, and the setting.

Mr. KENNEDY. Yes. And I would assume, with regards to a broader mental health issue, some of that is, obviously, a lifelong condition and some of that with adequate treatment and access to care can be successfully managed. Is that fair?

Ms. BRANDT. That is fair, yes.

Mr. KENNEDY. So you can imagine my concern, Ms. Brandt, when I hear that five States, Maine, Arizona, Utah, Wisconsin, and Kansas, have applied for waivers to impose lifetime limits on Medicaid patients in their States, knowing that substance use orders and mental health problems are often lifetime challenges, and knowing that Medicaid is a single largest payer of behavioral health service in this country.

How do I understand the testimony that you have given so far, and this administration's stated commitment to provide access to care, particularly in the midst of an opioid epidemic, recognizing that for the young people that are afflicted with this epidemic, it is going to be a lifelong issue and a lifelong challenge with a policy of lifetime caps? How do I rectify that?

Ms. BRANDT. Well, as I mentioned before, we have been working to try and work with States to try and give them as much flexibility as they can to manage the populations in their area to hopefully get the right treatment in the right setting for the right duration.

Mr. KENNEDY. I appreciate your answer, but how is a lifetime limit ever going to be the appropriate response for somebody facing a lifetime illness?

Ms. BRANDT. Well, I can't speak to that specifically, but, again, we are committed to working to give the States the flexibility they need to hopefully provide the right types of treatments for their individual constituents.

Mr. KENNEDY. So with regards to a similar policy and a work requirement, is there a study that you are aware of that indicates that Medicaid—that people are healthier, not the causation between health and work, but between work and health? Are you aware of a study that shows that work will make somebody healthier?

Ms. BRANDT. I cannot speak to such a study.

Mr. KENNEDY. I can't either. I am not sure there actually is one. And so I am curious as the administration tries to push forward with a Medicaid work requirement, you had said earlier that the philosophy of this administrator was to put patients over paperwork.

I think we can agree that when it comes to a work requirement, the paperwork necessary for an individual patient to try to either,
one, prove that they are working is an additional administrative burden; and two, to try to provide, assuming that you are carving out some sort of exemption for people under certain conditions, mental illness, caregiver, student, others, that that is an additional administrative hurdle on top of that. How is that putting patients above paperwork?

Ms. BRANDT. Well, with the States where we have already gone ahead and worked with them, one of the things that we tried to do was to make sure that the States would make reasonable modifications.

And we are trying to work with them to ensure that they are striking that appropriate balance, to ensure that they are getting people access to the treatment they need without hopefully having additional bureaucratic requirements.

Mr. KENNEDY. And if somebody is suffering with a mental illness, such that they—as I know over the course of—you have been dedicated to public health and health policy for a long time, the challenges that those individuals and families have with getting access to care and maintaining the care that they need, and the struggles that they go on on a daily basis to sometimes get through the day, the administrative burden added for them to prove that they are—should be exempt for those work requirements, does that not make it even harder for them to do so? And if so, isn’t the risk of them losing access to their healthcare and Medicaid even higher to one of the most at-risks populations we have got?

Ms. BRANDT. Well, to your point, that is one of the reasons that we remain committed to trying to work with States to sort of strike that reasonable balance I talked about. We want to make sure people have reasonable access and the appropriate access to the care they need in those States, and, hopefully, balance that with the requirements needed to be able to show that they need that care.

Mr. KENNEDY. And how would a work requirement ever tilt in the way of a patient for access to health?

Ms. BRANDT. As I said, we are working with States to try and make sure to assure that balance.

Mr. KENNEDY. Appreciate that. Thank you.

Yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for your questions.

Mr. GRIFFITH. Thank you, Mr. Chairman.

Appreciate you being here this afternoon.

The Medicaid Pharmacy Home Act that the Committee is considering would require that States take into account a patient’s history of receiving care in geographic proximity to providers and pharmacies when locking a patient into two providers and two pharmacies. How would CMS define proximity?

Ms. BRANDT. Well, that is a good question and something that in each of our rulemaking, we actually look to do. We recognize that we are always looking to make sure that we can ensure appropriate access for patients.

As I said, we want to make sure people are getting the right treatment in the right setting, and so it is something that we are
definitely always looking to determine what is the right proximity. Is it driving distance? Is it actual mileage distance? What is the appropriate balance? And that is something that we do through notice-and-comment rulemaking and working with individuals such as yourself.

Mr. Griffin. And you anticipated the next part of my question, because I was going to go to, historically it has been a mileage requirement, but in districts like mine, which have mountains in them, one town might be closer as the crow flies, but not nearly as close on driving time.

I have got a classic situation in one of my areas where in Dickenson County, Haysi, and Clintwood, on the map may look like they are 15 miles apart but there is a mountain in between.

And because of the road that goes around the mountain, I have been advised by the mayor of Haysi that he allots—it doesn’t always take him that long, but he allots an hour to get from one down to the other. When he has a meeting over in Clintwood, he has to allocate an hour on his calendar, weather, coal trucks, timber trucks, a slow driver worried about the curves, all can make that trip a lot longer, and there may be closer facilities that the drive time is better for, or whatever, and keeping that in mind. And I just ask that as you all look at this—and we will too—if you would keep that in mind, I would greatly appreciate it.

Ms. Brandt. We certainly will.

Mr. Griffin. Thank you.

In MACPAC’s report this past June, the commission noted research in health affairs that found States with prescription drug monitoring programs requirements saw reduction in opioids prescribed to Medicaid enrollees, reducing the total scripts in the dosage as well, and a reduction in Medicaid spending on those prescriptions. A 2016 CMS bulletin also highlighted similar findings.

Wouldn’t you agree that this evidence demonstrates the critical role of the PDMPs in addressing the opioid epidemic, saving both lives and dollars?

Ms. Brandt. Yes. We absolutely think the PDMPs play an important role. Forty-nine States currently have a PDMP, and we are very much committed to continuing to work with them to ensure that they are as effective as possible.

For instance, the State of New York, which has been requiring prescribers to access a PDMP, has seen a 75 percent drop since 2013 and the number of patients who use multiple prescribers and pharmacies for controlled prescription drugs just because of the PDMP.

Mr. Griffin. And appreciate that.

The Medicaid Partnership Act draft before us allows States flexibility in how they design their programs. However, it also ensures that PDMPs are a part of Medicaid’s provider clinical flow work. If more physicians and pharmacists were checking the PDMP, would you expect the number of opioid prescriptions to decrease? I would.

Ms. Brandt. Well, as stated with the example I just gave you from New York, we think that there is a lot of promise to having greater access to PDMPs, and to making sure that people are utilizing them.
Mr. GRIFFITH. Now, here is an interesting twist that we have to try to figure out. If you have the prescribers checking it, is it duplicative to have the pharmacy checking it also?

Ms. BRANDT. Well, it is a good question. And, as I mentioned before, we view the pharmacist as well as the prescriber as part of that care coordination team. So it is something where prescribers have been checking this, but we also view the pharmacist as a part of the discussion, and it is something we are certainly open to discussing with you all.

Mr. GRIFFITH. Yes. I think we do need to discuss it, because one of the things that it also says is is that if there is a patient in hospice or palliative care, they would be exempt from the requirement to consult the PDMP. How is a pharmacist going to know that? The prescriber should know that, but——

Ms. BRANDT. At this point in time, I do not believe that type of information would be available to people checking the PDMP, so that would be an impediment.

Mr. GRIFFITH. Right. So we have got to figure that out if we are going to go forward on that particular line of the bill. But I do think we are all trying to work in the same direction, and I appreciate any input that you can give us to make our bill, as we go forward and discuss it, better and practical.

Ms. BRANDT. Well, we look forward to offering technical assistance, and this is an area that we have been very focused on, so thank you.

Mr. GRIFFITH. Thank you, and I yield back.

Mr. BURGESS. The chair thanks the gentleman.

The chair recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes for your questions, please.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it.

Ms. BRANDT. Thank you.

Mr. BILIRAKIS. I appreciate your testimony as well.

Ms. BRANDT. Thank you.

Mr. BILIRAKIS. No problem. It has been a long day for everyone.

Mr. BILIRAKIS. Last week, CMS issued final rules for Medicare Part C and D, which include the rules for the lock-in program. This program is important for me not only because I authored the provision, but also because addiction is a serious problem that cuts across age, gender, and income.

Programs like Medicare need to have and use all the tools available to help beneficiaries. Let’s see, can you update the Committee on what changes CMS did with this implementation of the drug management program for at-risk beneficiaries, also known as lock-in, in Medicare’s Part D program, please.

Ms. BRANDT. Certainly. As I mentioned in my oral testimony, we were very appreciative of the additional tool that Congress gave us. This is a very important tool in our fight at the Federal level against the opioid epidemic.

Starting next year, plan sponsors have the option to go ahead and implement a lock-in requirement, which would require a beneficiary to use certain providers and/or certain pharmacies, depending on what is deemed appropriate.
There is also a proposal in the President’s budget to do mandatory lock-in for plans. Again, ours is a “may” not a “shall” right at the moment, but the President’s budget has a “shall.” But we think that the lock-in authority is something that will be very helpful.

We have seen a lot of good results from States. Many of the States have been using lock-in authority. And we think that some of the early results from States we have seen, such as Pennsylvania, which has saved about $55 million in 2016 from using lock-in authority, are a good indicator of where we can go with this authority going forward.

Mr. BILIRAKIS. The President’s budget has a “shall,” recommends a “shall”—

Ms. BRANDT. Right.

Mr. BILIRAKIS [continuing]. As opposed to the “may”?

Ms. BRANDT. Correct.

Mr. BILIRAKIS. And my original bill had a “shall” as opposed to the “may.” Why do you think it is so important to—if that is your position as well, because I agree it should be a “shall.” Why do you think it is so important that we say “shall,” and require them to have the lock-in program under Medicare as opposed to giving them a choice?

Ms. BRANDT. Again, it is an important extra tool for our toolbox. And if the tool is optional, it doesn’t mean it can always be used. But if the tool is mandatory, that means it can and should be used. And it is just another important tool to allow us to address those really high over-utilizers and to be able to take important steps to limit their usage and to be able to protect the program.

Mr. BILIRAKIS. And, again, we want to emphasize this is only for high risk?

Ms. BRANDT. Only for high risk. Only for those who are particularly high risk. And as I indicated from the results we saw from the State of Pennsylvania, we think they will also have cost implications to the programs in terms of savings, which is something that we are always looking for, particularly in the Medicare side of the house.

Mr. BILIRAKIS. Very good. Thank you. Under Medicare, yes. Thank you.

Next question. Do I have time? Yes, I think I am all right. Almost every State Medicaid program runs or authorizes a lock-in program using, physicians or pharmacies, or a combination of both. Every State Medicaid program runs their program differently from each other.

Does CMS currently collect data from States on their Medicaid lock-in programs, such as how it is structured, eligibility triggers, estimated cost savings, outcome measures, or other data that could help States with establishing best practices?

Ms. BRANDT. So we are starting to do that through our Medicaid drug utilization review program. Our DUR reports that we get are allowing us to start to get that sort of information.

We are still sort of, I would say, solidifying exactly what requirements we are getting, but it does allow us to get a snapshot of what is working. And that is how I was able to give you an example from Pennsylvania, where we were able to see some initial posi-
tive results from their lock-in program. So it is something that we are starting to collect.

Mr. BILIRAKIS. How many States actually collect this data?

Ms. BRANDT. I would have to get back to you with that. I don’t know the exact number of States.

Mr. BILIRAKIS. But there are advantages for the States to collect this data?

Ms. BRANDT. Absolutely. Because as you can tell, you can provide savings data. It also provides data on how it reduces over utilization and other important markers that we can use from a program management perspective.

Mr. BILIRAKIS. OK. Very good. Thank you.

I yield back, Mr. Chairman. Appreciate it.

Mr. BURGESS. The chair thanks the gentleman.

The gentleman yields back.

The chair recognizes the gentleman from Indiana, Dr. Bucshon, 5 minutes for your questions, please.

Mr. BUCSHON. Thank you, Mr. Chairman.

I was a surgeon before, and I was in healthcare. I have seen this problem coming for 25 years, caught up to us pretty quickly for a variety of reasons. There is no one particularly at fault, but I think we kind of got caught with that.

And, it is going to take us a while to get out of this problem. It is a multifactorial in origin as well as the solutions to it, all the way from border security and preventing the 90 percent of heroin that comes to the United States from coming across our southern border, all the way to the other end of the spectrum where we have to provide affordable treatment options for people who are currently addicted.

And I believe that some more emphasis maybe should be placed on innovative treatments, including medications and devices, to help individuals manage pain without becoming dependent on opioids.

And CMS plays a critical role in this effort. That is why I have worked with Scott Peters, who is down at the end, on the Post-operative Opioid Prevention Act to create a temporary pass-through payment to encourage development of nonopioid drugs for post-surgical pain management and Medicare.

Additionally, I am working on a draft legislation to add an evaluation of management of chronic pain to the Medicare initial assessment, which would include an emphasis on nonopioid pain management alternatives. Have you had a chance to look at those options?

Ms. BRANDT. I have not personally, but I know that our office has been reviewing them for technical assistance.

Mr. BUCSHON. OK. It is important to remove barriers to access for patients new options for management of post-surgical and chronic pain in order for society to shift from the overreliance on opioids.

My daughter, for example, had her wisdom teeth taken out, and her dentist wrote a prescription for 60 opioids. Of course, my wife
and I are doctors. We never filled it. We said, some ice on the cheeks and a little bit of Advil and Tylenol. But you see the extent of this problem.

We still, even as a provider, I will say that providers are part of the solution, and I think we are doing much better, but we have a way to go. It is a cultural shift that we need. It is starting in training, I think, all the way up through current practitioners, and I think that we are going to get there.

I know there are barriers to nonpharmaceutical therapies for chronic pain. I think someone asked you earlier about that. How can those barriers be addressed and primarily its coverage decisions from CMS, honestly, to increase the utilization of evidence-based therapies, particularly FDA-approved medical devices for pain?

Ms. BRANDT. So as I mentioned earlier, we are constantly looking at CMS to determine how we can look at evidence-based criteria to improve our coverage decisions. One of the things we really would like to do and are trying to do is, within our statutory authority, to expand the amount of nonopioid alternative treatments that we can cover as much as possible.

And we are committed to working with the FDA and our other partners to really try and expand our reach of that as much as possible. We have been working very much with NIH to get more clinical evidence to support our coverage decisions and are continuing to try and fast track all of that to open up as many new options as we can.

Mr. BUCSHON. And administrator Verma met with the Doctors Caucus this morning, and we talked a little bit about that. And I know that that is a goal to try to, and you may need some more authority legislatively, I think, to adapt, because we need to be more nimble here. If we have something that is FDA approved, we need to get coverage decisions in a more nimble way, not reinvent the wheel.

And I have found, since I have been in Congress—this is my 8th year—that coverage decisions are a barrier to access more than, I think, I really realized. And it is nobody's fault; it is just the way it is.

Some of the bills before us today will increase access to methadone also. An informational bulletin on best practices for addressing prescription opioid overdoses, misuse, and addiction in Medicaid was issued by your predecessors in the Obama administration. That bulletin cautioned that methadone, in particular, accounts for a disproportionate share for opioid-related overdoses and death. Methadone, as everyone knows, is an opioid.

The bulletin also warned of an increased risk of morbidity, mortality associated with methadone in the Medicaid population. Mr. Chairman, I ask for unanimous consent to submit that CMS report for the record.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. BUCSHON. I know every member here wants the patients to get the care they need, but we also need to make sure it is the right treatment from the right provider at the right time.
Can you talk about CMS's current work—briefly, because I am almost out of time—to better understand the clinical risks the literature associates with methadone?

Ms. BRANDT. Certainly. Again, we have been looking at different ways that methadone can be utilized where it is appropriate, both for opioid use disorder and how it is currently being utilized for acute pain, in determining whether or not there are alternative treatments or other ways that we can work with you all in Congress to expand our statutory ability to be able to use methadone where appropriate for OUD.

Mr. BUCSHON. OK. Thank you.

Mr. Chairman, I yield back.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from New Jersey, Mr. Lance, 5 minutes for questions, please.

Mr. LANCE. Thank you very much.

And good afternoon to you all.

In a CMS report on the Medicaid Health Home State Plan option, CMS noted States report that they plan to continue the Health Home Programs after the current law 8-quarter enhanced Federal match ends—and I think it is a 90 percent match—in part, because they are saving money.

CMS explained States believe that the cost savings are a result of the improved health status and reduced utilization, which are expected to, at a minimum, cover the costs of the Health Home Program and anticipate savings in excess of health home costs.

Mr. Chairman, I ask that the report be submitted for the record.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. LANCE. Thank you.

Given these findings, what impact would an additional year of enhanced Federal matching for Health Homes have for States? Do you think more States would adopt this special model to provide care coordination and wraparound services for patients with substance abuse disorders?

Ms. BRANDT. We have seen good initial results from the Health Home, particularly in Vermont, with the hub-and-spoke model that we have there. The Health Home has seemed to be very positive and had very good results.

So it is something that we are supportive of because the Health Homes do provide us with another option to provide the right care in the right setting, and Health Home can be an important part of that.

Mr. LANCE. I would imagine that funding is safe if patients are permitted to stay in their homes. I think that that probably is a cost saver.

Ms. BRANDT. I can't speak to that specifically, because I haven't seen numbers to support that. But like I said, at least initially, based on the Vermont model, it does seem that they have achieved some savings using the Health Home model.

Mr. LANCE. I thank you very much.

And, Mr. Chairman, I yield back 3 minutes.

Mr. BURGESS. The chair thanks the gentleman.
The chair recognizes the gentlelady from Indiana, Mrs. Brooks, 5 minutes for your questions, please.

Mrs. BROOKS. Thank you, Mr. Chairman.
And thank you for being here and for your work.

One of the reasons why I think the opioid epidemic has become so pervasive is because of the prevalence of pain, and pain being the most common reason Americans access the healthcare system to begin with, and number one cause of disability in the country. We know pain is a major contributor to healthcare costs, not to mention societal costs and the economic loss because of the opioid crisis.

But how can HHS and CMS ensure that educators, or providers rather, are better educated about pain management alternatives, including the technological alternatives to opioids that Dr. Bucshon was just talking about?

In a previous answer, I know you mentioned the Medicare Learning Network. I would like to know a little bit more about how you are doing more of the education for providers?

Ms. BRANDT. Ma’am, it is a great question. I think the pain issue is one that we have really tried to address through multiple fronts at CMS. Part of it is having more of a discussion with providers about pain.

Our quality measures used to have pain management survey questions in them. We have changed those to have it be more of a discussion about pain instead of how can we just manage your pain. It is having a discussion about the type of pain and sort of why that is happening and trying to figure out the right solution.

We have also been working on quality reporting on adverse events in the hospital to sort of work with physicians to say, OK, how can we have a better understanding of this? How do you know what the alternatives are?

So part of that is through the outreach we do through our quality improvement organizations, our QIOs, and our quality improvement network. They do a lot of outreach in physician and hospital education.

We use the Medicare Learning Network, MLN, that I talked about before, where we issue a lot of bulletins electronically that go to physicians and hospitals to update them on, Hey, here is a new treatment that you might not be aware of, or, Here is some new developments that we have on coverage for alternative treatments.

We have also tried very much to have more of an ongoing dialogue through open-door forums and just more one-on-one educational interactions with various medical societies and others, to really educate them about what we are doing, and to hear from them about how we can do better.

So I think there is always more that we can do, but we have really been trying to do it through both an in-person and virtual approach, and think we can do more.

Mrs. BROOKS. How do you know about the utilization of that type of information?

Ms. BRANDT. Well, that is the challenge. We have a good idea of how many people subscribe, for instance, to our Medlearn Matters
articles. We have a good idea of how many people participate in our open-door forums and things like that.

But a lot of that information then gets disseminated on even further from there, so it is hard for us to completely track. But we are trying to do a better job of targeting our outreach.

And one of the things that our stakeholder sessions taught us was that we really are thinking through how we can better partner with our Federal partners and our private sector partners, the plans, a lot of the associations and others, to do more coordinated outreach and education in this space, and that is something we are currently working on.

Mrs. BROOKS. When we passed in CARA, the interagency group that was formed with various Federal partners to focus on prescribing practices? Are you familiar with that group?

Ms. BRANDT. I know that we have participation in many types of groups like that. I am not sure if it is the one specifically described in CARA. I can get back to you. But we are in active coordination and discussions with CDC, NIH, SAMHSA-HRSA, all of the different components within HHS, DEA, and others to kind of work and sort of figure out how our piece as a payer impacts with the different pieces that they have from the other perspectives.

Mrs. BROOKS. I would be interested in you getting back to us as to whether or not——

Ms. BRANDT. We will certainly follow up.

Mrs. BROOKS [continuing]. This was part of CARA. And I would like to know, and I think it would be important for you to participate.

Would you agree, however, that we could continue to do even more prescriber education? And I am working on a bill to require more prescriber education, but to allow it to be focused at the State level, and to have the societies and the other entities at the State level oversee that type of training, because not all States require continuing medical education. Were you aware of that?

Ms. BRANDT. I did not know that.

Mrs. BROOKS. So that is something that not all States currently have, and so right now, it is all voluntary. Everything is voluntary, is it not?

Ms. BRANDT. Yes.

Mrs. BROOKS. Unless the State is requiring it. Some States do. Indiana happens to now require it.

Ms. BRANDT. Right.

Mrs. BROOKS. Thank you.

I yield back.

Ms. BRANDT. Thank you.

Mr. BURGESS. The chair thanks the gentlelady.

The gentlelady yields back.

The chair recognizes the gentleman from Georgia, Mr. Carter, 5 minutes for your questions, please.

Mr. CARTER. Thank you, Mr. Chairman.

Thank you, Ms. Brandt, for being here. Appreciate it very much. I want to talk to you, first of all, about abuse deterrent formulations. To be quite honest with you, in my years of practice in pharmacy, when this first came out, I wasn’t too high on it.
But now that we have developed as much of a problem as we have with the opioids and drugs of abuse, I am beginning to warm up to it quickly. And I see the usefulness of it and the fact that you won’t be able to crush it so that you can’t snort it or turn it into an injection.

I understand that there might be some extra cost involved. I am wondering what kind of barriers that your agency is seeing in using these medications, and what is limiting the use to access to these types of medications?

Ms. BRANDT. So right at the moment, we agree that abuse deterrent opioids are definitely a potential tool in tackling this epidemic. At this point, the epidemic is so pervasive that we are looking at any and all tools.

Mr. CARTER. Exactly. I would agree with that.

Ms. BRANDT. We need to explore all. I think under our current statute, we cannot tell our plan sponsors what to negotiate and what types of drugs that they have to cover on their formularies. It is the plan sponsors’ responsibility to do negotiations and negotiate with drug manufacturers and determine which of the FDA-approved medications to make available to the——

Mr. CARTER. Now, who sets forth those results and regulations? Is that in the statute?

Ms. BRANDT. It is under current statute, yes, sir.

Mr. CARTER. So that is something we in Congress can help you with?

Ms. BRANDT. You have the ability to influence that, yes.

Mr. CARTER. OK. Well, that was my next question, how can we help you? And you just answered it. We can help you by rewriting those rules and regulations to include this.

Ms. BRANDT. As I said, right at the moment, we cannot interfere in those negotiations under the statute as it is currently written. If you all were to change that, that could potentially give us more flexibility.

Mr. CARTER. Right. Well, as this evolves and as it continues, it is certainly something we need to be looking at from a perspective here.

I want to go now to the Medicaid Pharmacy Home Act. And before I ask you just a couple of questions about it, I want to compliment my colleague, Mr. Bilirakis, in his work on this. I think this is good.

I have been involved during my time of practicing pharmacy with lock-ins, and I see the advantage of them, but I also see some concerns. I do think that they can help lower the incidents of fraud and abuse.

But at the same time, I am just wondering in the legislation—pharmacy preference is very important. And I have often wondered when these programs are used how they determine which pharmacy is going to be the lock-in pharmacy.

What do you think about pharmacy preference and about the patient having the ability to request a certain pharmacy?

Ms. BRANDT. Well, I think, as I said, we currently have this as an optional authority, starting in 2019, for our plan sponsors to do lock-in. And part of it is working with the beneficiary to make sure
that it is a pharmacy that fits for them, that is geographically appropriate, that is somewhere that they can access.

And part of that is the right care and the right setting that I was talking about before. So I think that our expectation is that pharmacies and plans will work with the patients and the providers to make that best fit.

Mr. CARTER. Well, one of my concerns is access to the medication. I have seen situations where they are locked in to a pharmacy. That is the only place they can get it, and that pharmacy might not have a certain product that they need, and, therefore, the access is denied.

What do you think about having more than one pharmacy in that situation?

Ms. BRANDT. Well, that is one of the reasons where we gave some flexibility to be able to potentially have, in certain instances, pharmacies or providers and, again, trying to do so in a limited way to sort of limit the potential for abuse, but yet, still be able to give those options that you are talking about.

Mr. CARTER. Well, I am glad to hear you say that, because I think that is going to be extremely important. I know that the lock-in provisions can work, but I am very concerned about accessibility and particularly about patient preference. That is very important.

And certainly, in this situation, I think it would be most important in working with the patient to make sure that they are getting the pharmacy preference of their choice would be paramount, I think, in this situation.

Well, thank you for what you are doing. Appreciate you being here today.

Mr. Chairman, I yield back.

Ms. BRANDT. Thank you.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman.

All members of the subcommittee having had an opportunity to ask questions with the exception of the chairman, the chairman will now recognize the gentleman from the full committee, Mr. Tonko of New York, 5 minutes for your questions.

Mr. TONKO. Thank you, Mr. Chair. Thank you for letting me waive onto the subcommittee.

Before I begin, Mr. Chair, I have a unanimous consent request. I have here letters of support for the Medicaid Reentry Act from National Association of Counties, the American Medical Association, the American Society of Addiction Medicine, the American Psychiatric Association, Community Resources for Justice, the International Community Corrections Association, the National Commission on Correctional Healthcare, and the Coalition to Stop Opioid Overdose.

I would ask unanimous consent, Mr. Chair, that these letters be entered into the record.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. TONKO. Thank you, Mr. Chair, for holding this important hearing and for including legislation that I have authored, the Medicaid Reentry Act, as a part of this conversation.

And welcome, Ms. Brandt.
My goal with the Medicaid Reentry Act is simple: To reduce overdose deaths among individuals leaving jail or prison and returning to the community. We have heard from earlier hearings in this committee that this is a uniquely vulnerable population with the risk of overdose reaching as high as 129 times that of the general population during the first 2 weeks of post release.

To reiterate, 129 times more likely to die of an overdose during the period in time when an individual is supposed to be getting a second chance at life. That number is astounding and should serve as a moral call to action for our nation.

The good news is that we are not helpless when it comes to solutions. We just need to have the will to see them through. Expanding quality addiction treatment to individuals while incarcerated can dramatically improve health outcomes and reduce overdose deaths and recidivism.

Early reviews of a groundbreaking program in Rhode Island that provides access to all forms of medication-assisted treatment in jails and prisons resulted in a 61 percent decline in overdose deaths post release.

However, widespread implementation of programs like this still face a number of obstacles, not least of which is funding. That is where my legislation enters in, as it would grant States new flexibility to draw Federal Medicaid funds for services provided to existing incarcerated Medicaid beneficiaries in the 30-day period prior to release.

It is just common sense to initiate treatment for incarcerated individuals who are about to be released while they are in a stable, controlled setting rather than the moment they are thrown back out into the often chaotic environment to which they will be returning.

I would like to get some feedback from CMS on ways that the agency can utilize Medicaid as a tool to help this vulnerable population. And so, Ms. Brandt, given this administration's openness to providing States with structured waiver guidance when it comes to outdated payment restrictions in Medicaid when these policies stand in the way of providing beneficiaries quality addiction treatment such as the IMD waiver guidance, I am wondering if CMS has contemplated, or would be open to, promoting limited waiver opportunities around the inmate payment restriction that would similarly promote the agency's goal of reducing overdose deaths and improving care coordination for beneficiaries?

Ms. Brandt. Well, this is an issue actually that we have heard from several stakeholders about. And we have had some very extended conversations internally, and I think we are very much willing to work with you and this committee to look at what the options are, because we understand that this is a big issue. It is one that several States have come to us about, and we would be very much willing to talk with you all about where we could potentially have some flexibilities.

Mr. Tonko. That is wonderful. It is just encouraging that the agency would commit to working with me and other interested stakeholders to explore the possibilities of developing 1115 waiver guidance around the inmate payment restriction issue, so I appreciate that.
One other obstacle that Medicaid beneficiaries leaving correction settings face is that many States terminate rather than suspend Medicaid coverage for incarcerated individuals. When States terminate benefits, this can lead to a lengthy reapplication process and gaps in care at a time when these beneficiaries are most vulnerable.

How can CMS take a leadership role in encouraging States to suspend rather than terminate Medicaid benefits for incarcerated individuals which public health advocates overwhelmingly agree is a best practice?

Ms. BRANDT. That is another issue that has come to our attention and that we have been talking about how we can work with States to perhaps share best practices or better guidance, and look forward to continuing to work with you and the Committee on possible solutions.

Mr. TONKO. Well, whatever we can come up with. I am open to suggestions that your agency can offer us in terms of speaking to the needs of the incarcerated population. The stats are very much a guiding tool.

And we need to develop policy, I believe, that will substantiate the effective use of taxpayer dollars and not have recidivism be part of it, and in a bolder sense, save lives.

So I thank you very much for your kind attention and look forward to working with the agency, with you, in particular.

And, Mr. Chair, I yield back.

Ms. BRANDT. Thank you.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

I am going to recognize myself for questions.

And, Mr. Tonko, I will just point out the—that is an issue that has been worked on in the past, in particular, with individuals who have been charged but then released so they were not actually found guilty.

And they fall into that conundrum that you describe, and they have to go through the reapplication process. And that is really not an agency problem; that is a legislative problem at some point in the distant past governed by offset, and that was an offset that produced a pay-for for some other policy that some other Congress thought was important. But I agree with you, that needs to be remedied, and I have heard from people as well.

Mr. TONKO. All right. Well, I thank you, and I look forward to working with you also, Mr. Chair.

Mr. BURGESS. Let me just ask you—and, Ms. Brandt, I also want to just address the Bilirakis bill on the lock-in. Many, many, many years ago when I was a resident in training an attending physician pointed out to us that one of the highest risk situations in medicine was when two doctors were writing insulin orders or more than one doctor was writing insulin orders.

He said, in fact, the only thing more dangerous than two doctors writing insulin orders is two doctors writing pain med orders. Any way you stop and think about it, in the continuity of care and do people communicate with each other, and you can very quickly get into a high-risk situation.
So I think the lock-in provision is—and some people see that as a restriction of access, but actually, I see that as continuity of care and actually good patient care. And I hope we get a chance to work on that when we do our formal markup.

Mr. Burgess talked about the methadone program. When I was in medical school in the 1970s, I actually spent a month in a methadone clinic. I don’t think it has changed a lot since the 1970s.

Ms. Brandt. Probably not.

Mr. Burgess. And it was hard on people to—you have to go every day. You have to sign in. You have to wait your turn. You have to take your stuff. People have to see you take your stuff. It becomes very, very hard to maintain outside employment because you are spending so much time dealing with the methadone maintenance. I don’t know if there is a way to change that, but I think Dr. Bucshon is onto something. We do need to think about how we are administering that.

We have a GME transparency bill, one that I have been interested in. There was a GAO report that said graduate medical education in 2015, State agencies—State and Federal Medicaid agencies spent over $16 billion for graduate medical education making Medicaid the second largest payer of graduate medical education.

But they also pointed out a lack of transparency. Do you agree that it is important to know how those dollars are being spent and where they are being spent?

Ms. Brandt. Absolutely. Transparency on spending of that is very important.

Mr. Burgess. So you would be in agreement that better transparency going forward with our Medicaid GME dollars makes sense?

Ms. Brandt. All Federal dollars need to be accounted for.

Mr. Burgess. Thank you for that. I certainly agree.

Now, I mentioned in my opening statement, and I think we heard from Mr. Shimkus on the protecting legitimate access to patients who are on—not just cancer patients but people who have chronic pain conditions and are maintained on an opiate and it works well, and, in fact, they are able to maintain outside employment and family relationships. So while they may be habituated they are not addicted, they don’t exhibit addictive behavior, unless, of course, their chain of therapy is broken. So the forced attenuation of therapy or the rapid attenuation of therapy is something that many outside groups are concerned about. I am concerned about that because I think we will drive some of these individuals from their structured maintenance on an opiate for their chronic pain, and they will look for other avenues, and as we all know, those other avenues are heroin and fentanyl, and they are not safe because of the quality control that the criminal element does not participate in, and that is where our deaths come from.

So I want us to be careful about the prescriptions going out, and I think your overuse of work that you are doing is extremely important, and I want to be supportive of that, but I think we also have to recognize there are people where, again, we can’t tighten that bolt down any more without breaking it off, and that would be a bad thing.

Ms. Brandt. No, absolutely. We absolutely concur.
Mr. BURGESS. Just on the issue of the overuse or overutilization, and I appreciate that you are focusing on providers, I appreciate you are focusing on patients, but I have got to tell you, one of the things that has been frustrating for me, the CMS has a lot of data at your disposal, and we have come up against problems where pharmacies in relatively small communities have received way too much product for the patient populations they are treating, and I hope you will use when you talk about overutilization, yes, focus on the doctors who are outliers, focus on the patients who are overconsumers, but really, those fact manufacturers who to whom you are then writing reimbursements, that needs to be part of the equation, as well. And I will just tell you here at the committee level we need help with that. While there are other agencies that have not been as helpful or as forthcoming as they could have been, but CMS does have that data, and we need your help on that.

I have a number of other questions that I am going to submit in writing because I can see Mr. Green is getting nervous, but I do want to thank you for your time today, and I think we have learned a lot today in this hearing, and I know there was some criticism that we were taking on a little bit too much work, but I think it is important, and I don't think there was anything that we heard today that was superfluous or duplicative or anything that actually wasn't important for us to hear. But I thank you for your testimony.

Let's see. We are going to recess until tomorrow morning at 10:15 at which time we will reconvene with our second panel that is going in a room upstairs. Obviously, Ms. Brandt, you are excused, and we appreciate your participation, but without objection, the subcommittee will go into recess and convene tomorrow morning at 10:15 a.m.

[Whereupon, at 6:00 p.m., the subcommittee recessed, to reconvene at 10:15 a.m., Thursday, April 12, 2018.]
COMBATING THE OPIOID CRISIS: IMPROVING THE ABILITY OF MEDICARE AND MEDICAID TO PROVIDE CARE FOR PATIENTS, DAY 2

WEDNESDAY, APRIL 12, 2018

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:16 a.m., in room 2123 Rayburn House Office Building, Hon. Michael Burgess (chairman of the subcommittee) presiding.

Members present: Representatives Burgess, Guthrie, Barton, Shimkus, Latta, Lance, Griffith, Bilirakis, Bucshon, Brooks, Mullin, Hudson, Collins, Carter, Walden (ex officio), Green, Engel, Schakowsky, Butterfield, Matsui, Castor and Kennedy.

Also present: Representatives Kinzinger and Tonko.

Staff present: Daniel Butler, Staff Assistant; Zachary Dareshori, Legislative Clerk, Health; Paul Eddatel, Chief Counsel, Health; Margaret Tucker Fogarty, Staff Assistant; Caleb Graff, Professional Staff Member, Health; Jay Gulshen, Legislative Associate, Health; Ed Kim, Policy Coordinator, Health; Drew McDowell, Executive Assistant; James Paluskiewicz, Professional Staff, Health; Kristen Shatynski, Professional Staff Member, Health; Jennifer Sherman, Press Secretary; Josh Trent, Deputy Chief Health Counsel, Health; Jacquelyn Bolen, Minority Professional Staff; Waverly Gordon, Minority Health Counsel; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Una Lee, Minority Senior Health Counsel; and Samantha Satchell, Minority Policy Analyst.

Mr. BURGESS. The Subcommittee on Health will come back to order.

We want to thank our witnesses for being here and joining us again this morning, taking their time to testify before the subcommittee. Each witness will have an opportunity to give an opening statement followed by questions from members.

This is a continuation of yesterday’s hearing, so we will not go through opening statements from the top of the dais. People heard enough from us yesterday.

So, today we are going to hear from the Honorable Michael Botticelli, the Executive Director, Grayken Center for Addiction, Boston Medical Center; Mr. Toby Douglas, Senior Vice President for Medicaid Solutions, Centene Corporation; Mr. David Guth, CEO of Centerstone; Mr. John Kravitz, the Chief Information Officer from
STATEMENTS OF MICHAEL BOTTICELLI, EXECUTIVE DIRECTOR, GRAYKEN CENTER FOR ADDICTION, BOSTON MEDICAL CENTER; TOBY DOUGLAS, SENIOR VICE PRESIDENT FOR MEDICAID SOLUTIONS, CENTENE CORPORATION; DAVID C. GUTH, JR., CHIEF EXECUTIVE OFFICER, CENTERSTONE; JOHN M. KRAVITZ, CHIEF INFORMATION OFFICER, GEISINGER HEALTH SYSTEM; AND SAM K. SRIVASTAVA, CHIEF EXECUTIVE OFFICER, MAGELLAN HEALTHCARE

STATEMENT OF MICHAEL BOTTICELLI

Mr. BOTTICELLI. Thank you, Chairman Burgess, Ranking Member Green, and members of the committee. I am a privilege and honor to be before you again. And I really want to thank you for your continued leadership on this issue.

I really want to focus today on how we can make progress, continued progress, against the opioid epidemic, and particularly the roles of Medicaid and Medicare in combating this crisis.

As I said and as your introduction, I am the Executive Director of the Grayken Center of Boston Medical Center. We are the largest safety net provider in New England with approximately 42 percent of our patients entering through Medicaid and another 27 percent through Medicare.

For decades, BMC has been a leader in treating substance use disorders. Many BMC programs have been replicated not only across Massachusetts, but nationally. The Grayken Center for Addiction at BMC encompasses over 18 clinical programs for substance use disorders.

I offer my perspective not only as the Executive Director, but with over 25 years’ experience in addiction services, having formerly the honor of serving as the Director of the White House Office of National Drug Control Policy and as the Director of the Massachusetts Department of Public Health. My perspective is also as a person in long-term recovery with over 29 years in recovery.

The experience at BMC and in Massachusetts highlight the critical role that Medicaid plays in addressing the opioid epidemic, and this cannot be overstated. The vast majority of BMC patients receiving treatments for opioid addiction have Medicaid, which is widely available to low-income individuals and families and covers a comprehensive set of benefits that allow our providers at BMC to offer our patients the highest-quality care while also at the same time reducing healthcare costs.

Massachusetts Medicaid covers all three FDA-approved medications, includes naloxone on its formulary, and will soon cover residential rehabilitation services and recovery coaching services, all benefits which are not available in many other state Medicaid programs. Sadly, in America today access to treatment is very much dependent on where a person lives.
Among the many bills under consideration by your committee are new opportunities for Medicaid to play a more substantial role in addressing the opioid epidemic, and here are a few, I think, for action:

All FDA-approved medications for opioid use disorder should be available to patients. Evidence for medication for addiction and treatment is unequivocal. Patients with medication experience significantly improved rates of recovery and, simply put, they don’t die. Yet, many settings do not make all or some of the medications available because of coverage rates and often ideas and philosophy. Only one in five people with opioid use disorders receive medication, while the percentage for youth is even less. In the words of Secretary of Health and Human Services Alex Azar, “Failing to offer medication is like trying to treat an infection without antibiotics.”

And, like any disease, clinicians need as many treatment tools as possible because what works for one person might not work for the next. However, many patients are limited to what medications they can access, if any. Medicare, for example, does not cover outpatient opioid treatment programs, although there are bills, including one by Ranking Member Pallone, to address this. And also, any federally-funded substance use disorder treatment program that bills Medicaid or Medicare should be required to provide medications consistent with approved best practices.

Medicaid and Medicare should make naloxone universally available, preferably without a copay. In 2017, Massachusetts for the first time saw an 8.3 percent drop in annual opioid overdose deaths, the first year it decreased since 2010, but at the same time the number of non-fatal overdoses went up. What it suggests is that broad availability of naloxone in Massachusetts is keeping more people alive while the epidemic is continuing to grow. Just last week, the Surgeon General of the United States urged people to carry naloxone.

Overdose data in Massachusetts also show that individuals recently released from incarceration overdose at 120 times the rate of the general public, most often within the first 2 weeks. This devastating trend emphasizes the need to focus on transitions of care for patients leaving incarceration, as well as treatment during incarceration, as several bills under review by this committee have proposed.

Despite modest decreases in prescribing in the United States over the past few years, prescribing opioids is still a driver of this epidemic. Medicare and Medicaid should mandate that prescribers have continuing medical education around safe prescribing as well as they register and use state-based prescription drug monitoring programs in order to more appropriately treat pain and to diligently track prescribing patterns.

To complement these successful efforts to reduce opioid prescribing, we need to ensure that patients have access to non-pharmacologic pain management strategies such as acupuncture, physical therapy, and cognitive behavior therapy. Unfortunately, only about half of state Medicaid programs specifically support these services.
Access to services continues to be a barrier in many parts of the country. One study showed that only 40 percent of counties in the United States did not have an outpatient treatment program that accepted Medicaid, and CMS could do more to expand its network.

BMC has many treatment programs that have become national models. The foundation of all these programs is the absence of stigma. Without exception, patients who are aided to recovery at BMC credit the lack of judgment they felt in our programs. Medicaid and Medicare can and should do more to get evidence-based addiction treatment to all these patients. Addiction is a disease, and long-term recovery should be the expected outcome of any treatment.

Thank you, and I look forward to your questions.

[The prepared statement of Mr. Botticelli follows:]
Testimony of Michael Botticelli, Executive Director
Grayken Center for Addiction at Boston Medical Center
April 12, 2018

U.S. House of Representatives Committee on Energy and Commerce Health Subcommittee Hearing
Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients

Thank you Chairman Burgess, Ranking Member Green, Chairman Walden, Ranking Member Pallone, and Members of the Health Subcommittee, for the opportunity to speak today about how we can make progress against the opioid epidemic and particularly the roles of Medicaid and Medicare in combating the opioid crisis.

My name is Michael Botticelli. I am the Executive Director of the Grayken Center for Addiction at Boston Medical Center. Boston Medical Center is the largest safety-net provider in New England, with approximately 42% of our patients insured through Medicaid, and another 27% through Medicare.

For decades, Boston Medical Center, or BMC, has been a leader in treating substance use disorders. Many BMC programs have been replicated across Massachusetts and nationally. The Grayken Center for Addiction at BMC, launched last year with a $25 million gift from the Grayken family, encompasses over eighteen clinical programs for substance use disorders and serves as the umbrella for all of BMC’s work in addiction including treatment, training, research, and prevention.

Michael Botticelli, Executive Director
Grayken Center for Addiction at Boston Medical Center
U.S. House Energy & Commerce Committee | 04.12.18
I offer my perspective as the Executive Director of the Grayken Center, as well the insight gained from my over 25-year career in addiction services, formerly having served as the Director of the White House Office of National Drug Control Policy and as Director of the Massachusetts Bureau of Substance Addiction Services. My perspective is also as a person in recovery.

The experience at BMC and in Massachusetts highlight the critical role that Medicaid plays in addressing the opioid epidemic. This cannot be overstated. The vast majority of BMC patients receiving treatment for opioid addiction have Medicaid, which in Massachusetts is widely available to low-income individuals and families and covers a comprehensive set of benefits that allow our providers at BMC to serve our patients most appropriately.

Massachusetts' Medicaid program, known as MassHealth, covers all three FDA-approved medications for opioid use disorder, includes naloxone on its formulary, and covers residential treatment and recovery coach services, all benefits which are not available in many other state Medicaid programs. Sadly, in America today, access to substance use disorder treatment is very much determined by where a person lives.

Among the many bills under consideration by your committee are numerous opportunities for Medicaid to play a more substantial role in addressing the opioid crisis. I would like to briefly discuss a few of the areas that I think are most pressing for action:

- All FDA-approved medications for opioid use disorder should be available to patients. The evidence for medication for addiction treatment (MAT) is unequivocal – patients with medication experience significantly improved rates of recovery. Yet, many settings do not make some or all MAT available because of misunderstanding or lack of training. Only one in five people with opioid

Michael Botticelli, Executive Director
Grayken Center for Addiction at Boston Medical Center
U.S. House Energy & Commerce Committee | 04.12.18
use disorder receive medication, while the percentage for youth is even less.\textsuperscript{1} In the words of Secretary of Health and Human Services Alex Azar: “Failing to offer MAT is like trying to treat an infection without antibiotics.”\textsuperscript{2} And, like any disease, clinicians need as many treatments as possible, since what is right for one person might not be right for the next one. However, many patients are limited as to what medications they can access, if any. Medicare, for example, does not cover outpatient Opioid Treatment Programs, although there are bills, including one by Ranking Member Pallone to address this. Any federally-funded substance use disorder treatment program, and any program that bills Medicaid or Medicare should be required to provide medications consistent with approved best practices.

- Medicaid and Medicare should make naloxone universally available without a co-pay. In 2017, Massachusetts for the first time saw an 8.3% drop in annual opioid overdose deaths, the first year of decrease since 2010. But, at the same time, the number of non-fatal opioid overdoses went up.\textsuperscript{3} What that suggests is that broad availability of naloxone in Massachusetts is keeping more people alive while the epidemic is continuing to grow.

- Overdose data in Massachusetts also shows that individuals recently released from incarceration overdose at 120 times the rate of the general public, most often within the first two weeks

\textsuperscript{2} U.S. Department of Health and Human Services Secretary Alex Azar. Plenary Address to National Governors Association. February 24, 2018.

Michael Botticelli, Executive Director
Grayken Center for Addiction at Boston Medical Center
U.S. House Energy & Commerce Committee | 04.12.18
following release. This devastating trend emphasizes the need to focus on transitions to care for patients leaving incarceration, as well as treatment during incarceration, as several bills under review by this committee have proposed.

- Despite modest decreases in prescribing in the United States over the past few years, prescribing of opioids is still a major driver of this epidemic. Medicaid and Medicare should ensure that prescribers have continuing education around safe prescribing, as well as that they register for and use state-based Prescription Drug Monitoring Databases, in order to more appropriately treat pain and diligently track prescribing patterns to limit forum shopping for opioids.

- To complement the largely successful efforts to reduce opioid prescribing, we need to ensure that patients have access to non-pharmacologic pain management practices, such as acupuncture, physical therapy and cognitive behavioral therapy. Unfortunately, only about a half of state Medicaid programs specifically support or require these services.

- Access to services continues to be a barrier in many parts of the country. A study by Emory University showed that 40% of counties in the United States did not have an outpatient treatment program that accepted Medicaid. CMS can and should use its network adequacy standards for both managed Medicaid and Medicare Advantage plans to ensure sufficient access to treatment services. While provider reimbursement rates through Medicaid are set by states, and each state

---


Michael Botticelli, Executive Director
Grayken Center for Addiction at Boston Medical Center
U.S. House Energy & Commerce Committee | 04.12.18
has its own budget constraints, CMS could do more to illuminate and ameliorate the issue of low provider enrollment in Medicaid, which contributes to a lack of access to SUD and behavioral health treatment in many parts of the country.

BMC has many treatment programs that have become national models. The foundation for all of these programs is the absence of stigma. Without exception, patients who were aided to recovery at BMC credit the lack of judgement they felt in our programs. Medicaid and Medicare can and should do more to get evidence-based addiction treatment to patients. We can all do more to see that people with substance use disorders are welcomed as patients.

Addiction is a disease, and recovery should be the expected outcome of that disease.

Thank you for your time. I look forward to your questions.

Michael Botticelli, Executive Director
Grayken Center for Addiction at Boston Medical Center
U.S. House Energy & Commerce Committee | 04.12.18
Mr. Burgess. We thank you for your testimony.
Mr. Douglas, you are recognized for 5 minutes, please.

STATEMENT OF TOBY DOUGLAS

Mr. Douglas. Mr. Chairman, members of the committee, thank you so much for inviting me to this hearing and your leadership on this issue.

My name is Toby Douglas. I am the Senior Vice President for Medicaid Solutions at Centene Corporation. Centene is the largest Medicaid managed care plan in the country, serving 7.1 million members in 25 different States. I am also the Commissioner on the Medicaid and CHIP Payment and Access Commission, known as MACPAC, and a board member on Medicaid Health Plans of America, a health plan association. And previously, I was a longstanding Medicaid director and behavioral health director in California for the Department of Health Care Services. So, my testimony today is really based on my experience in all these positions as well as my interactions with colleagues in these various states and managed care organizations who are all working together to combat this epidemic.

The epidemic disproportionately affects Medicaid beneficiaries. And a few facts from my written testimony:

- Opioid addiction is estimated to be 10 times as high in Medicaid as in commercial populations.
- Medicaid beneficiaries are prescribed opioids twice as much as individuals in commercial insurance.
- And Medicaid has higher rates of hospitalization and emergency department use for drug poisoning and six times the risk of overdose death.

So, Centene, other Medicaid MCOs, and States are taking a comprehensive approach on prevention, treatment, and recovery. First, we are working with members and providers to prevent addiction from occurring by curbing excessive prescribing patterns. We are preventing overdose. And finally, we are facilitating treatment and recovery in chronic opioid users.

I am going to lay out different areas where Congress can enact policies that really further the ability of Medicaid managed care organizations and states to take a comprehensive approach to prevention and treatment.

First, there needs to be the adoption of best practices and ensuring appropriate prescribing and utilization patterns and increased member and provider education. For example, States and MCOs are taking several actions related to improved formulary management. MCOs and States are removing medications from the formulary that could have a greater potential for misuse. They are limiting early refills and prescription quantities and duration. And finally, some plans, including Centene, are using prescription data to lock in high-risk individuals to one prescriber and/or one pharmacy to fill opioid prescriptions.

Congress should also invest in the development of continuum-of-treatment modalities, including the use of medication-assisted treatment and ASAM criteria. Several States as well as managed care organizations are working to expand the availability of MAT, recognizing there is a significant shortage in this area, and they
are implementing very innovative models that are using the expertise of both a hub, which serves as kind of a center of excellence, and spokes to expand the access to MAT in primary care settings.

Congress should eliminate the Medicaid payment restriction on residential treatment, also known as the IMD restriction in substance use. This is an important component of the overall continuum-of-treatment modalities and should be done within that context of ensuring there are a full continuum of services.

Congress should invest in state adoption of prescription drug monitoring programs and use strategies to ensure all appropriate entities, including both the Medicaid agency systems, managed care entities, and providers have efficient access to PDMP data.

Congress should reform 42 CFR Part 2 to align substance use disorder privacy protections with HIPAA. The lack of alignment between Part 2 and HIPAA really is a challenge for overall primary care and behavioral health integration, and there needs to be the reform to align those privacy protections with HIPAA, but at the same time maintaining the important patient information around substance use from any type of use for criminal, civil, or administrative proceedings.

And finally, the last point I leave you with is that Congress should look to invest in State officials Medicaid leadership as well as ensuring that leadership is investing appropriately in managed care organizations. States continue to face considerable staff turnover in their Medicaid agencies and leadership. And in order to ensure that States have the right leadership to address this epidemic as well as future public health crises, there needs to be an investment in the appropriate resources, so that both the States as well as the MCOs can execute the right policies.

Thank you very much.

[The prepared statement of Mr. Douglas follows:]
Toby Douglas, Senior Vice President, Medicaid Solutions, Centene Corporation
Testimony on Combatting the Opioid Crisis

Good morning. My name is Toby Douglas and I am the Senior Vice President for Medicaid Solutions at Centene Corporation. Centene is the largest Medicaid Managed Care plan in the country serving 7.1 million Medicaid members in 25 states. I am also a Commissioner on the Medicaid and CHIP Payment and Access Commission known as MACPAC, and a board member on the Medicaid Health Plans of America (MHPA) Association. Previously, I was a long standing Medicaid Director and behavioral health official in California serving as the Director of the California Department of Health Care Services. My testimony today is based on my experience in all these positions as well as my interactions with colleagues in these various states and MCOs who are all working together to combat this epidemic.

Centene, other Medicaid MCOs, and states are taking a comprehensive approach of prevention, treatment and recovery, working with members and providers to:

- Prevent addiction from occurring by curbing excessive prescribing patterns,
- Prevent overdose, and
- Facilitate treatment and recovery in chronic opioid users.

In order to address and end the crisis, Congress must enact policies that further state and Medicaid Managed Care Organizations' (MCOs) ability to take a comprehensive approach to prevention and treatment. Congress should invest in initiatives that advance the following:

- The adoption of best practices in ensuring appropriate prescribing and utilization patterns and increased member and provider education
• The development of continuum of treatment modalities including the use of Medicaid Assisted Treatment and ASAM criteria.

• The elimination of the Medicaid payment restriction on residential treatment (IMDs) for substance use in order to ensure there is a full continuum of treatment modalities.

• State adoption of Prescription Drug Monitoring Programs (PDMP) and the use of strategies to ensure all appropriate entities, including Medicaid agencies, health systems, managed care entities, and providers, have efficient access to PDMP data.

• The reform of 42 CFR Part 2 to align SUD privacy protections with HIPAA, while maintaining appropriate protections for patient SUD information, in order to advance physical and behavioral health integrated care approaches.

• Investment in Medicaid state officials and MCOs that can effectively implement the continuum of approaches to addressing this epidemic and future public health epidemics.

Background
The opioid epidemic disproportionately affects Medicaid beneficiaries. For example:

• Medicaid beneficiaries age 18–64 have a higher rate of opioid use disorder than privately insured individuals, comprising about 12 percent of all civilian, non-institutionalized adults in this age group but about one-quarter of those with an opioid use disorder. Opioid addiction is estimated to be 10 times as high in Medicaid as in commercial populations.
• Medicaid beneficiaries are prescribed pain relievers at higher rates than those with other sources of insurance. Medicaid beneficiaries are prescribed opioids at twice as often as individuals with private health insurance.

• They also have a higher risk of overdose and other negative outcomes, from both prescription opioids and illegal opioids such as heroin and illicitly manufactured fentanyl. For example they have higher rates of hospitalization and emergency department use for drug poisoning and six times the risk of overdose death.

• But, it is the case, that Medicaid beneficiaries with an opioid use disorder have higher treatment rates than privately insured adults with the same condition.

State Medicaid programs and Medicaid MCOs are responding to the opioid crisis by preventing addiction from occurring, curbing excessive prescribing patterns, and facilitating treatment and recovery of chronic opioid users.

Preventing Addiction from Occurring by Curbing Excessive Prescribing Practices

The first area I would like to address is the focus on curbing excessive prescribing practices of opioids to reduce overuse and overdose.

• States and MCOs are taking several actions related to improved formulary management: MCOs and states are removing medications from the formulary that could have a greater potential for misuse. They are limiting early refills and prescription quantities and duration. Finally, some plans, including Centene, and states are using prescription data to lock in high-risk individuals to one prescriber for all opioids and/or one pharmacy to fill opioid prescriptions.
At Centene, we are implementing clinical policies to help prevent opioid dependency from ever occurring:

- Limit supplies to seven days for certain types of patients (limit is less than seven days when desired by states)
- Limit daily dosage based upon strength of the opioid
- Require use of immediate-release formulations before extended-release opioids are dispensed. Exceptions to this approach exist as dictated by state specific mandates.
- Exceptions for special populations such as oncology, sickle cell, and palliative care

MCOs and states are also focusing on provider education. For example, one California plan initiated a campaign to educate providers about the risks of high dose prescribing and authorization review requirements. State and MCOs have also offered trainings on evidence based practice guidelines, pain management toolkits, practice design tools.

At Centene, we offer complementary CME detailing best practices in opioid prescribing, addiction treatment and chronic pain management. We have also implemented prescriber profiling as a way of educating providers. This includes prescriber comparisons to their peers, highlighting opioid utilization and dosing profiles, and dangerous drug combinations such as opioid + benzodiazepine.

States are also including Opioid safety as part of their delivery system reform 1115 waivers. Providers, in many states, are participating in projects that aim to
increase evidence based strategies for the treatment of chronic pain, and include increasing multi-modal therapies as the standard of care.

- A new approach that states and MCOs are taking is using Project ECHO, (Extension for Community Healthcare Outcomes), a tele-mentoring approach, to train evidence based models of pain management. This offers remote and/or face-to-face training and technical assistance to increase prescriber skills. In California, the ECHO is being used as a collaborative model for serving underserved American Indian population in order to:
  - Link front-line clinicians to resources and supports to help them to improve care quality and accessibility.
  - Improve Medication Assisted Treatment access for Tribal and Urban Indian communities

- One of the most useful tools available for monitoring prescribing rates across providers and improving appropriate rates is a state's Prescription Drug Monitoring Program (PDMP). Best practices in this areas include:
  - Strategies to ensure all appropriate entities, including Medicaid, health systems, managed care entities, and providers, have access to PDMP data. This could include practices for sharing proactive PDMP reports to these entities, rather than awaiting specific queries or data requests.
  - Common data elements and user-friendly methods for accessing PDMP data.
Strategies to ensure all prescribing providers submit timely data to the POMP. This should address steps states can take to integrate PDMPs into electronic health records (EHR).

- While the PDMP is a terrific resource, it can be a negative time sink for providers. Centene health plans have started supporting our providers by offering, at no cost, front end tools which drastically improve the usability and efficacy of the PDMP sites.

- Another approach that MCO and states are taking to address prescribing patterns is through value based payment models. Specific strategies include enhanced payments for:
  - Appropriate post-surgical or post-emergency department discharge prescribing of opioids and/or opioid addiction treatments; adoption of opioid review committees; use of registries to track chronic pain patients; and physicians attending opioid education trainings.

Through our efforts, Centene has seen a reduction in inappropriate utilization. Since 2015, by all measures, we have seen improvement in our utilization trends, consistent with our stated goals. Results 2015 to 2017 include:

- reduced total # of members using opioids by 50% over 3 years
- # Members utilizing Opioids for >30 days decreased 14-30% year on year
- Total # opioid utilizers decreased 10-15% year on year
- Total # Opioid Prescriptions decreased 15-20% year on year
Member Treatment and Outcomes

The second area I want to address is states and MCOs’ focus on expanding access to treatment for Medicaid beneficiaries in order to improve outcomes.

As context, there are general shortages of providers providing substance use treatment services and even greater shortages of Medicaid participating providers. MACPAC found the following:

- In 2016, 62 percent of specialty SUD facilities report that they accept Medicaid.
- SUD provider participation varies greatly by state; provider participation in Medicaid ranges from 29 percent in California, to 91 percent in Vermont.
- About 60 percent of U.S. counties have at least one outpatient SUD facility that accepts Medicaid, although this rate is lower in many Southern and Midwestern states.
- Counties with a higher percentage of black, rural, or uninsured residents are less likely to have one of these facilities.

Medication Assisted Treatment (MAT).

- There continues to be a shortage of MAT providers. That being the case, several states and MCOs are also working to expand the availability of MATs-- Medication-Assisted Treatment (MAT) recognizing the significant shortages. MAT, as defined by SAMHSA, is the use of medications, in combination with counseling and behavioral therapies, to provide a “whole-patient” approach to the treatment of substance use disorders. These approaches apply the value of integrating MAT into the primary care setting to expand access and leveraging
centers of excellence that can provide expertise and support to providers and patients.

- States, through waivers, and MCOs are training providers and expanding the continuum of MAT. For example in California and Vermont, the states are implementing MAT Expansion Projects. The projects strategically focus on populations with limited MAT access, including rural areas and American Indian and Native Alaskan communities, and increasing statewide access to buprenorphine. The states are implementing a hub and spoke model. The Regional Hubs offer daily support for patients with complex addictions. At the spokes, doctors, nurses, and counselors offer ongoing opioid use disorder treatment fully integrated with general healthcare and wellness services. This framework efficiently deploys opioid use disorder expertise and helps expand access to opioid use disorder treatment to the entire state. These innovative models in CA and VT are spreading to other states via MCOs and state policies.

- Several states have also implemented Medication Units to increase access in rural areas to MAT. This includes, AZ, CA, IA, and KS. These states are finding great success as a Medication unit increases access, offers MAT in the community, and cuts down on patients’ traveling.

ASAM criteria

- Another important component of the continuum of treatment solutions is ASAM including the many components of medication-assisted treatment (MAT).

MACPAC has found that there is considerable variation in available ASAM services across states, since many are optional under the Medicaid statute.
On average, state Medicaid programs cover six of the nine services described by ASAM.

Nearly half of states provide anywhere from four to seven services.

Seven states only cover up to three services.

Only 10 states offer the full continuum of care.

- Congress should enact policies that further state and MCO adoption of the continuum of ASAM treatment services.

One of the ASAM treatment policies that Congress must address relates to residential treatment and the IMD exclusion. Many states and MCOs point to the IMD exclusion as a barrier to treatment. And the 15-day limit for managed care IMD in lieu of services has been operationally challenging. While 21 states have sought Section 1115 waivers to provide residential SUD treatment in IMDs, the waiver process is cumbersome and not the long run solution. Congress should act to eliminate the exclusion of Medicaid payment for beneficiaries residing in a residential treatment setting.

And, based on discussions with key experts, the elimination of the IMD exclusion should be tied to evidence regarding whether individuals with substance use disorders experience greater treatment gains in residential treatment settings than in outpatient treatment, or if specific lengths of stay are associated with certain therapeutic gains. As such, it is important to emphasize that the elimination of the IMD rule must be part of a comprehensive solution that
encourages states and MCOs to provide a continuum of ASAM treatment modalities.

Primary care and behavioral health integration.

- MCO and states are taking approaches to develop team based physical and behavioral health approaches to address treatment. For example, Centene is using analytic tools, coupled with team based, behavioral health treatment capabilities, to identify and treat members with hidden, previously untreated, impactable behavioral health disorders (anxiety, depression, trauma) which are often the root cause of polysubstance use/abuse.

Reform of 42 CFR Part 2

- Promoting effective and timely sharing of data across physical health and SUD care teams requires statutory changes or reform of 42 CFR Part 2. Part 2 statute and SAMHSA regulations create more stringent privacy protections for patient SUD data than for other sensitive health data protected by modern HIPAA rules.

- The lack of alignment between Part 2 and HIPAA creates challenges across the healthcare system, from state Medicaid agencies to managed care plans and down to individual provider practices. Congress should prioritize reform of 42 CFR Part 2 to align SUD privacy protections with HIPAA, while maintaining appropriate protections for patient SUD information – namely prohibiting such information from being used to initiate or substantiate criminal, civil, or administrative proceedings.
• In doing so, individuals with SUD can realize the benefits of integrated care approaches without fear of adverse impacts on their families and livelihoods for seeking treatment.

I leave you with one final point. States continue to face considerable staff turnover in their Medicaid agencies. In order to ensure that states have the right leadership to address the epidemic and invest the appropriate resources in MCOs to execute policies on behalf of the states, Congress should implement policies that support state recruitment and retention of strong Medicaid executive leadership. A stable and strong state leadership team will be best equipped to respond to the opioid crisis and future public health crises.
STATEMENT OF DAVID C. GUTH, JR.

Mr. GUTH. Thank you, Mr. Chairman, and my thanks to the Committee for your comprehensive work on this epidemic that is ravaging our country. I want to say a special thank you to Representatives from our service area: Congressmen Guthrie, Bucshon, Brooks, Bilirakis, Shimkus, and Blackburn.

And I am honored to be here today not only as the voice of my colleagues at Centerstone, but really on behalf of the nearly 180,000 people at Centerstone that we serve each year.

So, a little bit about Centerstone. We are celebrating our 63rd year of service as a not-for-profit behavioral health organization, and we provide a comprehensive set of services throughout our footprint of Florida, Indiana, Illinois, Kentucky, and Tennessee. We also serve individuals beyond that footprint, principally through our network of specialized therapists providing service to men and women who serve this country in uniform and their loved ones.

Do we really know how to treat opioid addiction? Do we have proven treatments and recovery strategies to move people out of opiate dependency and into recovery? And the simple answer is, yes, we do. But, unfortunately, far too few people have access to comprehensive evidence-based treatment they need.

There are many reasons why this is the case. A major challenge is a lack of providers. We know that there are more than 30 million Americans, living principally in rural communities, who have no access to treatment whatsoever for their condition, let alone comprehensive evidence-based ones.

Another challenge is that in places where treatment options do exist, many available are woefully inadequate. This stems from the fact that fundamentally we do not as a Nation treat opioid use disorder like the chronic disease that it is. And despite the body of evidence, there are no standards of quality care that providers are held to and no consistent protocols for care. This is a dramatic departure from our treatment of other severe health conditions. The experience for someone seeking treatment for substance use, opioid use in this case, disorder is entirely different than that of a heart patient. If an opiate-addicted person visits five different treatment centers, they might well receive five different treatment protocols. What happens is where they present makes a greater difference in terms of what they are offered than how they present, and we must change that.

There is no set path a provider is encouraged to follow when no one is holding that provider accountable for administering an evidence-based protocol or for ensuring that the patient has a positive outcome. It is often the case that other healthcare providers that may be engaged in that patient’s care around other disorders may not even know that their patient is in treatment for their addiction, let alone have access to the full medical record.

In short, fragmented care and absence of quality standards and immense workforce shortages result in delayed access or no access at all to lifesaving care. This is what we have to change.
Opioid use disorder is similar to heart disease in that there is no one magic bullet for treating it. You cannot take a pill so that it will disappear. It is a condition based on the patient's presentation and severity that requires a combination of treatments—medication, therapy, follow-up care—and a condition that may require significant changes in a person's life to overcome. Fortunately, there is data that shows what can work. This is why we support treatment initiatives that approach addiction as a chronic and relapsing disease with emphasis on building a patient's recovery.

However, in order to ensure positive outcomes, we also need to modernize our health IT infrastructure and optimize our workforce. I realize that saying all of this is the solution is much easier said than done. Getting people in need the right care close to home means dealing with standards of care, infrastructure issues, knowledge gaps, technology gaps, and serious shortages among addiction treatment providers.

Fortunately, many of the bills that have been introduced before this committee address these issues. Centerstone supports all legislative action that eliminates barriers to care and, instead, creates and rewards providers for following quality standards, so that when a patient walks through the door of any treatment provider, they have the best chance of receiving the right services that will help them on the path to recovery.

We support advances in technology-enabled solutions such as prescription drug monitoring programs and incentives to modernize behavioral health IT. Investments in the health IT backbone of our behavioral health system are a critical tool in improving care.

As our chief medical officer often says, the most costly care that we provide across this nation is care that does not work. We must address that.

I am going to leave you with a quick story of a gentleman that received his care at Centerstone. His name is Keith Farah. He is now a peer support specialist at Centerstone. He struggled with severe and persistent addiction for years. As he put it, “I had given everyone who loved me more than enough reasons to give up. I was homeless, unemployed, and a convicted felon. Even worse, I was hopeless and terrified of living life sober.” He made the decision to enter into Centerstone’s Addiction Recovery Center, and today he celebrates a life he never dreamed of.

So, I know I am out of time here. I just want to say, on behalf of all of the teams that provide services to our communities, on behalf of the board members that volunteer their time and energies to advance this, I want to thank you for your attention to this and the opportunity to provide commentary. And I look forward to your questions. Thank you, Mr. Chairman.

[The prepared statement of Mr. Guth follows:]
STATEMENT OF DAVID C. GUTH, JR.
CHIEF EXECUTIVE OFFICER
CENTERSTONE AMERICA

BEFORE THE
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES

“COMBATTING THE OPIOID CRISIS: IMPROVING THE ABILITY OF MEDICARE AND MEDICAID TO PROVIDE CARE FOR PATIENTS”

APRIL 12, 2018
I. ESTABLISH A STANDARD OF CARE FOR COMPREHENSIVE ADDICTION TREATMENT

Today, there is no set path a provider is encouraged to follow in treating a patient with an opioid use disorder (OUD) or a substance use disorder (SUD). No one is holding that provider accountable for administering evidence-based protocols, or for ensuring that patients achieve positive outcomes. Standards of quality care have not been widely accepted, so no consistent protocols for care currently exist across our Nation. Therefore, we must establish a standard of care for comprehensive addiction treatment so that individuals across the country may have access to the same standard of care, no matter where or when they seek help.

To this end, Centerstone recommends developing a “gold standard” certification that would establish “clinical excellence hubs” as preferred providers for courts, corrections, emergency departments, etc. for trusted patient referrals. These clinical excellence hubs would need to demonstrate use of evidence-based interventions, linkages to a full continuum of care, including services geared towards increasing patients’ recovery capital, and report on patient outcomes. As an incentive, excellence hubs could be eligible for federal funds upon a showing of successful implementation and reporting on well-vetted and defined treat-to-target metrics.

The Comprehensive Opioid Recovery Centers Act (H.R.5327) is an appropriate legislative vehicle to bring about this shift. The bill would authorize SAMHSA to award 3-5 year competitive grants to eligible entities that met certain quality and procedural standards in providing SUD services. OUD, SUD, and other behavioral health conditions are chronic diseases. 6 out of 10 people with an SUD also suffer from another form of mental illness. People with OUD or SUD tend to also suffer from other physical ailments. Due to these comorbidities, health homes are particularly effective in treating patients with behavioral health disorders because they provide whole-person care. Centerstone has developed and implemented its very own patient centered health homes in Indiana, Illinois, Kentucky, and Tennessee to provide integrated, patient-centered care to consumers with co-occurring, complex conditions. Through our health homes, Centerstone has achieved

1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2211734/
2 https://www.chcs.org/media/HH-IRC-Health-Homes-for-Opioid-Dependency.pdf
demonstrable outcomes within our patient population: 84% of our patients with high blood pressure saw lower readings after 12 months; recipients also reported a 56% improvement in anxiety levels and a 53% improvement in general health. Participants awarded this model a 98% approval rating. Health homes can improve patient outcomes at a significant cost savings.

The federal government can help spur innovation in whole-person, integrated care via the Medicaid Incentives for Health Homes to Treat Substance Use Disorder (H.R.) bill.

Though health homes are effective in treating complex patient populations efficiently, providers across the country are coming up with diverse ways to treat their own patient populations. Providers should be afforded the latitude to develop and test new care models that put patients first. The federal government should incentivize value-based, integrated addiction treatment models. At Centerstone, for example, we are developing a “Per Member Per Month” (PMPM) model for outpatient treatment within our recovery oriented medication assisted treatment (RO-MAT) framework. This model requires treating the patient holistically, building their recovery capital, and for the majority of our patients, working toward a discontinuation protocol from medication assisted treatment.

The Alternative Payment Model for Treating Substance Use Disorder (H.R.) would allow providers the requisite flexibility in designing and implementing whole-person treatment models without the reimbursement barriers of our predominantly fee-for-service system.

As it currently stands, fee-for-service contracts infrequently reimburse for key services within the continuum of care. As the evidence-base evolves, fee-for-service contracts are slow to keep up with research findings on best practices. For example, the use of peers in emergency rooms have been shown to be an effective way to engage patients during a narrow window of opportunity when they may desire to start pursuing treatment. Research indicates that use of peer supports leads to significant decreases in substance use, symptom improvement, and better management of patients’ own conditions. These outcomes are largely achieved by a sense of trust.

1 https://centerstone.org/our-resources/health-homes/what-is-a-health-home/
2 https://centerstone.org/blog/research-studies/centerstone-integrated-addictions-care-and-care-3-years
supportive accountability, and by the non-judgmental attitude peers exhibit towards patients. As a result of the opioid epidemic, Centerstone has seen a dramatic uptick in hospital requests for our mobile crisis services. Mobile crisis services entail a licensed counselor, case manager, or peer specialist travelling to an emergency department where an individual typically presents after an overdose, to engage an individual in their recovery. Staff time in transit to and from an emergency department, staff mileage, as well as emergency department engagement services, however, are not typically adjusted for in our reimbursement rates. Fortunately, Centerstone staff in several of our footprint states have recently been able to provide these services thanks to 21st Century Cures STR grants.

This represents a particular example of why the Alternative Payment Model for Treating Substance Use Disorder (H.R. ) bill is important to behavioral health providers in offering up-to-date evidence-based care. Additionally, the Preventing Overdoses While in Emergency Rooms Act of 2018 (POWER Act) (H.R.876), which would authorize the Secretary of HHS to award grants to eligible health care sites to deploy coordinated care to patients presenting with SUD in emergency departments could enable providers to utilize peers in a meaningful way within the greater continuum of care.

As a Nation, we need to take steps to ensure that evidence-based treatments are available in all communities, and that we are not inadvertently supporting sub-standard care. The federal government can incentivize high standards in care delivery by tying federal dollars to evidence-based services only. Specifically, reimbursement protocols should reward trusted providers who work systematically to improve patient outcomes. Lawmakers should take steps to ensure that federal dollars are not misused by inadvertently flowing federal funds to “MAT pill mills,” which offer suboptimal care to patients and may even exacerbate the problem dedicated providers are aiming to fix. Furthermore, as more rogue actors move into this space, quality providers are experiencing increasing levels of denials while administering sound, evidence-based addiction treatments to individuals. Medical staff in several of our accredited addiction treatment facilities across several states are increasingly forced to navigate tremendous administrative hurdles; for instance, they report record levels

of Medicaid and commercial insurance denials and prior authorizations for OUD treatment and, in some cases, report being asked to submit upwards of 70 pages of clinical documentation for treatment of a single patient. This disconnect between quality and reimbursement has fostered an environment in which predatory MAT prescribers thrive and quality providers — those committed to offering a full continuum of care mirrored after nationally recognized clinical models — are backed into a tight financial corner. This reality causes millions of dollars to be spent on claims management instead of patient care. To safeguard against this, Centerstone recommends that federal dollars only flow to providers of evidence-based services. Providers serving OUD and SUD populations should demonstrate the ability to offer a comprehensive continuum of evidence-based services before receiving taxpayer dollars. Payment models should be linked to standardized outcomes and designed to incentivize integrated, whole-person care models for addictions treatment, particularly for patients with co-occurring and complex conditions.

The Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018 (RESULTS Act) (H.R.5272) is a straightforward mandate to tie federal dollars to evidence-based services only. To ensure Congress and the public is properly and timely informed on services that prove either effective or ineffective, the bill to Require state Medicaid programs to report on the 10 behavioral health measures that are included in CMS' 2018 Core Set of Adult Health Care Quality Measures for Medicaid (H.R.____) as well as the Improving Medicaid Timeliness Act (H.R.____) are legislative tools that could bring about the more consistent gathering, reporting, and analyzing of critically important behavioral healthcare data.

II. OPTIMIZE THE BEHAVIORAL HEALTH WORKFORCE

We know that there are more than 30 million people living in rural communities in which no treatment options of any kind exist today — let alone comprehensive, evidence-based ones. By the year 2025, workforce projections estimate that there will be a workforce shortage in the fields of substance abuse and mental health.
treatment of approximately 250,000 providers across all disciplines. In 2013, all nine types of behavioral health practitioners had shortages. Currently, six provider types have estimated shortages of more than 10,000 FTEs, including psychiatrists, clinical and counseling psychologists, substance abuse and behavioral disorder counselors, mental health and substance abuse social workers, and mental health counselors. With immense gaps in treatment access and fatal opioid-related overdoses at an all-time high, it is imperative that we take steps to address from multiple angles.

Licensed marriage and family therapists (LMFTs) and licensed mental health counselors (LMHCs) hold licensures on par with license clinical social workers (LCSWs), yet their exclusion under Medicare is somewhat arbitrary. As a result of this workforce gap, providers face significant barriers when recruiting within the limited allowable provider types, particularly in rural areas. This shortage in eligible workers also results in wait times that can be 4 times higher amongst Medicare patients, as opposed to under Medicaid, which permits for reimbursement of LMHC and LMFT services in some of our sites.

The Mental Health Access Improvement Act of 2017 (H.R.3032) would allow LMFT and LMHC services to be reimbursed by Medicare. This bill would enable faster access to care for Medicare and some commercial patients, as well as optimize our current workforce to operate at the top of its licensure.

Peer support services are currently accepted as evidence-based practices by both CMS and SAMHSA. These services are currently reimbursable under Medicaid. Therefore, certified peer supports should gain the ability to serve SUD patients under Medicare. Though peers serve as a vital “connective tissue” in the continuum of care, certified peer supports should be utilized in the context of a broader continuum of care, managed by a licensed addiction or mental health specialist to ensure patients receive appropriate evidence-based treatment planning, treatment intensity, services, and receive treatment for the proper length of time. The recognition of peer support specialists in Medicare will likely spur commercial plans to advance access to this type of provider in the future.

The bill to support the peer support specialist workforce (H.R. ) may serve as an appropriate legislative vehicle to bring about this goal.

11) https://www.ca.gov/vitalgroup/paid-workers/
According to a 2018 State of Workforce Management Survey, the top priority for behavioral health not-for-profit providers is recruiting and retaining top talent, with the primary challenges being (a) an inability to offer competitive pay and benefits, and (b) a lack of qualified applicants. The Substance Use Disorder Workforce Loan Repayment Act of 2018 (H.R.5102) would function to directly alleviate the supply problem because it would provide a loan-repayment incentive to individuals choosing to practice in workforce shortage areas. The bill would authorize the HRSA to pay up to $250,000 of an individual’s program loan obligations for those who complete a period of service in an SUD treatment job in a mental health professional shortage area or in a county particularly badly impacted by the opioid epidemic.

Telehealth has a dual purpose of both connecting patients to lifesaving care that may have previously been beyond their physical reach, and also of reducing the effects of a behavioral health workforce shortage. Lawmakers should fully optimize the value of our behavioral health workforce by affording them a wider latitude to treat SUD patients via telemedicine. A Medicare provider can only be reimbursed for telehealth services if the patient is located at a specified “originating site” – a restriction that clearly limits the purpose of telehealth. The Access to Telehealth Services for Opioid Use Disorders Act (H.R. ) would allow HHS to waive certain telehealth requirements for eligible practitioners providing SUD services to Medicare patients diagnosed with an SUD. By essentially waiving the “originating site” restriction for certain Medicare patients, this bill will expand the number of providers that are able to treat the elderly in their own home, and will significantly improve access to addiction treatment services to these patients.

The Ryan Haight Act makes it illegal for a practitioner to issue a prescription for a controlled substance via telemedicine without having first conducted at least one in-person medical evaluation of the patient. There are currently three FDA-approved medications for the treatment of opioid use disorder: naltrexone, methadone, and buprenorphine. These medications are recognized by the National Institute of Drug Abuse, American Society of Addiction Medicine, and the Substance Abuse and Mental Health Services Administration as essential tools.

12 https://www.dhhs.gov/about/laboratory/research/laboratory-research/fda-approved-drugs
date Accessed May 20, 2018
in responding to the opioid epidemic. Under current law, non-SAMHSA practitioners who wish to prescribe Suboxone (brand name for buprenorphine) to a patient they are treating via telemedicine would need to first perform an in-person evaluation, had they not already done so. Following this regulatory mandate for buprenorphine prescribing, however, may be overly burdensome in many circumstances, and may prevent many patients from receiving life-saving treatment. Thus, we recommend that licensed community mental health and addiction providers, who follow nationally recognized models of treatment, gain access to a special registration process so that they may register with the DEA to prescribe substances now commonly embraced in MAT practice, without a prior in-person patient/provider encounter.

To bring about this end, we support the Special Registration for Telemedicine Clarification Act of 2018 (H.R.), which calls for the promulgation of interim final regulations on the topic of special registration for health care providers to prescribe controlled substances via telemedicine without the initial in-person contact. Additionally, the Improving Access to Remote Behavioral Health Treatment Act of 2018 (H.R.), which mandates final regulations on the topic of community mental health centers registering with the DEA to prescribe controlled substances via telemedicine, is an important step in getting “all hands on deck” to alleviate the supply shortage and improve access to care.

III. MODERNIZE OUR NATION’S BEHAVIORAL HEALTH INFRASTRUCTURE

Behavioral health providers will be slow to tackle the opioid epidemic without a significant improvement and modernization in our information technologies. Investments in the health IT backbone of our behavioral health care delivery system are a critical tool in improving care and moving our industry from one that is siloed and inefficient to one that is integrated and provides whole-person care.
The Confidentiality of Substance Use Disorder Patient Records rule – 42 CFR Part 2 – is a stringent rule that prevents providers from systematically treating OUD/SUD patients in reliance on complete and accurate patient histories. In moving towards more robust integrated care models where every member of a patient’s treatment team needs to understand a patient’s full medical/SUD history, Part 2 stands as a hindrance to whole-person care. Part 2 has never been applied universally: only federally assisted alcohol and drug abuse programs providing SUD diagnosis or treatment are subject to the stringent Confidentiality of Substance Use Disorder Patient Records rule – 42 CFR Part 2.\(^\text{15}\)\(^\text{18}\) Part 2 prevents these federally funded providers from accessing a patient’s full substance use history without the patient’s prior written consent. In contrast, non-federally assisted providers throughout the country are governed only by HIPAA. Re-disclosures of protected patient information occasionally cited by patient privacy groups are currently illegal. Thus, improper re-disclosures of information are not a reflection of a weak privacy law, but rather, are a reflection of improper on-the-ground practice, which can be challenged in court. Thus, we urge lawmakers to align 42 CFR Part 2 with HIPAA for the purposes of treatment, payment, and health care operations. Common sense legislation like The Overdose and Patient Safety Act (H.R. 3545), would align Part 2 with HIPAA for the purposes of treatment, payment, and health care operations, and strengthen protections against the use of substance use disorder records in criminal proceedings. The Amendment in the Nature of a Substitute to H.R. 3545 has strengthened language regarding penalties for improper re-disclosures. Centerstone supports that added language, but stresses the need for the statutory alignment to be for purposes of treatment, payment, and healthcare operations, and not solely for the purposes of treatment (as in the AINS).

"Limited data exists to track the opioid crisis and identify weaknesses in current responses (e.g. prescribing practices, treatment availability, individuals at risk), but is held in different databases across a multitude of public and private organizations, and significant proportion is not in real-time."\(^{19}\) A national standard for an interoperable, real time prescription drug monitoring program (PDMP) would address these challenges, and would also help providers identify patients who may be at risk for opioid abuse. Technology and standards are
available today across the country that have the ability to inform, standardize, and enhance the information that is available to clinicians at the points of prescribing and dispensing. PDMPs are crucial sources of data for providers.

Regarding interoperability, PDMPs are profoundly different across state lines and in how they are integrated with health IT in each state. **Improving interoperability of PDMPs will allow providers the ability to check patient prescription histories, alert providers to individuals with patterns indicative of misuse, and prevent patient doctor shopping.**

Regarding the timeliness of information transferred, PDMPs currently run on batched information, only being utilized retroactively to track dispensing data for patients. **If PDMPs ran real-time, many prescriptions would not be dispensed; others would never be written.** Checking a real-time PDMP would allow a clinician to not only stop the medication from potentially falling into the hands of an individual exhibiting addictive behaviors, but to address those potential harmful behaviors and help refer to treatment or alternate therapies, something we term a “warm hand-off.”

Currently, in order to check a state’s PDMP, most clinicians are required to log in to a system separate from their normal medical record software (EHR, prescription dispensing system, etc.), query the site, analyze the report results, and then return to their original workflow. **To facilitate real-time access to data and reduce prescriber burden, patient data must be accessible within workflow.**

Finally, we suggest capitalizing on PDMP technologies and leveraging them to be more than simply a data-gathering tool; any **national PDMP standards should link patients to treatment by automating, or incenting, a Screening, Brief Intervention and Referral to Treatment (SBIRT) function** in order to help providers catch patients who may otherwise fall through the cracks. SBIRT is an evidence-based preventative measure designed to move patients, who may need help, into treatment. SBIRT uses tools like Motivational Interviewing to identify those at risk for developing an SUD and help those who already have an SUD. Generally, SBIRT increases an individual’s chance for early intervention and access to treatment. By linking SBIRT functions to a PDMP system, we would not only be able to “flag” at-risk patients, but also screen and refer them to appropriate treatments.
There are several legislative proposals on the topic of PDMPs: the Prescription Drug Monitoring Act of 2017 (H.R. 1854), the bill to enhance and improve state-run prescription drug monitoring programs (H.R. ____), and the Medicaid PARTNERSHIP Act (H.R.). Each of these proposals has strengths and weaknesses, but none address all of the core challenges we see in the current system nationwide: lack of interoperability among states or with other health IT, data latency, data not within workflow for providers and dispensers, and unable to trigger SBIRT. We recommend that the final PDMP proposal address each of these challenges.

Unfortunately, there will be little or no data sharing among Medicare, Medicaid and state initiatives, such as PDMPs, unless robust electronic health records (EHRs) are universally adopted and used by substance use and mental health providers. EHRs and related connectivity services are increasingly the means by which data is shared. Community Mental Health Centers (CMHCs) like Centerstone know that the optimal way to treat mental illness and substance use disorders is to couple those behavioral health services with primary care, which, in effect, treats the whole person with comprehensive, multidisciplinary services systematically combined to provide the best outcomes. Information technology provides the vital link in this process by facilitating the exchange of authorized health data between care providers. Providing technology-enabled coordinated, integrated care to OUD/SUD patients can enhance outcomes, improve efficiency, and lower costs across the entire healthcare spectrum. Thus, value-based care requires building an expanding set of technological capabilities, such as interoperable EHRs.

Unlike the majority of the health care system, however, substance use providers were not eligible for financial incentives to bolster their EHRs under the HITECH Act. Though behavioral health providers know the short and long-term benefits of utilizing robust technologies, these providers often operate on very narrow profit margins, thereby making up-front investments in robust EHR technologies extremely challenging, or even impossible. Thus, the bill to amend title XI of the Social Security Act to promote testing of incentive payments

---

for behavioral health providers for adoption and use of certified electronic health record technology (H.R. 3331) would authorize CMMI to distribute incentive payments to behavioral health providers, such as psychiatric hospitals, Community Mental Health Centers, psychologists, social workers, and addiction treatment providers, for adopting and using certified EHR technology to improve care coordination.

On behalf of all of us at Centerstone, we Thank You for your attention to the opioid crisis. We look forward to working closely with you to find ways the federal government can help us save and improve the lives of Americans across our country.

Sincerely,

David C. Guth, Jr.
CEO, Centerstone America
Mr. Burgess. Thank you for your testimony.

Mr. Kravitz, you are recognized for 5 minutes, please, for an opening statement.

STATEMENT OF JOHN M. KRAVITZ

Mr. Kravitz. Good morning, Chairman Burgess and members of the Health Subcommittee of the House Energy and Commerce Committee.

My name is John Kravitz. I am the Senior Vice President and Chief Information Officer of Geisinger Health System. I want to thank the Committee for holding this hearing on a key issue facing the Nation, one that Geisinger and healthcare providers are addressing. And that is to combat the national opioid crisis.

Geisinger has employed a multifaceted approach to curb the use of opioids, such as utilizing information technology and electronic prescribing, implementing best practices for pain management, embedding pharmacists in our primary care clinics, establishing drug take-back programs, and others. Collectively, these initiatives have significantly reduced the use of opioids for our patients and members and increased quality of care and outcomes by reducing costs.

With our history as an innovator of health IT and care delivery models, we saw opportunity to reverse these trends. Our physician leadership proposed, by limiting or eliminating the prescribing of opioids in the clinical setting, Geisinger could minimize and prevent patients' exposure to these drugs and consequent risk of developing an addiction that could lead to overdose or death.

Reducing opioid addictions could also ease the burden on healthcare providers. In an analysis of 942 of our patients who are also insured by our organization, overdoses were found in opioids with steep increases in acute care cost as well as emergency department services prior to an overdose.

We developed and initiated several approaches that focus on changing physician practice patterns to reduce the prescribing of opioids, including creating a provider dashboard which is linked to our electronic health record to identify current practice patterns for our providers. We found that providers greatly vary in their approaches to prescribing opioids, and the smallest number of providers are typically the ones that prescribe the largest number of opioid prescriptions. When we had this information, we could target the outliers and provide them with the best practice for pain management.

This includes the pain management program for surgical patients where we counsel patients and their families to expect some manageable level of pain for minor procedures and the use of non-addictive alternatives for managing pain. In cases where our physicians believe an opioid prescription is in the best interest, they are highly encouraged to order smaller quantities, seven days or less.

While I am not a clinician, I am pleased that information technology plays an important role in Geisinger's approach to decreasing use of opioids. There are several concerns, for example, with prescribing opioids through a paper process, including drug diversion, prescription forgery, provider DEA numbers being exposed to the public, and doctor shopping to obtain opioids. We have implemented the following initiatives to help alleviate these concerns:
We are tracking documentation on our electronic health records and dashboards that show providers reviewed the mandatory PDMP programs, documenting findings in the patient’s medical records. We are integrating specifically from a pain app that we have developed on a mobile device that measures physical activity, patient-reported pain, and other metrics into the dashboard and feeding into the medical record. And finally, we have deployed an EPCS program. Back in August 23rd of 2017 and through February of 2018, 74 percent of our providers of controlled medications have been prescribed through the EPCS system. All 126 of our clinics are on this process and having great success.

Our results are encouraging. We have reduced opioid prescriptions by half since launching these initiatives two years ago, and monthly average of opioids, we had been prescribing about 60,000 per month; we are down to 31,000 and that number is dropping.

Additional information on cost savings we realized from implementing the electronic prescribing of controlled substances were reducing by 50 percent the number of patient calls to determine if their paper prescriptions had been ready for them. So, we initially had about 660,000 calls per year from our patients for opioid prescriptions. We have reduced that to close to 330,000.

With the number of diversions decreasing, we are able to decrease the size of our diversion staff to monitor and manage those, and provider time, most importantly, to write an opioid prescription with the EPCS system had gone from a time period of 3 minutes to write a paper prescription to 30 seconds with the EPCS system. Nursing time as well for opioid scripts went from 5 minutes to 2 minutes. These cost savings accrued approximately $1 million in savings in time and hard-dollar savings for our organization.

Although the dashboard may be unique to Geisinger, we believe other health systems and hospitals can generate similar reports for opioid prescribing, and their electronic health records and clinical entry systems can do the same work that we have been doing. The initiatives rolled out by Geisinger are broadly applicable to other healthcare systems across the country, and we encourage others to apply these strategies to their organizations. To succeed, organizations need the support of their physician leadership. We are a physician-led organization. This is a process change that has to occur with physicians; it is not technology. Technology is told to support this.

Everything we do at Geisinger is about caring. Part of our caring means that we believe that our members and our patients deserve the best care possible and the best outcomes. That is why we emphasize and support evidence-based medicine and care delivery, including e-prescribing of opioids. The evidence and results are clear. E-prescribing has reduced forgery and diversion while helping patients avoid all unnecessary exposure to addiction and harm.

So, I would like to close out with a couple of concluding comments. We have found that the electronic prescribing process has led to quality improvements in care while reducing opioid prescriptions, drug diversions, prescription forgery, and reducing total cost of care.

Thank you again for the opportunity to provide these thoughts on this critical issue, and I entertain any questions.
Good morning, Mr. Chairman and members of the Health Subcommittee of the House Energy and Commerce Committee. My name is John Kravitz, and I am Geisinger’s Chief Information Officer. I want to thank the Committee for holding this hearing on a key health issue facing our nation – one that Geisinger along with other health care providers is addressing to combat the national opioid crisis.

Opioid addiction and related deaths have skyrocketed in the United States. The death rate from opioid overdoses was five times higher in 2016 than in 1999, and my home state of Pennsylvania has the fourth highest death rate per 100,000 population. Many of the counties with the highest death rates are served by Geisinger.

Geisinger is one of the nation’s largest integrated health services organizations serving a population of more than 3 million residents throughout central, south-central and northeast Pennsylvania, and in southern New Jersey at AtlantiCare, a member of Geisinger. Our physician-led system includes approximately 32,000 employees, nearly 1,800 employed physicians, 13 hospital campuses, 2 research centers, a school of medicine, and a 580,000-member health plan.

[The prepared statement of Mr. Kravitz follows:]
plan. Geisinger has repeatedly garnered national accolades for our innovative care delivery models, integration, quality and service.

Geisinger has employed a multi-faceted approach to curb the use of opioids, such as utilizing information technology and electronic prescribing (e-prescribing), implementing best practices for pain management, embedding pharmacists in our primary care clinics, establishing drug take-back programs, and others. Collectively, these initiatives have significantly reduced the use of opioids by our patients and members, and increased quality care outcomes while reducing costs. Today my testimony will focus on our approach and experience with e-prescribing of opioids and the integration of information technology, and detail how this effort has translated to the reduction of opioid prescriptions and the costs of care.

With our history as an innovator in the use of electronic health records and care delivery models, we saw an opportunity to reverse these trends. Our physician leadership proposed that by limiting or eliminating the prescribing of opioids in the clinical setting, Geisinger could minimize or prevent a patient’s exposure to the drugs and the consequent risk of developing an addiction that could lead to overdose and death. Reducing opioid addictions could also ease the burden on health care providers. An analysis of 942 Geisinger patients who overdosed on opioids found a steep increase in the use of acute care – especially expensive emergency department services – prior to an overdose.
We developed and initiated several approaches that focus on changing physician practice patterns to reduce the prescribing of opioids — including creating a provider dashboard linked to our electronic health record to identify current practice patterns among our providers. We found that our providers varied greatly in their approaches to prescribing opioids, with a relatively small number being heavy prescribers. We then used this information to first target the outliers and provide them with best practices for pain management.

This includes a pain management program for surgical patients where we counsel patients and their families to expect some manageable pain after relatively minor procedures — and the use of non-addictive alternatives for managing pain. In cases where our physicians believe an opioid prescription is in the best interest of the patient, our physicians are encouraged to use the smallest effective dosage prescribed for seven days or less.

For chronic pain patients and those patients at risk of addiction, Geisinger recommends rehabilitation, exercise, cognitive behavioral therapies, acupuncture, yoga and tai chi rather than opioids. This approach is supported by a study published by two Geisinger palliative care physicians that determined opioid therapy to treat chronic pain sometimes did more harm than good. Besides the risk of addiction, the researchers cited depression, impaired wound healing, disordered breathing in sleep, fractures, improper functioning of the hypothalamus and pituitary glands, and even death.
While I am not a clinician, I am pleased that information technology plays an important role in Geisinger’s approach to decreasing the use of opioids. There are many concerns, for example, with prescribing opioids through a paper process, including: drug diversion, prescription forgery, provider DEA number exposure to the public, and doctor shopping to obtain opioids.

We have implemented the following initiatives to help alleviate these concerns:

- Tracking documentation within the electronic health record and dashboard that shows providers reviewed the mandated state-run Prescription Drug Monitoring Program (PDMP) if they considered prescribing a controlled substance.
- Documenting findings in the patients’ medical records.
- Integrating data from a pain app that measures physical activity, patient-reported pain and other metrics into the dashboard and the patients’ medical records.
- Enabling electronic prescribing for controlled substances. We started this on August 23, 2017, and by February of this year 74 percent of Geisinger’s controlled medications were e-prescribed, with all 126 of our clinics using e-prescribing.

Our results are encouraging, as we have reduced opioid prescriptions by about half after launching these initiatives – from a monthly average of 60,000 opioid prescriptions down to 31,000. We are now working to integrate this multifaceted approach for reducing opioid prescriptions throughout our entire organization. And we continue to look for other innovative ways to address the opioid crisis. For instance, we have pioneered an opioid takeback program that gets unused opioids out of the home medicine cabinet where they could potentially be abused.
Additional information on cost savings we realized from implementing electronic prescribing of controlled substances includes the following:

- We reduced by 50 percent the number of patient calls to determine if their paper prescriptions were available, from 660,000 per year to around 330,000 calls.
- With the number of diversions decreased, we reduced the size of the diversion staff.
- Provider time to write an opioid script went from 3 minutes per script to 30 seconds, and nursing time to prepare an opioid script went from 5 minutes to 2 minutes.

These savings have been accruing approximately $1 million savings in time and hard dollar costs.

Although the dashboard may be unique to Geisinger, we believe other health systems and hospitals can generate similar reports on opioid prescribing through their electronic health records or clinical order entry systems. The initiatives rolled out by Geisinger are broadly applicable to health care systems across the United States, and we encourage others to apply these strategies in their organizations. To succeed, organizations will need support from their physician leadership and a commitment to eliminating all unnecessary opioid prescribing.

Everything we do at Geisinger is about caring. Part of that caring means that we believe our patients and members deserve access to the best care and treatment. That is why we emphasize and support evidence-based medicine and care delivery – including e-prescribing of
opioids. The evidence and results are clear. E-prescribing has reduced forgery and diversion while helping patients to avoid unnecessary exposure to addiction and harm.

Supporting the goal of eliminating opioid addiction will take significant commitments from not only the health care industry, but from all of us—government and communities—working together to support individuals and families dealing with addiction. Geisinger wants to be a resource and an engaged partner in the process, and we welcome the opportunity to work with Congress in developing legislation and policy to improve the health of our patients and communities.

In conclusion, we have found that the use of electronic prescribing has led to improved quality care outcomes while reducing:

- Opioid prescriptions
- Drug diversion
- Prescription forgery
- Total costs of care

Thank you again for the opportunity to provide you with our thoughts on this critical health issue. I am happy to answer any questions you may have.
Mr. Burgess. And thank you for your testimony.

Now, Mr. Srivastava, you are recognized for 5 minutes for your opening statement, please.

STATEMENT OF SAM K. SRIVASTAVA

Mr. Srivastava. Thank you, Mr. Chairman. Mr. Chairman, Ranking Member, and all members of the House Energy and Commerce Committee, thank you for inviting me to testify today on the challenges addressing the opioid crisis and offer thoughts about legislative ideas within the Medicaid and Medicare programs.

Magellan Health is a leader in the management of complex population health. For over 40 years, we have been pioneers in behavioral health, innovators in specialty health, and experts in pharmacy services. We work with health plans, employers, providers, and government agencies, and we serve 25 million people with behavioral health services and 24 million people with specialty health services. We are also privileged to be able to serve a lot of the members here right on our panel today.

We bring a wide range of experience and challenges facing the country with regard to the terrible opioid epidemic. The Committee is well aware of the facts of the opioid epidemic. The most recent CDC report says that over 42,000 overdose deaths occurred by opioids in 2016. This is truly a national epidemic, and we commend the Committee for its work to develop bipartisan legislation to reduce and prevent addiction and to provide treatment and recovery for those facing this disabling disease. We look forward to continuing to partner with all of you as we move forward in the legislative process.

So, let me start by saying that the draft bills that have been recently introduced are critically important components to developing a comprehensive response to the crisis. While we have not thoroughly reviewed all of these bills, our initial takeaway is that they point in the right direction and the Committee is on the right track.

We need to expand capacity for treatment and recovery services, develop programs for at-risk populations that limit access to highly addictive drugs. We need to allow further access to drug monitoring program data, so providers, health plan clinicians, and care coordinators can access an individual’s controlled substances history to identify potentially inappropriate prescribing, dispensing, and the use of opioids and other lethal drugs. We also need to update privacy laws that limit the provider’s ability to share information on substance use which may hinder a provider from making informed healthcare decisions. These are all critical components for an overall framework to help address the opioid crisis.

Let me offer a couple of observations. A more detailed discussion of our organization’s views can be found in my written testimony to the Committee. But expanding access to evidence-based medication-assisted treatment, or MAT, is an important cornerstone to treatment and recovery. MAT combines FDA-approved medications with evidence-based behavioral health therapies and psychosocial interventions, such as peer recovery and support services, to provide a whole patient approach to treating substance abuse disorder. MAT is a highly effective treatment option and has been shown to
reduce drug use and overdose deaths and improve retention in treatment. Now because Magellan believes in MAT as an effective treatment, we are committed to taking steps to ensure that it is more readily available and paired closely to peer recovery and support services.

To further improve the adoption and availability of evidence-based MAT, we recommend expanding the ability to prescribe MAT through the use of telehealth. We also recommend and encourage the use of other practitioners to be eligible to prescribe MAT, such as nurse practitioners and other medical professionals. We ask that the Committee also consider a pay bump or other incentives to provide treating patients with a substance use disorder through MAT, and we also encourage that all forms of MAT be covered under Medicare Part B.

A major barrier to care coordination for those who suffer from opioid addiction is the limits of health privacy data regulations placed on healthcare organizations for people with substance use disorders. The vast majority of today's integrated care models rely on HIPAA-permissible disclosures and information sharing to support care coordination; that is, without the need for the individual's written consent to share relevant medical treatment details between providers.

42 CFR Part 2 currently does not allow the confidential sharing of information on substance use disorder diagnosis and treatment for care coordination or when individuals move from one health plan to another. Excluding substance use disorder from the care coordination hinders the ability to continue to develop comprehensive treatment plans and coordination of services.

Magellan recommends the statute be amended to permit sharing of substance use disorder information for purposes of treatment and healthcare operations, as defined by HIPAA and for medical care. Also essential to the modernization of Part 2 is the express permissibility of substance use disorder diagnosis and treatment information to be included in electronic medical records.

We would like to thank again the Committee for the opportunity to offer some thoughts and recommendations on how to address the opioid crisis. Magellan has seen firsthand the magnitude of this crisis, and we are fully committed to continue to provide evidence-based, effective care services to those with substance use disorders. We look forward to working with the Committee in partnership to address the critical crisis facing our nation. Thank you.

[The prepared statement of Mr. Srivastava follows:]
Written Statement of
Sam K. Srivastava
CEO, Magellan Healthcare
Magellan Health, Inc.

Before the
Committee on Energy and Commerce
Subcommittee on Health
U.S. House of Representatives

“Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients”

April 12, 2018
• Addressing our nation’s opioid crisis requires a multifaceted approach—from disrupting traditional healthcare models to new public policy, which will encourage more cross-system integration and help ensure access to comprehensive healthcare services. Magellan Health, Inc. (Magellan) believes turning the tide on the opioid crisis begins with each of us: individual healthcare stakeholders doing our part to help respond.

• This Subcommittee has provided an important, continual spotlight through multiple hearings and discussions with those involved on the front lines of this epidemic. Magellan commends the Subcommittee for its efforts to develop bipartisan legislation that addresses the multiple challenges to reduce and prevent opioid misuse and to provide treatment and recovery for those living with opioid use disorder (OUD).

• In support of the Subcommittee’s work, we welcome the opportunity to share Magellan’s thoughts about legislative ideas to improve the Medicare and Medicaid programs’ abilities to ensure effective and efficient OUD treatment and services for enrollees.

• Magellan has been a strong advocate for policy solutions that promote clinically appropriate opioid prescribing, in addition to policies that support opioid misuse prevention and access to evidence-based, comprehensive OUD treatment and recovery services. These legislative ideas and policy solutions for the Subcommittee to consider include:
  o Addressing barriers to the capacity for, and access to, evidence-based, comprehensive substance use disorder treatment and recovery services, including:
    - Allowing other types of practitioners to be eligible to prescribe medication-assisted treatment (MAT);
    - Increasing Medicaid reimbursement for MAT when combined with psychosocial interventions to promote capacity and access; and,
    - Promoting the continuum of behavioral health services within the Medicare program, including all forms of MAT, psychosocial interventions and recovery supports (such as peer recovery support services), among others;
  o Facilitating care coordination and continuity by modernizing 42 C.F.R. Part 2 to allow the confidential sharing of information on substance use diagnosis and treatment between healthcare providers and with health plans and pharmacy benefit managers (PBMs) for the purposes of care coordination;
  o Optimizing the completeness and interoperability of state prescription drug monitoring programs, and extending access to health plans and PBMs; and,
  o Incentivizing other targeted and systemic solutions, including the appropriate prescribing of opioids through clinical and pharmacy management techniques and tools; requiring electronic prescribing of controlled substances; the expansion of accessible drug take-back programs and drug-disposal options; and, the extension of flexibility to health plans and PBMs to exclude and/or remove pharmacies engaging in fraudulent practices from their networks.
Good morning Mr. Chairman, Ranking Member, and members of the Health Subcommittee. Thank you for the opportunity to be here today for this important conversation on the opportunities and challenges of addressing the opioid crisis within the Medicare and Medicaid programs. Addressing our nation’s opioid crisis requires a multifaceted approach—from disrupting traditional healthcare models to new public policy, which will encourage more cross-system integration and help ensure access to comprehensive healthcare services. We also believe turning the tide on the opioid crisis begins with each of us: individual healthcare stakeholders doing our part to help mitigate and respond to this crisis.

As the Subcommittee knows well, opioid misuse and diversion have evolved into a health crisis affecting communities across the country. Only last week the Centers for Disease Control and Prevention (CDC) released an analysis concluding 63,632 individual lives were lost to drug overdoses in 2016, approximately two-thirds (or 42,000 individuals) of which involved a prescription or illicit opioid. These stark figures reflect a 28 percent increase over 2015, suggesting—as the CDC states—“the opioid overdose epidemic in the United States continues to worsen.” While the scale and deepening of this crisis may seem self-evident, its broad scope and reach may not. These latest figures further suggest drug-overdose deaths from opioids increased in every demographic group; across rural, urban, and suburban communities; and, in each state and Washington, D.C. Unlike previous drug-related public health crises, this epidemic affects everyone—without regard for age, gender, race, or socioeconomic status.

This Subcommittee – as well as the full House Energy and Commerce Committee, the House Ways and Means Committee, and the corresponding committees in the United States Senate – has provided an important, continual spotlight through multiple hearings and discussions with those involved on the front lines of this epidemic. We commend the Subcommittee for its work and its efforts to develop bipartisan legislation that deals with the multiple challenges to reduce and prevent addiction and to provide treatment and recovery for those who face this debilitating, chronic condition.

In support of the Subcommittee’s work, we welcome the opportunity to share Magellan’s own efforts to preempt and respond to the opioid crisis, and our thoughts about legislative ideas – specific to the prevention of, treatment for, and recovery from opioid use disorder (OUD) – to improve the Medicare and Medicaid programs’ abilities to ensure effective and efficient healthcare, for enrollees, especially substance use disorder (SUD) treatment and services. We hope these experiential, practical, and policy contributions further support the Subcommittee’s important work to address the crisis. Specifically, we believe investment in mental health and SUD treatment and services (“behavioral health services”) is the most effective way to prevention addiction and mitigate ongoing effects of opioid misuse and diversion.

Magellan Health, Inc. (Magellan) started as a behavioral health company more than 40 years ago and has been an early pioneer in innovative, comprehensive models to promote, educate, and guide effective, evidence-based SUD prevention, treatment, and recovery services. Our experience supporting individuals living with mental health and substance use disorders (MH/SUDs) – including OUD – through complete-person care has demonstrated the importance of leaning into the complexity and interplay between an individual’s behavioral, medical, and pharmaceutical
needs to positively impact overall health and wellness. This focus on complex population health, we believe, is essential for helping individuals living with SUDs, including OUD, and healthcare providers make the most informed decisions about the actions they can take to lead, or help their patients to lead, healthy, vibrant lives.

Today, Magellan provides behavioral health services to more than 25 million Americans through state Medicaid programs and Medicare; employer- and union-sponsored health plans, including approximately 100 health plans across the country; and, the U.S. Department of Defense, for which we provide family supports and behavioral health services to service members and their families. Within the Medicare program, we are a Part D Plan in 20 of the Centers for Medicare & Medicaid Services’ (CMS’s) 34 regions, and a Dual-Eligible Special Needs Plan and Medicare-Medicaid Plan in the northeast, covering both Medicare and Medicaid in Massachusetts and New York. We also serve more than 1.5 million Medicaid and Children’s Health Insurance Program enrollees through a range of innovative state programs in four states (Florida, Massachusetts, New York, and Virginia), including:

- **In the state of Florida**, a pioneering approach to supporting people living with serious mental illness that is the first of its kind in the nation. Magellan Complete Care of Florida is a unique Medicaid specialty plan that connects behavioral, physical, pharmacy, and social needs—including supportive housing—into a plan of care that is individualized, coordinated, and cost effective.

- **In the commonwealth of Pennsylvania**, comprehensive county-based behavioral health services through the HealthChoices program in Bucks, Cambria, Delaware, Lehigh,
Montgomery, and Northampton counties. To help respond to the opioid crisis facing Pennsylvania's communities and townships, Magellan Behavioral Health of Pennsylvania helped increase access to SUD treatment and services, and utilization of medication assisted treatment (MAT), including new detox (40) and rehabilitation (100) beds, as well as increased methadone-maintenance capacity (245).2

- **To help the commonwealth of Virginia** respond to communities impacted by the opioid crisis, Magellan promotes capacity and access through the Governor's Access Plan (GAP), a new SUD benefit and delivery system, and the Addiction and Recovery Treatment Services (ARTS) demonstration program, a new comprehensive Medicaid SUD treatment benefit, which includes expanded as well as new SUD benefits and increased reimbursement rates for some services: expanded inpatient and community-based residential detoxification benefit, new peer recovery support services benefit, and expanded short-term SUD residential treatment benefit.

I. **How Magellan Health is Helping to Address the Opioid Crisis**

Magellan contracts with approximately 80,000 specialized and credentialed behavioral health providers nationwide. Given our focus on complete-person care, we also have built a full-service pharmacy benefit management (PBM) division, which today provides Medicaid pharmacy services to 26 states and the District of Columbia. These assets, plus our tools as a health plan, allow Magellan to take a uniquely comprehensive approach to the opioid crisis.

Magellan continues to work to facilitate consistency of, and appropriate practices for, prescribing opioids ("opioid stewardship"). In November 2017, Magellan Rx Management, Magellan’s PBM division, announced the implementation of a standard formulary and utilization management approach consistent with the CDC’s 2016 Guideline for Prescribing Opioids for Chronic Pain.¹

Currently, under our standard formulary and utilization management approach, we limit the daily dosage of opioids dispensed based on the strength of the opioid. Under the same standard approach, we currently require the use of immediate-release formulations before extended-release opioid formulations are dispensed. In addition, starting in the first quarter of 2018, Magellan’s standard formulary and utilization management approach began limiting the supply of opioid analgesics dispensed for certain acute prescriptions for individuals new to therapy to seven days. ² We will enroll all of our clients utilizing our standard approach in all of these measures unless the client directs us to implement an alternative approach. However, even for those clients (whether it be state Medicaid programs, commercial health plans, or employers) choosing to develop an alternative, our practice is to consult with and recommend best practices – such as the CDC’s 2016 Guideline – so our clients can make fully-informed decisions.

Our commitment to appropriate prescribing practices does not stop here. Magellan is taking a consistent leadership role in promoting screening, assessment, and evidence-based treatment for individuals with OUD and other SUDs, and is continuing to work with our public and private

---

¹ CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain," Recommendations and Reports, MMWR 65, no. 1 (March 18, 2016): 1-49, https://www.cdc.gov/mmwr/volumes/65/mm6501e1.htm

² Under our program (as with most utilization management rules), the patient is eligible for an exception only if the patient’s physician provides information that satisfies the applicable clinical criteria for such an exception.
sector customers to implement and innovate opioids-related initiatives reflecting clinical, evidence-based guidelines, including:

A. **Before opioids are prescribed**, including by (1) **promoting evidence-based, including non-narcotic and non-pharmacological, pain management therapies**; (2) **piloting reSET®, a U.S. Food and Drug Administration- (FDA-) approved digital alternative for pain management therapy**; and, (3) **expanding access to comprehensive, evidence-based behavioral health programs**, which identify and address MHSUDs and other physical health conditions that may lead to misuse.

B. **When opioids are prescribed**, including by (1) **applying clinical edits and dosing limits that reinforce CMS and CDC best practices**, including the CDC’s 2016 Guideline, to require review and authorization of opioid prescriptions; (2) **comprehensive drug utilization review and prior authorization criteria for immediate- and extended-release formulations of opioids**; (3) **claims surveillance, advanced analytics, and pharmacist-led academic detailing using clinical algorithms to proactively identify potentially at-risk individuals and prescribers with increased risk factors**; (4) **case management to proactively engage patients early in pain management treatment using opioids to**

---

5. reSET® provides healthcare providers and patients with an evidence-based, non-pharmacological treatment option. The pilot is designed to improve education, treatment, and outcomes for individuals living with SUD. The pilot leverages advanced analytics to identify both physician and patient opportunities, including clinical outcomes to provide detailed information on how to access reSET® once prescribed. Industry partnerships like this allow Magellan to unlock the way treatment is delivered and offer practical solutions to meet the complex needs we face because of this crisis.

6. Examples of these initiatives include: care coordination, which helps individuals access the MHSUD treatment and services appropriate to them at the right time and from the right source; stepping into community resources; self-help tools, office-based and virtual providers, and treatment facilities; access and engage, which helps providers in care settings quickly identify potential SUDs and refer individuals to treatment and services. Virtual Care Solutions, which bring the latest screenings, information and evidence-based treatments to a computer, tablet or smartphone, enabling individuals to virtually participate in their treatment on their own terms and in their own time; and, digital cognitive behavioral therapy (CBT), which offers CBT modules for a number of MHSUDs, providing access to care for individuals residing in rural and underserved communities and those who may otherwise not seek help.

7. Criteria include number of claims, morphine milligram equivalent (MME) dose (to limit the daily dosage of opioid dispensed based on the strength of the opioid), and quantity and duration of treatment (to limit a seven-day supply of opioids dispensed for acute prescriptions for individuals new to this form of pain management therapy).
reduce the likelihood of long-term therapy and prevent misuse; (5) **Opioid New Start**, which educates members who have been prescribed opioids for the first time; (6) **drug disposal assistance** to direct individuals to safe disposal facilities in their communities; and (7) **a toll-free hotline**, staffed by behavioral health experts and available 24/7 for individuals who need help understanding their opioid prescription or feel like they are (or are at risk of) misusing.

C. **If opioids are misused**, (1) **case management programs** employing specialized opioid addiction pathways to ensure members receive individualized treatment plans; (2) **office-based opioid treatment and MAT**, which increase access to SUD treatment and enable individuals with OUD to begin the journey to recovery in a comfortable and safe, community-based outpatient environment, avoiding hospitalization or institutionalization; (3) **peer recovery support programs**, including Certified Peer Support Specialists, or individuals in recovery from a SUD whom use their own lived experience with a SUD, including OUD, to help others on their road to recovery; and, (4) **MYLIFE**, offered through our public-sector programs, including Medicaid, a safe place for children, youth and young adults to discuss ways they or a loved one are impacted by mental health conditions and/or SUDs, including OUD, and providing support through a network of friends experiencing the same or similar circumstances.

II. **How Magellan Health is Partnering in Support of a Concerted Response to the Crisis**

We also are committed to a coordinated, multi-pronged, and collaborative, cross-stakeholder approach to addressing the opioid crisis. As a reflection of this, Magellan joined 15 other
healthcare payers to announce our joint endorsement of eight National Principles of Care for the identification, promotion, and reward of quality SUD treatment. (The principles were derived from the U.S. Surgeon General’s 2016 report, Facing Addiction in America.) The initiative is part of the Substance Use Disorder Treatment Task Force, launched in April 2017 by Shatterproof. (Shatterproof is a national nonprofit organization, founded by a parent who lost a child to a substance use disorder, dedicated to ending the devastation SUDs cause families.)

In addition, Magellan is participating in America’s Health Insurance Plans’ Safe, Transparent Opioid Prescribing (STOP) initiative. The initiative – the product of collaboration between clinical experts and the health insurance industry – supports widespread adoption of the CDC’s 2016 Guideline and other clinical guidance for pain care and appropriate opioid prescribing. We are using the initiative’s STOP Measure – a robust, evidence-based methodology – to assess how participating providers’ practices within our healthcare division, Magellan Healthcare, compare to the CDC’s Guideline.

We also are working collaboratively to identify strategies to help physicians, clinicians, and other prescribers to manage better their patients’ pain while reducing the risk of opioid misuse and diversion. Dr. Caroline Carney, chief medical officer for Behavioral and Specialty Healthcare, of Magellan Healthcare was named to the National Quality Forum National Quality Partners™ (NQP) Opioid Stewardship Action Team. The action team developed and published the NQP Playbook™: Opioid Stewardship (March 2018), which provides concrete strategies and implementation examples for clinicians committed to effective pain management, improving prescribing practices, and identifying strategies and tactics for managing care of individuals at high risk of misusing opioids, while building on current public- and private-sector efforts to address the
crisis. Magellan also has joined a private-sector coalition to form the Facing Addiction Gold Standard Alliance for the purposes of developing a gold-standard system of care for SUD screening, treatment and recovery, initially focused on alcohol use disorder and OUD.

Our commitment to a concerted, multi-stakeholder effort also includes the pharmacy industry, where Magellan joined eight other pharmacy care providers and PBMs in a joint letter to President Donald Trump highlighting steps we have taken to address the opioid crisis. Our letter highlights our joint pharmacy industry pledge to “manage opioid utilization consistent with the CDC’s 2016 Guideline for opioid prescribing.”

III. Legislative Ideas and Policy Solutions for the Subcommittee to Consider

In addition to the steps Magellan has taken as a company, we have been strong advocates for policy solutions that promote clinically appropriate opioid prescribing, in addition to policies that support opioid misuse prevention and access to evidence-based, comprehensive SUD treatment and recovery services. Our experience informs three areas (A.-C., below) where we believe changes could improve the Medicare and Medicaid programs’ abilities to respond to and help address the opioid crisis. In addition, we have outlined a fourth, broader area (D., below) inclusive of several specific policy opportunities to help incentivize other targeted, and often systemic, policy solutions.

While we have not thoroughly reviewed each of the bills being discussed by the Subcommittee today, our initial analysis is the passage of this package of legislation would be a major step in the right direction. We agree with the Subcommittee: we must expand capacity for treatment and
recovery services. We must develop specific programs for at-risk populations. We must develop thoughtful, evidence-based mechanisms to limit access to these highly addictive pharmacological pain management therapies to only those where it is clinically appropriate. We must put in place faster, accessible, and more comprehensive information-sharing systems to help healthcare providers and care coordinators understand and clinically respond to an individual’s controlled substance history, identify misuse, and mitigate unforeseen co-prescribing risks. We improve our ability to identify potentially inappropriate prescribing or dispensing practices, such as the co-prescribing of opioids and benzodiazepines or psychostimulants, and do so preemptively. We must modernize outdated privacy laws that limit a provider’s ability to share information on substance use, which may hinder a provider from being able to make informed healthcare recommendations to patients. Each of these critical, individual policy components form an overall legislative framework to help address the opioid crisis in the Medicare and Medicaid programs.

A. Addressing barriers to capacity for, and access to, evidence-based, comprehensive SUD treatment and recovery services

In 2015, the U.S. Department of Health and Human Services (HHS) targeted three priority areas to address the opioid crisis: opioid prescribing practices to reduce OUD and overdose; expanded use and distribution of naloxone; and expansion of MAT to reduce OUD and overdose.8 Research shows MAT when combined with psychosocial interventions, such as psychotherapy and peer recovery support services, is superior to MAT or psychosocial intervention on its own and significantly increases treatment adherence and reduces opioid misuse when compared with non-

pharmacological (i.e., non-MAT) approaches. Further, retention in MAT has been further associated with other beneficial outcomes, including decreased drug use, improved social functioning, and reduced mortality.

The Substance Abuse and Mental Health Services Administration (SAMHSA), American Society of Addiction Medicine, and the National Council for Behavioral Health, among others, also have supported MAT when combined with psychosocial interventions for OUD treatment. Specifically, SAMHSA has noted that the combination of MAT with psychosocial interventions “can have a synergistic or additive effect and improve outcomes” and that use of MAT is “reasonable, practical and a desirable trend that should be greatly expanded.” The President’s Commission on Combating Drug Addiction and the Opioid Crisis also recommended MAT as a means for expanding access to effective OUD treatment. Despite this extensive evidence and broad-based support, the use of MAT when combined with psychosocial interventions continues to be underutilized, representing a small percentage of individuals with OUD and other SUDs whom seek and are in need of treatment.

The numerous barriers to utilization of this evidence-based, comprehensive SUD treatment and recovery model reflect several larger factors. Firstly, each of the three FDA-approved forms of MAT play a different role in SUD treatment and may be clinically appropriate for some individuals with OUD but not others. Secondly, utilization of MAT is affected negatively by the limited number of professionals and paraprofessionals available with such training and experience.\textsuperscript{15,16} According to SAMHSA, 48,626 providers currently are certified to prescribe MAT (i.e., hold a buprenorphine waiver under the Drug Addiction Treatment Act of 2000, or “DATA waiver”); of that current figure, approximately 72 percent are certified to prescribe MAT for 30 patients, with less than 20 percent (or 9,413) certified for 100 patients and 8 percent (or 4,100) for 275 patients.\textsuperscript{17} When compared to the 900,000 providers able to prescribe oxycodone, these figures alone demonstrate the significant gap in MAT capacity.\textsuperscript{18} As others have noted, “enlargement of the network of professionals authorized to deliver treatment and broadened access to MAT through such avenues as specialized community pharmacies, telemedicine and hub-and-spoke systems of care,” including through behavioral health value-based payment models, continues to be an area of opportunity.\textsuperscript{19} Thirdly, as an extension of this secondary barrier (or a cause of it), many healthcare providers remain hesitant regarding the effectiveness of MAT, leading to a gap between the number of high-quality providers with training and experience to prescribe MAT and the individuals affected by

OUD and other SUDs in need of treatment. Social stigma towards SUDs and MAT as a treatment modality is also a factor. (Indeed, despite the fact that approximately 75 percent of heroin users were introduced to opioids through prescription drugs, stigma continues to associate OUD and other SUDs with drug-seeking behavior and recreational use.\textsuperscript{20,21}) In addition, educating the healthcare community on evidence-based MAT protocols is needed to address pre-conceived notions, cognitive bias, and the impact of both forms of stigma on treatment access, treatment and recovery outcomes, and reduction rates in patient motivation to maintain treatment regimens and counseling programs.\textsuperscript{22} Professionals and paraprofessionals also need to find value in devoting more time to case management, which can promote the necessary complement of psychosocial interventions, while employing MAT protocols, which reduces the possibility of relapse and/or readmission to a SUD inpatient/residential rehabilitation program.

Fourth and finally, these logistical factors are compounded, at least in part, by variance and complexity in how MAT and the necessary psychosocial interventions are covered and paid for. While state Medicaid programs have implemented a range of policies to regulate and reduce prescription opioid use and misuse – including patient review and restriction in Medicaid fee-for-service or managed care, or both; preferred drug lists (PDLs); prescription drug monitoring programs (PDMPs); prior authorization requirements; and quantity limits on opioid dispensing – there remains opportunity for a similarly comprehensive effort to expand access to the full behavioral health continuum of care, specifically evidence-based, comprehensive SUD treatment.

and recovery services like MAT and psychosocial interventions.23 (A 2014 survey found significant variance and complexity among state Medicaid programs’ coverage and utilization review requirements for each FDA-approved form of MAT, including documentation and counseling requirements.24 According to a 2013 survey, only 28 states at that time covered all three FDA-approved forms of MAT under Medicaid.25) Some of the FDA-approved forms of MAT (methadone, buprenorphine, naltrexone) may not be available on current formularies and PDLs, and other services used in SUD treatment may be at state Medicaid agency and Medicare Advantage plan discretion (e.g., counseling, licensed clinical social work services, targeted case management, medication therapy management, and peer recovery supports).26,27

For these reasons, Magellan is committed to taking steps to ensure MAT is more readily available and that it is paired closely with psychosocial interventions, such as psychotherapy, CBT, and peer recovery support services. Magellan works closely with healthcare providers, health plans, and the Medicare and Medicaid programs to increase comfort with, and knowledge of, the effectiveness of MAT and psychosocial interventions, to encourage prescription of MAT with psychosocial interventions, and to incorporate MAT into formularies. Magellan also collaborates with health plans and the Medicaid program to incorporate all forms of MAT into respective formularies to promote appropriate access. As an example, Magellan collaborated with Pennsylvania to facilitate SUD treatment services for Medicaid enrollees through the commonwealth’s 20 Centers of

25. Ibid.
Excellence (COEs). The COEs are a central, efficient hub around which individuals living with SUDs can receive both primary and behavioral healthcare services, including comprehensive MAT and psychosocial interventions, thereby improving access to evidence-based, SUD treatment and recovery services.

Magellan’s Recommendations: To improve further the adoption and availability of evidence-based MAT, we recommend the following:

1. **Allowing other types of practitioners to be eligible to prescribe MAT**, including nurse practitioners, physician assistants, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists.

2. **Prescribing MAT through the use of telehealth.** We recommend expanding the ability to prescribe MAT through use of telehealth so long as such services are preceded by an in-person evaluation and accompanied by periodic face-to-face evaluations to ensure appropriateness of care.

3. **Increasing Medicaid reimbursement for MAT and psychosocial interventions to promote capacity and access.** We encourage the Subcommittee to consider a temporary “pay bump,” or other increased reimbursement incentive, to promote greater SUD workforce capacity for MAT and psychosocial interventions in the Medicaid program.
4. **Promoting increased capacity for, and access to, MAT within the Medicare program.** Within the Medicare program, we recommend coverage of all forms of MAT when dispensed through an OUD program (i.e., inclusive of psychosocial interventions and recovery supports). We further recommend allowing qualified providers, who are appropriately licensed to dispense MAT (and possess a DATA waiver), to enroll in Medicare Part B. We also encourage Medicare to provide access to evidence-based, non-pharmacological and non-addictive pharmacological therapies for pain management, as well as a continuum of behavioral health services in support of MAT, including psychosocial interventions and wrap-around recovery supports such as digital CBT and peer recovery support services.

5. **Promoting best practices across state Medicaid programs.** Magellan recommends CMS issue further guidance to state Medicaid programs detailing best practices for lessening disparities in Medicaid coverage and related requirements for coverage of SUD treatment and recovery services, such as the inclusion (1) of all FDA-approved forms of MAT on current formularies and placing naloxone on the PDL; and (2) as covered benefits, inpatient and outpatient detoxification, psychotherapy and counseling, peer recovery support services, and other community-based services and supports. We also recommend increasing the use of digital tools and technology used for SUD treatment and recovery, including digital CBT programs and web-based modules or apps. (These tools can strengthen peer recovery support services by improving access to evidence-based information and social supports.) We
recommend expanding access to recovery services, including ongoing, evidence-based psychiatric treatment, wrap-around services, and peer recovery support services.  

6. **Encouraging the development and adoption of comprehensive Medicaid programs for SUD treatment and recovery.** To best bring these elements (i.e., Item 5) together, Magellan recommends mechanisms – such as a time-limited federal medical assistance percentage (FMAP) increase – for encouraging the development and implementation by states of comprehensive Medicaid initiatives for SUD treatment. An example of such a comprehensive Medicaid initiative is the Virginia GAP and ARTS programs, which expanded the Medicaid SUD treatment benefit and further integrated inpatient and outpatient treatment with community-based recovery supports. We also recommend Congress encourage CMS to assess and share emerging models and promising practices within the Medicaid program to address the opioid crisis.

7. **Increasing provider awareness of MAT and other evidence-based SUD treatment and recovery modalities.** Magellan further recommends Congress encourage CMS to partner with the Health Resources and Services Administration (HRSA), SAMHSA, and medical and professional societies to increase provider:

---

28 Research has also shown that peer support is beneficial and cost-effective; peer specialist support programs in Wisconsin, New York, and Washington State reduced inpatient days by up to 63 percent, and decreased overall MH/SUD costs by approximately 47 percent.
a. Comfort and knowledge of the proven effectiveness of MAT;
b. Familiarity with evidence-based protocols for treatment;
c. Training in the use of MAT and psychosocial interventions; and,
d. Education and training on pain treatment and management, including effective, alternative/non-opioid therapies for pain management, safe opioid prescribing, and preventing the consequences of opioid misuse and overuse through tapering and other opioid-management strategies.

We also believe CMS, HRSA, and SAMHSA should incorporate MAT competencies and accreditation standards into academic curricula across medical, social service and criminal justice disciplines.

8. **Supporting a high quality, effective SUD treatment and recovery continuum.** We also recommend Congress encourage CMS and national accrediting bodies to collaborate and advance a nationally recognized mechanism to ensure accreditation of SUD treatment and service providers, with the future potential to include COE designations and to limit federal Medicare and Medicaid reimbursement only to accredited providers.

9. **Promoting healthcare transitions for individuals living with OUD and/or other SUD(s) whom are formerly incarcerated.** We also strongly support additional resources for immediate “warm” handoffs (i.e., supported healthcare coverage and service transitions) to OUD and/or SUD treatment for Medicaid and
Medicare enrollees in emergency departments after overdose and connecting family caregivers to appropriate support groups.

B. Facilitating care coordination and continuity by modernizing 42 C.F.R. Part 2

The vast majority of today’s integrated care models rely on Health Insurance Portability and Accountability Act- (HIPAA-) permissible disclosures and information sharing to support care coordination—that is, without the need for the individual’s written consent to share relevant treatment details, provider by provider. The same is true for the modern electronic infrastructure for information exchange. In an era of electronic medical records (EMRs), having incomplete records available for providers—because substance use disorder information (the confidentiality of which is governed separately, by 42 C.F.R. Part) cannot be included without individual consent—disallows providers from supporting their patients holistically. In some cases, providers may believe the EMR (to which they have access) reflects their patient’s complete clinical history. In such situations, a provider may prescribe, for example, opiates for back pain for a member with prior history of opioid misuse, which could lead to relapse. Access to complete medical information is critical for providers to ensure individuals have access to the healthcare services, supports, and treatments appropriate to their needs. In order for Medicare and Medicaid enrollees to receive the full benefits of integrated care, particularly enrollees with OUD and other SUDs, the care coordination exception permitted under HIPAA is necessary for 42 C.F.R. Part 2-governed SUD information.

Furthermore, while having to obtain any written consent is a barrier to achieving care coordination, the ability to obtain a more broad consent would certainly permit member information to be shared
more easily for care coordination and treatment purposes. It would also make it easier to include information in EMR systems noting whether the consent was constrained to individual providers. Consents having to list individual providers often have to be obtained repeatedly as members move through the system of care, leading to delays or barriers in coordinating a member’s care. These hurdles are extremely problematic for health plan entities who are responsible for coordinating the care received by their members to make certain it is optimally suited for each member; any change of provider by the member necessitates a new written consent. In the event a member changes their primary care provider, switches psychiatrists, or begins a new course of treatment with a cardiologist – all of whom need to know about the member’s SUD treatment history to ensure patient safety and proper treatment approaches – a new written consent must be obtained. Doing so is not always easy, particularly if the Medicare or Medicaid enrollee is unable to effectively understand or communicate due to their condition; or has other co-occurring conditions (such as a serious mental illness), which stymie the consent-collection process.

It is our belief – rooted in extensive experience with the behavioral health continuum in the Medicare and Medicaid programs – that the national opioid crisis is not being addressed nearly as effectively as it could be given the limitations posed by Part 2 on effectively coordinating care. For example, when a health plan is coordinating a Medicaid enrollee’s discharge from an inpatient detox facility and attempting to locate an appropriate outpatient therapist in the community, the Medicaid health plan is prohibited from informing the outpatient therapist that their new patient has a SUD diagnosis and was discharged from detox, and must hope that: the detox facility notifies the therapist of the treatment directly (although they – the therapist – too would first need to obtain written consent to do so as well); the therapist asks the member about any SUD history (and that the member responds truthfully); or, the member is forthcoming enough to inform the therapist
proactively. If none of these occurs, the therapist’s treatment plan will not address the crux of the Medicaid enrollee’s healthcare needs – their OUD or other substance use disorder – potentially leaving the individual at greater risk of relapse, re-admission, or worse.

Similarly, when a detox facility calls the enrollee’s Medicaid health plan for pre-authorization, the health plan is prohibited from advising the facility that this member could have been in detox multiple times in the past year and – as a result – may need their treatment approach adjusted accordingly to improve the member’s quality of care and overall outcome. An enrollee with a SUD may not provide the Medicaid health plan with written consent and may not share his or her treatment history with the facility, leaving the facility in the position of being unaware of this critical information and providing treatment or treatment recommendations in the dark. Other effects on care and health outcomes that Magellan has encountered in coordinating the primary and behavioral healthcare services of Medicare and Medicaid enrollees in compliance with Part 2 include:

- Due to the need to exclude SUD data from the information sharing necessary to successfully coordinate an enrollee’s care, the regulations result in fragmentation in treatment, less than optimal patient assessments, and treatment plans often created in a vacuum because the complete clinical picture is not available to the current provider, which can lead to adverse drug reactions, accidental overdose, inappropriate diagnosis, and ineffective treatment which targets the incorrect condition;

- The need to single out specific patient written consent for each individual provider prior to any disclosure of SUD information slows the treatment process considerably, creates great
inefficiencies, and may actually result in reinforcement of stigma associated with SUD treatment and services instead of overcoming it; and,

- The inability to share substance use patient information between providers without the express, written consent of the patient has created perceived liability situations for many physicians and other clinicians to the point that they may opt to refuse to treat any patient with a suspected history of substance use, particularly in primary care, which is most unfortunate since primary care providers often are in the most advantageous position to screen for and treat substance use disorders.

In our experience, we have seen multiple individual situations and dynamics adversely affected by Part 2. For these reasons, Magellan believes it is critical for healthcare providers and health plans to be able to assist their patients and members in recovery and with relapse prevention by sharing valuable SUD information – particularly when arranging for pre-authorization, referrals, step-down services, residential treatment, and other care coordination activities – without the need to obtain written consent for each individual provider. Health plans have a critical role in supporting improved health outcomes, mitigating opioid misuse, supporting individuals in recovery, and preventing relapse. The ability to use and disclose Part 2 information for these express purposes remains an unintended barrier to advancing screening, assessment, and evidence-based treatment for individuals at-risk of opioid misuse and individuals living with OUD and other SUDs.

Magellan’s Recommendations: Magellan strongly recommends the statute be amended to permit the sharing of SUD information for the purposes of treatment and health care
operations as defined by HIPAA. Also essential as part of this modernization of Part 2 is the express permissibility of SUD information's inclusion in EMRs.

C. Optimizing the completeness, workflow integration and interoperability of state PDMPs and extending access to such databases to health plans and PBMs

State PDMPs have been implemented in all but one state; despite this growth, only 31 states’ Medicaid programs and Washington, D.C.’s program are authorized to access state PDMP database information. In those states that do extend access, health plans, PBMs, behavioral health organizations, administrative services organizations, and/or other sub-contractors to state Medicaid programs and to the Medicare program – entities administering Medicare and Medicaid prescription drug benefits and SUD treatments and services – may not have access to PDMP data. These restrictions often extend across state lines, with wide variation with respect to whether or how database information is shared with other states. In addition, data collection intervals vary by state who oversee their own drug monitoring programs, with only a few states currently requiring real-time reporting on controlled substances to their PDMPs and some states excluding short-term prescriptions from database reporting requirements.

When and where PDMP data can be accessed by the Medicare and/or Medicaid program and the program’s contractors, data have not been well integrated into health IT systems or into professionals’ and paraprofessionals’, including prescribers’, routines and patient protocols.

29 Bernstein and Minor, Health Affairs (2017); Bernstein, MACPAC (2016)
Compounded by the fact that as many as one-third of primary care physicians may not be aware of these state databases, PDMPs often are underutilized by providers.30

**Magellan’s Recommendations:** Magellan recommends all Medicare and Medicaid providers check the prescription drug history of Medicare and Medicaid enrollees through the applicable state’s PDMP prior to dispensing an opioid. We also recommend Congress consider legislative ideas (e.g., increased FMAP for expenditures related to improving the PDMP in line with such activities) for encouraging states to (1) allow public payers, including Medicaid and Medicare, and their subcontractors (i.e., Medicaid health plans and PBMs, Medicare Advantage plans, and Part D plan sponsors, and the contractor’s “pharmacy director (or a designee)”), to access the PDMP; (2) make their PDMPs more easily accessible, including direct access or a daily data feed that can be synched with existing Medicare and Medicaid data systems; (3) ensure data accuracy and availability in as close to real time as is feasible; (4) better integrate across the country by ensuring state PDMP interoperability with other states; (5) improve completeness, workflow integration, and interoperability of PDMP reports into EMRs and HIEs to streamline provider and payer access and usability to allow these entities and supporting providers to have a comprehensive, real-time look at a patient’s clinical history; (6) partner with medical and professional societies to enhance education and training on availability of state PDMP databases and incorporating provider check requirements into daily routines and patient protocols to encourage real-time reporting; and (7) make PDMPs easier to use and report into by allowing prescribers to establish delegate accounts.

---

30 L. Rutkow et al., “Most Primary Care Physicians are Aware of PDMPs, But Many Find the Data Difficult to Access” Health Affairs 34 (2015): 844-87.
D. Incentivizing other targeted and systemic solutions

The scale and reach of the opioid crisis requires systemic solutions in addition to targeted approaches to mitigating barriers to information sharing and access to treatment and services, as we have suggested in our preceding recommendations. The following additional policy solutions—including those that have been tested by the experience of states embarking on state opioid crisis strategies and task-force activities—represent approaches to tackling some of the systemic roots of the opioid crisis:

1. **Encourage the appropriate prescribing of opioids through clinical and pharmacy management techniques and tools**

Between 1999 and 2014, the prescribing and dispensing of opioids “nearly quadrupled,” according to the CDC, “but there has not been an overall change in the amount of pain Americans report.”\(^{31}\) While the rate of opioid prescribing has decreased in the period since 2014 (from 72.4 opioid prescriptions per 100 persons in 2006, increasing 1.1 percent annually through 2012), the supply of prescription opioids remains high in the U.S.: approximately 66.5 opioid prescriptions per 100 person in 2016.\(^{32}\) These figures are stark when put into context: in 2013, approximately 250 million opioid prescriptions were written by healthcare providers — or a prescription for every adult in our nation. Ensuring appropriate prescribing of opioids (or opioid stewardship) requires each of us to rethink the treatment and management of acute or episodic pain—particularly since prescription

---


opioid use has become deeply entrenched in our clinical treatment culture. This rethink, however, must balance carefully the reality that at least 116 million Americans live with common chronic pain conditions, whose pain may be well managed with a prescription opioid today.\textsuperscript{33}

Striking this balance can prove challenging but is possible through the development of thoughtful, evidence-based protocols for physicians and pharmacists to prevent patients from being prescribed inappropriately addictive, pharmacological pain management therapies, such as opioids. These protocols may include reasonable medical management techniques, such as prior authorization and quantity limits, consistent with best practices. The CDC’s 2016 \textit{Guideline}, for example, includes recommendations such as: using non-opioid and non-pharmacological pain management therapies as a first line of therapy; prescribing the lowest dose and fewest opioids that would be effective when opioids are appropriate; regularly reviewing the risks associated with opioids with patients; and, closely monitoring patients to promote safer use and improved health and wellness outcomes.

These medical management tools also can be used to support value-based approaches to ensure individuals served by the Medicare and Medicaid program have access to effective and efficient healthcare to meet their unique needs.

Another key part of this is data: analyzing pharmacy claims information to identify when Medicare and Medicaid enrollees may be at risk of being prescribed opioids inappropriately, or in inappropriate amounts, including from multiple clinicians or in spite of a clinical history of OUD and/or other SUD. PDMPs, accessible by health plan and PBM physicians and pharmacists, are another valuable tool to help identify Medicare and Medicaid enrollees who may be receiving

opioids from multiple providers and pharmacies, or through cash payment. In some circumstances, this data can and should be used to designate a single physician and a single pharmacy (i.e., a provider- or pharmacy-assignment program, also known as “lock-in”) for individuals who may benefit from closer clinical engagement to address potentially inappropriate prescribing or misuse, carefully review for potentially dangerous co-prescribing, mitigate the risk of unintentional overdose, reduce hospital and emergency department admissions, and increase appropriate access to SUD treatment and recovery services.

Magellan’s Recommendations: Magellan recommends Congress consider legislative ideas for incentivizing the broad adoption of provider- and pharmacy-assignment programs, or lock-in, by state Medicaid programs, with flexibility to allow states to align the definition of at-risk beneficiaries with the Medicare program’s new lock-in authority and/or existing state criteria reflecting certain minimum standards the subcommittee believes are appropriate. We also recommend state Medicaid programs have in place comprehensive drug utilization review activities, including medical management techniques and tools aligning opioid stewardship with the CDC’s 2016 Guideline.

2. Require electronic prescribing of opioids

Fraud and abuse associated with paper-based prescriptions have been identified as a contributing factor to doctor- and pharmacy-shopping for opioids. Electronic prescribing (e-prescribing) can be an effective solution where health IT infrastructure is supportive, including benefits for providers, patients, payers and programs: improved monitoring of opioid use, reduced fraud through secure transmittal between providers and pharmacies, and improved patient safety via clinical alerts that
prevent adverse drug events in part by combining medical history with automated clinical
decisions support.

*Magellan’s Recommendation:* Magellan recommends Medicare and Medicaid providers be
required – where local health IT infrastructure is supportive – or, at minimum, incentivized
to e-prescribe opioids and other Schedule II controlled substances as a tool to mitigate opioid
misuse.

3. *Expand accessible, community-based drug take-back programs and/or safe, in-
home drug disposal options*

States increasingly are collaborating with local coalitions, pharmacies, health professional boards,
and the U.S. Drug Enforcement Administration (DEA) in drug take-back or drug disposal
programs, which offer a safe and anonymous way to dispose leftover opioid and/or other
prescription drugs, including other controlled substances, which can be diverted and misused.
Greater expansion of these local initiatives, including by expanding permanent drop-off locations
and investing in innovative approaches to in-home drug disposal, can promote proper disposal of
prescription opiates.

*Magellan’s Recommendation:* Magellan recommends CMS and the DEA coordinate to
ensure compliance and participation costs of hosting permanent drop-off locations do not
create unintentional barriers to local law enforcement, pharmacies and other entities
establishing and expanding the availability of drug take-back sites and programs.
4. **Extend flexibility to health plans and PBMs to exclude, remove pharmacies engaging in fraudulent practices**

“Any willing provider” and other pharmacy-network laws pose difficulties for Medicaid health plans, Medicaid PBMs, Medicare Advantage-Part D plans, and Part D plan sponsors to exclude and remove pharmacies from their plan- and provider-contracted networks that engage in fraudulent practices. Requiring health plans to allow any pharmacy willing to accept its terms and conditions to participate in its networks severely restricts a plan’s ability to exclude these so-called rogue pharmacies and enhance the quality of its pharmacy services for patients.

*Magellan’s Recommendation:* Magellan recommends Congress permit health plans and PBMs supporting the pharmacy benefits under the Medicare and Medicaid programs the flexibility to exclude and remove pharmacies engaging in fraudulent practices from their networks. We also recommend Part D plan sponsors be allowed to stop payment of suspect claims where there is a credible allegation of fraud.

***

A multifaceted approach is needed to address the evolution of this epidemic in real-time and to respond to the real-life effects of misuse and overuse. Both practical and policy solutions are needed here in Washington, D.C. and in state capitols across the country. Practical solutions include naloxone availability, safe and fully informed prescribing practices, easy and accessible disposal mechanisms, harm-reduction services, linkage into SUD treatment and wrap-around services, and further integration of primary and behavioral healthcare. Policy solutions are needed
to address the unintended gaps and barriers that make it harder for the Medicare and Medicaid programs to provide the best healthcare for enrollees.

Opioid dependence and addiction can start with triggers like acute pain, chronic pain, or surgery. Lack of education and awareness, or inappropriate prescribing practices, also can lead to misuse and abuse. Magellan recognizes that its work to address the opioid crisis must begin on the front end. It must help educate on the potential risks of prescription opioids and provide chronic care pain management, supported by personal health coaches and clinical experts in pain and addiction management, to help our Medicare and Medicaid members manage their pain without turning to opioids. It must help screen and engage to quickly identify potential problems and direct our members to treatment, including digital CBT and the broader use of personalized health technology that supports individuals actively participating in their own treatment on their own terms. Moreover, it must work to provide the lowest level of intervention for a specific healthcare issue or procedure to minimize or postpone the need for surgery that could lead to an opioid prescription, as clinically appropriate.

We would like to, again, thank the Subcommittee for the opportunity to share our experience and recommendations on how to address this national crisis. Magellan has a long history of providing evidence-based, comprehensive, and effective services to those living with substance use disorders. We provide integrated and comprehensive opioid risk and substance use management programs by bringing together behavioral, medical, and pharmaceutical programs to make a difference in people’s lives. Magellan has seen first-hand the magnitude of the opioid crisis and its impact on communities and families. We look forward to working with the Subcommittee in partnership to address this crisis facing our nation.
Mr. Burgess. Thank you. I want to thank all of our witnesses for your testimony and participating with us this morning.

And now, we will move into the question-and-answer portion of the hearing. Before beginning questioning, I would like to submit into the record a statement from the American College of Obstetricians and Gynecologists. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. Burgess. I would also like to submit for the record a New York Times article entitled, “Medicare Is Cracking Down on Opioids. Doctors Fear Patients Will Suffer.” I would like to submit that for the record. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. Burgess. And let me recognize myself, 5 minutes for questions.

Mr. Douglas, I think in your testimony—and I think it actually comes up as a repetitive theme—but just looking at your remarks that you have provided to the Committee, “Opioid addiction is estimated to be 10 times as high in Medicaid as in commercial populations,” and then, you go on to delineate some other statistics that indicate Medicaid beneficiaries are prescribed opiates twice as often as individuals with private health insurance.

I am going to ask you this question; you may not know the answer to it. I may be able to find the information elsewhere. But when was this phenomenon recognized? Is this relatively recent or is this something that has gone on for—I mean, Medicaid has been around since 1965. Has this been recognized in the ’60s and ’70s or is this a more recent phenomena?

Mr. Douglas. I don’t have the exact timing. But what I would say, given my previous life as a Medicaid director, that part of the phenomena within Medicaid is the growing role of Medicaid and being a broader program than just physical health. This problem in many ways was siloed off, with substance use being a separate program run in many cases by separate agencies.

And what we went through in the evolution in around 2010 0911 was acknowledging the importance of integrating in California behavioral and physical health. That started to drive more of Medicaid and, then, our more integrated MCOs to work to solve and recognize the impact it was having on inpatient, on emergency room utilization. It was impacting medical spend and the outcomes and the need to expand services, which is why California started moving forward with how do we expand and integrate, as well as acknowledging there was actually with a siloed program a lot of unfortunate fraud going on within our substance use program, and the need to integrate into a system would allow for making sure the right care and the continuum is being provided.

Mr. Douglas. As I said, the Medicaid agencies were starting to deal with this. When I look back on my time around 2010, around there, it was starting to become more and more of the need to think holistically about behavioral and physical health integration and brought these to the head.

Mr. Burgess. And I actually would be interested in what other panel members have to say about this. I am not asking the ques-
tion to be provocative. It is just that we are the payer here. The federal government is the Aetna, United, the Cigna. We are the payer. And if there is something about our structure that is putting people at risk, then I think we need to recognize that, and if there is a way to mitigate that risk, we ought to do so. So, are there any other thoughts that any of you have as to whether the identification of the type of coverage putting someone at risk, is that a real phenomenon or is that an observer bias?

Mr. Botticelli, you look like you want to make a statement.

Mr. Botticelli. I do, and no disrespect to Mr. Douglas. While we, I think, know the prevalence of substance use disorder in both Medicaid populations is high, and higher than the general population, there was a recent Kaiser health survey that just came out that shows the growing trend of substance use disorders and opioid use disorders prevalent in both commercial and employer plans. So, again, I think that while we do see slightly higher rates among Medicaid populations, I don’t think that the differences are as vast between kind of the Medicaid population and the commercial market as one would have previously thought.

Mr. Burgess. So, we can effectively ignore the type of coverage? It is of no consequence?

Mr. Botticelli. No, coverage is significantly consequential because I think what we also see in other studies is that coverage, quite honestly, accelerates access to treatment, and we have seen it with both Medicaid and commercial plans.

Mr. Burgess. So, intuitively, yes, that would be obvious.

I am going to run out of time.

And, Mr. Douglas, I also want to mention, thank you for bringing up Project ECHO, which was a product of this committee. And many of you have mentioned prescription drug monitoring programs and, of course, the NASPER authorization originated in this committee back in 2005. So, although the focus recently has been more intense, this subcommittee has been dealing with this problem for some time.

I see my time has expired. I am going to yield to Mr. Green 5 minutes for questions, please.

Mr. Green. Thank you, Mr. Chairman.

And again, I thank all our panelists.

One of the biggest issues of Americans struggling with opioid addiction and substance abuse generally are the barriers to treatments and ensuring there is a continuity of coverage, and particularly for vulnerable populations. Just that exchange, Dr. Botticelli, the compare between private insurance and Medicaid, at one time I assumed Medicaid was more. Coming from an urban area in Houston, Medicaid is such a predominant care for not only physical care, but also mental care. And my concern, Mr. Douglas, is that, if you are splitting off that, I think it ought to be a continuity of care between the physical doctor and—because, obviously, we know the behavioral and the physical is important. So, we need to have that coordination of care, whether it is through Medicare or the private sector, or whatever.

What would be the consequences if it becomes more difficult for Americans struggling with substance use disorders to receive Medicaid coverage?
Mr. BOTTICELLI. I think we have seen, yes, we would not be able to do what we do at Boston Medical Center were it not for a generous benefit through Medicaid. And not only do we see successful clinical outcomes on both the behavioral and the physical side, but we have also been able to demonstrate that we can actually lower healthcare costs by giving people good, comprehensive, quality care. We have seen, if we can get people in treatment, we can reduce emergency department admissions and hospitalizations, as well as get them to long-term recovery and really kind of miraculously return people to jobs, to the community.

I think, without coverage—and we have seen time and time again the devastating impact—that one would anticipate that we will see significant increases not only in mortality, but we are also dealing with other epidemic issues of hepatitis C. We are seeing outbreaks of HIV across the United States. And so, you are entirely correct that this is not just about adequate access to substance use treatment, but people need adequate access to the entire spectrum of physical health issues.

Mr. GREEN. I was interested, Mr. Douglas, in saying, in 2010, you saw the more concern or interest, and it was because of the separation maybe from behavioral care as compared to physical care. Was that because of the Affordable Care Act getting ready to kick in or expansion of private sector funding because of the Exchanges?

Mr. DOUGLAS. So, again, this is really, I want to say, through my lens in California as well as on the National Association of Medicaid Directors, working with Medicaid directors at that time again, of Medicaid directors’ acknowledgment. And I would believe that there were many factors. I think the Affordable Care Act was one of them, of understanding both looking more at how we were—at that time the Affordable Care Act, besides the expansion, was really focused on integrating care, as you said, of physical and behavioral health and aligning the right payment incentives and outcomes. And so, States were really looking holistically and realizing that, to address better health outcomes, there needed to be more integration and expansion of treatment modalities within behavioral health and substance use.

And so, we are now in Centene, and where we stand is we do still see differences by States in the availability and access to substance use treatment services, and it varies. While Medicaid has a richer benefit, it still varies in terms of the availability of substance use. In States where we do have Medicaid expansion, we are seeing the ability in the data of being able to address unmet need more within the substance use area.

So, it is a combination of factors. I don’t want to say that the ACA didn’t; the ACA spurred both expansion of benefits as well as thinking through how to integrate physical and behavioral health, as you said is so important.

Mr. GREEN. Thank you.

Mr. Chairman, you and I have had the opportunity, and a number of our members on both sides of the aisle, to attend the Commonwealth and the Alliance. Once a year we go off for a long weekend and have folks.
Mr. Kravitz, Geisinger, for a number of years, has been at those facilities. And coming from a guy from Texas with my accent, I didn’t know anything about Geisinger until then. But, then, I happened to have my father who moved back home, so to speak, from Houston, to northern Pennsylvania. He was a patient there. During his lifetime—he lived to be 91 and a half, a great life—but I was really impressed by Geisinger’s facility there treating the whole person.

Mr. Kravitz. Thank you.

Mr. Green. Anyway, I am out of time, Mr. Chairman. Thank you.

Mr. Burgess. The Chair thanks the gentleman.

The Chair recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for your questions, please.

Mr. Griffith. Thank you very much, Mr. Chairman.

And thank you all for being here today to testify.

Mr. Douglas, the Centers for Medicare and Medicaid Services recently released its 2016 Drug Utilization Review Report. The report noted that 26 Medicaid agencies have access to prescription drug monitoring program data. States can use this data from the PDMPs to manage the overutilization of opioids and detect fraud, waste, and abuse. On the other hand, 23 State Medicaid agencies report that they do not have access to the PDMP data. Can you describe how Medicaid agency officials would use PDMP data to combat opioid misuse?

Mr. Douglas. So, both, again, from the view of talking with both current and former State Medicaid directors as well as managed care organizations, the use of PDMP is really, really important in combating. We have seen effective use in ability to both make sure that our providers, they understand and have a clear sense of where our members are receiving other opioid prescriptions. And so, it creates alerts. It creates information that we can then, as we go through utilization management back as a managed care organization, to be able to create and prevent prescribing from occurring.

And so, in the cases where we have it, it effectively improves our ability to combat inappropriate prescribing patterns and utilization. And so, as I noted in my remarks, this is an area where I think Congress could do a lot in both incenting states to make sure that all entities, both the agencies, the Medicaid agencies, the providers, as well as the managed care organizations across all States and territories, have access to the data to combat and ensure there is judicious prescribing.

I would note—and I think you heard from some of my colleagues—that that is not going to be sufficient. We have to also figure out how to overlay this into EHRs and make sure it is as easy as possible for our providers. We are at Centene trying to do that, but it is more than just a role of managed care organizations to be able to solve this. It takes investment in IT systems and prescribing to make sure that there is easy utility and it fits into the workflow of our providers.

Mr. Griffith. One of your suggestions for ensuring all appropriate entities have access to PDMP data is to proactively share that data, the data reports, with each other. Can you explain how this would work in practice?
Mr. DOUGLAS. Well, this gets, again, to in practice the importance of IT, because, as providers work, it needs to be real-time. In terms of our responsibility for utilization management of pharmacy, there are requirements on turnaround times. And so, if the information is not shared quickly and through electronic means, we are either going to be out of compliance with our utilization management or providers are going to have problems within their workflow.

And so, in practice, it makes sense. In the actual real life right now, until we get better IT systems across all systems—I am sure in Geisinger and others it is there—but we need, especially with Medicaid providers, more investment.

Mr. SRIVASTAVA. So, Congressman, if I could add?

Mr. GRIFFITH. Yes, sir.

Mr. SRIVASTAVA. One is it is spot on that with PDMP we are data-rich, but we are processing-poor in this construct. You need interoperability to share it with health plans that share it with pharmacy providers and with providers. It needs to be at the workflow level, so that it is in an EMR. But, also, you are getting data that is not just those that are prescribed, but also cash pay. So, if a person seeks drugs, and it is through the benefit in Medicaid or the benefit within your employer, you are going to get information. But, if you are actually going and cash paying for drugs, that processed claim would also show up in this report. So, we are getting more data sources, and it needs to be at the point of care, where the individual can act and understand whether there is a lot of drug history there, to be able to change the regimen.

Mr. KRAVITZ. I would like to also add a comment, if you don’t mind.

Mr. GRIFFITH. Yes, sir.

Mr. KRAVITZ. From an information technology perspective, we use PDMP before any opioid is being prescribed for a patient. What is important, though, is not all States have reciprocity where they can go through and exchange information. We actually need to go to a level where we are closer to a national PDMP for patients traversing different State lines. Where there are reciprocal arrangements that are occurring, not all States participate. The other problem that is a national problem is a national patient identifier to make sure we have the right patient identified in the PDMPs.

The other component of that, while we have advanced IT systems, we don’t have the ability to put it into our workflow because our Commonwealth of Pennsylvania does not have APIs established yet to do that. We will have those in the next 3 months. We will automate that entire process, so that it doesn’t have to take the provider out of the workflow, but trigger those events in the background. So that they know if a patient is traversing multiple locations to try to get opioids.

Mr. GRIFFITH. I appreciate that, and I will have additional questions for the record.

Thank you, Mr. Chairman. I yield back.

Mr. BURGESS. The Chair thanks the gentleman.

And, Mr. Kravitz, I would point out that NASPER, which was the national PDMP authorized by this committee in 2005, for the first time it was funded in the last funding bill that we just passed
a few weeks ago. So, we are moving in that direction. It takes us some time, but we are getting there.

The Chair now recognizes the gentlelady from Illinois, Ms. Schaowsky, for 5 minutes for your questions, please.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

And speaking of what direction we are moving in, today's hearing on Medicaid and Medicare proposals to address the opioid epidemic actually comes on the same day that the House is considering the balanced budget amendment. I just want to comment on the effect that would have.

If enacted, the balanced budget amendment would undercut the structure of Medicare and Medicaid by opening both to dramatic cuts in funding. Republicans passed what I believe is a misguided tax bill that blows a $1.5 trillion hole in the budget, gives 83 percent of these tax cuts to the wealthiest among us. And we see Republicans offer budgets that would fill that gap by cutting more than $1.5 trillion in Medicare, Medicaid, and Social Security. And now, Republicans want to amend our Constitution to require that we can only spend in any given year what we raise in tax revenue in that same year, after just cutting those revenues. So, this is a serious threat to Medicaid, which is on the frontline of fighting the opioid epidemic, as we have been talking about.

So, let's see, who am I asking? Mr. Botticelli, what are some examples of the actual services that Medicaid programs cover for substance use disorder treatment?

Mr. BOTTICELLI. So, Medicaid—and I will talk specifically about a program that we have at Boston Medical Center——

Ms. SCHAKOWSKY. OK.

Mr. BOTTICELLI [continuing]. Where we have virtually 100 percent of our people who are Medicaid-eligible. That program serves over 700 people within the context of our adult primary care clinic. What we have been able to demonstrate through that is, at 12 months, we have 65 percent of people still engaged in treatment at 12 months or longer.

But I also think what is important, too, is, as I indicated, because of that program, we have been able to do a retrospective study of utilization of healthcare services prior to people getting treatment and, then, in the duration of treatment afterwards. What we have been able to show is we could actually reduce—emergency department admissions go down by two times and inpatient hospitalizations go down three times. So, not only do we see our ability to provide good, high-quality care for treatment, but, simultaneously, we are able to reduce healthcare costs for some of the highest utilizers of health care, not only within Boston Medical Center, but within our larger healthcare delivery system.

So, I think that is a really good example, and part of the reason that we are able to do that is through our Medicaid program, and largely because they also fund a whole host of medication-assisted treatment, a wide variety of other recovery support services that our patients need access to. So, I think it is a good example of the critical nature of our ability to execute high-quality care because of our patients' access to Medicaid.

Ms. SCHAKOWSKY. So, I am assuming, then—my next question, you sort of answered it in the positive—it would be the negative.
What would a drastic cut in Medicaid specifically mean for those enrollees receiving the care that you have outlined?

Mr. Botticelli. I think it would be devastating, and I don’t think I am overexaggerating kind of the impact that that would have for our patients’ ability to access care. I think it is very hard.

And I was actually the Director of Treatment Services in Massachusetts prior to healthcare reform and prior to Medicaid. So, I saw the issues that people had not only in terms of their ability to access care, but also some of the devastating consequences that we see.

I think Massachusetts is a good example of being able to achieve some modest reduction in overdose deaths, unlike many, many states across the country. And I think part of the reason that we are able to do that is because of our patients’ abilities to be able to access treatment when they need it.

Ms. Schakowsky. So, you are saying “modest”. Why isn’t it robust, for example, in lives that are saved?

Mr. Botticelli. Well, if you are one of the 10 percent of people that your life was saved in Massachusetts, that is robust. I think why I am kind of cautious is because deaths are still too high. Again, I think while we are all cautiously optimistic that a 10 percent reduction is good——

Ms. Schakowsky. It is good.

Mr. Botticelli [continuing]. It is moving in the right direction, it is still way too high. And we still had over 2,000 people in Massachusetts die in 2017, and that is just way too high, despite a 10 percent decrease.

Ms. Schakowsky. I am just going to skip to, what services can health homes provide for those with substance use disorder?

Mr. Botticelli. Actually, Mr. Douglas mentioned one. Vermont is a really great example of how you use health homes to not only increase access to treatment, but increase access in rural parts of the country. So, they use what is called a hub-and-spoke model where they induct people in the hubs and, then, move people to primary care sites in the spokes. And I don’t know the latest data, but they have been able to really significantly increase access to treatment. I think Rhode Island as well has utilized the health home model to dramatically increase access to treatment. So, I think a number of states have used this, but I also think it is really important, as we think about how do you push out treatment to rural parts of the country that don’t have a treatment program and don’t have providers. I think medical homes, some States have really implemented innovative programs to be able to do that.

Ms. Schakowsky. So, I am out of time. Mr. Douglas, so Vermont is an example of how it can work?

Mr. Douglas. That is correct, and it is spreading to other States. California, too, is doing it. It is an investment, and this is an important piece. The resource shortage can’t just be dealt with on substance use providers. We need to spread the best practices back into the physical health and the primary care, knowing that the expertise would be in the substance use treatment centers, but this hub-and-spoke, this idea of working together and providing the expertise and creating the incentives to do that through health homes
and ways to share. And telehealth and other opportunities are
great ways that we can better integrate the systems.
Mr. BURGESS. So, the short answer was yes.
Ms. SCHAKOWSKY. Thank you.
Mr. BURGESS. The gentlelady’s time has expired.
The Chair recognizes the Vice Chair of the subcommittee, Mr.
Guthrie, 5 minutes for questions.
Mr. GUTHRIE. Thank you very much. I appreciate it very much.
These questions are for Mr. Srivastava. Johns Hopkins Univer-
sity and the Clinton Health Foundation released a document in
2017 that contained a number of recommendations for combating
the opioid crisis. One recommendation was to support restricted re-
cipient programs, otherwise known as lock-in programs, for at-risk
populations. From what I understand, lock-in programs are de-
signed to restrict overutilization of opioids and to identify potential
fraud and abuse of controlled substances.
Mr. Srivastava, can you talk about if your organization has been
involved in a lock-in program and if you have found the program
to be useful in combating opioid abuse?
Mr. SRIVASTAVA. Thank you, Congressman.
In terms of lock-in programs, we actually support over 100
health plans across the country and serve their Medicaid and com-
commercial and Medicare needs. So, we have experience working with
Medicaid lock-in across the country. We also have our own special
needs plans in Florida, Massachusetts, New York, and Virginia.
Our experience has been in our special needs plans where within
Medicaid we have had the ability to lock in on prescribers where
there was a lot of overutilization. There was multiple providers as
well as multiple use within a period of time.
Today what we are finding is State by State there is different cri-
teria. So, for example, in Florida, you have to have three prescrip-
tions, three providers, and three different settings, and claims
within the last 180 days. But we found that lock-in allows for, one,
an integrated care plan to be developed for the individual. Two, it
eliminates a lot of drug-seeking behavior. And then, three, it allows
for transition beyond managing the pills themselves, but actually
helping the individual to get support cycle social support services
and treatment and recovery services afterwards.
So, we are finding that there has been good evidence that lock-
in programs work in Medicaid. It will be launched, I believe, in
2019 for Medicare as well. And so, general expectation is you will
see a broader user of that program.
Mr. GUTHRIE. OK. Thank you. And I have another question for
you. Some have expressed concern with going to the HIPAA stand-
ard for substance abuse/use disorder records for the purposes of
treatment, payment, and healthcare operations because they are
afraid the record will get into the wrong hands and they will be
fired from their job.
Can you tell me what are the activities that fall under these
three categories, so we have a better understanding of why it is so
important to have access to a patient’s record for treatment, pay-
ment, and healthcare operations?
Mr. SRIVASTAVA. So, confidentiality is critical and important. And
this kind of speaks to CFR 42 Part 2. Historically, all of how pro-
providers communicate and coordinate with health plans and with facilities to coordinate care has been to get a release under HIPAA to be able to maintain confidentiality to provide care.

And what is happening is we have stigmatized those individuals with substance use disorder and created CFR 42 as an added layer of protection. It has actually limited a provider's ability to actually coordinate care effectively.

And so, our recommendation is to think through and expand and modernize CFR to be regulated under HIPAA, which is confidentiality. But that, if an individual happens to have diabetes and has a substance abuse issue that they are seeking care from a provider, and then, they go to an outpatient setting or they go for treatment and recovery services, or they go to a dentist, that we are not having to, as a health plan be able to, or as a PCP be able to get permission from each individual provider to be able to coordinate the care.

At times, we don't know that that occurs. And so, as a result, there can be misuse, and as a result, can also be adverse outcomes.

Mr. GUTHRIE. So, if you use that information, what prevents an employer from having access to it?

Mr. SRIVASTAVA. Under HIPAA guidelines today, we are managing, as a health plan or as a provider, we are confidentially treating individuals who have cancer, individuals who might have AIDS/HIV, or any sort of kind of behavioral health SMI disorder, and we don't communicate that with the employers. So, we are kind of bound by HIPAA. We are also bound additively by CFR 42. So, from our perspective, it is confidentiality, and we are kind of trained as healthcare professionals not to be able to share that information beyond what is needed for a treatment plan and to be able to service the provider.

Mr. GUTHRIE. OK. Thank you. I thank you for your answers.

And I yield back my time.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back.

The Chair recognizes the gentleman from New York, Mr. Engel, 5 minutes for your questions, please.

Mr. ENGEL. Thank you, Mr. Chairman, for holding another hearing on this important topic.

In Westchester County, part of which is in my district, 124 people died due to opioids in 2016, and in the Bronx, New York, which is part of my district, more in New York have died of overdoses than in any other borough of New York City.

We must do more to turn the tide of the opioid epidemic, and we cannot hope to do that if we fail to recognize the importance of Medicaid. Medicaid covers nearly 4 in 10 non-elderly Americans grappling with an opioid addiction. Through the Medicaid expansion under the Affordable Care Act, states were afforded new resources to cover Americans living with substance use disorders and get them the treatment they need. We must continue to expand States’ capacity to combat the opioid crisis and take care to avoid hamstringing that capacity in any way.

This brings me to a number of bills we are considering today that I fear could hinder States’ ability to address this crisis, the Medicaid Pharmacy Home Act, the Medicaid Drug Improvement Act,
and the Medicaid Partnership Act. I worry that asking States to make complicated changes to their Medicaid programs in less than a year sets them up for failure. And since non-compliant States would be punished with FMAP penalties, States’ ability to deliver treatment and recovery services could be hampered as a result.

I also have concerns regarding the Medicaid Graduate Medical Education Transparency Act. In my opinion, the reporting required under this bill is overly prescriptive and burdensome and may take the limited resources states have for Medicaid GME and offer reporting that will not tell us very much. And I have heard similar concerns from stakeholders as well. After all, Medicaid spending constitutes just 16 percent of Federal spending on GME. So, this reporting would offer an extremely narrow picture of the training physicians are getting.

I also worry that the information gleaned from these reporting requirements could be viewed as a microcosm for State Medicaid programs’ holistic efforts to combat the opioid crisis, but it is my understanding that those efforts involve many facets of the healthcare system, not just physician training.

So, Mr. Douglas, I want to ask you, is that a fair assessment, that the efforts involve many facets of the healthcare system, not just physician training, and that information gleaned from these reporting requirements could be viewed as a microcosm for State Medicaid programs’ holistic efforts to combat the opioid crisis?

Mr. DOUGLAS. I am sorry, the question?

Mr. ENGEL. OK. Let me move on. I am not opposed to collecting more data on Medicaid GME or other GME programs. However, I think we need to be more thoughtful about the data we are asking states to collect when facing a shortage of providers, of said providers. But I don't believe this bill would address that, and solving the problem cannot be left solely to a group of specialists with specific training in substance use and addiction. A more comprehensive approach is needed. We need to be thinking about the full spectrum of providers and their roles in solving this crisis.

Mr. Douglas, let me try again. How can we improve and build our workforce so that said providers and others can help end this epidemic?

Mr. ENGEL. Great. As I noted in my written testimony, as well as the chairman mentioned, I think an important area we are focusing on, as a managed care organization at Centene as well as States, is around ways to make sure that we are educating providers and disseminating that education. Project ECHO is a great way of doing telementoring opportunities and really spreading, especially as it gets to rural and underserved areas. So, we have to focus both from making sure we are educating on the prevention side, but, then, as you noted, there has to be a continuum of service as the treatment modalities. From the lens of MACPAC that we have seen identified, there is a wide disparity, that you might have in Boston a larger rate of treatment modalities, but in many States the modalities aren’t all there. And so, the continuum of services on the treatment side from both outpatient to peer support, to MAT-related services, and, of course, as I mentioned before, there needs to be residential, where appropriate, on the evidence-based,
and that means eliminating the IMD exception. So, those are all approaches that need to be taken.

Mr. Engel. Thank you.

Let me quickly go to Mr. Botticelli, based on some of the comments that were made before I gave my question. Do you have any concerns about rolling back 42 CFR Part 2?

Mr. Botticelli. I do, both as a policymaker and a person in long-term recovery. Unfortunately, substance use disorders are different from other diseases. They are still highly stigmatized. They are subject to discrimination and criminal penalties.

SAMHSA, I think—and this is fully supporting the fact to give people good care, we need to integrate physical care with part of their substance use disorder treatment. I think all of us support better integrated and holistic care. But I do think a patient should have a right to consent to disclose their records. The Substance Abuse and Mental Health Services Administration actually just modified their regulations twice to support enhanced integration of 42 CFR Part 2 information, treatment information, into primary care records.

Mr. Engel. Thank you.

Thank you, Mr. Chairman.

Mr. Burgess. The Chair thanks the gentleman. The gentleman yields back.

The Chair recognizes the gentleman from Illinois, 5 minutes for your questions, please, Mr. Shimkus.

Mr. Shimkus. Thank you, Mr. Chairman.

Great to have you all here.

Mr. Botticelli, you were with the previous administration, were you not?

Mr. Botticelli. I was.

Mr. Shimkus. And what was that position again?

Mr. Botticelli. I was the Director of the White House Office of National Drug Control Policy.

Mr. Shimkus. Yes, great. Thank you for your service. And to segue now into what you do in Massachusetts, I think it is important. And this is an all-hands-on-deck process. Obviously, we are trying to do our best to affect the public policy and to help you all do your job.

But let me go to, in your testimony you mentioned one report which found only about half of the State Medicaid programs currently cover non-pharmacological alternatives to pain such as, as you have talked about, cognitive behavior therapy and physical therapy. Mr. Douglas, the Committee has heard from Medicaid directors about the importance of Federal funding for evaluation of non-pharmacological alternatives to build strong empirical basis for making coverage decisions.

Could you both please talk about the degree to which you think this research about the utility and cost-effectiveness of non-opioid alternatives already exists and what more Congress or CMS can do to help state Medicaid programs have the information needed in making coverage decisions that ultimately impact patients?

Mr. Botticelli. Great. I will start and, then, turn to Mr. Douglas.
Throughout the course of our work area, I think we have to be very careful, while we know we want to make sure that we are diminishing opioid prescribing, that we are giving patients access to really good pain management therapies. I think we are hearing more and more stories, quite honestly, of patients in legitimate pain not being able to access non-pharmacologic approaches. And so, I think we have to couple our efforts with not only opioid reducing, but making sure that we are giving people good access. We do have a number of evidence-based—and we need to continue to research non-pharmacologic approaches. We know acupuncture works. We know physical therapy works, yoga, exercise.

And so, again, I think if you talk to our clinicians at Boston Medical Center who deal with both substance use disorder and pain, that because our Medicaid program actually supports a wide variety of non-pharmacologic approaches, we are able to give patients good pain care and at the same reduce opioid prescribing.

Mr. SHIMKUS. Mr. Douglas?

Mr. DOUGLAS. Yes, I would just echo the points of Mr. Botticelli that there needs to be more work on this. Both from a state as well as an MCO perspective, we are continuing to want to ensure that we are doing evidence-based practices on treatment modalities. And that gets to being able both from a state policymaker to be able to give the Medicaid agencies the ability to test new treatment modalities or ensure that those modalities are being executed on. And so, without the evidence, you have disparity across States as well as you have a harder time for MCOs to get the best practices and the right care and the right setting to be provided. And so, we encourage there continue to be work in this area.

Mr. SHIMKUS. Yes. So, I will ask you to take this back and maybe submit some more information. And I appreciate that, but the question is, what more can we do legislatively or what can CMS do to help fill this space to give the information needed to help?

So, my follow-up question is going to be, one of the most dangerous things about opioids is that they are cheap or at least much cheaper than non-opioid alternatives, some. And your testimony and Mr. Botticelli also underscores the need to complement the largely successful efforts to reduce opioid prescribing. We need to ensure patients have access to non-pharmacological pain management practices. To that end, several of us on this committee have expressed concerns about the declining Medicare reimbursements for certain pain management procedures frequently performed by the ambulatory surgical centers because they are more expensive.

Can you talk about the importance of incentivizing non-opioid, non-pharmacological treatments and stemming the tide of opioid addiction, particularly as it relates to patients' access, Mr. Botticelli? And then, I want to go to Mr. Kravitz to answer this.

Mr. BOTTICELLI. I think part of the reason that we are in the predicament that we are in is that writing a prescription for opioids is not only far cheaper, but it is also far easier for the clinician to be able to write a prescription versus having a conversation with their patient on pain and pain expectations and pain management.

So, I think both CMS and Medicare need to do everything that they can, quite honestly, to provide financial incentives that drive
toward those other kind of pain management therapies. While there might be some modest cost increases in the short term in terms of those strategies, I think the return on investment of not getting people addicted and not having to go through all the other medical expenses probably far outweighs any modest increase in cost for those therapies.

Mr. SHIMKUS. Thank you.

And, Mr. Chairman, can Mr. Kravitz answer that?

Mr. KRAVITZ. Yes. So, at Geisinger Health System, we are very much in a consultative measure with our patients as well on the same topic. We take the time to counsel them and to look at all other alternatives for treatment for these patients. So, especially chronic disease patients, as I stated in my opening statement, we utilize things like rehabilitation, Tai Chi, yoga, things of that nature, to alleviate pain. And they have been proven to be successful.

In cases where they are not the case, where opioids do have to be prescribed, we are very careful and judicious to not extend an extensive prescription quantity for those patients. So, they don’t have the opportunity to get addicted to opioids.

Mr. SHIMKUS. Thank you very much.

Thank you, Mr. Chairman.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back.

The Chair recognizes the gentlelady from California, Ms. Matsui, 5 minutes for your questions, please.

Ms. MATSUI. Thank you, Mr. Chairman.

And I want to thank the witnesses for being here today.

And I also want to say, Mr. Chairman, thank you for holding this third hearing today on legislation to address this opioid epidemic. It is so important that we are focusing on a variety of perspectives on how to solve this crisis. We know the problem is multifaceted and the solution will be, too.

And I just want to also point out the importance of the Medicaid program in addressing this crisis. Medicaid serves a large proportion of the population with substance use disorder, and any effort to cut the program’s funding will severely jeopardize access to those services.

I also must say, while we must act urgently, I am concerned that, if we move the nearly 70 bills through our committee too quickly, some of the policies will have unintended consequences that will contribute to the problem rather than the solution. And I look forward to further discussions with my colleagues and stakeholders as we ensure that these policies are going to be as effective as possible.

I think that the biggest potential for transforming our healthcare system lies in the power of technology. Electronic health records have the potential to streamline care, increase coordination of care across providers, and aggregate data for population health management and research purposes. Telehealth provides the opportunity to get care to patients faster or in cases where they can’t otherwise have the access to the appropriate provider.

This has a huge potential to help us address the opioid epidemic. Technology can help us to integrate the behavioral health care and physical health care, treating a person as a whole and ensuring
that all of their needs are met in a timely manner. Most people with a substance use disorder have an underlying mental health issue and/or physical condition. If all conditions are not addressed, we will have less success in treating the addiction.

One of the ideas I am working on with Representatives Mullin and Blumenauer is how we can assure that substance use information can be shared for the purposes of care coordination and patient safety without infringing on patient privacy rights. None of that work will have any effect, though, if substance use and behavioral health providers don't even have electronic health records to facilitate the data sharing.

That is why I co-lead H.R. 3331 with my colleague on the Ways and Means Committee, Representative Jenkins. Behavioral health providers were left out of the Meaningful Use Program which encouraged adoption of electronic health records by hospitals and doctors. This would certainly extend an incentive to behavioral health providers via a demonstration project.

Mr. Kravitz, my understanding is that your organization has been successful as a result of investing in electronic health records. Could you please describe how electronic health records have improved quality of care and reduced cost?

Mr. Kravitz. Yes, I am happy to, Congresswoman. So, we have invested in electronic health records back in 1995. I think we were one of the earlier adopters of the EPIC electronic health record system, which has been predominantly used between EPIC and Cerner across the country with all scripts.

We have also invested heavily in analytics. In fact, we have a big data platform similar to Google, and we look at that data all the time. We analyze the data very carefully. In fact, one of our scenarios, we did a 10-year study with Geisinger Health Plan, which has 580,000 members in our population. We looked at that data very, very carefully, and that is where we recognized and realized that patients on opioids that were part of that process had higher levels of acute care stays before they had overdoses as well as ED visits were tremendously increased over the last 22 to 12 months prior to an overdose occurring.

So, information is key. The ability to integrate that data and interoperate that data with other systems is extremely important.

Ms. Matsui. So, you believe that this will be helpful to extend this to behavioral health providers?

Mr. Kravitz. Absolutely.

Ms. Matsui. OK, great.

Mr. Kravitz. Absolutely.

Ms. Matsui. Well, let me just right now, also, submit for the record here a letter from the Behavioral Health IT Coalition, which includes the American Psychological Academy, NAMI, Mental Health America, the National Council of Behavioral Health, in support of H.R. 3331, for the record.

Mr. Burgess. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Ms. Matsui. I also want, Mr. Douglas, thank you for your past service as a Medicaid director.

I currently have another bill coauthored with my colleague, Representative Harper, that will allow behavioral health clinics to reg-
ister with the DEA to be able to use telemedicine to prescribe controlled substances, increasing access to medication-assisted treatments in our communities.

Can you describe the benefits of medication-assisted treatment and detail the current barriers you see that might prevent its expansion?

Mr. DOUGLAS. Thank you.

So, as I mentioned in my written testimony, the expansion of medication-assisted treatment is a really important component of the overall continuum, especially as we learn and have substance use treatment providers working with primary care. As you said, being able to create more technology interfaces will be an important way to work across this idea of a hub-and-spoke with our primary care and sharing data back and forth. And so, as we are looking at more a holistic approach to medication-assisted treatment and primary care integrating with it, what you are laying out would really solidify and improve the infrastructure.

Ms. MATSUI. OK. Thank you.

And I have run out of time. I yield back.

Mr. BURGESS. The Chair thanks the gentlelady. The gentlelady yields back.

The Chair recognizes the gentleman from Texas, Mr. Barton, 5 minutes for your questions, please.

Mr. BARTON. Thank you, Mr. Chair.

I have a question for the chairman before I ask a question of——

Mr. BURGESS. The answer is no.

[Laughter.]

Mr. BARTON. I was going to say, did you think you are the greatest Health Subcommittee chairman we have ever had?

[Laughter.]

Mr. BURGESS. No, that would be Governor Deal.

Mr. BARTON. We have got about three dozen bills that we are looking at. Is it your plan to move all of these bills individually, collectively, some of them, none of them? What is the——

Mr. BURGESS. Well, as you will recall from my opening statement yesterday and previous opening statements in previous hearings that we have had—I am assuming the gentleman is yielding to me for an answer.

Mr. BARTON. Yes, sir, of course. I wouldn't ask a question if I didn't want you to answer it.

Mr. BURGESS. I don't have a precise answer to your question, but the fact that we are considering so many bills, and some of the bills we are considering are, in fact, still in draft form, we do want to be inclusive. We have done a significant amount of outreach. As you will recall, we had a many-hour hearing in this subcommittee in October where we invited every Member, not just from the committee and subcommittee, but from the entire Congress to come and share with us their thoughts on what the opioid epidemic looked like in their districts and how they were reacting to it, and ideas that they had. As a consequence of that interaction, a number of ideas were presented to the subcommittee, and we have been over the last several months going through those. Right now, most of them are in individual bill forms. It is quite likely there is some duplication; there is some consolidation that is available.
And as you will recall from bills like the Comprehensive Addiction Recovery Act from the last Congress, the Cures for the 21st Century, ultimately, numerous bills were consolidated into one larger bill. That could still happen, but also a part of me wants to consider them as individual bills. So that, as we go through at least the subcommittee markup and the full committee markup, there will be ample opportunity for people's ideas to be heard.

Mr. Barton. OK.

Mr. Burgess. I hope that satisfies your request for information. And I will yield back.

Mr. Barton. Well, you used half of my time. Well, I think it is important to give the subcommittee and the stakeholders some idea of the potential plan. And I wasn't here yesterday. I was at the Zuckerberg hearing on Facebook. So, I am just asking for my own illumination.

One of the bills is a bill by Mr. Tonko, H.R. 4005. He has actually introduced it. He is ahead of the curve here, which is kind of normal for him. He is one of our more energetic Members.

But this particular bill, I wish he wasn't so energetic, actually, because it allows Medicaid programs to receive matching Federal dollars for medical services to an incarcerated individual, which in Texas means somebody in jail for the 30-day period right before they are released. I have a real concern about that for a number of reasons.

So, I am going to ask Mr. Douglas if, under current law, the states couldn't ask CMS to use their 1115 waiver for a demonstration project to test this idea, instead of actually passing a federal statute.

Mr. Douglas. So, current Federal law prohibits payment, Medicaid payment, for individuals who are in prison, except for the one exception relates to for inpatient settings when they leave the actual prison facility and go to an inpatient setting. And that is clear in Federal law. So, even under an 1115 waiver, that could not occur.

Now, that being said, there are creative alternatives. Centene, as a managed care plan, are working in Ohio, for example. Ohio is very concerned, given recidivism. The high rate of individuals within the prison system, as they transition, have needs of social services, medical care, behavioral health, to do early transition work as a responsibility, knowing that they are going to be assigned to a managed care plan, and the managed care plan is going to have increased costs if they don't work in the transition. And so, that is occurring right now in states. And other states are doing that. There are different creative approaches, but there is no ability from a payment standpoint right now under Federal law.

Mr. Barton. OK. Well, thank you for that answer.

In my one second that I don't have, I want Mr. Kravitz to talk about e-prescribing and if he thought that could help in some other areas, in addition to what has been done under his business.

And I am only asking this question because the chairman took two-and-a-half minutes of my time.

[Laughter.]

Mr. Kravitz. So, we feel at Geisinger e-prescribing is very valuable to our organization. It is very much a patient or customer sat-
isfier as well compared to the old process of a paper script that of-
tentimes was not available to them and would cause multiple visits
to come back to a physician's office and able to get those.

What I can tell you is use of e-prescribing is very much endorsed
by our physicians. The second-factor authentication is seamless,
works very well. And that is why we are able to reduce the amount
time for prescribing an opioid prescription from 3 minutes to 30
seconds, because of the new process that we followed.

What I can also tell you is the first day—and we, typically, at
Geisinger don’t do things small, unfortunately—we did not do a
proof-of-concept with a small group of physicians. We hit 1330 phy-
sicians day one to enroll them in the program, and we have other
physicians that are requesting to be part of this process because it
is so efficient and it has worked so well for them.

The other point that I made about the PDMP, we are clamoring
to get the APIs or the integration points, so that we can do a lot
more automation behind the scenes and not obstruct the workflow
process or the physicians, so they could see more patients, to pro-
vide better quality care for more patients. That will be coming in
the next 3 months, and we are very eager to have that happen, so
that we can encourage that be part of the process.

Mr. Barton. Thank you.

Thank you, Mr. Chairman, for your courtesy.

Mr. Burgess. The Chair thanks the gentleman.

The Chair recognizes the gentleman from Massachusetts, Mr.
Kennedy, 5 minutes for questions, please.

Mr. Kennedy. Thank you, Mr. Chairman. Thank you for con-
tinuing the hearing.

Thank you to our witnesses for being here.

Mr. Botticelli, wonderful to be with you again. Thank you for
your service and your outspokenness on these incredibly important
issues.

I know we are here on a series of several dozen bills that are be-
fore this committee, which I hope many of them will see action, in-
cluding, Mr. Chairman, our own. Thank you for putting that on the
list.

I wanted to get your thoughts and members’ of the panel
thoughts on some of the broader priorities of this administration,
recognizing that the administration has acknowledged that there is
an opioid and behavioral health epidemic across this country. They
have indicated that they want to prioritize it. Yet, we have also
some policies come out of this White House that I was curious to
get your thoughts on. I did have a chance to question our CMS wit-
ness yesterday. So, maybe just going right down the list.

And, Mr. Botticelli, I was wondering, given your expertise on this
issue, can you explain to me how cutting Medicaid by $800 billion,
as the Trump administration budget does, is effective in addressing
behavioral health and addiction?

Mr. Botticelli. First of all, thank you, Congressman, for the
question and for your leadership not only here, but in Massachu-
setts.

I think we have broadly acknowledged that this is a public
health crisis that we have and we have got to focus these issues
largely on health responses to this issue. Tantamount to that re-
response is making sure that people have adequate access to insurance and coverage. And when you ask historic data, when you look at why people can't get treatment, the No. 1 reason why people can't get treatment is because they don't have adequate access to insurance.

Mr. KENNEDY. And so, does cutting $800 billion from Medicaid help or hurt?

Mr. BOTTICELLI. It hurts, and it hurts dramatically.

Mr. KENNEDY. And I am sorry to cut you off; I just want to get everybody else on the record.

Mr. Douglas, how would you respond to that? And be quick, just because I have got a couple of more of these.

Mr. DOUGLAS. Yes. No, I am going to turn this around. As you know, as a former Medicaid director and as a managed care, our responsibility is how to use the resources most effectively as possible. And so, the idea of cutting $800 billion, there are ways to achieve savings, but it has to be rational.

Mr. KENNEDY. So, does a $800 billion cut help or hurt an administration's ability to——

Mr. DOUGLAS. I can't answer without understanding what the flexibilities and the ability to provide the right services and the right setting.

Mr. KENNEDY. And, Mr. Guth?

Mr. GUTH. Yes, so this is a complex situation we are dealing with. This really goes back to the first question we had before this panel. And that is about the disparity in presentation with Medicaid and with private insurance. For a long time, people with private insurance didn't have access to substance use treatment, or very limited access. Most of the people I know that went through private insurance with these issues ended up spending college funds and retirement funds, in order to get care.

Mr. KENNEDY. So, Mr. Guth, would you support greater enforcement of mental health parity?

Mr. GUTH. I think we have got to do everything we can right now, Congressman, to ensure that people have access to care. And for the majority of Americans, that means access through some form of third-party coverage, and for many of them, that means either Medicaid or some other form of Federal funding.

Mr. KENNEDY. Mr. Kravitz?

Mr. KRAVITZ. I would say at Geisinger Health System we treat all patients equally. Eighteen percent of our patient population in our provider network are medical assistance patients; 44 percent are Medicare. We have a number of programs, and there are care management programs that address this. It would be my impression that it would hurt.

Mr. KENNEDY. Sir?

Mr. SRIVASTAVA. From Magellan's perspective, we fundamentally believe that health care needs to be not just below the neck, but above the neck. And so, it is a full whole patient approach. And so, to the extent we have adequacy of funding, to be able to have behavioral health, improve access for behavioral and physical health issues, then we are a proponent of that.
Mr. KENNEDY. I have got about a minute and a half left and two more issues I want to address with the panel. So, Mr. Botticelli, I will address them both to you, and just go down the line.

Given your expertise, how long does it take for somebody to recover from a mental/behavioral illness?

Mr. BOTTICELLI. So, this is a chronic disorder, and one could argue that it is a lifelong issue. The biggest predictor of success is duration and time in treatment.

Mr. KENNEDY. And so, two policies put forth by this administration, lifetime caps and work requirements, if you think work requirements could, in fact, be helpful to people suffering from mental/behavioral illness, I would ask anybody on the panel to point me to one single study that says so. So, your opinion on those two, lifetime caps and work requirements, coming from this administration?

Mr. BOTTICELLI. So, lifetime caps seem to me to be a violation of parity because I think that we understand that that has been a historic discriminatory tool that insurance companies have implemented to not treat this as a chronic disease and give people long-term care.

Mr. KENNEDY. OK. And work requirements?

Mr. BOTTICELLI. So, one, we know people on Medicaid generally now are working, and often working more than one job. And I think the ultimate goal of treatment, quite honestly, is to get people and restore them.

Mr. KENNEDY. Is there any study that you are aware of that says a work requirement increases health, understanding that people who are working can be healthier, but that causation goes the other direction?

Mr. BOTTICELLI. I have nothing.

Mr. KENNEDY. Mr. Douglas?

Mr. DOUGLAS. I don't know of studies on that. What I say is that this gets to the issue of underlying social determinants and making sure from States, as well as Medicaid organizations, Medicaid managed care plans, that we are working on how to engage people into ensuring they are getting both the right social and getting back into the workforce.

Mr. KENNEDY. Mr. Guth?

Mr. GUTH. Yes. So, we were working with two of our States that have these, are implementing work requirements, and the devil is in the detail because what you don't want to do is insist that somebody who is very, very sick get a job before they can have access to treatment. On the other hand, the plans that we are working with in the two States that we work with, Indiana and Kentucky, we are seeing administration—understanding that and making sure that we are not asking people who are actively sick to become employed before they become stable. So, I think it's all about the implementation.

Mr. KENNEDY. The CMS witness yesterday said they are trying to put patients before paperwork. Is there a work requirement initiative out there that does, in fact, lead to less administrative burden for somebody that is suffering from mental/behavioral illness to make sure that they stay on Medicaid?

Mr. GUTH. Can you ask that question again?
Mr. Douglas. What I would say is that what we are seeing in Indiana as well as in Arkansas, there are exceptions for certain populations such as those with substance use disorders.

Mr. Kennedy. I am about a minute over time. Thank you for your generosity, Mr. Chairman.

Mr. Burgess. That is all right. I have subtracted it from Mr. Latta’s time.

Mr. Green. Mr. Chairman, I ask unanimous consent—

Mr. Burgess. Oh, I beg your pardon. Does the gentleman have a unanimous consent request?

Mr. Green. The gentleman does. I ask unanimous consent that a letter from the telehealth and technology stakeholders and a letter from treatment providers in support of the access to telehealth services for their opioid and use disorders, I ask unanimous consent to place it in the record.

Mr. Burgess. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. Burgess. The gentleman from Ohio is recognized for 5 minutes for your questions, please, Mr. Latta.

Mr. Latta. Thank you very much, Mr. Chairman. And thanks again for holding this hearing today, because, again, combating this opioid epidemic is something we are all in and we have to do, because we are looking at these very sobering statistics that 115 Americans are dying every day in the State of Ohio. And I hate to keep repeating these statistics, but in 2015 we lost 3,050 people. In 2016, that number went up to 4,050. And then, the fiscal year ending at June 30th of last year, it was 5,232. So, it is an epidemic that we have got to take on and fight.

And I appreciate you all being here today.

Last week I held a roundtable in my district with local pharmacists to discuss the opioid crisis in Ohio. Most of the pharmacists agreed that prescription limits would help prevent addiction. Overprescribing of opioids for acute episodes of care can have dire consequences as pills can be diverted, misused, and perpetuate addiction.

In response to this problem, over 20 States, including Ohio, have adopted laws limiting the number of pills that a patient new to therapy prescribed an opioid for an acute episode can receive. These laws reflect guidelines promulgated by CDC which note that, for the vast majority of acute procedures, 3 to 7 days’ worth of therapy is sufficient. They also respect the judgment of the prescribing practitioner by providing for exceptions if a prescriber thinks in his or her best judgment that a longer duration of treatment is medically necessary.

Furthermore, we recently saw CMS finalize a similar policy for beneficiaries and wrote in Medicare Part D, driving home the severity of the problem and the belief that such rules will have a measured impact on opioid diversion and misuse.

Mr. Douglas, what impact would expanding this type of policy beyond Medicare have on the diversion and misuse of opioids?

Mr. Douglas. As I noted in my written testimony as well as earlier, we are doing a lot within Centene, as well as a lot of States are working on making sure that we are reducing the limits on duration as well as refills. And so, creating clear policies on that,
where we have been able to do that and work with the State, it helps on overprescribing as well as reduced inappropriate utilization. And so, this is an important area that we are seeing. In many States we can work and partner with our State agencies and be able to put in place those types of utilization controls. But incenting States and incenting managed care organizations, that is an important part of the overall continuum of how we need to prevent this epidemic.

Mr. LATTA. Thank you.

Mr. Guth, my district ranges from densely populated cities and towns to very rural areas. And we all know that the opioid epidemic knows no boundaries. Therefore, health access in rural America is vital, especially as it relates to the opioid epidemic. It is hard enough for individuals to make the decision to overcome addiction without the added barriers to access to treatment due to their location.

Would you go into some detail about the barriers are out there for opioid treatment for individuals in rural communities and what they face, and how we have to address those issues?

Mr. GUTH. Thank you. Yes, Congressman. There are several issues that jump out. One is that we have a shortage nationwide of professionals who are certified and trained in addiction services. So, that permeates the whole country, and it is most acutely felt in our rural areas.

Centerstone, most of the communities we serve are very small rural communities across the five states that we serve. So, we are very attuned to this issue.

Telemedicine can make a huge difference. There are current challenges with telemedicine, but we have been involved with telemedicine services since the early ‘90s. And we would wheel in these great big, giant monitors on these enormous carts. That was really to address the issue of access to care in our rural areas. In many cases it was the first time we could get a child psychiatrist into some of these communities. The very first time.

So, this issue is true with opioid use as well. We have to be able to provide expert care into our rural communities, but we have to address the overall shortage of practitioners nationwide in order to do that.

The other is we have to also recognize that there are other specialists involved in this care that are very important. Mr. Douglas mentioned peer support services. Those are critical, and we find that those services, if we can get them funded, which is very spoty, if we can get those services funded, we can provide some really vital linkages in our rural communities. We generally can have access to those individuals.

So, telemedicine, we are using apps right now to help people be connected remotely from their service provider. But when somebody is dealing with an acute psychiatric disorder or an acute addiction challenge, asking them from a rural community to drive hours into an urban area to seek service is really an insurmountable barrier for most of them. And what they will do is they will end up in the emergency room in a really critical state.

So, those are all issues that I think we would need to address. Technology plays a role. Workforce improvements play a role. And
the other is we really do need to be advancing the use of peer specialists. And we found peer specialists—we have got the data—peer specialists make a huge difference in the continuum of care.

Mr. LATTA. Thank you very much. Mr. Chairman, my time has expired and I yield back.

Mr. BURGESS. The gentleman is correct, his time has expired. Does the gentlelady from Florida wish to be recognized?

Ms. CASTOR. Yes, sir.

Mr. BURGESS. The gentlelady from Florida is recognized, 5 minutes for questions, please.

Ms. CASTOR. Well, thank you, Mr. Chairman.

And thank you to all the witnesses. I have been monitoring this hearing from another E&C hearing, and I am heartened by the discussion and the commitment, particularly relating to Medicaid and Medicare, and how we have to strengthen and modernize Medicaid to tackle all these challenges that we face, particularly opioids.

And I noted some of the discussion, coming from Florida, on the difference in treatment between expansion States and non-expansion States. We have hundreds of thousands, if not millions, of Floridians who really would benefit with consistent treatment, if we had expanded Medicaid. So, I know that is going to continue to be an issue.

A lot of these bipartisan bills are very positive, in my opinion, and I have heard what you have said about a number of them. But I don't think we are yet at the scale we need to really tackle the problem. I have heard others talk about a Ryan White type of commitment, something that is dependable and consistent moving forward that aren't relying on the budget battles of the Congress, so that providers and law enforcement, everyone across the board can really tackle the problem the way we need to.

Does anyone have a comment on that and about creating more of a Ryan White type of consistent commitment?

Mr. KRAVITZ. I will just mention this: I think when we look at the financial crisis, one of the things that our medical director points out is that a huge amount of the resources we are spending, we are spending on people that are returning for care. They are returning for care because they didn't get proper care to begin with. And we also look at the cost that we are spending in emergency rooms and acute care hospitalizations for folks that have untreated or undertreated substance use disorders or psychiatric disorders.

And I appreciate the breadth of bills that are before this committee and the work that everybody here has done on this crisis. But I think this is a huge call to action for all of us. And it is not just about doing more of what we are doing. We have to change.

I want you to think about this. I represent one of the largest non-profit providers in this space nationwide, and we are saying to you we need more regulation in this field; we need to be held to a higher standard; we need to be accountable for outcomes, and we also need to be accountable for providing a full continuum of care, so that people get the care they need, not the one specialty service that a provider has found a business model to support.

So, long answer to your question. Absolutely, it should be a huge call to action. We can't let this epidemic continue to rage across this country. This is a complex problem. It didn't happen overnight.
You heard the talk today about the different presentations, why people get into addiction to begin with, whether it is because of unmanaged pain or because of a co-occurring psychiatric disorder. There are lots of reasons for it. This is not a simple solution. But I would say a big focus needs to be on we have got to quit doing things that don’t work, and also understanding that the investment we make here will be more than realized with the savings in other areas, not even just the social impact of these issues, but in the medical costs in other areas of health care.

Ms. CASTOR. Thank you.

Mr. KRAVITZ. I hope that answers your question, Congressman.

Ms. CASTOR. Yes, and I have one more question, but if somebody wants to add quickly—yes, sir?

Mr. BOTTICELLI. For many years I presided over the treatment system in Massachusetts. I think if you talk to many providers, while grant funding is great, having a stable insurance-based program really ensures that we are going to have—we have been talking about provider workforce here and how critical it is. So, I think we need to make sure that we particularly ensure Medicaid coverage for people with substance use disorders. I think grants are great, but providers, I think, are often reluctant to get into this business——

Ms. CASTOR. Yes.

Mr. BOTTICELLI [continuing]. And stay in this business without a stable insurance base from which to build.

Mr. DOUGLAS. And if I could just say that, from both a state as well as an MCO, the idea of, well, Ryan White is really a trusted and needs to be an integrated approach. And so, looking at this through the lens of not creating a siloed solution, but how it integrates into the continuum of health and behavioral health.

Ms. CASTOR. Yes. Thank you.

Mr. Srivastava, in your testimony you mentioned that the number of physicians that prescribe MAT pales in comparison to providers able to prescribe oxycodone. And SAMHSA estimates over 48,000 providers currently certified to prescribe MAT versus 900,000 providers prescribing oxycodone. The lack of providers is undoubtedly more extreme in areas with a high proportion of Medicaid beneficiaries or in rural areas. How can we both increase the capacity to prescribe evidence-based treatment like MAT and realize the benefits? Could you expand specifically on the key lessons Magellan learned working in Pennsylvania and how that could be expanded elsewhere?

Mr. Srivastava. Absolutely. So, in Pennsylvania, for example, we recently launched, in partnership with the governor, we provide county-based behavioral health services. And so, we have created 20 centers of excellence which look at both primary care coupled with behavioral health care in an integrated fashion, connected by telehealth, and all evidence-based. And it allows for substance use disorder to be kind of effectively treated and managed. We also partner with Geisinger as well on some behavioral health——

Ms. CASTOR. And you had a specific recommendation on a temporary FMAP increase?

Mr. Srivastava. Correct. So, roughly, about 900,000 doctors today are licensed to be able to prescribe. Only 48,000 can pre-
scribe MAT services. So, there is a need to be able to, one, educate more providers and, two, to be able to potentially offer a pay bump, if you will, in order to incent those providers to take 8 hours out of their day to get certification and, then, training wrapped around that as well. And so, our sense is that there should be funding set aside to be able to drive more certifications, so that providers know how to prescribe medication-assisted therapy. We would augment that with tele-behavioral health, digital therapy, text therapy, and coupled with peer supports and care coordination.

Ms. CASTOR. Thank you. I will yield back.

Mr. CARTER [presiding]. The gentlelady has yielded.

The Chair recognizes the chairman of the Full Committee, the gentleman from Oregon, the Honorable Mr. Walden.

Mr. WALDEN. Thank you. Thank you, Mr. Carter. I appreciate it. And thanks to all our witnesses. Sorry I wasn’t here at the beginning. We have a concurrent hearing going on with the Secretary of Energy on energy-related issues before the Committee. But we really appreciate your participation.

So, I have a couple of questions I wanted to make sure and get in this morning. I think we all recognize the importance of ensuring that patients in Medicaid with substance use disorder have access to a continuum of care. One of the bills before the Committee is a targeted proposal that would remove a barrier to care and allow care in an IMD for up to 90 days in a 12-month period. Now this allows for longer treatment periods for all beneficiaries, not just selected subpopulations. And we believe this is budgetarily responsible as well. Virtually every stakeholder group that I have met with suggests that some of the IMD exclusions should be repealed or at least recalibrated, since residential treatment may be needed for some beneficiaries with substance use disorder.

So, my question for each of you is, do you agree that the bill before the Committee which offers a partial repeal of IMD is a helpful step to ensuring that Medicaid beneficiaries receive the care that they need? So, do you think this makes sense? We will start with you.

Mr. BOTTICELLI. Chairman Walden, I think while we are trying to do everything that we can to expand access to treatment, and particularly looking at Medicaid, I think just looking at the categorical waiving of IMD requirements, quite honestly, I think has a potential to exacerbate our problem.

Mr. WALDEN. Why is that?

Mr. BOTTICELLI. Well, one, I think we want to ensure, and I think CMS’s approach to looking at this issue through the 1115 waiver I think makes a lot of sense. Because what they have been saying to states is you need to demonstrate to us that you are not just providing residential and often expensive levels of care, but that you have a full continuum of care, outpatient services, medication-assisted treatment.

The other piece, too, and I think we have seen this and we are all talking about increasing access to medication-assisted treatment, but the reality is that only about 20 percent of our programs now provide access to medication-assisted treatment. And so, I worry that we are, in our efforts and, then, I think our good intents to expand access to treatment, we are focusing not necessarily on
the most effective treatment needed for people with substance use disorders——

Mr. WALDEN. All right.

Mr. Botticelli [continuing]. Which is often outpatient care.

Mr. WALDEN. Mr. Douglas?

Mr. DOUGLAS. So, I agree with a lot of what Mr. Botticelli said, but I would say the waiver process is still cumbersome. I have gone through it from California, seen it in other States. The regulation on the managed care side doesn’t go far enough.

That being said, so the idea of eliminating the IMD rule on substance use is very important from an MCO, and States support it, but it does need to be part of an overall continuum. It can’t be siloed because there are many cases where residential is not appropriate. We need to ensure that we are using ASAM evidence criteria and other treatment modalities within that and creating the right incentives——

Mr. WALDEN. Right.

Mr. DOUGLAS [continuing]. That there is in a continuum.

Mr. WALDEN. All right. Mr. Guth?

Mr. GUTH. So, I’m just going to reiterate very quickly some of the same things you have heard. We think it does need to be expanded. But I think, absolutely, we must have requirements on continuum of care, accountability around outcome, really criteria that places people in the right level of care. What we are all worried about—and I know this is the issue around this bill—is that, suddenly, we are going to have this plethora of very expensive care that is now just exploding across the country.

Mr. WALDEN. Right.

Mr. GUTH. The answer to that is to ensure that when these expansions are permitted, that they are coupled with requirements around continuum of care and documented evidence that people are placed in the least restrictive care appropriate to their presentation. That is known. We can do that, but we don’t do it in isolation. Like everything else we have talked about today, these are complex issues. So, we have to have solutions that have the complexity associated with them.

Mr. WALDEN. All right. Thank you.

Mr. Srivastava. In short, although we have the 1115 waiver process, supportive of an overall process. However, it is just one kind of solution in a suite of solutions. So, I don’t want to overprescribe the fact of the value created with this. It could create capacity, but at a cost that may not be sustainable.
Mr. WALDEN. All right. My time has expired again. Thank you all for your testimony and your answers to that question and others today.
I yield back.
Mr. CARTER. The gentleman yields.
The Chair recognizes the gentleman from Florida, Mr. Bilirakis, for 5 minutes.

Mr. BILIRAKIS. Thank you. I appreciate it, Mr. Chairman.
And I wanted to thank Mr. Botticelli for coming down to my district in the Tampa Bay area when he was the drug czar about a couple of years ago. It was very informative, the forum we had. So, I appreciate it very much.

Also, I want to talk about and I want to ask some questions on the lock-in. I know we have covered it a little bit, but I have a couple of bills with regard to that. So, I want to start with Mr. Douglas, if that is OK.

Yesterday CMS talked about the importance of lock-in as a tool to manage prescription drug abuse in Medicare Advantage and Medicare Part D. Lock-in is not new and has been used for years in Medicaid and commercial insurance. Since you run a Medicaid managed care plan, you might be able to talk about how lock-in programs operate and what you have seen.

Does your plan run a Medicaid lock-in program and, if so, can you tell me how you structure the program and what triggers you are looking for in identifying an at-risk beneficiary, please? Thank you.

Mr. DOUGLAS. So, yes, as you said, lock-in programs have been around for a long time, both from a State agency as well as from managed care programs. And Centene, in our States we have over 10 States where we do have lock-in programs. We work in partnership with the Medicaid agency to structure and be able to create the policies and procedures. There is no, I would say, one-size-fits-all approach to lock-in programs. In some States, the lock-in is around the prescriber; in other cases, it is about lock into a pharmacy. Or, it could be both prescriber and pharmacy being locked in and having the member have one prescriber and one pharmacy. So, it varies.

Now there are triggers in terms of the types of utilization, looking at how, for example, in one criteria I will go through they are looking at using three or four pharmacies within a 30-day period. Three or more prescribers within a 30-day period become triggers, utilizing five or more controlled substances in a 30-day period, different drug classes. So, we look at all different types of triggers and create that policy.

In many cases, the pharmacy board is part of the process, too, to make sure that they are integrated into the policy development along with the Medicaid agency. We, then, also, before we do the lock-in, there are notices sent out to members, notices sent out to prescribers and the pharmacies. So, everyone is onboard and understands the new process that is in place.

We have found this to be very effective. Again, you need to cast the net appropriately, and that is where having the right triggers and knowing who that you are bringing into the program, so you are not inappropriately restricting access to needed services. But,
where done, we have some evidence and data that has shown that we have been able to bend the cost curve and be able to still provide the right outcomes in these lock-in programs.

Mr. BILIRAKIS. Mr. Srivastava, do you want to elaborate? I know you answered that question when Mr. Guthrie asked you that question. But do you want to elaborate as to the triggers?

Mr. SRIVASTAVA. Sure.

Mr. BILIRAKIS. And how do you identify the at-risk beneficiaries?

Mr. SRIVASTAVA. Absolutely. Just to add on what I said previously, we operate two plans, in Florida and in Massachusetts today where we have a lock-in place on Medicaid. And we see kind of expanding that into Medicare Advantage in 2019.

Really, it is a community-based outreach effort to do lock-in effectively. So, it is engaging with the individual. Each State has different criteria as it relates to Medicaid. And so, we are kind of following the State's guidelines and trying to be coordinated. But it is coordinating with the individual and coordinating with primary care as well as specialty care. In a lot of these cases, these are individuals with physical health as well as comorbid behavioral health issues. And so, as a result, we are working with community-based mental health centers as well to be able to have a coordinated approach towards a lock-in related to a prescriber at a location, so that we can kind of reduce overuse or misuse of drugs.

But I think another key element is simply making sure that we have care management wrapped around that, as well as in-home services, peer supports, and access to tele-behavioral health and telehealth services as well, to make sure there is a coordination of care.

Mr. BILIRAKIS. How effective has the program been?

Mr. SRIVASTAVA. So, we have seen it has been effective in Florida, from our perspective, in your area, and we have been able to see kind of reduced utilization and stability in terms of outcomes. So, the recidivism or kind of admissions and readmissions related to things have gone down.

Mr. BILIRAKIS. Mr. Douglas, how effective has the program been?

Mr. DOUGLAS. Again, very effective, that we have seen a reduction in costs, overutilization, primarily from pharmacy spend, but also on the medical side as well from inpatient as well as emergency room. So, when done right, it has been very effective.

Mr. BILIRAKIS. OK. Very good.

I will yield back, Mr. Chairman. Appreciate it.

Mr. CARTER. The gentleman yields.

The Chair recognizes the gentleman from Indiana, Dr. Bucshon.

Mr. BUCSHON. Thank you, Mr. Chairman.

Mr. Kravitz, prior to becoming a Member of Congress, I was a cardiovascular and thoracic surgeon. As a physician, I believe that in order to properly address some part of the opioid crisis, we need to address the causes, one of which is how we diagnose and manage chronic pain. From your experience as a system, what is the most effective way for providers to engage patients about pain and pain management?

Mr. KRAVITZ. So, I have a personal situation. My wife today had a pain management visit due to an injury to her neck.

Mr. BUCSHON. Yes, particularly new patients and seniors also?
Mr. KRAVITZ. OK. So, she is a new patient, and seniors, the same way. Our prescribers and our specialty physicians—and I attended the visit with her to see a neurologist—they take the opportunity to counsel and discuss, to review what actually the injury is for that particular patient. Again, firsthand, I saw where opioids were not even introduced. That was discussed as not being an option in this case. Other methods with regard to physical therapy, behavioral therapy, things of that nature, in this case it is physical therapy, which will begin immediately. Injections and things like that which are non-opioid type of medications.

But we take the initiative to work with the patients, the same as with our Medicaid or Medicare population patients. We would much prefer not to go down the path of opioids because of the risk associated with opioids. And so, I think that has been our process, and I have seen it firsthand.

Mr. BUCSHON. The gist of it is it is critical to have the good evaluation of the causes of pain——

Mr. KRAVITZ. Absolutely.

Mr. BUCSHON [continuing]. And, also, proper counseling with the patient and family about alternative treatment? I will speak for the physicians. I am a physician. Historically, I think maybe we haven’t done that as well as a society as maybe we could have, right?

Mr. KRAVITZ. I think being part of a physician-led organization like Geisinger, and known for the innovation that our physicians lead and our technology supports, that has been our mantra, so to speak, that that is the direction we want to go. Is it a perfect organization? No, far from it, but we will continue to iterate and make it better and tighter as time goes by.

Mr. BUCSHON. Yes, and it is also pretty clear that it is important for care providers to have a complete understanding of not only the current pain problem, but their pain history.

CMS testified yesterday and it was mentioned that the way we look at pain needs to evolve from just treating the pain to a full conversation about pain management, and I think you would agree with that.

Mr. KRAVITZ. Yes, absolutely.

Mr. BUCSHON. So, we had that yesterday.

Mr. SRIVASTAVA. Congressman, if I could just add?

Mr. BUCSHON. Yes.

Mr. SRIVASTAVA. Geisinger is a vertically-integrated system that has complete access to data and a strong delivery model—we were on a network model. So, we serve about 7.5 million people today with chronic pain management services where we partner with health plans and partner with providers.

I think the key there is having strong data and analytics and offering up alternative therapies, as you outlined. The one piece that I will just add is that the alternative therapies wrapped around virtual care delivery is really a first-line therapy for us. So, how can you manage pain with cognitive-based therapy? Second, then, with telehealth or tele-behavioral health as well, text therapy as well, in order to kind of augment. So, there is a level of that compounded with home care services that could also alleviate pain beyond just opioid use.
Mr. BUCSHON. Yes. And again, for you, Mr. Srivastava, in your testimony you suggested that any willing provider requirements are problematic for health plans due to the behavior of some rogue pharmacies who engage in fraud. I would like to try to get a better understanding for that because I have a little bit of a skeptical view on that. It is my understanding that fraudulent behavior from a pharmacy is prosecuted by CMS and other state authorities. Is the concern that managed care plans have to take any pharmacy willing to accept the plan’s contract and maybe they don’t want to do that? Or, is the concern that pharmacies with problematic business patterns are not identified and pursued quickly enough?

Mr. SRIVASTAVA. It does not have to do with kind of building a network and accessing discounts. It has everything to do with having a quality network where things are credentialed and there is high-quality delivery. And if there is aberrant behavior, things that are outside the norm, that we should be able to not have to be required to contract with that entity. And we are not speaking to the majority or a large portion, but a very small portion.

Mr. BUCSHON. OK, yes, because, from my standpoint also not only as a Member of Congress, but as a physician, it is important for me to ensure that our Medicaid or Medicare patients have access to high-quality providers and pharmacies, and that situation not to be restricted in a way that makes it difficult for people to access their pharmacies.

Mr. SRIVASTAVA. It is all about the quality——

Mr. BUCSHON. Yes.

Mr. SRIVASTAVA [continuing]. And making sure there is a level there. Thank you.

Mr. BUCSHON. Fair enough. Thank you.

I yield back, Mr. Chairman.

Mr. CARTER. The gentleman yields.

The Chair recognizes the gentlelady from Indiana, Ms. Brooks.

Mrs. BROOKS. Thank you, Mr. Chairman.

Mr. Douglas, in your testimony you mentioned the importance—and a few of you did as well, and so, I would like to hear more from others—but you mentioned specifically the importance of provider education as one way to reduce opioid use and abuse, and including educating providers about the risks of high-dose prescribing and best practices in the treatment of pain and addiction risk associated with prescribing opioids for pain. I would like to hear a little bit more about the outcomes that you have seen, and others have seen, about provider education policies and whether or not it has led to a reduction in opioids prescriptions, and whether, with those outcomes and since you have implemented policies like this for your providers, how has it impacted the numbers of patients actually using opioids? And has there been a noticeable decrease in patients seeking treatment for their addiction? A lot of different——

Mr. DOUGLAS. Yes, a great question.

What I would say, first of all, I have seen directly from Centene that, for example, we offer free continuing medical education as one way to make sure on alternatives—we have talked about alternative therapies and treatment and better ways of pain management. Too, there are different projects—ECHO is going on—as ways to do this. And then, there is also, through 1115 waivers, a
lot of work going on where you see collaborative models of the best and evidence-based approaches on pain management.

What I would say in terms of outcomes is the hard thing to pinpoint on education is this is a continuum of prevention approaches, from what is going on out front, and we have talked about everything from very, very aggressive approaches around lock-in to really limiting prescription refills, to the length. So, we from Centene, and I have put it in my write-up, have seen significant reductions, in overall numbers. That being said, I can’t tell you it is just about education. It is about the comprehensive nature and approach, that you need to create the right incentives for States and Medicaid managed care organizations to be looking comprehensively and not just thinking education is going to solve it, but around all of the different approaches.

Mrs. BROOKS. Oh, certainly. No, there is no question that it needs to have a lot of different approaches.

Have your prescribers complained about prescriber education?

Mr. DOUGLAS. I would have to get back to you on it. I think this gets to a broader issue, and this is where you need to create the right investment. It is our providers, you know, we ask a lot of our providers. And so, we try to create the right platforms—and this gets to how, for example, CME, they already need to do it—ways that we are not just adding another additional burden without any payment. And so, it has got to be the balance between creating the right incentives and the right venues and right financing to ensure we are getting the high-performing providers who are paid adequately to provide the right access and the right types of treatment.

Mrs. BROOKS. Thank you.

You brought up provider education, Mr. Botticelli. Can you expand on either Mr. Douglas’ points or any additional of your own——

Mr. BOTTICELLI. Sure.

Mrs. BROOKS [continuing]. With respect to prescriber education? And prescribers meaning physicians, nurse practitioners, dentists, everyone.

Mr. BOTTICELLI. One of the issues that we saw driving overprescribing was, quite honestly, misleading information. As you talk to many prescribers, they will tell you that they were trained that these were not addictive drugs, that these should be prescribed liberally. And while I agree with Mr. Douglas that you can’t kind of pinpoint to one specific thing, I think it makes intuitive sense to give providers good, fact-based education as it relates to this issue.

Again, while I do think we need to provide incentives, and I say this not to overexaggerate, but while we have seen some modest declines in prescribing, we are still prescribing at three times the level that we were in 1999. And I don’t think it is unreasonable to ask a physician, kind of 15 years into this epidemic, to take some modicum of continuing medical education, either on safe prescribing or just on substance use issues in general.

Mrs. BROOKS. Thank you.

Mr. Kravitz, or any of the others, comments?

Mr. KRAVITZ. Yes, I would love to comment on that. So, I had mentioned in my testimony we have a provider dashboard. So, that
tracks providers that are high prescribers for opioids. We use that as part of our continuous monitoring for our physicians who we have educated and trained on this. We will continuously go back and address issues if we still see a persistent level of prescriptions being prescribed—overusing that term—but by these particular providers. And they could be nurse practitioners, physician assistants, anyone who has a DEA license number in this case. So, we address it. We are very much concerned about the quality of care delivered to our patients, and that is one of the areas where we focus on very heavily with analytics.

Mrs. BROOKS. Thank you.
I am out of time. I yield back. Thank you.
Mr. CARTER. The gentlelady yields.
The Chair now will recognize the gentleman from New York, Mr. Tonko, for 5 minutes.
Mr. TONKO. Thank you, Mr. Chair.
I don’t see Mr. Barton in the room, but I do want to address my colleague’s concerns and I appreciate his kind comments. But I want to make it abundantly clear, my bill does not expand Medicaid eligibility in any way. It simply would allow States the flexibility to provide for existing Medicaid beneficiaries who are returning into the community in less than a month.

Vast bodies of evidence confirm that individuals engaged in addiction treatment have lower rates of recidivism and lower healthcare costs, and we have undone many, many situations where they would have overdosed and died. That is what my bill does, straightforward. It is about being smart on crime and effective for the taxpayer.

In trying to address the opioid epidemic, one of the populations I have the greatest concerns about is individuals who have involvement with the criminal justice system. As I mentioned during the first panel, for individuals reentering society after a stay in jail or prison, the risk of overdose is as high as 129 times that of the general population during the first 2 weeks of post-release.

In States that have specifically collected data on this population, such as Rhode Island, we have seen that justice-involved individuals can account for at least 15 percent of the total overdose deaths. If we extrapolated that figure nationwide, we are talking about 10,000 deaths a year among individuals less than a year removed from correctional settings.

Mr. Botticelli, let me welcome you back to this committee and direct the question your way. Drawing on your previous role at ONDCP or your current position at BMC, what are some of the unique challenges that this justice-involved population faces in accessing effective addiction treatment, and how can we do a better job of meeting the needs of this population?

Mr. BOTTECELLI. Thank you for the opportunity to address you again.
Our data in Massachusetts underscores some data that you’ve already said, and we see people who are coming out of our jails and prisons overdose and die at one hundred and twenty times the rate of the general population. And while we’ve made success with many populations, that is one area where we need to have concern.
And I will tell you that, very interestingly, Boston Medical Center is right across from the Suffolk County Jail, and we actually try to make sure that we are getting people as they come out of prison into our services. But it often can be challenging. And even though we do a good job of trying to get people on insurance, being able to have that seamless coverage, actually start people on treatment while they are in jail becomes important.

And the last point that I will make is we have a significant number of sheriffs in Massachusetts who operate county houses of correction, who I think would have greater uptake of medication-assisted treatment while people are in jail. But part of the predicament that they run into is cost. To your point, with already Medicaid-eligible folks, if we have some modicum of transition services to be able to make sure that folks have that seamless bridge back to the community, that, to your point, not only can we reduce overdose deaths, but we would reduce costs and we would reduce recidivism.

Mr. Tonko. That is a smarter use of the taxpayer dollar.

Mr. Botticelli. It is.

Mr. Tonko. Thank you, Mr. Botticelli.

In an attempt to address some of the challenges you spoke about, I introduced the Medicaid Reentry Act, which would provide States with new flexibility to draw Federal matching funds for care provided to Medicaid-eligible, already Medicaid-eligible incarcerated individuals in the 30-day period prior to release, rather than waiting until the day of release itself.

Mr. Douglas, as a former State Medicaid director, would this type of increased flexibility have been useful to you as you crafted a response to the opioid epidemic?

Mr. Douglas. Absolutely. What we see, we have innovative programs now. I can see, and I mentioned earlier, in Ohio, where there is a lot of work going on between the correctional system and the managed care organizations where there is a pre-release program in place, that we do a lot of work.

Mr. Tonko. I am going to cut you short because I only have about 35 seconds left.

Mr. Douglas. OK, fine.

Mr. Tonko. But I appreciate it.

Mr. Douglas. Yes.

Mr. Tonko. For the rest of the panel, do you agree that initiating addiction treatment and care coordination services for reentering Medicaid beneficiaries before they leave a correction setting would improve their health outcomes, including overdose deaths for these individuals upon reentry, yes or no?

Mr. Kravitz. Yes.

Mr. Douglas. Yes, sir.

Mr. Guth. Yes.

Mr. Srivastava. We have experience in three States. Yes.

Mr. Tonko. OK. Mr. Douglas, coming back to you, your company has done some innovative work in the reentry space with subsidiary Buckeye Health Plan, a Medicaid managed care organization operating in Ohio. Buckeye participates in Ohio's Medicaid Pre-Release Enrollment Program under which managed care organizations provide care coordination services through
videoconferencing to certain high-risk incarcerated individuals prior to release from prison. Beneficiaries are provided an insurance card and a care plan the moment they walk out of a corrections facility.

I was hoping you could briefly describe Buckeye's participation in this program and share any data that you believe are significant for the previously-incarcerated beneficiaries who have enrolled with Buckeye.

Mr. DOUGLAS. Yes, and I am happy afterwards to provide for the record—we have a flyer that gives more detail on this—knowing that we are out of time.

But, just in a nutshell, we work 90 to 120 days before release getting them, making sure they are going to be enrolled in Medicaid, so that they are actually Medicaid-eligible. We develop a transition plan. We, through a videoconference, review that with their care manager. We schedule post-release appointments. Then, we make sure that pre-release that they are getting a 30-day supply of medicine, especially for those with behavioral health needs. And then, we do a care outreach 5 days after release to make sure they are connected to both integrated behavioral health services as well as social services. Across not just with Buckeye, our plan, but all of Ohio has had 20,000 former inmates enrolled in this program.

Mr. TONKO. Thank you, Mr. Douglas.

Finally, I will just state—and I know my time is out—but I will state that, if with this human health crisis, this opioid epidemic, our goal is to save lives, I challenge this committee to say no to addressing those who are incarcerated. It should not be a caste system here. Many people find themselves incarcerated because of this illness, and we need to be compassionate and I think effective with the taxpayers' dollars.

With that, I yield back, Mr. Chair.

Mr. CARTER. The gentleman yields.

The Chair now will recognize himself for 5 minutes.

I would like to ask unanimous consent to submit two letters for the record supporting the Pharmacy and Medically Underserved Areas Enhancement Act. Without objection.

[The information appears at the conclusion of the hearing.]

Mr. CARTER. Mr. Guth, I am going to start with you. I wanted to ask you, the recommendations that have been put forth by the President's Commission on Combating Drug Addiction and the Opioid Crisis stated that, “There is a great need to ensure that healthcare providers are screening for SUDs and know how to appropriately counsel or refer to a patient.” It would appear to me that this is an opportunity for Congress to direct CMS that CPT codes be expanded or added to, and that we identify patients at risk for opioid use disorders.

Mr. GUTH. Absolutely.

Mr. CARTER. Would you agree with that?

Mr. GUTH. Absolutely.

Mr. CARTER. Should we be looking at creating or amending CPT codes? As I understand it, it is done in other areas. In fact, it is done for chronic care with alcohol and substance abuse, and other areas as well.

Mr. GUTH. Absolutely. I am very much supportive of that.
Mr. CARTER. OK. Should we be encouraging the use of OUD tapering strategies that have been proven to work?

Mr. GUTH. Yes, and I think those go back to the fact that you have very different presentations for folks. You have individuals with very different recovery capital themselves. So, not everybody needs to be on medication-assisted therapy for the duration. I think this gets back to one size doesn’t fit all.

Mr. CARTER. Right, right.

Mr. GUTH. So, the short answer to your question is, yes, we ought to be including in the continuum of care tapering strategies.

Mr. CARTER. OK. I want to talk real quickly about one of the bills that is under consideration. That is the Partnership Act, and that is the use of the PDMPs, and specifically as it relates to pharmacists. And full disclosure is, I suspect you know, currently, I am the only pharmacist serving in Congress. I have over 30 years of experience in a retail setting. And I acknowledge the responsibility of pharmacists. We have an important responsibility, a very important responsibility, as possibly the last line of defense in the opioid crisis.

But, having said that, I will tell you we are not policemen. And to require pharmacists to be the only ones to be looking at a PDMP, and to be policing physicians who are writing the prescriptions, I think is somewhat unfair. I have often said the only thing worse for me, as a practicing pharmacist, to fill a prescription for someone who is going to be abusing it, would be to not fill a prescription for someone who truly needs it. It is unfair to expect a pharmacist to profile a patient and say, no, that patient doesn’t need that medication. That is unfair.

Now I get it. I understand a PDMP is different. I have sponsored the legislation creating the PDMP in the State of Georgia back in 2009. But, at the same time, I just want to get your thoughts on this. Without having the prescriber have to look at the PDMP, why are we having the pharmacist to look at it? To police the doctors? Anyone want to jump on that?

Yes, sir, Mr. Kravitz?

Mr. KRAVITZ. I think it is imperative that the provider be held accountable, prior to providing the prescription, that they must check the PDMP. And they are the source of this process. I think the pharmacist, which I have a daughter who is a pharmacist as well, and I think they are a checkpoint in the process. They should not be held accountable as the policing act.

Mr. CARTER. Thank you.

Any other comments? OK, and let me go back to you, Mr. Guth, because I thought it was interesting. In your opening statement, you said that the number of programs that are out there—and this is something that I have been very concerned about, the fact that I look at the opioid crisis and I look at two different components of it.

First of all, there is that tangible part, if you will, that I feel like we can get our arms around. How do we control the number of prescriptions, the pills that are going out? And what are those things that we do to limit the access to them?

But, then, there is the second component that is more challenging in my mind, and that is, how do we treat those people who
are already addicted? You said that, quite often, it depends on what program you enter into.

Mr. Guth. Yes. And let me give you an example close to home of how we have addressed this. So, Centerstone has a five-state primary footprint for our services, and we are the result of an affiliation of nonprofit providers who are all mission-driven organizations. As we brought these organizations together, we realized that the systems of care in each of these states vary dramatically, not only in the area of substance use treatment——

Mr. Carter. Right.

Mr. Guth [continuing]. But across the board, not based on the science of care, but based on how services evolved in those areas, access to human capital, state regulations, and, more often than not, funding, access to funding.

And so, what happens today is, let’s take this shortage of services for the 30 million people in rural communities. We can quickly go to a solution that says let’s give them access to medication-assisted therapy, light on the therapy, without all the continuum-of-care services. And we can turn around and say, hey, 30 million people now have access to substance abuse care. But that is not a single solution that addresses all the people that present.

Think about the fact that, if you or I present with an opioid disorder, we have got a lot of human capital support around us in our family, in our friends, or networks. We have got jobs. We have got a safe place to live. But, if that is not our situation, which is the case for many people that are battling this disorder, we need to make sure they have got access to——

Mr. Carter. Right, right.

Mr. Guth [continuing]. A sober living community, that they have got access to peer support.

Mr. Carter. Well, and it is one concern that I have because a lot of my colleagues—and I am not being critical; I just don’t think they understand—think all we have got to do is throw money at it, and if we can get to a certain point, then that is where we need to be. But my point is that not all programs are going to work for all people.

Mr. Guth. That is right.

Mr. Carter. That is difficult for us in Congress to disseminate. How do we know which programs work and which ones don’t?

Mr. Guth. I think you start by looking at whether the provider has access to, either directly or through strong referral relationships, a continuum of care.

Mr. Carter. A continuum of care is extremely important.

Mr. Guth. If anybody comes to you today and says, look, we have got the one solution, we have got the one program, the one protocol that is going to work for everybody, I think you ought to be looking very closely at that.

Mr. Carter. Right.

Let me ask one more thing. Mr. Douglas, or any of you, did I hear you say that only one out of five people in treatment are getting medication-assisted treatment? Are most of the patients who are under treatment for opioid addiction, are they getting medication-assisted treatment or are they just getting therapy? Almost all of them getting medication-assisted therapy?
Yes, I'm sorry?

Mr. Botticelli. So, despite the fact that I think all the data support that people on medication, as long as they are getting all the other behavioral and recovery supports, do far better on a medication versus treatment without the medications. But only a very small percentage of people are getting on it. And we still have a small percentage of our treatment programs who are even offering it.

But, while I agree with you that there are multiple pathways to treatment, I do think that every licensed substance use treatment provider who is getting a Federal dollar should be offering access to medication-assisted treatment. And I think it is really important because the data are pretty clear that people get into long-term recovery when they are on a medication versus when they are not. And again, this is not saying “either/or”. People need all the other recovery supports.

Mr. Carter. Right, right.

Mr. Botticelli. They need behavioral therapy. They need peer support services. But it is very clear, and again, I go back to Secretary Azar who said treating substance use disorders and treating opioid addiction without a medication is like treating an infection without an antibiotic.

Mr. Carter. Right.

Mr. Guth. And for the record, I absolutely agree with that. So, it is a point about having the other constellation services available.

Mr. Carter. Right. But you see what a difficult situation it puts us in. I mean, all of you know that this is a lifelong challenge. I mean, and you have to continue it, and it is expensive and everything else.

But I want to thank all of you for being here. This is extremely important. This is part of what, as I said earlier, the second component that I consider to be so very challenging for us, but so very necessary for those who need help. And we need them. We need them back to being productive members of our society.

So, I will yield back the remainder of my time.

Seeing there are no further members wishing to ask questions, I would like to thank all of our witnesses again for being here today.

I would like to submit statements from the following for the record: the American Association of Oral and Maxillofacial Surgeons, the Association for Behavioral Health and Wellness, AdvaMed, the American Hospital Association, the American Psychological Association, the American Society of Health System Pharmacists, the Association for Community Affiliated Plans, the College of Healthcare Information Management Executives, ePrescribing Coalition, the National Association for Behavioral Healthcare, the National Association of Chain Drug Stores, the National Association of Medical Directors, the National Indian Health Board, the Oregon Community Health Information Network, the Partnership to Amend Part 2, the Pharmaceutical Care Management Association, Property Casualty Insurance Association of America, Shatterproof, Imprivata, the Pharmacy Coalition, Express Scripts, the National Association of Counties, and Trinity Health.

[The information appears at the conclusion of the hearing.]
Mr. CARTER. I would also like to submit a joint statement from the Infectious Disease Society of America, the HIV Medicine Association, and the Pediatric Infectious Disease Society; a study entitled, “States With Prescription Drug Monitoring Mandates Saw a Reduction in Opioids Prescribed to Medicaid Enrollees,” published in Health Affairs, and the Center for Medicare and Medicaid Services 2016 Medicaid Drug Utilization Review Annual Report.

[The information appears at the conclusion of the hearing.]

Mr. CARTER. Pursuant to committee rules, I remind members that they have 10 business days to submit additional questions for the record, and I ask that witnesses submit their responses within 10 business days upon receipt of the questions.

Without objection, the subcommittee is adjourned.

[Whereupon, at 12:37 p.m., the subcommittee was adjourned.]
Medicare officials thought they had finally figured out how to do their part to fix the troubling problem of opioids being overprescribed to the old and disabled: In 2016, a staggering one in three of the 43.6 million beneficiaries of the program's drug plan had been prescribed the painkillers. Medicare, they decided, would now refuse to pay for long-term, high-dose prescriptions; a rule to that effect is expected to be approved on April 2. Some medical experts have praised the regulation as a check on addiction.

But the proposal has also drawn a broad and clamorous blowback from many people who would be directly affected by it, including patients with chronic pain, primary care doctors and experts in pain management and addiction medicine. Critics say the rule would inject the government into the doctor-patient relationship and could throw patients who lost access to the drugs into withdrawal or even provoke them to buy dangerous street drugs. Although the number of opioid prescriptions has been declining since 2011, they noted, the rate of overdoses attributed to the painkillers and, increasingly, illegal fentanyl and heroin, has escalated.

"The decision to taper opioids should be based on whether the benefits for pain and function outweigh the harm for that patient," said Dr. Joanna L. Starrels, an opioid researcher and associate professor at Albert Einstein College of Medicine. "That takes a lot of clinical judgment. It's individualized and nuanced. We can't codify it with an arbitrary threshold."

Underlying the debate is a fundamental dilemma: how to curb access to the addictive drugs while ensuring that patients who need them can continue treatment.

The rule means Medicare would deny coverage for more than seven days of prescriptions equivalent to 90 milligrams or more of morphine daily, except for patients with cancer or in hospice. (Morphine equivalent is a standard way of measuring opioid potency.)

According to Demetrios Kouzoukas, the principal deputy administrator for Medicare, it aims to further reduce the risk of participants "becoming addicted to or overdosing on opioids while still maintaining their access to important treatment options."

The Centers for Medicare and Medicaid Services estimates that about 1.6 million patients currently have prescriptions at or above those levels. The rule, if approved as expected at the end of a required comment and review period, would take effect on Jan. 1, 2019.

Dr. Stefan G. Kertesz, who teaches addiction medicine at the University of Alabama at Birmingham, submitted a letter in opposition, signed by 220 professors in academic medicine, experts in addiction treatment and pain management, and patient advocacy groups.

His patients include formerly homeless veterans, many of whom have a constellation of physical and mental health challenges, and struggle with opioid dependence. For them, he said, tapering opioids does not equate with health improvement; on the contrary, he said, some patients contemplate suicide at the prospect of suddenly being plunged into withdrawal.

“A lot of the opioid dose escalation between 2006 and 2011 was terribly ill advised,” Dr. Kertesz said. “But every week I’m trying to mitigate the trauma that results when patients are taken off opioids by clinicians who feel scared. There are superb doctors who taper as part of a consensual process that involves setting up a true care plan. But this isn’t it.”

Some two dozen states and a host of private insurers have already put limits on opioids, and Medicare has been under pressure to do something, too. Last July, a report by the inspector general at the Department of Health and Human Services raised concerns about “extreme use and questionable prescribing” of opioids to Medicare recipients. In November, a report from the Government Accountability Office took Medicare to task, urging greater oversight of opioid prescriptions.

If the rule takes effect, Mark Zobrosky’s experience could be a harbinger for many patients. Mr. Zobrosky, 63, who lives in the North Carolina Piedmont, takes opioids for back pain, which persists despite five surgeries and innumerable alternative treatments. He has an implanted spinal cord stimulator that sandpapers the edge off agony, and has broken four molars from grinding because of pain, he said. He receives Medicare as a result of his disability, including a private plan that pays for his drugs.

He submits to random urine tests and brings his opioids to his doctor to be counted every month. To prepare for mandatory reductions, his doctor has tapered him down to a daily dose equivalent of about 200 milligrams of morphine. (Mr. Zobrosky has a large frame; doctors say that opioid tolerance depends on many factors — one person’s 30 milligrams is another person’s 90.)

In February, Mr. Zobrosky’s pharmacist told him that his insurance would no longer cover oxymorphone. His out-of-pocket cost for a month’s supply jumped to $1,000 from $225, medical records show. “I can’t afford this for very long and I’m nervous,” he said.

A Medicare official who would speak only on background said that the limit for monthly high doses was intended not only to catch doctors who overprescribe, but also to monitor patients who, wittingly or not, accumulate opioid prescriptions from several doctors. When the dose is flagged, the pharmacist or patient alerts the doctor.

But it falls to pharmacists to be the bad-news messengers. James DeMicco, a pharmacist in Hackensack, N.J. who specializes in pain medications, said that negotiating opioid insurance rejections for patients was already “beyond frustrating.” He spends hours shuttling between doctors and insurers. “My heart goes out to patients because they feel stigmatized,” he said.

Dr. Anna Lembke, an addiction medicine expert at Stanford, sees merit in the intent of the proposed rule, if not its design.

“The C.D.C. declared a drug epidemic in 2011, which they unequivocally and rightly attributed to overprescribing,” she said. “Without external limits, I do not believe that prescribers will be able to limit their prescribing to the extent necessary to address this public health crisis.”
But, she added, Medicare also needed to establish a reasonable grace period to allow patients on high doses to taper down safely.

According to a draft of the rule, when a high-dose prescription is rejected, a doctor can appeal, asserting medical necessity — although there is no guarantee that the secondary insurer covering the drugs under Medicare would relent. A pharmacist may fill a one-time, emergency seven-day supply.

Opponents of the new limit say that doctors are already overwhelmed with time-consuming paperwork and that many will simply throw up their hands and stop prescribing the drugs altogether.

A delay or denial would put chronic pain patients — or those with inflammatory joint diseases, complex shrapnel injuries or sickle cell disease — at risk of precipitous withdrawal and resurgence of pain, doctors said.

The Medicare proposal relies on guidelines from the Centers for Disease Control and Prevention that say doctors should not increase an opioid to a dose that is the equivalent of 90 milligrams of morphine.

But experts say that Medicare misread the recommendations — that the C.D.C.’s 90-milligram red flag is for patients in acute pain who are just starting opioid therapy, not patients with chronic pain who have been taking opioids long-term. The acute pain patient, the guidelines say, should first be offered treatments like acetaminophen or ibuprofen. A short course of a low-dose opioid should be a last resort.

“We didn’t take a specific position on people who were already on high doses,” said Dr. Lewis S. Nelson, the chairman of emergency medicine at Rutgers New Jersey Medical School and University Hospital, who worked on the guidelines.

“We did say that established, high-dose patients might consider dosage reduction to be anxiety-provoking, but that these patients should be offered counseling to re-evaluate,” he added. “There is a difference between a C.D.C. guideline for doctors and a C.M.S. hard stop for insurers and pharmacists.”

Dr. Erin E. Krebs recently released a comprehensive study showing that patients with severe knee pain and back pain who took opioid alternatives did just as well, if not better than, those who took opioids. Nonetheless, she and seven others who worked on the C.D.C. guidelines signed the letter opposing the Medicare rule.

“My concern is that our results could be used to justify aggressive tapering or immediate discontinuation in patients, and that could harm people — even if opioids have no benefit for their pain,” said Dr. Krebs, an associate professor of medicine at the University of Minnesota.

“Even if we walk away from using opioids for back and knee pain, we can’t walk away from patients who have been treated with opioids for years or even decades now,” she added. “We have created a double tragedy for these people.”
April 11, 2018

The Honorable Greg Walden
Chairman
U.S. House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
U.S. House Energy and Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden, Ranking Member Pallone and the Energy and Commerce Committee:

On behalf of the American Pharmacists Association (APhA) and our members, I write to you today to express our gratitude for what you are doing to address the opioid crisis that is ravaging many of our communities. APhA and our members agree that more needs to be done to help the individuals and communities you serve who suffer as a result of the widespread misuse and abuse of prescription opioid pain relievers. APhA, founded in 1852 as the American Pharmaceutical Association, represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

As the most accessible health care practitioner, pharmacists are uniquely aware of the harm caused to individuals and communities by the opioid epidemic. And that is why it is so important to include the Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592) in the legislation you are crafting to address the opioid issue. H.R. 592 increases medically underserved Medicare Part B beneficiaries' access to health care through pharmacists' services. Many patients do not have adequate access to practitioners who can optimize their care and outcomes. Pharmacists are eager to fill these treatment gaps, but barriers in Medicare unnecessarily restrict patients from accessing these health care providers.

In response to the opioid epidemic, pharmacists, the medication experts on the patient's health care team, have enhanced their efforts and expanded their services to fill gaps in care. However, without being recognized by Medicare, pharmacists' services are not accessible to beneficiaries, despite being qualified to provide needed health care services. Although there are several root problems associated with the opioid epidemic, it is clear that more attention needs to be paid to the treatments patients are prescribed, how they take their medications, and what happens when they no longer need the prescription.

Pharmacists are involved in pain management programs that include medication tapering services, work in medication assisted treatment programs, and furnish naloxone where authorized. Depending on state authority, pharmacists working under collaborative practice agreements can initiate, monitor, modify, and discontinue medication therapy, including opioids, and order and interpret laboratory tests in collaboration with other members of the health care team. Patients living with chronic conditions frequently have medications, including opioids, from multiple providers. Pharmacists are often the only practitioner who sees the patient's complete medication profile and can help bridge the communication gap between health care providers by coordinating care and providing medication-related services. In addition, they are highly accessible as 89% of
Americans live within five miles of a community pharmacy. However, because Medicare and other payers do not cover pharmacist services, patients are unable to benefit from their expertise and care. To better utilize pharmacists in addressing the opioid epidemic, APhA urges Congress to pass H.R. 592, legislation that will improve patient outcomes and care by enabling patients to access the care and services from pharmacists — the health care practitioner with the most medication-related education and training.

APhA also notes the broad Congressional support for the Pharmacy and Medically Underserved Areas Enhancement Act which currently has over 250 cosponsors in the House of Representatives. We urge you to advance this legislation.

APhA welcomes a meeting to discuss ways pharmacists can improve patient care and the health care system generally, including ways to combat the opioid epidemic. Until then, APhA and our members will continue to collaborate with stakeholders to address the opioid epidemic. Thank you for continuing to prioritize patients and communities in your policymaking and efforts. If you have any questions or require additional information, please contact Alicia Kerry J. Mica, Senior Lobbyist, at AMica@aphanet.org or by phone to (202) 429-7507.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs
April 3, 2018

The California Pharmacists Association is a member of the Patient Access to Pharmacists’ Care Coalition (PAPCC), a multi-stakeholder and interdisciplinary initiative whose mission is to develop and help enact a federal policy proposal that would enable patient access to, and payment for, Medicare Part B services by state-licensed pharmacists in medically-underserved communities.

We write today to express appreciation for your efforts to address the opioid epidemic. California has been a leader in seeking solutions to this public health challenge and stand committed to working with Congress and other stakeholders to identify ways pharmacists can help curb opioid abuse and misuse and positively impact treatment. Pharmacists are the face of neighborhood healthcare with 89% of Americans living within five miles of a community pharmacy. In fact, pharmacists are frequently the health care professional that a patient will see most often. We believe that even greater engagement by pharmacists on the health care team can result in opportunities to improve outcomes for Medicare patients and reduce challenges, including those related to opioids.

Pharmacists play a unique role in patient care as they are the medication experts. While pharmacists are known for dispensing prescription medications and helping patients use them safely, today’s pharmacists are trained and licensed to provide a number of additional services needed by many Medicare beneficiaries. In 2013, California was the first state to pass extensive expanded scope of practice legislation to ensure pharmacists can utilize their expansive training and receive payment for serving privately-insured and Medicaid patients. This includes pharmacists playing an important role in helping to address opioid misuse and abuse as well as treatment. For example, because pharmacists have access to the patient’s complete medication profile, they can help bridge communication gaps that may exist among providers by coordinating and providing medication-related services. This is particularly important for patients living with chronic conditions who have medications from multiple providers.

Pharmacists are also involved in pain management programs that include medication tapering services and transitioning to non-opioid treatments; work in medication assisted treatment programs; and in California, can independently furnish the life-saving overdose reversal agent, naloxone. Further, California’s Advanced Practice Pharmacists work under collaborative practice agreements to initiate, monitor, modify, and discontinue medication therapy, including opioids.

Given the prevalence of the opioid problem in communities across the country, pharmacists, who are already in these communities can help provide better management and monitoring services to fill the gap in access to care. As the medication experts on the patient’s health care team and the most accessible health care practitioner in the community, it is of the utmost importance that Medicare patients also be
able to access pharmacists' services. Having broad access to pharmacists can help prevent prescription
drug misuse and abuse and improve treatment outcomes.

Dozens of your colleagues have cosponsored the Pharmacy and Medically Underserved Areas
Enhancement Act (H.R. 592) that would provide medically underserved beneficiaries with access to
Medicare Part B services provided by pharmacists. We appreciate the Committee's attention to H.R. 592
and look forward to working with you on its passage as an important way to help address the opioid
crisis.

Thank you, again, for your leadership in addressing the opioid epidemic. We welcome the opportunity
to work with you and the Coalition partners to better utilize pharmacists to help Medicare beneficiaries
access the care they need to positively impact this serious problem facing our nation. Should you have
any questions, please contact Michelle Rivas, CPhA Vice President, at (916) 779-4517 .

Sincerely,

Vinson C. Lee, PharmD, MS, FCPhA, FAMCP
President

cc: The Honorable Doris Matsui
    The Honorable Tony Cardenas
    The Honorable Anna Eshoo
    The Honorable Mimi Walters
    The Honorable Jerry McNerney
    The Honorable Dr. Raul Ruiz
    The Honorable Scott Peters

Jon R. Roth, MS, CAE
Chief Executive Officer
April 6, 2017

Congressman Greg Walden  
Chairman  
House Energy and Commerce Committee  
2185 Rayburn House Office Building  
Washington, DC 20515

Congressman Joe Barton  
Vice Chairman  
House Energy and Commerce Committee  
2107 Rayburn House Office Building  
Washington, DC 20515

Dear Representative Walden and members of the House Energy and Commerce Committee,

The Iowa Pharmacy Association (IPA) was established in 1885 and represents over 2,500 pharmacists, pharmacy technicians, student pharmacists, and pharmacy owners. The mission of IPA is to empower the profession of pharmacy to improve health outcomes. Across the state, pharmacists and pharmacies are located in all of Iowa’s 99 counties.

IPA greatly appreciates the efforts of the House Energy and Commerce Committee in spearheading the fight to address the opioid crisis. With one committee hearing remaining on opioids that will focus on Medicare and Medicaid, we would like to bring to the attention of the committee H.R. 592 and its potential to help stem this deadly epidemic. H.R. 592, the Pharmacy and Medically Underserved Areas Enhancement Act, would provide medically underserved beneficiaries with access to Medicare Part B services by pharmacists, consistent with state scope of practice law. Although H.R. 592 was not included on the agenda for the committee’s final hearing, we would like to highlight how patient access to pharmacists’ services can help address this crisis.

While pharmacists are known for dispensing prescription medications and helping patients use them safely, today’s pharmacists are trained and licensed to provide a number of additional services needed by many Medicare beneficiaries. Currently, these pharmacist services are not covered under Medicare Part B. As a result, beneficiaries’ access to the health care practitioner with the most medication-related education and training is limited and restricted mainly to services related to the dispensing of medications. By not including pharmacists among other Part B providers whose services are covered,
Medicare also makes it more difficult for patients and the other members of their health care team to work with pharmacists as a part of a coordinated, team-based approach to care.

As the medication experts on the patient’s health care team, pharmacists play an important role in helping patients manage chronic pain and preventing prescription drug misuse and abuse. Pharmacists are involved in pain management programs that include medication tapering services, work in medication assisted treatment programs, and furnishing naloxone where authorized. Furthermore, 89% of Americans live within five miles of a community pharmacy, making pharmacists the most accessible healthcare professional. Pharmacists can use their medication expertise to better manage pain treatments, including educating patients and families about the safe use of opioids as well as the potential need for and appropriate use of naloxone.

By allowing pharmacists’ services to be covered by Medicare Part B through H.R. 592, pharmacists can be better utilized in the fight against the opioid crisis by managing and optimizing the impact of medications, reviewing medications to help prevent overprescribing, tailoring care plans to patient needs, providing recommendations for non-opioid pain management alternatives, and educating patients regarding opioids. Therefore, we strongly urge you to consider H.R. 592 as the House Energy and Commerce Committee considers its options in addressing the opioid crisis. Thank you for your time and consideration.

Respectfully,

Kate Gainer
Executive Vice President, CEO
Iowa Pharmacy Association

Casey Ficek, J.D.
Director, Public Affairs
Iowa Pharmacy Association
April 11, 2018

The Honorable Greg Walden
Chairman
U.S. House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
U.S. House Energy and Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden and Committee Members:

As Executive Director of the Kentucky Pharmacists Association, an association representing the thousands of pharmacists in Kentucky providing vital services and products to your constituents, I urge you to include H.R. 592, the Pharmacy and Medically Underserved Areas Enhancement Act in the opioid legislation the Committee is currently drafting. Pharmacists must be better utilized in the fight against the opioid epidemic given their ability to manage/optimize medication impact, review medications to help prevent overprescribing, tailor care plans to patient needs, recommend non-opioid pain management alternatives, and educate patients regarding opioids.

H.R. 592 would provide access for Medicare beneficiaries in medically underserved communities to covered Medicare Part B services from their pharmacist at 85% of the physician rate, subject to state scope of practice laws. Almost 260 members of the U.S. House of Representatives – and nearly 80% of the House Energy & Commerce Committee – co-sponsored this legislation. Pharmacist provider status can better enable pharmacists to help address the opioid epidemic given the unique role they play in our health care system.

As the most accessible health care practitioner, with 89% of Americans living within five miles of a community pharmacy, pharmacists can use their medication expertise to identify at-risk behaviors, better manage pain treatments, and educate patients and families about the safe use of opioids as well as the potential need for and appropriate use of medications to reverse the effects of narcotic drugs, such as naloxone.

Pharmacists can also provide opioid management/preventive counseling and/or risk factor reduction interventions at the point of service, which has the potential to substantively reduce abuse. Pharmacists are already qualified to provide medication counseling. Their expertise could be leveraged to provide preventive opioid medication counseling for patients deemed to be at high risk of opioid overutilization. This could serve as an early intervention to prevent opioid misuse and could include a referral to additional treatment.

For patients living with chronic conditions, the sheer number of medications creates situations where abuse is a real possibility. As pharmacists often see the patient’s complete medication profile on a regular basis and develop personal relationships with beneficiaries, they can help bridge the communication gap between health care providers by coordinating and providing medication-related services. Pharmacists are part of the team helping patients with legitimate pain management needs achieve treatment goals.

Congress must consider initiatives that enhance healthcare capacity and strengthen community partnerships. This can be achieved by recognizing the value pharmacists offer as a member of the healthcare team and utilizing...
them at the top of their training in fighting the opioid crisis. This recognition is especially important in underserved communities specifically addressed in this legislation.

Please ensure H.R. 592 is included in the opioid legislative package so pharmacists can better help in the fight against the opioid epidemic.

Sincerely,

Mark A. Glasper
Executive Director
Kentucky Pharmacists Association
96 C. Michael Davenport Blvd.
Frankfort, KY 40601

tel: (502) 227-2203
fax: (502) 227-2258
e-mail mglasper@kshmanet.org
April 4, 2018

The Honorable Greg Walden
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Walden and Ranking Member Pallone:

Thank you for your efforts to address the opioid epidemic in our communities! As pharmacists, we are committed to working with Congress and other health professionals and stakeholders to identify ways pharmacists can help curb opioid abuse and misuse and positively impact treatment. We believe that engaging pharmacists on the health care team presents a unique opportunity to improve outcomes for Medicare patients and reduce challenges, including those related to opioids. Pharmacists play a unique role in patients’ care as they are the medication experts, and with 89% of Americans living within five miles of a community pharmacy, the pharmacist is likely the healthcare professional that a patient will see the most. They are active in their communities and are very concerned about the care of their patients.

While pharmacists are known for dispensing prescription medications and helping patients use them safely, today’s pharmacists are trained and licensed to provide a number of additional services needed by many Medicare beneficiaries. As part of the health care team, pharmacists can play an important role in helping to address opioid misuse and abuse and can be fully engaged with substance use disorder treatment. Given the prevalence of this problem in communities across the country, pharmacists, who are already in these communities, can help provide better management and monitoring services to fill the gap in access to care.

Pharmacists are the medication experts on the patient’s health care team and the most accessible health care practitioners. Accordingly, it is of the utmost importance that Medicare patients are able to access pharmacists’ services, which can help prevent prescription drug misuse and abuse, in addition to improve treatment outcomes. Authorizing pharmacist clinical services in the Medicare Part B benefit would expand beneficiaries’ access to care including medication and pain management services and treatment.

Scores of your colleagues have cosponsored the Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592) that would provide medically underserved beneficiaries with access to Medicare Part B services by pharmacists, consistent with state scope of practice law. We appreciate the Committee’s attention to H.R. 592 and look forward to working with you on its passage as an important way to help the address the opioid crisis.

Sincerely,

Larry D. Wagman, President
Chief Executive Officer

Copy: Representatives Upton, Walberg and Dingell
April 10, 2018

The Honorable Greg Walden  
Chairman, Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Frank Pallone  
Ranking Member, Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Walden and Ranking Member Pallone:

The National Association of Chain Drug Stores (NACDS) commends Chairman Walden and Ranking Member Pallone for your leadership in pursuing policy changes to address the opioid crisis. NACDS and our members remain committed to partnering with policymakers, law enforcement, and others to work on viable strategies to prevent prescription opioid diversion and abuse. An important element of any strategy to combat the opioid crisis should include policies that improve medication education and management and related services. As such, NACDS supports the expansion of community-based services and an enhanced role of retail community pharmacists in identifying and treating those with opioid addiction and believe this can best be accomplished through passage of H.R. 592/S. 109, the Pharmacy and Medically Underserved Areas Enhancement Act.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS’ nearly 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 152,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 20 countries. Please visit www.NACDS.org.

Access, quality, cost, and efficiency in healthcare are critical, especially for those who are medically underserved and/or are at-risk for substance abuse disorders. These may include seniors with cultural or linguistic access barriers, residents of public housing, persons with HIV/AIDS, as well as rural populations and many others. Many of these...
beneficiaries suffer from multiple chronic conditions. Significant consideration should be
given to policies and initiatives that enhance healthcare capacity and strengthen
community partnerships to offset provider shortages, particularly in communities with
medically-underserved populations. Retail pharmacies are often the most readily
accessible healthcare provider. Research shows that nearly all Americans (89%) live
within five miles of a retail pharmacy.

Despite the ability of pharmacists to improve access and care, current law does not
recognize them as a provider in the Medicare program. H.R. 592/S. 109, the Pharmacy
and Medically Underserved Areas Enhancement Act, would change this recognize
pharmacists as providers in medically underserved areas, thus creating better access to
services for these vulnerable populations. Not only would recognition of pharmacists
improve access, but it would lead to reduced healthcare costs as pharmacists would
provide already-covered Medicare services at 85% of the physician fee schedule.

Pharmacists have advanced education and training that equips them to provide many
services in addition to their role in providing patients with access to and information
about their prescription medications. These services include:

- Health Tests and Screening
- Management of Chronic Conditions and Related Medications
- Immunization Screening and Administration
- Point of Care Testing (e.g. Flu, Strep)
- Transition of Care Services

In addition to these vital services, pharmacists are also trained and equipped to help in the
battle against opioid abuse. Examples of ways pharmacists could help include:

- Assisting physicians with opioid treatment programs, which provide medication
  assisted treatment (MAT) for people diagnosed with an opioid-use disorder. CMS
  recently recognized the importance of MAT in its final FY2019 Call Letter, when
  it stated "...it is imperative to also ensure that Medicare beneficiaries have
  appropriate access to medication-assisted treatment (MAT)."

- Providing greater access to community-based Screening, Brief Intervention, and
  Referral to Treatment (SBIRT). SBIRT is an evidence-based practice used to
  identify, reduce, and prevent problematic use, abuse, and dependence on alcohol
  and substance abuse and includes a referral to treatment for those in need.

- Increased access to naloxone, a medication designed to rapidly reverse opioid
  overdose. Several states have recognized the importance of ensuring quick access
to this life-saving medication and have employed various approaches to reimburse and make it easier for pharmacists to provide naloxone to patients.

- Increased use of pharmacogenomic testing to determine the right pain medication and dosing. By performing pharmacogenetic testing, personalized medicine allows patients to be prescribed with the right drug to be administered for adequate pain control – to avoid experiencing dose-dependent side effects or lack of drug efficacy. A pain medication may alleviate pain for one patient while proving no relief for another. Pharmacogenetic testing can help alleviate this problem.

Retail community pharmacists are an underutilized resource in helping to identify and treat those with opioid addiction as well as educating consumers on the dangers of opioid abuse and addiction. Recognizing the value pharmacists play as a member of the healthcare team and utilizing them at the top of their training would greatly strengthen the battle against the opioid crisis. NACDS encourages members of Congress to support H.R. 592/S. 109, the Pharmacy and Medically Underserved Areas Enhancement Act.

**Conclusion**

We look forward to working with policymakers and other stakeholders to implement strategies and policies to turn the tide in the opioid epidemic.

Sincerely,

The National Association of Chain Drug Stores
April 9, 2018

Dear Chairman Walden and Ranking Member Pallone:

I want to thank you and the members of the House Energy and Commerce Committee for your efforts to address the opioid crisis. As you are aware, the incidents of opioid use rise among Americans monthly as the opioid epidemic continues to permeate every facet of American life. It does not distinguish between gender, or among age groups, nor consider socioeconomic variables. For individuals and families in New Jersey, the consequence of opioid misuse manifest through drug overdose, which is the leading cause of accidental death in our state. Though admissions to drug treatment programs have increased dramatically in the last decade, heroin overdose in New Jersey is three times the national average. Yet, a pharmacist, as one of the most accessible and essential health care practitioners, is unable to apply their extensive expertise and training to answer calls for help. Each state in the union faces similar challenges to those experienced here in New Jersey, and each state has a ready and willing pool of pharmacists trained to provide care to their patients. In federally designated medically underserved areas (MUA), (in New Jersey, 15 out of 21 counties in the state are medically underserved according to the U.S. Department of Health and Human Services) this means that there is a lack of patient care services within states, for at-risk populations that include the elderly. The data is too compelling to ignore.

Pharmacists are front-line health care professionals who interact with patients on a regular basis in a variety of settings (i.e.: local pharmacies, hospitals, clinics and residential facilities). In the forum of public opinion, pharmacists remain one of the most trusted professionals, and this recognition places them in a unique position to advocate for their patients and the care they need. As pharmacists integrate their services within existing health care delivery models, patient-centered care will increase. Pharmacists are equipped to practice within the changing health care landscape by practicing to the level of their education and experience.

Pharmacists play a unique role in patient care as the medication experts,
and with 89% of Americans living within five miles of a community pharmacy, they are frequently
the health care professional that a patient will see most often. In New Jersey, for example, there
are approximately 2,100 community pharmacies staffed by thousands of highly trained and
experienced pharmacists. It is the pharmacist practicing in the community who will be available
to respond immediately to an urgent call for help when a patient requests the opioid reversal
agent, naloxone, for example. Currently, pharmacists are involved in pain management programs
that include medication tapering services and medication assisted treatment programs related to
opioid misuse. Pharmacists can help fight against the opioid epidemic by managing and
optimizing the impact of medications, reviewing medications to help prevent overprescribing,
monitoring care plans that support the physicians’ treatments, and providing recommendations
for non-opioid pain management alternatives while educating patients regarding opioids.
However, Medicare beneficiaries’ access to the health care practitioner with the most medication­
related education and training is limited, often preventing the established and trusted relationship
between patient and pharmacist from reaching its potential. The omission of pharmacists’
services from Medicare Part B coverage restricts a coordinated, team-based approach to care. It is
critical that patients and other health care providers can utilize the medication experts on a care
team as efforts to enhance prevention, patient education, prescribing, tapering and treatment of
substance use disorder are implemented.

We believe that H.R. 592 will provide new avenues to address opioid abuse and misuse and
increase treatment options through pharmacist-provided care. Pharmacists can use their
medication expertise to identify at-risk behaviors, manage pain treatments, and educate patients
and families about the safe use of opioids and the use of medications to reverse the effects of
narcotic drugs in emergency situations. H.R. 592, the Pharmacy and Medically Underserved Areas
Enhancement Act, would provide medically underserved beneficiaries with access to Medicare
Part B services from pharmacists, in compliance with scope of practice laws in each state.

The New Jersey Pharmacists Association (NJPhA) urges you to include H.R. 592 in the
deliberations as the House Energy and Commerce Committee considers its options for addressing
the opioid crisis. I appreciate the opportunity to submit these comments on behalf of NJPhA, and I
look forward to providing additional information to assist you.

Sincerely,

Elise M. Barry, MS, CFRE
Chief Executive Officer
The Honorable Greg Walden  
Chairman  
House Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515  

Dear Chairman Walden,

Oregon State Pharmacy Association (OSPA) was founded in 1889 as a professional trade association representing its member community of pharmacists, pharmacy technicians, pharmacy students and others who have an interest in advancing the practice of pharmacy through advocacy and education and thereby improving the health of our fellow Oregonians.

We write today to express support and gratitude for your efforts to address the opioid epidemic. We are committed to working with Congress and other health professionals and stakeholders to identify ways pharmacists can help curb opioid abuse and misuse and positively impact treatment. We believe that more fully engaging pharmacists on the health care team presents a unique opportunity to improve outcomes for patients and reduce challenges, including those related to opioids. Pharmacists play a unique role in patients’ care as well as being the medication experts, and with 89% of Americans living within five miles of a community pharmacy, frequently the health care professional that a patient will see the most.

As the medication experts on the patient’s health care team, pharmacists play an important role in helping patients manage chronic pain and preventing prescription drug misuse and abuse. Pharmacists are involved in pain management programs that include medication tapering services, work in medication assisted treatment programs and furnish naloxone. In Oregon, pharmacists have the authority to prescribe naloxone to any individual or entity seeking naloxone.

Pharmacists can help fight against the opioid epidemic by managing and optimizing the impact of medications, reviewing medications to help prevent overprescribing, tailoring care plans to patient needs, providing recommendations for non-opioid pain management alternative and educating patients regarding opioids.

One of the greatest barriers for pharmacists to provide these services is that pharmacists’ clinical services are not covered under Medicare. As a result, beneficiaries’ access to the health care practitioner with the most medication-related education and training is limited, and restricted mainly to services related only to the dispensing of medications. By not including pharmacists among other providers whose services are covered, Medicare also effectively makes it more difficult for other members of the health care team and patients to work with pharmacists as part of a coordinated, team-based approach to care.

OSPA urges The House Energy and Commerce Committee to advance Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592/S.109) to help prevent opioid abuse
and misuse, increase treatment options and better manage patients’ pain through pharmacist-provided care.

It is critical that patients and other health care providers can utilize the medication experts on a care team as efforts to enhance prevention, patient education, prescribing, tapering and treatment of substance use disorder are implemented.

Thank you, again, for your leadership in addressing the opioid epidemic. We ask that you support and advance H.R. 592. We welcome the opportunity to work with you to better utilize pharmacist to help patients access the care they need to positively impact this serious problem facing our nation. Should you have any questions, please contact OSPA at 503-582-9055.

Sincerely,

Oregon State Pharmacy Association - Executive Committee

Kevin Russell, RPh, BCACP, Immediate Past President
Amy Valdez, RPh, President
Tiffanie Pya, PharmD, BCPS, President Elect
Linh Chau, RPh, Treasurer
Dear Chairman Walden and Ranking Member Pallone,

On behalf of the members of the Tennessee Pharmacists Association (TPA), I greatly appreciate the opportunity to submit these comments regarding the House Energy and Commerce Committee hearings on the opioid crisis. As the only 501(c)(6) professional organization in Tennessee representing approximately 3,000 pharmacists, student pharmacists, pharmacy technicians, and associate members in all pharmacy practice areas, TPA's mission is to advance, protect, and promote high-quality pharmacist-provided patient care in Tennessee. TPA would like to acknowledge and thank you for your efforts to address this very important public health issue.

I am writing to you today to express my support and appreciation for your efforts to address the opioid epidemic and to offer potential solutions to our nation's current opioid misuse and abuse epidemic. Pharmacists in Tennessee have been, and remain, committed to working with state and federal legislators, as well as other health professionals and stakeholders, to identify and implement strategies which support pharmacist involvement in preventing opioid abuse and misuse and positively impacting treatment for opioid addiction. Perhaps the most pressing and concerning issue with respect to our pharmacists' ability to play a more active role in combatting this opioid crisis is our notable absence from inclusion on the patient's health care team at the federal level. As the medication experts, it is essential that our pharmacists are fully empowered to improve outcomes for Medicare patients and to reduce medication-related challenges, including those related to opioids.

Pharmacists play a unique role in patients' care, and with 89% of Americans living within five miles of a community pharmacy, frequently the health care professional that a patient will see the most. Pharmacists can use their medication expertise to identify at-risk behaviors, better manage pain treatments, and educate patients and families about the safe use of opioids as well as the potential need for and appropriate use of medications to reverse the effects of narcotic drugs, such as naloxone.

Unfortunately, because our health care system is not currently fully engaging the most accessible and
knowledgeable medication expert, patients and other health care providers are placed at a significant
disadvantage.

Tennessee is now the second state, following the state of Washington, to enact state-level legislation
which formally recognizes pharmacists as medical providers and compensate them as such for the care
and services that are provided within their scope of practice. The enactment of this legislation in
Tennessee has opened up many discussions with payers and other health care providers about ways to
more fully integrate pharmacists as providers to positively affect the patient’s health care journey. One
of the most important discussions occurring in our state right now is the exploration of ways for our
pharmacists to play a more significant role in increasing patient access to opioid abuse prevention and
opioid addiction treatment services.

Here are some ways TPA believes pharmacists can play a more integral role in the fight against opioid
misuse and abuse:

- Pharmacists are equipped to provide opioid management, preventive counseling, and risk factor
  reduction interventions to patients at the point of care every day. These efforts have the
  potential to substantially reduce prescription drug abuse, especially for our patients who may
  be at high risk for opioid abuse and misuse.
- Pharmacists’ expertise can be leveraged to provide preventive opioid medication counseling for
  patients at risk of opioid overutilization, as well as play a greater role in Screening, Brief
  Intervention, and Referral to Treatment (SBIRT).
- Pharmacists can provide long-term management services for patients in recovery through the
  administration of long-acting injectable medication therapies, such as naltrexone and
  buprenorphine, to treat opioid dependence and addiction. By increasing patient access to these
  medication therapies through local community pharmacists, our patients in recovery from
  opioid dependence will have a greater chance of achieving positive therapeutic outcomes and
  maintaining successful long-term recovery.
- Pharmacists can serve as primary providers for emergency opioid reversal agents such as
  naloxone which will help to save lives through the prevention of opioid-related deaths.
  Pharmacists’ role in providing naloxone was recently reinforced by US Surgeon General (VADM)
  Jerome Adams, MD, MPH.
- Pharmacists can help patients living with chronic conditions, who often take a large number of
  medications, by identifying and mitigating the potential for patients’ misuse of medications.
- Pharmacists have access to the patient’s complete medication profile, which places them in a
  unique position to coordinate care and bridge the information and communication gap related
  to medication therapies between all health care providers, and especially those patients with
  legitimate pain management needs to help them achieve their treatment goals.
- Pharmacists can leverage their respect and trust with patients to enhance healthcare capacity
  and strengthen community partnerships. Including pharmacists as essential providers of care
  and formally recognizing the value pharmacists offer as a member of the healthcare team will
  allow our health care system the ability to utilize pharmacists to the full scope and extent of
  their training to help in the fight against opioid misuse and abuse, especially in our rural and
  underserved communities.

Unfortunately, because pharmacists’ services are not currently covered under Medicare Part B, our
pharmacists are still limited in their ability to care for our seniors, who are among our most vulnerable
patients. As a result, beneficiaries’ access to the health care practitioner with the most medication-
related education and training is limited, and restricted mainly to services related only to the dispensing
of medications. By not including pharmacists among other Part B providers whose services are covered, Medicare also effectively makes it more difficult for other members of the health care team and patients to work with pharmacists as a part of a coordinated, team-based approach to care.

Conclusion

On behalf of the Tennessee Pharmacists Association, I want to commend you and thank you again for efforts to combat the opioid epidemic. Pharmacists stand with you in the fight against this opioid epidemic. As one of the most accessible members of the health care team, pharmacists are willing and ready to help manage and optimize medication-related health outcomes, review medications to tailor care plans to patient needs, provide recommendations for non-opioid pain management alternatives, and educate patients regarding opioids. I urge you to consider including pharmacists in this federal opioid reform legislation through the inclusion of the Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592).

Thank you for your time and for this opportunity to submit these comments for your consideration. Please feel free to contact me if you have any questions.

Sincerely,

Micah Cost, PharmD, MS
Executive Director
Tennessee Pharmacists Association
micah@tnpharm.org
Dear Chairman Walden and Ranking Member Pallone,

As CEO of the Texas Pharmacy Association (TPA), an association representing nearly 30,000 pharmacists in Texas, I write today to express support and gratitude for your efforts to address the opioid epidemic. TPA is committed to working with Congress and other health professionals and stakeholders to identify ways Texas pharmacists can help curb opioid abuse and misuse and positively impact treatment. We respectfully request that H.R. 592, the Pharmacy and Medically Underserved Areas Enhancement Act, be included in the opioid package of legislation which you are diligently working. We believe that H.R. 592 will help prevent opioid abuse and misuse, increase treatment options and better manage patients’ pain through pharmacist-provided care; thus, helping communities in Texas address the opioid epidemic.

More fully engaging pharmacists on the health care team presents a unique opportunity to improve outcomes for Medicare patients and reduce challenges, including those related to opioids. Pharmacists are on the frontlines of health care and play a unique role in patients’ care. With 89% of Americans living within five miles of a community pharmacy, pharmacists are frequently the health care professional that patients see the most. As the most accessible health care practitioner, pharmacists can use their medication expertise to identify at-risk behaviors, better manage pain treatments, and educate patients and families about the safe use of opioids as well as the potential need for and appropriate use of medications to reverse the effects of narcotic drugs, such as naloxone. Pharmacists can also provide opioid management/preventive counseling and/or risk factor reduction interventions at the point of service, which has the potential to substantively reduce abuse.

While pharmacists have traditionally dispensed prescription medications and helped patients use them safely, today’s pharmacists are trained and licensed to provide a number of additional services needed by many Medicare beneficiaries. As part of the health care team, pharmacists can play an important role in helping to address opioid misuse and abuse as well as treatment. For example, because pharmacists see the patient’s complete medication profile, they can help bridge any communication gap that may exist among providers by coordinating and providing medication-related services. This is particularly important for patients living with chronic conditions who have medications from multiple providers.

Pharmacists working with other health care providers, improve care coordination and delivery, resulting in better health outcomes for Medicare patients. As the medication use experts, pharmacists can help...
prescribers determine the optimal drug for the indication, determine duration, appropriate quantities to
dispense in the outpatient settings, and oversee the plan through transitions of care. Given the
prevalence of the opioid problem in communities across Texas and the country, pharmacists, who are
already in these communities, can help provide better management and monitoring services to fill the
gap in access to care.

It is of the utmost importance that Medicare patients are able to access pharmacists’ services, which can
help prevent prescription drug misuse and abuse, in addition to improve treatment outcomes.
Authorizing pharmacist clinical services in the Medicare Part B benefit would expand beneficiaries’
access to care, including pain management education and treatment.

Thank you, again, for your leadership in addressing the opioid epidemic. The Texas Pharmacy
Association welcomes the opportunity to work with you to better utilise pharmacists to help Medicare
beneficiaries access the care they need to positively impact this serious problem facing Texas and our
nation. Should you have any questions, please contact me at Debbie.garza@texaspharmacy.org or (512)
615-9170.

Sincerely,

Debbie B. Garza, R.Ph.
Texas Pharmacy Association, CEO
April 10, 2018

The Honorable Greg Walden
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Walden and Ranking Member Pallone:

I am writing today on behalf of the members of Washington State Pharmacy Association to express appreciation for your efforts to address the opioid epidemic. Our Washington state pharmacists and pharmacy technicians are dedicated to working with Congress and other health professionals and stakeholders to identify ways pharmacists can help curb opioid abuse and misuse and positively impact treatment. We believe that by more fully engaging pharmacists on the health care team presents a unique opportunity to improve outcomes for Medicare patients and reduce challenges, including those related to opioids. Pharmacists play a unique role in patients’ care as they are the medication experts, and with 89% of Americans living within five miles of a community pharmacy, frequently the health care professional that a patient will see the most. Washington state has many rural communities and I can attest to the important role these pharmacists play in providing access to health care.

Today’s pharmacists are trained and licensed to provide many services in addition to dispensing prescription medications and helping patients use them safely. As part of the health care team, pharmacists can play an important role in helping to address opioid misuse and abuse as well as treatment. When pharmacists are able to work with other providers on the patient’s health care team, it improves care coordination and delivery, resulting in better health outcomes for Medicare patients. As the medication use experts, pharmacists can help prescribers determine the optimal drug for the indication, determine duration, appropriate quantities to dispense in the outpatient settings, and oversee the plan through transitions of care.

WSPA strongly believes that Medicare patients should be able to access pharmacists’ services as private insurance patients have been able to do here in Washington since 2015. Through pharmacists’ better engagement, we help prevent prescription drug misuse and abuse, in addition to improve treatment outcomes. Authorizing pharmacist clinical services in the Medicare Part B benefit would expand beneficiaries’ access to care including medication and pain management services and treatment.

Pharmacists in Washington, with a collaborative drug therapy agreement in place, are providing care in community pharmacies resulting in more rapid assessment and initiation of therapy, thus improving patient health outcomes. We believe it is important that Medicare patients have access to these same services where pharmacists provide care for ailments and conditions such as:

411 Williams Avenue South, Renton, WA 98057-2748
(p) 425.228.7171   (f) 425.277.3897   www.wsparx.org
1. Bronchospasm, wheezing, shortness of breath from asthma or COPD
2. Animal bite (Human, Dog, or Cat)
3. Eye or nasal symptoms from seasonal allergies or other allergic conditions
4. Herpes virus infections (cold sores, genital herpes, shingles)
5. Allergic reactions from bee stings (not anaphylactic)
6. Acute otitis media
7. Anaphylactic allergic reactions
8. Lacerations and abrasions
9. Nausea and vomiting (not related to motion sickness)
10. Contraceptive pregnancy prevention
11. Conjunctivitis
12. Nausea and vomiting caused by motion sickness
13. Wound infections from burns
14. Migraine headaches
15. Ear infections caused by bacteria
16. Lack of fluoride for oral health
17. Diarrhea that occurs while traveling
18. Uncomplicated urinary tract infections
19. Vaginal yeast infections
20. Streptococcal pharyngitis

Collaborative drug therapy agreements are the foundation for pharmacists to manage and monitor prescription pain treatment plans as well.

Over 250 of your colleagues have cosponsored the Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592) that would provide medically underserved beneficiaries with access to Medicare Part B services by pharmacists, consistent with state scope of practice law. We appreciate the Committee's attention to H.R. 592 and look forward to working with you on its passage as an important way to help the address the opioid crisis.

Thank you, again, for your leadership in addressing the opioid epidemic. Washington state pharmacists and pharmacy technicians welcome the opportunity to work with you to better utilize pharmacists to help Medicare beneficiaries access the care they need to positively impact this serious problem facing our nation.

Sincerely,

[Signature]
Jeff Rochon, Pharm.D.
Chief Executive Officer
The Centers for Medicare & Medicaid Services (CMS) has issued a series of Informational Bulletins on effective practices to identify and treat mental health and substance use disorders covered under Medicaid. The purpose of this Bulletin is to highlight emerging Medicaid strategies for preventing opioid-related harms. The epidemic of opioid overdose, misuse and addiction is a critical public health issue that affects the lives of millions of Americans, including those who are enrolled in the Medicaid program. This Informational Bulletin provides background information on overdose deaths involving prescription opioids, describes several Medicaid pharmacy benefit management strategies for mitigating prescription drug abuse and discusses strategies to increase the provision of naloxone to reverse opioid overdose, thereby reducing opioid-related overdose deaths. Wherever possible, the bulletin provides examples of methods states can use to target the prescribing of methadone for pain relief, given the disproportionate share of opioid-related overdose deaths associated with methadone when used as a pain reliever.

**Background**

Opioid misuse, overdose and addiction occurs in only a subset of individuals prescribed opioid medications for pain relief. However, because many individuals take opioids, the number of Americans affected is significant. According to the Centers for Disease Control and Prevention (CDC), deaths due to prescription opioid pain medication overdose in the United States have more than quadrupled from 1999 to 2011. Of the 43,982 drug overdose deaths in 2013, 37 percent were associated with prescription opioid analgesics (e.g., oxycodone, hydrocodone and methadone). A primary driver of the rapid rise in opioid overdose deaths was the increased...
number of prescriptions for opioid pain medications, especially prescriptions associated with high doses, longer course of treatment and in conjunction with benzodiazepine use. This increased prescribing was driven by concerns about insufficient treatment of pain and lack of accurate information about the potential for addiction.

In addition to the increase in drug-related deaths, the rise in opioid prescribing has led to increases in the prevalence of opioid use disorder. Inappropriate opioid prescribing can also result in costly medical complications such as nonfatal overdoses, falls and fractures, drug-drug interactions and neonatal conditions. These complications result in costly, preventable healthcare expenditures and cause an incalculable amount of emotional suffering.

Combatting the epidemic of opioid misuse, overdoses and addiction is the focus of a Department of Health and Human Services multipronged initiative. The initiative involves actions to improve opioid prescribing and risk mitigation strategies, increase the dissemination of overdose prevention education and expand use of naloxone (a prescription drug that reverses opioid overdoses) as well as access to substance use disorder (SUD) treatment, including medication assisted treatment for opioid use disorders.

Research shows the opioid epidemic has a disproportionate impact on Medicaid beneficiaries. Medicaid beneficiaries are prescribed painkillers at twice the rate of non-Medicaid patients and are at three-to-six times the risk of prescription painkillers overdose. North Carolina found that while the Medicaid population represented approximately 20 percent of the overall state population, it accounted for one-third of drug overdose deaths, the majority of which were caused by prescription opioids. One study from the state of Washington found that 45 percent of people who died from prescription opioid overdoses were Medicaid enrollees.

Though all prescription opioids can contribute to unintentional overdose and death, methadone in particular accounts for a disproportionate share of opioid-related overdoses and deaths. To address this, many state drug utilization review programs already incorporate utilization management criteria addressing the use of methadone. In order to reduce prescription opioid-related harms, states are encouraged to consider additional steps to reduce the use of methadone.

---

prescribed for pain relief. For decades, methadone has been safely and effectively used in medication assisted treatment for opioid use disorder. Under appropriate circumstances, methadone can also be an effective pain medication. However, methadone’s pharmacokinetics and pharmacodynamics make it a complex medication to prescribe for pain relief. As methadone’s use for pain relief has increased, so has the number of methadone related overdoses. While methadone represented less than 5 percent of opioid prescriptions dispensed between 2002 and 2008, it was implicated in one-third of opioid-related deaths during that time period. Between 2004 and 2006, the rate for methadone-related emergency department visits was approximately 23 times greater than for hydrocodone, and six times greater than for oxycodone. The CDC estimates that 30 percent of prescription opioid-related drug overdose deaths in 2009 involved methadone prescriptions for pain.

The increased risk of morbidity and mortality associated with methadone is evident in the Medicaid population. Between 2006 and 2010, the rate of methadone overdose was 10 times greater than that for other prescription opioids among the Washington Medicaid population. Further, overdoses involving methadone were more than twice as fatal as overdoses involving other prescription opioids. Tennessee found that the risk of out-of-hospital death in non-cancer Medicaid patients receiving methadone was 46 percent greater than that for those receiving morphine.

Given the disproportionate share of opioid-related overdose deaths associated with methadone prescribed for pain relief purposes, states may consider options to reduce the use of methadone prescribed as a pain reliever as part of their efforts to reduce opioid-related harms.

Given the high impact on the program, Medicaid plays an important role in curbing the epidemic of deaths and injuries from opioid medications. Medicaid programs can encourage the use of safer, effective alternatives to opioid pain medications—in particular, alternatives to methadone prescribed for pain relief—by working collaboratively with other state agencies to educate Medicaid providers about opioid prescribing and dispensing practices. Medicaid programs can consider pharmacy benefit management strategies such as reassessing preferred drug list (PDL) placement, introducing clinical criteria, prior authorization, step therapy, quantity limits, and

16 Ibid.
implementing drug utilization review (DUR) processes. These strategies should be revisited continually as the nature of the opioid epidemic evolves and new information emerges. States can also work to increase access to (and use of) Prescription Drug Monitoring Programs (PDMPs) to monitor opioid prescribing. Importantly, as part of a comprehensive strategy to address opioid use disorder and reduce opioid-related overdose deaths, states can consider strategies to increase the provision of naloxone and medically necessary substance use disorder treatment services. CMS initiatives and opportunities regarding substance use disorder are discussed at the end of this Bulletin.

Effective Medicaid Pharmacy Benefit Management Strategies

Opioid pain medication is one of many options to address pain relief; however, it is associated with significant risks such as sedation, cardiac arrhythmias, increased risk of falls and the development of substance use disorders. Reinforcing provider awareness about the appropriate use of opioid pain medications, as well as non-opioid analgesic options, is crucial to decreasing inappropriate opioid prescribing. Studies show limited evidence of long-term beneficial effects of long-term opioid therapy in improving chronic pain and functioning. In addition to patients’ clinical morbidities, the risks associated with opioid use vary depending on numerous factors including the dose, type, prescribed quantity, duration of treatment and the potential for drug-drug interactions including those precipitated by the concomitant use with other central nervous system depressants or sedatives (e.g. benzodiazepines) that increase the risk of respiratory depression. There is no formula for predicting which individuals who are prescribed opioid medications for pain will develop a substance use disorder (a dependency or addiction) or suffer an overdose. However, states can assist in minimizing these risks by implementing the following approaches:

Provider Education

States can improve opioid medication prescribing and dispensing practices by (1) supporting training for health care professionals (e.g., pharmacists, nurses, other prescribers); (2) disseminating opioid prescribing guidelines which include protocols for safer prescribing of methadone; and (3) providing clinician feedback on prescribing. These tools can highlight the importance of a complete patient assessment prior to prescribing opioid medications that would include an evaluation of the underlying etiology of pain and a screening for risk factors (e.g., substance use disorders, contraindicated medications, mental health conditions as well as parameters that could indicate higher risk for cardiac, hepatic or pulmonary adverse events like respiratory depression) that are associated with a higher probability of opioid-related harms.


22 Ibid.


These tools should also emphasize the need for ongoing patient monitoring. Educational materials can offer guidance on the decision to initiate opioid pain medications and, if appropriate, which type of medication to initiate. For instance, methadone, which is characterized by complicated and variable pharmacokinetics and pharmacodynamics, should be initiated and titrated cautiously only by clinicians who are familiar with its use and risks. Recent guidelines provide monitoring recommendations for prescribing methadone to specific patients.

Several state Medicaid agencies have been part of collaborative efforts to educate providers about opioid medication prescribing. For example, Washington State developed an opioid prescribing guideline in 2007 which has since been updated that uses an interagency state work group in collaboration with clinical experts. As part of a comprehensive effort, overdose deaths and hospitalizations for prescription opioids in Washington have declined in recent years.

Preferred Drug List

Medications are often designated as preferred or non-preferred drugs by the pharmacy and therapeutics committee (P&T) or DUR board of the state Medicaid agencies or contracted managed care organization. In most cases, providers are permitted to prescribe preferred drugs without seeking prior authorization. However, if a drug is listed as non-preferred on the PDL, the providers are usually required to obtain approval from the state Medicaid agency or managed care plan before the drug is paid for. States may subject a drug to such prior authorization consistent with the requirements of section 1927(d)(5) of the Act.

Given the significant evidence suggesting that the use of methadone contributes disproportionately to opioid overdose and deaths, the known complexities with appropriately prescribing this medication as well as the widespread availability of other medications to treat pain, we urge that states remove methadone for pain (outside of end of life care) from their preferred drug lists. This is consistent with the recommendation from the CDC that methadone should not be considered a drug of first choice by prescribers or insurers for chronic non-cancer pain. States that provide a prescription drug benefit will still have to make the drug available to Medicaid patients who need it, as long as it is a covered outpatient drug. By removing the drug from preferred status, states have the option of limiting its use to only those patients for whom treatment with other pain medications is ineffective.

Clinical Criteria

States may decide that methadone should remain a preferred drug while requiring edits that allow claims to be authorized for payment at the point-of-sale (POS) only when the recipients’ claims and/or diagnosis history satisfy each of the clinical criteria established to ensure appropriate utilization of the drug. For example, when states process methadone claims, the automated review of the recipients’ claim histories could confirm the presence or absence of any recent claims for benzodiazepines or long-acting opioids within a specified time period. The concomitant use of methadone with these medications could be precluded due to drug-drug interactions that increase the recipients’ risk of respiratory depression and opioid overdose. Additionally, before methadone claims are paid, the automated review could ascertain chronic pain diagnosis in the recipients’ diagnosis histories. When methadone claims do not satisfy these clinical criteria, payment would not be immediately authorized at the POS. Instead, the claims would be subject to the prior authorization process consistent with the requirements of the Act, which would require the provider to obtain approval from the state Medicaid agency or contracted managed care organization.

Step Therapy

A Medicaid program may require the trial of another agent prior to the use of a specific drug. For example, a state that has methadone on its PDL may require that, before authorizing payment, an examination of the recipient’s claims history is performed to ensure that the recipient used another preferred, long-acting opioid for a specified duration before beginning methadone therapy.

The state of Vermont implemented prior authorization criteria which involves step therapy for methadone recently. Among other criteria, this state has a requirement that before initially being prescribed methadone for pain, patients must have documented side effects, allergies, or treatment failure to a preferred, long-acting opioid.

Prior Authorization

Prior authorization typically means that the Medicaid agency or the contracted managed care organization will not pay for Medicaid beneficiaries’ medication unless the provider has obtained permission before prescribing the drug. The criteria for prior authorization often reflect evidence-based standards consistent with the compendia listed in 1927(g)(1)(B). For example, prior authorization can help ensure that prescriptions for pain in doses higher than 30 milligrams of methadone per day (the recommended maximum daily starting dose) are appropriate.

Virginia’s Medicaid program is one of 19 states with prior authorization criteria for long-acting opioid pain medication. Before long-acting opioids can be approved for managing chronic, nonmalignant pain, providers must (1) document that there is treatment plan that includes a diagnosis, the goals of therapy as well as an assessment of addiction risk; and (2) attest that the Virginia Board of Pharmacy PDMP database has been recently reviewed. Patients must sign a pain management contract that addresses the consequences of unexplained loss or shortage of
medications as well as those associated with obtaining similar prescription medications from other prescribers. Patients must also sign an agreement to use only one pharmacy further described below in patient review and restriction programs.

**Quantity Limits**

A state Medicaid agency or contracted managed care organization may impose quantity limits on medications as a way to promote safe and appropriate use of a medication, ensuring that they are not overprescribed. For example, quantity limits may be useful in verifying that a methadone prescription for pain is prescribed only for a specified duration, so the prescriber can reassess the recipient periodically. A significant percentage of states apply quantity limits to opioid products prescribed for pain.

**Drug Utilization Review**

Retrospective and concurrent drug utilization review (DUR) measures can be used to identify potentially inappropriate prescribing practices. States are encouraged to exercise sound clinical judgment and utilize available resources to aid their DUR programs and P&T committees. We note the availability of the Pharmacy Quality Alliance’s three measures of potential opioid misuse and abuse. These measures include receiving opioids (1) at high dosage, (2) from multiple prescribers and pharmacies, and (3) at high dosage and from multiple prescribers and pharmacies. In order to optimize care while discouraging fraud, waste and abuse of prescribed opioids, states are encouraged to consider implementing programs that provide ancillary care for beneficiaries diagnosed with chronic pain who have been found to be receiving unusually high doses of opioids, seeing multiple prescribers or pharmacies.

**Increase Access to and Use of State Prescription Drug Monitoring Programs**

PDMPs collect data from pharmacies, outpatient hospital pharmacies, outpatient clinics and other data submitters on dispensed, controlled substance prescriptions. To oversee its PDMP, each state designates an agency which may include, but is not limited to health departments, pharmacy boards or a state law enforcement agency. Additionally, each state controls who will have access to the database and for what purpose. Authorized users can obtain these data through a secure and electronically-accessible database. PDMPs have been shown to be effective in preventing drug diversion.

CMS understands that many Medicaid agencies have reported barriers that hinder their ability to utilize the PDMP database in their state. These barriers include lack of funding to maintain operation of the PDMP, prescribers not accessing the database to obtain patient history, lag time in submission of prescription data to the database, administrative limitations denying real-time access and restrictions limiting Medicaid agency access to the database. Reasons for limiting Medicaid agency access to PDMPs include state laws prohibiting Medicaid agency access, Medicaid pharmacy staff being denied access because they are not directly delivering healthcare, database access being limited to law enforcement members or access allowed only for active

---

investigations. In addition, some states allow patients to opt out of having their prescriptions entered into the database. However, despite these barriers, some states allow Medicaid programs to access PDMP data so they can better identify potential inappropriate prescribing and use of controlled prescription drugs, such as opioids, and some Medicaid agencies require prescribers and pharmacies to access patient history in the PDMP database prior to prescribing and dispensing controlled substances, thereby enhancing states’ DUR program oversight activities. There are several strategies states can pursue to increase PDMP adoption and functionality. For example, in states where Medicaid can access PDMP information, state Medicaid programs can consider including language into provider agreements and managed care contracts to require providers to access their state PDMP as a condition of provider agreement and payment, to the extent that such access is permissible under applicable Federal and state laws. Further, states can harness the benefits of their PDMP use by requiring mandatory electronic prescribing of controlled substances if consistent with applicable Federal and state laws. To enhance functionality, states could develop real-time data infrastructure between pharmacy POS systems and PDMPs to capture cash transactions. This would enable PDMP users to determine if beneficiaries are filling opioid prescriptions outside of the Medicaid benefit and/or are using multiple pharmacies. Such programs would be subject to applicable Federal laws as well as state privacy laws. In states where the Medicaid agency has limited access to the PDMP, state Medicaid directors could advocate directly with State Boards of Pharmacy and state legislators to promote access. Successful collaborative initiatives to reduce prescription opioid abuse in Oklahoma and Washington included promoting full access to PDMP data for monitoring and data research purposes.\(^{31,32}\)

In 2013, New York required prescribers to check the state’s PDMP before prescribing opioid pain medications. Since 2013, they reported a 75 percent drop in the number of patients who used multiple prescribers and pharmacies for controlled prescription drugs.\(^{33}\) In concert with related policies targeting inappropriate opioid prescribing, Florida found that oxycodone-caused mortality declined 25 percent in the month immediately following implementation of Florida’s PDMP.\(^{34}\) Other states showed a decrease in controlled substance prescriptions and patients visiting multiple practitioners seeking opioid pain medications. In addition, states were able to identify patients in need of addiction or pain management support. Improvements in prescribing behaviors and decreases in adverse effects are expected to be even greater when the PDMP is part of a health information technology system. PDMPs are most effective when they are used by all clinicians, don’t interfere with access to medicine for legitimate medical needs and protect sensitive personal and health information.\(^{35}\)


Most Medicaid programs have implemented Patient Review and Restriction programs (PRRs) to address possible patient overuse of opioid medications and other controlled prescription drugs. If a Medicaid agency finds that beneficiaries have used Medicaid services at a frequency or an amount that is not medically necessary, as determined in accordance with utilization guidelines established by the state, the agency may restrict those beneficiaries to obtain Medicaid services from designated providers for a reasonable period of time. Medicaid programs can only impose these restrictions if they (1) give patients notice and an opportunity for a hearing, (2) ensure that restricted patients still have reasonable access to Medicaid services, and (3) exclude emergency services from the restriction as described in 42 CFR 431.54(e). A number of state Medicaid programs including Louisiana, Washington, Oklahoma, Connecticut, Iowa, and North Carolina report that their PRRs have resulted in fewer narcotic analgesic pills prescribed and cost savings. 36

While states may consider the aforementioned approaches to reduce the risk of prescription opioid-related harm, states should develop policies and strategies that are consistent with the Mental Health Parity and Addiction Equity Act which seeks to ensure that financial and treatment limitations for mental health and substance use disorders are applied no more restrictively than medical/surgical benefits. 37 This includes the use of prior authorization, step therapy and quantity limits which may be seen as treatment limitations that would be inconsistent with the application of the Mental Health Parity and Addiction Equity Act to the Medicaid program. CMS is available to provide technical assistance on these points.

Increasing the Use of Naloxone to Reverse Opioid Overdose

In addition to the pharmacy benefit management and monitoring strategies described above, states can also work to increase the provision of naloxone to reverse drug overdoses and reduce the number of opioid-related overdose deaths.

Naloxone is a drug indicated for the complete or partial reversal of narcotic depression, including respiratory depression induced by opioids including natural and synthetic narcotics, propoxyphene, methadone and certain narcotic-antagonist analgesics. It is also indicated for the diagnosis of suspected acute opioid overdose. 38 Naloxone prevents or reverses the potential life-threatening effects of opioids, including respiratory depression, sedation, and hypotension, thereby allowing an opioid overdose victim to resume normal breathing. Naloxone has not been

shown to produce tolerance or to cause physical or psychological dependence and is not designated as a controlled substance by the Drug Enforcement Agency. In the absence of opioids or agonistic effects of other opioid antagonists, naloxone exhibits essentially no pharmacologic activity. However, in cases of opioid overdose emergency, naloxone is most effective with rapid onset of action and this requires it to be administered in a timely manner.

In most states, naloxone is not available as an over-the-counter drug. Instead, it can be provided by prescription during the regular course of medical care. Depending on a state’s laws, this medication can be provided by pharmacist-initiated collaborative practice agreements, pharmacist prescriptive authority, state authorizing legislation (which protects physicians who prescribe and citizens who administer take-home naloxone), or community-based overdose education and naloxone distribution programs.

To promote ease of access to this potentially life-saving treatment, some communities distribute naloxone kits (that may contain naloxone and syringes fitted with an atomizer for easier nasal administration as opposed to intravenously) and often provide training on the proper use of these products. The first FDA-approved naloxone nasal spray was approved in November of 2015. State Medicaid agencies vary in their coverage of take-home naloxone and the atomizer (i.e., a pump-driven device that sprays injectable naloxone into the nose) for its administration. Some states cover the cost of the drug only after preapproval or prior authorization on the basis of medical necessity. Some only cover the cost of the drug and not the atomizer. Others cover the cost of the drug (with or without the atomizer) only for selected Medicaid populations (e.g., individuals enrolled in managed care, fee-for-service, or an alternative benefit plan).

For example, New Mexico’s Medicaid program reimburses for naloxone rescue kits for beneficiaries at risk for opioid overdose.

State Medicaid programs, in coordination with other state organizations, have taken the following strategies to improve access to naloxone:

Include Naloxone on the Medicaid Preferred Drug List

Medicaid programs in a number of states such as California and New York include all injectable forms of naloxone including the auto-injectable form on their Medicaid Preferred Drug Lists. States that provide a prescription drug benefit are reminded that the Fee-for-Service program and the managed care organization contractors must provide coverage for drugs that are

---

covered outpatient drugs (that is, drugs from manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Act, unless specifically excluded from coverage by statute), such as the auto-injectable and intranasal formulations of naloxone, whether or not they are included on their Preferred Drug Lists.

**Expand Community-Based Naloxone Distribution Programs**

Providing naloxone kits to laypeople reduces overdose deaths while being safe and cost effective.44,45,46 U.S. and international health organizations recommend providing naloxone kits to patients in substance use treatment programs, individuals leaving prison and jail and laypeople who might witness an opioid overdose.47 As of 2014, the CDC reported that naloxone distributed to laypeople had resulted in more than 26,000 overdose reversals nationwide since 1996.48 Since 2006, Massachusetts has implemented an overdose education and naloxone distribution program that significantly reduced overdose deaths in the 19 communities.49

**Expand Access to Naloxone by Making It Available Without a Prescription**

On July 16, 2015, Ohio’s governor enacted emergency legislation that makes naloxone available without a prescription in the state. With this policy change, pharmacies can now offer naloxone over the counter to individuals cleared by a doctor or health official. Kentucky also enacted a similar approach in 2015 that allowed first responders or members of an opioid user’s family to receive naloxone without a prescription.

**Offer Training in Overdose Prevention and Response**

States such as Rhode Island are expanding the training that they provide for overdose prevention and response. To reduce overdose deaths, this training is being offered to opioid users, their families and friends, addiction treatment program staff, community coalitions, human services providers, correctional staff, first responders, prescribers, and pharmacists.

**State Laws That Have Been Enacted To Address Liability Concerns Related to Naloxone**

A number of states have passed laws that address both bystander and physician concerns regarding the distribution and administration of take-home naloxone. These laws generally provide legal protection to the physicians who prescribe and to the bystanders ("Good

---

Samaritans”) who possess or administer take-home naloxone. For example, state laws may provide immunity from civil or criminal liability by waiving criminal liability for possession of naloxone without a prescription, hypersons’ administration of naloxone, or authorizing prescriptions to third parties other than those at risk of overdose.

**Expanding Coverage and Access to Opioid Use Disorder Treatment**

As part of a comprehensive strategy to address opioid use disorder, states can assess their Medicaid benefits coverage, delivery systems, payment mechanisms and provider networks for substance use disorder services to ensure that effective treatments are available to beneficiaries when medically appropriate. This Informational Bulletin is the latest in a series of actions CMS has taken to support state efforts to effectively design, deliver and pay for services to treat substance use disorder. CMS is available to assist states in determining how to incorporate additional services and providers into their Medicaid programs, as we believe ensuring access to a robust set of treatment models is critical to combatting opioid use disorder and its healthcare complications.

In July 2014, CMS launched the Medicaid Innovation Accelerator Program (IAP), a strategic support platform designed to support states’ ongoing delivery system reforms. Based on our work with states and stakeholders, CMS identified substance use disorder as the first focus area for IAP efforts. The IAP provides states with expert resources, coaching opportunities and hands-on program support to accelerate policy, program and payment reforms appropriate for a robust SUD system. The goal of the IAP initiative on SUD is to support participating states to better identify individuals with SUD, enhance provider capacity to effectively treat individuals with SUD, and expand coverage for promising and evidence-based SUD services, such as medication-assisted treatment.

CMS also recently issued several Informational Bulletins regarding Medicaid coverage for behavioral health conditions, including a joint publication with the Substance Abuse and Mental Health Services Administration, the Centers for Disease Control and Prevention, and the National Institute on Drug Abuse describing best practices, state-based initiatives and useful resources for the delivery of medication-assisted treatment. In January 2015, CMS released an Informational Bulletin addressing early identification and treatment of adolescents with a SUD. Earlier this year, CMS also proposed several rules that, if finalized, would strengthen states’ ability to provide services to individuals with substance use disorder. In April 2015, CMS issued a proposed rule that would offer the protections of the Mental Health Parity and Addiction Equity Act to any beneficiary enrolled in a Medicaid or CHIP managed care organization. CMS is currently considering comments on the rule. In May 2015, CMS proposed a rule that would allow states to claim federal funds for managed care beneficiaries who receive crisis stabilization treatment in inpatient and sub-acute crisis facilities. This provision of the proposed managed care rule is designed to improve access to medically necessary short-term inpatient behavioral health services.


CMS recognizes the need to improve access to non-hospital based services as well. In July 2015, CMS issued guidance on a new opportunity under section 1115 demonstration authority to develop a full continuum of care for individuals with a SUD, including coverage for short-term residential treatment services not otherwise covered by Medicaid. This new opportunity is geared to support states engaged in broad and deep SUD system transformation efforts, enabling them to provide a full continuum of care by introducing service, payment and delivery system reforms to improve the care for individuals with SUD.

Our efforts directly support the Department of Health and Human Services initiative on opioid abuse and the recent Presidential Memorandum addressing prescription drug abuse and heroin use. In March 2015, Secretary Burwell launched a multi-pronged initiative to decrease opioid overdoses, overdose mortality and the prevalence of opioid use disorder. The Secretary’s initiative targets three priority areas: opioid prescribing practices, expanded use and distribution of naloxone, and expansion of medication-assisted treatment (MAT). In October 2015, President Obama issued a memorandum with the goals of reducing prescription opioid and heroin deaths, promoting appropriate and effective pain medication prescribing and improving access to treatment. The President’s memorandum directs certain federal departments and agencies to take several actions, including training federal health care prescribers on the appropriate and effective prescribing of opioid pain medications, reviewing health benefit requirements and policies in order to identify any barriers individuals with opioid use disorder would encounter in accessing MAT, and identifying any current practices, such as the use of methadone as a preferred or first-line pain management drug that are inconsistent with the goals of reducing opioid use disorders and overdoses. This bulletin is part of CMS' ongoing effort to support these initiatives.

In addition to considering the pharmacy benefit management strategies described in this bulletin to mitigate the risk of prescription opioid-related harm, states may consider reviewing their benefits coverage, service utilization and other data to assess if Medicaid enrollees with opioid use disorder have sufficient access to MAT services. MAT is the use of FDA-approved medications in combination with behavioral therapies to provide a whole-patient approach to treating SUDs. There is strong evidence that the use of MAT provides substantial cost savings and leads to improved quality of life and health outcomes for individuals with SUD, including opioid use disorder. Buprenorphine, methadone and naltrexone are the three medications approved by the FDA for opioid dependence. Studies have shown that the most effective treatments for opioid use disorders are those that include a set of comprehensive medical, social,

psychological and rehabilitation services that address all the needs of the individual.\textsuperscript{58}

Although MAT has significant evidence to support it as an effective treatment, it remains highly underutilized. Many Medicaid programs use benefit design requirements, such as prior authorization, that may reduce the use of and access to MAT. For example, as of 2013 prior authorization was required for the use of buprenorphine-naloxone in 48 Medicaid programs. A number of states also have total lifetime limits on the use of buprenorphine-naloxone, even though the scientific literature shows that opioid use disorder is a chronic disease.\textsuperscript{59} CMS is committed to assisting states in addressing opioid use disorder and providing effective treatment services for individuals with substance use disorder. CMS is available to provide technical support to states assessing access to MAT services for individuals with opioid use disorder.


\textsuperscript{59} Substance Abuse and Mental Health Services Administration. Medicaid coverage and financing of medications to treat alcohol and opioid use disorders. HHS Publication No. SMA-14-4854. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.
Resources


Additional information about the Centers for Medicare & Medicaid Services Medicare Part D opioid over utilization policy is available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCoverage/RxUtilization.html

Additional information about Recent Medicaid Prescription Drug Laws and Strategies is available on the National Alliance for Model State Drug Laws is available at: http://www.namsdll.org/


Additional information about Prescription Drug Monitoring Programs (PDMP) Center of Excellence is available at: http://www.pdmpexcellence.org/

Additional information about the Washington State Agency Medical Directors Group’s continuing medical education concerning opioid prescribing is available at: http://www.agencymeddirectors.wa.gov/quality.asp
April 11, 2018

The Honorable Michael Burgess
Chairman, Health Subcommittee
Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Gene Green
Ranking Member, Health Subcommittee
Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Walden, Ranking Member Pallone, Chairman Burgess and Ranking Member Green:

On behalf of the National Association of Counties (NACo) and the 3,069 counties we represent, I am writing to express our support for H.R. 4005, the Medicaid Reentry Act and H.R. 1925, the At-Risk Youth Medicaid Protection Act as you weigh proposals for combating the opioid crisis in the Health Subcommittee of the House Energy and Commerce Committee this week. County officials throughout the country are on the frontlines of our nation’s response to the opioid epidemic, and federal legislation like H.R. 4005 and H.R. 1925 provides vital support for local efforts to stem the tide of overdoses and fatalities that have impacted all corners of our country.

Counties nationwide spend $176 billion annually on justice and health systems, including the entire cost of health care for all arrested and detained individuals. We are required by federal law to provide health care for the 11.4 million individuals who pass annually through our local jails, 90 percent of which are owned and operated by county governments. As the opioid epidemic has taken hold of our country, the budgets of county jails and local governments at large have seen tremendous strain, hampering the ability of counties to provide needed services within and outside of our correctional facilities.

H.R. 4005, the Medicaid Reentry Act, would ease the strain on the local response to the opioid epidemic by allowing incarcerated individuals to receive federal Medicaid benefits for the 30-day period preceding their release from correctional facilities. This support would help county jails provide needed addiction treatments and pre-release coordination of services for individuals preparing to reenter their communities, thereby reducing the risk of overdose or fatality upon release. This coordination critical...
because individuals struggling with addiction are typically at a particularly acute risk of overdose in the period immediately following their release from correctional institutions. 1

Similarly, H.R. 1925, the At-Risk Youth Medicaid Protection Act, would prevent states from terminating Medicaid enrollment for justice-involved youth, thus allowing for more timely provision of addiction treatment services for juveniles released from county correctional facilities. When Medicaid benefits are terminated upon an individual’s incarceration, he or she must re-apply for those benefits when reentering the community, creating a potentially fatal gap in access to services. The alternative to termination is “suspension” of benefits—an option that has been adopted by numerous states and allows individuals to rapidly regain access to treatments upon release from custody.

Access to Medicaid benefits is a key component of the successful reentry of justice-involved individuals into their communities. According to the Bureau of Justice Statistics (BJS), nearly two-thirds (63 percent) of people in jail meet the criteria for drug dependence or abuse. 1 Many of these individuals have opioid use disorders and could benefit from access to Medication Assisted Treatment (MAT), which Medicaid programs cover in every state. Furthermore, studies show that individuals leaving correctional settings are up to 129 times more likely to fatally overdose in the two weeks following release into their communities. To effectively treat justice-involved individuals with substance use disorders, we must maximize treatment opportunities through Medicaid, and both H.R. 4005 and H.R. 1925 would make progress toward this goal.

We appreciate your continued leadership in combating the opioid epidemic and your focus on the intersection of the health and justice as you address this national challenge. For more information on the local response to the opioid crisis, please see the following report, A Prescription for Action: Local Leadership in Ending the Opioid Crisis, published by NACo and the National League of Cities (NLC), available electronically at www.opioidleadership.org. For more information on improving health outcomes for justice-involved individuals, please see NACo’s Medicaid Coverage and County Jails presentation, available electronically at www.naco.org.

If you have any questions, please feel free to contact NACo Associate Legislative Director Brian Bowden at 202.942.4275 or bbowden@naco.org. We continue to stand ready to work with you in support of healthy, vibrant and safe communities.

Sincerely,

Matthew D. Chase
Executive Director
National Association of Counties

---


November 3, 2017

The Honorable Paul D. Tonko
U.S. House of Representatives
2463 Rayburn House Office Building
Washington, DC 20515

Dear Representative Tonko:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express support for H.R. 4005, the "Medicaid Reentry Act." The AMA commends you for introducing this important bill, which would provide states with the flexibility to restart Medicaid coverage for eligible incarcerated individuals up to 30 days prior to their release. Such coverage is critical to help start treatment for addicted individuals before they are released back to civilian life and will help to save lives from opioid overdose deaths once they are released.

It is widely acknowledged that the incarcerated population has a higher rate of chronic diseases, mental health conditions, substance use disorders, and contagious diseases than the general population. Moreover, recent research demonstrates that individuals who are released back into the community post-incarceration are approximately eight times more likely to die of an opioid overdose in the first two weeks after being released compared to other times. Federal law currently prohibits the use of Medicaid funds for the cost of any services provided to an "inmate of a public institution," except when the individual is a patient in a medical institution. This policy, referred to as the Medicaid Inmate Payment Exclusion, has resulted in many states not enrolling their inmates in Medicaid. In addition, some state laws prohibit the submission of Medicaid applications during incarceration; whereas others permit submission, but no earlier than 30 days before release from custody. According to the Kaiser Family Foundation, the majority of states terminate, instead of suspend, Medicaid eligibility upon intake into a correctional system.

By allowing states to restart Medicaid coverage for eligible incarcerated individuals up to 30 days prior to their release, your bill would help to provide for critically needed health care, care coordination activities, and linkages to care for such individuals. This, in turn, would help establish coverage effective upon release, assist with transition to care in the community, and help reduce recidivism.

Thank you again for sponsoring this bill.

Sincerely,

James L. Madara, MD

AMA Plaza | 330 N. Wabash Ave. | Suite 3900 | Chicago, IL 60611-5885
April 9, 2018

The Honorable Greg Walden
Chairman
House Committee on Energy and Commerce
2185 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Committee on Energy and Commerce
237 Cannon House Office Building
Washington, DC 20515

The Honorable Michael Burgess
Chairman
Health Subcommittee
House Committee on Energy and Commerce
2218 Rayburn House Office Building
Washington, DC 20515

The Honorable Gene Green
Ranking Member
Health Subcommittee
House Committee on Energy and Commerce
2322 Rayburn House Office Building
Washington, DC 20515

Re: Support for H.R. 4005 – Medicaid Reentry Act

Dear Chairmen Walden and Burgess and Ranking Members Pallone and Green,

On behalf of the American Society of Addiction Medicine (ASAM), the nation’s oldest and largest medical specialty society representing nearly 5,000 physicians and allied health professionals who specialize in the prevention and treatment of addiction, I write to express ASAM’s support for Rep. Tonko’s Medicaid Reentry Act (H.R. 4005), which will be considered during the Health Subcommittee’s April 11th hearing entitled, “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care For Patients.”

The risk of opioid-related overdose death dramatically increases in the first days and weeks after an individual with untreated opioid use disorder is released from jail or prison.1 Providing treatment access during incarceration and warm handoffs to community-based care upon release can reduce this risk and help save lives. A recent joint policy statement by ASAM and the American Correctional Association (ACA) recommends that an individual’s reentry needs be addressed at
least one month prior to release to avoid any interruption in treatment, as an immediate appointment at an appropriate clinic upon release from incarceration is critical for treatment continuity for persons with opioid use disorder. Additionally, it recommends that treatment induction for those individuals who choose medication treatment for their disease begin at least 30 days prior to release. Passing legislation to facilitate pre-release treatment and connections to community-based care for individuals released from the criminal justice system should be a key part of a comprehensive Congressional response to the ongoing opioid addiction and overdose death epidemic.

Mr. Tonko’s bill addresses this need directly by granting states limited new flexibility to restart benefits for Medicaid-eligible incarcerated individuals 30 days prior to release. With this flexibility, states would be able to facilitate access to medication treatment for inmates prior to release and better coordinate care with community providers, allowing for uninterrupted, evidence-based treatment for these individuals during a transition when they are at heightened risk of overdose and death. This legislation does not expand Medicaid eligibility. ASAM is pleased to support H.R. 4005, the Medicaid Reentry Act, and strongly recommends it be included in any final opioid-related legislation package sent to the House floor.

Sincerely,

Kelly J. Clark, MD, MBA, DFASAM
President, American Society of Addiction Medicine

---


November 2, 2017

The Honorable Paul Tonko
U.S. House of Representatives
2463 Rayburn HOB
Washington, DC 20515

Dear Representative Tonko:

On behalf of the American Psychiatric Association (APA), the national medical specialty society representing more than 37,000 psychiatric physicians nationwide, we are writing in support a bill you introduced earlier this month, the Medicaid Reentry Act (H.R. 4005).

As you know, under current federal law, medical care—including care for the treatment of mental health and substance use disorders—provided in correctional facilities is categorically ineligible for reimbursement under the Medicaid program. While some efforts have been made in a few states following the passage of the Affordable Care Act (ACA), many individuals released from the criminal justice system continue to face insurmountable barriers to enrollment in Medicaid. Your bill would ease the transition for individuals leaving the criminal justice system by making the care provided in correctional facilities eligible for Medicaid reimbursement within thirty (30) days of an individual’s release.

States collectively spent $7.7 billion on health care for prison inmates in fiscal year 2011. This bill would both ease this financial burden and ensure a more seamless transition for eligible people with physical and mental health needs who are nearing their release. It is essential for continuity of care that individuals leaving the criminal justice system who received some form of mental health or substance use treatment while incarcerated have community treatment resources available after release. With these supports, eligible individuals will be better able to re-enter their communities with more than a mere referral to physical and mental health services, but instead an actual connection to and coverage for these services.

This issue is particularly relevant to the American Psychiatric Association’s mission to promote the highest quality care for individuals with mental illness and substance use disorders. According to the Bureau of Justice Statistics, more than
half of those in the criminal justice system suffer from a mental illness, while between one-half and three-quarters of inmates suffer from a substance use disorder.3

With the nationwide opioid crisis, the stakes are extremely high for individuals leaving the criminal justice system who may resort to using drugs. According to a recent study, former inmates within a week following their release were over eight times more likely to die from an overdose than inmates within 90 days to a year following their release.4 Allowing inmates to enroll in Medicaid prior to their release will decrease lapses in care that too often lead to tragic outcomes and instead boost former inmates’ ability to successfully re-enter their communities.

The Medicaid Reentry Act will have a positive impact on the ability of individuals leaving the criminal justice system to access and continue receiving quality mental health and substance use disorder services. Please let us know how we can be a partner in advancing this bill. If you have any questions, please contact Ashley Mild, Interim Chief of Government Relations, at amild@psych.org, or at (703) 907-8645.

Sincerely,

Saul Levin, M.D., M.P.A.
CEO and Medical Director

April 6, 2018

The Honorable Paul Tonko, Member of Congress
2453 Rayburn House Office Building
Washington, DC 20515

RE: Medicaid Reentry Act – H.R. 4005

Dear Congressman Tonko,

Community Resources for Justice (CRJ) is a non-profit agency that for 140 years has been providing services to society’s most challenged citizens. Our work is focused in three areas: reentry services for men and women returning home after incarceration; community-based supports for adults with intellectual or developmental disabilities; and policy, advocacy and technical support in criminal justice reform and police community relations.

On behalf of CRJ, our Board and staff and the thousands of individuals we serve, I urge you to support H.R. 4005, the Medicaid Reentry Act.

CRJ operates Residential Reentry Centers under contract with the Federal Bureau of Prisons in Manchester, NH; Pawtucket, RI; Albany, NY; and Boston, MA. We also serve State and County inmates in Boston. We serve nearly 1000 men and women each year in these programs. Over the last several years we have witnessed first-hand the devastating impact of the opioid crisis. In Massachusetts a recently released inmate is 120 times more likely to die of an overdose than anyone else.

H.R. 4005 – the Medicaid Reentry Act would allow inmates to begin their treatment prior to release and transition seamlessly to treatment in the community. Coverage under Medicaid 30 days prior to release from Prison or Jail would eliminate the break in the delivery of these essential life-saving services.

We believe that passage of HR 4005 will ensure continued treatment and dramatically reduce the death toll the opioid crisis has taken on our communities and we ask your support.

Thank you for your consideration. If I can be of any assistance I can be reached at jjlarivee@cri.org or 617-482-2520 x 2112.

Sincerely,

John J. Larivee
President and CEO

Community Resources for Justice
355 Boylston Street - Boston, MA 02116  
617.482.2520 - Fax 617.292.8054  www.cri.org
April 6, 2018

Congressman Greg Walden, Chairman
Energy and Commerce Committee
2185 Rayburn HOB
Washington, DC 20515

Dear Chairman Walden,

On behalf of the members of the International Community Corrections Association (ICCA), I write in strong support of the purpose and goals of the Medicaid Reentry Act, H.R. 4005, sponsored by Rep. Mike Tonko. The bill seeks to improve outcomes for justice-involved individuals who struggle with a substance use disorder.

Medicaid availability is especially critical now. There have been record deaths across the nation due to opiates and a peak is still expected. This is a chronic health condition that requires diligence and tenacity, as we know that addiction can be a long road without quick fixes. According to the American Society of Addiction Medicine, opioid addiction relapse mirrors remission and relapse statistics for other chronic diseases such as hypertension, diabetes and asthma. Unfortunately, our clients’ cases are compounded by the fact that they are much more likely to be diagnosed with mental illness or substance use disorders than the general population.

The criminal justice-involved population our members serve is actively working to overcome patterns of criminal thinking and behavior, seeking employment, and reconnecting with their families. In addition, some of these individuals suffering from mental illness and/or addiction either were not assessed in an incarcerate setting or are awaiting placement in treatment services. Representative Tonko’s Medicaid Reentry Act seeks to remedy these problems.

As the bill summary states, “Medicaid is generally prohibited from paying for expenses incurred while a beneficiary is incarcerated, even when an incarcerated individual remains Medicaid eligible. The Medicaid Reentry Act would grant states limited new flexibility to restart benefits for Medicaid-eligible incarcerated individuals 30 days prior to release, by allowing states to restart Medicaid benefits prior to release, states would be able to more readily provide effective addiction treatment and care coordination services pre-release, allowing for smoother transitions to community care and reducing the risk of overdose deaths.

1 Please see https://www.azm.org/docs/default-source/advocacy/azm-strategy-2-07-14.pdf?sfvrsn=0

International Community Corrections Association
2100 Stella Court
Columbus, Ohio 43215
post-release. This new flexibility would dovetail with innovative reentry programs already being implemented in communities across the country and would give individuals reentering society a fighting chance to live a healthier, drug-free life. This legislation does not expand Medicaid eligibility in any way."

Your committee understands the relationships that exist between human services and criminal justice and that the families we serve appear in a myriad of social service settings and applying pressure on one end only causes a build-up in another area. We applaud your leadership in creating an infrastructure that aims to address the suffering in this country. The Medicaid Reentry Act, we believe, will have an overall continued positive impact in reducing prison beds as well as reducing drug dependency while making our communities safer. In particular, our member agencies have a long history of successful treatment of criminal justice-involved individuals with substance use disorders. These changes allowing state and county flexibility is especially helpful as we continue to deal with the opiate crisis.

Thank you for this opportunity to express our views. Please feel free to contact me with any questions at eldonnalumma@cj.org.

Sincerely,

Ellen Donnarumma
President
International Community Corrections Association
April 11, 2018

The Honorable Greg Walden
Chairman
House Committee on Energy and Commerce
2185 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Committee on Energy and Commerce
237 Cannon House Office Building
Washington, DC 20515

The Honorable Michael Burgess
Chairman
Health Subcommittee
House Committee on Energy and Commerce
2185 Rayburn House Office Building
Washington, DC 20515

The Honorable Gene Green
Ranking Member
Health Subcommittee
House Committee on Energy and Commerce
237 Cannon House Office Building
Washington, DC 20515

Re: Support for H.R. 4005 – Medicaid Reentry Act

Dear Chairmen Walden and Burgess and Ranking Members Pallone and Green:

On behalf of the National Commission on Correctional Health Care, the only national organization committed solely to improving the quality of health care in jails, prisons and juvenile confinement facilities, I am writing to express the organization’s support for Rep. Tonko’s Medicaid Reentry Act (H.R. 4005). The bill is being considered during the Health Subcommittee’s April 11 hearing titled “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients.”

NCCHC believes that optimizing health insurance coverage and continuity of care represents a vital means for improving health care for correctional populations.

Most prison inmates and a large proportion of jail detainees and jail inmates lack health insurance, yielding worse health care access postrelease, disruptions in continuity of care for serious conditions, and worse health outcomes. This is especially true for individuals with untreated opioid use disorder, for whom the risk of opioid-related overdose and death dramatically increases in the first days and weeks postrelease. Lack of insurance coverage, particularly for mental health and substance abuse services, also increases the risk of re-arrest, resulting in a vicious, costly cycle of recidivism.

By granting states limited new flexibility to restart benefits for Medicaid-eligible incarcerated individuals 30 days prior to release, Mr. Tonko’s bill facilitates prerelease treatment, connections to community-based care, and uninterrupted treatment for opioid use disorders and other chronic conditions and communicable diseases. The result benefits not only the individuals newly released from the criminal justice system, but public health as well.

NCCHC is pleased to support H.R. 4005, the Medicaid Reentry Act.

Sincerely yours,

Barbara A. Wakeen, MA, RDN, CCHP
Chair, National Commission on Correctional Health Care
Statement for the Record
Of
The American College of Obstetricians and Gynecologists
Submitted by:
Hal C. Lawrence, III, MD, FACOG
Before the
House Committee on Energy and Commerce
Subcommittee on Health
Regarding
Combating the Opioid Crisis:
Improving the Ability of Medicare and Medicaid to Provide Care For Patients
April 11, 2018

Chairman Burgess, Ranking Member Green, and distinguished Members of the House Energy and Commerce Subcommittee on Health, thank you for the opportunity to submit a statement for the record in response to your April 11, 2018 hearing titled “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care For Patients.”

The American College of Obstetricians and Gynecologists (ACOG), representing more than 58,000 physicians and partners dedicated to advancing women’s health, appreciates the Committee’s attention to this important issue. I hope you will view ACOG as a resource and trusted partner as you continue to examine strategies to combat the ongoing opioid crisis.

I am the Executive Vice President and Chief Executive Officer at ACOG and in this capacity am keenly aware of the increase in opioid use disorder and overdose and its impact on the women we serve and their families. My statement will focus on the need for greater access to evidence-based treatment for pregnant and parenting women and the need for responses to opioid use during pregnancy to remain in the public health space and preserve the patient-physician relationship.

Health professionals, public health advocates, and bipartisan policymakers recognize that the United States is in the midst of a major opioid epidemic. The incidence of opioid use disorder (OUD) has risen dramatically over the past few years, including among women of reproductive age and pregnant and parenting women. According to the HHS Office of Women’s Health, the number of women dying from overdose of prescription drugs rose 471 percent between 1999 and 2015, compared to 218 percent for men, and heroin deaths among women increased at more than twice the rate of men. In rural areas, where the opioid crisis has hit hardest, pregnant women and women experiencing intimate partner violence are among populations with higher prevalence of misuse of prescription pain relievers.

Unsurprisingly, the high prevalence of OUD among reproductive age women means more women are using opioids while pregnant. This is also reflected in the rising incidence of neonatal abstinence syndrome (NAS), an expected and treatable medical condition associated with drug withdrawal in newborns exposed to opioids, including medication-assisted treatment,
or other drugs in utero. The unplanned pregnancy rate among women with OUD is 86 percent, a number that far surpasses the national average of 45 percent, making clear the need for increased access to contraception among women with OUD. Untreated OUD during pregnancy is associated with significant obstetric morbidity and mortality. Tragically, overdose and suicide are now the leading causes of maternal mortality in a growing number of states, including Texas.

During pregnancy, most women who use substances, including opioids, are motivated to change unhealthy behaviors and quit or cut back. Those who cannot stop using have a substance use disorder. In other words, continued substance use in pregnancy is a characteristic of addiction, a chronic, relapsing brain disease.

Evidence-based treatment for pregnant and breastfeeding women with OUD includes the use of medication-assisted treatment (MAT) such as methadone and buprenorphine. MAT is the recommended therapy for treating pregnant women with opioid use disorder, and is preferable to medically-supervised withdrawal, which is associated with higher relapse rates and poorer outcomes, including accidental overdose and obstetric complications. Use of MAT also improves adherence to prenatal care and addiction treatment programs. MAT, together with prenatal care, has been demonstrated to reduce the risk of obstetric complications among pregnant women with OUD.

Threats of incarceration, immediate loss of child custody, and other potential punishments drive pregnant and parenting women away from vital prenatal care and substance use disorder treatment. Research has found that non-punitive public health approaches to treatment result in better outcomes for both moms and babies. Immediately postpartum, women who bond with their babies, including via skin-to-skin care and breastfeeding, are more likely to stay in treatment and connected to the health care system. Further, breastfeeding is associated with decreased severity of NAS symptoms and reduced length of hospital stay for the newborn. Substance use disorder treatment that supports the family as a unit has proven effective for maintaining maternal sobriety and child well-being.

In 2015, the Government Accountability Office (GAO) report titled Prenatal Drug Use and Newborn Health: Federal Efforts Need Better Planning and Coordination found that “the program gap most frequently cited was the lack of available treatment programs for pregnant women...” In 2017, the GAO report titled Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome again cited barriers faced by pregnant women with OUD, including “the stigma faced by women who use opioids during pregnancy” and “limited coordination of care for mothers and infants with NAS,” making it “difficult for families to get the resources or support they need.”

Medicaid covers 42.6 percent of US births, and plays a critical role in ensuring healthy moms and babies. In 2012, more than 50 percent of pregnant female admissions aged 15 to 44 to treatment for opioid use disorder were covered by Medicaid. That same year, Medicaid covered 81 percent of the $1.5 billion that hospitals billed for treating NAS. As Congress seeks
to address the ongoing opioid epidemic, and in particular its toll on women, infants, and families, Medicaid will continue to be a key factor in ensuring access to treatment.

As the Committee considers policies to address the ongoing opioid epidemic, we urge you to consider the following:

- **Ensure full implementation of the Protecting Our Infants Act: Final Strategy, created pursuant to Public Law 114-91.** The Strategy, released by HHS in 2017, made several recommendations to address gaps in research; gaps, overlaps, or duplication in relevant federal programs; and coordination of federal efforts to address NAS with recommendations regarding maternal and child prevention, treatment, and services. The October 2017 GAO report made one recommendation: to implement the Strategy." However, HHS is clear that "full implementation will be contingent upon funding." In particular, we urge the Committee to:
  - Amend H.R. , Protecting NAS Babies Act, to develop a strategy to implement both Maternal and Child recommendations outlined in the Protecting Our Infants Act: Final Strategy. The GAO's 2017 recommendation to implement the Strategy did not distinguish or prioritize the maternal vs child strategies out of recognition of the importance of the mother-baby dyad when seeking to improve neonatal outcomes following opioid exposure during pregnancy. Limiting the implementation of the Strategy to only the Child recommendations will result in an incomplete and ineffective strategy to reduce NAS and improve child health.

- The need for urgent action to address the rising maternal mortality rate in the United States, which includes an increase in maternal deaths from overdose and suicide. States with maternal mortality review committees (MMRCs) bring together multi-disciplinary health care professionals to review individual maternal deaths and recommend policy solutions to prevent them in the future. MMRCs are critical tools to understanding maternal deaths, including those linked to opioid overdose, and identifying opportunities for prevention. **Advance H.R. 1318, the Preventing Maternal Deaths Act, introduced by Reps. Herrera Beutler (R-WA), DeGette (D-CO), and Costello (R-PA) to assist states with the creation or expansion of MMRCs.**

- Critical gaps in public and private insurance coverage lead to gaps in care or discontinuation of treatment. Women receiving pregnancy coverage through Medicaid or the Children’s Health Insurance Program (CHIP) may lose their access to MAT weeks after giving birth, during a particularly vulnerable time when relapse risk increases if treatment is not continued. **Explore coverage policies that ensure continued access to treatment for women postpartum.**

- **Reject proposals to legislate prescriber practices.** Addressing this ongoing epidemic will require dedication and partnership between policymakers, health care providers, and the public. Mandating prescribing practices and provider education requirements in
federal legislation is an inappropriate political interference in the practice of medicine. Instead, efforts to engage prescribers should focus on collaborative provider partnerships with the federal government through multi-stakeholder efforts to increase public awareness, and provider training and education. Specifically:

- Federal opioid prescribing limits are not supported by data, are not responsive to the variations in surgical specialty and patient population, and are not appropriate for federal legislation.
- Prescription Drug Monitoring Programs (PDMPs) are a valuable resource and can guide safe prescribing. ACOG recommends that, before prescribing opioids to their patients, ob-gyns and other health care providers take a thorough history of substance use and review the PDMP to determine whether patients have received prior opioid prescriptions. However, we do not support federal prescriber mandates and therefore urge drafters to amend H.R. Medicaid Partnership Act, to instead call for modernization and increased interoperability and usability of PDMPs, while strongly urging physicians to check their PDMP.
- ACOG has concerns with other legislative efforts to mandate state Medicaid activities with a penalty of a reduced federal medical assistance percentage (FMAP). Penalizing state noncompliance with reduced FMAP could result in reduced physician reimbursement, coverage, eligibility, and benefits. Medicaid will play an important role in addressing the ongoing opioid epidemic, and we encourage the Committee to consider incentives, rather than penalties, to encourage systems changes.

- Ensure continued access to women’s preventive care and the full range of contraceptives for Medicaid beneficiaries, including women of reproductive age with OUD, to drive down the high rate of unplanned pregnancies in this group as well as the rate of babies born with NAS. Reject legislative and administrative efforts to condition payment for health care services on factors other than medical and legal qualifications and standards. Congress should not deny federal funds, including reimbursement for covered services provided to Medicaid beneficiaries, to providers, programs, and health care facilities in cases where a provider is qualified to perform those services.

- Improve access to the full range of contraceptives for Medicare beneficiaries, including women of reproductive age with OUD. Medicare does not currently cover contraception for the purposes of preventing pregnancy, despite the fact that more than 900,000 women ages 18-44 receive insurance coverage through Medicare.

- Preserve Medicaid’s financing structure and ensure continued and sufficient federal funding to support Medicaid expansion as currently available. Proposals to reduce federal Medicaid expenditures by shifting costs to states or reducing enrollment or services will limit access to care for low-income women of reproductive age, including pregnant and parenting women, with OUD. Approximately 42.6 percent of births in the U.S. are financed by Medicaid, Medicaid covers the care of 81 percent of infants.
diagnosed with NAS,\textsuperscript{iv,vi} and approximately 25 percent of Americans with OUD are Medicaid beneficiaries.\textsuperscript{vii} Any changes to the Medicaid financing structure and/or Medicaid expansion will negatively impact access to care for this vulnerable population.

- Support testing of new models to improve access to treatment for pregnant and parenting women with OUD, including telemedicine pilots. Treatment gaps remain, despite continued efforts to increase the availability of programs tailored to the unique needs of pregnant and parenting women. Innovative models can help ensure treatment is effective and responsive to women's complex responsibilities, often as the primary or sole caregivers for their families. In addition:
  - The 2015 GAO study confirmed that "the program gap most frequently cited was the lack of available treatment programs for pregnant women."\textsuperscript{vii} As ACOG works to train more ob-gyns in prescribing buprenorphine and becoming treatment providers for their patients with opioid use disorder, additional capacity building is needed to assist with closing the access gap. H.R. \_ \_ Provider Capacity Demonstration Project, would assist with this effort. ACOG urges drafters to ensure the bill is consistent with evidence-based recommendations for treatment of pregnant and postpartum women. Specifically, ensure that activities to expand providers with certain qualifications includes the treatment and recovery needs of both pregnant and postpartum women, in accordance with guidelines issued by ACOG. This includes the current recommendation against detoxification of pregnant women, due to high relapse rates and the increased potential for adverse outcomes.
  - Advance H.R. 3192, the CHIP Mental Health Parity Act, to ensure that pregnant women with coverage under CHIP have coverage of mental health and substance use disorder treatment.
  - Ensure Section 501 of the Comprehensive Addiction and Recovery Act (CARA; Public Law 114-198) receives additional funding to improve access for all women seeking treatment. Section 501 authorized funds for treatment programs tailored specifically for pregnant and parenting women with OUD, including pilot programs to test innovative treatment models. Additional funding is needed to help close the treatment gap for this population.

- Facilitate better collaboration between health care providers and the child welfare system in responding to the rise of opioid use disorder among pregnant and parenting women and NAS. This epidemic is increasingly leading to children being placed in kinship care or foster care homes. State child welfare agencies do not currently have the resources necessary to address the impact of this epidemic on families. Obstetric care providers have an ethical responsibility to their pregnant and parenting patients with substance use disorder to discourage the separation of parents from their children solely based on substance use disorder, either suspected or confirmed.\textsuperscript{vi} Our shared priority is that infants born to families struggling with OUD have safe homes, and that the family unit is preserved when possible.
Section 503 of CARA added requirements for states to develop infant plans of safe care in instances when an infant experiences NAS following opioid exposure in utero. Unfortunately, those requirements came without resources for implementation or clear guidance, and has the potential to unintentionally lump together women who use illicit substances with those in active treatment or with a current prescription from a licensed health care provider. States need additional guidance, funds, and resources from the federal government to ensure infant safety and to keep families intact when appropriate.

States are encountering barriers to providing affected families the services they need to heal. If we are to truly help children impacted by this epidemic achieve their potential, we must apply a treatment-focused public health approach. Unfortunately, our current system is too often a punitive one that leaves pregnant and parenting women less likely to seek treatment and incentivizes placing children in foster care when they could safely remain at home with the appropriate treatment and support services. Ensure full implementation of the Family First Prevention Services Act (Division E, Title VII of the Bipartisan Budget Act; Public Law 115-123) to expand access to treatment services for vulnerable families while helping them stay together and heal.

- Expand access to MAT for women of reproductive age, including pregnant and parenting women, by enabling certified nurse-midwives (CNMs) to prescribe buprenorphine. In an ongoing effort to provide the best care for women suffering from OUD, ACOG offers buprenorphine training courses tailored to women’s unique health needs for obstetrician-gynecologists and other health care providers. Treating, prescribing, and referring for MAT services are all within the scope of practice for CNMs. Advance H.R. 3692, the Addiction Treatment Access Improvement Act, introduced by Reps. Tonko (D-NY) and Lujan (D-NM), to expand the qualified providers able to prescribe MAT.

- Continue to promote research into pharmacological and nonpharmacological treatments for both pregnant and breastfeeding women with opioid use disorder; non-opioid pharmacotherapies for pain management for women, including pregnant women; and both pharmacological and nonpharmacological treatments for newborns with NAS.

- Address barriers to accessing non-pharmacological pain relief, including transportation and childcare options for women seeking treatment for pain. In addition, the Committee should ensure that acute and chronic pain management with opioids are not denied to women of reproductive age, including pregnant and parenting women, out of concern for NAS when they are otherwise recommended.

- Consider amending H.R., Incentivizing Non-Opioid Drugs, to expand incentives to non-pharmacological pain relief. Ensure that coverage and reimbursement for non-pharmacological pain relief, including physical therapy, is
Thank you again for the opportunity to submit a statement for the record, and for your thoughtful approach to this issue. We look forward to working closely with you as you evaluate the legislation before you, consider edits, and develop a legislative package to comprehensively address the impact of the ongoing opioid crisis. I hope that you will consider ACOG a trusted partner in this space and will let us know if we can provide any additional assistance.

15 Medicaid and CHIP Payment and Access Commission. Supra note 2.
April 11, 2018

The Honorable Greg Walden
Chairman
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Energy & Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone:

We, the undersigned organizations, are writing to express our support for the Access to Telehealth Services for Opioid Use Disorders Act. This legislation is critical to expanding access to treatment for opioid use disorders in the Medicare program.

According to the Centers for Medicare and Medicaid Services (CMS), the Medicare population has among the fastest-growing rates of opioid use disorder, currently at more than 6 of every 1,000 beneficiaries. In order to stem the tide of this epidemic, Medicare beneficiaries must have access to treatment programs; however, more than half of U.S. counties lack any practicing behavioral health workers and 77 percent of counties report unmet behavioral health needs.

Technology can help bridge the gap of distance and stigma by allowing beneficiaries to receive care when and where they need it. Unfortunately, outdated laws and regulations prevent healthcare providers from using technology to provide care to most Medicare beneficiaries. The Access to Telehealth Services for Opioid Use Disorders Act is an important step in utilizing technology to combat the opioid epidemic by allowing the Secretary to waive these outdated laws and regulations if such waiver is expected to lower costs, improve quality, or increase access. This would allow Medicare beneficiaries to receive treatment when and where they need it – allowing providers to be with patients at the time of their most critical need.

Thank you for your leadership and dedication to combatting the scourge of opioid abuse and misuse disorders. We look forward to working with you to ensure passage of this important piece of legislation.

Sincerely,

American Art Therapy Association
American Foundation for Suicide Prevention
Association for Behavioral Health and Wellness
Centerstone
Health IT Now
Intermountain Healthcare
LifeWIRE Corp
Mental Health America
National Alliance on Mental Illness
New Directions Technology Consulting, LLC
Teladoc
April 11, 2018

The Honorable Frank Pallone, Jr.
Chairman
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Walden and Congressman Pallone:

We applaud your efforts to address the opioid crisis and thank you for taking legislative action. To that end, we are writing to urge your support for the Access to Telehealth Services for Opioid Disorders Act. This bill will address unmet treatment needs of Medicare beneficiaries with opioid addiction by expanding access to care through telemedicine.

As with the overall U.S. population, opioid addiction is rising among seniors. Opioid misuse among adults aged 50 and older in 2014 was higher than all years between 2002 and 2011, and a 2017 analysis of Medicare Part D data by the HHS Office of the Inspector General revealed that more than 500,000 Medicare Part D beneficiaries received high amounts of opioids in 2016, with the average dose far exceeding the manufacturer’s recommended amount.

For seniors who become addicted, therapy is an essential part of treatment. Cognitive behavioral therapy, family counseling, and other therapy approaches can help cope with stress, environmental factors and isolation that make staying off drugs difficult. However, for many seniors, finding a behavioral health specialist is challenging. In 2013, all nine types of behavioral health practitioners had shortages. Six provider types have estimated shortages of more than 10,000 FTEs, including psychiatrists; clinical and counseling psychologists; substance abuse and behavioral disorder counselors; mental health and substance abuse social workers; and mental health counselors. In rural areas, the challenge is particularly acute.

Telehealth can help. According to a 2012 HRSA report, telebehavioral health may be one of the more successful applications of telehealth across the spectrum of clinical services as outcomes and patient acceptance for telebehavioral health are comparable to face-to-face visits. The report went on to detail how telebehavioral health can improve care delivery, expand staff capacity, enhance training capacity and achieve cost savings.

2 https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf
Despite this evidence, a Medicare fee-for-service provider can only be reimbursed for telehealth if the patient is in an institutional setting in a rural area at the time of service. The institutional setting is referred to as an “originating site.” These restrictions significantly limit the number of telebehavioral health visits available in Medicare even though there are more than a dozen behavioral health codes approved for telehealth in Part B.

Access to Telehealth Services for Opioid Disorders Act will help fix this problem. The Act gives the Secretary of Health and Human Services the authority to waive rural and originating site restrictions for telehealth services that have been found to save money, improve quality of care, or improve access to services. This includes telebehavioral health services and lays the groundwork for greater use of telehealth services to address the opioid crisis among our nation’s seniors. By providing a mechanism to expand the number of providers that are able to treat the elderly in their own homes through telehealth, this Act will significantly improve addiction treatment for Medicare patients. In addition, as HHS and CMS consider the new Medicare Advantage telehealth benefit, coverage of behavioral health for opioid addiction will be a natural addition if the restrictions are already lifted in fee-for-service.

For the reasons above, we urge you to support the Access to Telehealth Services for Opioid Disorders Act. Thank you.

Sincerely,

Alliance for Connected Care
American Telemedicine Association
Association for Behavioral Health and Wellness
ACT! The App Association
National Association of Mental Illness
National Association of County Behavioral Health and Developmental Disabilities Directors
The Honorable Greg Walden  
Chairman  
House Energy & Commerce Committee  
2125 Rayburn House Office Building  
Washington, D.C. 20515  

Dear Chairman Walden,

We write to thank you for your leadership as the House Committee on Energy and Commerce continues to address the opioid epidemic, which is ravaging communities and families across the nation. More can and must be done both to treat the disease of opioid addiction as well as to prevent patients from becoming addicted in the first place. As the Committee demonstrates its leadership by developing comprehensive solutions to the opioid crisis, increasing patients’ access to pharmacists’ services must be a part of the conversation.

When traveling throughout our districts, we regularly hear from Medicare patients who are struggling to access affordable, convenient, and high quality healthcare services in their communities. We also know that these same patients are a particularly vulnerable population in the struggle against opioid addiction. In fact, in 2016, one out of every three Medicare Part D beneficiaries received at least one prescription opioid, 1 in 10 received opioids on a regular basis, and half a million received high amounts of opioids.[1] It is clear to us that more must be done to get these patients the care they need while also ensuring they fully understand how to properly use their prescribed medications. Pharmacists are trained to fill both of these roles.

That is why it is critically important the Committee support the Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592). Pharmacists are the face of healthcare in their communities. They are healthcare professionals trained to provide patients with basic health services and to counsel them on the safe use of their medications, including opioids. However, they are hamstrung by existing regulations and statute. H.R. 592 would empower this existing workforce by recognizing pharmacists as non-physician providers in Medicare Part B, enabling them to provide clinical services to address unmet healthcare needs of Medicare beneficiaries in underserved communities.

[1] HHS OIG Data Brief, July 2017 (OEI-02-17-00250)
Additionally, the sponsors of the *Pharmacy and Medically Underserved Areas Enhancement Act* have developed an amendment to the original bill language that would authorize CMS to create a new pharmacist intervention program. This program would help prevent prescription drug abuse among Medicare beneficiaries by targeting at-risk patients identified in the existing CMS Overutilization Monitoring System. It would fully utilize pharmacists' training as medication experts and allow them to engage with such patients to provide specialized opioid counseling, education, and risk factor reduction services.

As cosponsors of the *Pharmacy and Medically Underserved Areas Enhancement Act*, we believe strongly more can be done for Medicare patients by increasing their access to pharmacists' services. This simple change in policy would help prevent prescription drug misuse and abuse as well as improve treatment outcomes for Medicare patients in our districts. With 259 bipartisan cosponsors, these are the types of commonsense healthcare policies our constituents need and want. And we ask you to include this bill— as amended— as the Committee continues its work to address this serious problem facing our nation.

Sincerely,

[Signatures]

Earl L. "Buddy" Carter
Member of Congress

Mike Coffman
Member of Congress

Brian Fitzpatrick
Member of Congress

John J. Faso
Member of Congress

Steve Knight
Member of Congress

Pete Sessions
Member of Congress

Lou Barletta
Member of Congress

John Katko
Member of Congress
April 6, 2018

The Honorable Greg Walden  
Chairman  
House Energy & Commerce Committee  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Frank Pallone  
Ranking Member  
House Energy & Commerce Committee  
2125 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Walden and Ranking Member Pallone,

Walgreens and our approximately 30,000 pharmacists across the nation urge members of the Committee on Energy and Commerce to join 259 of your colleagues to champion the role of pharmacists, as front-line healthcare professionals, and the help they provide in filling the gaps for vulnerable populations in underserved communities. Many of these communities are also being ravaged by the opioid epidemic, indiscriminately destroying lives and families. As the face of community health care, Walgreens pharmacists care deeply about our neighbors and the impact this epidemic is having on the fabric of our communities.

That is why it is critically important the Committee support the Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592), enabling pharmacists even greater ability, as recognized non-physician providers in Medicare Part B, to provide clinical services to address unmet healthcare needs of Medicare beneficiaries in underserved communities. The bill would also authorize CMS to create a new pharmacist intervention program to prevent prescription drug abuse among Medicare beneficiaries by targeting at-risk patients identified in the CMS Overutilization Monitoring System. The program would allow pharmacists to engage with such patients to provide specialized opioid counseling, education and risk factor reduction services.

As the Committee demonstrates its leadership by developing comprehensive solutions to the opioid crisis, Walgreens stands ready to bring our own leadership, experience and capabilities to help in this critical effort to fight the disease of opioid drug addiction. Over the past two years, we have made significant contributions to address this issue, and, indeed, have been at the forefront of corporate America’s efforts to fight the opioid epidemic. Our primary initiative includes making safe medication disposal receptacles available in more than 600 store locations in 45 states and DC, and we have started installation of an additional 900 receptacles in communities challenged by the opioid crisis. To date, we have collected nearly 200 tons of unused medication—most notably controlled substances at the heart of this epidemic—with the goal of collecting 300 more tons over the next two years.
Even more can be done for Medicare patients by increasing their access to pharmacists' services, which can help prevent prescription drug misuse and abuse as well as improve treatment outcomes. This is particularly important for seniors, as one out of every three Medicare Part D beneficiaries, in 2016, received at least one prescription opioid, 1 in 10 received opioids on a regular basis, and half a million received high amounts of opioids.¹

Walgreens, as a proud member of the Patient Access to Pharmacists' Care Coalition, thanks you for your leadership in addressing the opioid epidemic. We welcome the opportunity to work with you to better utilize pharmacists to help Medicare beneficiaries access the care they need to positively impact this serious problem facing our nation.

Sincerely,

Alex Gourlay
Co-Chief Operating Officer
Walgreens Boots Alliance Inc.

¹ HHS OIG Data Brief, July 2017 (OEI-02-17-00250)
April 9, 2018

The Honorable Michael Burgess
Chair, House Energy and Commerce
Subcommittee on Health
2123 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Gene Green
Ranking Member, House Energy and Commerce Subcommittee on Health
2123 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Burgess and Ranking Member Green:

On behalf of the American Association of Oral and Maxillofacial Surgeons (AAOMS), the professional organization that represents 9,500 oral and maxillofacial surgeons (OMSs) in the United States, I would like to thank you for your leadership in seeking to address the nation’s prescription drug abuse epidemic. The issue is a significant public health concern to our membership.

Oral and maxillofacial surgery is the surgical specialty of dentistry. As such, management of our patients’ pain following invasive procedures is an important aspect of providing the best quality patient care. As lawful prescribers, we know, when used appropriately, prescription opiates enable individuals with acute and chronic pain to lead productive lives and recover more comfortably from surgical procedures. We also recognize, however, that pain medication prescribed following oral and maxillofacial surgery is frequently the first exposure many American adolescents have to opioids, and roughly 12 percent of all immediate-release opioid prescriptions in the United States are related to dental procedures. Dentists, including OMSs, have a responsibility to ensure we do not exacerbate a growing public health risk while ensuring our patients receive the relief they need following complex dental procedures.

AAOMS is committed to educating our membership about the potential for opioid abuse. This is evidenced by the numerous resources and education, including continuing education (CE) courses, in which we have encouraged members to participate or we have offered directly. Specifically, AAOMS:

- Published prescribing recommendations for the management of acute and postoperative pain for the OMS patient that urge non-narcotic pain management—rather than opioids—be utilized as a first-line therapy to manage a patient’s acute and post-surgical pain.

---

- Includes in nearly every AAOMS publication information and resources for our membership about opioid abuse.
- Partnered with the Substance Abuse and Mental Health Services Administration (SAMHSA) to create the free CE program, Safe Opioid Prescribing for Acute Dental Pain, specifically for dentist prescribers. The online program launched in January 2016 and is available online to our members.
- Partnered with National Institute on Drug Abuse (NIDAMED) to develop CE that teaches medical and dental prescribers how to talk to adolescents about substance abuse. The CE program titled, "Research-Based Clinical Strategies to Prevent and Address Adolescent Substance Use and Prescription Medication Misuse – Being Part of the Solution," was released in June 2017.
- Makes CE webinars available and hosts CE programs at AAOMS Annual Meetings on opioid abuse that address pain management alternatives to opioids.
- Promotes the Drug Enforcement Administration’s National Prescription Drug Take Back Days to our membership and encourages them to inform their patients.
- Developed educational materials for patients and caregivers, including an informational card on the Safe Use and Disposal of Prescription Medications that members can provide to their patients and communities.
- Participates in and promotes to our membership the Partnership for Drug-Free Kids Medicine Abuse Project.
- Partnered with Aetna to study alternative post-operative pain management techniques on their beneficiaries.

Our efforts appear to be working. AAOMS conducted a survey of a random selection of OMSs in January 2017 and January 2018. The surveys showed a decline in the number of opioids being prescribed. For example, 79 percent of respondents in 2018 reported they reduced their opioid prescribing for third molar cases over the last two years. And 85 percent of respondents in 2018 reported prescribing less than a three-day supply of opioids following third molar surgery—an increase of 10 percentage points since last year.

AAOMS recognizes, however, a variety of factors contribute to the current opioid epidemic. As your subcommittee seeks additional ways to address opioid abuse, we would like to offer the following input on several topics under consideration.

**Federal Continuing Education**

AAOMS supports CE on the topic of opioid abuse; however, AAOMS believes, to be most effective, CE should be managed at the state level because CE has traditionally been under the purview of the states. Additionally, CE should be appropriately proportionate to other CE requirements required to maintain state licensure and be customized so it is relevant to each type of prescribing situation. AAOMS further believes provider specialty organizations such as AAOMS should be included as accepted practitioner training organizations for CE requirements.
Prescription Drug Monitoring Programs
AAOMS supports properly funded prescription drug monitoring programs (PDMPs) that are updated in real time by dispensers and interoperative between states. Furthermore, approved auxiliary personnel should be authorized to access the system on the prescriber's behalf so doctors have adequate time to provide quality patient care. Finally, it should not be mandatory for prescribers to check a POMP for acute pain patients who receive an opioid prescription of less than seven days following an invasive surgical procedure, as the risk of abuse and diversion is low in these instances.

Prescribing Initiatives
AAOMS appreciates the development of prescribing guidelines and, as noted, the association recently developed prescribing recommendations that urge non-narcotic pain management be utilized as a first-line therapy to manage an OMS patient's acute and post-surgical pain. AAOMS believes any effort by government entities to develop prescribing guidelines should recognize the unique care provided by OMSs by both involving them in the development process and avoiding a one-size-fits-all approach as pain management needs vary from patient to patient. Furthermore, AAOMS supports efforts by appropriate agencies to secure approval of innovative solutions for alternative pain management options, which would reduce the need for opioids. This would include pharmaceuticals that extend the length of surgical site anesthesia, such as bupivacaine HCl.

If the federal government considers imposing a national dosage limitation restriction, AAOMS encourages any such restrictions to allow provider discretion because the management of pain severity varies by procedure and patient. Finally, AAOMS advocated in support of a provision in the Comprehensive Addiction and Recovery Act (P.L. 114-198) that would clarify federal law to allow pharmacies to partially fill a Schedule II drug, when allowed by state law. Federal efforts to encourage states to allow patients to obtain part of their prescription with the option to acquire the remaining amount only when necessary would lessen the risk of diversion of unused medications.

We welcome an opportunity to discuss these issues in greater detail and work with you to explore other possible solutions to curb the misuse of prescription drugs. Please contact Jeanne Tuerk, manager of the AAOMS Department of Governmental Affairs, at 800-822-6637 or jtuerk@aaoms.org for additional information.

Sincerely,

Brett L. Ferguson, DDS, FACS
AAOMS President
April 11, 2018

The Honorable Greg Walden, Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden:

On behalf of the Association for Behavioral Health and Wellness (ABHW) I am writing to express our support for H.R. 3545, the Overdose Prevention and Patient Safety Act (OPPS Act), sponsored by Representatives Mullin and Himes, and to strongly encourage inclusion of the OPPS Act in the opioid package that your committee is currently developing.

ABHW is the leading association working to raise awareness, reduce stigma, and advance federal policy to improve mental health and addiction care. Our members include top regional and national health plans that collectively care for approximately 175 million people.

H.R. 3545 would align 42 CFR Part 2 (Part 2) with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of health care treatment, payment, and operations (TPO) and strengthen protections against the use of substance use disorder records in criminal proceedings. Part 2 is an outdated 1970s federal regulation governing the confidentiality of drug and alcohol treatment and prevention records and it needs to be reformed. Part 2 sets requirements limiting the use and disclosure of patients' substance use disorder (SUD) records from federally assisted entities or individuals that hold themselves out as providing, and do provide, alcohol or drug use diagnosis, treatment, or referral for treatment. This can prohibit health plans, and others, from sharing this information with the health care providers on the front line caring for patients suffering from opioid and other substance use disorders. ABHW members say Part 2 is one of the biggest – if not the biggest – barriers to fighting the opioid crisis.

Obtaining multiple consents from the patient is challenging and obstructs whole-person, integrated approaches to care, which are part of our current health care framework. Part 2 regulations may lead to a doctor treating a patient and writing prescriptions for opioid pain medication for that individual without knowing the person has an opioid use disorder. Without written consent from the patient, ABHW member companies have had cases where the health plan cannot speak to the patient's primary care provider and other specialists about the patient's SUD, even if that provider is prescribing opioids to the patient.

For example, one health plan notes that it found over 200 members had been to emergency departments (EDs) over seven times in a six-month period. The health plan wanted to share this information through an automatic feed to the respective providers so they could take action in helping these members. However, because the information may have included whether or not a member was categorized as having a SUD, the plan was not able to provide the feed. This was especially troubling, since in reviewing the data, the health plan also found that some members were
attempting to obtain opioids from several different EDs. Unfortunately, because of Part 2, the health plan was not able to inform the provider that it appeared their patient may be misusing opioids.

The Substance Abuse and Mental Health Services Administration (SAMHSA) released two final rules on Part 2 in the past year. Both rules take small steps to modernize Part 2, but they do not go far enough. Legislative action is also necessary in order to modify Part 2 and bring substance use records into the 21st Century. Aligning Part 2 requirements with HIPAA allow the use and disclosure of patient information for TPO and improve patient care by ensuring that providers and organizations with a direct treatment relationship with a patient have access to his or her complete medical record. Without access to a complete record, providers cannot properly treat the whole person and may, unknowingly, endanger a person’s recovery and his or her life.

Harmonization of Part 2 with HIPAA would also increase care coordination and integration among treating providers and other entities in communities across the nation. We support provisions that preclude Part 2 information from being disclosed for non-treatment purposes to law enforcement, employers, landlords, divorce attorneys, or others seeking to use the information against the patient. We do not want consumers to be made vulnerable as a result of seeking treatment for a substance use disorder. However, disclosures of substance use disorder records for treatment, payment, and health care operations should be allowed. Separation of substance use from the rest of medicine increases the stigma around the disease and hinders patients from receiving safe, effective, high quality substance use treatment and integrated care.

Thank you for your leadership in addressing the opioid crisis, ABHW appreciates the opportunity to express our support for H.R. 3545 and we look forward to continuing this dialogue and working with you to end the overdoses and deaths that are ravaging our country. Please feel free to contact me at (202) 449-7660 to discuss these issues further.

Sincerely,

Pamela Greenberg, MPP
President and CEO
AdvaMed, the Advanced Medical Technology Association  
Statement for the Record  
Energy and Commerce Health Subcommittee Hearing “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care For Patients”  
April 11, 2018

AdvaMed commends the Subcommittee for its ongoing work to address the opioid epidemic. As members of the Subcommittee know, the opioid epidemic is devastating individuals, families and communities throughout the United States. We appreciate your focus on this critical issue and the opportunity to provide input from the perspective of medical technology innovators.

AdvaMed is the world’s largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed member companies produce technologies that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed’s members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of such technology purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have less than $30 million in annual sales.

Medical technologies play an important role in combatting the opioids crisis. Medical technology solutions have the potential to reduce our country’s dependence on opioids in many ways, including:

- serving as alternatives to manage acute and chronic pain before the first opioid is prescribed;
- monitoring pain and medication use;
- blocking difficult withdrawal symptoms and preventing overdose;
- improving medication management, lowering dependence and addiction, and monitoring dosage; and
- preventing diversion and inappropriate access to opioids.

Additionally, medical technology companies are developing innovations that are minimally-invasive, enabling patients to return to routine activities in a shorter period of time, while experiencing less pain and discomfort after surgery.

There are a number of policies related to medical technology that can help address the opioid crisis affecting our nation, and we are pleased to see that several of the bills being considered by the Subcommittee incorporate these ideas. We understand a multi-faceted legislative approach is
needed. We respectfully request that the following ideas be integrated into the Committee’s legislative efforts:

- **Increased educational opportunities regarding technology alternatives for pain management, surgical pain minimization, addiction treatment and proper dispensing and disposal of opioids are critical.** While the opioid crisis is widely known and discussed, opioid-related education for patients, physicians and our healthcare workforce is needed. This education should address medical technology alternatives to opioids for chronic and acute pain management, such as outlined in the FDA’s recently issued “Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain.” Some of these technologies may reduce pain (i.e., minimally invasive surgery), substitute for pharmacologic pain relievers, limit the time and dosage of opioids used, or help to manage addiction and monitor use. In the Medicare program, the opportunity to educate beneficiaries should begin at the first “Welcome to Medicare” physical with an initial pain assessment.

- **Appropriate steps should be taken to address the coverage, coding, and payment challenges related to the use of medical technology alternatives to opioids.** Medicare’s coverage, coding, and reimbursement policies should be reviewed and amended to encourage utilization of medical devices and other non-opioid pain management alternatives that can minimize reliance on opioids before the first prescription is written to treat acute, chronic, and surgical pain. The extent to which various opioid alternatives are currently covered, not covered, have limited coverage and face payment challenges should be addressed.

- **New quality measurement activities and metrics for physicians and providers related to pain management and use of non-opioid alternatives should be developed.** These might include requiring CMS to add clinical improvement activities related to the opioid crises to the improvement activity list for MIPS; requiring CMS to develop quality measures (or encouraging measure stewards) in the opioid space which address utilizing non-pharmacologic alternatives; requiring CMS to develop quality measures which incentivize providers to adopt minimally invasive surgical approaches that result in reduced post-surgical pain and opioid use.

- **Medicare policies should promote appropriate dispensing and disposal of opioid products.** While coverage and payment of opioid alternatives is important, proper dispensing and disposal of unused opioids is also a key to addressing the opioid crisis. Medical technology can assist in addressing the problem of improperly disposed of opioids both in and outside healthcare settings. Proper disposal of opioids can be incentivized by evaluating and modifying its requirements for dispensing and disposal of controlled substances that are included in Medicare’s Conditions of Participation; providing workforce training and education on proper disposal of controlled substances and the impact drug diversion has on patient safety; and requiring data collection on the extent to which hospitals are maintaining a robust chain of custody of controlled substances from dispensing until disposal.
Additionally, Congress should also request a GAO report to: (1) conduct an assessment of data available on rates of proper dispensing and disposal of controlled substances in hospitals and other health care facilities; (2) study the extent to which controlled substances are being dispensed and disposed of in hospitals consistent with current federal standards, and (3) issue recommendations for improving proper dispensing and disposal of controlled substances in hospitals, including the detection and prevention of drug diversion.

Thank you for tackling this important issue that threatens every part of our country. We are committed to working with you to address the opioid crisis in America and to help ensure that patients have the care options they need.
April 10, 2018

The Honorable Greg Walden
Chairman
Energy and Commerce Committee
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Energy and Commerce Committee
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – the American Hospital Association (AHA) thanks you for your leadership in addressing the nation’s opioid epidemic. As you begin to craft comprehensive legislation in the Energy and Commerce Committee, we write to reiterate our strong support of H.R. 3545, the Overdose Prevention and Patient Safety (OPPS) Act, which would align 42 CFR Part 2 with the Health Insurance Portability and Accountability Act for the purposes of treatment, payment and health care operations.

Clinicians treating patients for any condition need access to their complete medical histories, including information related to any substance use disorder (SUD), to ensure their patients’ safety, and delivery of the highest quality care. Partitioning a patient’s record to keep SUD diagnoses and treatments hidden from the clinicians entrusted to care for the patient, as required by 42 CFR Part 2, is dangerous for the patient, problematic for providers and contributes to the stigmatization of mental and behavioral health conditions.

Too many patients who suffer from an SUD have stories of how a well-intentioned emergency room physician or other clinician nearly prescribed them an opioid or another drug that would have endangered their life or sobriety. Such incidents occur because current law prevents some clinicians from accessing information on the patient’s SUD and treatment plan unless the patient has given consent.

Clinicians in our hospitals and health systems must go to extraordinary lengths to comply with the requirements of 42 CFR Part 2. For example, we have heard concerns from obstetricians who specialize in treating pregnant women with SUD diagnoses and other clinicians who treat both the physical and SUD diagnoses of patients. To ensure compliance with 42 CFR, Part 2, as currently
written, they must maintain two separate computers and two separate medical records. This adds burden and expense, but without benefit.

Recent revisions made by the Substance Abuse and Mental Health Services Administration (SAMHSA) to the Part 2 regulations are not a significant improvement over the previous requirements, and do little to eliminate the regulation’s barriers that impede the robust sharing of patient information necessary for effective clinical integration and quality improvement. Complete alignment of Part 2 with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule will therefore require statutory changes.

The importance of coordinated care for patients in treatment for opioid use disorder cannot be overstated, and 42 CFR Part 2, enacted more than 40 years ago, is a major barrier to such care. Congress must amend this law, which impedes the sharing of critical patient information that is necessary to deliver the most effective and efficient care. Applying the same requirements to all patient information – whether behavioral or medical – would support the appropriate information sharing essential for clinical care coordination and population health improvement, while safeguarding patient information from unwarranted disclosure. H.R. 3545 would achieve these goals and, we, therefore, urge the Committee to report this important legislation as introduced.

If you have questions or would like further information, please contact Priscilla A. Ross, Senior Associate Director, Federal Relations, at prross@aha.org or (202) 626-2677.

Sincerely,

Thomas P. Nickels
Executive Vice President

c: Members of the Committee on Energy and Commerce
Chairman Burgess, Ranking Member Green, and distinguished members of the House Energy and Commerce Subcommittee on Health, thank you for the opportunity to submit written testimony on behalf of the American Psychological Association for your hearing on how Medicaid and Medicare can better address our nation’s opioid crisis. The American Psychological Association and the American Psychological Association Practice Organization comprise nearly 115,700 members and associates who are clinicians, researchers, educators, consultants, and students.

Psychological services are key to both preventing and treating opioid addiction, including through behavioral and services research and direct provision of services. Psychologists are primary developers and providers of psychotherapeutic services, including cognitive behavioral interventions, that are preferred alternatives to the use of opioids for treating chronic pain, including back pain, arthritis, fibromyalgia, migraine, and neuropathic pain. Psychologists also provide psychosocial interventions that are integral to medication-assisted treatment (MAT), a provenly effective form of treatment for opioid addiction.

We urge the committee to support policy changes commensurate with the scale of the opioid crisis. More than 63,000 Americans died from a drug overdose in 2016, a 21% increase over the number of overdose fatalities in 2015. Given the White House Council of Economic Advisers’ estimate of the economic cost of the opioid crisis at more than $500 billion a year, new federal investments in prevention and treatment on the order of $3 billion per year are unlikely to be sufficient. Similarly, we believe policymakers should regard the opioid crisis as an opportunity...
to dramatically improve prevention and treatment services for all substance use disorders, not just opiate addiction, especially in light of the high rates of poly-substance use.

Both Medicaid and Medicare must be updated and strengthened to adequately respond to the opioid crisis. Medicaid covers nearly one quarter of nonelderly adults with an opioid addiction, helping save thousands of lives. Medicaid beneficiaries with an opioid use disorder are more likely to receive treatment than privately insured adults with an opioid disorder. After the state of Kentucky expanded Medicaid eligibility, there was a 700% increase in the number of Medicaid beneficiaries accessing substance use treatment services. In states that expanded eligibility for their Medicaid programs under the Affordable Care Act, rates of opioid-related hospitalizations of those without insurance dropped almost 80% after expansion.

Research suggests that more than 40% of people being treated for addiction to prescription painkillers have a co-occurring mental health disorder, such as depression or anxiety. Thus, to effectively address the opioid crisis, it is critical to increase access to mental health services. Given that Medicaid is the single largest payer for mental health services in the U.S., providing a quarter of all funding for treatment, any effective strategy must include strengthening and expanding the Medicaid program across the nation.

The Medicare program is an equally important area of focus in addressing the opioid crisis, as Medicare beneficiaries have among the highest and fastest-growing rates of diagnosed opioid use disorder. Chronic pain is one of the most prevalent symptoms among older adults, affecting this population more than any other age group. Despite the fact that older adults experience age-related decline in drug metabolism, the use of multiple prescriptions—including opioids, benzodiazepines, and other central nervous system drugs—is especially common in this population, and rates of polypharmacy appear to be rising. Consequently, even Medicare beneficiaries prescribed moderate amounts of opioids may be placed at risk due to the effects of interactions between opioids and other prescriptions. Unfortunately, a significant proportion of psychotropic drugs is prescribed for older adults in the absence of a diagnosed mental health disorder.

Curtailing the opioid epidemic among the Medicaid and Medicare populations will require improving beneficiary access to both substance use and mental health treatment services generally, as unaddressed mental health issues frequently contribute to, and complicate, addictive behaviors. As an example, patients with chronic non-cancer pain and comorbid depression are more likely than those without depression to receive opioids, use them for longer periods of time, and misuse or abuse them. At the same time, the use of opioids is associated with an increased risk of depression, even in patients who were free of depression prior to taking opioids.

There are several bills pertaining to Medicaid and Medicare that we believe would help prevent opioid addiction, improve treatment, and reduce the risks associated with clinically appropriate use of opioids. Not all of these bills were referenced in the committee's notice for this hearing.

- H.R. 3192, the CHIP Mental Health Parity Act, introduced by Rep. Joseph Kennedy (D-MA), would extend to Children's Health Insurance Program (CHIP) plans the same Affordable Care Act requirement of coverage of essential health benefits that exists for
Medicaid and private insurance plans. This would help ensure that the nearly 9 million children and youth who rely on CHIP for health care coverage have access to substance use and mental health treatment services. We also support H.R. 4998, the Health Insurance for Former Foster Youth Act, introduced by Rep. Karen Bass (D-CA), to provide Medicaid coverage continuity for former foster youth up to age 26.

- We support expanding access to Medicaid health home services for individuals with an opioid use disorder, as would occur under an untitled legislative proposal before the committee. As with other forms of addiction, the most effective treatment for opioid use disorder encompasses a broad array of patient needs. Medicaid health homes must provide comprehensive care management, care coordination, health promotion, comprehensive transitional care and follow-up, individual and family support, and referral to community and social support services.

- The Medicare Mental Health Access Act (H.R. 1173), introduced by Reps. Kristi Noem (R-SD) and Jan Schakowsky (D-IL), would allow clinical psychologists to practice independently in all Medicare-covered treatment settings, without the need for prior certification or approval by a physician. This would help prevent opioid abuse by increasing beneficiary access to non-opioid treatment for chronic pain and facilitating the implementation of integrated pain management programs. Psychologists’ services are also helpful in addressing potential opioid dependency risks associated with surgery. The legislation would make psychologists eligible for the same 10% bonus payments for services provided in mental health professional shortage areas that are now paid only to psychiatrists and other physicians, encouraging psychologists’ participation in the program in rural and underserved areas. By improving access to psychologists, it would also improve the diagnosis and treatment of substance use disorders, the provision of psychotherapy and behavioral health services as part of MAT, and the diagnosis and treatment of comorbid mental disorders and cognitive impairments.

- The Behavioral Health Information Technology Act (H.R. 3331), introduced by Rep. Lynn Jenkins (R-KS), would authorize a health information technology (IT) demonstration program within the Centers for Medicare and Medicaid Innovation for mental health and addiction treatment providers, including public or private psychiatric hospitals, community mental health centers, accredited residential or outpatient opioid treatment facilities, clinical psychologists, and clinical social workers. Unfortunately, due to the limited eligibility of previous electronic health record incentive payments, health IT infrastructure is often lacking within behavioral health settings.

- We support untitled legislation to allow Medicaid coverage of services for substance use disorder treatment provided in institutions for mental diseases (IMDs), as defined under the law, for up to 90 days per calendar year. Similarly, we also support H.R. 2687, the Medicaid Coverage for Addiction Recovery Expansion Act, introduced by Rep. Bill Foster (D-IL). This bill would amend Medicaid’s IMD exclusion to allow state coverage of substance abuse treatment services provided in certain inpatient facilities and establish a grant program for states to expand and establish youth addiction treatment facilities under Medicaid or CHIP. We also support the proposal to provide
Medicaid coverage protections for pregnant and post-partum women receiving inpatient treatment for a substance use disorder.

- Individuals in the grip of an opioid addiction often become involved in the juvenile or criminal justice system. Effective treatment can help prevent reentry into these systems, enabling an individual with an opioid or other substance use disorder to resume being a productive member of their family and community. We endorse two bills before the committee that would help secure coverage for these populations: **H.R. 1925, the At-Risk Youth Medicaid Protection Act**, introduced by Rep. Tony Cárdenas (D-CA), and **H.R. 4005, the Medicaid Reentry Act**, introduced by Rep. Paul Tonko (D-NY).

- We support initiatives to improve Medicare beneficiary awareness of issues associated with opioid use and of non-opioid treatments for chronic pain, as provided under the draft legislation to add resources on these topics to the Medicare Handbook, within Medicare Part D prescription drug plans, and as part of initial preventive physical examinations for new Medicare enrollees.

Thank you for the opportunity to comment on significant steps the committee can take to help address the opioid crisis and its effect on Medicaid and Medicare beneficiaries. We applaud the committee’s work on this vitally important issue and encourage you to view the American Psychological Association as a resource to the committee for further information or research.
Dear Chairman Burgess and Ranking Member Green,

ASHP (American Society of Health-System Pharmacists) respectfully requests that H.R. 592, the Pharmacy and Medically Underserved Areas Enhancement Act, be included in legislation being developed by the subcommittee to address the current opioid abuse crisis. ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's 45,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP shares the committee's commitment to combating the nation's opioid overdose and misuse epidemic. We believe that pharmacists, as the medication experts on the interprofessional healthcare team, play an essential role in opioid and substance misuse prevention, education, and assistance. ASHP has long prioritized efforts to address this public health crisis, engaging at the state level to strengthen prescription drug monitoring programs (PDMPs) and at the federal level to increase funding for treatment and prevention initiatives.

Currently, pharmacists' services are not covered under Medicare Part B. As a result, beneficiaries' access to the healthcare practitioner with the most medication-related education and training is limited, and is restricted mainly to services related to the dispensing of medications. By not including pharmacists among other Part B providers whose services are covered, patients are not receiving the benefits of a coordinated, team-based approach to care.

For patients living with chronic conditions, the sheer number of medications creates situations where misuse or abuse is a real possibility. Because pharmacists see the patient's complete medication profile on a regular basis, they can be the bridge between healthcare providers by coordinating and providing medication-related services.

Pharmacists can help fight the opioid epidemic by managing and optimizing the impact of medications, reviewing medications to tailor care plans to patient needs, providing recommendations for non-opioid pain management alternatives, and educating patients regarding opioids. This can be accomplished by recognizing the value pharmacists offer as members of the healthcare team and utilizing them at the top of their training in fighting the opioid crisis. This recognition is especially important in underserved communities specifically addressed in this legislation.

April 11, 2018

The Honorable Michael Burgess, Chairman
The Honorable Gene Green, Ranking Member
United States House of Representatives
Energy and Commerce Committee
Health Subcommittee
2125 Rayburn House Office Building
Washington, D.C. 20515
Again, ASHP thanks the subcommittee for its work on this public health crisis. As the subcommittee continues its work, we encourage you to view ASHP as a resource on this critical issue. Please contact me with any questions, or have a member of your team contact Christopher Topoleski, Director of Federal Legislative Affairs, at 301-664-8806 or at ctopoleski@ashp.org.

Sincerely,

Kasey K. Thompson, Pharm.D., M.S., M.B.A.
Chief Operating Officer & Senior Vice President
Statement for the Record by the

Margaret A. Murray, CEO
Association for Community Affiliated Plans

for the

House Energy and Commerce Health Subcommittee’s Hearing

entitled

“Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients”

April 11, 2018
Chairman Burgess, Ranking Member Green, Members of the Subcommittee:

On behalf of the Association for Community Affiliated Plans, please accept this statement for the record on the House Energy and Commerce Committee’s efforts to address America’s devastating opioid and substance use disorder crisis and for the hearing entitled, “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients.” As organizations on the front lines of health care in this country, America’s Safety Net Health Plans stand prepared to help Congress and maximize the potential in Medicare and Medicaid to address this crisis. We applaud Congress’ attention to this important issue.

ACAP represents 61 member plans in 29 states serving more than 20 million Americans receiving coverage through Medicaid, CHIP, Medicare Advantage D-SNPs, and the Health Insurance Marketplaces. Our members serve almost 1 of every 2 Medicaid enrollees in managed care, and our qualified health plan (QHP) members have seen substantial increases in coverage provided to enrollees in the Marketplaces nationwide. Collectively, our Safety Net Health Plan members serve nearly half of a million enrollees in stand-alone CHIP programs as well as many additional children in Medicaid expansion CHIP.

States and the Federal government have turned to managed care organizations (MCOs) to provide coordinated care services for people who rely on publicly-sponsored health coverage programs. Because of their prominent role in coordinating care for Americans enrolled in these programs, Safety Net Health Plans are uniquely situated to provide high-value care coordination for individuals in need of treatment for substance use disorders. Access to coverage (along with comprehensive, integrated physical and behavioral health care) is essential to address the needs of those suffering from mental illness and/or substance use disorders (SUD). Unfortunately, cost is one of the key barriers to treatment for the SUD-impacted population and the importance of Medicaid coverage for the low-income adult population is essential to helping address this crisis.

As the normal course of operations, Safety Net Health Plans assess member needs, identify treatment gaps, engage members, encourage medication adherence, develop individualized care plans, and coordinate care. These programs are particularly important to facilitate integrated physical and behavioral health care and social services for enrollees with substance use disorders.

Collectively, ACAP Safety Net Health Plans have a track record of implementing programs and policies that improve health care and patient safety for individuals with substance use disorder. For example, with implementation of their “Managing Pain Safely: Multiple Interventions to Dramatically Reduce Opioid Abuse” initiative, Partnership Health Plan of California reported a 75 percent decrease in unsafe opioid
doses, a 66 percent decrease in the number of members with opioid prescriptions, and a 74 percent decrease in prescription opioid escalations between January 2014 and November 2016. Recognizing the benefits of improved integration of physical and behavioral services, including the integration of mental health and SUD services, Neighborhood Health Plan of RI has instituted weekly, co-managed care rounds. Through the co-managed care rounds, medical and behavioral health providers jointly review the cases of select complex members and work to develop a member engagement strategy and care plan. These are just two examples of the vital role that coordinated care plans have in addressing the health care needs of people suffering under the crippling burdens of substance use disorder.

ACAP Comments on Legislation Being Considered by the Committee

ACAP applauds the members of the Committee for recognizing the important role that Medicare and Medicaid can play in addressing America's opioid crisis. Specifically, ACAP offers our comments on certain bills that are being considered as part of today's hearing:

Top Legislative Priority

- **H.R. _, Behavioral Health Measures**, legislation to amend title XI of the Social Security Act to require States to annually report on certain adult health quality measures, and for other purposes

  - **Comments**: In 2010, Congress required the development of a set of Adult Core Quality measurements in Medicaid. These measures provide federal and state policymakers with an assessment of the quality of care being provided to adults in this program. However, this measurement program is underperforming because states are not currently required to report on their state performance under these measures. This not only undermines policymakers' ability to understand what is working and what is not but also fails to offer sufficient insight as to whether the billions of dollars spent in Medicaid are effectively addressing the important health care issues addressed in these measures.

Building on the work done for Medicaid and CHIP quality reporting for children included in the recently-passed Bipartisan Budget Act (H.R.1892), ACAP strongly supports legislation that will institute a mandatory nationwide system of Medicaid quality measurement, reporting, and improvement for certain quality measures in Medicaid for adults. ACAP has long been on record in support of this approach, having previously endorsed the Medicaid and CHIP Quality Improvement Act.
H.R.2823/S.1317. ACAP notes that the existing Medicaid Adult Core Quality measurement set currently used by CMS includes several measures that are specifically related to opioids, SUD, and mental health services, including but not limited to:

- Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment
- Concurrent Use of Opioids and Benzodiazepines
- Follow-Up After Emergency Department Visit for Mental Illness or Alcohol and Other Drug Abuse or Dependence
- Use of Opioids at High Dosage in Persons Without Cancer

The reporting of these measures is particularly important given the severity of the opioid/substance use disorder crisis gripping America today. ACAP believes that the draft legislation offered by the Committee makes significant strides in addressing that issue and we strongly support it.

**Proposed Amendments:** While ACAP supports this legislation in its current form, ACAP urges the Committee to consider the following amendments:

- Given the urgency of the opioid crisis and the important need for federal policymakers to address this issue in a timely manner, ACAP urges Congress to expedite the implementation date for the State report required in subsection (d)(1) to 2021.

- To help understand the effectiveness of the treatment of substance use disorders, we urge the legislation to be amended to require states to report the measures delivered through managed care organizations, primary care case management, and fee-for-service programs separately.

**Other Legislative Priorities and Comments**

Although ACAP has seen the mandatory reporting of the Adult Core Quality Measures as a top legislative priority for years, we are also strongly supportive of other legislation addressing policy changes in the Medicare and Medicaid programs currently being considered by the Committee.
• **H.R. ___ CMS Action Plan**

  o *Comment:* ACAP supports legislation to provide for the development of a comprehensive Action Plan at the Centers for Medicare and Medicaid Services regarding recommendations for changes under Medicare and Medicaid to prevent opioids addictions and enhance access to medication-assisted treatment.

  o *Proposed Amendments*

    * With respect to the establishment of Stakeholder meetings under Section 1(c) of the draft bill and given the significant percentages of Medicare and Medicaid beneficiaries that receive benefits through health plans, ACAP urges the Committee to amend the language to include “Medicare Advantage plans and health plans operating in the Medicaid program” among the list of meeting participants.

    * With respect to the CMS report to Congress established under Section 2(b)(5) of the draft bill, ACAP urges the Committee to amend the language to include “Medicaid health plans” and “health plans operating as Medicare-Medicaid Plans under the dual eligible demonstrations.”

• **H.R. ___ Provide IMD Services Up to 90 Days for Medicaid Beneficiaries with SUD**

  **H.R. ___ Mom IMD**

  o *Comment:* ACAP has been on record in support of allowing States to provide Medicaid services for certain individuals with substance use disorders in institutions for mental diseases (IMD) and we support both bills that will improve the delivery of Medicaid IMD services.

Again, thank you for the opportunity to submit this statement for the record. We hope that you find ACAP’s input to be of assistance and we stand prepared to assist the Committee in its efforts to address America’s opioid crisis.

*For additional information on ACAP’s Medicaid policies, please contact Jenny Babcock at jbabcock@communityplans.net.*

*For additional information on ACAP’s Medicare policies, please contact Christine Lynch at clyneh@communityplans.net.*
The College of Healthcare Information Management Executives (CHIME) welcomes the opportunity to lend our voice to the important national dialogue addressing the opioid crisis. We appreciate the Committee’s interest in stemming the opioid epidemic that claimed the lives of 42,249 Americans in 2016, a number five times higher than in 1999.1 To that end, we are pleased to offer our perspective on H.R. 3528, Every Prescription Conveyed Securely Act, as well as, the Committee’s discussion draft on prescription drug monitoring programs (PDMPs).

CHIME is an executive organization dedicated to serving chief information officers (CIOs), chief medical information officers (CMIOs), chief nursing information officers (CNIOs) and other senior healthcare IT leaders. With more than 2,600 provider members in 51 countries and over 150 healthcare IT business partners, CHIME provides a highly interactive, trusted environment enabling senior professional and industry leaders to collaborate, exchange best practices, address professional development needs, and advocate the effective use of information management to improve the health and healthcare in the communities they serve.

CHIME’s Opioid Task Force is undertaking several initiatives aimed at curbing the pattern of addiction, including reviewing the impact of technology and data driven solutions. As the Committee deliberates the myriad ideas, bill and options for driving down the speed with which this disease is gripping our country, we offer the following input for your consideration:

H.R. 3528, Every Prescription Conveyed Securely Act

Our members recognize the value and importance of prescribing controlled substances electronically and agree that facilitating more use of EPCS can help combat the opioid epidemic. As of 2015, all states now allow for EPCS, yet the number of non-controlled substances which are sent electronically as compared to controlled substances sent electronically, is far greater. According to SureScripts data, the rates of clinicians scripting controlled substances electronically range between widely between 3.6% to 73.4%.

https://www.cdc.gov/drugoverdose/epidemiology.html
Our members have invested heavily in certified electronic health records which are required to support electronic prescribing of controlled substances. We recognize, however, that some vendors may be better equipped at supporting a single workflow.

Based upon data shared by some of our members in New York State, the first state in the nation to require their prescribers to script controlled substances electronically, they found:

- 73% reduction in lost or stolen narcotics
- 70% reduction in paper scripts
- Ability to monitor opioid scripts by provider (authenticated/registered) and patient to monitor for "frequent flyers" and patterns of behavior
- Providers can use portal to see patient uses of narcotics before prescribing
- Ability to monitor medical marijuana dispensing and use

Additionally, data conducted by the Pew Charitable Trusts found that, "After the implementation of use mandates, prescriber PUMP registrations increased in all three case study states (Kentucky, New York, and Ohio), as did requests for the controlled substance prescription histories of patients. For example, in New York, PDMP report requests increased from an average of 11,000 per month to 1.2 million per month in the six months after the mandate went into effect."

While the bill calls for adoption of EPCS in less than two years by January 1, 2020, we appreciate that the H.R.3528 has eight different waivers, and that lawmakers have considered a variety of scenarios in which mandating e-prescribing of a controlled substance may not be appropriate or feasible.

Prescription Drug Monitoring Programs

Our members appreciate the Committee’s attention to the importance of PDMPs and how they can be used to help address the opioid crisis. We furthermore appreciate that the Committee is looking to provider leaders in the space like Geisinger Health System in Pennsylvania, CHIME, through its Opioid Task Force, is seeking out those in our community who are employing models to reduce opioid addiction and mortality, and we are raising awareness of the epidemic.

Our members believe that it is critical to facilitate more use of PDMPs that better integrate with electronic health records. According to the Pew Charitable Trusts, 24 states have no access to integration solutions. To that end, we believe better integration is possible if:

1. States make available to providers open application programming interfaces (APIs) to allow a more seamless integration with providers’ electronic health records (EHRs);
2. Minimum data sharing standards are established;

2 http://www.pewtrusts.org/-/media/assets/2016/12/prescription_drug_monitoring_programs.pdf
3 http://www.pdmpassist.org/pdf/PDMP_Integration_Status_20171205.pdf
3. More consistency around when prescription data is loaded into PDMPs and thus available to prescribers. A good first step is to review trending data to determine the extent of variations;
4. Data contained in PDMPs is available to be imported into EHRs in granular detail. Integration with clinical decision support is needed to help facilitate prescribers' ability to run reports (e.g., lists in the PDMP view lists and running analytics). It could also help address concerns prescribers have around acting on decisions (and thus possible downstream liability issues) based on data that was only available to be "viewed" but never able to be incorporated into the medical record;
5. Proxy access for medical staff to access PDMPs to flag issues prior to a visit, as well as, allowing clinicians to have the data in a time efficient manner;
6. Transparency around how PDMP software scoring (i.e., algorithms that predict the potential for addiction);
7. Funding is available to help offset connection costs for providers; and
8. Alerts sent to prescribers flagging patients with a history of opioid use dependence could also be helpful. However, this could run afoul of 42 CFR Part 2 (consent rules for sharing mental health and substance abuse information). Further, until 42 CFR Part 2 and Health Insurance Portability and Accountability Act (HIPAA) are aligned, sharing patient's information on opioid use will present challenges. H.R. 3545, the Overdose Prevention and Patient Safety Act, if adopted, would address this situation by allowing substance abuse disorder information to be shared according to the same rules that govern HIPAA.

Discussion Draft to authorize CDC to conduct prevention activities related to controlled substances overdoses

The discussion draft aimed at authorizing, "the Centers for Disease Control and Prevention to carry out certain activities to prevent controlled substances overdoses, and for other purposes," takes aim at prevention and CHIME supports the notion of funding prevention through evidence-based grants, including activities designed to help states improve the efficiency of their PDMPs.

We are particularly pleased to see it would help support efforts to improve interoperability between PDMPs and EHRs to improve clinical decision-making. Furthermore, we believe the bill's support for evidence-based activities, which centers around facilitating information sharing between/among neighboring states, is also highly desirable. Finally, we are pleased to see the bill would also encourage the use of evidence-based grants in an effort to align controlled substances guidelines. We believe that more uniform use of the CDC's guidelines, especially through clinical decision-support and their mobile app, will be helpful. As the Committee considers grants, we hope they will also consider the utility of:

- Helping support providers use of PDMPs by helping defray some of the costs providers experience in connecting with PDMPs. For example, Ohio has offered these types of grants;
- Correctly matching patients with their records. The lack of a consistent patient identity matching strategy is the most significant challenge inhibiting the safe and secure electronic exchange of
health information. The ability to do so continues to be hampered by the funding prohibition barring federal regulators from identifying standards to improve positive patient identification. Therefore, evidence-based grants could be a critical driver to ensuring that we consistently identify and respond appropriately to the right patient and the right drug use patterns.

Conclusion

CHIME commends the Committee for its leadership and willingness to engage stakeholders on this critical public health issue facing our country. Should you have questions about our remarks or require additional information, please contact us at policy@chimecentral.org
April 11, 2018

The Honorable David Schweikert  
2059 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Mike Thompson  
231 Cannon House Office Building  
Washington, D.C. 20515

The Honorable Bill Johnson  
1710 Longworth House Office Building  
Washington, D.C. 20515

The Honorable Ben Ray Lujan  
2231 Rayburn House Office Building  
Washington, D.C. 20515

Dear Representatives Schweikert, Johnson, Thompson and Lujan:

The undersigned organizations write in support of H.R. 4841, the Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018. This legislation improves the prior authorization (PA) of medications in the Medicare program by streamlining the PA process and ensuring legitimate beneficiary access to prescribed medications while preventing misuse and abuse of medication under PA, such as many opioids. Most importantly, a more efficient PA process will help to improve health outcomes and reduce overall health costs.

Electronic prior authorization (ePA) streamlines this process by automating many of the communications among health care providers, payers and pharmacists, which, in turn, helps patients obtain their prescribed therapies without delay. Traditionally, payers and providers work through a PA process to determine whether a patient clinically needs a medication. Historically this has been completed through phone calls, paper forms and faxes. Physicians, on average, spend 20 hours per week working through paper PA requests. Because of the burdensome PA process, millions of prescriptions are abandoned at the pharmacy counter every year, causing non-adherence, disease progression and increased costs to the health system.

Simply put, current technology can largely automate the communication process, ensuring prompt and succinct answers to questions regarding the clinical need and efficacy for a patient’s medication. ePA uses electronic healthcare transaction standards – the SCRIPT standard developed by the National Council for Prescription Drug Programs - that providers, pharmacists and commercial health plans use every day. This greatly reduces the 20 hours of average weekly time spent resolving clinical questions to less than 10 hours per week. ePA provides a pathway for a quick determination of clinical appropriateness, assisting in the prevention of prescription misuse while maintaining access to medications for those with legitimate needs. When looking at opioid prescriptions, this is particularly impactful.

In the commercial market, ePA’s adoption has seen tremendous success. A recent survey shows that 90 percent of payers in the commercial market, 100 percent of pharmacies, and 70 percent of EHR systems are already ePA compatible and using the technology. Increasingly applying this same technology in Medicare would prevent many beneficiaries from facing rejection of prescribed medications at the pharmacy counter due to a needed PA.
Applying ePA to the Medicare Part D program would reduce provider burdens, improve patient access and adherence and decrease system costs. We support legislation that expands its use in the Medicare program.

Thank you for your leadership on this issue and we look forward to working with you to encourage the use of ePA within Medicare.

Sincerely,
American Academy of Ophthalmology
American Academy of Neurology
AstraZeneca
CoverMyMeds
Curadite
CVS Health
Express Scripts
GlaxoSmithKline
Healthcare Leadership Council
Health IT Now
LifeWIRE Corp.
McKesson
National Alliance on Mental Illness
National Consumers League
National Council on Patient Information and Education
National MS Society
Pharmaceutical Care Management Association
Prescriptions for a Healthy America
The Kennedy Forum
Dear Chairman Burgess and Ranking Member Green:

The National Association for Behavioral Healthcare (NABH)—on behalf of our more than 1,000 psychiatric hospitals, addiction treatment facilities, general hospital psychiatric and addiction treatment units, residential treatment centers, youth services organizations, outpatient networks, and other providers of care—thanks the Energy and Commerce Committee for its comprehensive agenda to combat the opioid crisis. The committee has shown it is committed to ending this public health crisis by hosting many hearings that have examined this issue from every angle.

NABH represents the entire behavioral healthcare continuum. Behavioral health encompasses both mental health and substance use disorders, and the behavioral healthcare continuum includes inpatient care, partial hospitalization services, residential treatment and outpatient services. Our diverse membership positions us well to help solve our nation’s deadly and pervasive opioid problem.

Background on the Opioid Crisis

Most substance use disorders (SUDs) go untreated. In 2016, 20.1 million Americans had an SUD and needed treatment. Within that group, only 11 percent of people received services, leaving 89 percent of these individuals without treatment of any kind. This is referred to as the “treatment gap.” Meanwhile, more than 69,000 people—roughly 174 people every day—died from a drug overdose in 2016, reflecting a 21-percent increase from 2015. Two-thirds of these deaths involved an opioid and were driven largely by heroin overdoses, which have increased 533 percent since 2002. These trends show no signs of stopping. In 45 states, opioid overdoses increased 30 percent from July 2016 through September 2017. Despite these statistics, only 19 percent of individuals with an opioid use disorder (OUD) received OUD treatment, and only 26 percent of individuals with a heroin use disorder received medication assisted treatment (MAT).

Reflected in this trend, opioid-related hospitalizations increased by 150 percent between 1993 and 2012. Between 2005 and 2014, the national rate of opioid-related inpatient stays increased 94.1 percent and the national rate of opioid-related emergency department visits nearly doubled with an increase of 99.4 percent. Every day, more than 1,000 people are treated in emergency departments for misuse of prescription opioids.

The good news is recovery from SUDs is possible with effective treatment. However, the rate of recovery is significantly low primarily because most patients do not access the treatment system. Effective treatment programs include a range of services that address individual patient needs, but too often patients do not receive evidence-based care. And when they do receive care, they rarely receive the right amount of care. Moreover, the range of treatment is not always coordinated and often falls short of managing symptom recurrence (known as “relapse”) and sustaining long-term recovery.
These data show clearly that we need to:

- provide states relief from the antiquated Institutions for Mental Diseases (IMD) exclusion;
- modify the federal approach to opioid grant funding by encouraging states to pilot financing models for addiction care that are independent of traditional grants; and
- expand access to all FDA-approved addiction medicines.

**Relief from the IMD**

Since 1965, the IMD exclusion has prohibited federal payments to states for services to adult Medicaid beneficiaries between the ages of 21 and 64 who are treated in facilities that have more than 16 beds, and that provide inpatient or residential behavioral health (SUDs and mental illness) treatment. While NABH supports a full repeal of the IMD, which two federal commissions—one non-partisan and the other bipartisan—recommended in the last year, we understand it may be necessary to take interim steps before that happens.

Changing the per-stay cap under the managed care rule to 25 days from 15 days would have a significant, positive effect on psychiatric hospital care and SUD treatment. Although most psychiatric hospital stays are fewer than 15 days, there are a significant number of cases in which it is "medically necessary" for patients to stay more than 15 days to stabilize their behavioral health conditions. In addition, residential stays for SUD treatment tend to be longer than hospital stays for mental health treatment. As a result, even though most SUD stays exceed the current limit, many of those cases could be accommodated with a cap of 25 days.

Additional options for providing relief from the IMD exclusion include:

- Establishing a "State IMD Flexibility Fund" that states can use to provide targeted relief from the IMD exclusion to treat patients under Emergency Medical Treatment and Active Labor Act (EMTALA), patients with co-occurring SUD and mental health conditions in states with 1115 SUD waivers (this is currently prohibited by CMS), or patients in managed care programs beyond 16 days. The fund would also allow states to design their own approaches to providing treatment for Medicaid beneficiaries in inpatient or residential treatment programs, based on approval from the Health and Human Services Department.
- Instituting a five-year nationwide emergency waiver from the IMD Exclusion to allow states to manage the opioid crisis. Under this approach, Congress could instruct CMS to temporarily lift the restriction and allow states to provide inpatient and residential treatment to Medicaid beneficiaries with behavioral health conditions. Congress could examine the outcome after the waiver expires and reconsider this approach based on outcomes.

**Grant Modification to Support Treatment**

Block grant funds and other supplementary grants are critical to the public safety net for individuals with addictions. However, this grant financing is limited, and it is not always the most effective approach to engage public-private partnerships in a way that could change the trajectory of the opioid crisis. In 2016, funding from the 21st Century Cures Act (Cures) began to flow to states through the Substance Abuse and Mental Health Services Administration’s (SAMHSA) block grant. But reports indicate that Cures funding is not reaching treatment services quickly enough. Private-sector health systems have untapped capacity that remains unused. These systems are poised to provide services immediately, which would reduce the treatment gap. We need a disruptive approach that leverages federal funds and private-sector resources to fight the opioid crisis.
Congress should create an Opioid and Substance Use Treatment and Recovery Fund to help states finance addiction-care services. This flexible financing model would direct federal funding toward effective evidence-based addiction treatment quickly. To be clear, this new financing mechanism is not intended to replace block-grant funding, nor is it meant to relieve existing insurers of their obligations under the Mental Health Parity and Addiction Equity Act. Rather, this would establish an additional method for states to receive and disburse funding quickly to for-profit and not-for-profit addiction treatment providers, who, in turn, are well-positioned to address the gaps in their existing SUD treatment programs.

Adopting this approach, Congress would authorize the Health and Human Services Department to distribute funding based on state-designed plans for treatment or recovery support services from licensed, not-for-profit and for-profit providers who treat individuals with opioid and substance use disorders or co-occurring substance use disorder and mental health disorders. The funds should cover public-private partnerships that provide services for direct inpatient, partial hospitalization, and intensive outpatient care, as well as outpatient counseling, medication and services provided in opioid treatment programs, office-based opioid agonist treatment, other FDA-approved addiction medicines, recovery-support services, expert addiction consultation services, collaborative care and telehealth.

This supplementary approach is a patient-focused financing model tailored to the individual's clinical needs and choice of treatment, setting and provider. It allows the funding to follow the patient along the behavioral healthcare continuum from access, to care, and throughout recovery.

42 CFR Part 2

Federal regulations established in the 1970s known as 42 CFR Part 2, or "Part 2," currently govern the confidentiality of medical information about individuals who have applied for or received substance abuse diagnosis or treatment in a program that primarily provides SUD treatment. Part 2 is more stringent (i.e., privacy-protective) than the Health Insurance Portability and Accountability Act of 1996 (HIPAA). And when Part 2 is applied to the current digital era, the regulations are an impediment to healthcare integration, which can endanger patients. Committee members should reform Part 2 to improve information-sharing while protecting individuals from using medical records in criminal, civil, and administrative prosecution and discrimination. NABH supports the Overdose Prevention and Patient Safety (OPPS) Act (H.R. 3545), which would accomplish this goal.

Medicare Beneficiary Access to Addiction Treatment

According to the Journal of the American Medical Association, "the population that uses Medicare...has among the highest and most rapidly growing prevalence of opioid use disorder, with more than 6 of every 1000 patients diagnosed and with hospitalizations increasing 10 percent per year." One cause of this problem is that while Medicare parts A and D cover methadone, part B does not cover methadone as an outpatient treatment for opioid addiction. Committee members should pass legislation to allow Medicare beneficiaries to access critical methadone treatment under Medicare part B in outpatient settings.

Helping Americans Seek Treatment Act (H.R. 4769)

SAMHSA has a national substance use disorder treatment resource called the National Helpline, a free, confidential, treatment referral and information service available 24 hours a day, seven days a week for individuals and families facing mental and/or substance use disorders. However, not many people know about the National Helpline, and it is not being used as widely as it could be. Committee members should support Rep. Tom Marino's (R-Pa.) Helping Americans Seek Treatment Act, which would establish a national campaign to increase awareness of the National Helpline.

Other Policies

The Committee should also consider ways to remove reimbursement and policy barriers to SUD treatment; increase parity enforcement authority at the U.S. Labor Department; revise policies to allow SUD treatment via telemedicine; and expand the use of MAT at all levels of care for adolescents, adults, and expectant mothers.
Thank you for considering our comments. We would be happy to provide detailed information on any of the recommendations included in this letter.

And we look forward to working with the committee and the entire Congress to ensure that all Americans have access to high-quality, life-saving behavioral healthcare services.

Sincerely,

Mark Covall
President/CEO

Brent Turner
Board Chairman
Statement

Of

The National Association of Chain Drug Stores

For

United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

On

“Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients”

April 11, 2018
2:15 p.m.

2322 Rayburn House Office Building
Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Burgess, Ranking Member Green, and the members of the Subcommittee on Health for your continued commitment to implementing strategies to curb prescription opioid abuse and diversion. The chain pharmacy community welcomes the opportunity to partner with lawmakers and other stakeholders for this purpose. NACDS and our members are focusing our energies on real, workable solutions that will address the problem of prescription drug abuse while also ensuring that legitimate patients are able to receive their prescription pain medications.

Chain pharmacies engage daily in activities with the goal of preventing drug diversion and abuse. Since chain pharmacies operate in almost every community in the U.S., we support policies and initiatives to combat the prescription drug abuse problem nationwide. We believe that holistic approaches must be implemented at the federal level.

Pharmacists take very seriously their role in helping to ensure safe use of medications – but they cannot do it alone. We support a collaborative approach to curb prescription drug abuse and preserve patient access to their medically-necessary pain medications. We believe that there are a variety of ways to help curb prescription drug diversion, and chain pharmacies actively work on many initiatives to reduce this problem. We thank you for the opportunity to provide recommendations on policy changes to prevent the abuse and diversion of prescription opioid medications.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS’ nearly 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 152,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 20 countries. For more information, visit www.NACDS.org.
As public health authorities have indicated, face-to-face interactions between pharmacists and patients have made pharmacists keenly aware of the extreme challenges and complexities associated with the opioid abuse epidemic.

Pharmacists and pharmacies fully understand that controlled substances are subject to abuse by a minority of individuals who improperly obtain controlled substance prescriptions from physicians and other prescribers. Pharmacists and pharmacies strive to treat medical conditions and ease patients' pain while simultaneously guarding against the abuse of controlled substances. The key is to guard against abuse without impeding our primary goal of assisting patients who need pharmacy services.

Based on our experiences, NACDS is pursuing a number of policy solutions to complement pharmacy’s collaboration with other stakeholders including healthcare professionals and law enforcement to address prescription opioid abuse in communities across the country.

**Utilizing Pharmacists to Combat the Opioid Crisis**

Retail community pharmacists are an underutilized component in helping to identify and treat those with opioid addiction as well as educating consumers on the dangers of opioid abuse and addiction. Recognizing the value pharmacists play as a member of the healthcare team and utilizing them at the top of their training would greatly benefit the battle against the opioid crisis.

Access, quality, cost, and efficiency in healthcare are critical, especially for those who are medically underserved and/or are at-risk for substance abuse disorders. These may include seniors with cultural or linguistic access barriers, residents of public housing, persons with HIV/AIDS, as well as rural populations and many others. Many of these beneficiaries suffer from multiple chronic conditions. Significant consideration should be given to policies and initiatives that enhance healthcare capacity and strengthen community partnerships to offset provider shortages, particularly in communities with medically-underserved populations.
Retail pharmacies are often the most readily accessible healthcare provider. Research shows that nearly all Americans (89%) live within five miles of a retail pharmacy.

Despite the ability of pharmacists to improve access and care, current law does not recognize them as a provider in the Medicare program. H.R. 592/S. 109, the Pharmacy and Medically Underserved Areas Enhancement Act, would change this to recognize pharmacists as providers in medically underserved areas, thus creating better access to services for these vulnerable populations. Not only would recognition of pharmacists improve access, but it would lead to reduced healthcare costs as pharmacists would provide already-covered Medicare services at 85% of the physician fee schedule.

Pharmacists have advanced education and training that equips them to provide many services in addition to their role in providing patients with access to information about their prescription medications. These services include:

- Health Tests and Screening
- Management of Chronic Conditions and Related Medications
- Immunization Screening and Administration
- Point of Care Testing (e.g. Flu, Strep)
- Transition of Care Services

In addition to these vital services, pharmacists are also trained and equipped to help in the battle against opioid abuse. Examples of ways pharmacists could help include:

- Assisting physicians with opioid treatment programs, which provide medication assisted treatment (MAT) for people diagnosed with an opioid-use disorder. CMS recently recognized the importance of MAT in its final FY2019 Call Letter, when it stated “...it is imperative to also ensure that Medicare beneficiaries have appropriate access to medication-assisted treatment (MAT).”
• Providing greater access to community-based Screening, Brief Intervention, and Referral to Treatment (SBIRT). SBIRT is an evidence-based practice used to identify, reduce, and prevent problematic use, abuse, and dependence on alcohol and substance abuse and includes a referral to treatment for those in need.

• Providing essential screenings and immunizations related to Hepatitis B, Hepatitis C, HIV, Tuberculosis (TB), and depression to improve the population health of communities. For example, one community pharmacy partnered with a state health department to provide HIV screening in their pharmacies. In this model, the state health department gains access points to their at-risk population through the reach of pharmacies and in-turn reimburses the pharmacies per screening provided. Data from this partnership shows that pharmacy can provide these services at a lower cost than the health department, and patients find the pharmacies to be less stigmatizing locations than other places to receive screenings.

• Increased access to naloxone, a medication designed to rapidly reverse opioid overdose. Several states have recognized the importance of ensuring quick access to this life-saving medication and have employed various approaches to reimburse and make it easier for pharmacists to provide naloxone to patients. Notably, the U.S. Surgeon General recently issued an advisory urging all Americans to learn how to use naloxone and keep it within reach.¹

• Increased use of pharmacogenomic testing to determine the right pain medication and dosing. By performing pharmacogenetic testing, personalized medicine allows patients to be prescribed with the right drug to be administered for adequate pain control – to avoid experiencing dose-dependent side effects or lack of drug efficacy. A pain medication may alleviate pain for one patient while providing no relief for another. Pharmacogenetic testing can help alleviate this problem.

To help alleviate these critical issues and provide more access to providers willing and able to help battle the opioid crisis, NACDS encourages members of Congress to support H.R.

Electronic Prescribing of Controlled Substances

Chain pharmacy supports policies that promote the use of electronic prescribing to transmit prescription information between prescribers and pharmacists. For controlled substances in particular, use of this technology adds new dimensions of safety and security in the prescribing process. Data from self-reported drug abusers suggest that between 3% and 9% of diverted opioid prescriptions are tied to forged prescriptions. Electronic controlled substance prescriptions serve to reduce the likelihood of diversion in this manner, as electronic controlled substance prescriptions cannot be altered, cannot be copied, and are electronically trackable. Furthermore, the federal DEA rules for electronic controlled substances prescriptions establish strict security measures, such as two-factor authentication, that reduce the likelihood of fraudulent prescribing. Notably, the state of New York saw a 70% reduction in the rate of lost or stolen prescription forms after implementing its own mandatory electronic prescribing law.4

The rate of electronic prescribing has increased significantly in recent years. In 2008, there were about 68 million electronic prescriptions.5 As of 2016, over 1.6 billion prescriptions were issued electronically, including approximately 45.3 million controlled substance prescriptions.6 Still, there is room for further improvement, particularly with controlled substances prescriptions which lag behind in overall adoption rates. While 90% of all pharmacies are enabled to receive electronic prescriptions, only 17% of prescribers have systems that can send electronic prescriptions for controlled substances.7

4 Remarks of Anita Murray, Deputy Director, New York State Department of Health at the Harold Rogers Prescription Drug Monitoring Program National Meeting (September 6, 2017).
7 Ibid.
To enhance healthcare providers’ utilization of this technology and to foster prescriber adoption, chain pharmacy urges the adoption of policies that encourage all prescriptions be issued electronically, with limited exceptions for situations in which issuing an electronic prescription may not be feasible. We support the Every Prescription Conveyed Securely Act (H.R. 3528), legislation that requires electronic prescribing for controlled substances in Medicare Part D. We thank Representative Mullin as an original cosponsor of this legislation and we ask that the Subcommittee work to pass this necessary legislation.

Nationwide Prescription Drug Monitoring Program
NACDS continues to support the important role of prescription drug monitoring programs (PDMPs) to help prevent drug abuse and diversion. Over the years, states have established PDMPs as a tool to provide critical information to prescribers and dispensers. However, many states have implemented their own approaches to designing and managing PDMPs, resulting in disparate data and access requirements. These challenges are compounded by the lack of interconnectivity and complete data sets among many PDMPs, impeding their optimal use.

PDMP databases are populated when pharmacies contribute records of dispensed controlled substance prescriptions to the state PDMP data repository. Pharmacies are required by state law to report dispensing information that identifies the patient, the drug and quantity received by the patient, the prescriber, and the pharmacy where the medication was dispensed. However, specific data reporting requirements vary by state.

Unfortunately, the state PDMPs are difficult to access and utilize. It can take an average of 2 to 6 minutes to access and run an individual report from states’ PDMP web portals. Given that there were approximately 492 million controlled substances prescriptions dispensed in 2016, if healthcare providers were to run a PDMP report for each patient who received a controlled substance prescription, this would require approximately 16 to 49 million

---

additional hours per year to access PDMP data for all dispensed controlled substances prescriptions.

Evidence suggests that physicians do not use PDMPs consistently, or at all, due to a lack of data timeliness to show real-time prescribing data in their workflow and lack of health IT integration with electronic health records (EHRs). NACDS supports health IT initiatives that equip providers with real-time data within EHRs. Improvement of health IT integration to combat the opioid crisis also would be facilitated through the use of electronic controlled substance prescriptions.

The experience of the state of New York – which enacted the I-STOP Law to enhance the PDMP and mandate use of electronic prescriptions – illustrates how PDMPs and e-prescribing, when used together, can improve opioid prescribing practices and reduce opportunities for prescription opioid abuse and diversion. According to data from the New York State Department of Health, increased use of PDMP data by prescribers led to an 8.7% reduction in the number of opioid prescriptions and a 10.4% reduction in the total number of patients who received an opioid prescription in the first year alone. Furthermore, following implementation of the e-prescribing mandate, the state saw a 70% reduction in the rate of lost or stolen prescription forms. Altogether, these policies contributed to a 98% reduction in the rate of doctor shopping.

As a result of the present functionality and interoperability challenges, NACDS is calling on stakeholders to work together to develop and implement a nationwide PDMP solution to harmonize state PDMPs. Such a system should be built in tandem with efforts that encourage e-prescribing for controlled substances in an effort to provide timely, in-

---

10 Remarks of Anita Murray, Deputy Director, New York State Department of Health at the Harold Rogers Prescription Drug Monitoring Program National Meeting (September 6, 2017).
11 After initially enacting the I-STOP law, the New York Bureau of Narcotics and Enforcement initially saw a 91.2% reduction in the rate of doctor shopping. Now that the e-prescribing mandate has been implemented, Feb. 2018 data shows that there has been a 98.8% reduction in incidence of doctor shopping since before I-STOP. BNE estimates that the additional decrease was, in part, due to e-prescribing. Data provided by Anita Murray, Deputy Director, New York State Department of Health (February 26, 2018).
**workflow analyses of real time data with actionable point of care guidance for prescribers and dispensers.**

Working in tandem with e-prescribing technology would help ensure that prescribers receive immediate, in-workflow information at the point-of-prescribing, thus eliminating the need to access another system or database. Moreover, this would help ensure that any federal or state opioid prescribing limits are followed.

A nationwide PDMP solution could take many forms, pulling information from several data sources, including: clinical data extracted from insurers, PBMs, and state PDMPs; and aggregated data via a commercial market solution. Additionally, controlled substances prescribing information could be included within EHRs. NACDS would support a nationwide solution through any of those vehicles, provided that the solution includes the following principles:

- The most effective use of PDMP data is in ensuring appropriateness of controlled substance use when the prescriber is issuing a prescription for a patient. To that end, prescribers should have real-time, actionable data at the point of care to better inform their prescribing decisions. We recommend that a nation-wide data solution be utilized by pharmacies as a secondary safeguard, in addition to the prescriber’s review. In exercise of their professional judgment, pharmacists can take necessary actions to investigate and attempt to resolve any concerns identified as a result of a query, as part of the process of determining whether or not to fill controlled substance prescriptions.
- Data is accessible to prescribers, dispensers, and supporting staff (e.g. automatic and free registration into PDMP).
- Compile data exclusively on controlled substances; stay focused on main mission.
- Sufficiently protect proprietary data rights of participating stakeholders.
NACDS strongly supports the development of a nationwide PDMP solution that includes the previously mentioned principles; however, we are agnostic to the specific format of the solution. In other words, this solution could be supported and housed within a federal agency (e.g., ONC, ONDCP) or it could be built and delivered entirely outside government through commercial market forces. Depending on the solution that moves forward, it could build upon existing state PDMP data or pull data from other sources – we are open to the most reasonable solution that harmonizes existing gaps and inconsistencies.

We were interested upon learning that at today’s hearing the Subcommittee will be considering a discussion draft of “Medicaid Providers and Pharmacists Required to Note Experiences in Record Systems to Help In-need Patients (PARTNERSHIP) Act,” which would allow the Medicaid program in each state to integrate PDMP usage into pharmacists’ workflow. Although we have concerns with specific parts of the legislation, we are encouraged by the effort to work toward a nationwide PDMP solution that would modernize and strengthen existing programs and provide timely information in the workflow of health care providers. We welcome the opportunity to work with lawmakers to advance legislation that would include the concepts in alignment with the important principles for a nationwide PDMP solution outlined above. We look forward to working with key stakeholders to discuss the development and implementation of a nationwide PDMP.

7-Day Supply Limit for Initial Opioid Prescriptions Issued for Acute Pain

NACDS supports policies establishing a 7-day supply limit for initial opioid prescriptions written for acute pain. This policy aligns with the Guideline for Prescribing Opioids for Chronic Pain developed by the Centers for Disease Control and Prevention (CDC) and serves to reduce the incidence of misuse, abuse, and overdose of these drugs.12

---

A clinical evidence review performed by the CDC revealed that a greater amount of early opioid exposure is associated with a greater risk for long-term use and addiction.\(^\text{13}\) Notably, the average day supply per opioid prescription has increased in recent years, growing from 13.3 to 18.1 days per prescription between 2006 and 2016.\(^\text{14}\) Considering this trend and the risk of early exposure to higher amounts of opioids, it is imperative that lawmakers adopt policies to promote careful prescribing practices for prescription opioids.

So far, over 20 states have adopted laws or other policies limiting the maximum day supply that can be authorized on an initial opioid prescription for acute pain (with appropriate exemptions, such as patients with pain due to cancer, hospice, or other end-of-life care, etc.).

Chain pharmacy encourages Congress to enact legislation that is standardized across the nation to promote consistent patient care and implementation across the country.

Moreover, this legislation should provide liability protection for pharmacists to ensure that pharmacists do not have to second-guess a prescriber and determine whether a prescriber appropriately issued a prescription for a days supply that exceeds the 7-day limit.

**Pharmacy “Lock-In”**

NACDS shares the goals of policymakers to curb the incidence of fraud and abuse and are interested in the Subcommittee’s consideration in today’s hearing of the “Medicaid Pharmacy Home Act,” which would create a Medicaid “lock-in” program through federal law. We have seen such programs implemented by commercial payers, as well as Medicare and state Medicaid programs, and believe they can be beneficial in helping prescribers ensure that patients are not being overprescribed opioids. However, any potential Medicaid program aimed at “locking in” a beneficiary to a certain pharmacy or pharmacies must ensure that legitimate beneficiary access to needed medications is not impeded. Policies to reduce overutilization must maintain access to prescription medications by the beneficiaries who need them most.

\(^{13}\) Ibid.

While the use of limited pharmacies could lower the incidence of fraud and abuse, as well as provide the potential for better care coordination, a lock-in provision could raise barriers to care and cause patient harm. For example, a patient could suffer harm to their health if their “locked in” pharmacy is unable to obtain their medication. Also, patients often legitimately see multiple doctors representing different specialties in different locations. In addition, there are instances, due to location and/or services offered (e.g. compounded or specialty drugs) in which a single pharmacy may not meet all of the needs of a specific patient.

In order to protect legitimate patient access while combatting prescription drug abuse and diversion, NACDS suggests the following definition of a pharmacy be included in the legislation:

*In the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy.*

This definition is used in the recently adopted Medicare Drug Management Program for At-Risk Beneficiaries (as contained in the Comprehensive Addiction and Recovery Act of 2016 (CARA)). With respect to combatting abuse and diversion, pharmacies sharing real-time data will ensure that beneficiaries are only obtaining the necessary prescriptions while protecting beneficiary access and health without compromising the integrity of the management program.

Additionally, NACDS recommends revision to the pharmacy selection process. Currently, the language requires the State to provide a process to allow affected individuals to submit a request to use a particular pharmacy. However, the legislative language is silent on whether the State would be required to honor that request. To ensure adequate access, NACDS suggests adding language to the bill to “require the State to use beneficiary preferences unless such selection would contribute to prescription drug abuse or drug diversion by the beneficiary.” This language mirrors that used in Medicare Part D lock-in program.
Finally, the current language requires the State to provide notice to the patient before enrollment in the drug management program. NACDS strongly encourages the legislation be changed to require two notices before enrollment. Not only would this mirror requirements under the Medicare Part D program, but multiple notices are especially important for the Medicaid population. The Medicaid population is more transient and often patients tend to change primary addresses and location due to living condition or financial needs. Including requirements for two notices, like those required under the Medicare Part D program, would ensure that beneficiaries are adequately notified in the event of a primary address change as well as further ensure that identified individuals receive proper monitoring and care.

**Conclusion**

NACDS thanks the Subcommittee for consideration of our comments. We look forward to working with policymakers and stakeholders on these important issues.
April 11, 2018

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor, and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Greg Walden
Chairman
Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20510

The Honorable Frank Pallone
Ranking Member
Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20510

Dear Chairman Hatch, Ranking Member Wyden, Chairman Walden, and Ranking Member Pallone:

On behalf of the nation’s Medicaid Directors, we are writing to request your consideration of statutory modifications to the rules governing the disclosure of substance use disorder (SUD) patient history and information. Specifically, Medicaid Directors seek alignment of 42 CFR Part 2 rules with the privacy protections under the Health Insurance Portability and Accountability Act (HIPAA), and believe this alignment will support the care coordination and integration activities that are critical to addressing the ongoing opioid crisis.

The National Association of Medicaid Directors (NAMD) is a bipartisan, nonprofit, professional organization representing leaders of state Medicaid agencies across the country. Our members drive major innovations in health care while overseeing Medicaid, which provides a vital health care safety net for more than 72 million Americans. The Medicaid program is one of the primary payers of behavioral health services in the nation.

The Part 2 statute is outdated and does not reflect current SUD treatment best practices, clinical understanding of addiction, or contemporary healthcare operations. While the Substance Abuse
and Mental Health Services Administration (SAMHSA), the agency responsible for administering Part 2, has worked to modernize Part 2 regulations— and in doing so has acknowledged Medicaid auditing authority and the role of managed care entities in today’s healthcare landscape— we continue to view Part 2 as creating serious barriers to effective SUD treatment. These barriers ultimately derive from the statutory misalignment between Part 2 and HIPAA.

Part 2 statute and SAMHSA regulations create more stringent privacy protections for patient SUD data than for other sensitive health data protected by modern HIPAA rules. Specifically, Part 2 requires patient consent each time a new provider would need access to the patient’s SUD medical records, rather than HIPAA’s generalized consent.

The lack of alignment between Part 2 and HIPAA creates challenges across the healthcare system, from state Medicaid agencies to managed care plans and down to individual provider practices. SAMHSA’s most recent rulemaking earlier this year still explicitly prohibits disclosure of Part 2 data for purposes of diagnosing, treating, or referring patients to SUD treatment (including care coordination and case management) without patient consent. This prohibition inhibits the integration of SUD care into primary care and other care models, places unnecessary administrative costs on states, plans, and providers, and can result in patient harm or death due to lack of full access to relevant SUD data.

Additionally, evidence shows significant comorbidities for individuals with SUD. For example, in FY 2011, 51% of Medicaid beneficiaries with SUD also had a mental health condition, nearly 13% had asthma, and over 10% had diabetes. As this data predates the option for states to expand Medicaid to 138% of the federal poverty level, these figures are likely higher today, further emphasizing the need for integrating SUD services into the full continuum of physical and behavioral health care.

We recognize the serious consequences that stem from illegal and unauthorized disclosure of SUD data. NAMD supports the prohibition on using SUD data to initiate or substantiate criminal, civil, or administrative proceedings against individuals with SUD. Statutory changes should facilitate appropriate data sharing across integrated care teams to support effective treatment and continue to assure patients that they will not face adverse action for seeking treatment. We believe the HIPAA construct, which protects other sensitive health information, is an appropriate vehicle for achieving these goals.

Thank you for your consideration of these comments. Please do not hesitate to reach out to NAMD for additional information on these requests.

Sincerely,

Judy Mohr Peterson
Med-QUEST Division Administrator
State of Hawaii
President, NAMD

Kate McEvoy
State Medicaid Director
State of Connecticut
Vice President, NAMD
National Indian Health Board

Statement of the National Indian Health Board
to the United States House Committee on Energy and Commerce, Subcommittee on Health
Combating the Opioid Crisis:
Improving the Ability of Medicare and Medicaid to Provide Care For Patients
For the Record of the United States Congress
April 11, 2018

Introduction
The National Indian Health Board (NIHB) would first like to thank Chairman Burgess for holding the hearing, “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care For Patients” on April 11, 2018. NIHB is a 501(c)3, not for profit, national Tribal organization founded by the Tribes in 1972 to serve as the unified, national voice for American Indian and Alaska Native (AI/AN) health in the policy-making arena. Our Board of Directors is comprised of distinguished and highly respected Tribal leaders in AI/AN health. They are elected by the Tribes in each region to be the voice of all 573 Tribes at the national level.

Since 1972, NIHB has advised the U.S. Congress, Indian Health Service (IHS), and other federal agencies about health disparities and service issues experienced in Indian Country. As such, the current opioid epidemic represents one of the most pressing public health crises affecting Tribal communities. While this epidemic is affecting many communities throughout America, it has disproportionately impacted Tribes and has further strained the limited public health and healthcare resources available to Tribes. The federal government must take concrete action to ensure Indian Country has the tools it needs to address opioid abuse and heal Tribal communities. Medicare and Medicaid are vital components of the Indian health system and the unique needs of Indian Country should be taken seriously when considering legislation.

Trust Responsibility
The federal promise to provide Indian health services was made long ago. Since the earliest days of the Republic, all branches of the federal government have acknowledged the nation’s obligations to the Tribes and the special trust relationship between the United States and Tribes. The United States assumed this responsibility through a series of treaties with Tribes, exchanging compensation and benefits for Tribal land and peace. In 2010, as part of the Indian Health Care Improvement Act, Congress reaffirmed the duty of the federal government to Americans Indians and Alaska Natives (AI/ANs), declaring that “it is the policy of this Nation, in fulfillment of its special trust responsibilities and legal obligations to Indians — to ensure the highest possible health status for Indians and urban Indians and to provide all resources necessary to effect that policy.”

The Indian Health Service is the primary agency by which the federal government meets the trust responsibility. IHS provides services in a variety of ways: directly, through agency-operated programs

---

1 The Snyder Act of 1921 (25 U.S.C. 13) legislatively affirmed this trust responsibility.
2 25 U.S.C. 1602
and through Tribally-contracted and operated health programs; and indirectly through services purchased from private providers. IHS also provides limited funding for urban Indian health programs that serve AI/ANs living outside of reservations. Tribes may choose to receive services directly from IHS, run their own programs through contracting or compacting agreements, or they may combine these options based on their needs and preferences.

Today the Indian healthcare system includes 46 Indian hospitals (1/3 of which are Tribally operated) and nearly 630 Indian health centers, clinics, and health stations (80 percent of which are Tribally operated). When specialized services are not available at these sites, health services are purchased from public and private providers through the IHS-funded purchased/referred care (PRC) program. Additionally, 34 urban programs offer services ranging from community health to comprehensive primary care. To ensure accountability and provide greater access for Tribal input, IHS is divided into 12 geographic Service Areas, each serving the Tribes within the Area.

It is important to note that Congress has funded IHS at a level far below patient need since the agency’s creation in 1955. In FY 2017, national health spending was $9,207 per capita while IHS spending was only $3,332 per patient.

The Opioid Epidemic in Indian Country

The national opioid epidemic represents one of the great public health challenges of the modern era. The Centers for Disease Control and Prevention (CDC) noted over 64,000 drug overdose deaths in 2016 alone, largely driven by prescription and illicit opioids. Among AI/ANs, the rate of drug overdose deaths is twice that of the general population, according to the IHS. Deaths from prescription opioid overdoses increased four-fold from 1999 to 2013 among AI/ANs. The CDC reported that AI/ANs consistently had the highest drug overdose death rate by race every year from 2008-2015, and the highest percentage increase in drug overdose deaths from 1999-2015 at 519%.

Regional data trends further demonstrate the high burden of the opioid epidemic within Tribal communities. According to the State of Alaska Epidemiology Center, AI/ANs had the highest overdose death rate by race from 2009-2014 at 20.2 deaths per 100,000 population. In Minnesota, the Department of Human Services reported that the age-adjusted death rate due to drug poisoning is four times higher among AI/ANs compared to Whites. Further, despite representing roughly 1.1% of the population for the state, AI/ANs accounted for 15.8% of those who entered treatment for opioid use disorder. Similarly, the Washington State Department of Health reported that from 2011-2015, the opioid overdose death rate was highest among AI/ANs at a rate of 29 deaths per 100,000 compared to 12 deaths per 100,000 for Whites. These statistics illuminate the critical need for more comprehensive interventions in Tribal communities to improve prevention and treatment measures.

---

4 Mack KA, Jones CM, Ballesteros MF. Illicit Drug Use, Illicit Drug Use Disorders, and Drug Overdose Deaths in Metropolitan and Nonmetropolitan Areas — United States. MMWR Surveill Summ 2017;66(No. SS-19):1–12. DOI: http://dx.doi.org/10.15585/mmwr.ss6619a1

NIHB Statement to Health Subcommittee, Opioid Crisis: Medicare and Medicaid
Addressing the opioid epidemic is a nationwide priority; however, access to critical opioid prevention and treatment dollars are not reaching many of the Tribal communities that are in serious need of these funds. As sovereigns, Tribes are not systematically included within statewide public health initiatives such as the recent prevention and intervention efforts created through the new opioid crisis grants found in the 21st Century CURES Act.

Medicare and Medicaid’s Role in Tribal Health

The IHS by law is the payer of last resort for Tribal members receiving health care. If AI/AN members are enrolled in Medicare or Medicaid (or employer or private insurance) those are billed first for reimbursement of services.

In authorizing IHS to bill Medicaid, Congress also took steps to ensure that the Federal government did not shift responsibility for Indian health care to the States. Congress amended the SSA to provide for 100% Federal Medical Assistance Percentage (FMAP) for services received through an IHS or Tribal facility. This provision ensures that all Medicaid services provided to AI/ANs that are received through an IHS or Tribal facility are reimbursed to the States at a 100% match by the United States. It was an express recognition of the federal government’s treaty obligations for Indian health. The House Committee Report stated that since the United States already had an obligation to pay for health services to Indians as IHS beneficiaries, it was appropriate for the United States to pay the full cost of their care as Medicaid beneficiaries. Congress intended that Medicaid funding be supplemental to IHS funding, and not replace it. As a result, Congress enacted a provision of law that ensures that Congress must not take into account collections from Medicare, Medicaid (and later, CHIP) in determining IHS appropriations. Medicaid has proven to be a critically important resource for IHS and Tribal health systems. The funding it has provided has helped extend scarce IHS discretionary appropriations, including Purchased/Referred Care (PRC) funding. PRC funding is used to cover the cost of care by providers outside the IHS system when an IHS or Tribal facility cannot provide the service itself. Medicaid helps extend PRC funding, which otherwise routinely runs out before the end of the year.

Medicaid and Medicare’s Role in Tribal Responses to the Opioid Crisis

In Tribal communities, specialty care is often deferred or delayed due to lack of funds at the Indian Health Service. For example, the FY 2018 IHS Congressional Budget Justification noted that the FY 2016 budget denied an estimated $371.5 million for an estimated 80,000 in services. As a result of these denials, patients are often forced to utilize prescription opioids instead of getting needed surgeries. This leads to increased dependency on opioids and little incentives to change the problem. However, if a patient is Medicare or Medicaid eligible, they have more options for obtaining needed surgery.

Congress should ensure that Medicare and Medicaid patients are better tracked to limit “pharmacy shopping.” Patients are currently able to fill their opioid prescriptions at any pharmacy, and can travel from one to another in order to obtain prescription opioids, with some patients even traveling across state
lines if they live in a border town. When patients travel across state lines it makes it harder to track them through the prescription drug monitoring program (PDMP) system, given that most, if not all, states lack data sharing agreements or ban data sharing altogether. Additionally, CMS should establish additional training for all providers—including those working in the Indian health system—to provide guidelines for prescribing non-cancer pain management and treatment. Those trainings should be specific to cultural needs in Tribal communities and be grounded in the role of traditional medicine. In Oregon, for example, the state banned prescribing opioids for spinal injuries and other forms of back pain. National standards—with appropriate engagement from stakeholders, including Tribes—should be created and disseminated to reduce risks provided by prescription pain management.

In 2017, the Office of Inspector General (OIG) within the United States Department of Health and Human Services (HHS) released a report stating that roughly 33% of Medicare Part D beneficiaries received an opioid prescription in 2016, amounting to roughly $4.1 billion in spending. Moreover, the OIG reported that roughly half a million Part D beneficiaries received an average dosage of greater than 120mg a day for at least 3 months, despite the fact that the 2016 CDC guidelines for opioid prescribing for chronic pain recommended no more than 90mg a day. To put that in context, 120mg is the equivalent of 16 tablets of 5mg Percocet per day.

CMS updated a Medicare Part D Opioid Drug Mapping Tool in late 2017 that allows the public to investigate provider opioid prescribing practices across the country. The data includes the provider’s name, zip code, state, opioid prescription count, and prescribing rate. Although this is an important resource, it does not include information about where and when the prescriptions were filled, how many (if any) refills were provided, the dosage, and demographics of the patient. In addition, the information does not include the provider’s place of employment, making it difficult to determine if there are any notable differences in prescribing rates between Tribal and IHS providers and other providers. In addition, it was not clear how CMS was intending to utilize the tool—whether it be to launch investigations into unscrupulous prescribing practices, or to identify providers who required additional training.

It is noteworthy to point out that physicians are required under the Drug Addiction Treatment Act (DATA) of 2000 to complete trainings and obtain a waiver to administer MAT drugs like buprenorphine, while no such trainings are mandated as a precondition for prescribing opioids which can lead to opioid use disorder (OUD).

The NIHB recommends that CMS work with the Drug Enforcement Agency (DEA) – which has jurisdiction over DATA 2000 waivers – and the Substance Abuse and Mental Health Services Administration (SAMHSA) – which has been largely responsible for administering MAT trainings and grants – to establish and require routine prescription opioid and substance use trainings for all Medicare and Medicaid billing providers as a precondition for renewing their license and retaining the authority to prescribe opioids.
The NlHB also recommends that the CMS Part D Opioid Drug Mapping Tool collect employment information so that the IHS and Tribes are able to track if providers on their payroll are engaging in suspicious or risky prescribing practices.

**Improving Medicare and Medicaid’s Data Sharing in Tribal Health Settings**

Data is the backbone of public health. However, for many Tribal health departments and epidemiology centers, access to timely, accurate and complete datasets are far from the norm. The 2010 permanent reauthorization of the Indian Health Care Improvement Act (IHCIA) provided states with a 100% Federal Medical Assistance Percentage (FMAP) for Medicaid services rendered to AI/ANs, and solidified a direct relationship between the Centers for Medicare and Medicaid Services (CMS) and the IHS that was further ensured by amendments to the Social Security Act.

Compounding the issue is the high probability of a Tribal member being racially misclassified on their health records. As previously cited, due to racial misclassification on death certificate data, the actual opioid death count among AI/ANs may be underestimated by as much as 35%. Without timely and accurate access to patient health data, it is close to impossible for a Tribe or Tribal epidemiology center to maintain accurate records of vital statistics, to quantify disparities in health outcomes between AI/ANs and other populations, or to ultimately make assessments of need.

Tribal health systems need improved access to national health surveillance systems that have been disaggregated by race and ethnicity. This is particularly important given that existing data collection systems such as Prescription Drug Monitoring Programs (PDMPs) do not collect patient race or ethnicity information or the patient’s medical condition. In addition, only the state of Alaska has explicitly authorized IHS prescribers and dispensers to access PDMP data. Although the IHS has taken steps to both train and require their providers to utilize the PDMP system, it is a critical issue that only one state has decreed special access for IHS providers despite their being federal-recognized Tribes in 36 states across the country.

The current PDMP system is state-based, meaning that each state has outlined its own regulations around surveillance, data reporting and data sharing. For instance, only a handful of states have authorized data sharing across state lines, while most states either restrict data sharing or have simply not engaged other states in data sharing agreements. In addition, states have different reporting guidelines meaning that while in one state providers are required to update the system with any new prescriptions within 24 hours, other states allow providers to take as long as a month to update the system. Establishing a system that streamlines and standardizes PDMPs would improve the overall effectiveness of the program by eliminating inconsistencies in how data is collected, analyzed and accessed.

The NlHB recommends that Congress find a solution to the current PDMP model that prioritizes efficiency, accountability and timeliness in data reporting and access, while also improving surveillance of AI/AN health conditions, including opioid overdoses and dependence rates. This will help ensure that Tribes have the necessary data to make decisions and identify needs.

**Support Needed for Tribal Solutions**

NIHB Statement to Health Subcommittee, Opioid Crisis: Medicare and Medicaid
Behavioral health initiatives in Tribal communities have the most potential for success when the program integrates traditional healing practices with Western models of care such as MAT and mental health counseling. For instance, the Port Gamble S'Klallam Tribe of Washington developed the Tribal Healing Opioid Response (THOR) initiative. The THOR program integrates evidence-based best practices such as expansion of access to MAT and naloxone with culturally-appropriate wellness activities such as powwows, youth and elder social events, and traditional games and community activities.

The program is designed to meet three overarching goals: to prevent opioid misuse and abuse; expand access to opioid use disorder treatment; and prevent deaths from overdose. The program utilizes an integrated approach that involves every sector of government and the community including the Tribal council, police force, health services divisions, youth workers, wellness staff, and community advocates and leaders. By employing an integrated approach, the THOR project is able to foster stronger community support and buy-in, diversify its stakeholders, and reach a wider net of at-risk populations.

The program's broad reach and holistic approach have gained the support of powerful stakeholders, which will help ensure the long-term effectiveness and uptake of the program. Some immediate outcomes include established partnerships with the Washington State Department of Health and the Olympic Community of Health, which brings together county and Tribal health officials to improve interagency coordination of addiction and overdose response efforts. In addition, the Port Gamble S'Klallam Tribal Council recently approved the adoption of the Washington State Good Samaritan Law, which provides civil and criminal protection for individuals who provide assistance to anyone experiencing an overdose.

Another Tribally developed program with great promise is the Chickasaw Nation of Oklahoma “Define Your Direction” campaign which encourages youth to make healthy choices and be positive role models when it comes to resisting prescription drug misuse and underage drinking in their communities. The program materials include videos, online and social media communications, and information on local behavioral health resources. The program has received support and funding from SAMHSA and the Southern Plains Tribal Health Board. The program has focused on youth not only to bolster primary prevention activities, but also because Chickasaw youth have been particularly impacted by the opioid crisis. For instance, American Indians living on Chickasaw Nation reported a statistically significant higher rate of prescription opioid misuse within the past 30 days compared to non-Natives living in Chickasaw, while 54% of youth who stated that they used prescription opioids in the past 30 days to get high shared that they obtained those drugs from friends or family.

Although these programs highlight the positive work being done in Tribal communities to address the opioid epidemic, many more resources are needed to develop a compendium of Tribal best practices to address behavioral health issues such as high rates of OUDs and substance use disorder (SUD). Nevertheless, examples of effective models that have been developed to treat other health conditions can and should be adapted to address behavioral health priorities. One nationwide example includes the Special Diabetes Program for Indians (SDPI). SDPI has been responsible for A1C levels among AI/ANs nationwide going down by an entire percentage point. In addition, rates of End Stage Renal Disease — one of the biggest contributors to Medicare costs — have decreased by 54%. Moreover, SDPI demonstrates a real life example of Western medicine working in tandem with traditional healing practices to create
major, positive gains in treating and preventing disease in Tribal communities. Medicare and Medicaid programs should embrace models like this for behavioral health.

NIHB also supports the expansion -- and commensurate Medicaid and Medicare reimbursement -- of the Community Health Aide Program (CHAP) to Tribes outside of Alaska. CHAP is an excellent example of reform that was developed in response to a need for providers in Alaska. CHAP, a Tribally created and driven model, was developed in response to unique Tribal communities' needs. CHAP trains local residents to provide basic health care, assuring that health services are available in the local community from culturally competent providers who speak the Native language. For more than 50 years, CHAP has proven as an effective method for diminishing the health disparities of Alaska Natives. Community-based, culturally-informed providers are desperately needed in the Indian health system. Behavioral Health aides (which are part of the CHAP program in Alaska) are a potential solution to fill this need in Indian Country. However, in order for them to be effective and provide quality care, they must be trained, not just on treatment, but also prevention, aftercare, and post-vention. As IHS works to expand the CHAP in the coming year, it is critical that both Medicare and Medicaid allow reimbursements for these types of providers.

The NIHB recommends that the Subcommittee investigate Tribal best practices to learn more about the high success rates of these programs, and encourages the Subcommittee to communicate directly with these and other successful Tribally-based initiatives in order to improve broad awareness, support and secure future funding. Programs like Medicare and Medicaid provide vital support to the Indian health system, and Congress should ensure that the Tribal community programs able to bill for third party reimbursement can incorporate traditional healing practices. Tribes have demonstrated their ability to counter OUD and SUD when given the resources and flexibility they need to ensure these programs are effective.

Conclusion

NIHB and the Tribes stand ready to work with the House Subcommittee on Health to develop new or improve existing regulations, programs, and funding streams that will assist Tribal Nations in addressing the opioid epidemic. We thank Chairman Burgess for this opportunity to provide our comments and recommendations for how Medicare and Medicaid can better work to reduce the scourge of opioid related deaths and dependence rates and look forward to further engagement with the Subcommittee on curbing the opioid epidemic within Tribal communities.

For any follow up questions, please contact Stacy A. Bohlen, NIHB Chief Executive Officer, at sbohlen@nihb.org or 202-507-4070.
April 11, 2018

The Honorable Greg Walden
Chair
Committee on Energy & Commerce
US House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy & Commerce
US House of Representatives
Washington, DC 20515

RE: Overdose Prevention and Safety Act (HR 3545)

Dear Chair Walden and Ranking Member Pallone:

On behalf of OCHIN, Inc., the largest federally-funded Health Center Controlled Network (HCCN) in the nation headquartered in Portland, Oregon, I am writing this letter to convey our strong support of HR 3545 known as the “Overdose Prevention and Safety Act.” OCHIN is a collaborative of health care organizations that are working together to provide integrated care for our nation’s most vulnerable patients. We provide technology and telehealth, training, research, analytics, consultation, advocacy, and other wrap-around support services to nearly 800 clinic locations nationwide.

OCHIN believes integrated care is a priority for not only our network of federally-qualified health centers, public health systems and other safety net clinics, but it is also a key component of ensuring cost-effective, safe, and truly holistic care for all patients served throughout the country. As you are aware, 42 CFR Part 2 (Confidentiality of Substance Use Disorder Patient Records) has served a vital role in supporting individuals as they engage in recovery from drugs and alcohol; however, it was constructed in an era that predated modern technology. The authors and supporters could not even begin to conceive of how patient care would evolve in the following decades. Today, we know that integrated primary, behavioral, dental and other health care is essential for delivering safe, effective, responsible, and affordable care. It is time that these outdated rules are updated to reflect the technology and processes that are foundational to coordinating treatment and other services, including the exchange of records via health information technology. Unfortunately, 42 CFR Part 2 continues to serve as a barrier to coordinated and safe care. Physicians, counselors, therapists, pharmacists, and others need to be able to easily share information about their shared patients in a seamless manner.

OCHIN is extremely encouraged by the bi-partisan support that the Energy and Commerce Committee has already received in its promotion of alternative payment models and other key activities. Aligning 42 CFR Part 2 with the federal HIPAA andHITECH rules is a next logical step in achieving streamlined, integrated care that is safe and effective, while supporting value-based pay. As you are evaluating your support for addictions treatment, we urge you to include the provisions that are in HR 3545 in any bill that is produced by the Committee.

OCHIN strongly supports the adoption of HR 3545 and aligning and streamlining care for our members. Thank you for your leadership on this very important issue.

Respectfully,

Jennifer Stoll
VP, Government Relations and Public Affairs, OCHIN
March 21, 2018

The Honorable Markwayne Mullin
United States House of Representatives
1113 Rayburn House Office Building
Washington, DC 20515

The Honorable Earl Blumenauer
United States House of Representatives
1111 Longworth House Office Building
Washington, DC 20515

Dear Representatives Mullin and Blumenauer:

The undersigned members of the Partnership to Amend 42 CFR Part 2 (Partnership) and additional stakeholder organizations applaud your leadership on the issue of substance use disorder privacy records and strongly support your bill, the Overdose Prevention and Patient Safety (OPPS) Act, H.R. 3545, to align 42 CFR Part 2 (Part 2) with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of health care treatment, payment, and operations (TPO). We appreciate the provision in your bill that strengthens protections against the use of substance use disorder records in criminal proceedings.

The Partnership is a coalition of over 40 health care stakeholder organizations committed to aligning Part 2 with HIPAA to allow appropriate access to patient information that is essential for providing whole-person care. The federal regulations governing the confidentiality of drug and alcohol treatment and prevention records, Part 2, set requirements limiting the use and disclosure of patients’ substance use records from certain substance use treatment programs. Obtaining multiple consents from the patient is challenging and creates barriers to whole-person, integrated approaches to care, which are part of our current health care framework. Part 2 regulations may lead to a doctor treating a patient and writing prescriptions for opioid pain medication for that individual without knowing the person has a substance use disorder. Separation of a patient’s addiction record from the rest of that person’s medical record creates several problems and hinders patients from receiving safe, effective, high quality substance use treatment and coordinated care.

We are pleased that your bill would align Part 2 with HIPAA’s consent requirements for the purposes of TPO, which will allow for the appropriate sharing of substance use disorder records to ensure persons with opioid use disorder and other substance use disorders receive the integrated care they need. Additionally, as we do not want patients with substance use disorders to be made vulnerable as a result of seeking treatment for addiction, this legislation strengthens protections of their records.

As you know, the Substance Abuse and Mental Health Services Administration (SAMHSA) released final rules in 2017 and 2018 which take some steps to modernize Part 2, but do not go far enough. Legislative action is also necessary in order to modify Part 2 and bring substance use records into the 21st Century. We thank you for leading that effort and look forward to working with you to advance this important bipartisan legislation.

Sincerely,

Academy of Managed Care Pharmacy
American Association on Health and Disability
American Hospital Association
American Psychiatric Association
American Society of Addiction Medicine
America's Essential Hospitals
America's Health Insurance Plans
AMGA
Association for Ambulatory Behavioral Healthcare
Association for Behavioral Health and Wellness
Association for Community Affiliated Plans
Blue Cross Blue Shield Association
The Catholic Health Association of the United States
Employee Assistance Professionals Association
Global Alliance for Behavioral Health and Social Justice
Hazelden Betty Ford Foundation
Health IT Now
Healthcare Leadership Council/Confidentiality Coalition
InfoMC
The Joint Commission
The Kennedy Forum
Mental Health America
National Alliance on Mental Illness
National Association of Psychiatric Health Systems
National Association of State Mental Health Program Directors
Netsmart
Otsuka America Pharmaceutical, Inc.
Premier Healthcare Alliance
Smith's Medical

Additional Stakeholder Organizations
Adventist Health
Adventist Health System
Aetna
AnMed Health
Anthem
Association of American Medical Colleges
Atlanticare
Atrius Health
Aurora Health
Avera Health
Banner Health
Baptist Healthcare System
Beacon Health Options
East Alabama Medical Center
First Health of the Carolinas
Greater New York Hospital Association
Henry Ford Health System
Johns Hopkins Health System
Lehigh Valley Health Network
LifeBridge Health
Marshfield Clinic
Mercy Health
Methodist Health System
Morehouse School of Medicine
Mosaic Life Care Medical Center
Mountain States Health Alliance
National Association of ACOs
New Directions Behavioral Health
PerformCare
SSM Health
St. Joseph's/Candler
Summa Health
Texas Health Resources
Trinity Health
University of Tennessee Medical Center
Pharmaceutical Care Management Association

Statement for the Record

Prepared for the

UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH

"Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients"

April 11, 2018
Introduction

PCMA appreciates this opportunity to submit a statement for the record for the hearing, "Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients." PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through self-insured employers, health insurers, labor unions, Medicare, Medicaid, SCHIP, and the Federal Employees Health Benefits Program (FEHBP). America's PBMs process the vast majority of the nation's 4.5 billion annual prescriptions.

We appreciate the Health Subcommittee's and full Energy and Commerce Committee's ongoing efforts to address the nation's opioid crisis. Our industry especially appreciates the Committee's efforts to limit Medicare beneficiaries at risk of abusing opioids to a specific pharmacy or prescriber. The bills under consideration today build on the Committee's prior work.

PBMs Are a Key Part of Mitigating the Opioid Crisis

PBMs can be an important partner for curbing the nation's opioid crisis. Given their role administering prescription drug benefits in real time and through the software systems they use to assess eligibility, determine cost sharing, and adjudicate claims, PBMs can see whether patients are using multiple prescribers and pharmacies, are getting a morphine-equivalent dosage well beyond that recommended by the Centers for Disease Control and Prevention (CDC), and are getting a longer days' supply than necessary.

Increasingly, as health information networks improve and physicians move to e-prescribing controlled substances, PBMs and prescribers will have almost complete information, in real time, on how, where, and when prescriptions for controlled substances are obtained and dispensed. Where the law will allow it, PBMs also will be able to use coverage determinations to address opioid prescriptions exceeding the CDC-recommended days' supply or morphine-equivalent dosage. PBMs already can lock in patients at risk to an appropriate pharmacy or pharmacy chain for their controlled substances in most state Medicaid programs and the commercial insurance market, and because of congressional action in CARA, next year will start a similar program in Medicare Part D.
There are significant additional steps policymakers can take to help private sector efforts to reduce opioid abuse.

Common-Sense Policy Solutions to Curb the Opioid Crisis

While the factors driving America’s opioid crisis are complex and do not lend themselves to easy solutions, targeted policy changes can help curb prescription opioid abuse and diversion. Below we suggest a number of policy measures to curb the crisis.

Mandatory Electronic Prescribing for Controlled Substances (EPCS): We believe that using federal program payment policy to require electronic prescribing (e-prescribing) for controlled substances could help reduce over-prescribing. In addition, e-prescribing has been shown to dramatically reduce medication errors and limit fraud, and after the Drug Enforcement Administration allowed e-prescribing for controlled substances in 2010, states followed. Currently all states permit EPCS, and as of spring 2018, seven states have passed laws requiring its use, and another 14 states have introduced bills to make EPCS mandatory.

We recommend that the Subcommittee use federal health program payments to require e-prescribing for controlled substances in Medicare and Medicaid. The PBM industry stands ready to help facilitate such a policy change. We believe H.R. 3528, the Every Prescription Conveyed Securely Act, would accomplish these goals and urge the Energy and Commerce Committee to pass this bill or one very similar to it. We would like to thank Congressman Markwayne Mullin for his leadership on this important legislation, which is also cosponsored by Committee Members Joe Kennedy, Paul Tonko, Billy Long, Chris Collins, Bill Flores, and Diana DeGette.

Evidence shows EPCS produces measureable savings and decreases opioid use. One health system in Pennsylvania found that after implementing EPCS, it reduced opioid prescriptions by approximately 50 percent (from 60,000/month to 31,000/month). The switch also resulted in significant cost savings. Across the health system, savings averaged $850,000 per month, which has thus far added up to ongoing cost savings of $5.1M from EPCS tools. Similarly, one New York hospital examined its emergency department prescription volume for opioids from before and after New York State adopted an EPCS mandate. The hospital reported a decrease of 53 percent of prescribed opiates, seeing decreases in all 15 common emergency diagnoses studied.
Further, e-prescribing platforms typically provide physicians a patient’s medication history, which informs physicians of prescriptions that other prescribers have written and pharmacies have dispensed, even ones for which patients have paid cash. This can be especially important for controlled substances, where patients may engage in doctor shopping to find one or more doctors to write a prescription for a dangerously addictive drug.

According to a recent study by Visante and Point of Care Partners, if the use of EPCS with access to comprehensive medication history were required nationally and its use by prescribers and pharmacies rose to optimal levels, the United States would realize annual savings of up to $53 billion, based on estimated annual savings of:

- $18 billion to $37 billion in reduced costs associated with fatalities related to opioid abuse;
- $7 billion to $14 billion saved due to decreased health care costs, decreased treatment costs, workplace productivity gains, and reduced criminal justice costs; and
- $1.6 billion saved from greater efficiencies in physician offices and pharmacies, and increased convenience for consumers given they do not have to spend time at the pharmacy waiting for their prescriptions to be filled.

If the use of EPCS with access to comprehensive medication history were required for Medicare Part D prescriptions and its use by prescribers and pharmacies rose to optimal levels, the federal government would realize savings of more than $2 billion annually, based on estimated annual savings related directly to Medicare beneficiaries of:

- $2 to $4 billion saved due to decreased health care costs, decreased treatment costs, workplace productivity gains, and reduced criminal justice costs; and
- $0.5 billion saved from greater efficiencies in physician offices and pharmacies, and increased convenience for consumers.

Improve and Integrate State Prescription Drug Monitoring Program (PDMP) and Require Prescriber Check: As described above, PDMPs can be an important tool to help identify and prevent prescription drug abuse. A key problem keeping PDMPs from operating optimally is that state PDMPs vary as to who may use a PDMP or receive its data. States also vary with respect to the agencies operating PDMPs and some fund their PDMPs adequately while others devote few resources. While there are efforts to
make PDMPs interoperable across state lines, at present many are not. Some state PDMPs have up-to-date data, while in others the data lags by months. The differences in data access, material support, and administration can make it difficult to make the best and timely use of PDMP data.

The Subcommittee could use federal health program payment policy to encourage PDMP data be updated in a timely manner, be interoperable across state lines, and easily accessible to prescribers and pharmacies. Requiring the use of, and integrating EPCS with, PDMPs may be particularly helpful in this regard. Additionally, prescribers should be required to check state PDMP databases when prescribing opioids, at least until EPCS is widely adopted and supplies similar information.

Suspension of Claims in Part D Where There Is a Credible Allegation of Fraud or Misuse: In Medicare Parts A and B, Medicare Administrative Contractors may suspend payment of claims upon a credible allegation of fraud. There is no similar policy for Medicare Part D. Part D plans may have evidence of fraud or diversion, but at present, they can do little more than refer the concern to a MEDIC, which may or may not act on the suspected fraud. To close this loophole, Part D plan sponsors should be allowed to suspend payment of suspect claims where there is a credible allegation of fraud. When a Part D plan sponsor suspects fraud with respect to a particular claim, the plan should have the latitude not to pay the pharmacy until the claim has been investigated further.

A recent Department of Health and Human Services Office of the Inspector General (OIG) report found that one in three Medicare Part D beneficiaries received a prescription opioid in 2016, and 400 prescribers had questionable opioid prescribing patterns for beneficiaries at serious risk of overdose—patterns far outside the norm, which the OIG says warrant further scrutiny. The same report also found over 22,000 Part D beneficiaries who appeared to be doctor shopping (i.e. they received high amounts of opioids and had multiple prescribers and pharmacies). Allowing Part D plan sponsors to suspend payment pending investigation would limit fraudulent transactions and could discourage those who seek to commit fraud from filing fraudulent claims in the first place.

In the specific case of the Part D stand-alone plans, the Bipartisan Budget Act of 2018 (BBA) allows them access to their enrollees' Part A and Part B Medicare data as of 2020. If the implementation of this provision could be accelerated to occur in 2019, it could allow Part D plan sponsors to better detect potential opioid fraud and misuse sooner. Additionally, policymakers should make it clear that the use of Part A and Part B
data to detect and ameliorate opioid fraud and misuse should not be interpreted as making “coverage determinations” as otherwise restricted in the BBA.

**Reconsider Limits on Use of Medicare Parts A and B Data by Medicare Part D Plans:** In the recent two-year budget deal, Congress included language that made Medicare Part A and Part B data available to Part D plans, but forbade Part D plans from using the data in any way to inform coverage decisions. As a result, plans will be unable to use data gleaned from a beneficiary’s inpatient and outpatient record to help guide patient-specific decisions on step therapy or prior authorization. Indeed, given the constraints, it is uncertain what the utility of the data would be and many Part D plans likely will not request the information. We recommend that the Subcommittee reconsider the new statutory limit on how Medicare Parts A and B data may be used by Part D plans.

**Electronic Prior Authorization:** PCMA supports innovations like electronic prior authorization that reduce physicians’ administrative burden and supports the use of the National Council for Prescription Drug Programs standards for facilitating it. We believe the Subcommittee should consider policies such as those in H.R. 4841, the Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018. We believe standardizing the electronic prior authorization process will make it a more effective tool for providers and plans and increase safety for patients.

**Refrain from Requiring Abuse Deterrent Formulations (ADFs) for Opioids:** ADFs for opioids may be one small part of more comprehensive efforts to stanch abuse of opioids, but when taken orally as intended, ADFs are just as easily abused as any other opioid. Thus, and as evidenced by the continued deepening of the crisis despite wide ADF availability, ADFs should not be seen as a magic bullet to stop opioid abuse. Further, any policy disallowing generic substitution of existing non-ADF generics in favor of using these alternative, much more expensive formulations will dramatically raise costs but do little to reduce opioid abuse. PCMA welcomed Food and Drug Administration (FDA) Commissioner Gottlieb’s recent pronouncement that FDA will be “taking a flexible, adaptive approach to the evaluation and labeling of ADF opioids.”

Public policy that promotes ADF-only opioids assumes that all patients who use opioids are drug abusers, and, moreover, ignores research showing that a large percentage of those abusing opioids ingest the drug. While technological innovations such as ADF have been developed to prevent opioid medications such as OxyContin from being crushed, dissolved, chewed, or cut, this does not prevent abuse and potential overdose.
because an individual can still ingest opioids as intended and in increasing amounts, whether they are ADF opioids or non-ADF opioids.

The Institute for Clinical and Economic Review (ICER) recently released a report examining the evidence on abuse-deterrent opioids. ICER rated the net health benefits of the ADF formulation of OxyContin and found no compelling evidence it was better than non-abuse-deterrent opioids, for producing lower rates of opioid abuse. Despite the fact that the evidence for abuse reduction isn’t compelling, the pharmaceutical industry persists in advocating for their mandatory use because they are far more expensive than generic opioids, and therefore more profitable for the drugmakers.

**Align Substance Abuse Treatment Privacy Laws with HIPAA to Encourage Better Care Coordination:** To help facilitate care coordination for those suffering from substance abuse, we encourage the Subcommittee to harmonize substance abuse records privacy policies with the Health Insurance Portability and Accountability Act (HIPAA) privacy rule. Under current substance abuse treatment privacy law at 42 CFR Part 2, addiction treatment providers must obtain individual, written consent from patients in order to share any information with non-addiction clinicians — the only exception being for “true emergencies.” The HIPAA privacy rule, by contrast, allows for health care providers and insurers to disclose information for treatment, payment, and health care operations, without further patient consent and subject to a minimum information necessary standard, so long as patients are given a notice explaining how their information will be used and disclosed. Obtaining multiple consents from a patient, as required under 42 CFR Part 2, is challenging and creates barriers to integrated approaches to care that produce the best outcomes for patients. The separate and different treatment in the law of substance-abuse-disorder patient history creates virtual care silos, and hinders good medical care. It also perpetuates the unnecessary division between physical and behavioral health and may serve to perpetuate stigma in the contemporary era of electronic health records integrated health care, and HIPAA privacy protections.

**Conclusion**

We thank the Subcommittee for this opportunity to share our views on how common-sense policy proposals can help curb America’s opioid crisis. PCMA stands ready to work with the Subcommittee, the full Committee, and all Members of Congress to address the overuse of opioids.
VerDate Nov 24 2008 10:18 Oct 18, 2018 Jkt 037690 PO 00000 Frm 00316 Fmt 6601 Sfmt 6601 I:\MY DOCS\HEARINGS 115\HEARINGS\115-116 CHRIS

6 Ibid.
8 Ibid.
12 Ibid.
STATEMENT OF PROPERTY CASUALTY INSURERS ASSOCIATION OF AMERICA

HOUSE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH

HEARING ON

Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients

April 11, 2018

PCI promotes and protects the viability of a competitive private insurance market for the benefit of consumers and insurers. PCI is composed of approximately 1,000 member companies and 350 insurance groups, representing the broadest cross section of home, auto, and business insurers of any national trade association. PCI members represent all sizes, structures, and regions, which protect families, communities, and businesses in the U.S. and across the globe. PCI members write $220 billion in annual premium, which is 37 percent of the nation's property casualty insurance marketplace.

We appreciate the Subcommittee on Health considering the impact of the opioid crisis on Medicare and Medicaid. The abuse of prescription painkillers is a serious public health and safety issue and is of great concern to our members. The United States is suffering from an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers. The CDC estimates that over 115 people die each day due to an opioid overdose.

From a workers compensation perspective, there is significant evidence that long-term opioid use results in longer disability, higher costs, and higher medical expenses. Most importantly, long-term opioid use will significantly hinder an injured worker's chance to return to work. The primary goal of an individual state workers compensation system is to provide injured workers the best care available, so they can return to work as soon as they are able and continue to be productive members of our society.

We appreciate the Centers for Medicare and Medicaid Services' (CMS) interest in discouraging the overuse of opioids and respectfully suggest that recognizing existing state-based workers compensation programs, which are already improving outcomes for injured workers, be considered in the calculation of Workers Compensation Medicare Set Asides (MSA). A significant number of Medicare beneficiaries began opioid treatment because of injuries or illnesses that arose during employment. These individuals who are receiving dosages as a part of a treatment plan approved under the workers compensation laws/plans of their respective states should not risk having such plans altered simply because they become Medicare beneficiaries.
PCI has aggressively worked at the state level to advocate for many solutions being recommended to address opioid overuse. Many state workers compensation systems have had success in addressing issues related to opioid use. While emergency room visits for opioid overdoses continue to increase nationally, long term opioid use by injured workers has fallen, in many states, over the last three years.

Texas is one of several states with effective workers compensation measures that have reduced opioid based prescription and reduced the number of individuals who have become addicted to these drugs. Initiatives such as evidence-based treatment guidelines, the closed formulary and system monitoring have proven to reduce opioid overuse among injured employees.

Following 2005 workers' compensation legislative reforms, Texas adopted a closed formulary that took effect for new workers' compensation claims with dates of injury on or after September 1, 2011 and for older (legacy) claims on September 1, 2013. The closed pharmacy formulary includes all FDA-approved drugs, except investigational and experimental drugs. The formulary also excludes drugs listed as “N” drugs (or “not recommended” drugs). Prescriptions that are excluded from the formulary require preauthorization from the insurance carrier before they may be dispensed to an injured employee. As a result:

- the formulary significantly reduced the number of injured employees receiving N drugs and reduced total pharmacy costs for the system by 15 percent in the first year;
- the frequency of all opioid prescriptions was reduced by 11 percent; and
- the frequency of “N” drug opioids was reduced by 81 percent between 2011 and 2012.

According to a recent study conducted by the Texas Department of Insurance’s Workers Compensation Research and Evaluation Group (REG), the number of claims receiving N-drug opioids with 90+ MMEs/day decreased from almost 15,000 in 2009 to less than 500 in 2015, while the number of claims receiving non-“N” drug opioids with 90+ MMEs/day decreased from approximately 8,800 in 2009 to less than 5,000 in 2015. According to the U.S. Centers for Disease Control and Prevention, patients receiving more than 90+ Morphine Milligram Equivalents (MMEs) per day have the highest risk of potential overdose.

Kentucky has also seen a significant impact on opioid use in workers compensation after the implementation of reforms in 2012. Kentucky’s reforms regulate pain clinics and require doctors and pharmacists to check the prescription monitoring data base (PDMP) and set limits on the dispensing of certain controlled substances. In 2013 the percentage of injured workers with pain medication who received opioid prescriptions fell to 44%, down from 54%, pre-reform. The number of prescriptions resulting from nonsurgical injuries decreased to 35%, down from 48% and more non-opioid pain medication was prescribed. This ultimately resulted in a smaller number of injured employees, on pain medication, receiving opioids on a long-term basis. The dosage given to injured workers who received opioid medication was decreased by 15%.

Several other states, including New York, Tennessee, Michigan, and Minnesota are also seeing the impact of state workers compensation systems focusing on this issue.

We respectfully request that as the Subcommittee continues to address the opioid crisis and ensures that CMS has the tools and processes in place to combat opioid misuse, that any legislation includes measures to assure consistency in the treatment of individuals whose treatment plans and drug formularies were developed under the applicable state-based workers compensation law.

Thank you for the opportunity to provide these comments.
April 10, 2018

The Honorable Greg Walden
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
House Committee on Energy & Commerce
2322A Rayburn House Office Building
Washington, DC 20515

The Honorable Michael Burgess
Subcommittee on Health
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Gene Green
Subcommittee on Health
House Committee on Energy & Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden, Ranking Member Pallone, Chairman Burgess and Ranking Member Green:

Thank you for your ongoing efforts to fight the opioid crisis. Addiction became personal for me and my family when I lost my son Brian to the disease on October 20, 2011. In the months that followed, it haunted me knowing how many families were being shattered every day by this disease. Shortly thereafter, I founded Shatterproof, the first national nonprofit organization dedicated to attacking addiction from all perspectives and sparing other families from the devastation my family has suffered.

Unlike most other chronic medical illnesses, substance use disorders (SUDs) have always carried a negative connotation. Years of misconstruing addiction heavily fueled our country’s public health crisis and have left the quality of treatment SUDs decades behind other chronic illnesses.

As a result, the epidemic continues to worsen according to recent data from the Centers for Disease Control (CDC), with an estimated 30 percent increase for emergency department visits due to suspected opioid overdoses from July 2016 through September 2017. In 2016, opioid overdoses took the lives of over 42,000 people.

While Congress has acted on the crisis with the Comprehensive Addiction and Recovery Act (CARA) and 21st Century Cures Act, and most recently provided nearly $4 billion in funding through the Fiscal Year 2018 Omnibus, there is more that can and should be done. Today, we respectfully submit the following recommendations and endorsements of legislation currently under consideration by the Committee, many of which would not require additional or new funding:

Prevention and Intervention

Provider Training Requirements. H.R. 2063, the Opioid PACE Act introduced by Rep. Brad Schneider (D-IL-10), would help to improve provider training on SUD issues by requiring training as a condition of obtaining and renewing a controlled substance registration with the Drug Enforcement Administration (DEA). It is critical that those who prescribe opioids have the proper training to do so, and therefore Shatterproof also strongly recommends the following additions to the bill:
1) Include language to ensure that the Department of Health Human Services (HHS) may only establish or support training modules that adhere to the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain.

2) Add a requirement that any provider obtaining or renewing a DEA registration number also be required to complete the Drug Addiction Treatment Act (DATA) 2000 waiver application process which would save many lives by increasing the number of qualified providers that are eligible to prescribe buprenorphine to treat opioid addiction.

**Improving the Effectiveness of Prescription Drug Monitoring Programs (PDMPs).** While we know legislation on this issue is still under development, Shatterproof strongly recommends that states do not receive any PDMP funding after August 1, 2019, unless and until the following PDMP standards have been met:

1) Mandatory query of the PDMP for schedule II, III and IV at first prescribing event and at least every 90 days thereafter;
2) Require input of dispensation information into the PDMP within 24 hours;
3) PDMP must include the most recent 12 months of prescription history (at a minimum);
4) Allow Medicare, Medicaid, health plans and pharmacy benefit managers to request access to state PDMP information; and
5) Require interstate PDMP data sharing with adjoining states (at a minimum).

The five preceding best practices have all been recommended in numerous white papers, and not including them in the final opioid package would be a lost opportunity to save countless American lives.

Shatterproof also recommends that PDMP funding should incentivize i) Integration of PDMP information into Electronic Health Records (EHR) and Pharmacy Dispensation Systems (PDS) and ii) Inclusion of data analytics and substance use disorder tools in the PDMP; both of these would be very beneficial to clinicians in helping their patients.

**Prescribing Limitations.** Shatterproof supports limiting prescriptions for controlled substances to three days for acute pain, with sensible exceptions for situations like chronic care and hospice. H.R. 5311, the CARA 2.0 Act introduced by Reps. Marsha Blackburn (R-TN-07) and Tim Ryan (D-OH-13) includes a three-day limit. We also support providing the Food and Drug Administration (FDA) with the authority to require unit dose packaging and/or safe disposal packaging. Limiting the pill count for acute pain prescriptions is critical to preventing more patients from becoming addicted in the first place.

**Treatment**

**Evidence-Based Treatment.** H.R. 5272, the Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse (RESULTS) Act introduced by Reps. Steve Sivers (R-OH-15) and Eliot Engel (D-NY-16), would require applicants for mental health or substance use disorder funding to demonstrate to HHS that the prevention or treatment activities are evidence-based. It is a fact that a large part of federal funding goes to prevention and treatment that is based on outdated methods, rather than going to prevention and treatment programs that utilize the research that has proven to save American lives.
This requirement would make significant progress towards incentivizing evidence-based approaches, while including a sensible exception for innovative programs.

**Health Information Technology for Behavioral Health Providers.** H.R. 3331, the Improving Access to Behavioral Health Information Technology Act introduced by Reps. Lynn Jenkins (R-KS-02) and Doris Matsui (D-CA-06) would provide long overdue incentive payments to behavioral health providers for adopting certified EHR technology, via a Center for Medicare and Medicaid Innovation (CMMI) demonstration. As you know, behavioral health providers were left out of the HITECH Act funding in 2009 for incentives to adopt electronic health records. Research has proven that one of the most important factors in successful treatment is coordination of care among the various professionals treating a patient. It is only right and morally just that these providers are able to adopt health IT to ensure care coordination with other provider types, just like any other disease.

**Changes to 42 CFR Part 2.** Rep. Markwayne Mullin’s (R-OK-02) amendment in the nature of a substitute to H.R. 3545, the Overdose Prevention and Patient Safety Act, strikes the right balance between allowing SUD records to be shared for the purposes of treatment in accordance with the Health Insurance Portability and Accountability Act (HIPAA), while also providing protections for discrimination or unauthorized disclosure. As stated above, one of the most important factors in successful treatment is coordination of care among the various professionals treating a patient. This can be accomplished most effectively through the use of EHRs; however in order to be effective, the EHRs need all relevant patient information including SUD records. This amendment will allow for the inclusion of this vital information in the EHR which will save lives by improving care coordination and also provide stronger HIPAA protections for this sensitive patient information. In addition, this also supports the important goal of ending the shame and stigma for American afflicted with this disease.

**Workforce Capacity.** H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Program introduced by Reps. Katherine Clark (D-MA-05) and Hal Rogers (R-KY-05), would allow for student loan forgiveness up to $250,000 for those who offer their training and talent in a SUD position. We desperately need more qualified health professionals in SUD professions and this student loan repayment incentive would go a long way toward meeting that need.

Another bill that would assist with improving workforce capacity is H.R. 3692, the Addiction Treatment Access Improvement Act introduced by Reps. Paul Tonko (D-NY-20) and Ben Ray Lujan (D-NM-03). This bill would make permanent the provisions from CARA to allow nurse practitioners and physicians assistants to prescribe buprenorphine, while also expanding on the eligible provider types to include clinical nurse specialists, certified nurse midwives and certified registered nurse anesthetists. It would also codify current regulations that allow certain providers to treat up to 275 patients with buprenorphine. The more qualified health providers who are able to prescribe buprenorphine, the more American lives that will be saved.

**Naloxone Training and Funding.** H.R. 992, the Opioid Abuse Prevention and Treatment Act introduced by Rep. Bill Foster (D-IL-11) would provide funding for training on how to safely administer naloxone. Shatterproof also recommends providing additional funding or other means to make it possible for every American at risk of an overdose caused by opioids and everyone in a position to save their lives to access naloxone. If naloxone is administered in time, it can save lives and give our loved ones a second chance.
Enforcement of the Mental Health and Addiction Equity Act of 2008. H.R. 4778, the Behavioral Health Coverage Transparency Act introduced by Rep. Joseph Kennedy (D-MA-04) would require health plans to disclose additional information to better assess how the law is being implemented. The bill would also require a minimum of 12 random audits per year to ensure the law is being implemented and enforced. We must ensure this law is being implemented fully to make treatment available to those who are dealing with addiction.

Best Practices for Post-Overdose Care. H.R. 5176, the Preventing Overdoses While in Emergency Rooms Act introduced by Reps. David McKinley (R-WV-01) and Mike Doyle (D-PA-14), would create a pilot program with 20 health care facilities to develop best practices for emergency departments as they discharge patients who have had an overdose. With opioid overdoses increasing, improving post-overdose care with proven best practices is crucial to helping a patient get a second chance.

There are many other smart initiatives being considered by this and other Committees to address the opioid crisis, but I strongly encourage you to include the proposals outlined above in any final package. These will make a lasting and meaningful impact on the opioid epidemic in the near-term and for years to come.

Every morning, I wake up thinking of the Serenity Prayer. The serenity to accept what I cannot change, and the courage to change the things we can. Our society must find the serenity to accept the lives that have already been lost, but waste no time in working together across party lines to find “the courage to change the things we can” and save countless lives. If there is anything that Shatterproof can do to assist in your efforts, please do not hesitate to call on us.

Sincerely,

Gary Mendell
Founder & CEO, Shatterproof
www.shatterproof.org
gmendell@shatterproof.org
Statement by:

Sean P. Kelly, MD
Chief Medical Officer, Imprivata
FACEP, Beth Israel Deaconess Medical Center
Assistant Clinical Professor of Emergency Medicine, Harvard Medical School

Thank you for the opportunity to submit comments for the record to the Energy and Commerce Committee on the legislation currently being considered to respond to this nation’s grave opioid crisis. I am pleased that the Committee is committed to addressing this critical issue and hope that my comments will be helpful as you consider the legislative steps that can be taken to improve our nation’s distribution of opioid medications. In particular, I’d like to share my unique perspective as an emergency physician and encourage the consideration of one bill included in the slate of proposals before you — H.R. 3528 — that would capitalize on technological advances to help address the growing epidemic.

At the Beth Israel Deaconess emergency room in Boston, I see firsthand the physical and emotional toll that the misuse of opioids takes on patients and their families each day. I treat multiple patients affected by opioid abuse and addiction during every shift, and I know I’m not alone. Each year, tens of thousands of Americans die from prescription drug overdoses, many of whom are supplied through illicit drug diversion and abuse.

H.R. 3528, the Every Prescription Conveyed Securely Act, would encourage a more secure opioid distribution chain by making Medicare reimbursements contingent on electronic prescribing. The bill has bipartisan support in the form of primary sponsors Reps. Katherine Clark (D-MA) and Markwayne Mullin (R-OK) and an additional 37 bipartisan cosponsors in the House. In the Senate a bipartisan companion bill was recently introduced by Sens. Michael Bennet (D-CO), Dean Heller (R-NV), Elizabeth Warren (D-MA), and Pat Toomey (R-PA), demonstrating this measure’s undeniable cross-party appeal.

Technology is well-suited to address this challenge by adding additional layers of security to the traditional controlled substances distribution chain. Specifically, Prescription Monitoring Programs (PMPs) and Electronic Prescribing of Controlled Substances (EPCS) can help curb opiate abuse by creating accountable and secure practices for those who prescribe and dispense controlled substances. While PMPs are more widespread, EPCS is a critical complement, providing a secure, transparent system that makes it easier to prescribe controlled substances to those patients that legitimately need them, while making it more difficult to commit fraud or abuse.

Electronic prescribing for controlled substances (EPCS) technology was approved by the Drug Enforcement Administration (DEA) in 2010 and has been steadily adopted by prescribers and pharmacists seeking to add an additional layer of security to the prescription of opiates. According to Surescripts, in 2015, 73% of prescriptions were delivered electronically, with 11% of controlled substances being done electronically. Just two years later, in 2017, 77% of prescriptions occurred electronically, with 21% now being done electronically.

Recent evidence compiled by the Geisinger Health System in Pennsylvania suggests that the use of EPCS can provide critical enhancements to prescription security while also lowering costs. After Geisinger implemented EPCS for their physicians, the hospital system is seeing an average of $850,000 in savings...
per month in the first year alone thanks to reduced call center needs, increased physician workflow productivity, and diversion control efforts. The use of EPCS also lessens the odds of costly mistakes due to handwriting or processing errors.

From the perspective I've gained in each of my professional roles, there are two critical points I'd like to make regarding technology's role in the prevention of opiate abuse:

1. Prescription monitoring is very effective, but it needs to be expanded and streamlined from a workflow perspective. PMPs also need to be supported by electronic prescribing so we, as physicians, can have access to the data we need on the prescribing patterns of our patients, and also have absolute trust in the integrity of the prescribing processes - right through to dispensing the medicine.

2. These technology-based solutions need to be applied thoughtfully and in a way that works for the care providers and their patients – not against them.

Although some progress has been made in recent years, these solutions remain alarmingly underutilized. According to the prescribing network Surescripts, more than 85 percent of all prescriptions are electronic, but only fourteen percent of prescriptions for controlled substances are made electronically. With the Drug Enforcement Agency (DEA) finalizing its rules for EPCS in 2010, there are few good reasons for the sluggish uptake.

Fortunately, states are increasingly taking action to unleash the potential of EPCS. New York has taken the lead through its Internet System for Tracking Over-Prescribing law, or I-STOP, that mandates the use of EPCS in conjunction with a PMP. Maine, Virginia, Arizona, Rhode Island, Connecticut, and North Carolina have followed suit by recently enacting legislation that will create an EPCS mandate in the coming years. And in addition to the bill currently before Congress, other state-level bills are currently pending in state legislatures across the country.

The legislation has also had significant buy-in from stakeholders across the health care sector. A letter in support of H.R. 3528 has been signed by important prescribing companies such as CVS and Walgreens, community pharmacists, the health information network Surescripts, and the manufacturer trade group Association for Accessible Medicines, among a litany of others.

The best way to achieve these positive outcomes is to enact federal legislation and create a national standard that providers can adhere by – and one that patients can count on. H.R. 3528 promises to save lives by ensuring that opioids are provided more securely and appropriately, and save money by reducing costly prescription errors and mistreatments. I urge the committee to consider their own version of the bill in the upper chamber and ensure that the legislation is enacted as part of the legislative solution to combating the opioid crisis.

As a healthcare community, we need to work closely together with care provider organizations and policymakers to implement prescribing strategies that are effective in addressing the problem and that we, as physicians, will actually use. I hope these comments will be helpful as you continue your critical charge of developing policies and practices that will help us all combat this dangerous epidemic.
Dear Representatives,

We write to thank you for your leadership on the Every Prescription Conveyed Securely Act and urge your colleagues in Congress to support this vital legislation. The opioid crisis is devastating families and communities from coast to coast. In 2016, more than 42,000 people died as a result of the crisis, more than any year on record according to the Centers for Disease Control and Prevention (CDC).1

A number of approaches have been summoned to attack this epidemic, but we believe that the use of already-existing electronic prescribing of controlled substances (EPCS) technology is going underutilized. EPCS reduces opportunities for diversion, as the DEA-approved electronic prescribing process provides more protection from diversion than the current system of paper and oral prescriptions. EPCS prescriptions cannot be altered, cannot be copied, and are electronically trackable. Furthermore, the federal DEA rules for EPCS establish strict security measures, such as two-factor authentication, that reduce the likelihood of fraudulent prescribing. Additionally, electronic prescribing offers new dimensions of safety and security for controlled substance prescriptions.

Over the past few years, the private sector has dramatically improved its use of E-Prescribing. Data from self-reported drug abusers suggest that between 3 percent and 9 percent of diverted opioid prescriptions are tied to forged prescriptions.2 While in 2013, 1 billion prescriptions were e-prescribed, in 2016, 1.6 billion prescriptions were e-prescribed. Yet, despite this vast growth, EPCS is lagging behind broader e-prescribing trends. According to health information network Surescripts, while approximately 90 percent of non-controlled substance prescriptions are e-prescribed, only 15 percent of prescriptions for controlled substances were submitted electronically in 2017.3

The Every Prescription Conveyed Securely Act promotes the use of EPCS to help address the opioid crisis by requiring that controlled substances for Medicare beneficiaries are prescribed electronically. This connection will encourage wider adoption of EPCS and help curtail “doctor shopping.”

FDA Commissioner, Scott Gottlieb, has indicated that a national e-prescribing system would allow his agency to think more strategically about controlled substances and their REMS program. EPCS could be

---

3 Surescripts. Data Brief, January 2018.
used to strengthen the tools at the disposal of prescribers and pharmacists and even present a solution to a
problem recognized by the Commissioner, interoperability across state lines.  

Seven states (New York, Maine, Virginia, Connecticut, North Carolina, Rhode Island, and Arizona) have
already passed legislation to mandate EPCS. These states now have a significantly more secure process in
place or in the works. The system provides security and convenience from start to finish: from the doctors'
electronic prescription-writing process to the pharmacy dispensing medications to the patient.

A national bill such as the one you have proposed would make available the promise of EPCS to the entire
country and mark a significant step forward in the fight against the opioid crisis. Your bill would help fill a
critical gap in the current prescription drug distribution chain.

The time to act on this common-sense policy is now. EPCS is a bi-partisan solution that the President's
Commission on Combating Drug Addiction and the Opioid Epidemic endorsed as a part of its November
2017 recommendations. In the same 2017 report the Commission states that each day 175 deaths are
attributed to the opioid epidemic. We can no longer afford to delay the advancement of policies, such as
electronic prescribing, that will help curb diversion and abuse rates and inform appropriate interventions.  

Thank you for your critical leadership with the Every Prescription Conveyed Securely Act. We encourage
your colleagues to cosponsor the bill and ensure its speedy passage in both chambers of Congress.

Sincerely,

Albertsons Companies
America's Health Insurance Plans
AmerisourceBergen
Association for Accessible Medicines
College of Healthcare Information Management Executives
CVS Health
Express Scripts
Health IT Now
Imprivata
National Coalition on Health Care
National Consumers League
National Association of Chain Drug Stores
Prime Therapeutics
Pharmaceutical Care Management Association
Rite Aid
Surescripts
Walgreens

---

4 Michael Mezher. Gottlieb: FDA Looking Beyond Opioids in Overtuse Epidemic. Regulatory Affairs Professionals
Society, Regulatory Focus™, February 2018. Available at: https://www.raps.org/news-and-articles/news-

5 The President’s Commission on Combating Drug Addiction and the Opioid Crisis, Recommendations on Drug
April 11, 2018

The Honorable Greg Walden
Chairman
Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Michael Burgess
Chairman, Health Subcommittee
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Gene Green
Ranking Member, Health Subcommittee
Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Walden, Ranking Member Pallone, Chairman Burgess and Ranking Member Green:

On behalf of the National Association of Counties (NACo) and the 3,069 counties we represent, I am writing to express our support for H.R. 4005, the Medicaid Reentry Act and H.R. 1925, the At-Risk Youth Medicaid Protection Act as you weigh proposals for combating the opioid crisis in the Health Subcommittee of the House Energy and Commerce Committee this week. County officials throughout the country are on the frontlines of our nation’s response to the opioid epidemic, and federal legislation like H.R. 4005 and H.R. 1925 provides vital support for local efforts to stem the tide of overdoses and fatalities that have impacted all corners of our country.

Counties nationwide spend $176 billion annually on justice and health systems, including the entire cost of health care for all arrested and detained individuals. We are required by federal law to provide health care for the 13.4 million individuals who pass annually through local jails, 90 percent of which are owned and operated by county governments. As the opioid epidemic has taken hold of our country, the budgets of county jails and local governments at large have seen tremendous strain, hampering the ability of counties to provide needed services within and outside of our correctional facilities.

H.R. 4005, the Medicaid Reentry Act, would ease the strain on the local response to the opioid epidemic by allowing incarcerated individuals to receive federal Medicaid benefits for the 30-day period preceding their release from correctional facilities. This support would help county jails provide needed addiction treatments and pre-release coordination of services for individuals preparing to reenter their communities, thereby reducing the risk of overdose or fatality upon release. This coordination critical.
because individuals struggling with addiction are typically at a particularly acute risk of overdose in the period immediately following their release from correctional institutions.\(^1\)

Similarly, H.R. 1925, the At-Risk Youth Medicaid Protection Act, would prevent states from terminating Medicaid enrollment for justice-involved youth, thus allowing for more timely provision of addiction treatment services for juveniles released from county correctional facilities. When Medicaid benefits are terminated upon an individual's incarceration, he or she must re-apply for those benefits when reentering the community, creating a potentially fatal gap in access to services. The alternative to termination is "suspension" of benefits—a provision that has been adopted by numerous states and allows individuals to rapidly regain access to treatments upon release from custody.

Access to Medicaid benefits is a key component of the successful reentry of justice-involved individuals into their communities. According to the Bureau of Justice Statistics (BJS), nearly two-thirds (63 percent) of people in jail meet the criteria for drug dependence or abuse.\(^2\) Many of these individuals have opioid use disorders and could benefit from access to Medication Assisted Treatment (MAT), which Medicaid programs cover in every state. Furthermore, studies show that individuals leaving correctional settings are up to 129 times more likely to fatally overdose in the two weeks following release into their communities. To effectively treat justice-involved individuals with substance use disorders, we must maximize treatment opportunities through Medicaid, and both H.R. 4005 and H.R. 1925 would make progress toward this goal.

We appreciate your continued leadership in combating the opioid epidemic and your focus on the intersection of the health and justice as you address this national challenge. For more information on the local response to the opioid crisis, please see the following report, A Prescription for Action: Local Leadership in Ending the Opioid Crisis, published by NACo and the National League of Cities (NLC), available electronically at www.naco.org. For more information on improving health outcomes for justice-involved individuals, please see NACo's Medicaid Coverage and County Jails presentation, available electronically at www.naco.org.

If you have any questions, please feel free to contact NACo Associate Legislative Director Brian Bowden at 202.942.4275 or bbowden@naco.org. We continue to stand ready to work with you in support of healthy, vibrant and safe communities.

Sincerely,

Matthew D. Chase  
Executive Director  
National Association of Counties

---


April 10, 2018

The Honorable Greg Walden
Chairman
Committee on Energy & Commerce

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy & Commerce

The Honorable Michael Burgess, MD
Chairman
Subcommittee on Health

The Honorable Gene Green
Ranking Member
Subcommittee on Health

Re: Trinity Health Comments on Combatting the Opioid Crisis

Dear Chairmen Walden and Burgess and Ranking Members Pallone and Green,

Trinity Health appreciates the work of this Committee on ways in which it can address the devastating impact of the opioid crisis. Our following recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all. We also believe that reverence—honoring the sacredness and dignity of every person—is inherently necessary to reducing opioid harm.

We strongly believe that health systems and hospitals must play a critical role in addressing opioid use and misuse. Trinity Health is committed to developing and implementing important opioid utilization reduction strategies, ensuring comprehensive education and awareness programs, engaging in robust advocacy, and measuring impact to ensure continuous improvement for all populations that we serve. Committed to putting the people and communities we serve at the center of every behavior, action and decision, Trinity Health is broadly collaborating—through our Opioid Utilization Reduction (OUR) initiative—for the system-wide development, evaluation and dissemination of evidence-based tools and protocols for optimizing care and reducing opioid harm.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. Trinity Health includes 93 hospitals as well as 109 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns $1.1 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with Graduate Medical Education (GME) programs providing training for 2,095 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 131,000 colleagues, including more than 7,500 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 22 Clinically Integrated Networks that are accountable for 1.3 million lives across the country.

If you have any questions on our comments that follow, please feel free to contact me at wellsdk@trinity-health.org or 734-343-0824. We look forward to working with you as the Committee advances a legislative package on these issues.

Sincerely,

Tonya K. Wells
Vice President, Public Policy & Federal Advocacy

Sponsored by Catholic Health Ministries | 20555 Victor Parkway • Livonia, MI 48153 • 734-343-1000 • trinity-health.org
Trinity Health is committed to partnering with all stakeholders to address opioid use through prevention, intervention, treatment, and recovery initiatives. As we work to address the country’s culture of pain, we must also recognize that a patient’s experience of pain depends on many factors including comorbidities, stress levels, and social supports. Trinity Health strongly believes that altering the course of opioid and substance use disorders must include the following imperatives that encompass prevention, intervention, treatment and recovery:

- Building awareness, education and engagement across all stakeholders including patients, providers, pharmacists, families and communities. Broad community education is critical.
- Ensuring resources and coordinated, comprehensive solutions across local, state and federal levels of government.
- Supporting a whole-person approach to meet the full range of an individual’s physical, behavioral and social support needs in an integrated fashion and recognizing that each of these dimensions impacts a patient’s experience of pain as well as his/her health and wellness.
- Enhancing prevention through communication, transparency and accountability among all stakeholders.
- Breaking down barriers to effective treatment and recovery including reducing stigma and ensuring appropriate insurance coverage.

While many state legislatures have enacted targeted measures to address the opioid crisis, a coordinated nationwide strategy that prioritizes appropriation of federal funding for programs to support the opioid efforts of state and local governments, hospitals, and community-based organizations is required. Ensuring that federal and state mitigation measures and provider education requirements or initiatives are as consistent as possible across all states to avoid duplication, confusion, and undue burden on providers is of critical importance.

**SUPPORT WHOLE-PERSON CARE**

**Comprehensive Coverage**

It is of critical importance that Congress ensure comprehensive insurance coverage is maintained for all vulnerable populations, including through Medicaid. Comprehensive coverage is especially important to opioid and substance use disorder prevention and treatment.

**42 CFR Part 2**

Congress is urged to align confidentiality requirements for sharing a patient’s substance use disorder records (known as 42 CFR Part 2) with the requirements in the Health Insurance Portability and Accountability Act (HIPAA) so that opioid and substance use disorders can be treated like other medical conditions, improving patient safety and continuity of care. Aligning the confidentiality of substance use records with HIPAA requirements – thereby granting health care providers access to information to diagnose and effectively treat patients who use opioids and other controlled substances – will better ensure integrated care across providers and settings. As a result of these antiquated regulations, opioid and substance use disorder diagnosis and treatment information gets locked away from other providers and care managers, fueling bifurcation, limiting care coordination, and creating safety risks for beneficiaries. Specifically, we urge Congress to include the Jessica Grubbs Legacy Act (S.1850)/the Overdose Prevention and Patient Safety Act (H.R. 3545) in any opioid-related package.

**Access to Non-Opioid and Non-Pharmacological Alternative Approaches to Pain Management**

Across Trinity Health’s continuum of care providers, we daily hear of struggles associated with coverage and access to non-opioid and non-pharmacological alternative approaches to pain management. Meaningful coverage – from both Centers for Medicare and Medicaid Services (CMS) and third-party payers – to non-opioid and non-pharmacologic alternatives is one of the most important long-term strategies policymakers can address to combat the opioid epidemic.
The crisis facing our nation. The Food and Drug Administration (FDA) also has an important role in supporting research into these alternatives and speeding alternatives and approvals to market. More comprehensive utilization of these modalities have great potential to reduce opioid use and improve patient functionality and outcomes.

As an example of non-opioid alternatives, Lyrica (pregabalin) is an extremely valuable medication in treating numerous neuropathic pain syndromes but has only been approved for minimal indications, such as fibromyalgia. This non-opioid medication is extremely effective for treating several neuropathic pain syndromes, but it is very difficult for a patient to garner approval for its use. Additionally, utilizing procedures — for example injections such as epidural steroids that can be used to treat acute exacerbations of radicular pain — is another critical example to reducing opioid use in patients. Coverage for these procedures, however, are increasingly being denied. Non-pharmacological alternatives — such as physical therapy and cognitive behavioral therapy — as well as complementary approaches — such as acupuncture and chiropractic therapy — are also critical. More comprehensive utilization of these alternative approaches is paramount to minimizing the risk that people develop opioid or other substance use disorders. Ensuring access to and low or no co-payments for non-opioid and non-pharmacological pain management modalities could reduce opioid misuse and improve patient functionality and outcomes.

Current CMS reimbursement policies, as well as those from other health insurance payers, create barriers to the adoption of these alternative strategies. This is a significant barrier in clinicians being able to consistently and more broadly embrace utilization of these alternative and complementary pain management approaches. We strongly urge that a broader range of pain management and treatment services — including alternatives to opioids, physical therapy, cognitive behavioral therapy, acupuncture, and chiropractic therapy — be adequately reimbursed by payers, including Medicare and Medicaid. Specifically, CMS should review and modify rate-setting policies that discourage the use of non-opioid treatments for pain.

Supporting a Team-Based Workforce

A critical component of ensuring that all individuals receive the best, evidence-based prevention, screening, and assessment is an effective workforce. We urge Congress to ensure CMS provides appropriate reimbursement and financial incentives for supporting a collaborative, team-based environment that includes psychiatrists, addiction medicine specialists, advance practice clinicians (e.g., PAs, NPs), psychologists, social workers, nurses, care coordinators, community health workers (CHWs), and peer-to-peer support specialists. Allowing these individuals to practice at the highest level of their education, training and licensure is also important.

Mental Health Parity

The Mental Health Parity and Addiction Equity Act of 2008 built on the Mental Health Parity Act of 1996 by requiring that coverage provide the same level of benefits for substance use and mental health as it does for other medical care. While parity is a requirement, enforcement remains a challenge. Parity regulations must be adequately and uniformly enforced for these policies to be effective and to ensure evidence-based, coordinated care is received for those with opioid and substance use disorders. CMS has an important role in this imperative. We also urge the Committee to examine additional ways to ensure all beneficiaries of federal health programs are benefiting from mental health parity and treated equitably relative to commercial and managed care plans.

OVERPRESCRIBING AND DATA TRACKING

Prescribing Guidelines and Requirements

It is critical that policymakers acknowledge and recognize the importance of ensuring that the pendulum not swing too far in the other direction as we collectively work to reduce opioid misuse and abuse. We strongly urge that public policies intended to reduce inappropriate use of opioids do not simultaneously create access barriers to pain management for patients for whom opioids are medically indicated and who are benefiting from such treatment.
While Trinity Health supports and, as discussed later in these comments, is widely disseminating the Centers for Disease Control (CDC) Guidelines for Prescribing Opioids for Chronic Pain, it is important that these clinical guidelines not be narrowly interpreted into overly restrictive policy and across-the-board requirements that could result in numerous negative, unintended consequences. For example, the CDC states: “This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.” Trinity Health strongly urges that public policies to address inappropriate opioid use should always include exceptions for hospice care, cancer diagnoses, end-of-life care, and palliative care. Many institutions and payers are establishing dose and time limits for all patients, irrespective of their underlying diagnosis, context or goals. Again, public policies must not be so overly restrictive that it inhibits clinical decision-making on the needs and circumstances of individual patients.

We also have significant concerns with the proposed 3-day limit on initial opioid prescriptions for acute pain in the CARA 2.0 package introduced in the Senate. A 3-day limit is overly restrictive public policy, as it inhibits clinical decision-making based on the needs and circumstances of individual patients and could cause significant harm for surgery patients in particular. Patients with legitimate pain needs could be left on a weekend, for example, without the availability of a clinician to provide additionally needed days of a prescription to treat their pain. Limiting the initial supply of an opioid prescription for acute pain to 7-days is a more reasonable approach to addressing the reservoir of unused prescription opioids, and less problematic for clinical decisions based on individual patient’s circumstances and needs. The CDC states: “When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.” CDC’s clinical guidelines acknowledge that three days is often sufficient but not always. Limiting to 3-days could also encourage prescribers to write second and third prescriptions to be used at a later date which could further exacerbate the problems surrounding opioid misuse and abuse.

To ensure that the pendulum not swing too far in the other direction and create access barriers to pain management for patients for whom opioids are medically indicated, we would also support funding to improve the pain management evidence base. This could, for example, support a supplement to the CDC Guidelines that provides greater direction beyond the primary care audience for which these Guidelines were originally intended.

Improving PDMP Utility
Prescription Drug Monitoring Programs or PDMPs hold great promise as demonstrated by the recent Health Affairs study, which found that both the number of opioid prescriptions and spending was significantly lower in states with a registration mandate or a registration and use mandate, compared to states without either. For example, opioid prescriptions declined 28 percent in Massachusetts from 2015 to 2017 with 97 percent of health care providers registered with their awareness tool that's getting an average of 125,000 searches a week. And the Ohio database processed more than 24 million queries from physicians and other health professionals in 2016 while the number of opioids dispensed to Ohio patients decreased 20 percent since 2013.

However, it is critical that policymakers address inadequate databases and ensure cross-state information exchange. This is particularly important for providers that practice near borders and have patients coming from a neighboring state to seek care. Additional investments should be made in innovative technology that advances interoperability and interstate data-sharing among PDMPs nationally. As a national health system operating in 22 states, we are proactively mapping out a system-wide strategy to ensure our electronic health records (EHRs) are able to capture states’ PDMP data to make the process as seamless as possible for providers. Ensuring cross-state exchange of information and active alert systems are critical next steps. We also urge
that these database efforts – including related requirements on providers – not be overly burdensome and are integrated into these existing databases, systems and workflow.

COMMUNICATION AND EDUCATION

Provider Education
Trinity Health's OUR initiative has identified prescriber education as the most critical need for our hospitals and clinicians to be successful with reducing opioid utilization and related harm. While we support increased prescriber education initiatives, we also have concerns that the varying requirements coming from local, state and federal entities is quickly becoming confusing. Ensuring that government mitigation measures – including provider education requirements – are not duplicative in nature and are as consistent as possible across all states is critically important to avoiding confusion and undue burden on providers.

Trinity Health strongly believes that providing prescribers with resources and education about national guidelines for safe and appropriate opioid prescribing is the foundation for opioid utilization reduction education. We support wide dissemination of the CDC Guidelines. Additionally, across the entire Trinity Health system, two critical prescriber education platforms are being rolled out – first is the SCOPE of Pain for basic overview training and secondly is the Center to Advance Palliative Care (CAPC) for pain management competency based training. Supporting advancement of responsible, evidence-based opioid prescribing and counseling through pain management education, safe prescribing training, and addiction training for all prescribers and dispensers throughout medical schooling and beyond is critical to policymaking. Additionally, Trinity Health has developed – and integrated into our electronic health record (EHR) – the attached, two-page opioid discharge education piece for patients. If the Department of Health and Human Services (HHS), including Medicare and Medicaid, were directed to coordinate the development of a national curriculum and standard of care for opioid prescribers, we strongly urge that all of the above referenced educational resources be utilized. We also urge that the Committee prioritize education requirements that are as consistent as possible across all states to avoid duplication, confusion, and undue burden on providers.

TREATMENT

Coverage and Access to Treatment
Breaking down barriers to effective prevention, screening and treatment is critical, and any opioid reduction strategy must be accompanied by increases in access to treatment. According to the National Institute on Drug Abuse (NIDA), every dollar invested in addiction treatment yields a return of up to $7 in reduced drug-related crime and criminal justice costs. When health care savings are included, the return on investment can exceed $12. CMS must ensure meaningful insurance coverage of and access to evidence-based medication-assisted treatment (MAT) for opioid use disorder. This includes limiting prior authorization requirements and ensuring there are no lifetime limits and no arbitrarily low dose and time limits for treatment of these patients in order to effectively improve patient outcomes. Significant access challenges also result from having too few providers certified to prescribe these medications, such as Buprenorphine, as well as the costs of these medications often prohibiting access as well. Congress should appropriate funding to expand MAT training and provide financial incentives for prescribers willing to secure waivers to prescribe Buprenorphine.

The impact of opioid use disorders impacts all age groups and demographics. Eliminating the restriction on Medicaid payments for inpatient treatment at large residential facilities (i.e., the Institutions for Mental Diseases (IMD) exclusion) is important to expanding treatment for those covered by Medicaid. For those covered by Medicare, it’s important that Methadone treatment be covered not just in the inpatient setting but in the outpatient setting as well.

ATTACHMENT TO THESE COMMENTS: Trinity Health's Patient Discharge Instructions on Opioids
What You Should Know About Opioid Medicine

What is an Opioid?

Opioid medications are used to treat moderate to severe pain. Morphine, Oxycodone (Percocet®), Hydrocodone (Dilaudid®) and Hydrocodone (Norco®) are some types of opioids.

How do Opioids work?

Opioids reduce the pain signals sent to your brain, which decrease your feelings of pain. Opioids may reduce your pain, but may not take all the pain away.

What are the risks from taking opioids?

Prescription opioids carry serious risks of physical dependence, addiction and overdose, with long term use. If you take too much or an opioid it can cause sudden death.

- Physical dependence means you have symptoms of withdrawal when a medication is stopped.
- Addiction is a brain disease. Medications change the structure of the brain and how the brain works. These brain changes may be long lasting and can lead to harmful behaviors.
- Overdose means you took too much medication. Opioid overdose can result in death.

Make sure you read all of the medication sheet you received with your prescription.

Call 911 right away if you have any of these signs of overdose:
- Pale or bluish skin color
- Trouble breathing
- Severe confusion; not knowing where you are
- Your heart is beating slower than normal
- You see or hear things that are not real

Tell the people you live with that you are taking a medicine that can stop your breathing. Ask them to watch for slow, shallow, or trouble breathing. Tell them to call 911 right away if you have trouble breathing or they cannot wake you up.

What you need to know while taking Opioid medication:
- Do Not take more medication, or higher doses than prescribed, as you may stop breathing or pass out.
- Do not take opioids more often or in higher doses than prescribed. Call your doctor if your pain is not controlled.
- Do Not drink alcohol (beer, wine or liquor) while taking this medication, as you may stop breathing or pass out.
- Do Not take sleeping pills (like zolpidem (Ambien®) or temazepam (Restoril®) or anti-anxiety medication (like alprazolam (Xanax®), diazepam (Valium®), and lorazepam (Ativan®) while taking this medication, as you may stop breathing or pass out.
- Do Not crush or alter opioid medication or take it in ways not prescribed by your doctor.
- Do not drive or do tasks that require you to be alert after taking this medication.
- If you are pregnant, talk to your doctor. Opioids may harm your pregnancy or baby.

What are the side effects from taking opioids?

The most common side effects are:
- Hard stools (Constipation)
- Upset stomach, throwing up and dry mouth
- Feeling sleepy
 Feeling more pain
 Confusion
 Depression, low mood, feeling sad or nervous
 Itching and sweating
 Trouble passing urine

 Will I become addicted to opioid medication?

 Addiction is not common when this medication is used for a short time. But, when opioid medications are
 misused addiction is possible. Talk with your doctor about how to switch to using only non-opioid pain
 treatment. Please talk to your doctor about your concerns about addiction.

 How do I safely store and dispose of my opioids?

 Storage:
 • Keep your medications secure.
 • Keep your medications, including any medication patches, out of reach of others (this includes children,
   friends, family and pets).
 • Keep your opioids, and all medications, in the pill bottle from the pharmacy. Keep the lid closed.

 Disposal:
 • Safely throw out unused opioids: Contact your local pharmacy for how to throw out unused opioid
   medications or find your local medicine take-back site (http://disposemymeds.org/)
 • Follow these steps if you can’t find a medicine take-back site to throw out expired, unused or unwanted
   medicines:
   o Step #1: Mix medicine with used coffee grounds, dirt, or kitty litter.
   o Step #2: Put medicines in a sealed plastic bag.
   o Step #3: Place plastic bag in the trash.
   o Step #4: Take prescription bottle and scratch out personal information, then recycle or throw
     away.
 • Throw out patch medications by folding them in half with the sticky sides together, and then flushing
   them down a toilet. Do not place them in the household trash where children or pets can find them.

 It is against the law to share or sell your opioid medication.

 What else can I use to treat my pain?

 Non-opioid pain medications (such as Tylenol®, Motrin®, and Aleve®) may also help with your pain. If
 your doctor approves, these medications may be used with an opioid medication ordered for you. Non-
 opioid pain medications also have risks and side effects; please ask your doctor if these medications are safe
 for you.

 Many opioid medications also have acetaminophen (Tylenol®) in it. Very bad, and sometimes deadly,
 liver problems can happen with too much acetaminophen use.

 What are other ways to help ease your pain?
 • Heat or ice
 • Stretching
 • A pillow under the painful area
 • Massage
 • Talking to someone about how your thoughts and feelings affect your pain
 • Listening to music

 Talk to your doctor to make sure these actions are safe for you.
April 10, 2018

The Honorable Greg Walden
Chairman
Energy & Commerce Committee
U.S. House of Representatives
2185 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Energy & Commerce Committee
U.S. House of Representatives
237 Cannon House Office Building
Washington, DC 20515

RE: Hearing on Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients

Dear Chairman Walden and Ranking Member Pallone:

Thank you for your Committee’s ongoing leadership in the federal response to the opioid epidemic, including the April 11 hearing on “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients.” The Infectious Diseases Society of America (IDSA), HIV Medicine Association (HIVMA), and the Pediatric Infectious Diseases Society (PIDS) collectively represent over 12,000 infectious diseases, pediatric infectious diseases and HIV physicians, researchers and other healthcare providers. Our members are increasingly concerned about how the opioid crisis is driving higher rates of infectious diseases including hepatitis B, hepatitis C, endocarditis, HIV as well as skin and soft tissues infections.

We write to express our support for several of the bills you will consider at the April 11 hearing. We also wish to share the following new materials to help enact policy solutions aimed at reducing the dangerous infections arising from opioid use disorder (OUD) and other substance use disorders.

- A fact sheet detailing the infectious disease-related impacts of the opioid epidemic.
- A policy brief outlining a comprehensive set of recommendations regarding the prevention, surveillance, workforce capacity and access to treatment.
- A letter to the National Institutes of Health (NIH) outlining key research questions on this complex set of issues.

Coverage and Payment

Healthcare coverage is essential to ensure that individuals with OUD, other substance disorders and related infectious diseases can access comprehensive healthcare including addiction, mental health and infectious diseases prevention and treatment. Our current fragmented healthcare system has coverage and payment restrictions that limit helpful responses to the opioid epidemic and associated infections.
The Medicaid program covers more than four in ten non-elderly adults with opioid addiction. People with Medicaid coverage are more likely to receive addiction treatment. A strong Medicaid program with coverage for mental health and substance use treatments along with preventative services must be maintained as a vital component of the opioid crisis response.

Many of the bills to be discussed during the April 11 hearing would strengthen the national response to the opioid crisis, and appear responsive to the epidemic’s complexity. We are pleased that Committee members will be discussing several bills that address policy issues identified by our societies as crucial to advance a comprehensive, effective response to the national opioid crisis. These are outlined in our recently released policy brief.

We offer our support for the bills noted below that will be discussed at the April 11 hearing. The bills align with policy recommendations identified by our ID and HIV physician members who work on the frontlines of the opioid epidemic to prevent and treat infectious diseases.

- **H.R. __, Use of Telehealth to Treat Opioid Use Disorder**

We support reducing payment barriers for telehealth under Medicare for the treatment of opioid use disorder and co-existing mental health conditions by allowing the Secretary to waive certain conditions. Employing telemedicine would help address the limited access to providers willing and able to prescribe medication for addiction treatment. In rural communities and underserved urban areas, a shortage of infectious disease and HIV experts is hindering our nation’s response to the opioid epidemic. Telemedicine programs such as Project ECHO have been well documented as increasing provider knowledge and improving patient outcomes.

Reimbursement for services provided through telehealth, including time devoted to consultation and training is critical.

- **H.R. 4005, the Medicaid Reentry Act**
- **H.R. 1925, the At-Risk Youth Medicaid Protection Act**

Uninterrupted treatment for justice-system involved individuals when they transition in and out of correctional settings is critical to prevent relapse and drug overdoses. With less fragmented care, individuals with communicable diseases including HIV, viral hepatitis and STDs can be identified and treated. Under current federal Medicaid rules, states can elect to allow justice-involved individuals to maintain their Medicaid coverage or initiate Medicaid coverage during incarceration. However, during the incarceration period, federal Medicaid reimbursement is limited to hospital stays of 24 hours. If Medicaid coverage began 30 days before release, community-based health care providers could start care. The benefits of this approach would mean medication for addiction treatment and treatment for communicable conditions, such as

---

HIV, viral hepatitis, and sexually-transmitted diseases would help reduce illness and prevent spread to unaware citizens upon an inmate release. Similarly, ensuring that justice-involved youth maintain their Medicaid eligibility and do not need to re-apply for coverage upon release will help to reduce barriers to access substance use, mental health, preventive and healthcare services for this population at high risk for drug overdose and acquiring communicable diseases upon release.

- H.R. 3192, the CHIP Mental Health Parity Act

A significant number of children experience trauma and separation from their biological family. Access to mental health and substance use treatment for the nearly 9 million children and adolescents covered by the Children Health Insurance Program should be key component of a comprehensive response to the opioid crisis. Also, young adults (between 18 and 25) are the most prominent abusers of prescription opioids. Youth between the ages of 13 and 24 accounted for 22% of all new HIV diagnoses in the U.S. in 2015. Access to comprehensive behavioral health care for children and adolescents is critical to prevent and treat substance use disorder and to reduce the risk of HIV among youth.

- H.R. __, Medicaid Incentives for Health Homes to Treat Substance Use Disorder

Encouraging states to adopt the Medicaid Health Home benefit for individuals with substance use disorder would hopefully expand access to the comprehensive, coordinated care needed to meet their complex healthcare needs. Extending the period for enhanced federal matching funds from eight to twelve fiscal periods would be an incentive. Studies from states that have implemented the health home benefit for individuals with substance use disorders, HIV, and other chronic conditions, indicate that health homes improve health outcomes, and can save money, by supporting the integration of medical care, behavioral health and social services and supports.

- H.R. __, Provide IMD Services Up to 90 Days for Medicaid Beneficiaries with SUD

Residential substance use treatment is an important component of the care continuum for effectively treating addiction. Despite recognizing the mental disease (IMD) exclusion as an impediment for providing comprehensive substance use and addiction treatment for Medicaid beneficiaries, policy changes to date have not effectively addressed this issue. A legislative fix that allows states to receive federal matching funds for 90 days per calendar year for residential treatment at an IMD would likely encourage more states to add IMD as a covered benefit. We are concerned that the state option is currently limited to five years and may end in 2023.

---

7National Institute on Drug Abuse. Abuse of Prescription (Rx) Drugs Affects Young Adults Most. 2016.
8Centers for Disease Control and Prevention. HIV Among Youth. 2018.
the scale of the opioid crisis, the need for residential substance use treatment as part of the care
continuum for Medicaid beneficiaries will continue after 2023.
Once again, IDSA, HIVMA and PIDS thank you for your attention to the opioid epidemic and its
infectious diseases complications. We welcome the opportunity to assist in your efforts. We can
be reached through the IDSA Senior Vice President for Public Policy and Government Relations
Amanda Jezek at ajezek@idsociety.org or the HIVMA Executive Director Andrea Weddle at
aweddle@hivma.org.

Sincerely,

Paul G. Auwaerter, MD, MBA, FIDSA
President, IDSA

Paul Spearman, MD, FPIDS
President, PIDS

Melanie Thompson, MD
Chair, HIVMA Board of Directors
States With Prescription Drug Monitoring Mandates Saw Reduction In Opioids Prescribed To Medicaid Enrollees

Hefei Wen¹, Bruce R. Schackman²,³, Brandon Aden²,⁴, and Yuhua Bao²,³,⁴
¹Department of Health Management and Policy, University of Kentucky, Lexington, Kentucky
²Department of Healthcare Policy and Research, Weill Cornell Medical College, New York, New York
³Department of Psychiatry, Weill Cornell Medical College, New York, New York
⁴Department of Medicine, Weill Cornell Medical College, New York, New York

Abstract

Prescription drug monitoring programs are promising tools to use in addressing the prescription opioid epidemic, yet prescribers' participation in these state-run programs remains low as of 2014. Statutory mandates for prescribers to register with their state's program, use it, or both are believed to be effective tools to realize the programs' full potential. Our analysis of aggregate Medicaid drug utilization data indicates that state mandates for prescriber registration or use adopted in 2011-14 were associated with a reduction of 9-10 percent in population-adjusted numbers of Schedule II opioid prescriptions received by Medicaid enrollees and amounts of Medicaid spending on these prescriptions. This effect was largely associated with mandates of registration, which were comprehensive in all adopting states, and not with mandates of use, which were largely limited in scope or strength before 2015. Our findings support the use of mandates of registration in prescription drug monitoring programs as an effective and relatively low-cost policy. Future research should further assess the value of strong mandates of use to ensure safer and more appropriate prescribing of opioids.

Between 1991 and 2010 the population-adjusted volume of opioid prescriptions in the United States more than doubled, increasing from 304 per 1,000 people to 680 per 1,000.¹

The increase in prescription opioid use coincided with a rapid escalation in nonmedical use of prescription opioids² and opioid overdose-related deaths.³,⁴ Prescribers of controlled substances are believed to be an important link in addressing the deadly drug overdose epidemic.⁵

Prescription drug monitoring programs are statewide databases that gather information from pharmacies on dispensed prescriptions of controlled substances. Prescribers are important intended users of these databases. A complete picture of each patient’s prescription history provided by the database can help prescribers identify patients at high risk of misusing controlled substances, while ensuring access to effective pain relief for patients who make

¹Corresponding author: Yuhua Bao, PhD, 402 E 67th St., New York, NY 10065; (212) 548-9573; yub2003@med.cornell.edu.
legitimate use of the drugs. The surging prescription opioid epidemic and earmarked federal 
grant funding for prescription drug monitoring programs\(^6\) have spurred a wave of 
implementations or upgrades of these programs during the past decade. To date, forty-nine 
states and the District of Columbia have such programs in operation—Missouri is the only 
state without a program in place.

Recent evaluations have provided evidence of the impact of prescription drug monitoring 
programs. A study using data that analyzed pain-related visits to physicians’ offices in 
twenty-four states over a ten-year period found that implementation of monitoring programs 
was associated with reduced prescribing of Schedule II opioids\(^7\)—the subclass of 
prescription opioids with the highest risk of abuse and dependence, according to the Drug 
Enforcement Agency. Another study, using mortality data from thirty-five states over a 
fifteen-year period, found substantial reduction in opioid overdose–related deaths associated 
with state implementation of a prescription drug monitoring program.\(^8\) Yet another study, 
using claims data for disability enrollees in Medicare for the period 2006–12, did not find an 
operating drug monitoring program to be associated with a decline in the rate of high-risk 
opioid use or treatment for prescription opioid overdose.\(^9\)

Participation by prescribers in their state’s monitoring program remained low in the years 
covered by these studies. A report by the Prescription Drug Monitoring Program Center of 
Excellence at Brandeis University estimated a median program registration rate of 35 
percent among licensed prescribers who prescribed at least one controlled substance in the 
period 2010–12.\(^10\) A national survey in 2014 found that 53 percent of primary care 
physicians used their state’s program at least once, but that many did not use it routinely.\(^11\)

Given that two of the three studies described above found the monitoring programs to have 
taken effect immediately following implementation,\(^7\)\(^8\) the observed impact might be due to 
increased awareness by prescribers about the prescription opioid epidemic in response to the 
launching of the monitoring program in their states, instead of their use of the programs on a 
regular basis. As states deploy policies to increase prescribers’ use of prescription drug 
monitoring programs, the impact of the ongoing use of the programs needs to be evaluated.

Prominent policy strategies employed by states include mandates that prescribers register 
with the drug monitoring program (a prerequisite for using it) and mandates that prescribers 
use the system under certain clinical circumstances, such as upon initial prescribing and 
every three months thereafter.\(^12\) Prescriber mandates are believed to be more effective in 
inducing prescribers to use the monitoring programs consistently, compared to campaigns to 
recruit prescribers to participate in the program—which are resource intensive and have had 
lackluster outcomes.\(^12\) By the end of 2015, twenty-three states had adopted mandates for 
prescriber registration, and twenty-nine states had adopted some version of a mandate to use 
the monitoring program.\(^12\) Examinations of data from the drug monitoring programs of 
Kentucky\(^13\) and of New York, Ohio, and Tennessee\(^12\) indicated that after implementation of 
the mandates, there were rapid increases in prescribers’ participation in these programs and 
decreases in high-risk behaviors related to opioid prescriptions that suggested that drugs 
were being misused or diverted to people for whom they were not prescribed.

\(^{10}\) Health Aff (Millwood). Author manuscript; available in PMC 2018 April 01.
In this study we assessed the effects of prescriber mandates, of both registration and use, on the number of prescription opioids received by Medicaid enrollees and Medicaid spending on these drugs. Medicaid enrollees have excessive burdens of chronic pain and are at a much higher risk of substance use disorders compared to populations with other types of insurance. Medicaid enrollees are thus at heightened risk for prescription opioid misuse and were five to six times as likely to die from opioid-related overdose compared to populations with other types of insurance. Reducing the number of unsafe prescriptions of opioids in the Medicaid population should be a priority for any state's drug control policies.

We used state-level aggregate data on prescription opioids received by Medicaid enrollees and Medicaid program spending on prescription opioids to examine the effects of mandates of both registration and use, adopted by twenty-five states in the period 2011–14. This comprehensive evaluation provides much-needed evidence that supports states' policies designed to further improve the impact of prescription drug monitoring programs.

## Study Data And Methods

### Data

Our primary data source was the 2011–14 Medicaid State Drug Utilization Files from the Centers for Medicare and Medicaid Services (CMS). To be eligible for federal matching funds, all states are required to report to the CMS the numbers of prescriptions for Medicaid-covered outpatient drugs and Medicaid spending on these drugs through fee-for-service Medicaid and Medicaid managed care programs. This requirement resulted in nearly complete data on all Medicaid-covered prescription drug use nationwide.

The Medicaid State Drug Utilization Files identify prescription drugs with their eleven-digit, three-segment National Drug Code numbers and provide information on the total number of prescriptions and pre-rebate Medicaid spending (that is, spending not accounting for rebates paid by drug manufacturers) associated with each National Drug Code in each calendar quarter. According to the data, in 2014, 165.5 million opioid prescriptions were dispensed to Medicaid enrollees nationwide, which accounted for 7.3 percent of the number of prescription drugs paid for by Medicaid programs in that year. Opioids containing hydrocodone (37 percent of all opioids) and opioids containing oxycodone (22 percent) were the top opioids dispensed. Per population opioid prescriptions dispensed varied greatly across states, with an interquartile range of 15–23 prescriptions per quarter per 100 enrollees (see online Appendix A).

Opioids dispensed to patients in the emergency departments or inpatient settings or paid for with cash were not included in these data.

### Study Population

We restricted our study period to 2011–14 because the pace of states' adoption of mandates picked up only after 2012, and the most recent Medicaid State Drug Utilization Files available were for the fourth quarter of 2014. We excluded two states (Missouri and Pennsylvania) and the District of Columbia, none of which had implemented a monitoring program (based on user access date) before 2015. We also excluded two states (Alabama and...
Measures

The two outcome measures we examined were the number of filled prescriptions (including both new prescriptions and refills) and the amount of pre-rebate Medicaid spending on prescription opioids in each quarter per 100 Medicaid enrollees. The numbers of Medicaid enrollees for each state-quarter pair were included in public data from CMS. Prescription opioids were identified by linking the National Drug Code numbers with information in the Approved Drug Products with Therapeutic Equivalence Evaluations, known as the Orange Book, published by the Food and Drug Administration. We excluded buprenorphine, which is commonly used for medication-assisted treatment of opioid use disorder. Prescription opioids were further categorized as Schedule II or Schedule III opioids based on their classification by the Drug Enforcement Agency, which reflected a recent reclassification of all hydrocodone-containing combination opioids (such as Vicodin and Lortab) from Schedule III to Schedule II. Schedule II opioids are considered to have greater potential for abuse and dependence, compared to Schedule III opioids. We converted the nominal Medicaid spending values in the study period to December 2014 dollars, based on the national monthly Consumer Price Index.

Implementation of mandates for registration, use, or both related to prescription drug monitoring programs was defined based on the effective date of each statutory mandate. The Prescription Drug Monitoring Project of the National Alliance for Model State Drug Laws provided us with effective dates of state mandates. During our study period, seventeen states implemented mandates of registration, and twenty implemented some version of mandates of use. Because many states implemented both types of mandates, twenty-five states implemented a mandate of some kind. Appendix A provides a summary of mandate policies adopted by the forty-six states included in our study. For each state-quarter pair, we determined whether the state had any mandate (of registration or use), a mandate of registration only, a mandate of use only, or mandates of both registration and use. We set each of the policy indicators to 1 for each full quarter after the effective date of the mandate or mandates. Appendix A provides examples from four hypothetical states.

While mandates of registration typically apply to all licensed prescribers in a state, the comprehensiveness of mandates of use varies widely across states. They differ in terms of types of drugs and types of prescribers to which the mandate applies, the circumstances under which prescribers are mandated to use the system, and whether prescribers are to exercise their subjective judgment as to what constitutes inappropriate use in deciding whether to use the system (Appendix A).

In recent years, mandates of use have imposed increasingly broad and obligatory criteria and thus have become stronger and more comprehensive over time. In contrast, the mandates of use that states adopted in our study period were weak, with three exceptions: Kentucky (whose mandate became effective in 2012), New York (2013), and Tennessee (2013). We considered these three mandates to be strong for two reasons: They require all prescribers,
regardless of practice settings, to query the monitoring programs when first prescribing an opioid or benzodiazepine and subsequently at least every twelve months should prescribing continue, and they do not allow prescriber discretion on whether to query the program based on subjective judgment about possible inappropriate use. Because of the limited number of state-quarter pairs in which there were strong mandates of use in our study period (21 of 736 state-quarter pairs), we chose not to differentiate between strong and weak mandates of use in our main analysis, but we examined them separately in an exploratory analysis.

Analysis

The staggered implementation of mandates across states created a natural experiment. Our analysis compared the numbers of opioid prescriptions and Medicaid spending on prescription opioids per 100 Medicaid enrollees in state-quarter pairs exposed to mandates and those not exposed to mandates. We estimated a series of linear models for both outcomes. In addition to the key independent variable of exposure to mandates, we included a set of dichotomous state indicators, one for each state (state fixed effects), to control for across-state differences in the population-adjusted volume of prescriptions and Medicaid spending on prescription opioids dispensed to enrollees. We also included a set of year fixed effects to control for nationwide trends in these outcomes.

In addition, our models controlled for state-level policies and general economic conditions that varied over time, including a dichotomous indicator of newly implemented prescription drug monitoring programs during the study period (for nineteen states), a dichotomous indicator of states’ implementation of Medicaid expansion under the Affordable Care Act in 2014 or the partial implementation of Medicaid expansion between 2011 and 2013, the Medicaid managed care penetration rate, measured as the percentage of all Medicaid enrollees in comprehensive managed care programs; the percentage of the noninstitutionalized population living in poverty (measured at the state-year level); and state-year level unemployment rate. Standard errors were derived by taking into account clustering at the state level.

In our main analysis, we first estimated the effect of any mandate of registration or use. Then, in a separate analysis, we estimated the effects associated with mandates of registration only, mandates of use only, and mandates of both registration and use. Separate analyses were conducted for Schedule II, Schedule III, and all opioids. In an exploratory analysis, we further broke down mandates of both registration and use into mandates of registration and weak mandates of use versus mandates of registration and strong mandates of use, since all three states that adopted relatively strong mandates of use (Kentucky, New York, and Tennessee) also had mandates of registration when their mandates of use went into effect.

Limitations

Our study had several limitations. First, we could not tell whether the changes associated with states’ implementation of mandates that we found reflected a trend toward more appropriate and safer prescribing of opioids to Medicaid patients. Nor were we able to evaluate whether such mandates had any unintended effects that deterred appropriate opioid

Health Aff (Millwood). Author manuscript; available in PMC 2018 April 01.
prescribing. To shed some light on this point, we conducted a separate analysis by focusing on fentanyl, morphine, and hydromorphone—opioids commonly used to treat cancer pain.\textsuperscript{13} Combined, these three drugs accounted for 7.6 percent of all prescription opioids dispensed to Medicaid enrollees.

Second, we did not have data on actual prescribers' registration with and use of their state's drug monitoring program. Because of their aggregate nature, the Medicaid State Drug Utilization Files did not allow us to derive patient-level measures such as daily morphine milligram-equivalent doses, multiple provider episodes (an indicator of possible misuse of controlled substances), or overlapping opioid prescriptions or total days of supply—measures that would capture high-risk patient behaviors related to opioid prescriptions. Thus, our study is unable to shed much light on the behavioral pathways by which state mandates had an effect on prescription opioid use.

Third, states that adopted mandates might have experienced more rapid growth in the opioid epidemic compared to other states, which would tend to bias our results in the direction of suggesting that the mandates lacked effects. Alternatively, implementation of mandates might have coincided with other reasons for changes in opioid prescriptions, such as Medicaid policies limiting coverage of high-dose opioid prescriptions or placing certain opioids on more restrictive formulary tiers,\textsuperscript{30} which would bias our estimates in the opposite direction. Thus, our results are associational rather than causal, but the net impact of the biases (after they cancel each other out) is unknown.

\section*{Study Results}

Based on our data for 736 state-quarter pairs, the average number of opioid prescriptions per quarter per 100 Medicaid enrollees was 21.3 (95\% confidence interval: 20.7, 21.8). Schedule II (average: 14.9; 95\% CI: 14.5, 15.3) and Schedule III opioids (average: 6.4; 95\% CI: 6.3, 6.6) accounted for 70 percent and 30 percent of all opioids, respectively. Average total Medicaid spending per quarter per 100 enrollees on all opioids was $874.0 (95\% CI: 839.5, 908.4), of which $519.4 (95\% CI: 500.1, 538.7) was spent on Schedule II and $354.5 (95\% CI: 331.6, 377.5) on Schedule III opioids (dollar amounts do not sum to total because of rounding).

Our analysis indicated that mandates of any kind, of either registration or use, were associated with a 9–10 percent reduction in the use of Schedule II opioids by Medicaid enrollees over our study years, 2011–2014. The average numbers of Schedule II opioid prescriptions per quarter per 100 Medicaid enrollees were 15.3 without any mandate, compared to 13.9 with some kind of mandate (Exhibit 1). Average Medicaid spending on Schedule II opioids per quarter per 100 enrollees over the study years was $536.7 without any mandate, compared to $477.0 with a mandate (Exhibit 2). The difference in the numbers of Schedule III opioid prescriptions between states with and those without mandates was minimal and not significant (Exhibit 1). There was a difference of 6.6 percent in the numbers of all opioid prescriptions between states with and those without mandates, but that change was not significant.
In our analysis that differentiated between mandates of registration and mandates of use, we found that both the numbers of prescriptions and the amounts of Medicaid spending were significantly lower (by approximately 10 percent) in states with a mandate of registration alone or a mandate of registration and use, compared to states with no mandate (Exhibits 3 and 4). In contrast, having a mandate of use alone was not associated with a significant decrease in Schedule II opioid prescriptions or spending. None of the mandate policy categories was associated with significant changes in the number of prescriptions of or spending on Schedule III opioids or all opioids (data not shown).

Full regression outputs of our main analyses are provided in Appendix A4.21 Our exploratory analysis further broke down mandates of use into strong versus weak mandates and examined changes in both outcomes associated with five categories of mandate policies (Appendix A5).21 Similar to the results in our main analysis, mandates of registration alone were associated with a reduction of more than 10 percent in both outcomes, compared to no mandates. Mandates of use alone (all of which were considered weak mandates) did not have an effect on either outcome. Changes associated with mandates of registration and weak mandates of use were similar to those associated with mandates of registration and strong mandates of use.

In the analysis that focused on drugs commonly used for cancer pain, we did not find any mandate policy to be associated with a significant change in the number of prescriptions of or Medicaid spending on these drugs (Appendix A6).21

Discussion
The past few years have seen an acceleration in states' adoption of statutory mandates that prescribers register with their state's prescription drug monitoring program, use the program, or both. Our analysis of data from the Medicaid State Drug Utilization Files indicated that such mandates implemented in the period 2011–14 were associated with a reduction of 9–10 percent in population-adjusted prescriptions of and Medicaid spending on Schedule II opioids for enrollees. No effect was seen for Schedule III opioids. Our results also suggest that reductions in numbers of Schedule II opioid prescriptions were largely associated with mandates of registration and not with mandates of use—which were generally weak during our study period. Our estimates suggest that if every state adopted a mandate of registration, Medicaid programs nationwide would save over $166 million (95% CI: 18 million, 314 million) from reduced spending on Schedule II opioids over 12 months (Appendix A7).21

An important policy implication is that mandates of registration alone could be effective in promoting safer and more contained prescribing of opioids with the highest potential for abuse and dependence. This is contrary to the common belief that mandating registration only might have limited effects, since mandates of registration alone do not guarantee that prescribers will actually use the monitoring programs.21 Since registration with the system was the prerequisite for querying it, mandates of registration might have substantially lowered the initial hurdle involved in using the system by making prescribers familiar with the process of using it. In addition, the fact that such mandates require all prescribers to
register with the monitoring program might have further raised prescribers' awareness of misuse and abuse of controlled substances among their patients, leading to subsequent changes in prescribing practices. If it is indeed the case that mandates of registration would encounter far less pushback from the provider community and are less costly to enforce (for example, registration can be enforced as a condition for license renewal), compared to mandates of use, states that do not yet have any mandate in place should consider adopting at least mandates of registration.

Our findings suggest that mandates of use alone implemented before 2015 had limited effects on the numbers of opioid prescriptions received by Medicaid enrollees or Medicaid spending on these drugs. Consistently, mandates of use had very limited incremental effects when combined with mandates of registration. Of note, in seventeen of the twenty states that implemented some mandate of use during our study period, the mandates were of limited scope (for example, applying only to prescribers in opioid addiction treatment programs), strength (for example, relying on prescribers' judgment to determine the need to query the drug monitoring program), or both. Our findings suggest that weak mandates of use are unlikely to be an effective tool to induce population-wide changes in opioid prescribing.

Three states (Kentucky, New York, and Tennessee) adopted strong mandates of use during our study period. Our exploratory analysis did not find a greater reduction in opioid use by Medicaid patients associated with these strong mandates of use (all of which were in combination with mandates of registration), compared to weak mandates of use in combination with a mandate of registration. This is in contrast to findings of single-state evaluations that have reported rapid increases in prescribers' use of the monitoring programs, reductions in multiple provider episodes, and reductions in total volume of prescribing of certain drugs after the programs were implemented. Although our study used a much stronger design than the single-state before-and-after approach, we had a limited number of states with strong mandates and limited follow-up time after their implementation (nine quarters for Kentucky, five for New York, and seven for Tennessee). Thus, our findings are at best preliminary and need to be revisited as more recent data become available.

In addition, future studies using data that capture patient-level high-risk opioid prescription patterns will shed more definitive light on the effectiveness of mandates in changing prescribing behaviors.

Despite encouraging evidence that supports the use of mandates, enforcement remains a challenge—but more so for mandates of use than for mandates of registration. For example, Massachusetts adopted a policy according to which the renewal of a prescriber's registration to prescribe controlled substances triggers the prescriber's registration with the prescription drug monitoring program. Such approaches are believed to be more effective and efficient than campaigns to recruit prescribers to register voluntarily.

For mandates of use—especially strong mandates with comprehensive coverage of prescribers and clinical circumstances—no such readily regulatory mechanisms are available for enforcement. Extensive state monitoring of prescribers' compliance may not be possible—or if it is possible, it may be costly. However, provider organizations may be able to regulate their members by integrating monitoring program reports with electronic medical
records, health information exchange systems, or both\textsuperscript{32} and by enforcing queries of the drug monitoring program as a condition of prescribing under defined circumstances. Technical barriers to such regulation could be surmountable, but there might be a lack of incentives on the part of provider organizations to implement the regulation, especially if prescribers strongly resist complying with the mandate of use. In addition, data security and patient confidentiality remain serious concerns when patient data are integrated across different systems.\textsuperscript{32}

Conclusion

Our analysis of aggregate Medicaid dmg utilization data indicates that state mandates for prescribers to register with or use the prescription drug monitoring programs adopted in 2011–14 were associated with reductions of 9–10 percent in population-adjusted numbers of Schedule II opioid prescriptions received by Medicaid enrollees and amounts of Medicaid spending on these prescriptions. This reduction was largely associated with mandates for prescribers to register with their state’s monitoring program and not with the generally weak mandates to use the programs that we found in the study period. States’ adoption of mandates has accelerated in recent years. Future studies need to provide updated assessments of the role of strong mandates of use in ensuring safer and more appropriate use of prescription opioids.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

An early version of this article was presented at the AcademyHealth Annual Research Meeting in Boston, Massachusetts, June 27, 2016. This work was funded by a pilot grant from the Center for Health Economics of Treatment Interventions for Substance Use Disorders, NIDA, and NIDHIV, a National Institute on Drug Abuse Center of Excellence (Grant No. P50DA04050). Bruce Schackman and Brandon Aden are funded by the National Institute on Drug Abuse (Grant No. P50DA04050). The authors thank the National Alliance for Model State Drug Laws for providing the effective dates of state mandates. The authors also thank Philip Jeng for his excellent assistance with the manuscript.

Notes


21. To access the Appendix, click on the Appendix link in the box to the right of the article online.


Biographies

Hefei Wen is an assistant professor of health management and policy at the University of Kentucky, in Lexington.

Bruce R. Schackman is a professor of healthcare policy and research at Weill Cornell Medical College, in New York City.
Brandon Aden is an assistant professor of medicine and of healthcare policy and research at Weill Cornell Medical College.

Yuhua Bao (yub2003@med.cornell.edu) is an associate professor of healthcare policy and research at Weill Cornell Medical College.
Average predicted numbers of opioid prescriptions per 100 Medicaid enrollees per quarter in states with and without mandates for prescribers to register with or use the prescription drug monitoring program, 2011–14

Source/Notes: SOURCE Authors’ analysis of data for 2011–14 from the Medicaid State Drug Utilization Files. NOTES Schedule II opioids are the subclass of prescription opioids with the highest risk of abuse and dependence. Schedule III opioids have a lower potential for abuse and dependence than Schedule II opioids. As explained in the text, Alabama, Missouri, Pennsylvania, Utah, and the District of Columbia were excluded from the analysis. The error bars indicate 95% confidence intervals. **p < 0.05
Exhibit 2.
Average predicted Medicaid spending on prescription opioids per 100 enrollees per quarter in states with and without mandates for prescribers to register with or use the prescription drug monitoring program, 2011–14

Source/Notes: SOURCE Authors' analysis of data for 2011–14 from the Medicaid State Drug Utilization Files. NOTES Spending (in 2014 dollars) is before rebates paid by drug manufacturers. Schedule II and Schedule III opioids are explained in Exhibit 1 Notes. As explained in the text, Alabama, Missouri, Pennsylvania, Utah, and the District of Columbia were excluded from the analysis. The error bars indicate 95% confidence intervals. **p < 0.05
Exhibit 3.
Average predicted numbers of prescriptions for Schedule II prescription opioids per 100 Medicaid enrollees per quarter in states with and without mandates for prescribers to register with and/or to use the prescription drug monitoring program, 2011–14

Source/Notes: Authors’ analysis of data for 2011–14 from the Medicaid State Drug Utilization Files. NOTES Schedule II opioids are explained in the Exhibit 1 Notes. Mandates of registration require prescribers to register with the state’s monitoring program. Mandates of use require that prescribers use the program under certain circumstances, such as for a new prescription. Significance denotes the difference between a mandate policy category and no mandate. As explained in the text, Alabama, Missouri, Pennsylvania, Utah, and the District of Columbia were excluded from the analysis. The error bars indicate 95% confidence intervals. **p < 0.05.
Exhibit 4.
Average predicted Medicaid spending on Schedule II prescription opioids per 100 enrollees per quarter in states with and without mandates for prescribers to register with and/or to use the prescription drug monitoring program, 2011–14
Source/Notes: Source: Authors’ analysis of data for 2011–2014 from the Medicaid State Drug Utilization Files. NOTES: Spending (in 2014 dollars) is before rebates paid by drug manufacturers. Schedule II opioids are explained in the Exhibit 1 notes. Mandate policy categories are explained in the Exhibit 3 Notes. Significance denotes the difference between a mandate policy category and no mandate. As explained in the text, Alabama, Missouri, Pennsylvania, Utah, and the District of Columbia were excluded from the analysis. The error bars indicate 95% confidence intervals. **p < 0.05.
Medicaid Drug Utilization Review
State Comparison / Summary Report
FFY 2016 Annual Report
Prescription Drug Fee-For-Service Programs

October 2017
Executive Summary of 2016 State Medicaid DUR Annual Reports

DUR is a two-phase process that is conducted by the Medicaid state agencies. In the first phase, Prospective DUR (ProDUR), the state’s Medicaid agency’s electronic monitoring system screens prescription drug claims to identify problems such as therapeutic duplication, drug-disease contraindications, incorrect dosage or duration of treatment, drug allergy, and clinical misuse or abuse. The second phase, Retrospective DUR (RetroDUR), involves at least quarterly examination of claims data to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care and implements corrective action when needed.

Each State Medicaid program under Section 1927(g)(3)(D) of the Social Security Act (the Act) is required to submit an annual report on the operation of its Medicaid Drug Utilization Review (DUR) program. States are required to report on their prescribing patterns, cost savings generated from their DUR programs and their programs’ operations, including adoption of new innovative DUR practices. On February 23, 2017, the Centers for Medicare & Medicaid Services (CMS) sent the FFY 2016 Medicaid DUR Annual Reporting tool to states for completion. The Medicaid DUR Utilization Review State / Comparison Summary Report, which compiles the state report findings, is published on Medicaid.gov annually and serves as a resource for states, researchers and CMS on the topic of DUR in Medicaid programs. Below is a brief summary of the findings.

I. Demographics

All states including the District of Columbia submitted a 2016 Medicaid DUR Annual Report, with the exception of Arizona. The information reported is focused primarily on Medicaid Fee-For-Service DUR activities. For Federal Fiscal Year (FFY) 2016 and 2017, states were not required to submit an annual report on the specifics of Medicaid managed care organization (MCO) DUR activities. However, states and MCOs are required to submit an annual report for the FFY 2018 DUR reporting period and every FFY period thereafter.

II. Prospective DUR (ProDUR)

ProDUR functions are done at the point-of-sale (POS) when the prescription is being filled at the pharmacy. Forty-five states (90%) contract with an outside vendor to process their POS claims. Thirty-eight states (76%) use First Data Bank as their ProDUR criteria source. All states set early refill thresholds as a way of preventing prescriptions from being refilled too soon. States reported thresholds ranging from 70% to 90%, with an average of 79% of the prescription being used before a non-controlled prescription could be refilled. For controlled drugs, which include opioids for example, the range reported is 70% to 100%, with an average of 84% of the prescription being used before the prescription could be refilled.

III. Retrospective DUR (RetroDUR)

RetroDUR allows states to examine drug claims to identify patterns of abuse or misuse. These functions reside primarily with a contractor in 34 states and with an academic organization in 11 states. The DUR Board identifies those categories of prescription claims to be examined to screen for patterns of fraud, abuse, gross overuse, or medically unnecessary care and then takes corrective actions. In 43 states (86%), the DUR Board approves the RetroDUR criteria to be followed by the contracted organization.
IV. DUR Board Activity

The states provided a summary of their DUR Board activities, which can be found in each individual state report. Seven states (14%) reported that they have Medication Therapy Management (MTM) programs approved by CMS. MTM is a professional service, separate from the function of dispensing prescriptions, provided by pharmacists whose aim is to optimize drug therapy and improve therapeutic outcomes for patients.

V. Physician Administered Drugs

To date, 13 states (26%) for the Prospective DUR and 22 states (44%) for the Retrospective DUR have designed or redesigned their Medicaid Management Information System (MMIS) systems to incorporate Physician Administered Drugs (i.e. drugs paid through the physicians and hospitals programs) into their DUR criteria.

VI. Generic Policy and Utilization Data

All states reported generic utilization percentages for all covered outpatient drugs reimbursed during the 2016 reporting period. The average percentage generic utilization was 82%, which accounts for an average of 22% of the total dollars reimbursed by Medicaid for drugs during the reporting period.

VII. Program Evaluation /Cost Savings/Avoidance

Based on states’ reported estimates, DUR activities saved on average about 18% on drug cost savings/cost avoidance compared to the total Medicaid drug spend.

VIII. Fraud, Waste and Abuse Detection

A. Lock-In Programs

Almost all Medicaid agencies, except Florida, 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. Lock-In programs restrict beneficiaries whose utilization of medical services is documented as being excessive. Beneficiaries are restricted to specific provider(s) in order to monitor services being utilized and reduce unnecessary or inappropriate utilization. In addition, 24 states (48%) have a documented process in place that identifies potential fraud or misuse of non-controlled drugs by a beneficiary.

Thirty-nine states (78%) have a process to identify potential fraudulent practices by prescribers, and thirty-six states (72%) have a process to identify potential fraudulent practices by pharmacies. These processes trigger actions such as denying claims written by that prescriber or claims submitted by that pharmacy, alerting the state Integrity or Compliance Unit to investigate, or referring to the appropriate licensing Board or another state governmental agency (e.g. Attorney General, OIG and DEA) for follow-up.
B. Prescription Drug Monitoring Programs

Prescription Drug Monitoring Programs (PDMPs) are statewide electronic databases that collect designated data on controlled substances that are dispensed in the state. Depending on the state, physicians and pharmacists have access to these databases to identify prescribers and patients that are engaging in potential fraud or misuse of controlled substances. In 2016, forty-nine states (98%) reported having a PDMP in their state. Twenty-six states (53%) have some ability to query the PDMP database, while the remaining twenty-three states (47%) do not have the ability to do so.

Only 13 states (27%) require that prescribers access the patient history in the database prior to prescribing restricted (controlled) substances. As of the close of this reporting period, Missouri reports to be the only state that is not implementing a PDMP. While 19 states (39%) report that they also have access to Border States PDMPs, thirty-six states (73%) indicated that they face a range of barriers that hinder their ability to fully access and utilize the database to curb abuse.

C. Pain Management Control

Fourteen states (28%) reported that they obtained the Drug Enforcement Administration (DEA) Active Controlled Substance Registrant’s File in order to identify those prescribers not authorized to prescribe controlled drugs. Forty-four states (88%) reported having measures in place to either monitor or manage the prescribing of methadone for pain management.

D. Opioids

Thirty-seven states (74%) have edits in place to limit the quantity of short-acting opioids and thirty-nine states (78%) have edits in place to limit the quantity of long-acting opioids.

E. Morphine Equivalent Daily Dose (MEDD)

Eighteen states (36%) have set recommended Morphine Equivalent Daily Dose (MEDD) screens. The state limits the amount of products containing morphine or morphine derivatives that a patient may receive in a specific time frame in order to reduce potential abuse or diversion. Twelve states (24%) report that they give providers information on how to calculate the MEDD.

F. Buprenorphine and Buprenorphine/Naloxone Combinations

Forty-three states (86%) set limits on the daily milligrams of buprenorphine that can be prescribed. Details on the limit amounts, length of treatment and maintenance dosing can be found in the report.

G. Antipsychotics/Stimulants

Forty-three states (86%) have programs in place to either manage or monitor the appropriate use of antipsychotic medications in children. Thirty-eight of these states (88%) monitor all children, not just those children in foster care or a subset of children specified by a young age limit. The 43 states have provided a brief synopsis of the specifics of their programs. Delaware and Montana only monitor children in foster care. It should be noted that some states have legislation in place that prohibits any restriction being placed on the prescribing of medications used to treat mental or behavioral health conditions. Forty-seven states (94%) have restrictions or special programs in place to either monitor or control the use of stimulants.
IX. Innovative Practices

Thirty-seven states (74%) listed in the full report have submitted innovative practices that they initiated.

X. E-Prescribing

Twenty-one states (42%) have the capability to enable the prescriber to access patient data history and pharmacy coverage limitations prior to prescribing for a specific patient. Electronic prescribing helps to improve the quality of the prescribing process and helps providers identify drugs that have lower-cost generics or are more cost effective.

XI. Managed Care Organizations (MCOs)

States are currently not required to report on the nature and scope of DUR activities in their MCOs, even though more states are moving their beneficiaries into MCOs. Thirty-eight states (76%) have MCOs. Nineteen states (50%) report that prescription coverage is included (carved-in) to the capitation rate. Eighteen states (47%) report the agency sets requirements for the MCO pharmacy benefit. Twenty-nine states (76%) require their MCOs to have a targeted intervention program (i.e. CMC/ Lock-In) for the misuse or abuse of controlled substances. Lastly, only 10 states (26%) require their MCOs to monitor or report their MCO DUR activities.

As stated above, for Federal Fiscal Year (FFY) 2016 and 2017, states were not required to submit an annual report on the specifics of Medicaid managed care organization (MCO) DUR activities. However, states and MCOs are required to submit an annual report for the FFY 2018 DUR reporting period and every FFY period thereafter.

1. In the Medicaid and CHIP Managed Care Final Rule (CMS-2390-F) published on May 6, 2016, CMS finalized that states require MCOs to operate DUR programs that comply with Section 1927(g) of the Social Security Act as well as have the MCOs provide a detailed report of their DUR program activities to the state on an annual basis.
Medicaid Fee for Service Program Drug Utilization Review Annual Report
Comparison/Summary Report FFY 2016

Table of Contents

I. DEMOGRAPHICS ................................................................. 1
II. PROSPECTIVE DUR (ProDUR) ......................................... 1
III. RETROSPECTIVE DUR (RetroDUR) ................................. 11
IV. DUR BOARD ACTIVITY .................................................. 14
V. PHYSICIAN ADMINISTERED DRUGS ................................. 18
VI. GENERIC POLICY AND UTILIZATION DATA ......................... 19
VII. PROGRAM EVALUATION/COST SAVINGS/COST AVOIDANCE ... 22
VIII. FRAUD, WASTE AND ABUSE DETECTION ......................... 27
      A. LOCK-IN or PATIENT REVIEW AND RESTRICTIVE PROGRAMS ... 27
      B. PRESCRIPTION DRUG MONITORING PROGRAM (PDMP) ........... 35
      C. PAIN MANAGEMENT CONTROLS ..................................... 40
      D. OPIOIDS ...................................................................... 42
      E. MORPHINE EQUIVALENT DAILY DOSE (MEDD) ..................... 46
      F. BUPRENORPHINE and BUPRENORPHINE/NALOXONE COMBINATIONS ... 49
      G. ANTIPSYCHOTICS/STIMULANTS ..................................... 53
IX. INNOVATIVE PRACTICES .................................................. 60
X. E-PRESCRIBING ............................................................... 61
XI. MANAGED CARE ORGANIZATIONS (MCOs) ............................. 62

2016 DUR Comparison/Summary Report –October 2017
I. DEMOGRAPHIC INFORMATION

49 States plus DC completed the FFY 2016 Medicaid DUR Annual Report. AZ has the majority of its Medicaid population in Managed Care Organizations (MCOs); therefore, the state is not currently required to submit an annual DUR report.

II. PROSPECTIVE DUR (ProDUR)

II-1. Indicate the type of your pharmacy POS vendor – (Contractor, State-operated, or Other).

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>State-operated</td>
<td>IL, MN, ND, SD, WA</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Contractor</td>
<td>AK, AL, AR, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IN, KS, KY, LA, MA, MD, MI, MO, MS, MT, NC, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, TN, TX, UT, VA, VT, WI, WV, WY</td>
<td>45 (90%)</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Vendor | State
--- | ---
Change Healthcare | IA, ME, UT, VT, WY
Conduent | CA, HI, MA, MS, MT, NM
CSRA | NC, NY
DXC* | AL, KS, PA, RI
HID* | TX
HPF* | CT, DE, OK, OR*, WI
Magellan | AK, AR, DC, FL, ID, KY, ME, NE, NH, SC, TN
Molina | LA, NE, NV
OptumRx | GA, IN, NV
Other | N/A
State-operated | IA, MN, ND, SD, WA
Wipro Infocomm Healthcare Services Inc. | MO
Xerox | CO, MD, OH, VA

Note

*Change Healthcare Formerly Goold Health Systems
*Conduent Formerly Xerox State Healthcare, LLC
*DXC Formerly Hewlett Packard Enterprise Services
*HID Health Information Designs
*HPF Hewlett Packard Enterprise
*OR Hewlett Packard Enterprise Services operates the POS claims system and Prospective DUR services. Oregon State University (OSU)/Oregon Health Sciences University (OHSU) College of Pharmacy is subcontracted to operate the Retrospective DUR services.
*OH Xerox State Healthcare through June 11, 2016 Goold Health Systems beginning June 12, 2016
II-2. If not State-operated, is the POS vendor also the MMIS Fiscal agent?

| Answer | State | Number of States
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AL, CA, CO, CT, DE, HI, KS, LA, MD, MS, MT, NC, NJ, NM, NY, OK, PA, RI, VA, WI, WV</td>
<td>21 (47%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, AR, DC, FL, GA, IA, ID, IN, KY, MA, MD, ME, MI, NE, NH, NV, OH, OR, SC, TN, TX, UT, VT, WY</td>
<td>24 (53%)</td>
</tr>
</tbody>
</table>

II-3. Identify the prospective DUR criteria source.

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Data Bank</td>
<td>AK, AL, AR, CA, CO, CT, DC, FL, HI, ID, IL, KS, KY, LA, MA, MD, MI, MS, MO, MS, MT, NC, ND, NE, NH, NM, NY, OK, OR, PA, RI, SC, SD, TN, VA, WI, WV</td>
<td>38 (76%)</td>
</tr>
<tr>
<td>Medispan</td>
<td>GA, IA, IN, NV, UT, WA, WY</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>Other</td>
<td>DE, ME, OH, TX, VT</td>
<td>5 (10%)</td>
</tr>
</tbody>
</table>

If the answer to II-3 above is "Other", please specify:

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>DE</td>
<td>Micromedex</td>
</tr>
<tr>
<td>ME</td>
<td>Medispan, Clinical Literature, CMS and FDA alerts and other State programs.</td>
</tr>
<tr>
<td>OH</td>
<td>First DataBank through June 11, 2016 Medispan beginning June 12, 2016</td>
</tr>
<tr>
<td>TX</td>
<td>Some of the pre-DUR criteria are from First Data Bank and some others, such as the high acetaminophen dose, are set by the states.</td>
</tr>
<tr>
<td>VT</td>
<td>Medispan, Clinical Literature, FDA Safety Alerts</td>
</tr>
</tbody>
</table>

II-4. Are the new prospective DUR criteria approved by the DUR Board?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, CO, CT, DC, DE, FL, HI, IL, IN, KS, KY, IA, LA, MA, ME, MS, MT, NC, NJ, NM, NY, OK, PA, TX, UT, VA, VT, WI, WV, WY</td>
<td>31 (62%)</td>
</tr>
<tr>
<td>No</td>
<td>AR, CA, GA, IA, ID, MD, MI, MN, MO, ND, NE, NV, OK, OR, RI, SC, SD, TN, WA</td>
<td>19 (38%)</td>
</tr>
</tbody>
</table>

2016 DUR Comparison/Summary Report –October 2017
If the answer to II-4 above is "No", please explain:

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AR</td>
<td>New ProDUR criteria for new drugs to system are automatically updated as new drugs are added to the system.</td>
</tr>
<tr>
<td>CA</td>
<td>The DUR board advises and makes recommendations regarding prospective DUR criteria; however, final approval is made by DHCS.</td>
</tr>
<tr>
<td>GA</td>
<td>Criteria is from Medispan.</td>
</tr>
<tr>
<td>IA</td>
<td>This is a collaborative effort between the State, POS Contractor and DUR. Most new Proposed criteria are reviewed by the DUR.</td>
</tr>
<tr>
<td>ID</td>
<td>The DUR Board reviews; however, they do not approve or disapprove any vendor criteria.</td>
</tr>
<tr>
<td>MD</td>
<td>Although the DUR Board does not review and approve all new prospective DUR criteria, a summary of prospective DUR alerts is reviewed and discussed at all DUR meetings. Individual criteria may be recommended by the Board for implementation. All new severity level 1 drug intervention criteria is automatically implemented by the point-of-sale (POS) vendor as it becomes available from First Data Bank.</td>
</tr>
<tr>
<td>MI</td>
<td>MDHHS and the DUR Board reviewed the ProDUR criteria when the First Data Bank (FDB) criteria was first implemented. After that, the Board felt comfortable with the completeness of the FDB criteria.</td>
</tr>
<tr>
<td>MN</td>
<td>Informational edits are not reviewed by the DUR Board. High dose or quantity limit edits which cause the claim to reject are reviewed by the DUR Board.</td>
</tr>
<tr>
<td>MO</td>
<td>Automatic updates are made from FirstDataBank which are incorporated in our DUR criteria.</td>
</tr>
<tr>
<td>ND</td>
<td>The DUR Board meets quarterly so their responsibility is to review all new retrospective DUR criteria.</td>
</tr>
<tr>
<td>NE</td>
<td>The DUR Board recommends criteria, however, final approval is made by DHCS.</td>
</tr>
<tr>
<td>NV</td>
<td>Medispan provides the criteria, the DUR Board does not review or approve new criteria.</td>
</tr>
<tr>
<td>OR</td>
<td>DUR criteria are updated by FDB. There is an ability to modify how the alerts are responded to (override required or information only), but not to change the criteria itself.</td>
</tr>
<tr>
<td>RI</td>
<td>The prospective DUR criteria is auto loaded from First Data Bank.</td>
</tr>
<tr>
<td>SC</td>
<td>Criteria is primarily provided by FDB and not reviewed by the DUR Board. Edits outside of these provided by FDB or existing edits may reviewed/recommended by the State.</td>
</tr>
<tr>
<td>SD</td>
<td>DUR reviews retrospective claims data.</td>
</tr>
<tr>
<td>TN</td>
<td>DUR Board reviews products that become an issue. With a 3-hr quarterly meeting, it's not possible to review all new products, nor is it necessary.</td>
</tr>
<tr>
<td>WA</td>
<td>Standard automated DUR criteria which are overridable by pharmacists with the use of submitted DUR codes are provided through the MediSpan drug file and applied by the OptumRx claim processing system. These DUR criteria are not reviewed by the DUR Board. Active DUR criteria in the form of prior authorization requirements (including quantity and dosing limits, step therapy, etc.) applied by the state which are based solely on the definition of medically accepted indications are also not reviewed by the DUR Board, as federal rule already requires the state to use medically accepted indications as a standard. The DUR Board reviews these active Prospective DUR criteria which represent predetermined standards more stringent than medically accepted indication alone.</td>
</tr>
</tbody>
</table>

II-5. When the pharmacist receives a Pro DUR message that requires a pharmacist's review, does your system allow the pharmacist to override the alert using the "conflict, intervention and outcome" codes?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>43 (86%)</td>
</tr>
<tr>
<td>No</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>AK, AL, AR, CA, CT, DC, DE, FL, GA, ID, IN, KS, KY, LA, MA, MD, MI, MO, MS, MT, NC, ND, NE, NH, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
<td></td>
</tr>
</tbody>
</table>
Il-6. How often do you receive and review periodic reports providing individual pharmacy provider activity in summary and in detail?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monthly</td>
<td>AL, CT, DC, KY, MA, MS, MT, NC, ND, NE, NH, NM, VA</td>
<td>13 (26%)</td>
</tr>
<tr>
<td>Quarterly</td>
<td>AR, DE, GA, HI, IL, NV, NY, OK, OR, SC, VT</td>
<td>11 (24%)</td>
</tr>
<tr>
<td>Annually</td>
<td>CA, IA, PA, RI, SD, TX, UT</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>Never</td>
<td>AR, CO, FL, IA, ID, IL, IN, KS, MD, ME, MI, MN, MO, NJ, TN, WA, WI, WV</td>
<td>18 (36%)</td>
</tr>
</tbody>
</table>

a) If the answer to Il-6 above is “Never”, please explain why you do not receive and review the reports.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AR</td>
<td>We have not requested the contractor to provide ProDUR response reports on individual pharmacies. Instead, we requested the contractor to provide reports on the drugs involved in ProDUR edits with the highest number of overrides (therapeutic duplication (TD), early refill (ER), drug-drug interaction (DDI)) to look for reasons for the overrides. It was found that the vast majority of the overrides were for the 2 drug classes that had TD of 2 concurrent agents and were the 2 drug classes where we allow TD in the PA point of sale criteria algorithm (LA opioid + SA opioid, and SA C-II stimulant for booster dose = LA C-II stimulated). For the early refill override, after changing to Magellan as the pharmacy vendor, we were able to implement a hard edit on ER of non-controlled drugs if pharmacy tried to fill earlier than 75% of days' supply expired. In addition, we were able to place an &quot;accumulation&quot; edit on all drugs (controlled drugs and non-controlled drugs) that were filled early (e.g., 7 days early, which is at the 75% level that is set for almost all drugs and does not require a PA) and the beneficiary can only &quot;accumulate&quot; a total of 15 days' supply &quot;early&quot; on each drug entity (same drug/same strength/same dosage form) during a 180 day look-back period to decrease/excessive stockpiling/abuse of drugs. The ProDUR edit for drug-drug interactions that were overridden were not contraindicated in the literature, they only said dispense with caution, which leaves it up to the professional judgment of the pharmacist filling the prescription. It was more beneficial to actually review the drugs involved in the ProDUR categories than to review massive reports on individual pharmacies that would tell us nothing helpful.</td>
</tr>
<tr>
<td>CO</td>
<td>This will be changing in February 2017, when transitioning to Magellan PBMS.</td>
</tr>
<tr>
<td>FL</td>
<td>The Medicaid Program Integrity department reviews the pharmacy provider activity, not Pharmacy Policy.</td>
</tr>
<tr>
<td>IA</td>
<td>We do not allow overrides at the pharmacy level. Individual pharmacy claim activity is reviewed biannually, by the top 100 pharmacies by paid amount and top 100 pharmacies by prescription count.</td>
</tr>
<tr>
<td>ID</td>
<td>An individual pharmacy provider report is not generated at this time.</td>
</tr>
<tr>
<td>IL</td>
<td>The MMIS system in place for FY16 does not have this capability.</td>
</tr>
<tr>
<td>IN</td>
<td>The claims processing system has logic in place to determine appropriate pharmacy provider submissions of conflicts, interventions, and outcome codes. We continue to evaluate the utility of this type of reporting.</td>
</tr>
<tr>
<td>KS</td>
<td>The State pharmacy department is currently discussing what process can be used to monitor this.</td>
</tr>
<tr>
<td>MD</td>
<td>Reports are generated and reviewed ad hoc or as necessary.</td>
</tr>
<tr>
<td>MN</td>
<td>We do not have plans to use them. If the concern is large enough, the State pharmacy department from the future.</td>
</tr>
<tr>
<td>ME</td>
<td>Currents we do allow pharmacies to override conflict/interactions as they are not messaging back to the pharmacies.</td>
</tr>
<tr>
<td>NJ</td>
<td>Prospective DUR alerts cannot be overridden by the pharmacy provider.</td>
</tr>
<tr>
<td>TN</td>
<td>Haven’t thought about it. We have to trust our network pharmacists’ judgment. At the same time, some DUR alerts that are routinely overridden should be investigated. This type of a report/overview/analysis might be valuable if it was very specific and a target was identified. To this point, the Board or the State's staff has not considered this. Perhaps in the future.</td>
</tr>
<tr>
<td>WA</td>
<td>Washington Medicaid considers potential misuse of submitted DUR codes to be an issue of fraud and abuse, rather than a clinical issue, and defer review of submitted DUR codes to the SURF audit function as permitted under 42 CFR 456.714, and limits the review activities of DUR staff to those that focus on what constitutes appropriate and medically necessary use. Use of DUR codes is not specifically followed up on in reporting across all pharmacy providers, but are reviewed for accuracy and appropriateness during individual pharmacy audits.</td>
</tr>
<tr>
<td>WI</td>
<td>Wisconsin is currently in the process of modifying the DUR alerts. After completion of this work, Wisconsin will need to evaluate and revise the prospective DUR reports.</td>
</tr>
<tr>
<td>WV</td>
<td>They are received upon request.</td>
</tr>
<tr>
<td>WY</td>
<td>They have been reviewed in the past and were not found very useful.</td>
</tr>
</tbody>
</table>
b) If you receive reports, do you follow-up with those providers who routinely override with interventions?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 32 States)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, DC, DE, KY, LA, MA, MI, NC, ND, NE, SC, SD, UT</td>
<td>14 (44%)</td>
</tr>
<tr>
<td>No</td>
<td>CA, CT, GA, HI, MS, MT, NH, NM, NV, NY, OH, OK, OR, PA, RI, TX, VA, VT</td>
<td>18 (56%)</td>
</tr>
</tbody>
</table>

c) If the answer to b) above is "Yes", by what method do you follow-up?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 14 States)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact pharmacy</td>
<td>AK, DC, LA, MA, ND, NE, SD</td>
<td>7 (50%)</td>
</tr>
<tr>
<td>Refer to Program Integrity for Review</td>
<td>DE, NC, SC</td>
<td>3 (21%)</td>
</tr>
<tr>
<td>Other (explain)</td>
<td>AL, KY, MI, UT</td>
<td>4 (29%)</td>
</tr>
</tbody>
</table>

If the answer to b) above is "Other", please explain:

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AL</td>
<td>Alabama Medicaid has an Academic Detailing program that provides scheduled face-to-face visits to providers.</td>
</tr>
<tr>
<td>KY</td>
<td>We do both Contact Pharmacy and Refer to Program Integrity for Review.</td>
</tr>
<tr>
<td>MI</td>
<td>We would contact pharmacy and may refer to program integrity for review.</td>
</tr>
<tr>
<td>UT</td>
<td>Situational specificity</td>
</tr>
</tbody>
</table>

II-7. Early Refill:

a) At what percentage threshold do you set your system to edit?

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of States</th>
<th>Percentage Threshold</th>
<th>Average</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-controlled drugs:</td>
<td>50</td>
<td>9%</td>
<td>70%</td>
<td>90%</td>
<td></td>
</tr>
<tr>
<td>Controlled drugs:</td>
<td>50</td>
<td></td>
<td>90%</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

b) When an early refill message occurs, does the State require prior authorization for non-controlled drugs?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CO, CT, DC, DE, FL, GA, HI, ID, IL, IN, KY, MA, MD, ME, MN, MO, MS, MT, NM, NV, NY, OH, OK, PA, SC, TX, UT, VA, VT, WA, WV, WY</td>
<td>36 (72%)</td>
</tr>
<tr>
<td>No</td>
<td>CA, IA, KS, LA, MI, NC, ND, NE, NH, NJ, OR, RI, SD, WI</td>
<td>14 (28%)</td>
</tr>
</tbody>
</table>

2016 DUR Comparison/Summary Report –October 2017 Page 5
If the answer to (b) above is “Yes”, who obtains authorization?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 36 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist</td>
<td>OK, TX, WA</td>
<td>3 (8%)</td>
</tr>
<tr>
<td>Prescriber</td>
<td>ID, MS, NY, TN</td>
<td>4 (11%)</td>
</tr>
<tr>
<td>Either</td>
<td>AK, AL, AR, CO, CT, DC, DE, FL, GA, HI, IL, IN, KY, MA, MD, ME, MI, MT, NM, NV, OH, PA, SC, TN, UT, VA, VT, WV, WY</td>
<td>29 (81%)</td>
</tr>
</tbody>
</table>

If the answer to (b) above is “No”, can the pharmacist override at the point of service?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 14 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CA, KS, LA, MI, NC, ND, NE, OR, RI, WI</td>
<td>10 (71%)</td>
</tr>
<tr>
<td>No</td>
<td>IA, NH, NJ, SD</td>
<td>4 (29%)</td>
</tr>
</tbody>
</table>

(c) When an early refill message occurs, does the State require prior authorization for controlled drugs?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 41 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CO, CT, DC, DE, FL, GA, HI, ID, IL, IN, KY, MA, MD, ME, MI, MN, MO, MS, MT, ND, NE, NM, NV, NY, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
<td>41 (82%)</td>
</tr>
<tr>
<td>No</td>
<td>CA, IA, KS, LA, NC, NH, NJ, OR, RI</td>
<td>9 (18%)</td>
</tr>
</tbody>
</table>

If the answer to (c) above is “Yes”, who obtains authorization?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 41 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist</td>
<td>MN, OK, TX, WA, WI</td>
<td>5 (12%)</td>
</tr>
<tr>
<td>Prescriber</td>
<td>CT, DE, FL, HI, ID, IN, MS, NY, PA, TN</td>
<td>10 (24%)</td>
</tr>
<tr>
<td>Either</td>
<td>AK, AL, AR, CO, DC, GA, IL, KY, MA, MD, ME, MI, MO, MT, ND, NE, NM, NV, OH, SC, SD, UT, VA, VT, WV, WV, WY</td>
<td>26 (64%)</td>
</tr>
</tbody>
</table>

If the answer to (c) above is “No”, can the pharmacist override at the point of service?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 9 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CA, KS, LA, NC, OR, RI</td>
<td>6 (67%)</td>
</tr>
<tr>
<td>No</td>
<td>IA, NH, NJ</td>
<td>3 (33%)</td>
</tr>
</tbody>
</table>
II-8. When the pharmacist receives an early refill DUR alert message that requires the pharmacist's review, does your state’s policy allow the pharmacist to override for situations such as:

a) Lost/stolen Rx

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CA, KS, LA, MD, MO, NC, NE, NH, OH, OR, RI, SD, TX, WA, WI</td>
</tr>
<tr>
<td>No</td>
<td>AK, AL, AR, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, MA, ME, MI, MN, MS, MT, ND, NJ, NM, NV, NY, OK, PA, SC, TN, UT, VA, VT, WV, WY</td>
</tr>
</tbody>
</table>

b) Vacation

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CA, FL, LA, MD, MO, NC, NE, NH, OH, OR, SD, TX, WI</td>
</tr>
<tr>
<td>No</td>
<td>AK, AL, AR, CO, CT, DC, DE, GA, HI, IA, ID, IL, IN, KS, KY, MA, ME, MI, MN, MS, MT, ND, NJ, NM, NV, NY, OK, PA, RI, SC, TN, UT, VA, VT, WA, WV, WY</td>
</tr>
</tbody>
</table>

c) Other

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AL, AR, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KY, MA, MD, MI, MN, MS, MT, NJ, NM, NV, NY, OK, PA, RI, TN, UT, VA, VT, WV, WY</td>
</tr>
<tr>
<td>No</td>
<td>AK, CA, DE, KS, LA, ME, MO, NC, ND, NE, NH, OH, OR, SC, SD, TX, WA, WI</td>
</tr>
</tbody>
</table>

If the answer to II-8 c) above is “Yes”, please provide details:

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>Lost/stolen only in the event a police report has been filed and upon coordination/approval from prescriber.</td>
</tr>
<tr>
<td>CA</td>
<td>The pharmacist can override the early refill DUR alert message if medically necessary.</td>
</tr>
<tr>
<td>DE</td>
<td>Change in direction can have pharmacist override.</td>
</tr>
<tr>
<td>KS</td>
<td>Spilled medications.</td>
</tr>
<tr>
<td>LA</td>
<td>All other situations may be overridden using the pharmacist's professional judgment.</td>
</tr>
<tr>
<td>ME</td>
<td>Nursing Home admissions.</td>
</tr>
<tr>
<td>MO</td>
<td>All early refill denials require the pharmacist to contact the helpdesk for individual override each time the edit posts.</td>
</tr>
<tr>
<td>NC</td>
<td>Change of Therapy.</td>
</tr>
<tr>
<td>ND</td>
<td>Prescription must be 60% utilized. Will make exceptions for seizure medication.</td>
</tr>
<tr>
<td>NE</td>
<td>Lost or stolen controlled substance require a prior authorization.</td>
</tr>
<tr>
<td>OH</td>
<td>Other early refill reasons include change in dose, patient transitioning to a nursing facility, patient requires two prescriptions of the same IAX, and wrong days supply.</td>
</tr>
<tr>
<td>OR</td>
<td>No explanation provided by state.</td>
</tr>
<tr>
<td>SC</td>
<td>Change in therapy, medically necessary, LTC, are among other accepted clarifications.</td>
</tr>
<tr>
<td>SD</td>
<td>Situational.</td>
</tr>
<tr>
<td>TX</td>
<td>For any early refill reasons, the State requires a phone call from dispensing pharmacy. It requires an HHSC clinical staff to review and, if necessary, reach out to the prescriber for a reasonable explanation.</td>
</tr>
<tr>
<td>WA</td>
<td>Washington State has two levels of early refill rejections, one of which is a 'hard' edit requiring authorization, the other being a 'soft' DUR edit overrideable by pharmacists. Soft early refill edits occur at an ingredient level and are primarily informational regarding what a client has filled at other pharmacies than the one submitting the current claim. Hard early refill edits are specific to the particular pharmacy and prescription being filled, and require authorization. Pharmacists can self-authorize.</td>
</tr>
</tbody>
</table>
II-9. Does your system have an accumulation edit to prevent patients from continuously filling prescriptions early?

<table>
<thead>
<tr>
<th>State</th>
<th>Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>19 (38%)</td>
</tr>
<tr>
<td>No</td>
<td>31 (62%)</td>
</tr>
</tbody>
</table>

If the answer to II-9 above is "Yes", please explain your edit.

**State** | **Explanation**
---|---
AK | Allows for 7 days accumulation over a 120 day look-back period
AL | The Refill Too Soon logic is an Early Refill Accumulation Limit that allows a beneficiary, who fills prescriptions early, a maximum accumulation of 15 days' supply filled early during a 180-day look-back period. If the new daily dose has not increased, the system will calculate the next date of fill automatically based on remaining supply. If the new daily dose has increased, the system will calculate the next date of fill based on the remaining supply from all historical claims.
AR | Refill too soon - carryover days accumulate from month to month
IN | The claims processing system will evaluate the days supply for historical claims against the days supply of new claims. If the new claim's daily dose has increased, the system will extend the look-back period. If the new claim's daily dose has not increased, the system will calculate the next date of fill based on the remaining supply from all historical claims.
KY | The system does have this capability and Kentucky does currently use a three (3) day tolerance per month.
LA | We have accumulation edits on hydrocodone and on proton pump inhibitors. Both edits require clinical override from our prior authorization center.
MI | MI has refill tolerance and dispensing the accumulation edit to prevent patients from continuously filling prescriptions early.
ND | Max 15 days accumulation in 180 days for controlled. Max 10 days accumulation in 180 days for non-controlled.
NY | The enhanced edit denies a claim if more than a 10-day supply of medication is remaining of the cumulative amount that has been dispensed over the previous 90 days, and will augment current editing where claims are denied when less than 75% of the previously dispensed amount has been used (the more stringent rule will apply). Members may, with prescriber intervention, have the ability to refill their prescription(s) early through the process of prior authorization, allowing for ample supply of their medication(s) on hand.
OK | Cumulative Early Refill edit is triggered when the member has received early fills for the medication in the past 240 days and the combined extra day's supply of the early fills is equal to 110% or more of the days' supply on the current claim being submitted. The edit is not up stimulant medications only.
RI | Only allows one original and 5 refills per prescription.
SC | Claim will deny if 75% of previous supply has not been used in non-contro., 85% in controls.
WV | The edit keeps members from getting a thirteen month supply in 12 months by not allowing them to refill their prescriptions early each month, based on the total number of units obtained during a rolling 12-month period.
Scheduled drugs II-V require 90% of the days supply to be used and no more than seven (7) days accumulation over a one hundred eighty (180) day look back period before a refill or new claim for the same medication will be allowed. All other medications require 80% of the days supply be used and no more than fifteen (15) days of accumulated medication over a one hundred eighty (180) day look back period before a refill or a claim for the same medication will be allowed.

If the answer to II-9 above is "No", do you plan to implement this edit?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage of 31 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CO, DC, DE, MA, MD, MS, MT, NC, NE, SD, UT, VT 12 (39%)</td>
</tr>
<tr>
<td>No</td>
<td>CA, CT, HI, IA, KS, ME, MN, MO, NJ, NV, OH, OR, PA, TN, TX, VA, WA, WI 19 (61%)</td>
</tr>
</tbody>
</table>

II-10. Does the state or the state’s Board of Pharmacy have any policy prohibiting the auto-refill process that occurs at the POS?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AL, DE, FL, GA, IL, MA, MD, MS, NC, NE, NY, OK, SC, SD, TN, TX, UT, VA, WV, WY 20 (40%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, AR, CA, CO, CT, DC, HI, IA, ID, IN, KS, KY, IA, ME, MI, MN, MO, MT, ND, NE, NJ, NM, NY, OH, OR, PA, RI, VT, WA, WI 30 (60%)</td>
</tr>
</tbody>
</table>

II-11. Has the state provided DUR data requested on Table I - Top 10 Drug Claims Data reviewed by the DUR Board?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CA, CO, CT, DC, DE, FL, GA, HI, IA, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MS, MT, NC, ND, NE, NJ, NM, NV, NY, OK, OR, SC, SD, TN, TX, UT, VA, VT, WA, WI 43 (86%)</td>
</tr>
<tr>
<td>No</td>
<td>ID, MO, OH, PA, RI, WI, WV, WY 7 (14%)</td>
</tr>
</tbody>
</table>

II-12. Section 1927(g)(A) of the Social Security Act requires that the pharmacist offer patient counseling at the time of dispensing. Who in your state has responsibility for monitoring compliance with the oral counseling requirement? Check all that apply.

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid agency</td>
<td>AK, AL, AR, CA, CO, CT, FL, HI, MI, SC 5 (14%)</td>
</tr>
<tr>
<td>State Board of Pharmacy</td>
<td>AK, AL, AR, CA, DC, DE, GA, IA, ID, IN, KS, KY, LA, MA, MD, ME, MI, MN, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SD, TN, TX, UT, VA, WY, WV, WV, WY 43 (86%)</td>
</tr>
<tr>
<td>Other, please explain</td>
<td>IL, MO, NY 3 (9%)</td>
</tr>
</tbody>
</table>
If the answer to II-12 above is "Other", please explain:

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>IL</td>
<td>The Illinois Department of Financial and Professional Regulation (IDFPR) licenses pharmacists in the State of Illinois and the IDFPR pharmacy inspectors during the course of pharmacy inspections evaluate compliance with the requirement for prospective drug regimen review and counseling. IDFPR inspectors report findings to the State Board of Pharmacy which disciplines pharmacists and pharmacies.</td>
</tr>
<tr>
<td>MO</td>
<td>The Missouri Medicaid Audit and Compliance unit monitors compliance with the oral counseling requirement.</td>
</tr>
<tr>
<td>NY</td>
<td>On-site pharmacy inspections performed by Office of Professional Discipline</td>
</tr>
</tbody>
</table>

II-13. Has the state included Attachment I – Pharmacy Oral Counseling Compliance Report, a report on state efforts to monitor pharmacy compliance with the oral counseling requirement?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NM, NV, NY, OH, OK, OR, RI, SC, SD, TN, TX, UT, VA, VT, WA, WV, WY</td>
</tr>
<tr>
<td>No</td>
<td>AR, MA, MI, PA, WV</td>
</tr>
</tbody>
</table>
III. RETROSPECTIVE DUR (RetroDUR)

III-1. Identify, by name and type, the vendor that performed your retrospective DUR activities during the time period covered by this report (company, academic institution or other organization).

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company</td>
<td>AK, AL, AR, CT, DC, DE, FL, GA, HI, IA, ID, IN, KS, KY, LA, ME, MI, MN, MO, NC, ND, NH, NJ, NM, PA, RI, SC, SD, TN, TX, VA, VT, WI, WV</td>
<td>34 (68%)</td>
</tr>
<tr>
<td>Academic Institution</td>
<td>CA, CO, IL, MA, MS, NV, OH, OK, OR, UT, WY</td>
<td>11 (22%)</td>
</tr>
<tr>
<td>Other organization</td>
<td>MD, MT, NE, NY, WA</td>
<td>5 (10%)</td>
</tr>
</tbody>
</table>

Organization by Name and Type

<table>
<thead>
<tr>
<th>Organization</th>
<th>State (* served by more than one organization)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company</td>
<td></td>
</tr>
<tr>
<td>Change HealthCare</td>
<td></td>
</tr>
<tr>
<td>Cognizant Health Information Design</td>
<td></td>
</tr>
<tr>
<td>Magellan</td>
<td></td>
</tr>
<tr>
<td>Molina Medicaid Solution</td>
<td></td>
</tr>
<tr>
<td>Mountain Pacific Quality Health</td>
<td></td>
</tr>
<tr>
<td>NorthStar HealthCare Consulting</td>
<td></td>
</tr>
<tr>
<td>OptumRx Administrative Services</td>
<td></td>
</tr>
<tr>
<td>Xerox</td>
<td></td>
</tr>
<tr>
<td>Academic Institution</td>
<td></td>
</tr>
<tr>
<td>Oregon State University</td>
<td></td>
</tr>
<tr>
<td>State University of NY at Buffalo</td>
<td></td>
</tr>
<tr>
<td>SD State University College of Pharmacy</td>
<td></td>
</tr>
<tr>
<td>University of California, San Francisco (UCSF)</td>
<td></td>
</tr>
<tr>
<td>University of Cincinnati College of Pharmacy</td>
<td></td>
</tr>
<tr>
<td>University of Colorado School of Pharmacy</td>
<td></td>
</tr>
<tr>
<td>University of Illinois College of Pharmacy Staff</td>
<td></td>
</tr>
<tr>
<td>University of Mass</td>
<td></td>
</tr>
<tr>
<td>University of Massachusetts Medical School</td>
<td></td>
</tr>
<tr>
<td>University of Mississippi School of Pharmacy</td>
<td></td>
</tr>
<tr>
<td>University of Oklahoma College of Pharmacy, Pharmacy Management Consultants</td>
<td></td>
</tr>
<tr>
<td>University of Utah College of Pharmacy Drug Regimen Review Center (DRRC)</td>
<td></td>
</tr>
<tr>
<td>University of Vermont, School of Pharmacy</td>
<td></td>
</tr>
<tr>
<td>Other Organization</td>
<td></td>
</tr>
<tr>
<td>Nebraska Pharmacists Association</td>
<td></td>
</tr>
<tr>
<td>Washington State Health Care Authority</td>
<td></td>
</tr>
</tbody>
</table>
III-1. a) Is the retrospective DUR vendor also the Medicaid fiscal agent?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>DC, HI, LA, NJ, NM, VA, WA</td>
<td>7 (14%)</td>
</tr>
<tr>
<td></td>
<td>AK, AL, AR, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KS, KY, MA, MD, ME, MI, MN, MO, WV, WY</td>
<td>43 (86%)</td>
</tr>
<tr>
<td>No</td>
<td>MS, MT, NC, ND, NE, NH, NV, NY, OH, OR, PA, RI, SC, SD, TN, TX, UT, VT, WI</td>
<td>8 (16%)</td>
</tr>
</tbody>
</table>

III-1. b) Is this retrospective DUR vendor also the developer/supplier of your retrospective DUR criteria?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CO, CT, DC, DE, FL, GA, IA, IL, IN, KS, KY, MA, MD, ME, MI, MN, MO, WV, WY</td>
<td>42 (84%)</td>
</tr>
<tr>
<td>No</td>
<td>CA, HI, ID, IA, NE, OH, OK, UT</td>
<td>5 (10%)</td>
</tr>
</tbody>
</table>

If the answer to III-1 (b) above is "No", please explain:

State Explanation

- **CA**: Retrospective DUR criteria are developed jointly by UCSF and DHCS with input and recommendation by the DUR board. Final approval of criteria is made by DHCS.
- **HI**: Developed in-house by Hawaii Medicaid with DUR Board input.
- **ID**: Idaho Medicaid pharmacy program clinical pharmacists develop the Retro-DUR criteria.
- **LA**: Retrospective DUR criteria are developed through collaboration of pharmacists at DHH, Molina Medicaid Solutions, and the University of Louisiana-Monroe.
- **NE**: Retrospective DUR criteria are developed jointly by DHSS, the POS vendor and the RetromDUR vendor.
- **OH**: Developed in-house.
- **OK**: The University utilizes MediSpan drug information applications.
- **UT**: The DURC may or may not recommend Retrospective DUR criteria, and Utah Medicaid may or may not accept presented or modified criteria.

III-2. Does the DUR Board approve the retrospective DUR criteria?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CO, CT, DC, DE, FL, HI, ID, IL, IN, KS, KY, MA, MD, ME, MI, MN, MO, WV, WY</td>
<td>43 (86%)</td>
</tr>
<tr>
<td>No</td>
<td>CA, GA, IA, NV, OK, WA, WY</td>
<td>7 (14%)</td>
</tr>
</tbody>
</table>
If the answer to III-2 above is "No", please explain:

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>The DUR board advises and makes recommendations regarding prospective DUR criteria; however, final approval is made by DHCS.</td>
</tr>
<tr>
<td>GA</td>
<td>The DUR Board is advisory only; the Department of Community Health approves criteria.</td>
</tr>
<tr>
<td>IA</td>
<td>Change Healthcare utilizes MediSpan for retrospective DUR criteria involving a complex screening process.</td>
</tr>
<tr>
<td>NV</td>
<td>The DUR Board offers topics and reviews results, but does not approve before letters are sent.</td>
</tr>
<tr>
<td>OK</td>
<td>Guidelines have been approved, and new criteria are updated as it comes from MediSpan as long as it meets the set parameters.</td>
</tr>
<tr>
<td>WA</td>
<td>Washington State Medicaid performs ongoing periodic retrospective review of pharmacy claims at least quarterly to identify areas of clinical concern. In general these are performed for the purpose of identifying potential problems for presentation to the DUR Board, prior to the Board's involvement. Review which does not result in identification of a significant problem does not lead to Board presentation. When data and analysis of areas of concern are presented to the Board, in most instances their recommended follow up is Prospective DUR interventions, which the State wraps educational components into.</td>
</tr>
<tr>
<td>WV</td>
<td>Retrospective topics are often discussed with the Board, but specifics are handled by the DUR Manager independently.</td>
</tr>
</tbody>
</table>

III-3. Has the state included Attachment 2 - Retrospective DUR Educational Outreach Summary, a year end summary of the Top 10 problem types for which educational interventions were taken?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Number of States</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>49</td>
<td>98%</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>2%</td>
</tr>
</tbody>
</table>
IV. DUR BOARD ACTIVITY

IV-1. State is including a summary report of DUR Board activities and meeting minutes during the time period covered by this report as Attachment 3 - Summary of DUR Board Activities

<table>
<thead>
<tr>
<th>Answer</th>
<th>Number of States</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>50</td>
<td>100%</td>
</tr>
</tbody>
</table>

IV-2. Does your State have a Disease Management Program?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CA, DC, IA, IN, MA, ME, MO, ND, NY, OK, OR, PA, TX, UT, VT, WA, WV, WY</td>
<td>18 (26%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, AL, AR, CO, CT, DE, FL, GA, IL, ID, IA, KS, KY, LA, MD, MI, MN, MS, MT, NC, NE, NH, NJ, NM, NV, OH, RI, SC, SD, TN, VA, WI</td>
<td>32 (44%)</td>
</tr>
</tbody>
</table>

If the answer to IV-2 above is “Yes”, have you performed an analysis of the program’s effectiveness?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 18 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>IN, MA, ME, TX, UT, VT</td>
<td>6 (33%)</td>
</tr>
<tr>
<td>No</td>
<td>CA, DC, IA, MO, ND, NY, OK, OR, PA, WA, WV, WY</td>
<td>12 (67%)</td>
</tr>
</tbody>
</table>

If the answer to above is “Yes”, please provide a brief summary of your findings.

State Findings

IN: The Managed Care Entities (MCEs) provide disease management programs which are monitored and evaluated through the MCEs’ quality improvement processes. This is accomplished at the individual health plan level and not at the state level.

MA: We were able to identify xx million in inappropriate drug therapy through the State Pharmacy Care Management program (PCM).

TX: Texas Medicaid Wellness Program Overview.

1. Background-The Texas Medicaid Wellness Program, launched in March 2011, is a targeted care management program provided by the Texas Health and Human Services Commission and McKesson Health Solutions Care Management. The program operates under the authority of a 1915(b) waiver approved by the Centers for Medicare and Medicaid Services (CMS) and serves certain Medicaid clients in fee-for-service (traditional Medicaid) who are not in another waiver program, who have one or more chronic conditions, and are high cost and high risk based on the existence of clinical gaps in care. The majority of clients currently served are Supplemental Security Income (SSI) clients under the age of 21. The goal of the program is to improve clinical outcomes while decreasing the overall cost of care for high-risk Medicaid members through targeted clinical intervention and care management. The Wellness Program replaced the Texas Medicaid Enhanced Care Program, the previous Medicaid disease management program that originated in 2004. The Enhanced Care Program served mostly adults with specified chronic health conditions.

2. Population Served-The Wellness Program serves Medicaid clients enrolled in fee-for-service (FFS), or otherwise known as traditional Medicaid, who are not in another waiver program, have one or more chronic conditions, and are high cost and high risk clients based on the existence of clinical gaps in care. The Wellness Program serves approximately 12,000 Medicaid clients.

While the majority of clients served by the program are SSI clients under age 21, some adults are also served by the program. Of the total SSI pediatric population, approximately 59% of unique members have one or more of these top five conditions: Developmental disability, Attention deficit disorder (ADD) or attention deficit and hyperactivity disorder (ADHD), Asthma, Depression, Cancer. The same top five conditions are the top five cost drivers, making up 77% of the total claims costs of program eligible SSI children.
The goal of the Wellness Program is to promote improved health outcomes by supporting and sustaining the client-provider relationship and building connections between HHSC, providers, clients, and community resources. A focused provider outreach team informs providers of services available through the program, provides practice support, and enables collaboration among providers and regional care teams. Community-based multidisciplinary care teams provide intensive care coordination, one-on-one patient counseling, health assessments, and personalized care plans to help clients better self-manage their conditions. The team includes: - Primary registered nurses, - Social workers, - Behavior health workers, and - Promotors/community health workers. The teams live in their clients' communities and use evidence-based clinical guidelines to coordinate care with the clients' physicians and treat mental and advocate on their behalf. The clients benefit by having access to regionally-based resources that help implement personalized care plans, manage follow-up appointments, obtain equipment and medications, and arrange transportation to appointments. Also included for educational purposes are program mailings and focused communications applicable to the Wellness Program population, including children and their caregivers.

4. Summary of the Program Performance Evaluation - As specified in the contract with AxisPoint Health, a total of 20% of AxisPoint Health's per member per month (PMPM) fees for Texas Medicaid Wellness Program (TMWP) is at risk based on performance related to the following three areas: 1. Cost Savings, 2. Humanistic Measures, 3. Clinical Measures. For all three performance areas, Mercer relied on the eligibility, claims fees and AxisPoint Health survey and clinical results provided by HHSC and did not audit the data or verify the survey or clinical results independently. Mercer did assess the eligibility and claims data for consistency and reasonableness. Financial Reconciliation and methodology The Texas Health and Human Services Commission (HHSC) contracted with Mercer Government Human Services Consulting (Mercer), part of Mercer Health & Benefits LLC to determine a savings reconciliation based on the performance of AxisPoint Health in Program Period 5 (PP5), March 1, 2015 through February 29, 2016. The TMWP's financial reconciliation is a cost saving evaluation that compares the actual costs against the expected costs during PP5 for those members that meet the Reconciliation Population criteria, as defined in the contract. The expected costs are determined by projecting the baseline costs (March 1, 2015 - February 29, 2016) of the Reconciliation Population to PP5 using appropriate trend factors. To calculate the net savings Mercer used the following methodology: 1. Determined the total expected costs by multiplying the total Participants' member months (MMs) for PP5 by the risk-adjusted expected PMPM claim costs in PP5. 2. Subtracted the risk-adjusted expected PMPM claims costs for the participants from the actual PMPM claims costs incurred by the participant to determine PMPM gross savings for each of the four aid categories: TANF Adults, TANF Child,SSI-Adults, SSI-Child. 3. Multiplied the PMPM gross savings by the Participants' total MMs for PP5 to arrive at the aggregate gross savings. 4. Calculated net savings as the aggregate gross savings less the fees for the participating members, aggregated in total for the TMWP. 5. Determined net savings as the percentage of claims by dividing the net savings by the expected claims cost, aggregated in total for the TMWP. 6. Determined net savings percentage in $56,092,419. To determine the fee payback, Mercer used the following formula per the contract: Payback = (Reconciled Fees) x (Percentage of Fees at Risk for the Net Savings) x [1 - (Actual Net Savings % from above 5%) if net savings as a percent of expected costs fall below 5% guarantee. The net savings percentage is above the guaranteed minimum of 5%. Mercer determined that no portion of the 8% of total fees paid to AxisPoint Health was due back to HHSC. Humanistic Measures: To evaluate the impact of humanistic quality measures on the percentage of reconciled fees at risk, Mercer relied on the AxisPoint Health survey data provided by HHSC. According to the results of the survey provided by AxisPoint Health:

- Measure one (Participants Satisfaction Survey) was met and included the following two metrics:
  1) Survey collected, by clients who completed a biannual assessment, exceeded the goal of 955 for this metric (3842 surveys collected).
  2) The overall Participant satisfaction point-estimated benchmark of 99 was achieved (actual of 95.2).
- Measure two (Participant Health Status Survey) was met and included the following two metrics:
  1) Survey collected by clients who completed an initial assessment exceeded the goal of 941 for the Short-Form (SF)-10 (for clients age 5-17). On the follow-up Physical Health Summary (PHS) and Psychosocial health Summary (PSS) scores, the mean PHS value of 40.54 and the mean PSS value of 45.56 showed improvements of 1.94 and 3.30 respectively over the baseline results.
  2) Survey results for clients who completed an initial assessment for the SF-12 for clients age 18 and older were not reported as less than 25% of the population was in this age group. As stipulated in the contract, the SF-12 survey tool was used only if at least 25% of the managed clients were age 18 and older.

Clinical Quality
For performance related to the clinical quality, the following 15 clinical quality measures agreed to by the parties for program period 2 and after. These quality measures may be reconsidered and reevaluated annually to determine their applicability to the actual population resulting from predictive modeling outcomes.

1) Follow-up Care for Children prescribed ADHD Medication (Continuation and Maintenance Phase)
2) Annual Hemoglobin A1c Testing Assessment
3) HEDIS: Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents
4) Follow-up after Hospitalization for Mental Illness (FL30)
5) HEDIS (EOC): Use of Appropriate Medications for People with Asthma
6) Annual Number of Children with Asthma ER Visits
7) Well Child Visit in the Third, Fourth, Fifth, and Sixth Years of Life
If the answer to IV-2 above is "Yes", is your DUR Board involved with this program?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 18 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>MA, ME, MO, WV</td>
<td>4 (28%)</td>
</tr>
<tr>
<td>No</td>
<td>CA, DC, IA, IN, ND, NY, OK, OR, PA, TX, UT, VT, WA, WV</td>
<td>14 (76%)</td>
</tr>
</tbody>
</table>

IV-3. Does your State have an approved CMS Medication Therapy Management Program?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>FL, IA, ME, MN, MO, OR, WI</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, AL, AR, CA, CO, CT, DC, DE, GA, HI, ID, IL, IN, KS, KY, LA, MA, MD, MI, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WV, WY</td>
<td>43 (86%)</td>
</tr>
</tbody>
</table>

If the response is "Yes" to IV-3 above, have you performed an analysis of the program's effectiveness?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 7 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>FL, WI</td>
<td>2 (29%)</td>
</tr>
<tr>
<td>No</td>
<td>IA, ME, MN, MO, OR</td>
<td>5 (71%)</td>
</tr>
</tbody>
</table>
If the response is “Yes”, please provide a brief summary of your findings:

<table>
<thead>
<tr>
<th>State Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>FL Qualitative findings support several benefits based on the responses to open-ended questions and survey items. For example, MTM participants consistently stated that their medication adherence was positively enhanced by participation in the program. Furthermore, they also indicated greater understanding of their medications.</td>
</tr>
<tr>
<td>WI A report titled, “Medication Therapy Management: Evaluation and Lessons Learned” was published in July 2016. Among a variety of measures and demographic findings, the report included a comparison of Medicaid members receiving MTM service to a central group (that did not receive MTM services), since the program was initiated in September 2012. Key findings include: The MTM program increased all medical costs by $556 per member per year compared to the central group. This includes a $389 increase in pharmacy costs (approximately 70% of the total cost increase). Inpatient costs for members receiving MTM services were $102 per member per month less than the control group (with nearly the same number of claims among both groups), suggesting the MTM program may be improving member health. The full report can be viewed at: <a href="https://www.dhs.wisconsin.gov/publications/p01558.pdf">https://www.dhs.wisconsin.gov/publications/p01558.pdf</a>. A similar report will be conducted in the future to determine if MTM services have an impact on the health of members with chronic conditions over time.</td>
</tr>
</tbody>
</table>

If the answer to IV-3 above is “Yes”, is your DUR Board involved with this program?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 7 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>MO, WI</td>
<td>2 (29%)</td>
</tr>
<tr>
<td>No</td>
<td>FL, IA, ME, MN, OR</td>
<td>5 (71%)</td>
</tr>
</tbody>
</table>

If answer to IV-3 above is “No”, are you planning to develop and implement a program?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 43 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CA, CO, DC, IL, MA, MI, MS, ND, OK, SC, TN, TX, VT, WY</td>
<td>14 (33%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, AL, AR, CT, DE, GA, HI, ID, IN, KS, KY, LA, MD, MT, NC, NE, NH, NJ, NM, NV, NY, OH, PA, RI, SD, UT, VA, WA, WV</td>
<td>29 (67%)</td>
</tr>
</tbody>
</table>
V. PHYSICIAN ADMINISTERED DRUGS

The Deficit Reduction Act requires collection of NDC numbers for covered outpatient physician administered drugs. These drugs are paid through the physician and hospital programs.

V-1. Has your MMIS been designed to incorporate this data into your DUR criteria for Prospective DUR?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, CT, HI, KY, MA, ME, MI, MO, NJ, NY, PA, SC, WA</td>
<td>13 (26%)</td>
</tr>
<tr>
<td>No</td>
<td>AL, AR, CA, CO, DC, DE, FL, GA, IA, ID, IL, IN, KS, LA, MD, MN, MS, MT, NC, ND, NE, NH, NM, NV, OH, OK, OR, RI, SD, TN, TX, UT, VA, VT, WI, WV</td>
<td>37 (74%)</td>
</tr>
</tbody>
</table>

If answer to V-1 above is “No”, do you have a plan to include this information in your DUR criteria in the future?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 37 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CA, CO, DC, DE, IA, ID, IL, MS, ND, NV, OR, SD, VA, VT, WV</td>
<td>15 (41%)</td>
</tr>
<tr>
<td>No</td>
<td>AL, AR, FL, GA, IN, KS, LA, MD, MN, MT, NC, NE, NH, NM, OH, OK, RI, TN, TX, UT, WI, WV</td>
<td>22 (59%)</td>
</tr>
</tbody>
</table>

V-2. Has your MMIS been designed to incorporate this data into your DUR criteria for Retrospective DUR?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, CA, CT, FL, GA, HI, KY, LA, MA, ME, MI, MN, MO, ND, NV, OH, OR, PA, SC, SD, VT, WA</td>
<td>22 (44%)</td>
</tr>
<tr>
<td>No</td>
<td>AL, AR, CO, DC, DE, IA, ID, IL, IN, KS, MD, MS, MT, NC, NE, NH, NJ, NM, NV, OK, RI, TN, TX, UT, VA, WI, WV, WY</td>
<td>28 (56%)</td>
</tr>
</tbody>
</table>

If answer to V-2 above is “No”, do you have a plan to include this information in your DUR criteria in the future?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 28 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CO, DC, IA, ID, IL, MS, NC, VA, WV</td>
<td>9 (32%)</td>
</tr>
<tr>
<td>No</td>
<td>AL, AR, DE, IN, KS, MD, MT, NE, NH, NJ, NM, NY, OK, RI, TN, TX, UT, WI, WV</td>
<td>19 (68%)</td>
</tr>
</tbody>
</table>
VI. GENERIC POLICY AND UTILIZATION DATA

VI-1. State is including a description of policies used that may affect generic utilization percentage as Attachment 4 - Generic Drug Substitution Policies:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Number of States</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>50</td>
<td>100%</td>
</tr>
</tbody>
</table>

VI-2. In addition to the requirement that the prescriber write in his/her own handwriting "Brand Medically Necessary" for a brand name drug to be dispensed in lieu of the generic equivalent, does your state have a more restrictive requirement?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CA, CO, CT, DE, GA, IA, ID, IL, IN, KS, KY, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NV, NY, OH, OK, OR, PA, SD, TN, TX, UT, VT, WA, WI, WV, WY</td>
<td>42 (84%)</td>
</tr>
<tr>
<td>No</td>
<td>DC, FL, HI, IA, NM, RI, SC, VA</td>
<td>8 (16%)</td>
</tr>
</tbody>
</table>

If the response is "Yes" to VI-2 above, check all that apply.

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Require that a MedWatch Form be submitted</td>
<td>AK, AL, AR, CT, DE, IA, IN, KS, MO, MS, ND, NH, NV, SD, TN, WV, WY</td>
<td>19 (45%)</td>
</tr>
<tr>
<td>Require medical reason for generic product prescription</td>
<td>AL, DE, ID, KS, MO, MS, MT, ND, NH, NV, OK, SD, UT, WV</td>
<td>14 (33%)</td>
</tr>
<tr>
<td>Prior authorization is required</td>
<td>AK, AL, AR, CO, DE, GA, IA, ID, IL, IN, KS, MA, MD, ME, MI, MS, MO, MT, ND, NH, NJ, NV, OH, OK, OR, PA, SD, TN, TX, UT, VT, WI, WV, WY</td>
<td>35 (83%)</td>
</tr>
<tr>
<td>Other – please explain</td>
<td>CA, CT, ID, KY, ME, MI, NC, NE, NY, WA</td>
<td>10 (24%)</td>
</tr>
</tbody>
</table>

If the response is "Other", please explain:

State Explanation

- **CA**: If a brand name drug does not appear on the Medi-Cal List of Covered Drugs, an approved Treatment Authorization Request may be required before dispensing.
- **CT**: A BMM PA is required unless the brand name drug is on the PDL. A DAW/1 submitted on electronic prescriptions is acceptable.
- **ID**: Must fail 2 generic products
- **KY**: In addition to DAW/1, Kentucky also requires PA for non-preferred brands
- **ME**: Maine does not allow DAW/1 for prescriptions, as everything is driven by the MaineCare PDL.
- **MI**: Selected drugs classes determined by the state legislature are exempt from prior authorization
- **NC**: Detail information on how many brand names are non-preferred and require PA
- **NE**: A prescriber must submit a MC-6 Form, which declares that the brand name is medically necessary.
- **NY**: On April 26, 2010, New York Medicaid implemented a cost containment initiative which promotes the use of certain multi-source brand name drugs when the cost of the brand name drug is less expensive than the generic equivalent.
- **WA**: Washington Medicaid allows a brand to be dispensed without authorization when prescribed Dispense as Written, but will only reimburse the dispensing pharmacy the same amount it would for the generic equivalent. If the pharmacy wishes to receive higher reimbursement for the brand, they must request authorization. When authorization is requested, the State contacts the prescriber to review the medical necessity for use of the branded product over a generic alternative.
VI.3. Indicate the generic utilization percentage for all covered outpatient drugs paid during this reporting period, using the computation instructions in Table 2 - Generic Drug Utilization Data.

<table>
<thead>
<tr>
<th>State</th>
<th>Generic Utilization Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>70%</td>
</tr>
<tr>
<td>TX</td>
<td>71%</td>
</tr>
<tr>
<td>DC</td>
<td>72%</td>
</tr>
<tr>
<td>FL</td>
<td>74%</td>
</tr>
<tr>
<td>CT</td>
<td>75%</td>
</tr>
<tr>
<td>NC</td>
<td>77%</td>
</tr>
<tr>
<td>VT</td>
<td>78%</td>
</tr>
<tr>
<td>MD</td>
<td>78%</td>
</tr>
<tr>
<td>MS</td>
<td>78%</td>
</tr>
<tr>
<td>NE</td>
<td>79%</td>
</tr>
<tr>
<td>NJ</td>
<td>79%</td>
</tr>
<tr>
<td>AL</td>
<td>80%</td>
</tr>
<tr>
<td>SC</td>
<td>80%</td>
</tr>
<tr>
<td>MO</td>
<td>81%</td>
</tr>
<tr>
<td>CO</td>
<td>81%</td>
</tr>
<tr>
<td>MT</td>
<td>81%</td>
</tr>
<tr>
<td>SD</td>
<td>81%</td>
</tr>
<tr>
<td>WI</td>
<td>81%</td>
</tr>
<tr>
<td>LA</td>
<td>81%</td>
</tr>
<tr>
<td>WY</td>
<td>81%</td>
</tr>
<tr>
<td>AK</td>
<td>81%</td>
</tr>
<tr>
<td>ID</td>
<td>82%</td>
</tr>
<tr>
<td>DE</td>
<td>82%</td>
</tr>
<tr>
<td>NV</td>
<td>82%</td>
</tr>
<tr>
<td>NM</td>
<td>82%</td>
</tr>
<tr>
<td>OK</td>
<td>82%</td>
</tr>
<tr>
<td>TN</td>
<td>82%</td>
</tr>
<tr>
<td>IN</td>
<td>82%</td>
</tr>
<tr>
<td>MI</td>
<td>83%</td>
</tr>
<tr>
<td>IA</td>
<td>83%</td>
</tr>
<tr>
<td>MN</td>
<td>83%</td>
</tr>
<tr>
<td>ND</td>
<td>83%</td>
</tr>
<tr>
<td>UT</td>
<td>83%</td>
</tr>
<tr>
<td>WV</td>
<td>83%</td>
</tr>
<tr>
<td>GA</td>
<td>84%</td>
</tr>
<tr>
<td>NH</td>
<td>84%</td>
</tr>
<tr>
<td>NE</td>
<td>84%</td>
</tr>
<tr>
<td>NY</td>
<td>84%</td>
</tr>
<tr>
<td>IL</td>
<td>84%</td>
</tr>
<tr>
<td>OH</td>
<td>85%</td>
</tr>
<tr>
<td>MA</td>
<td>85%</td>
</tr>
<tr>
<td>AR</td>
<td>86%</td>
</tr>
<tr>
<td>VA</td>
<td>86%</td>
</tr>
<tr>
<td>KY</td>
<td>87%</td>
</tr>
<tr>
<td>KS</td>
<td>88%</td>
</tr>
<tr>
<td>OR</td>
<td>89%</td>
</tr>
<tr>
<td>WA</td>
<td>89%</td>
</tr>
<tr>
<td>RI</td>
<td>90%</td>
</tr>
<tr>
<td>PA</td>
<td>91%</td>
</tr>
<tr>
<td>HI</td>
<td>95%</td>
</tr>
<tr>
<td>Average</td>
<td>82%</td>
</tr>
</tbody>
</table>

2016 DUR Comparison/Summary Report –October 2017
Indicate the percentage dollars paid for generic covered outpatient drugs in relation to all covered outpatient drug claims paid during this reporting period using the computation instructions in Table 2 - Generic Drug Utilization Data.

<table>
<thead>
<tr>
<th>State</th>
<th>Percentage Dollars Paid for Generics in relation to Total Drug Spend</th>
</tr>
</thead>
<tbody>
<tr>
<td>DC</td>
<td>6%</td>
</tr>
<tr>
<td>NJ</td>
<td>9%</td>
</tr>
<tr>
<td>WA</td>
<td>9%</td>
</tr>
<tr>
<td>FL</td>
<td>9%</td>
</tr>
<tr>
<td>GA</td>
<td>9%</td>
</tr>
<tr>
<td>NH</td>
<td>10%</td>
</tr>
<tr>
<td>MD</td>
<td>13%</td>
</tr>
<tr>
<td>SC</td>
<td>15%</td>
</tr>
<tr>
<td>GA</td>
<td>15%</td>
</tr>
<tr>
<td>ME</td>
<td>15%</td>
</tr>
<tr>
<td>NV</td>
<td>16%</td>
</tr>
<tr>
<td>TX</td>
<td>17%</td>
</tr>
<tr>
<td>CT</td>
<td>17%</td>
</tr>
<tr>
<td>TN</td>
<td>17%</td>
</tr>
<tr>
<td>DE</td>
<td>18%</td>
</tr>
<tr>
<td>WV</td>
<td>19%</td>
</tr>
<tr>
<td>MI</td>
<td>19%</td>
</tr>
<tr>
<td>MT</td>
<td>20%</td>
</tr>
<tr>
<td>PA</td>
<td>20%</td>
</tr>
<tr>
<td>MS</td>
<td>20%</td>
</tr>
<tr>
<td>WI</td>
<td>20%</td>
</tr>
<tr>
<td>ID</td>
<td>20%</td>
</tr>
<tr>
<td>KY</td>
<td>20%</td>
</tr>
<tr>
<td>WY</td>
<td>20%</td>
</tr>
<tr>
<td>OK</td>
<td>21%</td>
</tr>
<tr>
<td>MA</td>
<td>22%</td>
</tr>
<tr>
<td>VT</td>
<td>22%</td>
</tr>
<tr>
<td>OH</td>
<td>22%</td>
</tr>
<tr>
<td>CO</td>
<td>22%</td>
</tr>
<tr>
<td>AL</td>
<td>23%</td>
</tr>
<tr>
<td>IA</td>
<td>23%</td>
</tr>
<tr>
<td>AK</td>
<td>24%</td>
</tr>
<tr>
<td>NE</td>
<td>24%</td>
</tr>
<tr>
<td>MN</td>
<td>25%</td>
</tr>
<tr>
<td>UT</td>
<td>25%</td>
</tr>
<tr>
<td>MO</td>
<td>26%</td>
</tr>
<tr>
<td>KS</td>
<td>27%</td>
</tr>
<tr>
<td>IL</td>
<td>27%</td>
</tr>
<tr>
<td>SD</td>
<td>27%</td>
</tr>
<tr>
<td>VA</td>
<td>27%</td>
</tr>
<tr>
<td>NM</td>
<td>27%</td>
</tr>
<tr>
<td>NC</td>
<td>27%</td>
</tr>
<tr>
<td>LA</td>
<td>28%</td>
</tr>
<tr>
<td>RI</td>
<td>29%</td>
</tr>
<tr>
<td>IN</td>
<td>29%</td>
</tr>
<tr>
<td>AR</td>
<td>31%</td>
</tr>
<tr>
<td>OR</td>
<td>32%</td>
</tr>
<tr>
<td>HI</td>
<td>34%</td>
</tr>
<tr>
<td>ND</td>
<td>38%</td>
</tr>
<tr>
<td>NY</td>
<td>49%</td>
</tr>
</tbody>
</table>

Average 22%
VII. PROGRAM EVALUATION/COST SAVINGS/COST AVOIDANCE

VII-1. Did your State conduct a DUR program evaluation of the estimated cost savings/cost avoidance?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Number of States</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>50</td>
<td>100%</td>
</tr>
</tbody>
</table>

VII-2. Who conducted your program evaluation for the cost savings estimate/cost avoidance (company, academic institution, other institution)?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company</td>
<td>AK, AL, AR, CT, DC, DE, FL, GA, IA, ID, IN, KS, KY, LA, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OR, PA, RI, SC, SD, TN, TX, VA, VT, WI, WV</td>
<td>38 (76%)</td>
</tr>
<tr>
<td>Academic Institution</td>
<td>CA, MA, OK, WY</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Other Institution</td>
<td>CO, HI, IL, MD, NY, OH, UT, WA</td>
<td>8 (16%)</td>
</tr>
</tbody>
</table>

Organization Name and Type

<table>
<thead>
<tr>
<th>Organization</th>
<th>State (served by more than one organization)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change HealthCare</td>
<td>IA, IL, ME, VT</td>
</tr>
<tr>
<td>Conform</td>
<td>DC, MS, NM, TX*</td>
</tr>
<tr>
<td>DXRx</td>
<td>KS*</td>
</tr>
<tr>
<td>Good Health System</td>
<td>AL*, AR*, CT*, DE*, KS*, MD*, ND, NV*, PA, RI, SD, TX*, WI, WY*</td>
</tr>
<tr>
<td>Health Information Design</td>
<td>CT*, DE*, OR,</td>
</tr>
<tr>
<td>Magellan</td>
<td>AK, AR*, FL, ID, KY, ME, NE, NH, SC, TN</td>
</tr>
<tr>
<td>Minnesota does internally except for RetroDUR</td>
<td>MN</td>
</tr>
<tr>
<td>Molina Medicaid Solution</td>
<td>LA, NJ, WV*</td>
</tr>
<tr>
<td>Mountains Pacific Quality Health</td>
<td>MT</td>
</tr>
<tr>
<td>Myers and Stauffer</td>
<td>NC</td>
</tr>
<tr>
<td>OptumRx Administrative Services</td>
<td>GA, IN, NV</td>
</tr>
<tr>
<td>Xerox</td>
<td>MD*, MO, VA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Academic Institution</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of California, San Francisco (UCSF)</td>
<td>CA</td>
</tr>
<tr>
<td>University of Cincinnati College of Pharmacy</td>
<td>OH*</td>
</tr>
<tr>
<td>University of Massachusetts Medical School</td>
<td>MA</td>
</tr>
<tr>
<td>University of Oklahoma College of Pharmacy, Pharmacy Management Consultants</td>
<td>OK</td>
</tr>
<tr>
<td>University of Utah College of Pharmacy Drug Regimen Review Center (DRRC) provided calculations</td>
<td>UT*</td>
</tr>
<tr>
<td>University of Wyoming, School of Pharmacy</td>
<td>WY*</td>
</tr>
</tbody>
</table>
### Other Organization

- Conduent (formerly known as Xerox) for retro-DUR.
- Health Information Designs (HID) for Prospective Clinical and PDL prior authorizations.
- Change Healthcare Pharmacy Solutions for SMAC and DUR Bureau of Professional and Ancillary Services
- Hawaii State Medicaid DUR Coordinator
- Internal State Analysis
- NYS Dept. of Health evaluates ProDUR and Health Information Designs, LLC evaluates RetroDUR.
- Washington State Health Care Authority
- Molina Healthcare (ProDUR) and Health Information Services IL*
- Hawaii State Medicaid (ProDUR) and Health Information Services TX*
- NYS Dept. of Health evaluates ProDUR and Health Information Designs, LLC evaluates RetroDUR.
- Washington State Health Care Authority
- Molina Healthcare (ProDUR) and Health Information Services WA
- Pro-DUR is HP; Retro-DUR is HID
- Prospective DUR cost savings estimate was conducted by HID
- Retrospective DUR cost savings estimate was conducted by Pro-DUR
- HPE
- HID
- Pro: Good Health Systems; Retro: University of Cincinnati

### VII-3. Please provide your ProDUR and RetroDUR program cost savings/cost avoidance in the chart below.

<table>
<thead>
<tr>
<th>State</th>
<th>ProDUR Total Estimated Avoided Costs</th>
<th>RetroDUR Total Estimated Avoided Costs</th>
<th>Other Cost Avoidance</th>
<th>Grand Total Estimated Avoided Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>4,413,924</td>
<td></td>
<td></td>
<td>4,413,924</td>
</tr>
<tr>
<td>AL</td>
<td></td>
<td>1,360,374</td>
<td></td>
<td>1,360,374</td>
</tr>
<tr>
<td>AR</td>
<td>13,771,693</td>
<td>2,307,028</td>
<td>68,212,488</td>
<td>84,291,209</td>
</tr>
<tr>
<td>CA</td>
<td>229,440,897</td>
<td></td>
<td></td>
<td>229,440,897</td>
</tr>
<tr>
<td>CO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>52,331,017</td>
<td>6,350,322</td>
<td></td>
<td>58,681,339</td>
</tr>
<tr>
<td>DC</td>
<td></td>
<td>135,442</td>
<td></td>
<td>135,442</td>
</tr>
<tr>
<td>DE</td>
<td>228,669</td>
<td>38,855</td>
<td></td>
<td>267,524</td>
</tr>
<tr>
<td>FL</td>
<td>305,736,319</td>
<td>1,141,935</td>
<td>21,832,727</td>
<td>328,710,981</td>
</tr>
<tr>
<td>GA</td>
<td>79,367,532</td>
<td></td>
<td></td>
<td>79,367,532</td>
</tr>
<tr>
<td>HI</td>
<td></td>
<td></td>
<td></td>
<td>45,000</td>
</tr>
<tr>
<td>IA</td>
<td></td>
<td></td>
<td></td>
<td>330,629</td>
</tr>
<tr>
<td>ID</td>
<td>17,031,162</td>
<td>11,325,875</td>
<td></td>
<td>28,357,037</td>
</tr>
<tr>
<td>IL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IN</td>
<td>123,090,000</td>
<td>587,004</td>
<td></td>
<td>123,680,000</td>
</tr>
<tr>
<td>KS</td>
<td>177,384</td>
<td></td>
<td>8,608</td>
<td>185,992</td>
</tr>
<tr>
<td>KY</td>
<td>43,062,709</td>
<td>380,241</td>
<td>16,965,249</td>
<td>60,408,199</td>
</tr>
<tr>
<td>LA</td>
<td>31,018,451</td>
<td>754,519</td>
<td></td>
<td>31,782,970</td>
</tr>
<tr>
<td>MA</td>
<td>201,759,043</td>
<td></td>
<td>4,799,635</td>
<td>206,558,678</td>
</tr>
<tr>
<td>MD</td>
<td>49,013,260</td>
<td>274,299</td>
<td></td>
<td>49,287,559</td>
</tr>
<tr>
<td>ME</td>
<td>2,316,411</td>
<td></td>
<td></td>
<td>2,316,411</td>
</tr>
<tr>
<td>MN</td>
<td>380,417,254</td>
<td>50,340</td>
<td></td>
<td>380,962,594</td>
</tr>
<tr>
<td>MS</td>
<td>48,641,315</td>
<td>1,557,279</td>
<td></td>
<td>49,998,594</td>
</tr>
</tbody>
</table>

2016 DUR Comparison/Summary Report – October 2017
<table>
<thead>
<tr>
<th>State</th>
<th>PredUR Total Estimated Avoided Costs</th>
<th>RetroDUR Total Estimated Avoided Costs</th>
<th>Other Cost Avoided</th>
<th>Grand Total Estimated Avoided</th>
</tr>
</thead>
<tbody>
<tr>
<td>MO</td>
<td>44,276,042</td>
<td>581,729</td>
<td>-</td>
<td>44,857,771</td>
</tr>
<tr>
<td>MS</td>
<td>12,930,137</td>
<td>-</td>
<td>-</td>
<td>12,930,137</td>
</tr>
<tr>
<td>MT</td>
<td>8,503,090</td>
<td>6,554</td>
<td>18,970,371</td>
<td>46,810,308</td>
</tr>
<tr>
<td>NC</td>
<td>394,299,743</td>
<td>124,000</td>
<td>82,103,778</td>
<td>476,337,521</td>
</tr>
<tr>
<td>ND</td>
<td>-</td>
<td>147,121</td>
<td>-</td>
<td>147,121</td>
</tr>
<tr>
<td>NE</td>
<td>46,90,828</td>
<td>7,177</td>
<td>15,317</td>
<td>46,983,261</td>
</tr>
<tr>
<td>NH</td>
<td>388,145</td>
<td>127,660</td>
<td>1,069,610</td>
<td>1,585,414</td>
</tr>
<tr>
<td>NJ</td>
<td>10,847,453</td>
<td>-</td>
<td>-</td>
<td>10,847,453</td>
</tr>
<tr>
<td>NM</td>
<td>2,019,348</td>
<td>6,473</td>
<td>-</td>
<td>2,025,823</td>
</tr>
<tr>
<td>NV</td>
<td>124,791,692</td>
<td>-</td>
<td>-</td>
<td>124,791,692</td>
</tr>
<tr>
<td>NY</td>
<td>53,249,136</td>
<td>4,854,705</td>
<td>-</td>
<td>58,103,841</td>
</tr>
<tr>
<td>OH</td>
<td>8,596,979</td>
<td>-</td>
<td>-</td>
<td>8,596,979</td>
</tr>
<tr>
<td>OK</td>
<td>125,758,040</td>
<td>448,066</td>
<td>(4,308,363)</td>
<td>121,897,744</td>
</tr>
<tr>
<td>OR</td>
<td>35,167</td>
<td>9,391</td>
<td>22,213,655</td>
<td>22,258,213</td>
</tr>
<tr>
<td>PA</td>
<td>-</td>
<td>483,659</td>
<td>-</td>
<td>483,659</td>
</tr>
<tr>
<td>RI</td>
<td>3,055,302</td>
<td>972,016</td>
<td>-</td>
<td>4,028,318</td>
</tr>
<tr>
<td>SC</td>
<td>4,826,400</td>
<td>593,276</td>
<td>-</td>
<td>5,419,676</td>
</tr>
<tr>
<td>SD</td>
<td>-</td>
<td>76,590</td>
<td>-</td>
<td>76,590</td>
</tr>
<tr>
<td>TN</td>
<td>49,319,374</td>
<td>195,671</td>
<td>-</td>
<td>49,514,045</td>
</tr>
<tr>
<td>TX</td>
<td>35,437,072</td>
<td>15,558,788</td>
<td>-</td>
<td>51,001,464</td>
</tr>
<tr>
<td>UT</td>
<td>18,147,272</td>
<td>431,094</td>
<td>-</td>
<td>18,578,366</td>
</tr>
<tr>
<td>VA</td>
<td>23,600,741</td>
<td>309,451</td>
<td>6,922,396</td>
<td>32,822,598</td>
</tr>
<tr>
<td>VT</td>
<td>2,320,296</td>
<td>-</td>
<td>7,501,864</td>
<td>9,822,160</td>
</tr>
<tr>
<td>WA</td>
<td>38,617,018</td>
<td>-</td>
<td>11,792,642</td>
<td>50,409,660</td>
</tr>
<tr>
<td>WI</td>
<td>-</td>
<td>995,145</td>
<td>-</td>
<td>995,145</td>
</tr>
<tr>
<td>WV</td>
<td>19,233,219</td>
<td>4,085,921</td>
<td>115,735</td>
<td>23,434,877</td>
</tr>
<tr>
<td>WY</td>
<td>24,001,323</td>
<td>5,093,589</td>
<td>-</td>
<td>29,096,212</td>
</tr>
<tr>
<td>Average</td>
<td>52,873,338</td>
<td>1,247,960</td>
<td>16,593,208</td>
<td>76,412,471</td>
</tr>
</tbody>
</table>
VII-4. Please provide the estimated percent impact of your state’s cost savings/cost avoidance program compared to total drug expenditures for covered outpatient drugs.

Grand Estimated Net Savings Amount / Total Dollar Amount X 100 = % Impact of Cost Savings/Avoidance compared to Total Drug Spend

<table>
<thead>
<tr>
<th>State</th>
<th>Percent Impact of Cost Savings/Avoidance Compared to Total Drug Spend</th>
</tr>
</thead>
<tbody>
<tr>
<td>AL</td>
<td>0%</td>
</tr>
<tr>
<td>DE</td>
<td>0%</td>
</tr>
<tr>
<td>IA</td>
<td>0%</td>
</tr>
<tr>
<td>ND</td>
<td>0%</td>
</tr>
<tr>
<td>SD</td>
<td>0%</td>
</tr>
<tr>
<td>WI</td>
<td>0%</td>
</tr>
<tr>
<td>DC</td>
<td>1%</td>
</tr>
<tr>
<td>PA</td>
<td>1%</td>
</tr>
<tr>
<td>CO</td>
<td>2%</td>
</tr>
<tr>
<td>OH</td>
<td>2%</td>
</tr>
<tr>
<td>MO</td>
<td>3%</td>
</tr>
<tr>
<td>AK</td>
<td>4%</td>
</tr>
<tr>
<td>CT</td>
<td>4%</td>
</tr>
<tr>
<td>HI</td>
<td>4%</td>
</tr>
<tr>
<td>SC</td>
<td>4%</td>
</tr>
<tr>
<td>TN</td>
<td>4%</td>
</tr>
<tr>
<td>TX</td>
<td>5%</td>
</tr>
<tr>
<td>VT</td>
<td>5%</td>
</tr>
<tr>
<td>NJ</td>
<td>6%</td>
</tr>
<tr>
<td>NM</td>
<td>6%</td>
</tr>
<tr>
<td>CA</td>
<td>7%</td>
</tr>
<tr>
<td>KS</td>
<td>8%</td>
</tr>
<tr>
<td>MD</td>
<td>8%</td>
</tr>
<tr>
<td>MS</td>
<td>9%</td>
</tr>
<tr>
<td>NH</td>
<td>10%</td>
</tr>
<tr>
<td>WV</td>
<td>10%</td>
</tr>
<tr>
<td>GA</td>
<td>12%</td>
</tr>
<tr>
<td>ID</td>
<td>14%</td>
</tr>
<tr>
<td>OR</td>
<td>14%</td>
</tr>
<tr>
<td>UT</td>
<td>15%</td>
</tr>
<tr>
<td>WA</td>
<td>16%</td>
</tr>
<tr>
<td>AR</td>
<td>17%</td>
</tr>
<tr>
<td>MN</td>
<td>20%</td>
</tr>
<tr>
<td>NY</td>
<td>21%</td>
</tr>
<tr>
<td>RI</td>
<td>21%</td>
</tr>
<tr>
<td>ME</td>
<td>24%</td>
</tr>
<tr>
<td>NE</td>
<td>24%</td>
</tr>
<tr>
<td>OK</td>
<td>24%</td>
</tr>
<tr>
<td>IN</td>
<td>26%</td>
</tr>
<tr>
<td>NC</td>
<td>27%</td>
</tr>
<tr>
<td>VA</td>
<td>29%</td>
</tr>
<tr>
<td>MT</td>
<td>34%</td>
</tr>
<tr>
<td>MA</td>
<td>35%</td>
</tr>
<tr>
<td>MI</td>
<td>36%</td>
</tr>
<tr>
<td>LA</td>
<td>37%</td>
</tr>
<tr>
<td>NV</td>
<td>44%</td>
</tr>
<tr>
<td>WY</td>
<td>62%</td>
</tr>
<tr>
<td>FL</td>
<td>66%</td>
</tr>
<tr>
<td>KY</td>
<td>79%</td>
</tr>
<tr>
<td>IL</td>
<td>87%</td>
</tr>
<tr>
<td>Average</td>
<td>18%</td>
</tr>
</tbody>
</table>

2016 DUR Comparison/Summary Report -October 2017
VII-5. State is providing the Medicaid Cost Savings/Cost Avoidance Evaluation as Attachment 5 "Cost Savings/Cost Avoidance Methodology".

<table>
<thead>
<tr>
<th>Answer</th>
<th>Number of States</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>50</td>
<td>100%</td>
</tr>
</tbody>
</table>
VIII. FRAUD, WASTE AND ABUSE DETECTION

VIII A. LOCK-IN or PATIENT REVIEW AND RESTRICTIVE PROGRAMS

VIII A I. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by beneficiaries?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CA, CO, CT, DC, DE, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
</tr>
<tr>
<td>No</td>
<td>FL</td>
</tr>
</tbody>
</table>

Number of States (Percentage)
- Yes: 49 (98%)
- No: 1 (2%)

If the response to VIII A I above is "Yes", what action(s) does this process initiate? Check all that apply.

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deny claims and require prior authorization</td>
<td>CO, CT, DC, DE, GA, ID, IL, IN, KY, MA, ME, MI, MO, MT, ND, NE, NJ, OK, SC, TN, TX, UT, VT, WV</td>
</tr>
<tr>
<td>Refer to the lock-in program</td>
<td>AK, AL, AR, CO, CT, DC, DE, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MO, MS, MT, NC, ND, NE, NJ, NM, NV, OH, OK, OR, RI, SC, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
</tr>
<tr>
<td>Refer to Program Integrity Unit</td>
<td>AK, AL, AR, CO, CT, DC, DE, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MO, MS, MT, NC, ND, NE, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, UT, VA, VT, WV, WI</td>
</tr>
<tr>
<td>Other (e.g. SURS, Office of Inspector General)</td>
<td>AK, AL, CA, GA, IN, KY, MD, MI, MN, MS, MT, NC, NH, NJ, NY, PA, SD, TN, VA, VT, WI</td>
</tr>
</tbody>
</table>

Number of States (Percentage of 49 states)
- Deny claims and require prior authorization: 24 (49%)
- Refer to lock-in program: 42 (86%)
- Refer to Program Integrity Unit: 33 (67%)
- Other: 21 (43%)

If the response to the above is "Other", please explain:

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>SURS, MFCU</td>
</tr>
<tr>
<td>AL</td>
<td>Refer to MFCU if necessary.</td>
</tr>
<tr>
<td>CA</td>
<td>22CCR 5079J details available utilization restrictions when the Department has determined that a beneficiary is misusing or abusing Medi-Cal benefits. Audit &amp; Investigations Branch (IB) is responsible for working beneficiary cases. IB has an intake process for complaints which entails an initial case review and if warranted, assignment of a case to an investigator. Subsequent actions are dependent upon the outcome of IB's investigation.</td>
</tr>
<tr>
<td>GA</td>
<td>Referred to Office of Inspector General</td>
</tr>
<tr>
<td>IN</td>
<td>Submit to FSSA Bureau of Investigations for member investigation</td>
</tr>
<tr>
<td>KY</td>
<td>Board of Pharmacy, Audit Vendor, Surveillance Utilization Review System (SURS), Special Investigative Unit (SIU), Attorney General (AG), Office of Inspector General (OIG)</td>
</tr>
<tr>
<td>MD</td>
<td>SURS, OIG, Controlled Dangerous Substances Integration Unit (CDSIU)</td>
</tr>
<tr>
<td>MI</td>
<td>The Office of Inspector General performs SURS for both providers and beneficiaries.</td>
</tr>
<tr>
<td>MN</td>
<td>Questionable utilization is referred to the SURS program and they determine the action from there.</td>
</tr>
<tr>
<td>MS</td>
<td>Depends on situation. Could refer to Mississippi Attorney General's Medicaid Fraud Control Unit</td>
</tr>
<tr>
<td>MT</td>
<td>We follow a member through a Fraud Review determination and when Fraud may be occurring, the member is referred to the Division of Criminal Investigations.</td>
</tr>
</tbody>
</table>

2016 DUR Comparison/Summary Report –October 2017
VIII-A2. Do you have to a "lock-in" program for beneficiaries who misuse or abuse controlled substances?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, CA, CO, CT, DC, DE, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MS, MO, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
<td>48 (96%)</td>
</tr>
<tr>
<td>No</td>
<td>FL, SD</td>
<td>2 (4%)</td>
</tr>
</tbody>
</table>

If answer to VIII-A2 above is "Yes", what criteria does your state use to identify candidates for lock-in? Check all that apply.

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 48 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of controlled substances (CS)</td>
<td>AK, AL, AR, DC, DE, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MS, NC, ND, NH, NJ, NM, NV, NY, OH, OK, OR, PA, SC, TN, TX, VA, VT, WA, WI, WV, WY</td>
<td>40 (83%)</td>
</tr>
<tr>
<td>Different prescriptions of CS</td>
<td>AK, AL, AR, CO, CT, DC, DE, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
<td>46 (96%)</td>
</tr>
<tr>
<td>Multiple pharmacies</td>
<td>AK, AL, AR, DC, DE, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
<td>44 (92%)</td>
</tr>
<tr>
<td>Number days' supply of CS</td>
<td>AK, AL, AR, CT, DC, GA, IA, KS, LA, MD, MI, MO, MS, ND, NM, NY, OK, OR, PA, SC, TX, VT, WI, WV</td>
<td>23 (48%)</td>
</tr>
<tr>
<td>Exclusivity of short-acting opioids</td>
<td>GA, IA, KS, NM, NV, NY, OK, PA, SC, TX, VT</td>
<td>10 (21%)</td>
</tr>
<tr>
<td>Multiple ER visits</td>
<td>AK, AL, CO, GA, IA, ID, IN, KS, KY, ME, MI, MN, MO, MS, MT, ND, NE, NH, NJ, NY, OK, OR, PA, TN, UT, VA, VT, WA, WI, WV</td>
<td>30 (63%)</td>
</tr>
</tbody>
</table>
If answer to VIII-A2 above is "Yes", do you restrict the beneficiary to?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States</th>
<th>(Percentage of 48 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriber only</td>
<td>AR, CT, DC, DE, MA, MD, NH, NV, OH, OR, RI, SC, TN, WV, WV</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Pharmacy only</td>
<td>AK, AL, CA, CO, GA, HI, IA, ID, IL, IN, KS, KY, LA, ME, MI, MN, MO, MS, MT, NC, ND, NE, NM, NV, OK, PA, TX, UT, VA, VT, WA</td>
<td>16 (33%)</td>
<td></td>
</tr>
<tr>
<td>Both prescriber and pharmacy</td>
<td>AK, AL, CA, CO, GA, HI, IA, ID, IL, IN, KS, KY, LA, ME, MI, MN, MO, MS, MT, NC, ND, NE, NM, NV, OK, PA, TX, UT, VA, VT, WA, WI</td>
<td>32 (67%)</td>
<td></td>
</tr>
</tbody>
</table>

If answer to VIII-A2 above is "Yes", what is the usual "lock-in" time period?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States</th>
<th>(Percentage of 48 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td>AK</td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>AL, AR, CO, CT, DC, ID, IL, MA, MS, MT, NC, NH, RI, UT, VA, WV, WV</td>
<td>17 (35%)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>CA, DE, GA, HI, IA, IN, KS, KY, LA, MD, ME, MI, MN, MO, ND, NE, NJ, NM, NV, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WI</td>
<td>30 (63%)</td>
<td></td>
</tr>
</tbody>
</table>

If the answer to above is "Other," please explain:

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>Two years according to 22CCR 50793.</td>
</tr>
<tr>
<td>DE</td>
<td>Lock in does not have an end date, but can be reviewed at the client's request.</td>
</tr>
<tr>
<td>GA</td>
<td>6-12 months.</td>
</tr>
<tr>
<td>HI</td>
<td>There has been no usual &quot;lock-in&quot; time period since 2009 when the ABD population moved into managed care plans. No one has been &quot;locked-in&quot; since 2009.</td>
</tr>
<tr>
<td>IA</td>
<td>24 months or longer. Note: During FY 2016, the structure of the program changed with the transition to MCO.</td>
</tr>
<tr>
<td>IN</td>
<td>2 years, and then re-evaluation for graduation or re-enrollment.</td>
</tr>
<tr>
<td>KS</td>
<td>2 years.</td>
</tr>
<tr>
<td>KY</td>
<td>Twenty-four (24) months initial lock-in period with annual reviews thereafter for appropriateness of continuance in the program.</td>
</tr>
<tr>
<td>LA</td>
<td>24 months.</td>
</tr>
<tr>
<td>MD</td>
<td>24 months.</td>
</tr>
<tr>
<td>MI</td>
<td>Varies on severity and site dependent of review of urinalysis and medical chart.</td>
</tr>
<tr>
<td>MN</td>
<td>2 Years.</td>
</tr>
<tr>
<td>MO</td>
<td>24 months.</td>
</tr>
<tr>
<td>ND</td>
<td>Participants are locked in for a period of 24 months of eligibility.</td>
</tr>
<tr>
<td>NE</td>
<td>Until a subsequent review shows that the patient is properly utilizing services and their lock-in doctor agrees the patient should be removed from the lock-in program.</td>
</tr>
<tr>
<td>NJ</td>
<td>Each patient enrolled in the Lock-In Program is evaluated every 24 months for necessity of Lock-In status.</td>
</tr>
<tr>
<td>NM</td>
<td>Time period is decided on a case by case basis.</td>
</tr>
<tr>
<td>NV</td>
<td>Indefinite, we do not have a process for review to remove from lock-in.</td>
</tr>
<tr>
<td>NY</td>
<td>Two years of lock-in for the first offense. Thereafter, for a continuation (due to continued abuse or abuse while restriction/lock-in still in place) or re-restriction/lock-in, the second term would be three years, and the third time or more would be six years.</td>
</tr>
<tr>
<td>OH</td>
<td>18 months.</td>
</tr>
<tr>
<td>OK</td>
<td>24 months for new lock-in referrals, then reviewed yearly.</td>
</tr>
<tr>
<td>OR</td>
<td>18 months.</td>
</tr>
<tr>
<td>PA</td>
<td>5 years as approved by CMS in 1985 audit of PA's Lock-In Program.</td>
</tr>
<tr>
<td>SC</td>
<td>Minimum of 2 years, with periodic evaluation at least annually.</td>
</tr>
</tbody>
</table>

2016 DUR Comparison/Summary Report - October 2017
Indefinite. Each enrollee subject to Lock-in is re-reviewed at least once per year, and is eligible to have the Lock-in edit removed based on findings, all listed in Tennessee State Rules.

First lock-in is 36 months; second lock-in is 60 months; third lock-in is lifetime. If convicted of felony, the first lock-in could be lifetime.

Clients are placed on "lock in" for three years. Periodic interim reviews are performed which may release them earlier.

VIII-A3. On the average, what percentage of the FFS population is in lock-in status annually?

<table>
<thead>
<tr>
<th>State</th>
<th>Percentage of the FFS population in lock-in status annually</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO</td>
<td>0.000%</td>
</tr>
<tr>
<td>HI</td>
<td>0.000%</td>
</tr>
<tr>
<td>KY</td>
<td>0.000%</td>
</tr>
<tr>
<td>MS</td>
<td>0.000%</td>
</tr>
<tr>
<td>NH</td>
<td>0.000%</td>
</tr>
<tr>
<td>NM</td>
<td>0.000%</td>
</tr>
<tr>
<td>OH</td>
<td>0.000%</td>
</tr>
<tr>
<td>MO</td>
<td>0.002%</td>
</tr>
<tr>
<td>LA</td>
<td>0.005%</td>
</tr>
<tr>
<td>TX</td>
<td>0.006%</td>
</tr>
<tr>
<td>OR</td>
<td>0.010%</td>
</tr>
<tr>
<td>MI</td>
<td>0.013%</td>
</tr>
<tr>
<td>AR</td>
<td>0.014%</td>
</tr>
<tr>
<td>MT</td>
<td>0.020%</td>
</tr>
<tr>
<td>SC</td>
<td>0.026%</td>
</tr>
<tr>
<td>AL</td>
<td>0.040%</td>
</tr>
<tr>
<td>CT</td>
<td>0.059%</td>
</tr>
<tr>
<td>IL</td>
<td>0.060%</td>
</tr>
<tr>
<td>PA</td>
<td>0.080%</td>
</tr>
<tr>
<td>DC</td>
<td>0.100%</td>
</tr>
<tr>
<td>KS</td>
<td>0.100%</td>
</tr>
<tr>
<td>MA</td>
<td>0.100%</td>
</tr>
<tr>
<td>WY</td>
<td>0.100%</td>
</tr>
<tr>
<td>NE</td>
<td>0.120%</td>
</tr>
<tr>
<td>IN</td>
<td>0.180%</td>
</tr>
<tr>
<td>AK</td>
<td>0.200%</td>
</tr>
<tr>
<td>DE</td>
<td>0.200%</td>
</tr>
<tr>
<td>GA</td>
<td>0.200%</td>
</tr>
<tr>
<td>ID</td>
<td>0.200%</td>
</tr>
<tr>
<td>NC</td>
<td>0.205%</td>
</tr>
<tr>
<td>NY</td>
<td>0.250%</td>
</tr>
<tr>
<td>TN</td>
<td>0.250%</td>
</tr>
<tr>
<td>UT</td>
<td>0.370%</td>
</tr>
<tr>
<td>OK</td>
<td>0.390%</td>
</tr>
<tr>
<td>ND</td>
<td>0.400%</td>
</tr>
<tr>
<td>NV</td>
<td>0.450%</td>
</tr>
<tr>
<td>IA</td>
<td>0.500%</td>
</tr>
<tr>
<td>ME</td>
<td>0.550%</td>
</tr>
<tr>
<td>RI</td>
<td>0.550%</td>
</tr>
<tr>
<td>WI</td>
<td>0.550%</td>
</tr>
<tr>
<td>CA</td>
<td>1.000%</td>
</tr>
<tr>
<td>MD</td>
<td>1.000%</td>
</tr>
<tr>
<td>MN</td>
<td>1.000%</td>
</tr>
<tr>
<td>NJ</td>
<td>1.000%</td>
</tr>
<tr>
<td>VA</td>
<td>1.000%</td>
</tr>
<tr>
<td>VT</td>
<td>1.000%</td>
</tr>
<tr>
<td>WA</td>
<td>1.500%</td>
</tr>
<tr>
<td>WV</td>
<td>2.000%</td>
</tr>
<tr>
<td>Average</td>
<td>0.325%</td>
</tr>
</tbody>
</table>
VIII-A4. Please provide an estimate of the savings attributed to the lock-in program for the fiscal year under review.

<table>
<thead>
<tr>
<th>State</th>
<th>Estimate of the savings attributed to the lock-in program for the fiscal year under review</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>$0</td>
</tr>
<tr>
<td>AR</td>
<td>$0</td>
</tr>
<tr>
<td>CA</td>
<td>$0</td>
</tr>
<tr>
<td>CO</td>
<td>$0</td>
</tr>
<tr>
<td>DE</td>
<td>$0</td>
</tr>
<tr>
<td>GA</td>
<td>$0</td>
</tr>
<tr>
<td>HI</td>
<td>$0</td>
</tr>
<tr>
<td>IA</td>
<td>$0</td>
</tr>
<tr>
<td>ID</td>
<td>$0</td>
</tr>
<tr>
<td>IN</td>
<td>$0</td>
</tr>
<tr>
<td>KS</td>
<td>$0</td>
</tr>
<tr>
<td>KY</td>
<td>$0</td>
</tr>
<tr>
<td>MA</td>
<td>$0</td>
</tr>
<tr>
<td>ME</td>
<td>$0</td>
</tr>
<tr>
<td>MI</td>
<td>$0</td>
</tr>
<tr>
<td>MN</td>
<td>$0</td>
</tr>
<tr>
<td>ND</td>
<td>$0</td>
</tr>
<tr>
<td>NE</td>
<td>$0</td>
</tr>
<tr>
<td>NH</td>
<td>$0</td>
</tr>
<tr>
<td>NM</td>
<td>$0</td>
</tr>
<tr>
<td>OH</td>
<td>$0</td>
</tr>
<tr>
<td>VA</td>
<td>$0</td>
</tr>
<tr>
<td>WA</td>
<td>$0</td>
</tr>
<tr>
<td>WI</td>
<td>$0</td>
</tr>
<tr>
<td>DC</td>
<td>$500</td>
</tr>
<tr>
<td>RI</td>
<td>$1,801</td>
</tr>
<tr>
<td>OR</td>
<td>$4,800</td>
</tr>
<tr>
<td>MD</td>
<td>$5,340</td>
</tr>
<tr>
<td>LA</td>
<td>$13,000</td>
</tr>
<tr>
<td>MI</td>
<td>$20,335</td>
</tr>
<tr>
<td>NJ</td>
<td>$50,488</td>
</tr>
<tr>
<td>WY</td>
<td>$47,242</td>
</tr>
<tr>
<td>AL</td>
<td>$57,902</td>
</tr>
<tr>
<td>SC</td>
<td>$100,000</td>
</tr>
<tr>
<td>TN</td>
<td>$109,116</td>
</tr>
<tr>
<td>TX</td>
<td>$112,563</td>
</tr>
<tr>
<td>WV</td>
<td>$115,757</td>
</tr>
<tr>
<td>OK</td>
<td>$192,708</td>
</tr>
<tr>
<td>MT</td>
<td>$252,868</td>
</tr>
<tr>
<td>NV</td>
<td>$374,787</td>
</tr>
<tr>
<td>VT</td>
<td>$451,434</td>
</tr>
<tr>
<td>CT</td>
<td>$506,948</td>
</tr>
<tr>
<td>UT</td>
<td>$679,250</td>
</tr>
<tr>
<td>IL</td>
<td>$684,033</td>
</tr>
<tr>
<td>SC</td>
<td>$4,606,631</td>
</tr>
<tr>
<td>NV</td>
<td>$5,895,900</td>
</tr>
<tr>
<td>MO</td>
<td>$6,635,649</td>
</tr>
<tr>
<td>PA</td>
<td>$5,790,000</td>
</tr>
<tr>
<td>Average</td>
<td>$1,566,498</td>
</tr>
</tbody>
</table>

2016 DUR Comparison/Summary Report –October 2017
VIII-A5. Do you have a documented process in place that identifies possible fraud or abuse of controlled drugs by prescribers?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AL, AR, CA, CO, CT, DC, DE, GA, IA, IL, IN, KS, KY, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WV, WI</td>
<td>39 (78%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, FL, HI, ID, IA, MT, NH, NM, NV, OR, WY</td>
<td>11 (22%)</td>
</tr>
</tbody>
</table>

If answer to VIII-A5 above is "Yes", what actions does this process initiate? Check all that apply.

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 39 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deny claims written by this prescriber</td>
<td>CA, CO, GA, IN, MA, MD, MI, MO, NJ, SC, TN, VT, WA, WV</td>
<td>14 (36%)</td>
</tr>
<tr>
<td>Refer to Program Integrity Unit</td>
<td>AL, AR, CA, CO, CT, DC, DE, GA, IA, IL, IN, KS, KY, MA, MD, ME, MI, MO, MS, NC, ND, NJ, OH, OK, PA, RI, SC, SD, TN, TX, VA, VT, WA, WV, WI</td>
<td>35 (90%)</td>
</tr>
<tr>
<td>Refer to the appropriate Medical Board</td>
<td>AL, CO, DC, DE, GA, IA, IL, IN, KS, KY, MA, MD, ME, MI, MO, MS, NC, ND, NJ, OH, OK, PA, RI, SC, SD, TN, TX, VA, VT, WA, WV, WI</td>
<td>27 (69%)</td>
</tr>
<tr>
<td>Other - please explain: CA, GA, IL, KS, MD, MI, MN, MO, MS, NC, NE, NY, PA, TN, VT, WA</td>
<td>16 (41%)</td>
<td></td>
</tr>
</tbody>
</table>

If (d) "Other" above is selected, please explain:

- CA Prepare new policy such as quantity restrictions, and further review by Audit & Investigations Branch (IB) Medical Review Branch (MRB).
- IL Also report to the Illinois Department of Financial and Professional Regulation, which issues professional licenses.
- KS Reforms are sometimes made to the Attorney General's Office.
- MD SURS, OR, Controlled Substance Integration Unit (RISIU).
- MI Prescribers may be suspended or sanctioned and prescriptions written by this prescriber would then be denied at point-of-sale.
- MN Refer to DHS's Office of Inspector General (OIG). DEA
- MO DUR Board review of provider/participant cases.
- MS DEA
- NC An audit of specific claims would be performed.
- NE Program Integrity Unit is reviewing reports produced through the data warehouse of outliers for further review.
- NY Medicaid Director/DUR case reviewers refer potential prescriber fraud cases to the DUR program, from which they are forwarded to the Office of the Medicaid Inspector General (OMIG) for further review and/or possible investigation.
- PA Refer to MFCS and initiate payment suspension if appropriate.
- TN Since pharmacy is carved out of the managed care plans and is FFS, all prescribers are contracted with the MCOs. Prior to referring to authoritative regulatory boards, the prescriber would be referred to the relevant Medicaid Fraud and Residential Abuse unit.
- VT DUR Board review of provider/participant cases.
- WA Items A, B, and C are not applicable in every case. All three may be pursued, but only a single action may be taken in some cases.
VIII-A6. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by pharmacy providers?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AL, AR, CA, CO, CT, DC, DE, GA, IA, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NJ, NY, OH, OK, PA, RI, SC, SD, TX, UT, VA, WA, WV</td>
<td>36 (72%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, FL, HI, ID, KS, MT, NE, NM, NV, OR, CO, VT, WI, WY</td>
<td>14 (28%)</td>
</tr>
</tbody>
</table>

If answer to VIII-A6 above is “Yes,” what actions does this process initiate? Check all that apply.

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 36 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deny claim</td>
<td>CO, GA, IN, KY, LA, MA, MD, ME, MI, MO, NJ, NV, WV</td>
<td>12 (33%)</td>
</tr>
<tr>
<td>Refer to Program Integrity Unit</td>
<td>AL, AR, CA, CO, CT, DC, DE, GA, IA, IL, IN, KY, MA, MD, ME, MI, MO, MS, NC, ND, NJ, OH, OK, PA, RI, SD, TX, UT, VA, WA, WV</td>
<td>31 (86%)</td>
</tr>
<tr>
<td>Refer to Board of Pharmacy</td>
<td>AL, CA, CO, CT, DE, GA, IA, IL, IN, KY, MA, ME, MI, MO, MS, NC, ND, NJ, OK, PA, SD, WV</td>
<td>21 (58%)</td>
</tr>
<tr>
<td>Other - please explain</td>
<td>CA, GA, IL, IN, KY, MD, MI, MO, MS, NC, NE, NY, PA, SC</td>
<td>15 (42%)</td>
</tr>
</tbody>
</table>

If (d) "Other" above is selected, please explain.

**State** | **Explanation**
--- | ---
CA | Prepare new policy such as quantity restrictions, and further review by Audit & Investigations Branch (IB) Medical Review Branch (MRB).
CO | Referral to Office of Inspector General
IL | Also report to the Illinois Department of Financial and Professional Regulation, which issues professional licenses
IN | Audit recoupment, Prepayment review program
KY | Desk audits are conducted by a vendor.
MD | OIG conducts audits of Maryland pharmacies to ensure compliance with regulations for all medications for Medicaid.
MI | Pharmacies may be suspended or sanctioned which results in the denial of claims submitted by the pharmacy at point-of-sale.
MN | Refer to DHHS's Office of Inspector General
MO | DUR Board review of provider/participant cases.
MS | Refer to Mississippi Attorney General's Medicaid Fraud Control Unit
NC | An audit of specific claims would be performed.
NY | Professional StaffDUR case reviewers refer potential prescriber fraud cases to the DUR program, from which they are forwarded to the Office of the Medicaid Inspector General (OMIG) for further review and/or possible investigation.
PA | Refer to MFCS
SC | Yes, a ranking report has been developed for pharmacy providers based on composite scores to several algorithms and numerous measures.
VIII-A7. Do you have a documented process in place that identifies potential fraud or abuse of non-controlled drugs by beneficiaries?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AL, CA, CO, CT, GA, HI, IA, KY, LA, MA, ME, MI, MN, MT, NE, NJ, NY, OK, PA, UT, WA, WI, WV</td>
<td>24 (48%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, AR, DC, DE, FL, ID, IL, IN, KS, MD, MO, MS, NC, ND, NM, NV, OH, OR, RI, SC, SD, TN, TX, VA, VT, WY</td>
<td>26 (52%)</td>
</tr>
</tbody>
</table>

If answer to VIII-A7 above is "Yes," please explain your program for fraud or abuse of non-controlled substances.

State Explanation

- **AL**: Through eligibility and URC, recipients are referred to MFU.
- **CA**: Audit Investigations Branch (IB) uses all available information to develop and work cases, initiate audits, and assist in investigations, including review of claims data and trends of non-controlled drugs.
- **CO**: Retrospective DUR analysis and prior authorization identifies these issues.
- **CT**: The quality assurance program at DSS performs random claims samples of controlled and non-controlled drugs to identify anomalies in payment and claims processing.
- **GA**: Retrospective analysis of potential fraud/abuse on a case-by-case basis.
- **HI**: Establishing quantity limits or other DUR management strategies are documented processes.
- **IA**: If fraud or abuse of a non-controlled substance is identified, the member would be referred to Program Integrity for further investigation.
- **KY**: Refill too soon, ProDUR checks, desk audits, RetroDUR audits, quantity limits, accumulation edits, and other general DUR activities or system edits.
- **LA**: Program Integrity Unit performs this function and will refer as needed.
- **MA**: Medicaid checks MassPAT for outlier behavior episodically and develops corrective action.
- **ME**: Review and referred system to identify overuse and internal clinical review for placement within the lock-in program.
- **MI**: Community with high utilization of emergency room prescribers and pharmacies including those that paid with cash are subject to review.
- **MN**: Questionable utilization is referred to the SURES program and they determine the action from there.
- **MT**: We run a statistical report that reviews usage for controlled substances.
- **NE**: Quantity limits are in place for many non-controlled substances.
- **NH**: The Program Integrity Unit performs this function and will refer as needed.
- **NJ**: Lock into a pharmacy and negative PA. Negative PA is designed to block payment of a prescription service.
- **NY**: Professional RetroDUR case reviewers refer potential prescriber fraud cases to the DUR program, from which they are forwarded to the Office of the Medicaid Inspector General (OMIG) for further review and/or possible investigation.
- **OH**: Administration of the lock-in program.
- **OK**: Medicaid claims are considered when locking members in.
- **PA**: Review for the Lock-In Program includes all medications. Recipients may be restricted for fraud, waste, or abuse of non-controlled substances.
- **UT**: The BERC has algorithms to identify recipients who may be misusing or abusing non-controlled drugs.
- **WA**: Washington Medicaid does not differentiate between controlled and non-controlled substances for its lock-in program. Although it is usually controlled substances which most easily result in a client being placed in lock-in, any documentable fraud, abuse, or even unintentional misuse of the prescription drug benefit can lead to placement.
- **WI**: Fraud and abuse must be reported regardless if the drug is a controlled drug or non-controlled drug. Providers may report fraud and abuse by going to the OIG fraud and abuse website or by calling the fraud and abuse hotline.
- **WV**: Our early refill edit and quantity limit edit protect against a member obtaining more than 12 months supply of any drug in a year. Drugs requiring a PA typically require at minimum an approved diagnosis.
VIII B. PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

VIII-B1. Does your state have a Prescription Drug Monitoring Program (PDMP)?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MS, MT, NC, ND, NE, NH, NJ, NM, NY, OH, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
</tr>
<tr>
<td>No</td>
<td>MO</td>
</tr>
</tbody>
</table>

If answer to VIII-B1 above is "Yes," does your agency have the ability to query the state's PDMP database?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AL, CA, CT, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MS, MT, NC, ND, NV, OH, OK, SC, SD, TN, TX, UT, VA, WA, WV</td>
</tr>
<tr>
<td>No</td>
<td>AK, AR, CO, DC, DE, FL, GA, HI, IA, MN, NE, NH, NJ, NM, NY, OR, PA, RI, TX, UT, VA, WI, WV</td>
</tr>
</tbody>
</table>

If answer to VIII-B1 above is "Yes," do you require prescribers (in your provider agreement with the agency) to access the PDMP patient history before prescribing restricted substances?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CT, DE, KS, KY, MA, ND, NI, NY, PA, SC, VA, VT, WV</td>
</tr>
<tr>
<td>No</td>
<td>AK, AL, AR, CA, CO, DC, FL, GA, HI, IA, ID, IL, IN, LA, MD, ME, MI, MN, MS, MT, NC, NE, NJ, NM, NY, OH, OR, PA, RI, SC, SD, TN, TX, UT, VA, WI, WV</td>
</tr>
</tbody>
</table>

If answer to VIII-B1 above is "Yes," please explain how the state applies this information to control fraud and abuse.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>n/a</td>
</tr>
<tr>
<td>AL</td>
<td>n/a</td>
</tr>
<tr>
<td>AR</td>
<td>Medicaid Pharmacy Program does not have access to the PDMP.</td>
</tr>
<tr>
<td>CA</td>
<td>The California Department of Health has a Prescription Drug Monitoring Program (PDMP) system called the Controlled Substance Utilization Review and Evaluation System (CURES), which allows pre-registered users including licensed healthcare providers, pharmacies, authorized to dispense controlled substances, law enforcement, and regulatory boards to access timely patient-controlled substance history information. Access to such information helps prescribers and pharmacists better evaluate their patients' care, allowing them to make better prescribing and dispensing decisions, and cut down on prescription drug abuse in California. The Audit &amp; Investigations Branch (IB) uses all available information to develop and work cases, initiates audits, and assists in investigations. Audit &amp; Investigations Branch (IB) examines PDMP information on prescribers, dispensers, and beneficiaries during the course of A&amp;I's usual work. We cannot access the PDMP.</td>
</tr>
<tr>
<td>CT</td>
<td>State law requires all prescribers to review a patient's controlled substance history report if writing for more than a 72 hour supply. The provider agreement with the agency requires prescribers to adhere to all state laws and regulations.</td>
</tr>
<tr>
<td>DC</td>
<td>The Department of Health has jurisdiction over the PDMP.</td>
</tr>
</tbody>
</table>
**DE** For prior authorizations on controlled substances, the prescriber must indicate on the prior authorization form that the PDMP was checked.

**FL** xa

**GA** The State does not have access to the PDMP database.

**HI** Review of all FFS narcotic claims done quarterly for quantities greater than 25. Dental has low quantities and SHOTR rarely has a claim.

**IA** The state is unable to access this data. The PMP is only available to authorized healthcare practitioners to review their patient's use of controlled substances.

**ID** The clinical pharmacy staff at IDHW will access the PDMP in cases where it is brought to their attention if fraud/abuse is thought to be occurring. The PDMP is also accessed in RetrosUR topics that may require if it conducting reviews.

**IL** Prescribers are asked to check ILPMP for hepatitis C medications, ADHD medications, and chronic opioid use. FFS checks ILPMP as well and information helps in understanding medication use as well as identifying patients for potential lock-in

**IN** INSPECT Program

**IA** We incorporated this into our Long-Acting Opioids criteria during FY 2014.

**KY** Prescribers must attest to the fact that the PDMP was consulted prior to particular drugs being approved.

**LA** The additional data accessed through PDMP assist the LDH pharmacy staff in determining fraud and abuse.

**MA** Medicaid checks MassPAT for outlier behavior epidemically and develops corrective action

**MD** Information obtained from the PDMP is used for the Corrective Managed Care (CMC) program through the FFS program if a formal investigation is being conducted.

**ME** We answered no above.

**MI** MDHHS requires prescribers of medication assisted therapy (MAT) agents to be registered and access the PDMP. In addition, the MI Department of Licensing and Regulatory Affairs (LARA) monitors prescribing patterns and investigates. MDHHS also works closely with the OIG and the AG offices.

**MN** There is very strict criteria as to when SURS can access the PDMP in the case of a recipient under investigation for fraud and abuse.

**MS** Program Integrity uses the data to evaluate suspicious cases involving beneficiaries and providers.

**MT** We review utilization between Flexible Rx and the PDMP looking for cash pay on the PDMP, that are not found in Flexible Rx.

**NC** For treatment of opioid dependance, prescribers are required to access the PDMP patient history before a PA will be granted.

**ND** Require prescribers to access PDMP before approving prior authorizations on some narcotics.

**NE** No access.

**NH** For all long acting narcotic prescriptions, it is required that the physician access the PDMP prior to prescribing the medication.

**NJ** Although our agency does not have the ability to access NJ PDMP, we ask prescribers and pharmacy providers to access PDMP before approving prior authorizations on controlled medications.

**NM** The NM Board of Pharmacy has a PDMP accessible prescribers and pharmacists.

**NV** Will check potential abusers for cash paid claims in the PMP. Lock-in recipients are also checked.

**NY** In NYS, all prescribers writing a prescription for a Schedule II-IV controlled substance have a mandatory duty to consult the Prescription Monitoring Program Registry, with limited exceptions. The mandatory duty to consult the PDMP provisions affords practitioners with current, patient-specific controlled substance prescription information intended to inform the practitioner of controlled substance utilization by their patient at the point of prescribing. As of June 14, 2016, all prescribers in New York State can access to New Jersey, Connecticut, Massachusetts, Rhode Island, New Hampshire and Vermont's PDMP data. NYS is working with Pennsylvania to share data once they are able. NYS is also sharing PDMP information with other states including Virginia, West Virginia, South Carolina, Minnesota, Indiana and the District of Columbia.

**OH** Used to verify whether the Medicaid claims are all controlled substances received by patient

**OK** Evaluate members for the lock-in program and individual review of members to prevent excess abuse.

**OR** VIII-B1 = No

**PA** Prescribers are required to query the PDMP for an existing patient when the following clinic situations apply: 1. For each patient the first time the patient is prescribed a controlled substance by the prescriber for purposes of establishing a baseline and a thorough medical record; or 2. If a prescriber believes or has reason to believe, using sound clinical judgment, that a patient may be abusing or diverting drugs; or 3. Each time a patient is prescribed an opioid drug product or benzodiazepine by the prescriber.

**RI** Requests the prescribers use the PDMP.

**SC** State may pursue audits of PDMP - state may then recoup monies for office visit on those prescriptions where PDMP was not documented/verified

**SD** The answer is no.

**TN** Providers are now required per State Law to check the CSMDD (Controlled Substance Monitoring DB), and are required within our P.A. requirements for specific medications in an effort to control fraud and abuse. CSMDD is also used during Lock-In re-reviews, as cash purchases are used during the process.
If answer to VIII-B1 above is "Yes," do you also have access to border-states' PDMP information?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage of 49 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>19 (39%)</td>
</tr>
<tr>
<td>No</td>
<td>30 (61%)</td>
</tr>
</tbody>
</table>

2016 DUR Comparison/Summary Report—October 2017  Page 37
VIII-B2. Are there barriers that hinder the agency from fully accessing the PDMP that prevent the program from being utilized the way it was intended to be used to curb abuse?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CA, CO, CT, DC, FL, GA, HI, IA, ID, IL, IN, KS, MA, MD, MI, MN, NC, NE, NH, NJ, NM, NV, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WI, WV, WY</td>
</tr>
<tr>
<td>No</td>
<td>DE, KY, LA, ME, MS, MT, ND, NY, OH, SC, SD, TN, VT</td>
</tr>
</tbody>
</table>

If answer to VIII-B2 above is "Yes," please explain the barriers (e.g. lag time in prescription data being submitted, prescribers not accessing, and pharmacists unable to view prescription history before filling script).

**State Explanation**
- **AK**: Medicaid program does not have access to the PDMP. The agency has limited access. Prescribers/pharmacists are not required to access prior to writing dispensing prescriptions.
- **AL**: The Agency has limited access. Prescribers/pharmacists are not required to access prior to writing dispensing prescriptions.
- **AR**: Medicaid program does not have access to the PDMP. The agency has limited access. Prescribers/pharmacists are not required to access prior to writing dispensing prescriptions.
- **CA**: Enrolment by California's prescribers and pharmacists was experiencing delays due to restructuring of the CURES program under the Department of Justice and State Budgetary restrictions. A streamlined application and approval process for access to the Controlled Substance Utilization Review and Evaluation System (CURES) 2.0 was completed in FY 2016. California law (Health and Safety Code Section 11165.1) requires all California licensed prescribers to prescribe scheduled drugs to register for access to CURES 2.0 by July 1, 2016 or upon issuance of a Drug Enforcement Administration Controlled Substance Registration Certificate, whichever occurs later. California licensed pharmacists must register for access to CURES 2.0 by July 1, 2016, or upon issuance of a Board of Pharmacy Pharmacist License, whichever occurs later.
- **CO**: The state is prohibited by legislation from accessing the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **CT**: As part of the Department of Social Services, the agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **DE**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **FL**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **GA**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **HI**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **IA**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **IL**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **IN**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **KS**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **LA**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **ME**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **MI**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **MN**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **MO**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **MS**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **MT**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **NE**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **NH**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **NJ**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **NM**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **NV**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **NY**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **OH**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **OK**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **OR**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **PA**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **RI**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **SC**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **SD**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **TN**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **TX**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **UT**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **VA**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **WA**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **WI**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **WV**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.
- **WY**: Medicaid agency is not able to access the PDMP. Access is restricted to our Medicaid Fraud Unit only.

2016 DUR Comparison/Summary Report – October 2017
NJ NJ POMP grants access to prescribers and pharmacists who are licensed by the State of New Jersey and in good standing with their respective licensing boards. Licensed pharmacy staff conducting DUR is considered unauthorised users since they are not directly delivering healthcare.

NM Access is only available at pharmacy and prescriber offices.

NV Only the State staff have access to the data. Contractors for the State are not allowed to access the PMP unless they have responsibility for direct patient care. Unable to query by prescriber. The agency may only query one member at a time. There is no way to access aggregated prescriber data.

OK Papers do not have access to the PMP in Oregon

PA The PMP is managed by the Department of Health and is not accessible to the Department of Human Services Medicaid Program for fraud and abuse.

RI State law requires the user of the PMP to have a DEA number.

TX The Department of Public Safety does not allow the Medicaid program access to PDMP.

UT Utah Medicaid is limited by the State Statute in how it may access and use data from the PDMP.

VA not allowed to access by state law

WA Washington State continues to struggle with uptake of PMP usage by prescribers.

WI The PDMP is managed by a different agency.

WV Access to the PMP is limited to one person at our department and queries are capable of only pulling up one member at a time.

WY The Board of Pharmacy has reviewed their statute and rules and determined that the Department of Health should not have access to the PDMP.

VIII-B3. Have you had any changes to your state’s Prescription Drug Monitoring Program during this reporting period that have improved the agency’s ability to access PDMP data?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 49 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, HI, IL, MA, MI, MS, MT, SC, VT</td>
<td>9 (18%)</td>
</tr>
<tr>
<td></td>
<td>AL, AR, CA, CO, CT, DC, DE, FL, GA, IA, ID, IN, KS, KY, LA, MI, ME, MN, NC</td>
<td>40 (82%)</td>
</tr>
<tr>
<td>No</td>
<td>ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SD, TN, TX, UT, VA, WA, WI, WV, WY</td>
<td></td>
</tr>
</tbody>
</table>

If answer to VIII-B3 above is “Yes,” please explain.

**State Explanation**

AK During FY2016, the agency did not have access to the PDMP. New laws in 2016 made advancements in decreasing barriers; effective data in 2017.

IL Recent law opened PDMP to agency access.

IL ILPMP continues to expand the number of neighboring states' data that is visible.

MA Upgrades to the State PMP, now referred to as MassPAT, MassPAT also checks for slight changes in a patient’s name or birth date – an alternate spelling or inverted digits, as patients may provide variations on their information when trying to obtain extra drugs without drawing attention.

ME The PDMP servers have been updated to improve data availability.

MS Have executed a memorandum of agreement with State Board of Pharmacy for Medicaid to obtain all PMP claims for Medicaid beneficiaries each month for use in Retro-DUR program.

MT We have access to other states now and delegate access.

SC Prescribers required to access PDMP (effective 4/1/2015)

VT We are currently in the midst of transitioning, having just migrated to a new system on the 15th of June, 2017. This will greatly improve the interface and functionality to providers and others utilizing the system.
VIII C. PAIN MANAGEMENT CONTROLS

VIII-C1. Does your state or your agency require that Pain Management providers be certified?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>NJ, OH, SC, TN, TX</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, AL, AR, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NM, NV, NY, OK, OR, PA, RI, SD, UT, VA, VT, WA, WI, WV, WY</td>
<td>45 (90%)</td>
</tr>
</tbody>
</table>

VIII-C2. Does your program obtain the DEA Active Controlled Substance Registrant's File in order to identify prescribers not authorized to prescribe controlled drugs?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, CT, IA, ID, MI, MO, MS, ND, NH, PA, SC, WA, WV</td>
<td>14 (28%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, CA, CO, DC, DE, FL, GA, HI, IL, IN, KS, KY, LA, MA, MD, ME, MN, MT, NC, NE, NJ, NM, NV, NY, OH, OK, OR, RI, SD, TN, TX, UT, VA, VT, WI, WV</td>
<td>36 (72%)</td>
</tr>
</tbody>
</table>

If answer to VIII-C2 above is "Yes," do you apply this DEA file to your ProDUR POS edits to prevent unauthorized prescribing?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 14 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AL, CT, IA, MI, MO, ND, SC, WA</td>
<td>8 (57%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, ID, MS, NH, PA, WV</td>
<td>6 (43%)</td>
</tr>
</tbody>
</table>

If answer above is "Yes," please explain how the information is applied.

State  | Explanation
-------|-----------------------------------------------------
AL     | Claims are denied for controlled drugs prescribed by a provider not on the DEA file.
CT     | The information is applied at the point of sale.
IA     | Claims are blocked at the point of sale for prescribers not authorized to prescribe controlled substances.
MI     | The POS system has business rules that check for XDEA license eligible prescribers of office-based opioid dependency drug therapies.
MO     | If the DEA is inactive or restricted, claims for controlled substances are denied POS.
ND     | If no active DEA, claims for controlled substances are denied.
SC     | Claims for unauthorized prescriber/invalid DEA are denied.
WA     | During automated prescriber file loads, providers without DEA numbers are identified and added to restricted prescriber networks which do not allow the dispensing of Schedule II medications written by the provider.
If answer to VIII-C2 above is "No," do you plan to obtain the DEA Active Controlled Substance Registrant's file and apply it to your POS edits?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage 36 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes CO, DC, MA, ME, NJ, SD</td>
<td>6 (17%)</td>
</tr>
<tr>
<td>No AR, CA, DE, FL, GA, HI, IL, IN, KS, KY, LA, MD, MN, MT, NC, NE, NM, NV, NY, OH, OK, OR, RI, TN, TX, UT, VA, VT, WI, WY</td>
<td>30 (83%)</td>
</tr>
</tbody>
</table>

VIII-C3. Do you apply this DEA file to your RetroDUR reviews?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes MI, NH</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>No AK, AL, AR, CA, CO, CT, DC, DE, FL, GA, HI, ID, IL, IN, KS, KY, LA, MA, MD, ME, MN, MO, MS, MT, NC, ND, NE, NJ, NM, NV, NY, OH, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
<td>48 (96%)</td>
</tr>
</tbody>
</table>

If answer to VIII-C3 above is "Yes," please explain how it is applied.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI</td>
<td>Our vendor's RetroDUR system loads the DEA registrant file and can be queried for reports as needed, including prescribers without a valid DEA but prescribing controlled substances, etc.</td>
</tr>
<tr>
<td>NH</td>
<td>Used to identify prescribers not authorized to prescribe controlled substance medications.</td>
</tr>
</tbody>
</table>

VIII-C4. Do you have measures in place to either monitor or manage the prescribing of methadone for pain management?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes AK, AL, AR, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NJ, NY, OH, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
<td>44 (88%)</td>
</tr>
<tr>
<td>No HI, NM, NV, RI, SD</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Other IN</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>
If answer to VIII-C4 above is “Yes,” please check all that apply.

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 44 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist override</td>
<td>ID, KY, MO, OH</td>
<td>4 (9%)</td>
</tr>
<tr>
<td>Deny claim and require PA</td>
<td>AK, AL, AR, CA, DC, DE, FL, ID, IL, KS, KY, LA, MA, MD, ME, MI, MO, NC, ND, NH, NJ, OR, PA, TN, VA, VT, WV</td>
<td>37 (84%)</td>
</tr>
<tr>
<td>Quantity limits</td>
<td>AK, AL, DC, DE, FL, GA, ID, KS, LA, MA, ME, MI, MN, MO, MS, MT, NC, ND, NJ, NY, OH, OK, OR, PA, SC, TX, UT, VT, WA, WV, WY</td>
<td>31 (70%)</td>
</tr>
<tr>
<td>Intervention letters</td>
<td>CT, DE, IA, ID, IL, MD, MI, NC, ND, NH, SC, WI</td>
<td>12 (27%)</td>
</tr>
<tr>
<td>Morphine equivalent daily dose program</td>
<td>AK, AR, CO, ID, MA, ME, MN, OR, WY</td>
<td>9 (20%)</td>
</tr>
<tr>
<td>Step therapy or clinical criteria</td>
<td>AL, DC, DE, ID, IL, KY, MA, MI, MO, MT, ND, NH, NY, OK, OR, PA, UT, WA</td>
<td>18 (41%)</td>
</tr>
</tbody>
</table>

If answer to VIII-C4 above is either “No or Other,” please explain what you do in lieu of the above or why you do not have measures in place to either manage or monitor the prescribing of methadone for pain management.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HI</td>
<td>No FFS recipient since 2009 has been in need of a pain management program. This is an issue for our managed care plans though.</td>
</tr>
<tr>
<td>NV</td>
<td>Methadone is non-preferred on our PDL. We are looking into ways to better control its use.</td>
</tr>
<tr>
<td>RI</td>
<td>The P &amp; T Committee determined methadone would be a preferred agent. Fee-for-Service is a secondary claim for the most part and the primary payer makes that determination.</td>
</tr>
<tr>
<td>SD</td>
<td>Reviewing as a part of a broader opioid management program.</td>
</tr>
<tr>
<td>IN</td>
<td>Indiana law requires methadone to be dispensed only for the treatment of pain in an outpatient setting. Prior authorization is required if the member is over the established dosing limit or has greater than four prescribers of opiates.</td>
</tr>
</tbody>
</table>

VIII D. OPIOIDS

VIII-D1. Do you currently have POS edits in place to limit the quantity of short-acting opioids?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CA, CO, DE, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, ND, NE, NH, NY, OH, OK, OR, PA, SD, TN, UT, VA, VT, WI, WV, WY</td>
<td>37 (84%)</td>
</tr>
<tr>
<td>No</td>
<td>CT, DC, HI, MA, MN, NC, NJ, NM, NV, RI, SC, TX, WA</td>
<td>13 (28%)</td>
</tr>
</tbody>
</table>
a) If answer to VIII-D1 above is “Yes,” what is your maximum daily limit in terms of numbers of units (i.e., tablets, capsules)? Please indicate the number of unit(s) per day.

<table>
<thead>
<tr>
<th>State</th>
<th>Number of unit(s) per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>Varies; no more than 8 for some</td>
</tr>
<tr>
<td>AL</td>
<td>2</td>
</tr>
<tr>
<td>AR</td>
<td>6 units per day, but cannot exceed an accumulated quantity of total SAO of 93 units in previous 31 days.</td>
</tr>
<tr>
<td>CA</td>
<td>Short-acting opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 75-day period.</td>
</tr>
<tr>
<td>CO</td>
<td>4</td>
</tr>
<tr>
<td>DE</td>
<td>4 units for acute period and then 2 units a day for chronic pain</td>
</tr>
<tr>
<td>FL</td>
<td>12</td>
</tr>
<tr>
<td>GA</td>
<td>Varies; 5 opioid fills per 30 days</td>
</tr>
<tr>
<td>IA</td>
<td>Varies by drug</td>
</tr>
<tr>
<td>ID</td>
<td>Specific to each individual drug.</td>
</tr>
<tr>
<td>IL</td>
<td>6</td>
</tr>
<tr>
<td>IN</td>
<td>60 MME for new opiate utilizers</td>
</tr>
<tr>
<td>KS</td>
<td>Other - drug specific</td>
</tr>
<tr>
<td>KY</td>
<td>Depends on drug</td>
</tr>
<tr>
<td>LA</td>
<td>4</td>
</tr>
<tr>
<td>MD</td>
<td>Depends on product - please use link for further quantity limits. <a href="https://mmcp.dhmh.maryland.gov/pap/docs/QL.pdf">https://mmcp.dhmh.maryland.gov/pap/docs/QL.pdf</a></td>
</tr>
<tr>
<td>ME</td>
<td>15 day limit with continuation requiring PA for additional units and clinical rationale for long term use</td>
</tr>
<tr>
<td>MI</td>
<td>6</td>
</tr>
<tr>
<td>MO</td>
<td>40</td>
</tr>
<tr>
<td>MS</td>
<td>186</td>
</tr>
<tr>
<td>MT</td>
<td>Oxycodone 8/day</td>
</tr>
<tr>
<td>ND</td>
<td>Limit quantity on all short-acting opioids and the quantity varies by drug and strength</td>
</tr>
<tr>
<td>NE</td>
<td>5</td>
</tr>
<tr>
<td>NH</td>
<td>N/A</td>
</tr>
<tr>
<td>NY</td>
<td>Edits for Opioids - Short-Acting-Limited to a total of four (4) opioid prescriptions every 30 days; Exemption for diagnosis of cancer or sickle cell disease-Limited prescription for opioid-naive patients limited to a 15-day supply. - Exception for diagnosis of cancer or sickle cell disease: PA required for initiation of opioid therapy for patients on established benzodiazepine opioid dependence therapy: PA required for initiation of opioid therapy in patients currently on benzodiazepine therapy. - STEP THERAPY (S1): Nucynta® (tapentadol IR) – Trial with methylone and one (1) preferred opioid before tapentadol immediate-release (IR) – FREQUENCY/QUANTITY/DURATION (F/Q/D): Quantity Limits: Nucynta® (tapentadol IR): Maximum 6 (six) units per day; 180 units per 30 days. - Nucynta® (tapentadol IR): Maximum daily dose of tapentadol IR and tapentadol ER formulations used in combination not to exceed 500mg/day. - Morphine and congener immediate-release (IR) non-combination products (codeine, hydrocodone, morphine, oxycodone, oxymorphone): Maximum 6 (six) units per day; 180 (one hundred eighty) units per 30 (thirty) days. - Xartemis® XR (oxycodone/acetaminophen): Maximum 4 (four) units per day, 120 (one hundred twenty) units per 30 (thirty) days. - Additional alternate parameters: To be applied to patients without a documented cancer or sickle cell diagnosis: Morphine and congeners immediate-release (IR) combination products maximum recommended: acetaminophen (4 grams), aspirin (4 grams), ibuprofen (1.2 grams), or the FDA approved maximum opioid dosage as listed in the PI, whichever is less. - Duration Limits: 90 days for patients without a diagnosis of cancer or sickle-cell disease.</td>
</tr>
<tr>
<td>OH</td>
<td>Based on MED or APAP dose</td>
</tr>
<tr>
<td>OK</td>
<td>4</td>
</tr>
<tr>
<td>OR</td>
<td>120 MME</td>
</tr>
<tr>
<td>PA</td>
<td>Varies by drug</td>
</tr>
<tr>
<td>SD</td>
<td>30 days supply</td>
</tr>
<tr>
<td>TN</td>
<td>120mg/10mg oxycodone &amp; hydrocodone, 300mg/30mg hydrocodone</td>
</tr>
<tr>
<td>UT</td>
<td>180 tablets per 30 days regardless or product or strength</td>
</tr>
<tr>
<td>VA</td>
<td>4</td>
</tr>
<tr>
<td>VT</td>
<td>Dependent on the medication requested</td>
</tr>
<tr>
<td>WI</td>
<td>16</td>
</tr>
<tr>
<td>WV</td>
<td>4</td>
</tr>
<tr>
<td>WV</td>
<td>6</td>
</tr>
</tbody>
</table>
b) If answer to VIII-D1 above is "Yes," what is your maximum days supply per prescription limitation?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 day supply</td>
<td>AL, CO, DE, FL, GA, ID, KY, IA, ME, MO, MS, MT, NE, NH, OK, OR, SD, TN, UT, WI, WV</td>
</tr>
<tr>
<td>90 day supply</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Other; please explain</td>
<td>AK, AR, CA, IA, IL, IN, KS, MD, MI, ND, NY, OH, PA, VA, VT, WV</td>
</tr>
</tbody>
</table>

If answer to (b) above is "Other," please explain.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>34 days</td>
</tr>
<tr>
<td>AR</td>
<td>Prescription drug coverage is for up to a 31-day supply. SAO agents have a cumulative quantity edit. System adds units of every SAO claim in previous 31 days and if the incoming claim will cause the cumulative quantity of the opioid agents received in previous 31 days to exceed 93 units, the incoming claim will reject at point of sale.</td>
</tr>
<tr>
<td>CA</td>
<td>Short-acting opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 31-day period.</td>
</tr>
<tr>
<td>IA</td>
<td>30-day supply - 186 total quantity allowed for short-acting agents per month. Only 1 short-acting opioid allowed at a time. Requests that require prior authorization or Four Prescription Policy override: if appropriate, first request receives short-term approval.</td>
</tr>
<tr>
<td>IL</td>
<td>For initial fillers of opioids, a 7-day supply followed by an additional 7-day supply in a rolling 45 day period is permitted without prior authorization.</td>
</tr>
<tr>
<td>IN</td>
<td>Driven by drug-specific individual quantity limits.</td>
</tr>
<tr>
<td>MD</td>
<td>Allows up to 34-day supply.</td>
</tr>
<tr>
<td>MI</td>
<td>34 days supply.</td>
</tr>
<tr>
<td>ND</td>
<td>34 days max for all products unless primary insurance allows &gt; 34 days or if product package size / dosing often results in &gt; 34 days (e.g. transcend).</td>
</tr>
<tr>
<td>NY</td>
<td>90 days supply limit. Limited to a total of four (4) opioid prescriptions every 30 days. Exemption for diagnosis of cancer or sickle cell disease. CLINICAL CRITERIA: Clinicians should be provided with additional criteria for opioid therapy for patients with cancer.</td>
</tr>
<tr>
<td>OH</td>
<td>34 days.</td>
</tr>
<tr>
<td>PA</td>
<td>Prior authorization is required for short-acting opioids after 7 days for children under 21 and after 14 days for adults.</td>
</tr>
<tr>
<td>VA</td>
<td>10 days.</td>
</tr>
<tr>
<td>VT</td>
<td>7-day supply for initial fill, 30 day limit overall for IR products. 50 MME limit for adults, 24 MME limit for children effective 7/1/17.</td>
</tr>
<tr>
<td>WV</td>
<td>34 day supply.</td>
</tr>
</tbody>
</table>

VIII-D2. Do you currently have POS edits in place to limit the quantity of long-acting opioids?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CA, DE, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MS, MT, ND, NE, NH, NJ, NV, NY, OH, OR, PA, SC, SD, TN, UT, VA, VT, WA, WV, WY</td>
</tr>
<tr>
<td>No</td>
<td>CO, CT, DC, HI, MN, MO, NC, NM, RI, TX, WI</td>
</tr>
</tbody>
</table>

2016 DUR Comparison/Summary Report –October 2017
a) If answer to VIII-D2 above is "Yes," what is your maximum daily limit in terms of numbers of units (i.e. tablets, capsules)?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 39 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 units/day</td>
<td>AL, AR, GA, IA, ID, KY, LA, MD, ME, MI, MS, MT, ND, NE, NV, OH, OR, PA, SC, TN, VT, WA, WV</td>
<td>23 (59%)</td>
</tr>
<tr>
<td>3 units/day</td>
<td>AK, CA, DE, FL, IL, IN, KS, MA, NH, NJ, NY, OK, SD, UT, VA, WY</td>
<td>16 (41%)</td>
</tr>
</tbody>
</table>

b) If answer to VIII-D2 above is "Yes," what is your maximum days supply per prescription limitation?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 39 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 day supply</td>
<td>AL, FL, GA, ID, KY, LA, MA, MS, MT, NE, NH, NV, OK, OR, SC, SD, UT, VT</td>
<td>18 (46%)</td>
</tr>
<tr>
<td>90 day supply</td>
<td>AK, AR, CA, DE, IA, IL, IN, KS, MD, MI, MN, ND, NJ, NY, OH, PA, TN, VA, WA, WV, WY</td>
<td>21 (54%)</td>
</tr>
</tbody>
</table>

If answer to (b) above is "Other," please explain.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>34 days</td>
</tr>
<tr>
<td>AR</td>
<td>The long-action opioid (LAO) agents have a quantity limit based on FDA approved frequency of drug—e.g., once daily limit is 1 per day, qd the limit is 3 per day, q12h the limit is 2 per day, or a patch applied every 72 hours the limit is 10 patches per 30 days, etc. A claim can be filled for up to a 31-days' supply, so the max on a drug could be 31 for 31 days' supply, or 62 for a 31-days' supply, etc., depending on the FDA approved dosing frequency of the long-action opioid agent.</td>
</tr>
<tr>
<td>CA</td>
<td>Long-acting opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 7-day period.</td>
</tr>
<tr>
<td>DE</td>
<td>All long acting opioids are prior authorized. Specific clinical reviews allow for individual entry. Routinely the authorization is for 1 year. If there is any concern the authorized quantities are for a month at a time.</td>
</tr>
<tr>
<td>IL</td>
<td>- 30-day supply = 120 max quantity total per month for long-acting agents - Only 1 long-acting opioid allowed at a time - Requests that require prior authorization or Four Prescription Policy override: if appropriate, first request receives short-term app</td>
</tr>
<tr>
<td>IN</td>
<td>Quantity limits placed on certain long-acting opioid products for a maximum quantity of each agent per month.</td>
</tr>
<tr>
<td>KS</td>
<td>driven by drug-specific individual quantity limits</td>
</tr>
<tr>
<td>MD</td>
<td>Allow up to 34 day supply</td>
</tr>
<tr>
<td>ME</td>
<td>15 day limit similar to short acting opioids</td>
</tr>
<tr>
<td>MI</td>
<td>34 days supply with specific quantity limitations on certain long-acting narcotics such as fentanyl patches and ER oxycodone.</td>
</tr>
<tr>
<td>ND</td>
<td>We limit all long acting products to no more than FDA approved dosing. 34 days max is our entire program max (unless primary insurance allows &gt; 34 days)</td>
</tr>
<tr>
<td>NJ</td>
<td>30 day or 160 units whichever is greater.</td>
</tr>
<tr>
<td>NY</td>
<td>90 day supply—Hydromorphone ER, oxymorphoNE ER—Maximum 4 (four) units per day, 120 units per 30 days—Morphine ER (MS Contin 100mg only)—Maximum 4 units per day, up to 5 times a day, maximum 120 units per 30 days—All other long acting opioids are either 2 or 3 times a day.</td>
</tr>
<tr>
<td>OH</td>
<td>34 days</td>
</tr>
<tr>
<td>PA</td>
<td>All long acting opioids require prior authorization for all beneficiaries. The day supply approved is determined on a case-by-case basis.</td>
</tr>
<tr>
<td>TN</td>
<td>30 days- Fentanyl-10 patches/30, Embeda-2 capsules/day, Kadian-130mg, 159mg, 200mg: 1 capsule/day, others 2/day.</td>
</tr>
</tbody>
</table>
The agency limits all long-acting opioids to dosage frequency according to FDA labeling, which may be 1, 2, or 3 units per day depending on the product. The maximum days supply is no more limited than for any other medication (34 days).

VIII-D3. Do you currently have edits in place to monitor opioids and benzodiazepines being used concurrently?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CT, DE, ID, IN, KY, MT, NY, OR, TN, TX, VA, WY</td>
</tr>
<tr>
<td>No</td>
<td>AK, AL, AR, CA, CO, DC, FL, GA, HI, IA, IL, KS, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NH, NJ, NM, NV, OH, OK, PA, RI, SC, SD, UT, VT, WA, WI, WV</td>
</tr>
</tbody>
</table>

If answer to VIII-D3 above is “Yes,” please explain.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>Retrospectively we have criteria to identify the concurrent use of opioids and benzodiazepines together but there is nothing at POS to identify and monitor the use of these medications.</td>
</tr>
<tr>
<td>DE</td>
<td>Prior authorization for all long acting and high dose opiates are only be approved if the client is not receiving a benzodiazepine.</td>
</tr>
<tr>
<td>ID</td>
<td>Use FDA edit to monitor.</td>
</tr>
<tr>
<td>IN</td>
<td>Retrospective DUR established to monitor concurrent claims for opioids and benzodiazepines. A near real-time letter is faxed to the prescriber notifying them of the combination therapy and risks associated with this therapy.</td>
</tr>
<tr>
<td>KY</td>
<td>Standard ProDUR system edits require a pharmacist intervention for this combination.</td>
</tr>
<tr>
<td>MT</td>
<td>We limit benzodiazepines when used with methadone.</td>
</tr>
<tr>
<td>NY</td>
<td>PA required for initiation of opioid therapy in patients currently on benzodiazepine therapy.</td>
</tr>
<tr>
<td>OR</td>
<td>Prior authorization criteria for benzodiazepines and opioids restrict concurrent use.</td>
</tr>
<tr>
<td>TN</td>
<td>Because all require PA, and are denied if enrollee is using chronic opioid or a buprenorphine-containing opioid addiction product.</td>
</tr>
<tr>
<td>TX</td>
<td>Combination of Alprazolam, Carisoprodol, and Hydrocodone, effective since 2013: Claims with a 14-day overlap with each of the 3 drugs (Alprazolam, Carisoprodol, and Hydrocodone) in the last 35 days, the claim will reject. This is applied to clients of all age groups. Also, during FY 2016, an edit was approved by the DUR Board to monitor for any combination of opioids + benzodiazepines, muscle relaxants + benzodiazepines, or the combination of all three drugs (muscle relaxants, benzodiazepines, and opioids). The annual report for 2017 will include the implementation effective date for this pro-DUR edit.</td>
</tr>
<tr>
<td>VA</td>
<td>FirstDataBank's Alertspace ProDUR edits.</td>
</tr>
<tr>
<td>WY</td>
<td>Prior authorization is required for concurrent use.</td>
</tr>
</tbody>
</table>

VIII-E. MORPHINE EQUIVALENT DAILY DOSE (MEDD)

VIII-E1. Have you set recommended maximum morphine equivalent daily dose measures?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CO, CT, DE, ID, IN, MA, ME, MI, MN, NC, ND, OH, OR, VA, VT, WA, WY</td>
</tr>
<tr>
<td>No</td>
<td>AK, AL, AR, CA, DC, FL, GA, HI, IA, IL, KS, KY, LA, MD, MO, MS, MT, NE, NJ, NM, NV, NY, OK, PA, RI, SC, SD, TN, TX, UT, WI, WV</td>
</tr>
</tbody>
</table>

2016 DUR Comparison/Summary Report -October 2017 Page 46
If answer to VIII-E1 above is "Yes", indicate the recommended maximum mg per day:

<table>
<thead>
<tr>
<th>State</th>
<th>Milligrams per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO</td>
<td>300</td>
</tr>
<tr>
<td>CT</td>
<td>90</td>
</tr>
<tr>
<td>DE</td>
<td>120</td>
</tr>
<tr>
<td>ID</td>
<td>120</td>
</tr>
<tr>
<td>IN</td>
<td>60</td>
</tr>
<tr>
<td>MA</td>
<td>120</td>
</tr>
<tr>
<td>ME</td>
<td>30</td>
</tr>
<tr>
<td>MI</td>
<td>120</td>
</tr>
<tr>
<td>MN</td>
<td>120</td>
</tr>
<tr>
<td>NC</td>
<td>750</td>
</tr>
<tr>
<td>ND</td>
<td>90</td>
</tr>
<tr>
<td>OH</td>
<td>80</td>
</tr>
<tr>
<td>OR</td>
<td>120</td>
</tr>
<tr>
<td>VA</td>
<td>120</td>
</tr>
<tr>
<td>VT</td>
<td>50</td>
</tr>
<tr>
<td>WA</td>
<td>120</td>
</tr>
<tr>
<td>WY</td>
<td>180</td>
</tr>
</tbody>
</table>

If answer to VIII-E1 above is "No," please explain the measure or program you utilize.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>No formal policy for a set maximum recommendation in FFY2016; prior authorization criteria and guidance references caution when using in excess of 100 MED</td>
</tr>
<tr>
<td>AL</td>
<td>Placed max units manually</td>
</tr>
<tr>
<td>AR</td>
<td>During FFY 2016, we utilized therapeutic duplication edits to prevent multiple concurrent therapy of SAO and multiple concurrent therapy of LAO. The clinical edits did allow 1 SAO + 1 LAO. Quantity limits on the SAO were reduced to a cumulative quantity of 90 units in previous 31 days—this edit added all SAO claims filled in a rolling 31 days. Methadone was moved to non-preferred status for chronic pain patients—only cancer patients could receive methadone without a PA, and no PAs were being approved for chronic pain patients. Quantity limits were already in place for LAO products. The MME program was implemented Nov. 8, 2016, which is FFY 2017. The MME program in FFY 17 does provide information to prescriber providers and pharmacy providers.</td>
</tr>
<tr>
<td>CA</td>
<td>All opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 75-day period.</td>
</tr>
<tr>
<td>DC</td>
<td>FDA approved maximum daily dosing limits from the First Data Bank weekly file are edited at POS and are implemented prospectively during claims adjudication.</td>
</tr>
<tr>
<td>FL</td>
<td>A limitation will be implemented in the 3rd quarter of calendar year 2017.</td>
</tr>
<tr>
<td>GA</td>
<td>We are moving in the direction of implementing a max MED in the future. Currently, our QLLs vary not based on MED.</td>
</tr>
<tr>
<td>HI</td>
<td>FDA approved quantity edits for excessive quantity per First Data Bank.</td>
</tr>
<tr>
<td>IL</td>
<td>We do not do MME. Dose limits and max monthly quantities are used for individual agents.</td>
</tr>
<tr>
<td>KY</td>
<td>We have a policy that limits narcotic analgesic daily supply based on the FDA maximum dose of each drug per day. Kentucky is considering moving to maximum morphine equivalent daily dosing. Currently the Commonwealth utilizes the maximum dosing guidelines found in package inserts (PI).</td>
</tr>
<tr>
<td>LA</td>
<td>Dose limits are applied to opioid products with established maximum doses.</td>
</tr>
<tr>
<td>MO</td>
<td>During FFY 2016, quantity limits were used to limit opioid doses.</td>
</tr>
<tr>
<td>MS</td>
<td>Approved by DUR Board in September 2016. Prospective edits being programmed.</td>
</tr>
<tr>
<td>MT</td>
<td>We plan to set the maximum at 180 mg MEDD in September 2017.</td>
</tr>
<tr>
<td>NE</td>
<td>The DUR Board made specific recommendations to limit opioid use and these limits are in the planning stages of implementation.</td>
</tr>
<tr>
<td>NJ</td>
<td>Pre-DUR editing in place</td>
</tr>
<tr>
<td>NM</td>
<td>Topic is under consideration.</td>
</tr>
<tr>
<td>NV</td>
<td>The DUR Board reviews utilization of these products at nearly all quarterly meetings. Implementation is planned for 2017.</td>
</tr>
</tbody>
</table>
The NYS DURB has recommended quantity/frequency/duration limits to promote the safe and clinically effective use of opioids in the New York State Medicaid Program. The process examines FDA recommended dosages and considers equivalent MED levels. The combined efforts of the Medicaid Prescriber Education Program (MPEP), the Drug Information Response Center (DIRC) and Retrospective Drug Utilization Review (RetroDUR) program promotes the clinical effectiveness and medical appropriateness of opioid utilization by way of point-of-sale (POS) prospective edits, RetroDUR evaluations and the application of educational interventions for prescribers and pharmacists. In addition, on March 27, 2016 New York State began mandatory e-prescribing controlled substances.

OK
We review the number of medications taken on a monthly basis. Quantity limits along with only covering one short-acting and one long-acting concurrently.

PA
Quantity limits are drug specific based on FDA labeling and medical literature.

RI
Prescriber choice however we will be implementing limits in 2017.

SC
MED to be implemented First Quarter 2018

TN
We are in the middle of the process, moving slowly towards a limit of 120mg/day.

TX
Maximum quantity measure per each prescription claim.

UT
Tablet limits

WI
Wisconsin monitors these drugs through edits such as quantity limits and early refill alerts. Wisconsin has also looked at specific drugs through RetroDUR and targeted interventions. Prescribers identified during these processes receive a letter which alerts them to the clinical concern.

WV
Drug edits are in place on each drug based on the number of units allowed. In FFY 2015 we had not initiated our MME edit yet. In 2017 we are using >50 MME per day over the last 90 days.

VIII-E2. Do you provide information to prescribers on how to calculate the morphine equivalent daily dosage?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, CA, CO, CT, DC, IA, ID, IN, MA, MD, ME, MI, MS, NC, ND, OR, TN, VA, VT, WA</td>
<td>20 (40%)</td>
</tr>
<tr>
<td>No</td>
<td>AL, AR, DE, FL, GA, HI, IL, KS, KY, LA, MN, MO, MT, NE, NM, NV, NY, OH, OR, PA, RI, SC, SD, TX, UT, WI, WV, WY</td>
<td>30 (60%)</td>
</tr>
</tbody>
</table>

If answer to VIII-E2 above is "Yes," how is the information disseminated?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 20 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Website</td>
<td>CO, CT, DC, IA, MA, ME, NC, OR, TN, WA</td>
<td>10 (50%)</td>
</tr>
<tr>
<td>Provider notice</td>
<td></td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Educational seminars</td>
<td>MS</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Other, please explain</td>
<td>AK, CA, ID, IN, MD, MI, ND, VA, VT</td>
<td>9 (47.5%)</td>
</tr>
</tbody>
</table>
If answer to above is "Other," please explain.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>Website, prior authorization criteria and forms</td>
</tr>
<tr>
<td>CA</td>
<td>The Medi-Cal DUR program published an educational bulletin entitled, &quot;Clinical Review: Morphine Equivalent Daily Dose to Prevent Opioid Overuse&quot; to the Medi-Cal DUR website. This bulletin defined morphine equivalent daily dose (MEDD) and provided evidence to support using MEDD as an indicator of potential dose-related risk for prescription opioid overdose. The bulletin provided links to several online MEDD calculators, as well as additional resources to providers. The bulletin was also emailed to all providers who subscribe to the Medi-Cal Subscription Service.</td>
</tr>
<tr>
<td>ID</td>
<td>Drug Utilization Review Board Newsletter, posted electronically, provides opioid conversion charts.</td>
</tr>
<tr>
<td>IN</td>
<td>Targeted letters to prescribers based on RetroDUR Activity</td>
</tr>
<tr>
<td>MD</td>
<td>Drug Utilization Review Board Newsletter, posted electronically, provides opioid conversion charts.</td>
</tr>
<tr>
<td>MI</td>
<td>Provider notices were sent. The information was sent to providers as a quantity limit via soft POS edit message and later coded as a hard denial.</td>
</tr>
<tr>
<td>ND</td>
<td>Limit of 90 is for immediate release products only. PRN doses limited to 15% of current extended release narcotic dosage. Providers are referred to a variety of website calculators.</td>
</tr>
<tr>
<td>VA</td>
<td>A Medicaid Memo was posted to the state website with a blast email sent to those enrolled in the service. A patient specific letter was sent to those prescribers whose patients had received a prescription above the new limit.</td>
</tr>
<tr>
<td>VT</td>
<td>Provider notice and website</td>
</tr>
</tbody>
</table>

VIII-E3. Do you have an algorithm in your POS system that alerts the pharmacy provider that the morphine equivalent daily dose prescribed has been exceeded?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CA, DC, DE, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, MD, MI, MO, MS, ND, NE, NH, NJ, NM, NY, NV, OH, OK, PA, RI, SC, SD, TN, TX, UT, VA, WA, WY</td>
</tr>
<tr>
<td>No</td>
<td>AK, AL, AR, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, MT, NC, OR, VT, WY</td>
</tr>
</tbody>
</table>

VIII-F. BUPRENORPHINE and BUPRENORPHINE/NALOXONE COMBINATIONS

VIII-F1. Does your agency set total mg/ day limits on the use of buprenorphine and buprenorphine/naloxone combination drugs?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, MT, NC, ND, NH, NJ, NV, NY, OH, OK, PA, TN, TX, UT, VA, VT, WA, WV, WY</td>
</tr>
<tr>
<td>No</td>
<td>HI, NM, OR, RI, SC, SD, WI</td>
</tr>
</tbody>
</table>
If answer to VIII-F1 above is “Yes,” please specify the total mg/day?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>12mg</td>
<td>DE, PA</td>
</tr>
<tr>
<td>16mg</td>
<td>GA, ME, MT, TN, TX, VA, VT, WV, WY</td>
</tr>
<tr>
<td>24mg</td>
<td>AK, AL, AR, CO, DC, FL, IA, ID, IL, IN, KY, LA, MD, ME, MN, NJ, ND, NE, NH, NV, NY, OK, UT, WA</td>
</tr>
<tr>
<td>other, please explain</td>
<td>CA, CT, KS, MA, MO, MS, NJ, OH</td>
</tr>
</tbody>
</table>

If answer to above is “Other,” please explain.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>There is a maximum quantity of four dosage units per day, regardless of strength. The maximum allowable total daily dose is 48 mg.</td>
</tr>
<tr>
<td>CT</td>
<td>An informational alert is set at point of sale for any buprenorphine prescription that exceeds 24 mg per day.</td>
</tr>
<tr>
<td>KS</td>
<td>24mg</td>
</tr>
<tr>
<td>MA</td>
<td>32mg</td>
</tr>
<tr>
<td>MO</td>
<td>The first 180 days are limited to 32mg/day. After 180 days the limit is 16mg/day.</td>
</tr>
<tr>
<td>MS</td>
<td>Step down therapy; up to 24 mg/day during induction and stabilization phase (month 1-2), up to 16 mg/day during maintenance phase (months 3 and beyond).</td>
</tr>
<tr>
<td>NJ</td>
<td>32 mg</td>
</tr>
<tr>
<td>OH</td>
<td>16 mg Suboxone equivalent</td>
</tr>
</tbody>
</table>

VIII-F2. What are your limitations on the allowable length of treatment?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td>GA, TN</td>
</tr>
<tr>
<td>12 months</td>
<td>AK, AL, CA, CO, CT, DC, DE, FL, ID, IL, KS, KY, MA, MD, MN, MO, MS, MT, ND, NH, NJ, NM, NV, NY, OH, OR, PA, RI, SC, SD, TX, VT, WA, WI, WV</td>
</tr>
<tr>
<td>no limit</td>
<td>AR, HI, IA, IN, LA, ME, MI, NC, NE, UT, VA, WY</td>
</tr>
</tbody>
</table>

If “Other”, please explain.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AR</td>
<td>The standard PA form allows 24 months if criteria is met; after 24 months a prescriber request is reviewed on a case-by-case basis and prescriber must provide additional documentation for this review, such as taper schedule plan and progress notes.</td>
</tr>
<tr>
<td>HI</td>
<td>No pain management has been needed since 2009.</td>
</tr>
<tr>
<td>IA</td>
<td>24mg/d for a maximum of 3 months</td>
</tr>
<tr>
<td>IN</td>
<td>Buprenorphine/naloxone prior authorizations are granted every 6 months with a maximum 34-day supply if all criteria are met. Buprenorphine prior authorizations are granted for a 34-day supply if all criteria are not.</td>
</tr>
<tr>
<td>LA</td>
<td>3 months</td>
</tr>
</tbody>
</table>
VIII-F3. Do you require that the maximum mg per day allowable be reduced after a set period of time?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>DE, IA, LA, ME, MI, MO, MS, MT, TN, UT, WY</td>
<td>11 (22%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, AL, AR, CA, CO, CT, DC, FL, GA, HI, ID, IL, IN, KS, KY, MA, MD, MN, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TX, VA, VT, WA, WI, WY</td>
<td>39 (78%)</td>
</tr>
</tbody>
</table>

a) If answer to VIII-F3 above is "Yes," what is your reduced (maintenance) dosage?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 11 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8mg</td>
<td>TN, WY</td>
<td>2 (18%)</td>
</tr>
<tr>
<td>12mg</td>
<td>DE</td>
<td>1 (9%)</td>
</tr>
<tr>
<td>16mg</td>
<td>IA, LA, MO, MS</td>
<td>4 (36.5%)</td>
</tr>
<tr>
<td>other, please explain</td>
<td>ME, MI, MT, UT</td>
<td>4 (36.5%)</td>
</tr>
</tbody>
</table>

If answer to (a) above is "Other," please explain.

**State Explanation**

- ME: look at reduction in mg over a time period and PA submissions
- MI: tapering required based on an individualized care plan
- MT: as low as possible for each member
- UT: no set dose, taper required for re-auth

b) If answer to VIII-F3 above is "Yes," what are your limitations on the allowable length of reduced dosage treatment?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 11 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td>DE, IA, LA, MO, MS, MT, TN, WY</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>no limit</td>
<td>DE, IA, LA, MO, MS, MT, TN, WY</td>
<td>8 (72%)</td>
</tr>
<tr>
<td>other, please explain</td>
<td>ME, MI, UT</td>
<td>3 (28%)</td>
</tr>
</tbody>
</table>
If answer to (a) above is "Other," please explain.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ME</td>
<td>as indicated in previous answer</td>
</tr>
<tr>
<td>MI</td>
<td>These are reviewed on a case by case basis.</td>
</tr>
<tr>
<td>UT</td>
<td>No set dose, taper required for re-auth.</td>
</tr>
</tbody>
</table>

VIII-F4. Do you have at least one preferred buprenorphine/naloxone combination product available on your PDL?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, CA, CO, CT, DC, DE, GA, HI, IA, ID, IL, IN, IA, MA, MD, ME, MI, MN, MS, MT, NC, ND, NE, NH, NM, NV, NY, OH, OK, OR, PA, RI, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
</tr>
<tr>
<td>No</td>
<td>AL, AR, FL, KS, KY, NJ, SC</td>
</tr>
</tbody>
</table>

VIII-F5. Do you currently have edits in place to monitor opioids being used concurrently with any buprenorphine drug?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AR, CO, DC, DE, GA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MO, MS, MT, ND, NE, NH, NJ, NV, OK, PA, RI, TN, TX, VA, WY</td>
</tr>
<tr>
<td>No</td>
<td>AL, CA, CT, FL, HI, IA, IL, MI, MN, NC, NM, NV, OH, OR, SC, SD, UT, VT, WA, WI, WV</td>
</tr>
</tbody>
</table>

If answer to VIII-F5 above is "Yes," can the POS pharmacist override the edit?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage of 30 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>MD, RI, VA</td>
</tr>
<tr>
<td>No</td>
<td>AK, AR, CO, DC, DE, GA, ID, IL, IN, KS, KY, LA, MA, ME, MO, MS, MT, ND, NE, NH, NJ, NY, OK, PA, TN, TX, WY</td>
</tr>
</tbody>
</table>
VIII G. ANTIPSYCHOTICS/STIMULANTS

VIII-G1. ANTIPSYCHOTICS

VIII-G1-1. Do you have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CA, CO, CT, DE, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, NE, NV, NY, OH, OR, PA, RI, SC, SD, TN, TX, VA, VT, WA, WI, WV, WY</td>
<td>43 (86%)</td>
</tr>
<tr>
<td>No</td>
<td>DC, HI, ND, NH, NJ, NM, UT</td>
<td>7 (14%)</td>
</tr>
</tbody>
</table>

a) If answer to VIII-G1-1 above is “Yes,” do you either manage or monitor:

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 43 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>only children in foster care</td>
<td>DE, MT</td>
<td>2 (5%)</td>
</tr>
<tr>
<td>all children</td>
<td>AK, AL, AR, CA, CO, CT, DE, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, NE, NV, NY, OH, OR, PA, RI, SC, SD, TN, TX, VA, VT, WA, WI, WV, WY</td>
<td>38 (88%)</td>
</tr>
<tr>
<td>other, please explain</td>
<td>IL, KS, WI</td>
<td>3 (7%)</td>
</tr>
</tbody>
</table>

If answer to (a) above is “Other,” please explain

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>IL</td>
<td>Prior authorization is required for all children under DCFS care; all children less than 8 years of age who are prescribed atypical antipsychotic medications; and all children prescribed long-acting atypical antipsychotics.</td>
</tr>
<tr>
<td>KS</td>
<td>Children and adults</td>
</tr>
<tr>
<td>WI</td>
<td>7 years of age or younger</td>
</tr>
</tbody>
</table>

b) If answer to VIII-G1-1 above is “Yes,” do you have edits in place to monitor? Check all that apply.

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 43 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child Age</td>
<td>AK, AR, CA, CO, CT, DE, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, MD, MI, MN, MS, MT, NC, NE, NV, NY, OH, OR, PA, RI, SC, SD, TN, TX, VA, VT, WA, WI, WV, WY</td>
<td>42 (98%)</td>
</tr>
<tr>
<td>Dosage</td>
<td>AK, AL, CA, CO, CT, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MS, MT, NV, NY, OH, OR, PA, RI, SC, SD, TN, TX, VA, VT, WA, WI, WV, WY</td>
<td>33 (77%)</td>
</tr>
<tr>
<td>Polypharmacy</td>
<td>AK, AL, CA, CO, CT, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MS, MT, NV, NY, OH, OR, PA, RI, SC, SD, TN, TX, VA, VT, WA, WI, WV, WY</td>
<td>33 (77%)</td>
</tr>
</tbody>
</table>
c) Please briefly explain the specifics of your antipsychotic monitoring program(s).

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>Atypical antipsychotics for children</td>
</tr>
<tr>
<td>AL</td>
<td>Medical justification is required for polytherapy.</td>
</tr>
<tr>
<td>AR</td>
<td>We use a point-of-sale (POS) algorithm for age and dose of specific antipsychotic after the initial prior authorization. All &quot;new starts&quot; to an antipsychotic agent for children age 9 years and younger (&lt;10 years) require a manual review prior authorization by the Medicaid Pharmacy Program child psychiatrist. Prescriber required to submit letter explaining medical necessity, along with chart notes &amp; documentation to substantiate request, and lab data for fasting glucose and lipid panel. All requests for doses exceeding the allowed dose for age and all requests for additional antipsychotic agents are reviewed by the Medicaid Pharmacy Program child psychiatrists. Prescriber must submit all documentation to substantiate the request, including chart notes, etc.</td>
</tr>
<tr>
<td>CA</td>
<td>An approved Treatment Authorization Request is required for any antipsychotic medication for all Medi-Cal beneficiaries 0-17 years of age. In addition, DHCS Pharmacy Benefits Division, DHCS Behavioral Health Division, and California Department of Social Services (CDSS) continue to collaborate on a Quality Improvement Project entitled, &quot;Improving the Use of Psychotropic Medication among Children and Youth in Foster Care.&quot; The purpose of this program is to reduce the rate of antipsychotic polypharmacy, improve the rate of compliance with age-specific antipsychotic dose recommended guidelines, and improve the rate of children and youth in foster care with at least one psychotropic medication who have a annual metabolic risk assessment. The goals are to reduce polypharmacy and improve compliance with dosing guidelines and annual metabolic risk assessment.</td>
</tr>
<tr>
<td>CO</td>
<td>Prior authorization for less than approved age groups and more than maximum doses are in place. Other complex cases go to our child psychiatrist for interconsult.</td>
</tr>
<tr>
<td>CT</td>
<td>HID performs 1,000 RetroDUR reviews for the pediatric population each month and the majority of the criteria used to review the pediatric population have to do with mental health drugs. An additional program exists and is administered by the Department of Children and Families for children in foster care only. The Psychotropic Medication Advisory Committee (PMAC) oversees the use of psychotropic medications in the foster care population and have specific edits, maximum doses, monitoring guidelines, etc. associated with prescribing of these medications. Some of the criteria used for the pediatric RetroDUR program have been adopted from the PMAC criteria.</td>
</tr>
<tr>
<td>DE</td>
<td>Agents on the atypical antipsychotic agents are set to the FDA approved indications. Synergy is also achieved in Delaware by the Department of Family Services working with Medicaid on foster children to reduce unnecessary therapies.</td>
</tr>
<tr>
<td>FL</td>
<td>Florida continues to perform 2nd medical review. The second medical review is performed by a board certified child psychiatrist. The psychiatrist review is required for all prescriptions of children less than six and in some cases for children up to age 18.</td>
</tr>
<tr>
<td>GA</td>
<td>Require the use of an atypical antipsychotic form, which delineates important parameters such as use of psychiatrist, age of patient, list of atypical agents, patient medication and family history, medical necessity of medications, etc.</td>
</tr>
<tr>
<td>IA</td>
<td>Age edit on inpatient members less than five (5) years of age. Age edit on all other antipsychotics for members less than six (6) years of age. Duplicates therapyedit on all antipsychotics for members 0 through 17 years of age. A 10 day grace period is allowed to allow transition between antipsychotic medications.</td>
</tr>
<tr>
<td>ID</td>
<td>Targeted DUR interventions for foster children and children &lt; or = 5 years.</td>
</tr>
<tr>
<td>IL</td>
<td>Atypical antipsychotics in children</td>
</tr>
<tr>
<td>IN</td>
<td>Antipsychotics require prior authorization when used in duplication, low doses, or when a drug-specific quantity limit has been exceeded.</td>
</tr>
<tr>
<td>KS</td>
<td>We have a PA in place for children and adult criteria for use and multiple use of antipsychotics. We have adult dose limits and are bringing the child dose limit to the DUR board July 2017.</td>
</tr>
<tr>
<td>KY</td>
<td>A diagnosis driven prior authorization is required for all second generation antipsychotics. There are max daily doses edits and checks for therapeutic duplication. (Not more than one (1) antipsychotics at a time).</td>
</tr>
<tr>
<td>LA</td>
<td>Requirements for antipsychotics include appropriate diagnostic, therapeutic duplication (3rd agent), dose and age limit, and clinical reauthorization for age &gt; 6 years.</td>
</tr>
<tr>
<td>MA</td>
<td>Behavioral health medication polypharmacy: pharmacy claims for 4 or more behaviorally health medications (i.e., alpha agonists, antidepressants, antipsychotics, atorvastatin, benzodiazepines, bupropion, central stimulants, hypnotics, and mood stabilizers) filed within a 60-day period. Antipsychotic polypharmacy: overlapping pharmacy claims for 2 or more antipsychotics for 60 days within a 90 day period. Any pharmacy claim for an antipsychotic, antidepressant, atorvastatin, benzodiazepine, bupropion, or mood stabilizer for members less than 6 years old. Clinical stimulants and antipsychotics blocked for members less than 3 years old.</td>
</tr>
<tr>
<td>MD</td>
<td>In October 2015, MIMPP established the peer review program for mental health drugs. This peer reviewed authorization process informs clinicians of relevant pharmacologic and non-pharmacologic clinical information for decision-making and ensures the appropriate use while limiting adverse sequelae in Medicaid's valuable pediatric population. The program initially addressed the use of antipsychotics in recipients &lt;5 years of age. During FFY 2013, all recipients &lt;10 years of age required prior authorization. As of January 2014, the program was expanded to include all recipients &lt;18 years of age.</td>
</tr>
</tbody>
</table>

2016 DUR Comparison/Summary Report –October 2017 Page 54
ME: PA requirements limiting age, length of therapy as well as metabolic monitoring.

MI: We utilize a behavioral health academic detailing program which is operationalized through our Magellan contract. It is a monthly academic detailing mailing and face-to-face pharmacy consultant intervention with the most exceptional provider or specific educational topics.

MN: Monthly, the U.S. Children’s Division receives reports that identifies children on multiple psychotropic drugs.

MO: For children 0 to 5 years old, atypical antipsychotics deny at point of sale and must be reviewed by a clinical consultant for approval or denial. For children 5 to 9 years old, all new and non-adherent requests for atypical antipsychotics will deny at point of sale and must be reviewed by a clinical consultant for approval or denial. For children 5 to 9 years old, that are already established along with children 9 to 18 years old atypical antipsychotics will approve as long as they are on only 1 atypical, have appropriate diagnosis, dose does not exceed recommended maximum doses and are adherent to therapy 60 of the most recent 90 days. Requests that are reviewed by a clinical consultant require submission of at least the past 6 months of progress notes from the prescribing provider, results of baseline fasting lipid profile and fasting glucose, BMI%tile and notation of any evidence-based behavioral therapy that the participant is or will be participating in.

MS: Electronic PA age edits, quantity limits for all beneficiaries, diagnosis edit for adults and polypharmacy edit for children.

MT: We require atypicals to be prescribed by a psychiatrist for those under six. We provide pharmacy case management for foster children.

NC: In April 2011, the N.C. Division of Medical Assistance partnered Community Care of North Carolina to implement a registry to document the use of anti-psychotic therapy in N.C. Medicaid and N.C. Health Choice beneficiaries ages 0 through 17. A+KIDS was created due to well-documented safety concerns and limited information about the efficacy of using anti-psychotic agents in children. A+KIDS encourages the use of appropriate baseline and follow-up monitoring parameters to facilitate the safe and effective use of anti-psychotics in this population.

NE: Minimum age limits, quantity limits, daily dose limits and a review by a board-certified child and adolescent psychiatrist is required for requests outside of these limits.

NV: Children age 7-17 are allowed use drug from each class (antidepressant, antianxiety, antipsychotic, anticonvulsant) without PA up to three medications total. The fourth needs PA.

NY: DUR Board recommended drug-specific minimum age parameters have been established. (Automatic bypass for established therapy.) Fee for service diagnosis parameters for second-generation antipsychotics in the pediatric population. Diagnosis requirement for the initial prescription for patients between minimum age (as defined by the DURB for the FFS population) and 18 years of age. (Automatic bypass for established therapy.)

OH: Retrospective review of claims.

OK: Educational mailings to prescribers of psychotropic drugs used in children particularly when prescription deviate from evidence based norms in patient population.

OR: Please note that this criteria is monitored monthly. If a reviewer identifies an issue a letter is sent to the prescriber.

PA: A prescription for either a preferred or non-preferred Antipsychotic regardless of quantity limit when prescribed for a child under 18 years of age requires prior authorization.

RI: Health Information Design has specific KIDS criteria that identifies use of psychotropics and stimulants in children. Criteria is monitored monthly. If a reviewer identifies an issue a letter is sent to the prescriber.

SC: Patient must have received developmentally-appropriate, comprehensive psychiatric assessment with diagnosis, impairments, treatment target and treatment plans clearly identified and documented. 1. Informed consent for this medication must be obtained from the parent or guardian that 1. Family assessment must have been performed to include parental psychopathology and treatment needs. Also family functioning and patient-child relationship must be evaluated. 2. Psychosocial treatment MUST have been in place for at least 12 weeks without adequate clinical response. Psychosocial treatment must continue for the duration of medication therapy. Parental involvement is required. Exception: Parent is danger to self or others. Only approve one antipsychotic at a time. Exception: tapering of one agent while titrating another.

SD: Child Protective Services.

TN: PA required for all atypical antipsychotics. Enrollee must meet all criteria to qualify for atypical use.

TX: The HCSC has a clinical prior authorization edit in place for both the typical and atypical antipsychotics for adults and the children enrolled in Medicaid. The edit screens for age limits, mono-therapy for inosin, or major depressive disorder, and for the concomitant use of more than two different antipsychotics. Psychotropic medication utilization review (PMUR) tool was developed to assist in identifying members whose psychotropic medications utilization fall outside the parameters. The criteria set forth by the 2013 version of the PMUR for Foster Children was developed by the Texas Department of Family and Protective Services (DFPS), the Department of State Health Services (DSHS), and the Health and Human Services Commission (HHSC). Some of the criteria include: 1) Four (4) or more psychotropic medications prescribed concomitantly. 2) Prescribing of two (2) or more concomitant stimulants, two (2) or more concomitant alpha agonists, two (2) or more concomitant antidepressants, two (2) or more concomitant antipsychotics, two (2) or more concomitant mood stabilizers. 3) The psychotropic medication dose exceeds usual recommended doses (FDA and/or literature based maximum dose). 4) Psychotropic medications are prescribed for children of very young age including children receiving the following: stimulants - less than three (3) years of age, Alpha Agonists - less than four (4) years of age, Mood Stabilizers - less than four (4) years of age, Antipsychotics - less than four (4) years of age.
Prescribing by primary care provider who has not documented previous specialty training for a diagnosis other than the following (unless recommended by a Psychiatrist consultant): attention Deficit Hyperactive Disorder (ADHD), uncomplicated anxiety disorders, uncomplicated depression. 6) Antipsychotic medication(s) prescribed continuously without appropriate monitoring of glucose and lipids at least every 6 months. 7) Multiple psychotropic medications for a given mental disorder. 8) Inappropriate medication for patient diagnosed with a mental disorder. 9) Absence of a thorough assessment of the Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-V) diagnosis in the child's medical record. Finally, H.B. 915 Section 533.0161(b), Government Code, of the 2013 83rd legislature, requires quarterly report on monitoring psychotropic medication by the HHSC Medicaid Vendor Drug Program and to notify the home state of any child placed in Texas under Interstate Compact on the Placement of Children (ICPC) when the medication regimen is outside the parameters. The parameters mimic the PMUR parameters listed above.

VA Service authorizations are required for the use of antipsychotics in children under the age of 18.

VT a) PA process for all antipsychotics for children b) 18 years or less PA for diagnosis and max daily dose c) less than 5 years of age PA is reviewed by Medical Director. d) Non-specialists have access to Psychiatrists at University of Vermont for psychiatric consultation.

WA The agency maintains dose limits stratified by patient age, limitations against ongoing duplication, and polypharmacy. These limits have been recommended by a Pediatric Mental Health Workgroup and approved by the DUR Board. Exceeding any of these review thresholds triggers a required consultation through our Second Opinion Network program, in which pediatric psychiatrists engage in a one-on-one consultation with the prescriber.

WI Wisconsin monitors the use of antipsychotic drugs in young children through prior authorization (PA). The PA process is intended to scrutinize the prescribing of antipsychotic drugs for mood disorders and the monitoring of metabolic effects of this class of drugs. Child psychiatrists who are contracted with the state perform peer to peer outreach when needed.

WV A prior authorization is required for all children under 18 years of age.

d) If you do not have antipsychotic monitoring program, do you plan on implementing a program in the future?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CA, CO, CT, DC, DE, FL, IA, ID, IL, IN, KS, LA, MA, ME, MI, MN, MO, MS, MT, NC, NE, NH, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WV, WI</td>
</tr>
<tr>
<td>No</td>
<td>GA, HI, KY, MD, ND, NJ, UT, VA, WI</td>
</tr>
</tbody>
</table>

If answer to (d) above is “No,” please explain why you will not be implementing a program to monitor the appropriate use of antipsychotic drugs in children.

<table>
<thead>
<tr>
<th>State</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GA</td>
<td>Currently have a program in place. Plan on continuing current program.</td>
</tr>
<tr>
<td>HI</td>
<td>FFS is not in need of one because other programs cover and monitor antipsychotic drugs for children (DOH CAMHD and Medicaid managed care plans).</td>
</tr>
<tr>
<td>KY</td>
<td>Kentucky already has one in place that is reviewed periodically.</td>
</tr>
<tr>
<td>MD</td>
<td>Question 83 does not apply to Maryland since we already have a program in place - see question 92a for explanation. There was no option for &quot;N/A&quot;.</td>
</tr>
<tr>
<td>ND</td>
<td>Legislation prevents managing antipsychotic medications in North Dakota.</td>
</tr>
<tr>
<td>NJ</td>
<td>There are guidelines provided by the New Jersey Department of Children and Families for the use of psychotropic medications in children.</td>
</tr>
<tr>
<td>UT</td>
<td>Utah Medicaid will consider this in the future.</td>
</tr>
<tr>
<td>VA</td>
<td>Already implemented.</td>
</tr>
<tr>
<td>WI</td>
<td>The State of Wisconsin already has a program in place to monitor the appropriate use of antipsychotic drugs in children.</td>
</tr>
</tbody>
</table>
VIII-G2. STIMULANTS

VIII-G2-1 Do you have any documented restrictions or special program in place to monitor, manage or control the use of stimulants?

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AK, AL, AR, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, MT, ND, NE, NH, NJ, NM, NV, NY, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
</tr>
<tr>
<td>No</td>
<td>MD, NC, OH</td>
</tr>
</tbody>
</table>

a) If answer to VIII-G2-1 above is "Yes," is your program limited to:

<table>
<thead>
<tr>
<th>Answer State</th>
<th>Number of States (Percentage of 47 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>children</td>
<td>AK, AL, AR, CA, CT, DC, FL, HI, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, MT, ND, NE, NH, NJ, NM, NV, NY, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
</tr>
<tr>
<td>adults</td>
<td>CO, DE, GA, IA, NJ, NM, RI</td>
</tr>
<tr>
<td>both</td>
<td>AK, AL, AR, CA, CT, DC, FL, HI, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, MT, ND, NE, NH, NJ, NM, NV, NY, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
</tr>
</tbody>
</table>

b) Please briefly explain your program.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>Quantity limits</td>
</tr>
<tr>
<td>AL</td>
<td>Stimulants are included in the Preferred Drug List (PDL) and have maximum quantity limits.</td>
</tr>
<tr>
<td>AR</td>
<td>A manual review prior authorization is required for all adults age 18 and older. The prescriber must submit documentation and include documentation that symptoms are present in 2 locations, e.g., if beneficiary is working and where/what, or if in school and include where/number of hours. All beneficiaries must comply with the point of sale clinical dose edits and therapeutic duplication edits.</td>
</tr>
<tr>
<td>CA</td>
<td>The use of stimulants for Medi-Cal beneficiaries is restricted to use in Attention Deficit Disorder in individuals from 4 years through 16 years of age only. Any use outside of these restrictions requires an approved Treatment Authorization Request.</td>
</tr>
<tr>
<td>CO</td>
<td>Stimulants are managed on the PDL. Complex cases can also be referred to the child psychiatrist.</td>
</tr>
<tr>
<td>CT</td>
<td>HID performs 1,000 RetrDUR reviews for the adult and pediatric populations each month and the majority of the criteria used to review the pediatric population have to do with mental health drugs, including stimulants. An additional program exists and is administered by the Department of Children and Families for children in foster care only. The Psychotropic Medication Advisory Committee (PMAC) oversees the use of psychotropic medications in the foster care population and have specific edits, maximum doses, monitoring guidelines, etc. associated with prescribing these medications. Some of the criteria used for the Pediatric RetrDUR program have been adopted from the PMAC criteria. Additionally, stimulant use is also reviewed during the monthly RetrDUR adult reviews.</td>
</tr>
<tr>
<td>DC</td>
<td>Clinical criteria is in place for all stimulants with requirements for diagnosis, age appropriate use, anticipated length of therapy and days supply limits. Prior authorization can be set for up to one 1 year.</td>
</tr>
<tr>
<td>DE</td>
<td>Adults must be on the less abuse potential long-acting agents of generic Concerta and Vyvanse first and fail before approval of any other agent will be considered.</td>
</tr>
<tr>
<td>FL</td>
<td>High dose limitations are placed on all stimulants. A close prior authorization review is performed on all children less than 6.</td>
</tr>
<tr>
<td>GA</td>
<td>Stimulant use in adult population requires prior authorization.</td>
</tr>
<tr>
<td>HI</td>
<td>ICD-10 and age requirements are drug specific.</td>
</tr>
</tbody>
</table>
| IA    | Requires PA for members 21 years of age and older. Documentation diagnosis of ADHD meets the DSM-V criteria and is confirmed by a standardized rating scale. Symptoms must have been present before 12 years of age and there...
**ID**

All products have age and Quantity Limits. Adults must have documented diagnosis of ADHD and any adults with a substance abuse diagnosis cannot receive medication.

**IL**

All attention deficit hyperactivity medications (ADHD) in children less than 6 years of age require special prior authorization request form. Medications for ADHD are allowed for clients who are 6 through 18 years of age. Adults (19 years and older) require prior authorization for ADHD medications.

**IN**

Stimulants require prior authorization when used in duplication or when a drug-specific quantity limit has been exceeded.

**KS**

We have PA criteria and dosing limits for both adults and children.

**KY**

A diagnosis driven prior authorization is required on all stimulants. There are also max dose per day edits and therapeutic duplication edits (not more than one (1) long-acting agent).

**LA**

Stimulants are reviewed in the retrospective DUR program for stimulant-induced insomnia and use in young children. Prospective edits include duplication of therapy with stimulants and with narcolepsy agents, diagnosis requirement, and clinical preauthorization for young children.

**MA**

Behavioral health medication polypharmacy: pharmacy claims for 4 or more behavioral health medications (i.e., alpha2 agonists, antidepressants, antipsychotics, atomoxetine, benzodiazepines, bupropion, central stimulants, hypnotics, and mood stabilizers) filled within a 60-day period Central stimulant polypharmacy: overlapping pharmacy claims for 2 or more central stimulants (immediate-release and extended-release formulations of the same chemical entity are counted as one) for 60 days within a 90 day period.

**ME**

Managing daily dosing requirements

**MI**

Prior authorization required for members over the age of 18 years and under the age of 6 years.

**MN**

We have quantity limits in place.

**MO**

Under 6 years old requires prior authorization. 6 to 18 years old requires appropriate diagnosis on file and within approved dosage limitations for it to approve transparently. Greater than 23 years of age requires prior authorization.

**MS**

Electronic PA age edits and quantity limits for all beneficiaries and diagnosis edit for adults.

**MT**

We use Smart PA to prevent overuse.

**ND**

First fill limitation (14 days initial supply), only see long acting and one short acting allowed concurrently and they must be the same molecule (e.g. they can't be on dexmethylphenidate extended release and methylphenidate immediate release concurrently), FDA max doses and age limits.

**NE**

Non-preferred drugs require review for compliance and doses are monitored. Edits are in place to prevent use of more than one stimulant and high doses in children.

**NH**

When a stimulant is prescribed for an adult a Prior Authorization (PA) is required. A PA is required for non-preferred products for children.

**NJ**

A prior authorization is required to obtain an approved diagnosis from the prescriber.

**NM**

Stimulants require prior authorization for those 18 years of age or older.

**NV**

PA criteria for both adults and children established by the DUR Board.

**NY**

Quantity limits for patients less than 18 years of age to include:

- Short-acting CNS stimulants: not to exceed 3 dosage units daily with maximum of 90 days per strength (for titration)
- Long-acting CNS stimulants: not to exceed 1 dosage unit daily with maximum of 90 days. Concerta 36mg not to exceed 2 units daily.
- Quantity limits for patients 18 years of age and older to include:

  - Short-acting CNS stimulants: not to exceed 3 dosage units daily with maximum of 20 days
  - Long-acting CNS stimulants: not to exceed 1 dosage unit daily with maximum of 30 days. Concerta 36mg not to exceed 2 units daily.
- For patients 18 years of age and older: a 90 day supply may be obtained with confirmation of FDA approved, Compendia supported or Medicaid covered diagnosis.

**OK**

Under Age of 5 requires a psychiatrist consult, over age of 21 must fill out Prior Authorization. Quantity limits in placed based on FDA approved dosing.

**OR**

Doses exceeding quantity limits require prior authorization and prescribing by a specialist.

**PA**

A prescription for a preferred or non-preferred Stimulant and Related Agent for a recipient under 4 years of age or for a recipient 18 years of age or older requires prior authorization.

**RI**

Prior authorization program.

**SC**

Edits for indication and age - 6 years of age Narcolepsy products require diagnosis confirmed by sleep study (documentation required). Shift work diagnosis requires copy of work schedule.

**SD**

Quantity Limits.

**TN**

PA required for all scheduled stimulants for adults, and required for children 21 and under only if daily dosage is higher than 80 mg/day of all products.

---

2016 DUR Comparison/Summary Report - October 2017  Page 58
| TX | HBHC has a clinical prior authorization (PA) for all stimulants and non-stimulants used for treatment of ADHD/ADHD. The PA criteria screen for age limit, ADHD/ADHD diagnosis codes for adults, concomitant use of two short acting or two long acting products, and diagnosis of history of drug abuse. |
| UT | Prior authorization requirements |
| VA | 34 days supply, managed by P&T Committee criteria |
| VT | Certain Stimulants require PA and/or quantity limits |
| WA | Program for children is the same as described for antipsychotics above. Adults have maximum dose limits as well as expedited authorization requirements for validation of diagnosis. |
| WI | Wisconsin has both documented restrictions and special programs to monitor, manage or control the use of stimulants. These include diagnosis restrictions; allowed diagnoses are ADHD and narcolepsy; Prior authorization required for non-preferred stimulants on the Preferred Drug List. System edits for early refill that can be overridden in certain circumstances by calling a specialized pharmacy call center. Children’s Mental Health work group has focused on stimulant use. Interventions have included several targeted mailings to prescribers as well as peer to peer outreach from constant child psychiatrists. |
| WV | Members are limited to 1 short-acting + 1 long-acting stimulant and these must be composed of the same chemical entity. |
| WV | Dosage limits apply to all ages. Diagnosis is required for those over 17 years of age. |
IX. INNOVATIVE PRACTICES

The 37 states listed below have initiated innovative practices during the past year. A description of their innovative practice can be found in Attachment 6 of the individual state report: Drug Utilization Review Annual Report | Medicaid.gov

| AK, AL, AR, CA, CO, CT, DC, DE, FL, GA, ID, IL, IN, KS, MA, MD, ME, MI, MO, MS, MT, NC, ND, NH, NJ, NY, OH, OK, OR, TN, TX, UT, VA, VT, WA, WI, WV |
X. E-PRESCRIBING

X-1. Does your MMIS or pharmacy vendor have a portal to electronically provide, patient drug history data and pharmacy coverage limitations to a prescriber prior to prescribing, upon inquiry?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AL, AR, CT, DE, FL, GA, ID, IN, KY, LA, ME, MI, MN, MO, MT, NJ, NM, OK, UT, WV</td>
<td>21 (42%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, CA, CO, DC, HI, IA, IL, KS, MA, MD, MS, NC, ND, NE, NJ, NV, NY, OH, OR, PA, RI, SC, SD, IN, WA, VT, WI, WY</td>
<td>29 (58%)</td>
</tr>
</tbody>
</table>

a) If answer to X-1 above is "Yes," do you have a methodology to evaluate the effectiveness of providing drug information and medication history prior to prescribing?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 21 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AR, CT, DE, FL, MI, MO, NM, OK, TX</td>
<td>9 (43%)</td>
</tr>
<tr>
<td>No</td>
<td>AL, GA, ID, IN, KY, LA, ME, MN, MT, NJ, UT, WV</td>
<td>12 (57%)</td>
</tr>
</tbody>
</table>

b) The 8 states listed below explain the evaluation methodology in Attachment 7 "E-Prescribing Activity Summary" and can be found in Attachment 7 of the individual state report: Drug Utilization Review Annual Report | Medicaid.gov

| State | AR, CT, DE, FL, MI, NM, OK, TX |

c) If answer to X-1 above is "No," are you planning to develop this capability?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CO, DC, IA, IL, MA, ND, NJ, NV, SD, VA, VT, WA</td>
<td>12 (41%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, CA, HI, KS, MD, ME, NC, NE, NY, OH, OR, PA, RI, SC, TN, WI, WY</td>
<td>17 (59%)</td>
</tr>
</tbody>
</table>

X-2. Does your system use the NCPDP Origin Code that indicates the prescription source?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>AL, AR, CO, CT, DC, DE, FL, GA, HI, ID, IL, IN, KS, KY, LA, MA, MD, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NY, OH, OK, OR, PA, SC, TN, TX, UT, VT, WA, WI, WV, WY</td>
<td>41 (82%)</td>
</tr>
<tr>
<td>No</td>
<td>AL, CA, IA, ME, MN, OR, RI, SD, VA</td>
<td>9 (18%)</td>
</tr>
</tbody>
</table>
XI. MANAGED CARE ORGANIZATIONS (MCOs)

XI-1. Does your state have MCOs?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State/States</th>
<th>Number of States (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CA, CO, DC, DE, FL, GA, HI, IA, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, ND, NE, NH, NJ, NM, NV, NY, OH, OK, PA, RI, SC, TN, TX, UT, VA, WA, WI, WV</td>
<td>38 (76%)</td>
</tr>
<tr>
<td>No</td>
<td>AK, AL, AR, CT, ID, ME, MT, NC, OK, SD, VT, WY</td>
<td>12 (24%)</td>
</tr>
</tbody>
</table>

XI-2. Is your pharmacy program included in the capitation rate (carved-in)?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State/States</th>
<th>Number of States (Percentage of 38 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>DE, HI, IA, IL, KS, KY, LA, MA, MS, ND, NJ, NM, NV, NY, OH, PA, SC, UT, VA</td>
<td>19 (50%)</td>
</tr>
<tr>
<td>No</td>
<td>CO, GA, MN, MO, NE, TN</td>
<td>6 (16%)</td>
</tr>
<tr>
<td>Partial</td>
<td>CA, DC, FL, IN, MD, MI, NH, OR, RI, TX, WA, WI, WV</td>
<td>13 (34%)</td>
</tr>
</tbody>
</table>

If answer to XI-2 above is "partial," please specify the drug-categories that are carved out.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>Selected HIV/AIDS/ Hepatitis B treatment drugs; selected alcohol and heroin detoxification and dependency treatment drugs; selected coagulation factor; and selected drugs used to treat psychiatric conditions (including antipsychotics and MAO inhibitors)</td>
</tr>
<tr>
<td>DC</td>
<td>HIV antiretroviral medications</td>
</tr>
<tr>
<td>FL</td>
<td>Hemophilia claims</td>
</tr>
<tr>
<td>IN</td>
<td>Healthy Indiana Plan (HIP) 2.0, Hoosier Healthwise, and Hoosier Care Connect (HCC) are carved-in. Fee-for-service members are carved-out.</td>
</tr>
<tr>
<td>MD</td>
<td>During FFY 2016, antiretrovirals for the treatment of HIV/AIDS, mental health medications and substance use disorder medications were included in the carve-out program.</td>
</tr>
<tr>
<td>MI</td>
<td>Mental health drugs, substance abuse treatment, hemophilia drugs, HIV and selected drugs for rare metabolic diseases.</td>
</tr>
<tr>
<td>NH</td>
<td>Medications to treat Hepatitis C and hemophilia, and Carbaglu and Revivic</td>
</tr>
<tr>
<td>OR</td>
<td>Mental health drugs</td>
</tr>
<tr>
<td>RI</td>
<td>Stop-loss arrangements for Hepatitis C drugs</td>
</tr>
<tr>
<td>TX</td>
<td>Hepatitis C treatment and Orkambi are carved-out (non-risk payments).</td>
</tr>
<tr>
<td>WA</td>
<td>Hemophilia factor product for maintenance use in outpatient setting and HCV treatment are carved-out.</td>
</tr>
<tr>
<td>WI</td>
<td>Managed Care Organizations carve-out drugs and provider-administered drugs in Wisconsin by specific program. In FFY 2016 the carve-out program was FamilyCare. FamilyCare is a long-term care program which helps frail elders and adults with disabilities get the services they need to remain in their homes.</td>
</tr>
<tr>
<td>WV</td>
<td>Hemophilia and Hepatitis C</td>
</tr>
</tbody>
</table>

XI-3. Does the state set requirements for the MCO’s pharmacy benefit? (e.g. same PDL, same ProDUR/Retro DUR)?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State/States</th>
<th>Number of States (Percentage of 38 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CA, DE, FL, IA, IL, KS, MD, MI, MS, NI, NY, OH, PA, SC, TX, UT, WA, WV</td>
<td>18 (47%)</td>
</tr>
<tr>
<td>No</td>
<td>CO, DC, GA, HI, IN, KY, LA, MA, MN, MO, ND, NE, NH, NM, NV, OR, RI, TN, VA, WI</td>
<td>20 (53%)</td>
</tr>
</tbody>
</table>
If answer to XI-3 above is “Yes,” please check all requirements that apply below.

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 18 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulary Reviews</td>
<td>CA, DE, FL, IL, MD, MI, NJ, NY, OH, PA, SC, UT, WA</td>
<td>13 (72%)</td>
</tr>
<tr>
<td>same PDL</td>
<td>DE, FL, IA, KS, MS, TX, WV</td>
<td>7 (39%)</td>
</tr>
<tr>
<td>same RetroDUR</td>
<td>IA, KS</td>
<td>2 (11%)</td>
</tr>
<tr>
<td>same ProDUR</td>
<td>IA, KS, MS</td>
<td>3 (17%)</td>
</tr>
</tbody>
</table>

If answer to XI-3 above is “Yes,” please briefly explain your policy.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>Medi-Cal MCOs are required to provide a pharmacy benefit that is comparable to the Medi-Cal FFS pharmacy program and their preferred drug lists (PDLs) are required to be comparable to the Medi-Cal List of Contract Drugs. All drugs included on the Medi-Cal List of Contract Drugs must be covered and cannot be more restrictive than FFS. Managed Care Organizations (MCOs) must have their own DUR program that determines the most suitable treatment and prior authorization requirements for their organizations. They do not have the same ProDUR or RetroDUR as the fee-for-service program.</td>
</tr>
<tr>
<td>DE</td>
<td>MCOs must follow the state Medicaid PDL to a 95% compliance rate. Plans may not be more restrictive with criteria, but must follow the same PDL.</td>
</tr>
<tr>
<td>FL</td>
<td>MCO Pharmacy representatives are required to attend meetings of the DUR and P&amp;T Committee.</td>
</tr>
<tr>
<td>IL</td>
<td>MCOs must have at least one preferred drug in each drug class and cannot be more restrictive than FFS.</td>
</tr>
<tr>
<td>KS</td>
<td>The state HID pharmacist prepares documents for the DUR board based on suggestions from the state and the MCOs. The MCOs follow the state PDL and all DUR approved PA as well as any state policy.</td>
</tr>
<tr>
<td>MD</td>
<td>A comprehensive drug use management program has been in place for several years which evaluates each MCO drug benefit, including: P&amp;T Committee management and procedures, formulary content/management, prior authorization procedures and criteria, generic substitution, drug utilization review and disease management. A review and assessment of each MCO Drug Use Management Program is conducted annually.</td>
</tr>
<tr>
<td>MI</td>
<td>The MCO contract requires that the plan's formulary include coverage available for all outpatient covered drugs identified on the Fee-For-Service Michigan Pharmaceutical Product List (MPPL). MCOs have been required to reimburse at same amount or higher than FFS. As of January 2015, MCOs were required to use Universal Preferred Drug List and same clinical criteria.</td>
</tr>
<tr>
<td>MS</td>
<td>MCOs were required to comply with state DUR standards.</td>
</tr>
<tr>
<td>NJ</td>
<td>Plans establish their own formularies and prior authorization processes. Plan formularies must include all categories of prescription drugs on the NYS Medicaid fee-for-service list of reimbursable drugs.</td>
</tr>
<tr>
<td>OH</td>
<td>70% agreement on PDLs.</td>
</tr>
<tr>
<td>PA</td>
<td>The requirements for the outpatient drug services provided by the Medicaid MCOs are defined in Exhibit 8BB of the Health Choices Agreement. The amount, duration, and scope of covered outpatient drugs must be consistent with coverage under the Fee-For-Service Program. The Department reviews and approves all MCO formularies, prior authorization policies and drug utilization management programs prior to implementation.</td>
</tr>
<tr>
<td>SC</td>
<td>The MCO may implement a PDL with coverage of products meeting the State’s coverage of products. Management of products within these classes - with the exception of any designated “protected classes” - is decisions of the MCO. Formulary and PDL requirements are enforced through Provider Contract Management team.</td>
</tr>
<tr>
<td>TX</td>
<td>MCO coverage and PA criteria must be the same or more lenient than FFS.</td>
</tr>
<tr>
<td>UT</td>
<td>MCO coverage and PA criteria must be the same or more lenient than FFS.</td>
</tr>
<tr>
<td>WA</td>
<td>The MCO contract requires that the plan's formulary include coverage available for all outpatient covered drugs identified on the Fee-For-Service Michigan Pharmaceutical Product List (MPPL). MCOs have been required to reimburse at same amount or higher than FFS. As of January 2015, MCOs were required to use Universal Preferred Drug List and same clinical criteria. Currently the state is prescriptive with the plans in coverage criteria for antipsychotics and medication assisted treatments.</td>
</tr>
<tr>
<td>WV</td>
<td>MCOs must follow our PDL criteria.</td>
</tr>
</tbody>
</table>
If answer to XI-3 above is “No,” do you plan to set standard in the future?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 20 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>DC, HI, LA, MA, ND, NV, RI, VA</td>
<td>8 (40%)</td>
</tr>
<tr>
<td>No</td>
<td>CO, GA, IN, KY, MN, MO, NE, NH, NM, OR, TN, WI</td>
<td>12 (60%)</td>
</tr>
</tbody>
</table>

XI-4. Does the state require the MCOs to report their DUR activities?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 38 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CA, DE, IA, KS, LA, MD, MI, PA, TX, UT</td>
<td>10 (26%)</td>
</tr>
<tr>
<td>No</td>
<td>CO, DC, FL, GA, HI, IL, IN, KY, MA, MN, MO, MS, ND, NE, NI, NJ, NM, NV, NY, OH, OR, RI, SC, TN, VA, WA, WI, WV</td>
<td>28 (74%)</td>
</tr>
</tbody>
</table>

a) If answer to XI-4 above is “Yes,” please explain your review process.

<table>
<thead>
<tr>
<th>State</th>
<th>Explanation</th>
</tr>
</thead>
</table>
| CA    | MCOs are required to submit Policies and Procedures for DUR, treatment outcomes system to optimize the quality of pharmacy services. The DUR review includes:  
- Range and type of drugs taken by members  
- General drug utilization patterns of the plan  
- List of pharmacy interventions for Quality Improvement Projects (e.g., Asthma, Diabetes, HTN, etc.)  
- DUR alert/edit program to detect drug-drug interactions, high dose alert, etc., in order to alert dispensing pharmacy  
- Pharmacy service and drug utilization encounter data, including pharmacy claims, which are provided to the state on a monthly basis |
| DE    | The MCOs report their activities as part of their state-specific P&T meetings. There is also an exchange of informal reports. |
| IA    | MCOs submit their DUR activities to the state on a quarterly basis which are reviewed by the state and DUR Coordinator. |
| KS    | The MCOs submit monthly reports regarding PDL and DUR approved criteria adherence. In addition, the MCOs present an annual report to the Kansas Medicaid DUR board. |
| LA    | We have a monthly report that addresses DUR activities initiated by MCOs. |
| MD    | Through the annual MCO Drug Use Management Assessment, each MCO is required to report all DUR policies and procedures, as well as specific documents related to oversight of the drug use evaluation process and maintenance of patient confidentiality. The assessment also requires reporting of types of prospective or retrospective programs, including any program specifically related to the use of controlled substances by participants. |
| MI    | MCOs are contractually required to provide details about their DUR activities upon request. |
| PA    | The MCOs are required to submit an annual DUR Report to the Department. |
| TX    | The MCOs report to the Contract Performance Management (CPM) team on the number and the nature of their retro-DUR activities. They are not required to report on the financial outcomes of those activities. For the pre-DUR activities (clinical PAs), the MCOs must seek the DUR Board’s approval before implementing a retro-DUR intervention. Otherwise, they must be presented to the DUR and Formulary teams at Vizagur Drug Program for approval. |
| UT    | MCOs must submit a slightly modified version of this report to FFS Medicaid. The MCO reports are attached. |

b) If answer to XI-4 above is “No,” do you plan to develop a program to have MCOs report their DUR activities in the future?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 28 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CO, DC, HI, IL, KY, MA, MN, MS, ND, NE, NH, NJ, NM, NV, NY, OH, OR, RI, SC, VA, WA, WI, WV</td>
<td>23 (82%)</td>
</tr>
<tr>
<td>No</td>
<td>FL, GA, IN, MO, TN</td>
<td>5 (18%)</td>
</tr>
</tbody>
</table>
c) If answer to (b) above is "No," please explain.

**State** | **Explanation**
---|---
FL | The plans may not be more restrictive than the FFS criteria.
GA | The State does not plan to develop a program requiring MCOs to report their DUR activities in the future. The MCOs operate independently and report their DUR activities in ways they see fit without intervention from the State.
IN | The office continues to evaluate the effectiveness of this type of reporting.
MO | Our MCOs do not provide pharmacy benefits.
TN | TennCare is 100% managed care, but pharmacy is totally carved out. The MCO does not pay for any Covered Outpatient Drugs for Tennessee Medicaid enrollees.

**XI-5.** Does all of the Medicaid MCOs in your state have a targeted intervention program (i.e. CMC/Lock In) for the misuse or abuse of controlled substances?

<table>
<thead>
<tr>
<th>Answer</th>
<th>State</th>
<th>Number of States (Percentage of 38 states)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>CO, DC, DE, GA, IL, IN, KS, KY, MA, MD, MI, MN, MO, MS, ND, NH, NJ, NM, NV, OH, OR, PA, RI, SC, TX, UT, VA, WA, WV</td>
<td>29 (76%)</td>
</tr>
<tr>
<td>No</td>
<td>CA, FL, HI, IA, LA, NE, NY, TN, WI</td>
<td>9 (24%)</td>
</tr>
</tbody>
</table>

If answer to XI-5 above is "No," please explain.

**State** | **Explanation**
---|---
CA | Some of the MCOs have Lock In programs, however not all of the MCOs have verified programs.
FL | The plans may have a lock in program, but it is not required.
HI | 1-2 continue to work on their program.
IA | 2 of the 3 MCOs have a lock in program for the misuse or abuse of controlled substances. One MCO did not have a program in place for FY 2016.
LA | 4 of the 5 existing MCO plans have a Lock-in Program. The other plan intends to create a Lock-in Program in the near future.
NE | Pharmacy was carved out of managed care in FY 2016.
NY | In New York, the Office of the Medicaid Inspector General (OMIG) is the organizational component dedicated to anti-fraud and abuse activities. The OMIG is an independent entity within the New York State Department of Health. New York has implemented a rigorous lock-in program for beneficiaries with a demonstrated pattern of abusive utilization of Medicaid services. There primary providers may include a primary medical provider, pharmacy, hospitals, durable medical equipment providers, dentist, and podiatrist. In addition, restricted beneficiaries who are eligible for managed are transitional into managed care. The MCOs also have their own restriction programs, which are monitored by OMIG.
TN | Not applicable. The State Pharmacy program runs the Lock-in program.
WI | The FamilyCare Partnership contract does not establish requirements for a Lock-in or CMC program.

If you have any questions regarding an individual state's report or for detailed state information, please visit the link:

**Drug Utilization Review Annual Report | Medicaid.gov**
Ms. Kimberly Brandt  
Principal Deputy Administrator for Operations  
U.S. Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Ms. Brandt:

Thank you for appearing before the Subcommittee on Health on April 11, 2018, to testify at the hearing entitled "Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmitted letter by the close of business on May 15, 2018. Your responses should be mailed to Zack Darseshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.darseshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.  
Chairman  
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment
Virtually every stakeholder group that I have met with agrees that the IMD exclusion should be repealed as part of Congress ensuring Medicaid patients have access to a continuum of care. Many things have changed since the 1960s when this payment rule was adopted and now it is widely recognized that residential treatment is appropriate for some beneficiaries with substance use disorder. A full repeal of the IMD exclusion is still cost-prohibitive, with the Congressional Budget Office pegging the price tag of that policy at about $60 billion. But before us we have a targeted proposal that would remove a barrier to care and allow care in an IMD for up to 90 days in a 12 month period. This allows for longer treatment periods for all beneficiaries, not just selected subpopulations. Do you agree that a partial repeal of the IMD is a good first step to ensuring that Medicaid beneficiaries receive the care they need? If so, how quickly do you think states will be able to react to this change?

Answer: CMS is committed to making sure the right patient is getting the right treatment in the right setting. As you may know, a 90 day limitation could trigger the Mental Health Parity and Addiction Equity Act for some providers and insurers. However, the White House has announced the Administration’s support for legislative changes to the IMD exclusion. In the meantime, CMS has implemented a bold new policy that encourages States to submit demonstration projects for CMS approval under which Medicaid could cover services for patients in an IMD that would ordinarily not be covered by Medicaid. As discussed at the hearing, from October 31, 2017 through May 8, 2018, CMS has approved demonstration projects in six states, and these states can receive federal financial participation for the continuum of services to treat addictions to opioids and other substances, including services provided to Medicaid enrollees with a substance use disorder (SUD) who are short-term residents in residential and inpatient treatment facilities that meet that definition of an IMD. While I am unable to respond on behalf of states’ ability to react to such change, CMS has had and is having discussions with other states about approving similar flexibilities in other demonstrations. We look forward to working with the Committee and Congress on this issue.


2 The states as of 5/8/2018 are: Louisiana, New Jersey, Utah, Indiana, Kentucky, and Illinois.
2. I was pleased to see you mentioned in your testimony CMS’s efforts to keep moving forward on Transformed Medicaid Statistical Information System. I am glad to hear that 49 states, DC, and Puerto Rico are reporting data now through this system. More accurate and timely Medicaid data is important for helping us combat the opioid crisis and it’s important for improving Medicaid’s role as a payer overall. As you know, Ranking Member Pallone and I, along with our counterparts in the Senate, sent the Administrator a letter on March 16th asking about the agency’s progress implementing Transformed Medicaid Statistical Information System. I look forward to a formal response to that letter in coming days, but I want to ask about a comment in your testimony. You noted T-MSIS includes data on prescription opioids, and CMS is thinking about how to work with states in innovative ways to use this data in a way that will augment efforts to combat opioid misuse. Certainly, there is bipartisan interest in understanding how CMS is overseeing drug spending in the Medicaid program – whether it’s the Medicaid drug rebate program, or the role of opioids, or other issues. While I know the data is imperfect, could CMS start releasing some sample data so Congress and the public have better information?

Answer: CMS has made significant progress with its federal T-MSIS information technology (IT) platform, and CMS is continuing to work on T-MSIS data quality and technical compliance as a priority for 2018. CMS continues to focus on improving the quality and completeness of the state submissions, technical compliance and building the agency’s Medicaid and CHIP data analytic capacity. We look forward to making data more widely available as quality improves.

3. To help move the ball forward on this Medicaid data initiative, what does it take to boost CMS plans to use for program oversight efforts – do you need more resources and staff to move faster on this?

Answer: CMS is dependent upon the 50 states, the District of Columbia, and the U.S. territories to submit complete, accurate, and current T-MSIS data on a monthly basis, which complicates CMS’s ability to ensure a robust and accurate data set. Additionally, states need to consider how changes to their systems could adversely impact the T-MSIS dataset on timeliness or data quality, and work with CMS to protect against degradation of data during implementation of changes to state systems. This will be an ongoing effort requiring states prioritize T-MSIS data quality and technical compliance, as we work to improve the completeness and accuracy of state-submitted data and stabilize this new system and data set.

For the success of T-MSIS, CMS recognizes the need to devote staff and resources to this initiative so we can meet our collective goals of high-quality, timely Medicaid and CHIP data, especially early on in the program. It is worth noting that States, in addition to CMS, must staff and resource this initiative appropriately. In order to help ensure States give appropriate priority to T-MSIS, CMS has conveyed the importance of T-MSIS in quarterly meetings with State Medicaid Directors, as well as other communications with them. In terms of the Federal resources devoted to this initiative, Administrator Verma supported increased funding for contractor resources to bolster support for Medicaid and CHIP IT investments, data analytics, data quality oversight, and technical assistance to states. In Fiscal Year 2018, CMS has obligated
$15 million in contract funding to support development, operations and maintenance efforts, as well as state technical assistance. CMS expects to maintain a strong commitment in this area.

4. MACPAC and CMS have highlighted research that shows that patients enrolled in Medicaid have a higher risk of opioid overdose than patients covered by other payers. As a physician, I understand many Medicaid patients may have chronic conditions and long-term pain that can skew what the data looks like. I believe CMS and states share my concern over the vulnerability of Medicaid patients emphasized in these reports. Can you explain what CMS is doing to conduct oversight of state Medicaid programs and partner with them to drill down on the areas of vulnerability and protect patients who may be at risk of opioid misuse or overdose?

Answer: While the Federal government establishes general guidelines for Medicaid, states design, implement and administer their own programs. States are required to report on their providers’ prescribing patterns, including prescription opioids, as part of the Medicaid Drug Utilization Review (DUR) program. This is a two-phase process that is conducted by the state Medicaid agencies. During the first phase, (prospective DUR), the state agency’s electronic monitoring system screens prescription drug claims to identify problems such as therapeutic duplication, contraindications, incorrect dosage, and clinical misuse or abuse. The second phase (retrospective DUR) involves ongoing and periodic examination of claims to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care.

The President’s FY 2019 Budget includes a proposal that would establish minimum standards for Medicaid Drug Utilization Review programs. Currently, CMS does not set minimum requirements for these programs, and there is substantial variation in how states approach this issue. Establishing minimum standards would not only help increase oversight of opioid prescriptions and dispensing in Medicaid, but would save the program an estimated $245 million over 10 years.

5. The Medicaid PARTNERSHIP Act will allow state flexibility in how states design their PDMP programs. However, it also ensures that PDMPs are a part of Medicaid provider’s clinical workflow, which is critically important, given that a 2014 national survey “found that 53 percent of primary care physicians used their state’s program at least once, but that many did not use it routinely.” If more physicians and pharmacists were checking the PDMP would you expect the number of unsafe prescriptions of opioids to decrease?

Answer: PDMPs can certainly play an important role in the response to the opioid crisis. In 2016, forty-nine states (98%) reported having a PDMP in their state. Twenty-six states (53%) have some ability to query the PDMP database, while the remaining twenty-three states (47%) do not have the ability to do so. Only 13 states (27%) require that prescribers access the patient history in the database prior to prescribing restricted (controlled) substances. As of the close of this reporting period, Missouri reported to be the only state that was not implementing a PDMP, although in July 2017 the Governor signed an executive order to implement a PDMP. While 19 states (39%) report that they also have access to Border States PDMPs, thirty-six states (73%) indicated that they face a range of barriers that hinder their ability to fully access and utilize the
database to curb abuse.  

There is evidence that use of a PDMP can reduce potentially problematic prescribing. In New York State, all prescribers writing a prescription for a Schedule II-IV controlled substance have a mandatory duty to consult the Prescription Monitoring Program Registry, with limited exceptions. The mandatory duty to consult the PDMP provision affords practitioners with current, patient-specific controlled substance prescription information intended to inform the practitioner of controlled substance utilization by their patient at the point of prescribing. Following the implementation of its PDMP, New York saw a 75 percent decrease from 2012 to 2013, in the number of patients who use multiple prescribers and pharmacies for controlled prescription drugs.

The CMS Quality Improvement Organization (QIO) Program has made an effort to record and post information about individual state PDMPs. The purpose of these short recordings is to promote use and increase understanding of the similarities and differences between state PDMPs.

6. Representative Tonko’s bill would allow states to use federal Medicaid dollars to pay for treatment of prisoners 30-days prior to release back into the community. So, for example an inmate with substance use disorder Medicaid would pay for the first Vivitrol shot and subsequent shots would be given after release. I understand that the incarcerated population needs to be part of our opioid discussion, but I am worried about states just shifting costs to CMS. It seems like we can do better coordination under current law, without spending billions of Medicaid dollars more on prisoners. For example, Pennsylvania has a program where the state Department of Corrections pays for the first shot of Vivitrol and then after release, if the inmate is eligible for Medicaid, Medicaid picks up the costs for subsequent shots. If Pennsylvania can figure out how to do this, why can’t other states under current law?

7. There are currently non-incarcerated people who may be low-income and uninsured, and some may even be Medicaid eligible. For example, a study in San Diego concluded that nearly 80% of more than 13,000 uninsured patients in in hospital emergency departments over 11 months were eligible for some form of government insurance. Shouldn’t we prioritize non-criminals first? Wouldn’t it make sense to prioritize a low-income, but uninsured group and help facilitate their enrollment into Medicaid first?

Answer to #6 and #7: CMS is committed to making sure patients get the right care, in the right setting. We are also committed to working with states to find innovative and efficient ways to provide care to those eligible for Medicaid coverage. States need the flexibility to operate their Medicaid programs in the way that best meets their needs. CMS is willing to work with

---

4 https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/#_blank
5 https://www.cdc.gov/drugoverdose/policies/waggetes.html
6 https://goiprogram.org/prescription-drug-monitoring-program-state-videos
interested states to help them share best practices and offer better guidance around these issues, and we look forward to continuing to work with you and the Committee on possible solutions.

8. Numerous studies have found that Medicaid enrollees have excessive burdens of chronic pain and are at a much higher risk of substance use disorders compared to populations with other types of insurance. Similar studies have found that Medicaid enrollees are thus at heightened risk for prescription opioid misuse and were five to six times as likely to die from opioid-related overdose compared to populations with other types of insurance. Because of this, according to the authors of one such study (which I would like to submit for the record), “reducing the number of unsafe prescriptions of opioids in the Medicaid population should be a priority for any drug control policies.” I believe that we have several bills before us today that will help achieve that goal. Our Pharmacy Home Bill, our PDMP Bill, and our DUR bill for example. Does the Administration believe that these policies will help to advance the important goal of reducing the number of opioids in the Medicaid population?

Answer: This Administration agrees that reducing the number of unsafe prescriptions of opioids is an important part of combating the opioid crisis. Last month, President Trump highlighted the Administration’s commitment to tackling the opioid crisis by announcing a goal of cutting the number of opioid prescription fills by one-third within three years. To reduce opioid misuse without restricting access to legitimate services, Medicaid programs can utilize several medical management techniques, including quantity limits. As of FY 2016, thirty-seven states have edits in place to limit the quantity of short-acting opioids that will be covered for a beneficiary and thirty-nine states have similar edits in place to limit the quantity of long-acting opioids. 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. In addition, the President’s FY 2019 Budget includes a proposal that would establish minimum standards for Medicaid Drug Utilization Review programs. Currently, CMS does not set minimum requirements for these programs, and there is substantial variation in how states approach this issue. Establishing minimum standards would not only help increase oversight of opioid prescriptions and dispensing in Medicaid, but would save the program an estimated $245 million over 10 years.

There is also evidence that use of a PDMP can reduce potentially problematic prescribing. In New York State, all prescribers writing a prescription for a Schedule II-IV controlled substance have a mandatory duty to consult the Prescription Monitoring Program Registry³, with limited exceptions. The mandatory duty to consult the PDMP affords practitioners with current, patient-specific controlled substance prescription information intended to inform the practitioner of controlled substance utilization by their patient at the point of prescribing. Following the

---

⁵ https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/#_blank
implementation of its PDMP, New York saw a 75 percent decrease from 2012 to 2013 in the number of patients who use multiple prescribers and pharmacies for controlled prescription drugs.\(^7\)

Lock-in programs are one of many valuable tools available to states in their efforts to address the opioid epidemic and could also be valuable for Medicaid managed care programs. Under current law,\(^8\) 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.

CMS is happy to work with the Committee and provide technical assistance on the legislation you are considering.

9. Last fall, CMS released its 2016 Drug Utilization Review report. The report noted that 26 Medicaid agencies have access to PDMP data. States can use PDMP data to manage the overutilization of opioids and detect fraud, waste, and abuse. On the other hand, 23 state Medicaid agencies report that they do not have access to PDMP data. Given how some states have seen PDMPs help protect patients and reduce reliance on opioids, I think that this bill helps those states equip the Medicaid agency with an important tool that can be used to fight this epidemic. Can you describe how Medicaid agency officials would use PDMP data to combat opioids?

Answer: PDMPs are one of many valuable tools available to states in their efforts to address the opioid epidemic. Currently, 49 States have implemented a PDMP, and 13 States require prescribers to check the PDMP before prescribing controlled substances. We encourage States and providers to take advantage of these programs, and we are making efforts to improve the interoperability of these valuable programs.

States which allow Medicaid programs to access PDMP data may enhance the states’ drug utilization review program oversight activities. Successful collaborative initiatives to reduce prescription opioid abuse in Oklahoma and Washington included promoting full access to PDMP data for monitoring and data research purposes.

There is also evidence that use of a PDMP can reduce potentially problematic prescribing. In New York State, all prescribers writing a prescription for a Schedule II-IV controlled substance have a mandatory duty to consult the Prescription Monitoring Program Registry,\(^9\) with limited exceptions. The mandatory duty to consult the PDMP provision affords practitioners with current, patient-specific controlled substance prescription information intended to inform the practitioner of controlled substance utilization by their patient at the point of prescribing.

Following the implementation of its PDMP, New York saw a 75 percent decrease from 2012 to

\(^7\) https://www.cdc.gov/drugoverdose/policy/successes.html
\(^8\) 42 CFR 431.54(e)
\(^9\) https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/#_blank
2013 in the number of patients who use multiple prescribers and pharmacies for controlled prescription drugs.13

10. I have a question pertaining to the Medicaid Pharmacy Home Act, which requires states to have a provider/pharmacy assignment program for patients whom the state identifies as potentially misusing or abusing controlled drugs. In 2012, CMS highlighted the importance of these “lock-in” programs as an element of a robust state Medicaid controlled prescription drug program. This past October, CMS released its annual Drug Utilization Review report. The report notes that while 48 states are currently using lock-in programs, some states make lock-in programs optional for managed care organizations. Lock-in programs are effective in reducing overprescribing and in states like Pennsylvania and New York the program has resulted in reducing patient harm and saved money due to curbing unnecessary utilization. The Pharmacy Home Act codifies a requirement that requires Medicaid managed care plans have a similar program. Can you think of a reason why managed care organizations should not be asked to use this important tool?

11. I want to address a point that my colleague brought up about lock-in programs being used to theoretically deny Medicaid beneficiaries prescription drugs they need or restrict access. Not only do I see that the bill exempts populations for the program such as beneficiaries in hospice, but I am aware of a 2016 Pew Charitable Trust Report which showed that 38 of 41 states surveyed operate a similar program. If lock-in programs really are meant to restrict access and deny people drugs they medically need, why is it that both Republican and Democratic states are using them? I think such critiques are misleading smokescreens. We are here to adopt proven technological solutions that help protect patients and ensure they get the care they need. If members and stakeholders want to be thoughtful and have constructive improvements to the draft proposal, we certainly welcome them.

Answer to #10 and #11: Under current law14, 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.

Lock-in programs are one of many valuable tools available to states in their efforts to address the opioid epidemic and could also be valuable for Medicaid managed care programs. The President’s FY 2019 Budget includes a proposal that would allow CMS to make lock-in programs mandatory within the Medicare Part D program.

12. In your testimony, you discussed Medicare's Overutilization Monitoring Program which helps plans identify at-risk beneficiaries so plans can take appropriate clinical steps to prevent opioid misuse or overdoses. Does this program also share this data

14. 42 CFR 431.54(e)
with state Medicaid programs so they can ensure the best care for beneficiaries who are dually enrolled in Medicare and Medicaid?

a. If yes, can you explain how the process works to get this information to state programs and how quickly this process works?
b. If no, can you please have your staff look into the feasibility of sharing this data with state programs and get back with the Committee?

Answer: Each Medicaid drug management program has its own criteria and requirements for reviewing and addressing recipients who may be at-risk for prescription drug abuse or misuse and its own interventions. Furthermore, Medicaid programs are not required to comply with section 1860D-4(c)(5) as Part D drug management programs are. Currently, Medicare’s Overutilization Monitoring System does not provide information to state Medicaid programs. However, we are always looking for ways to improve the coordination of care between beneficiaries who are dually enrolled in Medicare and Medicaid. To date, states have not requested this information from us. State Prescription Drug Monitoring Programs likely include much of the same information.

13. In your testimony, you describe how Medicare Part D plans receive the quarterly pharmacy risk assessments which list pharmacies identified by CMS at high risk. Does CMS also share this data with state Medicaid programs to help ensure the best care for patients who are dually enrolled in Medicare and Medicaid?

a. If not, would CMS be willing to look at how it might be possible to share this data with state programs and get back with the Committee?

Answer: Pharmacy Risk Assessments, provided quarterly to Medicare Part D plans by the Medicare Drug Integrity Contractor (MEDIC), are not currently provided to state Medicaid programs because there could be privacy and security concerns related to sharing the content of these assessments with all state Medicaid programs. However, we are always looking for ways to improve the coordination of care between beneficiaries who are dually enrolled in Medicare and Medicaid.

14. The National Association of Boards of Pharmacy reports that 39 states already mandate use of PDMPs. What has your experience been in using PDMPs to combat the opioid crisis? What is your sense on how providers and dispensers view the usefulness of PDMPs?

Answer: PDMPs are one of many valuable tools available to states in their efforts to address the opioid epidemic. Currently, 49 States have a PDMP, and 13 States require prescribers to check the PDMP before prescribing controlled substances. We encourage States and providers to take advantage of these programs, and we are making efforts to improve the interoperability of these valuable programs.

Many States have seen promising results from the use of PDMPs. For example, in New York State, all prescribers writing a prescription for a Schedule II-IV controlled substance have a
mandatory duty to consult the Prescription Monitoring Program Registry, with limited exceptions. The mandatory duty to consult the PDMP provision affords practitioners with current, patient-specific controlled substance prescription information intended to inform the practitioner of controlled substance utilization by their patient at the point of prescribing. Following the implementation of its PDMP efforts, New York saw a 75 percent decrease from 2012 to 2013 in the number of patients who use multiple prescribers and pharmacies for controlled prescription drugs.

The CMS Quality Improvement Organization (QIO) Program has made an effort to record and post information about individual state PDMPs. The purpose of these short recordings is to promote use and increase understanding of the similarities and differences between state PDMPs.

15. Numerous studies have found that Medicaid enrollees have excessive burdens of chronic pain and are at a much higher risk of substance use disorders compared to populations with other types of insurance. Similar studies have found that Medicaid enrollees are thus at heightened risk for prescription opioid misuse and were five to six times as likely to die from opioid-related overdose compared to populations with other types of insurance. Because of this, according to the authors of one such study, which I quote: “reducing the number of unsafe prescriptions of opioids in the Medicaid population should be a priority for any drug control policies.” I believe that we have several bills before us today that will help achieve that goal. Our Pharmacy Home Bill, our PDMP Bill, and our DUR Bill for example. Do you believe that these policies will help to advance the important goal of reducing the number of opioids in the Medicaid population?

Answer: This Administration agrees that reducing the number of unsafe prescriptions of opioids is an important part of combating the opioid crisis. Last month, President Trump highlighted the Administration’s commitment to tackling the opioid crisis by announcing a goal of cutting the number of opioid prescription fills by one-third within three years.

To reduce opioid misuse without restricting access to legitimate services, Medicaid programs can utilize several medical management techniques, including quantity limits. As of FY 2016, thirty-seven states have edits in place to limit the quantity of short-acting opioids that will be covered for a beneficiary and thirty-nine states have similar edits in place to limit the quantity of long-acting opioids. 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. In addition, the President’s FY 2019 Budget includes a proposal that would establish minimum standards for Medicaid Drug Utilization Review programs. Currently, CMS does not set minimum requirements for these programs, and there is substantial variation in how states approach this issue. Establishing minimum standards would not only help increase

---

oversight of opioid prescriptions and dispensing in Medicaid, but would save the program an estimated $245 million over 10 years.

There is also evidence that use of a PDMP can reduce potentially problematic prescribing. In New York State, all prescribers writing a prescription for a Schedule II-IV controlled substance have a mandatory duty to consult the Prescription Monitoring Program Registry 19, with limited exceptions. The mandatory duty to consult the PDMP provision affords practitioners with current, patient-specific controlled substance prescription information intended to inform the practitioner of controlled substance utilization by their patient at the point of prescribing. Following the implementation of its PDMP, New York saw a 75 percent decrease from 2012 to 2013 in the number of patients who use multiple prescribers and pharmacies for controlled prescription drugs 20.

Lock-in programs are one of many valuable tools available to states in their efforts to address the opioid epidemic and could also be valuable for Medicaid managed care programs. Under current law 21, 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.

CMS is happy to work with the Committee and provide technical assistance on the legislation you are considering.

16. The Medicaid HUMAN CAPITAL Act would provide enhanced funding for states to recruit highly-experienced Medicaid directors, Chief Information Officers, and Chief Financial Officers. In Mr. Douglas’s testimony, he discusses the importance of strengthening Medicaid’s role as a payer in combatting opioid misuse. He notes “Congress should implement policies that support state recruitment and retention of strong Medicaid executive leadership,” because as he explains, a stable and strong state leadership will be best equipped to respond to the opioid crisis and further public health crises.” In your opinion, is it helpful to improving Medicaid’s role in addressing the opioid epidemic and other public health challenges by helping states secure the most talented, innovative, and experienced leadership possible?

Answer: In order to have a well-run Medicaid program, states need to have good staff, and we appreciate the great work being done by our state partners. Every state is different, and CMS has typically deferred to states to determine the incentives that would be most appropriate for recruiting and retaining staff.

17. I am interested in the draft that proposes a demonstration project to increase provider capacity in Medicaid for treating substance use disorder. States could apply to use the funds to recruit or train current or new providers. However, I do

---

19 https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/#_blank
20 https://www.cdc.gov/drugoverdose/policy/successes.html
21 42 CFR 431.54(e)
have several concerns with the idea. Given all the funds that Congress has authorized to support provider capacity such as GME as well as grants from HRSA, SAMSHA, and CDC. Is this idea duplicative? I am also unclear why we would start a new program when those are well established and have staff that understand workforce capacity. Can you comment on that?

Answer: One of the core components in our efforts to address the opioid epidemic is making sure beneficiaries have adequate access to treatment. We have already approved several substance use disorder demonstration projects and in order to bolster States' flexibility and we are actively encouraging more states to apply.

Effectively combatting the opioid crisis will require collaboration across the Federal government. The goal should be to establish collaborative, complementary roles while avoiding duplication and overlap. CMS is committed to working with our partners across HHS, the Administration, and Congress to address this epidemic.

The Honorable Leonard Lance

1. The 2019 Call Letter states that Part D beneficiaries with cancer-related pain are excluded from the 'Overutilization Monitoring System.' Can you please clarify how CMS intends to also exclude patients diagnosed with conditions beyond cancer but that are cancer-like in their association with extreme pain?

Answer: Through rulemaking (CMS-4182-F), CMS finalized regulations to implement certain provisions of the Comprehensive Addiction and Recovery Act (CARA) to further reduce the number of beneficiaries who may potentially misuse or overdose on opioids while still having access to important treatment options. The final approach builds on and integrates with the Overutilization Monitoring System (OMS), as also discussed in the 2019 Call Letter.

Through this final rule, CMS has established a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse, or "at-risk beneficiaries." Specifically, under drug management programs, Part D plans will engage in case management of potential at-risk beneficiaries, through contact with their prescribers, when such beneficiary is found to be taking a specific dosage of opioids and/or obtaining them from multiple prescribers and multiple pharmacies who may not know about each other. Sponsors may then limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are "frequently abused drugs" to a selected prescriber(s) and/or network pharmacy(ies) or through beneficiary-specific claim edits after case management with the prescribers for the safety of the enrollee.

CMS developed clinical guidelines with stakeholder input that will be used to identify potential at-risk beneficiaries. The clinical guidelines for 2019 are expanded OMS criteria, which take into consideration the level of opioids used and the number of opioid prescribers and opioid dispensing pharmacies.
Also, we finalized the definition for exempted beneficiary: An exempted beneficiary, with respect to a drug management program, will mean an enrollee who: (1) has elected to receive hospice care or is receiving palliative or end-of-life care; (2) is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or (3) is being treated for active cancer-related pain.

CMS will report potential at-risk beneficiaries who meet the minimum criteria of the clinical guidelines to sponsors through the OMS. To the extent CMS data shows a beneficiary meeting the exclusion criteria, they would not be listed in the OMS report. Sponsors may have more current data or obtain information through the case management and notification processes to further exempt beneficiaries. The case management process may also identify other beneficiaries with extreme pain due to other conditions where the prescriber asserts that the use is medically necessary, including patients diagnosed with conditions beyond cancer but that are cancer-like in their association with extreme pain if deemed medically necessary. These beneficiaries would not be subject to a limitation on access to coverage for frequently abused drugs.
May 2, 2018

The Honorable Michael Botticelli
Executive Director
Grayken Center for Addiction
Boston Medical Center
715 Albany Street
Boston, MA 02118

Dear Mr. Botticelli:

Thank you for appearing before the Subcommittee on Health on April 11, 2018, to testify at the hearing entitled “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients.”

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 15, 2018. Your responses should be mailed to Zack Darcshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.darcshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment
May 15, 2018

The Honorable Greg Walden  
Chairman  
Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Frank Pallone, Jr.  
Ranking Member  
Energy and Commerce Committee  
2322A Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Michael C. Burgess, M.D.  
Chairman  
Subcommittee on Health

The Honorable Gene Green  
Ranking Member  
Subcommittee on Health

Dear Chairman Walden, Chairman Burgess, Ranking Members Pallone and Green,

Thank you for the opportunity to appear before the Subcommittee on Health on April 12, 2018, to testify at the hearing entitled “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients.”

Accompanying this letter are my responses to the additional questions for the record from Chairman Burgess and Ranking Member Pallone. Thank you in advance for your consideration of my comments. As always, if I can be of any additional assistance, please do not hesitate to be in touch.

Sincerely,

[Signature]

Michael Botticelli  
Executive Director  
Grayken Center for Addiction at Boston Medical Center
Answers to Questions for the Record from Michael Botticelli, Executive Director
Grayken Center for Addiction at Boston Medical Center
May 15, 2018

U.S. House of Representatives Committee on Energy and Commerce Health Subcommittee Hearing
Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients

The Honorable Michael C. Burgess, M.D.

1. The National Association of Boards of Pharmacy reports that 39 states already mandate use of PDMPs. What has your experience been in using PDMPs to combat the opioid crisis? What is your sense on how providers and dispensers view the usefulness of PDMPs?

Prescription Drug Monitoring Programs (PDMPs) have been highly successful in reducing excessive opioid prescribing and identifying problematic drug interactions, e.g. prescriptions for opioids and benzodiazepines. Robust PDMPs — which have real-time data and high numbers of registrants and users — have been shown to significantly reduce both problematic prescribing and opioid overdose deaths. To enhance the utility of state PDMPs, it is important that federal resources be sufficient to ensure data sharing among states and the interoperability with electronic medical records to minimize the burden on prescribers.

2. Numerous studies have found that Medicaid enrollees have excessive burdens of chronic pain and are at a much higher risk of substance use disorders compared to populations with other types of insurance. Similar studies have found that Medicaid enrollees are thus at heightened risk for prescription opioid misuse and were five to six times as likely to die from opioid-related overdose compared to populations with other types of insurance. Because of this, according to the authors of one such study, which I quote: “reducing the number of unsafe prescriptions of opioids in the Medicaid population should be a priority for any drug control policies.” I believe that we have several bills before us today that will help achieve that goal. Our Pharmacy Home Bill, our PDMP Bill, and our DIUR bill for example. Do you believe that these policies will help to advance the important goal of reducing the number of opioids in the Medicaid population?


Michael Botticelli, Executive Director
Grayken Center for Addiction at Boston Medical Center
U.S. House Energy & Commerce Committee | 05.15.18
Yes, I believe though with the caveat that efforts to ensure reductions in the number of opioids in the Medicaid population are coupled with increased access to evidence-based non-pharmacologic pain management services as a means to avoid the possible unintended consequence of not appropriately treating members’ pain.

3. The Medicaid HUMAN CAPITAL Act would provide enhanced funding for states to recruit highly-experienced Medicaid directors, Chief Information Officers, and Chief Financial Officers. In Mr. Douglas’s testimony, he discusses the importance of strengthening Medicaid’s role as a payer in combating opioid misuse. He notes "Congress should implement policies that support state recruitment and retention of strong Medicaid executive leadership," because as he explains, a stable and strong state leadership will be best equipped to respond to the opioid crisis and further public health crises.” In your opinion, is it helpful to improving Medicaid’s role in addressing the opioid epidemic and other public health challenges by helping states secure the most talented, innovative, and experienced leadership possible?

No comment – I defer to my other esteemed panelists.

4. I am interested in the draft that proposes a demonstration project to increase provider capacity in Medicaid for treating substance use disorder. States could apply to use the funds to recruit or train current or new providers. However, I do have several concerns with the idea. Given all the funds that Congress has authorized to support provider capacity such as GME as well as grants from HRSA, SAMSHA, and CDC. Is this idea duplicative? I am also unclear why we would start a new program when those are well established and have staff that understand workforce capacity. Can you comment on that?

While a demonstration project to increase provider capacity in Medicaid for treating substance use disorder (SUD) might be duplicative, there are, as it stands, too few providers trained and authorized to treat SUD, especially in Medicaid, so we need to continue aggressive efforts to increase provider capacity in this most critical area. It is worth examining whether existing programs are adequately resourced to achieve these goals.

The Honorable Frank Pallone, Jr.

1. The need for access to opioid use disorder treatment is growing for Medicare beneficiaries. Unfortunately, a number of gaps in coverage exist that limit beneficiaries' options for receiving treatment.

2. What are some of the existing opioid use disorder treatment gaps in Medicare and why are these important to resolve?

3. We have heard how the best treatment for opioid use disorder includes both medication and behavioral therapies. Medicare covers some, but not all of these necessary treatments, specifically Methadone for maintenance therapy for opioid use disorder is not available for Medicare beneficiaries who require

Michael Botticelli, Executive Director
Grayken Center for Addiction at Boston Medical Center
U.S. House Energy & Commerce Committee | 05.15.18
(Combined answers to Medicare questions 1-8)

Many patients are limited as to what medications they can access, if any. An existing opioid use disorder treatment gap of note is Medicare does not cover outpatient Opioid Treatment Programs, although there are bills, including one by Ranking Member Pallone to address this.

4. Why is it important to include all aspects of opioid use disorder treatment for beneficiaries suffering with substance abuse?

It is of the utmost importance for Medicaid and Medicare to cover all aspects of opioid use disorder treatment, including all three FDA-approved forms of MAT. As is the case with any disease, clinicians caring for patients with opioid use disorder need as many treatments as possible at their disposal, since based on clinical assessment and patient preference, what is the right course of treatment for one person might not be right for the next one. In addition, a wide variety of therapeutic and recovery services have a role to play in promoting recovery, especially considering the high rates of co-occurring disorders in people with opioid use disorder, e.g. combining pharmacologic treatment with behavioral therapy.

5. How can we expand the scope of services existing providers offer and increase the overall numbers of providers available to treat substance abuse disorders?

There exists a huge gap between the number of people with opioid use disorder and the proportion of this population that is prescribed medication. The small percentage of providers that prescribe all three FDA-approved medications could be dramatically increased by requiring all federally-funded substance use disorder treatment programs to provide all three FDA-approved medications, and that they remain consistent with approved best practices going forward. As some states have demonstrated, the use of CMS’ 1115 waiver process has allowed states to successfully increase the services that qualify for federal reimbursement. In Massachusetts, for example, Residential Rehabilitation and Recovery Coach services will become Medicaid reimbursable services. This waiver process also allows states to waive IMD requirements by demonstrating a continuum of services. This is a much more reasoned and prudent approach than just eliminating the IMD exclusion alone.

6. What areas would you recommend CMS focus on to improve opioid use disorder treatment?

Please refer to my answers to previous questions and recommendations offered in my testimony.

7. How can Medicare assist in increasing the number of MAT prescribers available to treat opioid use disorders?

Both Medicare and Medicaid should evaluate their reimbursement structures for ways to remove barriers and provide greater incentives to increase the number of MAT prescribers.
May 2, 2018

Mr. Toby Douglas
Senior Vice President for Medicaid Solutions
Centene Corporation
7700 Forsyth Boulevard
St. Louis, MO 63105

Dear Mr. Douglas:

Thank you for appearing before the Subcommittee on Health on April 11, 2018, to testify at the hearing entitled "Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 15, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.darezori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment
May 31, 2018

The Honorable Michael C. Burgess, M.D.  
Chairman
Committee on Health
House of Representatives
Washington D.C., 20515-6115

Via electronic delivery

Dear Chairman Burgess and Ranking Member Green:

I am writing in response to your May 2, 2018 letter to Mr. Toby Douglas requesting additional information following Mr. Douglas’s testimony on April 12, 2018 at the hearing entitled “Combating the Opioids Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients.” Thank you again for the opportunity to testify.

Addiction to prescription pain medications has become a public health epidemic in the United States. According to the Centers for Disease Control and Prevention, the amount of opioid prescriptions dispensed has nearly quadrupled from 1999 to 2014. Opioid misuse, overdose and other significant complications, such as neonatal abstinence syndrome, drug-drug interactions, and fatal overdoses, have significantly increased over the last decade. Emphasizing the prevention of opioid misuse is a significant priority for Centene Corporation.

Centene is a diversified, multi-national healthcare enterprise that provides a portfolio of services to government sponsored health care programs, focusing on under-insured and uninsured individuals. Our geographic footprint facilitates our ability to develop and apply evidenced based clinical best practices, particularly for substance abuse and opioid misuse, while fulfilling our purpose of transforming the health of the community, one person at a time.

1. "Can you describe advances that have been made with using prescription drug monitoring programs (PDMPs), and what barriers remain? My sense is that innovative and effective technological solutions exist, but not all states have yet changed their policies to adopt them?"

   The majority of state PDMPs are authorized to send reports to providers, medical licensing boards, and law enforcement agencies when a prescriber’s or recipient’s activity exceeds the threshold established by the PDMP. Advances in recent years include real-time reporting for more current and precise data that is available in some, but not all states.

   PDMPs exist across 49 states, as well as St. Louis County, the District of Columbia, and Guam. Amongst these PDMPs, there is variability within the technological infrastructure supporting the data analytic capabilities. Therefore, creating interoperability across state lines between the existing PDMPs would improve their effectiveness. Inconsistent PDMP utilization by providers creates a challenge to all states, because the effectiveness of PDMPs is dependent on their use. Educational programs that teach providers about the importance of PDMPs can overcome these barriers. Additionally, lack of integration into current clinical workflows is another reported barrier, as properly configured incorporation of PDMP data into existing electronic health record (EHR) and electronic prescription systems would facilitate more accessible and timely information for providers.

   Furthermore, expanding access to PDMPs to include third party payers, with a plan for proper protection and appropriate use, could improve health outcomes at a population level. This premise has been suggested previously and has been supported in the literature."

7700 Forsyth Boulevard
St. Louis, MO 63105
314-725-4474

CENTENE.COM
2. "There are currently non-incarcerated people who may be low-income and uninsured, and some may even be Medicaid eligible. ... Shouldn't we prioritize non-criminals first? Wouldn't it make sense to prioritize a low-income, but uninsured group and help facilitate their enrollment into Medicaid first?"

Centene is committed to improving the health of the community through health insurance solutions for the under-insured and uninsured, and through specialty services that align with our focus on whole health. Centene provides high-quality, culturally-sensitive healthcare coverage and services to millions of people across the United States and internationally. Through our local healthcare programs, we collaborate with a network of physicians, hospitals and supportive healthcare services to deliver the best care for each and every person.

According to the Centers for Disease Control and Prevention (CDC), the opioid epidemic has impacted the Medicaid population disproportionately. A retrospective analysis conducted in Washington during 2004-2007 determined that the number of overdose deaths involving prescription opioids was 5.7 times greater for Medicaid beneficiaries. Similarly, measuring poisonings death rates involving opioid analgesics in New York during 2003-2012 revealed that Medicaid enrollees had higher death rates for opioid prescriptions than non-Medicaid enrollees each year. Furthermore, the Medicaid and CHIP Payment and Access Commission stated in their June 2017 report to Congress that Medicaid beneficiaries age 18-64 have a higher rate of opioid use disorder than privately insured individuals, comprising about 12 percent of all civilian, non-institutionalized adults in this age group but about one-quarter of those with an opioid use disorder.

3. "Do you think that quality information on IMDs already exists and that the IMD Additional Info Act before us will synthesize it in a useful way or do you think the bill will help to gather new information about IMDs?"

According to a recent report to Congress from MACPAC regarding Institution for mental diseases (IMD) exclusions, information regarding IMDs should help Congress and other stakeholders better understand the current state of data collection for the purpose of quality oversight over IMDs, as directed by the IMD Additional Information Act.

4. "In testimony we received from CMS yesterday, Kim Brandt discussed Medicare's Overutilization Monitoring Program which helps plans identify at-risk beneficiaries so plans can take appropriate clinical steps to prevent opioid misuse or overdoses. She also described how Medicare Part D plans receive the quarterly pharmacy risk assessments which list pharmacies identified by CMS at high risk. Does CMS also share any of these data under either program with state Medicaid programs to help ensure the best care for patients who are dualy enrolled in Medicare and Medicaid? Would it be useful for State Medicaid programs and other programs to have this information to provide the best integrated care for patients?"

The Medicare Overutilization Monitoring Program facilitates drug utilization review for dosing, pharmacy utilization, and member count, among other metrics, for beneficiaries that exceed prescription triggers set by CMS. Enhanced interagency communication could enable more expansive data and clinically driven decisions to impact member outcomes.

5. "I was thinking about Representative Torres's bill that would allow prisoners to receive health care funded by Medicaid 30-days prior to release. Mr. Douglas, couldn't a state apply for a waiver to achieve this? And if
Identification and treatment of opioid use disorder during incarceration with medication-assisted therapy and behavioral support therapy is a strategy to address the rates of overdose and opioid use disorder in the community.

6. "HR 4998 has the goal of helping foster youth who move to another state be able to access health coverage. I would note at least three concerns with the bill as drafted. First, the draft seems to lower the age of foster care youth that can be considered as a mandatory group from 18 to 14. Second, the bill forces states to cover this population in Medicaid, rather than allowing them in private market coverage. Third, while foster youth may be at risk for opioid abuse, if we are going to spend federal dollars, given there are thousands of Americans right now at risk for overdose death due to opioid abuse, I think it could be more responsible to prioritize dollars for treatment for these patients. Mr. Douglas, do you share this concern? And is there anything particular that you are aware of that happens to children in foster care when they turn 14 that may explain this age threshold?"

Foster youth engagement is key for healthier outcomes. A key factor to consider regarding age threshold is to consider when the foster youth is in a relatively stable housing situation in order to know where the youth is to better connect with them.

7. "If lock-in programs really are meant to restrict access and deny people drugs they medically need, why is it that both Republican and Democratic states are using them?"

Pharmacy lock-in programs are designed to assign beneficiaries to specific providers or pharmacies, preventing unnecessary or inappropriate utilization. Its intent is to prevent members from obtaining excessive quantities of prescription drugs through multiple visits to physicians and pharmacies. Members with high medication utilization and using multiple pharmacies and/or physicians may experience uncoordinated care, incur serious drug interactions, and have a greater potential for medication misuse.

8. "What has your experience been in using PDMPs to combat the opioid crisis? What is your sense on how providers and dispensers view the usefulness of PDMPs?"

Prescription drug monitoring programs (PDMPs) are effective mechanisms to identify patients at risk for opioid misuse. It has been well documented that proper utilization of PDMPs improves clinical decision making, reduces doctor shopping, improves health outcomes, and reduces drug and medical costs. PDMPs allow prescribers and pharmacists, as well as other individuals and entities (such as researchers, and medical licensing boards) that are authorized to access the data, to monitor controlled substance use by patients, the prescribing practices of medical practitioners, and population-level drug use trends. Congress should consider legislation that will open access to PDMPs for managed care organizations.

9. "Numerous studies have found that Medicaid enrollees have excessive burdens of chronic pain and are at a much higher risk of substance use disorders compared to populations with other types of insurance...."
quote: “Reducing the number of unsafe prescriptions of opioids in the Medicaid population should be a priority for any drug control policies.” I believe that we have several bills before us today that will help achieve that goal. Our Pharmacy Home Bill, our PDMP Bill, and our DUR bill for example. Do you believe that these policies will help to advance the important goal of reducing the number of opioids in the Medicaid population?

As previously discussed in the response to question #2, there is strong evidence to support the observation that the opioid epidemic has impacted the Medicaid population disproportionately. Policies that seek to improve the lives of Medicaid beneficiaries through addressing prescription drug monitoring programs, utilization of criteria of the American Society of Addiction Medicine, and implementation of clinical best practice guidelines, will have an impact to combat opioid misuse.

10. “The Medicaid HUMAN CAPITAL Act would provide enhanced funding for states to recruit highly-experienced Medicaid directors, Chief Information Officers, and Chief Financial Officers. In Mr. Douglas’s testimony, he discusses the importance of strengthening Medicaid’s role as a payer in combating opioid misuse. He notes “Congress should implement policies that support state recruitment and retention of strong Medicaid executive leadership,” because as he explains, a stable and strong state leadership will be best equipped to respond to the opioid crisis and future public health crises.” In your opinion, is it helpful to improving Medicaid’s role in addressing the opioid epidemic and other public health challenges by helping states secure the most talented, innovative, and experienced leadership possible?”

A stable and strong state Medicaid leadership team will be best equipped to respond to the opioid crisis and future public health crises.

11. “I am interested in the draft that proposes a demonstration project to increase provider capacity in Medicaid for treating substance use disorder. States could apply to use the funds to recruit or train current or new providers. However, I do have several concerns with the idea. Given all the funds that Congress has authorized to support provider capacity such as GME as well as grants from HRSA, SAMSHA, and CDC. Is this idea duplicative? I am also unclear why we would start a new program when those are well established and have staff that understand workforce capacity. Can you comment on that?”

Provider education is important for facilitating best practices amongst providers. Such instruction on evidence based practice guidelines, pain management toolkits, low dose prescribing policies, avoiding stigmas in addiction treatment, and chronic pain management are key components for provider education programs. Multiple modalities of provider education may provide synergistic mechanisms to render changes in prescribing behaviors.

Again, thank you for the opportunity to testify and provide feedback on your additional questions for the record. We appreciate your interest in this matter and trust that this information is helpful.

Sincerely,

Jonathan Dinesman
Senior Vice President, Government Relations
Centene Corporation
3 Alexander GC, Fredericks S, Dieter AC eds. The Opioid Epidemic: From Evidence to Impact; Johns Hopkins Bloomberg School of Public Health; Baltimore, MD: 2017
7 Prescription Drug Monitoring Program Center of Excellence at Brandeis. Briefing on PDMF Effectiveness. Updated September 2014.
Mr. David Guth
CEO and Co-founder
Centerstone America
44 Vantage Way
Nashville, TN 37228

Dear Mr. Guth:

Thank you for appearing before the Subcommittee on Health on April 11, 2018, to testify at the hearing entitled “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients.”

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 15, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment
Re: Additional Questions for the Record

Dear Chairman Burgess and Ranking Member Pallone,

Once again, thank you for inviting Centerstone to participate in the “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients” hearing on April 11th/12th. Below, please find our responses to your additional questions for the record.

1. Individuals who are opioid dependent often have complex social, physical, or behavioral health comorbidities. For example, six out of 10 people with a substance use disorder also suffer from another form of mental illness and could benefit from increased care management. What kinds of benefits does a SUD Health Home offer to a Medicaid beneficiary that would not be available outside of the model? Can you provide details on how states have taken the concept of team-based care, which includes: wrap-around services such as comprehensive care management, care coordination, and support services and put that into practice using the health home waiver?

The Patient Protection and Affordable Care Act (ACA) established authority for states to develop and receive federal reimbursement for health home services for their state’s Medicaid populations with chronic illness(es).¹ Health Home services support the provision of coordinated, comprehensive medical and behavioral health care to patients with chronic conditions through care coordination and integration that assures access to appropriate services, improves health outcomes, reduces preventable hospitalizations and emergency room visits, promotes use of health information technology (HIT), and avoids unnecessary care.² An eligible chronic condition includes, but is not limited to: a mental health condition, a substance use disorder, asthma, diabetes, heart disease, and being overweight.³

At Centerstone, through our Medicaid Health Home⁴, we are able to not only provide patients with a host of direct medical and behavioral health services, but also to connect them with needed wrap-around services, which increase their chances of staying healthy. Through Tennessee Health Link⁵, we provide the

1 https://www.health.ny.gov/health_care/medicaid_program/medicaid_health_homes/
2 https://www.health.ny.gov/health_care/medicaid_program/medicaid_health_homes/
3 https://www.ssa.gov/OF_Home/act/title15/I1459.html#M10
4 https://centerstone.org/our-services/services-directory/healthlink
5 https://www.tn.gov/health-care-innovations/primary-care-transformation/tennessee-health-link.html

Our Noble Purpose: Delivering Care that Changes People’s Lives
following six types of services: (1) comprehensive care management – including a patient-centered health assessment and active management of your customized care plan; (2) care coordination – making sure all of a patient’s healthcare providers actively work together to deliver the highest quality care; (3) health promotion – helping patients take charge over their own health through education, annual screenings and disease prevention; (4) transitional care – helping patients after any hospital or emergency room visit by answering their questions and ensuring they receive appropriate follow-up care; (5) patient and family support – identifying ways to aid patients in treatment, providing a mix of check-ins and wellness coaching as needed to help maximize recovery; and (6) referral to social supports – linking patients to any other resources or services they may need such as housing, employment, legal, peer support, etc.

The benefits of an SUD health home are that people receive not only one-time interventions as is typical in the status-quo fee-for-service healthcare environment, but also, just as importantly, receive a range of services that help them stay in treatment, get relevant check-ups, deal with other, co-occurring health challenges, participate in and with their communities, and feel able to stay in control of their medical and behavioral health needs. Through better coordinated behavioral and physical health services, health homes produce improved member outcomes, greater provider accountability and flexibility when it comes to the delivery of appropriate care for each individual, and improved cost control for the state.

A Centerstone client success story, generated 08/14/17, follows:

When T.M. enrolled into “Health Home,” he was in bad shape. He had lost his job and his insurance. His housing situation was uncertain. His diabetes was out of control. At his enrollment interview, his blood glucose level was 312. The pain in his legs and feet were a constant reminder of his ill health. In the prior year, he had lived in five different places. His health was on a general downward trajectory. All of this weighed heavily on his mind, and his anxiety was starting to get the better of him.

A year later, a blood test revealed that T.M.’s glucose level was 70 - a decrease of 442 points. When asked what changes he had made to achieve this change, T.M. said that it was “Health Home” that brought everything together for him. It wasn’t just eating habits that were contributing to his diabetes. It was stress, lack of medication, and unstable housing that made eating right seem far from a priority. T.M. now says that the biggest change for him was in his thinking. After attending the Mindfulness class offered through our “Health Home” program, he realized he couldn’t keep doing what he was doing. “It’s about keeping your mind in the moment. It’s all a new normal.” When faced with a craving, he says he has to “be mindful of whether I want to be sick today or if I want to live.”

Health has been a long term issue for T.M., and he has tried other programs in the past. In describing other programs, T.M. said that no one knew what everyone else was doing. His care had gaps in services and staff members gave him conflicting information, all of which lead to frustration. T.M. explained that Health Home was different because of the team approach. He continues to say that the Health Home program helped him to find his weaknesses and his strengths, but more importantly, that the program helped him to hone his strengths. Whenever he finds himself slipping back into old habits, he knows that he can contact people that care. “The support system is really spectacular.”

This type of integrated, whole-person care is the type of care that health homes are designed to provide. With such dramatic positive results, Centerstone fully supports further health home initiatives not only for patients with SUD, but for patients with any chronic disease(s).

2. One goal of Health Homes is to provide care in primary care settings and help participants effectively manage their conditions by increasing preventive care. For example, South Dakota’s Health Home has increased access to primary care: is this something you are seeing across your Health Homes?

Our Noble Purpose: Delivering Care that Changes People’s Lives
A health home is not necessarily a physical place, although it can be one. Rather, a list of eligible providers, a team of health professionals, or a health team may become designated health home providers as long as they work together to make sure patients get the care and services they need to stay healthy. Preventive care is only one of the multiple aims health homes are designed to address. In short, Centerstone is seeing increased access to primary care through these initiatives.

Centerstone operates health homes in Illinois, Indiana, Kentucky, and Tennessee. Outcomes from our health home in Clarion, Illinois, for example, indicate that within 6 months of enrolling in a health home, our patients exhibited improved blood pressure, improved body mass indexes, normalized carbon monoxide levels, smaller waist circumferences, and a decreased frequency of feeling depressed. Within one year, our patients exhibited significantly improved plasma glucose, triglyceride, and cholesterol levels. Outcomes from our health home in Tennessee show similar results. With enrollments continuing to grow in our health home models, we agree that health homes increase access to primary care, but even more than that, they increase access to high-quality, whole-person care.

It is important to note, however, that although health homes are permitted by law, we are nevertheless constrained by allowable billing codes. This means that Centerstone has only been able to set these up via grant funding, which is inevitably unstable and temporary. Thus, seeing as health homes improving patient outcomes and reducing costs, we recommend a more permanent space for health homes in the behavioral health space.

3. The National Association of Boards of Pharmacy reports that 39 states already mandate use of PDMPs. What has your experience been in using PDMPs to combat the opioid crisis? What is your sense on how providers and dispensers view the usefulness of PDMPs?

The usefulness of PDMPs is highly dependent upon the level of sophistication of the health IT system providers utilize. Currently, in order to check a state's PDMP, most clinicians are required to log in to a system separate from their normal medical record software (EHR, prescription dispensing system, etc.), query the site, analyze the report results, and then return to their original workflow. (An image indicating this process is shown to the right.) A 2016 study on the usefulness of PDMPs in emergency departments, for example, found that the PDMP task took a longer time to complete (mean = 4.22 minutes) and greater number of mouse clicks to complete (mean = 50.3 clicks) than other tasks (CT-pulmonary embolism = 1.42 minutes, 24.8 clicks; prescription = 1.30 minutes, 19.5 clicks; SureScripts = 1.45 minutes, 9.5 clicks). This makes clear that accessing PDMP data is not currently user-friendly. The core challenges we see in utilizing PDMPs for the most clinically effective purposes are: (1) lack of interoperability among

---

4 https://www.health.ny.gov/health_care/medicaid/program/medicaid_health_homes/
5 https://www.medicaid.gov/medicaid/plan/health-homes/index.html
6 For more detailed results, please see Exhibit 1, attached.
7 For more detailed results, please see Exhibit 2, attached.
8 Image provided by HealthITNow.
states or with other health IT, (2) data latency, (3) data is not within workflow for providers and dispensers, and (4) the fact that it is unable to trigger a Screening, Brief Intervention and Referral to Treatment (SBIRT) function.

As long as providers communicate with others along the care continuum by phone and fax, our industry will be unable to fully utilize the tools to treat and prevent SUD effectively that PDMPs can offer. To harness the full potential of PDMPs, all providers must have access to some minimum specified standard of technology. A national PDMP would help providers identify patients who may be at risk for opioid abuse. A national standard for an interoperable, real time PDMP would address the challenges of limited data tracking, weak responses to overprescribing, and under informed prescribers. PDMPs are crucial sources of data for providers. Improving interoperability of PDMPs will allow providers the ability to check patient prescription histories, alert providers to individuals with patterns indicative of misuse, and prevent patient doctor shopping. PDMPs currently run on batched information, only being utilized retroactively to track dispensing data for patients. If PDMPs can real-time, many prescriptions would not be dispensed; others would never be written. Checking a real-time PDMP would allow a clinician to not only stop the medication from potentially falling into the hands of an individual exhibiting addictive behaviors, but to address those potential harmful behaviors and help refer to treatment or alternate therapies, something we term a “warm hand-off.” To facilitate real-time access to data and reduce prescriber burden, patient data must be accessible within workflow.

Finally, PDMP technologies should be more than simply a data-gathering tool; any national PDMP standard should link patients to treatment by automating, or incenting, a Screening, Brief Intervention and Referral to Treatment (SBIRT) function to help providers catch patients who may otherwise fall through the cracks. SBIRT is an evidence-based preventative measure designed to move patients, who may need help, into treatment. By linking SBIRT functions to a PDMP system, we would not only be able to “flag” at risk patients, but also screen and refer them to appropriate treatments, thereby increasing their chances of recovery.

It is our sense that providers would use information offered by PDMPs more regularly and consistently in making decisions with their patients were it more easily accessible. The usefulness of PDMPs is currently far from being realized. However, this presents us with a great opportunity for improvement.

4. Numerous studies have found that Medicaid enrollees have excessive burdens of chronic pain and are at a much higher risk of substance use disorders compared to populations with other types of insurance. Similar studies have found that Medicaid enrollees are thus at heightened risk for prescription opioid misuse and were five to six times as likely to die from opioid related overdose compared to populations with other types of insurance. Because of this, according to the authors of one such study, which I quote: “reducing the number of unsafe prescriptions of opioids in the Medicaid population should be a priority for any drug control policies.” I believe that we have several bills before us today that will help achieve that goal. Our Pharmacy Home Bill, our PDMP Bill, and our DUR bill for example. Do you believe that these policies will help to advance the important goal of reducing the number of opioids in the Medicaid population?

The goal of reducing the number of opioids in the Medicaid population is a laudable goal, and should be a goal for all subsets of the American population.

Regarding H.R. Medicaid Pharmacy Home Act: This bill mandates states to operate a qualified drug management program for at-risk beneficiaries identified by the states. The program functions to: (1) identify at-risk individuals, (2) mandate that those individuals be assigned/choose two health care providers and two pharmacies that would always be in charge of prescribing and dispensing any controlled substances to them. An at-risk individual would be enrolled for a year and then re-evaluated. It is unclear to us whether

Our Noble Purpose: Delivering Care that Changes People’s Lives
states should be the ones identifying at-risk individuals. Without further information detailing how these persons would be identified, and what the added benefit of having two go-to prescribers and pharmacies would be (in excess of the benefit derived from having providers and pharmacists check PDMPs), we feel that commenting on this bill is outside our scope of expertise.

Regarding the Medicaid DRUG Improvement Act: This bill mandates that states have claims review automated processes, put in place automatic denials of excess refills, and put in place protocols to protect children from inappropriate prescriptions of antipsychotic medications. Without further information detailing what practices these protocols would be based upon, we feel unable to properly comment on this proposal.

In short, however, we recommend that legislation improve and incent PDMP use so that providers utilize this technology more systematically to identify at-risk patients and make more fully informed decisions when prescribing medications. Regarding the PDMP bill(s) in the House: The Prescription Drug Monitoring Act of 2017 (H.R. 1854), the bill to enhance and improve state-run prescription drug monitoring programs (H.R.____) introduced by Reps Griffith and Pallone, and the Medicaid PARTNERSHIP Act (H.R.____) each have strengths and weaknesses, but none address all of the core challenges we describe above. Thus, we recommend that the final PDMP proposal address each of the above-defined challenges.

5. The Medicaid HUMAN CAPITAL Act would provide enhanced funding for states to recruit highly-experienced Medicaid directors, Chief Information Officers, and Chief Financial Officers. In Ms. Douglas’s testimony, he discusses the importance of strengthening Medicaid’s role as a payer in combating opioid misuse. He notes “Congress should implement policies that support state recruitment and retention of strong Medicaid executive leadership,” because as he explains, “stable and strong state leadership will be best equipped to respond to the opioid crisis and further public health crises.” In your opinion, is it helpful to improving Medicaid’s role in addressing the opioid epidemic and other public health challenges by helping states secure the most talented, innovative, and experienced leadership possible?

At Centerstone, we believe that when employees feel valued, they do better work. Without having directly observed state Medicaid leaders in their roles, we assume that this general maxim would apply in their context, as well.

6. I am interested in the draft that proposes a demonstration project to increase provider capacity in Medicaid for treating substance use disorder. States could apply to use the funds to recruit or train current or new providers. However, I do have several concerns with the idea. Given all the funds that Congress has authorized to support provider capacity such as GME as well as grants from HRSA, SAMSHA, and CDC, is this idea duplicative? I am also unclear why we would start a new program when those are well established and have staff that understand workforce capacity. Can you comment on that?

Centerstone has not specifically looked into whether these grants are duplicative, but it is nevertheless our experience that many GME grants are more oriented towards medical facing practitioners and not on supporting work to close the 20 year science to practice gap in behavioral health. Today, adherence to evidence based practices in behavioral health settings can be quite low. For example, according to researchers at the University of Southern California, “a minority of patients with schizophrenia (in some instances less than 10%) are receiving evidence-based psychosocial interventions.” Moreover, the National Institute on Drug Abuse notes, “ninety percent of privately funded substance abuse treatment programs in the United States offer cognitive-behavioral therapy (CBT), but one-third of these do not provide their counselors with any formal training in the intervention.”

12 http://www.chhs.ca.gov/CH2052/Default.aspx?DocumentId=92f40f9b-3f76-4064-8f9c-582283b871e5

Our Noble Purpose: Delivering Care that Changes People’s Lives
For providers serving safety net populations, Medicaid rates are typically lower than the actuarial cost of delivering the service the patient receives. Thus, providing additional training on fidelity to evidence based models may not be attainable for many providers. At Centerstone, through our Research Institute and funding from a mixture of grants and philanthropic donations, we have started some initial investments into assessing clinical model fidelity, as well as providing support in clinical translations. With approximately 5,000 staff, however, we have to be extremely careful and precise in evaluating specific pilots and interventions. In brief, we recommend urging SAMSHA/CMS to ensure some of the GME funds and associated grants for recruitment and training be directed toward behavioral health providers and inclusive of a range provider types (psychiatric, social work, and peer support).

1. How does Centerstone use telehealth as part of its comprehensive addiction care model? How can telehealth be used to deliver the supportive services that are crucial to long-term recovery?

In Indiana, Centerstone utilizes telehealth in the context of an integrated health home model that serves persons with co-occurring physical and mental health concerns. Through this model, we have been able to provide contiguous care to consumers who had previously only experienced fragmented, expensive care. We have observed the following results within our population: 84% of our patients with high blood pressure saw lower readings after 12 months, recipients reported a 56% improvement in anxiety levels, and patients showed a 53% improvement in general health. Participants awarded this model a 98% approval rating. We’ve also seen a significant reduction in ER utilization within this population.

Given the positive outcomes and cost saving associated with our health home model, Centerstone is actively exploring implementing telehealth in the context of an integrated addiction care model. To pilot this, our first area of focus is the utilization of telehealth to help with psychiatric capacity needs to better address the shortage of available psychiatrists in some of our rural locations in Southern Indiana and Illinois. Ultimately, we would like to have Centerstone Kentucky provide medication assisted treatment services via telemedicine to rural areas in Illinois and Indiana because it has been much easier to recruit and retain certified addictionologists in urban areas (in this case Louisville, KY) than in some of our more rural counties. To be able to do this, however, we need to have our physicians licensed and credentialed in all the states they may end up providing services within. The process of licensing and credentialing in each state, as you may suspect, is very costly. Onboarding new physicians who encounter longer-than-anticipated delays in licensing and credentialing across state lines, coupled with low Medicaid rates, has resulted in our medical services running at a deficit. Thus, even for providers who can recruit addiction specialists, the current licensing and reimbursement realities pose significant threats to the long-term viability of the most dedicated providers in the space. Another barrier is caused by the Ryan Haight Act, which prohibits the prescribing of MAT via telemedicine without an initial in-person encounter. We eagerly await DEA guidance regarding a special registration process that may extend telemedicine capabilities.

Thus, lawmakers should fully optimize the value of our behavioral health workforce by affording them a wider latitude to treat SUD patients via telemedicine. The Access to Telehealth Services for Opioid Use Disorders Act (H.R. 5603) would allow HHS to waive certain telehealth requirements for eligible practitioners providing SUD services to Medicare patients diagnosed with an SUD. Licensed community mental health and addiction providers, who follow nationally recognized models of treatment, should gain access to a special registration process so that they may register with the DEA to prescribe substances now commonly embraced in MAT practice, without a prior in-person patient/provider encounter. To bring about this end, we support the Special Registration for Telemedicine Clarification Act of 2018 (H.R. 5483), and the Improving Access to Remote Behavioral Health Treatment Act of 2018 (H.R. 5594).

Our Noble Purpose: Delivering Care that Changes People’s Lives
3. Provider shortages in the field of behavioral health services field create continuing challenges for those seeking treatment. How can telehealth help to fill this gap?

According to the National Rural Health Association, 30 million Americans currently live in rural counties where access to addiction treatment services and medications is unavailable\(^1\). At Centerstone, with much of our population living in rural areas, we are quite attune to this reality. For example, Scott County, IN is a rural county in Southern Indiana and is a 45 minute drive from Louisville, KY, where the Centerstone Addiction & Recovery Center and several of our addiction specialists are located. In striving to build out our continuum of care in the Scott County area, we sought to utilize some of our psychiatric capacity in Louisville to complement therapy, peer, and other supportive services that we offered. However, despite their close proximity, it took over 6 months to finalize the licensing and credentialing process to get just 1 prescriber licensed and credentialed to provide psychiatric services, across state lines, to one of our own facilities. This is extremely costly for providers who need to hire new staff to meet telehealth capacity. Moreover, this process causes an unacceptable delay for some of the regions hit hardest by the opioid crisis.

More broadly, as direct to home/direct to consumer services become more widely available, we will become more skilled at triaging clients and treating them in the most appropriate settings. Therefore, site restrictions generally prevent providers from delivering care to patients where and when they need it, and are an antithesis to the purpose of telehealth. Telehealth services will alleviate problems of access to care.

We are seeing telehealth advances in other healthcare arenas, but some of the slowest dissemination has occurred in mental/behavioral health – arguably one of the fields most suited for telehealth and technology-enabled care. Earlier this year, for instance, the Bipartisan Budget Act\(^1\) took steps to facilitate telehealth in Medicare Advantage plans, provide nationwide access to telestroke, and improve access to telehealth-enabled home dialysis therapy.\(^2\) The Veteran Affairs Administration finalized rules to deliver telehealth wherever a veteran may need services.\(^3\) These are significant steps toward removing barriers to the use of telehealth, and the same can be done for the mental/behavioral health space.

To address workforce shortage gaps, Centerstone recommends that lawmakers advance the Mental Health Access Improvement Act of 2017 (H.R.3032) that would allow LMFT and LMHC services to be reimbursed by Medicare, as well as optimize our current workforce to operate at the top of its licensure. Peer support services are currently accepted as evidence-based practices by both CMS and SAMHSA. Peer supports serve as a vital “connective tissue” in the continuum of care. The bill to support the peer support specialist workforce may help peers become more integral in the behavioral health workforce. Additionally, a top priority for behavioral health not-for-profit providers is recruiting and retaining top talent, with the primary challenges being (a) an inability to offer competitive pay and benefits, and (b) a lack of qualified applicants. The Substance Use Disorder Workforce Loan Repayment Act of 2018 (H.R.5102) would function to directly alleviate the supply problem.

Lastly, we urge committee members to continue to evaluate options to break down regulatory barriers for the delivery of telehealth, such as originating site definitions and cross state licensing requirements. These collective actions would greatly ameliorate the behavioral health workforce shortage.

\(^1\) [Source](https://www.ruralhealthweb.org/NRHA/media/Enrage_NRHA/Advocacy/Policy%20documents/Treating-the-Rural-Opioid Epidemic_Feb-2017_NRHA-Price-Paper.PDF)


\(^3\) [Source](https://healthdatareport.com/news/va-telehealth-rule-should-enable-the-delivery-of-care-across-state-lines)
4. How can better coverage of psychotherapy and behavioral health services delivered via telehealth expand access to psychosocial treatment that is necessary to promote long-term recovery from opioid use disorders?

Coverage of psychosocial support services via telehealth – such as peer support specialists and all licensed therapists – can increase the continuum of outpatient services geared toward sustained recovery. Congress and the Administration can break down barriers for use of peer support services, delivered via telehealth, in both Medicaid and Medicare. Peer support services are currently accepted as evidence-based practices by both CMS and SAMHSA. Research indicates that use of peer supports leads to significant decreases in substance use, symptom improvement, and better management of patients' own conditions. These outcomes are largely achieved by a sense of trust and by the non-judgmental attitude peers exhibit towards patients.

Licensed marriage and family therapists (LMFTs) and licensed mental health counselors (LMHCs) hold licenses on par with licensed clinical social workers (LCSWs), yet their exclusion under Medicare is somewhat arbitrary. As a result of this workforce gap, providers face significant barriers when recruiting within the limited allowable provider types, particularly in rural areas. Shortage in eligible workers also results in wait times that can be 4 times higher amongst Medicare patients, as opposed to under Medicaid, which permits for reimbursement of LMHC and LMFT services in some of our sites. The Mental Health Access Improvement Act of 2017 (H.R.3032) would allow LMFT and LMHC services to be reimbursed by Medicare. This bill would enable faster access to care for Medicare and some commercial patients, as well as optimize our current workforce to operate at the top of its licensure. We ask that this language be added to the final opioid proposal.

5. At present, providers utilize a variety of interventions for opioid use disorders and lack a standardized approach for treatment. In some instances, patients may receive only medication treatment or behavioral treatment, while other providers offer comprehensive care for opioid use disorder.

a. Why is this problematic in our efforts to fight the opioid epidemic?

This is problematic because there is no gold standard for comprehensive SUD treatment. If a patient walks into 5 separate facilities, they may receive 5 different treatment protocols. Furthermore, adherence to best practices and evidence-based protocols is quite varied, so a patient may not even receive an intervention that is considered an evidence-based practice. Without a clear standard of care for SUD treatment, we are unable to determine quality, compare outcomes, and ultimately provide the best quality of care for patients. This results in costly and fragmented care that can potentially obstruct the aim of reversing the opioid crisis. This is particularly true in the case of MAT “pill mills,” which may be exacerbating the problem. There is no question that the industry is in desperate need of well-vetted standard for comprehensive, evidence-based SUD care.

To this end, Centerstone recommends developing a “gold standard” certification that would establish “clinical excellence hubs” as preferred providers for courts, corrections, emergency departments, etc. for trusted patient referrals. These clinical excellence hubs would need to demonstrate use of evidence-based interventions, linkages to a full continuum of care, including services geared towards increasing patients' recovery capital, and report on patient outcomes. The Comprehensive Opioid Recovery Centers Act (H.R.5327) is an appropriate legislative vehicle to bring about this shift.

b. While we know the best treatment for opioid use disorders combines medication-assisted treatment and behavioral health therapy, no value-based models exist to incentivize this standard of treatment. Is there

a need for value-based payment models for the treatment of opioid use disorder, and how might such payment models improve the quality of care for patients?

Centerstone supports linking value-based payment models to meaningful outcomes designed to incentivize integrated, whole-person care models for addictions treatment, particularly for patients with co-occurring and complex conditions. To ensure quality in patient care and outcomes, we recommend that providers serving Medicaid/Medicare eligible beneficiaries for SUD demonstrate the ability to offer a comprehensive continuum of evidence-based services. At Centerstone, we are in the process of developing a value-based model for outpatient SUD treatment. This model includes treating the patient holistically, building their recovery capital, and for the majority of our patients, where appropriate, working toward a discontinuation protocol from medication-assisted treatment. In all models we include treat to target metrics to assess a patient’s progress along the treatment continuum.

To better address the move toward value-based care for SUD treatment, health homes are particularly effective in treating patients with behavioral health disorders because they provide whole-person care. The federal government can help spur innovation in whole-person, integrated care via the Medicaid Incentives for Health Homes to Treat Substance Use Disorder (H.R. __). Moreover, the federal government can incentivize value-based, integrated addiction treatment models. The Alternative Payment Model for Treating Substance Use Disorder (H.R. __) would allow providers the requisite flexibility in designing and implementing whole-person treatment models without the reimbursement barriers of our predominantly fee-for-service system. Lastly, reimbursement protocols should reward trusted providers who work systematically to improve patient outcomes. The Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018 (RESULTS Act) (H.R. 5272) is a straightforward mandate to tie federal dollars to evidence-based services. To ensure optimal implementation of this potential law, it is critical that meaningful recovery-oriented outcomes measures are linked to the appropriate EBPs, thus better ensuring valid and reliable results.

c. What measures of quality should be considered in the development of a value-based payment model for opioid use disorder?

Centerstone’s Integrated Addictions Care services meet clients where they are, and focus on goals that are important to each client. All clients enrolled in this model have a treatment team consistent with their level of care; treatment teams may include a prescriber (MD, NP), therapist, care coordinator, team leader, or recovery coach that have expertise in integrated addictions care. Services provided within the Centerstone Addictions Care model are adapted to client needs and are provided by one treatment team that offers specialized care within our integrated care clinical pathway. This pathway is designed to provide services for clients with substance use and/or co-occurring disorders that cause preventable ER visits, hospitalizations, are interfering with the client’s ability to seek employment, and impacting the client’s quality of life. To accomplish this, here are some of the outcome measures Centerstone has begun implementing in our integrated, SUD treatment pilots:

- **Superb Customer Service** is measured by the Health Home customer service survey. This survey asks:
  - “How likely is it that you would recommend (provider’s name) health home to a friend or colleague?”
  - “How confident do you feel managing your condition(s)?”
  - “How connected do you feel to your care team?”

Our Noble Purpose: Delivering Care that Changes People’s Lives
Excellent Access to Care is measured by:
- % clients receiving appropriate level of care engagement intensity
- % clients who access routine care < 10 days
- % clients who access urgent care < 3 days

Treat to Target Care process goals:
- % of clients whose improvement is tracked
- % of clients not improving that:
  o Receive a significant treatment plan change
  o Are staffed in a treatment team meeting
- % of clients that experience symptom improvement to ASAM Level 1.
  o % of urine analyses free drugs of abuse (Note: this outcome measure can assist in drawing a line between MAT pill mills and providers who are appropriately administering MAT)

We hope our comments address your questions pointedly and completely. Please let us know if we can provide any further information, and feel free to reach out to us should you wish to discuss any of these items in more detail. Thank you all, again, so much for your concerted efforts. We look forward to continuing to work with you.

Sincerely,

/\nLauren McGrath
Vice President of Public Policy
Centerstone

/\nMonica Nemec
Director of National Policy
Centerstone

Our Noble Purpose: Delivering Care that Changes People's Lives
May 2, 2018

Mr. John Kravitz,
Chief Information Officer
Geisinger Health Systems
2601 Market Place, Suite 420
Harrisburg, PA 17110

Dear Mr. Kravitz:

Thank you for appearing before the Subcommittee on Health on April 11, 2018, to testify at the hearing entitled "Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 15, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment
May 9, 2018

John M. Kravitz
SVP/Chief Information Officer
Geisinger System Services
100 North Academy Avenue
MC 30-25
Danville, PA 17821

Zack Dareshori
Legislative Clerk
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

To Whom It May Concern,

Please find my responses to questions posed by Congressman Burgess at the Combatting the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients on Thursday, April 12, 2018.

Additional Questions for the Record
The Honorable Michael C. Burgess, M.D.
1. The National Association of Boards of Pharmacy reports that 39 states already mandate use of PDMPs.
   Our experience has been favorable. Our physicians are mandated by our organization to check the PDMP for suspicious patient activity regarding opioid use. We are not currently able to automatically review the PDMP from within our EHR System with the use of APIs. For now, a provider must log into the state PDMP system to access.

   What has your experience been in using PDMPs to combat the opioid crisis?
   Our providers have found it very useful in identifying "frequent fliers" in opioid prescription requests.

   What is your sense on how providers and dispensers view the usefulness of PDMPs?
   It is cumbersome for reasons mentioned earlier, however very functional.

2. Numerous studies have found that Medicaid enrollees have excessive burdens of chronic pain and are at a much higher risk of substance use disorders compared to populations with other types of insurance. Similar studies have found that Medicaid enrollees are thus at heightened risk for prescription opioid misuse and were five to six times as likely to die from opioid related overdose compared to populations with other types of insurance. Because of this, according to the authors of one such study, which I quote: “reducing the number of unsafe
prescriptions of opioids in the Medicaid population should be a priority for any drug control policies." I believe that we have several bills before us today that will help achieve that goal. Our Pharmacy Home Bill, our PDMP Bill, and our DUR bill for example. Do you believe that these policies will help to advance the important goal of reducing the number of opioids in the Medicaid population?

We believe the Pharmacy Home Bill will limit the number of prescriptions per hour that a pharmacist can fill in a retail operation. This may give more time for pharmacists to review their state POMP for people soliciting opioids from multiple sources.

We look at three methods to reduce the number of opioids prescribed:

1. Look to alternative methods to manage pain other than opioid prescriptions, via pain management solutions including rehabilitation, tai chi, yoga, etc.
2. Consider a higher co-payment for opioid medications, which may deter MA patients from obtaining opioids and selling them on the street at a higher price per pill.
3. Need to consider the patient who is using opioids. One method is to perform a toxicity screen test on a patient for positive identification of using opioids for health purposes prior to administering a prescription. Another thought is to not limit the opioid prescription for a stage 4 cancer patient who needs to manage pain through end of life.

3. The Medicaid HUMAN CAPITAL Act would provide enhanced funding for states to recruit highly-experienced Medicaid directors, Chief Information Officers, and Chief Financial Officers. In Mr. Douglas's testimony, he discusses the importance of strengthening Medicaid’s role as a payer in combatting opioid misuse. He notes "Congress should implement policies that support state recruitment and retention of strong Medicaid executive leadership," because as he explains, a stable and strong state leadership will be best equipped to respond to the opioid crisis and further public health crises." In your opinion, is it helpful to improving Medicaid's role in addressing the opioid epidemic and other public health challenges by helping states secure the most talented, innovative, and experienced leadership possible?

Talented, informed professionals almost always make better choices. We need to obtain qualified, educated and informed professionals in these roles for decision making.

4. I am interested in the draft that proposes a demonstration project to increase provider capacity in Medicaid for treating substance use disorder. States could apply to use the funds to recruit or train current or new providers. However, I do have several concerns with the idea. Given all the funds that Congress has authorized to support provider capacity such as GME as well as grants from HRSA, SAMSHA, and CDC. Is this idea duplicative? I am also unclear why we would start a new program when those are well established and have staff that understand workforce capacity. Can you comment on that?

We believe there are not sufficient providers to treat substance abuse. There are also potential litigation concerns for these providers with regulatory or tort protection for the responsible treatment of the patient.
Thank you for the opportunity to testify. Geisinger is happy to be a resource for the Committee on this important issue.

Regards,

John M. Kratz
SVP/Chief Information Officer

JMK/ajh
May 2, 2018

Mr. Sam Srivastava
CEO
Magellan Health
55 Nod Road
Avon, CT 06001

Dear Mr. Srivastava:

Thank you for appearing before the Subcommittee on Health on April 11, 2018, to testify at the hearing entitled “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients.”

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 15, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael F. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment
Response of Sam K. Srivastava, CEO of Magellan Healthcare, Magellan Health, Inc.

Questions for the Record

May 15, 2018

“Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients”

April 12, 2018

Committee on Energy and Commerce
Subcommittee on Health

Q1: The Centers for Medicare and Medicaid Services recently released its annual Drug Utilization Review report. I was surprised to learn that while 48 states are currently using lock-in programs, some states make lock-in programs optional for managed care organizations. Lock-in programs are effective in reducing overprescribing and in states like Pennsylvania and New York the program has resulted in significant savings. Can you think of a reason why managed care organizations should not be asked to use this important tool?

As your question suggests, the Centers for Medicare & Medicaid Services (CMS) released in October 2017 the agency’s federal fiscal year (FFY) 2016 Medicaid Drug Utilization Review (DUR) State Comparison/Summary Report, which found “[a]lmost all Medicaid agencies, except Florida, 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” for their Medicaid fee-for-service beneficiaries.1 (The state of Florida does permit lock-in in Medicaid managed care, effective September 2016; see Footnote 2.) Provider-and pharmacy-assignment, or lock-in, strategies have a long history in Medicaid and, more recently, have begun to expand to other healthcare payers, including Medicare under the Comprehensive Addiction and Recovery Act of 2016.

While CMS’s annual DUR report currently does not include information on provider-and pharmacy-assignment strategies within Medicaid managed care, a June 2017 analysis prepared by Open Minds reviewed 38 states with such strategies, finding 27 states require of, or make optional for, Medicaid managed care organizations (MCOs).2 Specifically, the analysis found variation in whether implementation of such strategies was required of, or optional for, MCOs, whether the strategies were actively operating in a state, enrollment ranges, and criteria for enrollment. Similarly, the Journal of Managed Care Pharmacy published an abbreviated discussion of states’ Medicaid lock-in strategies.

enrollment criteria, which also suggests significant variability between and amongst state Medicaid programs. 4

In our experience with state Medicaid managed care programs, we view provider- and pharmacy-assignment strategies as an important component within a comprehensive suite of tools – based on both the evidence and best practice – to identify and prevent the inappropriate use/overuse of opioids, as well as to promote access to substance use treatment and services for beneficiaries with opioid use disorder (OUD). For example, for Florida’s and Virginia’s Medicaid managed care programs, Magellan’s MCOs – Magellan Complete Care of Florida and Magellan Complete Care of Virginia – monitor opioid drug utilization through comprehensive member-identification programs that include provider- and pharmacy-assignment strategies. As discussed in my Written Statement (Page 29), we believe such strategies are an important tool within our DUR programs for Medicaid managed care beneficiaries:

Magellan recommends Congress consider legislative ideas for incentivizing the broad adoption of provider- and pharmacy-assignment programs, or lock-in, by state Medicaid programs, with flexibility to allow states to align the definition of at-risk beneficiaries with the Medicare program’s new lock-in authority and/or existing state criteria reflecting certain minimum standards the subcommittee believes are appropriate. We also recommend state Medicaid programs have in place comprehensive drug utilization review activities, including medical management techniques and tools aligning opioid stewardship with the CDC’s [Centers for Disease Control and Prevention’s] 2016 Guideline [for Prescribing Opioids for Chronic Pain].

To my Written Statement, I also would add that – in addition to variability in states’ Medicaid lock-in programs – one of the other issues we have seen is the impact of the Emergency Medical Treatment and Labor Act (EMTALA). Because of EMTALA, these strategies cannot account for inappropriate prescribing occurring through hospital emergency departments. To address this potential issue, some lock-in programs may attempt to assign a beneficiary to a hospital, but that introduces its own complexities and practicalities (e.g., multiple potential prescribers within the hospital system, role of the hospital’s own pharmacy, etc.). As Congress considers legislative ideas for broadening and standardizing states’ Medicaid lock-in programs, these additional issues could be considered along with minimum enrollment criteria (e.g., Medicare criteria, above) and program parameters (e.g., beginning with what can be enforced across the board—assigning a beneficiary to a particularly pharmacy or pharmacy chain).

Q2: A 2017 report by Johns Hopkins University and the Clinton Health Foundation included several recommendations for combating the opioid crisis. One of those was related to the ability of insurers to access PDMP data. The report recommends to (and I quote) “authorize third-party payers to access PDMP data with a plan for appropriate use and proper protections.” Mr. Srivastava will your organization work with this committee to ensure that third-party payers have access to PDMP data in a way that meets proper privacy protections?

As discussed in my Written Statement (Pages 25-26), while state prescription drug monitoring programs (PDMPs) have been implemented in all but one state, only 31 states’ Medicaid programs and Washington, D.C.’s program are authorized themselves to access the state PDMP. Moreover, in those that do extend access to the state’s Medicaid program, MCOs, pharmacy benefit managers (PBMs), behavioral health organizations, administrative services organizations, and/or other sub-contractors to a state’s Medicaid

programs – entities often administering Medicaid prescription drug benefits and substance use disorder (SUD) treatments and services – may not have access to PDMP data.

Our experience supporting state Medicaid managed care programs aligns with the findings of the Johns Hopkins University and Clinton Health Foundation report: third-party payers, including Medicaid MCOs and PBMs, often have no to limited ability to access PDMP data. In our March 2, 2018 response to the Committee’s “Medicaid Managed Care Organization Survey,” we provided detail on the opioids-related initiatives of Magellan Healthcare’s MCOs.

In our experience, while Magellan’s MCOs often have the ability to access the state’s PDMP, the nature and extent of that access varies. For example, our Magellan Complete Care of Virginia MCO has the ability to access the commonwealth of Virginia’s PDMP for the purposes of our patient utilization management and safety (PUMS) program rounds—a DUR program for Medicaid beneficiaries identified pursuant to Virginia Department of Medical Assistance Services (i.e., the Virginia Medicaid agency) specifications. In Florida, however, current state law does not allow practitioners in a Medicaid managed care setting to have access to the state’s PDMP. Similarly, in Massachusetts, access to the commonwealth’s PDMP requires a U.S. Drug Enforcement Agency (DEA) number be entered; pharmacists in a managed care setting would not have a DEA number.

For these reasons, in both my Written Statement and our March 2 survey response to the Committee, Magellan has recommended allowing public payers (including Medicaid and Medicaid), and their subcontractors (i.e., MCOs, PBMs, and the contractor’s “pharmacy director (or a designee)”), the ability to access a state’s PDMP. As we have demonstrated through our Magellan Complete Care of Virginia MCO, which has the ability both to (a) access the commonwealth’s PDMP and (b) have our MCO’s staff pharmacists and care managers check this PDMP, should Congress advance legislative ideas to “authorize third-party payers to access PDMP data,” we will continue to ensure our access and that of our staff meets proper privacy protections.

Maintaining the protection and confidentiality of our members’ health information and medical records – whether under the Health Insurance Portability and Accountability Act (HIPAA) or Title 42 of the Code of Federal Regulations (CFR) Part 2 – is an important responsibility Magellan takes extremely seriously. Much of what Magellan does on behalf of our members living with SUDs necessitates disclosing Part 2-covered, patient-identifying information within the healthcare system, including interfacing and interacting with providers, while protecting the privacy and confidentiality of these individuals. However, the vast majority of today’s integrated care models – including those bringing together pharmacy data from state PDMPs with physical and behavioral healthcare services – rely on HIPAA-permissible disclosures and information sharing without the need for the individual’s written consent to share relevant treatment details, provider by provider.

As discussed in detail in my Written Statement (Page 21-25):

Magellan strongly recommends the statute [at 42 CFR Part 2] be amended to permit the confidential sharing of SUD information for the purposes of treatment and health care operations as defined by HIPAA. Also essential as part of this modernization of Part 2 is the express permissibility of SUD information’s inclusion in electronic medical records (EMRs).

Q3: In testimony, you suggest that “any willing provider” requirements are problematic for health plans due to the behavior of some rogue pharmacies who engage in fraud. I would like to better understand this concern, as my understanding is that actual fraudulent behavior would cause a pharmacy to be prosecuted by CMS and or state authorities. So is the concern that managed care plans have to take any pharmacy willing to accept the plan’s contract, or the concern that
pharmacies with problematic business patterns are not identified and pursued quick enough, or still get in due to network adequacy requirements? I ask this because we want to ensure Medicaid programs have the right tools, but also that patients can access high quality providers and pharmacies of their choice.

In our experience, there often are substantial volumes of information from an array of sources related to potentially credible allegations of overprescribing which CMS, state authorities, health plans, and PBMs review and assess for potential action. Such processes appropriately take time to ensure allegations are credible and warrant exclusion. However, during this review period, the states have the ability to “place on hold” prescribers or pharmacies (even temporarily) within Medicaid, based on credible allegations of overprescribing (or fraud) rather than waiting for formal exclusions and while an investigation is ongoing.

Similarly, under Medicare Parts A and B, CMS may suspend payments pending an investigation of credible allegations of fraud, and this has contributed to efforts to prevent abusive practices. Under Part D, however, Medicare Advantage-Prescription Drug (MA-PD) plans and Prescription Drug Plans (PDPs) do not have this ability. In fact, MAPD plans and PDPs initially must pay claims even if there are major reasons to believe fraud is involved.

As discussed in my Written Statement (Pages 30-31):

Magellan recommends Congress permit health plans and PBMs supporting the pharmacy benefits under the Medicare and Medicaid programs the flexibility to exclude and remove pharmacies engaging in fraudulent practices from their networks. We also recommend Part D plan sponsors be allowed to stop payment of suspect claims where there is a credible allegation of fraud.

Since my testimony and submission of this Written Statement, Representatives Tom MacArthur, Chris Collins, David Schweikert, Ann McLane Kuster, Earl Blumenauer, and Paul Tonko introduced (on May 3) H.R. 5676, which would authorize the suspension of payments by Medicare PDPs and MA-PD plans pending investigations of credible allegations of fraud by pharmacies. We view this legislation’s introduction as a positive development.

Q4: In your testimony, Mr. Srivastava, you note that Magellan works with 80,000 behavioral health care providers nationwide. Mr. Guth’s testimony highlights how in 2013, all nine types of behavioral health practitioners had shortages. So I am interested in hearing from you about how we address the supply of credential health care providers, given the demand the opioid crisis is placing on the health care system. You mentioned the idea of increased matching funds in Medicaid, but it’s not clear to me that such an approach would be as effective as some might think.

MACPAC’s review of the primary care payment bump in the ACA concluded – and I quote – “there is not enough evidence to definitively determine whether the payment increase had an effect on provider participation or enrollee access to primary care in Medicaid.” One of the bills before us contemplates understanding how Medicaid GME dollars are used, while another bill seeks to provide increased matching funds for some capacity building, but seems a bit vague and open-ended as to what it would actually fund. I would like each panelist to quickly explain two or three concrete actions Congress could take to ensure current providers are adequately trained and a couple of concrete actions to foster the development of more behavioral health providers.

In addition to the October 2014 findings of the Medicaid and CHIP Payment and Access Commission (MACPAC), the Urban Institute – in their review of various evaluations – also found “[i]nitial evidence is mixed on whether the increase in primary care fees, or ‘fee bump,’ successfully increased access to...
primary care for Medicaid enrollees. The Urban Institute review, however, accompanied its own analysis of the payment bump’s impact on the Medicaid-to-Medicare primary care fee index. In their discussion of the fee index analysis, they note “that when the temporary federal policy expired, many states continued to pay higher fees for primary care than they did in 2012, suggesting that even a temporary federal policy had lasting effects on some states’ approaches to Medicaid reimbursement” (emphasis added). A 2017 research report by the RAND Corporation also examined the primary care payment bump, finding the effect on physician participation was dampened because “participation was already high before the policy was rolled out.” The RAND report specifically mentioned stakeholders from Kansas, Nebraska, and New Jersey sharing this interpretation, with stakeholders in Florida suggesting the policy’s impact was limited because it did not address their “biggest... issue”: “specialist participation in the Medicaid program.”

We share these analyses with the Committee because current Medicaid participation rates for SUD treatment providers may be very different from primary care physicians (PCPs) and specialists. In 2015, 70 percent of all office-based physicians accepted new Medicaid patients and, in 2011-12 (pre-payment bump), two-thirds of PCPs and 72 percent of specialists participated in Medicaid. According to a draft chapter for MACPAC’s June 2018 Report to Congress, staff estimate only 60 percent of counties have at least one outpatient SUD facility that accepts Medicaid and 62 percent of SUD facilities participate in Medicaid, with ranges from 29 percent (California) to 91 percent (Vermont).

Unlike with pre-payment bump and contemporary PCP participation in the Medicaid program, as well as contemporary specialists’ participation, SUD provider participation in Medicaid is not “already high.” Even a temporary federal policy may have a lasting effect on SUD provider participation in Medicaid. Further, such a policy could complement other legislative ideas for increasing high-quality SUD provider participation in Medicaid. For example, increased matching funds could be tied to — rather than an across-the-board payment bump — specific behavioral health workforce providers/provider types (1) with low participation in Medicaid and (2) whom have attained accreditation, certification, or other training/commitment in their practice to adhere to evidence-based treatment and services.

In addition to this legislative idea of increased matching funds for increasing SUD treatment provider participation in Medicaid, my Written Statement (Pages 17-21) outlined nine specific opportunities for Congressional action on provider training (no. 7) and the behavioral health workforce (nos. 1-6 and 8). Here we reiterate these and offer additional ideas to ensure physicians and other providers are better prepared to prevent and respond to opioid misuse and to foster the behavioral health workforce:

Enhancing Physician and Provider Training

(a) Reducing the social stigma associated with OUD and the use of MAT, including by reframing OUD and other SUDs as chronic conditions requiring ongoing treatment and MAT and psychosocial interventions as effective, evidence-based treatment strategies. As the National Governors Association also has suggested, a CMS-led, multi-stakeholder awareness campaign may include: information on the risks associated with opioids and step-by-step directions for taking these prescription drugs that minimize the chances of developing OUD or overdosing; and, referrals and other resources for individuals with OUD and other SUDs seeking treatment who may not have regular access to, or ability to afford, health insurance.

(b) Enhancing provider knowledge of treatment modalities and available resources. As discussed in my Written Statement (Pages 14-15):


Specifically, Congress may encourage CMS to partner with the Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), and medical and professional societies to increase provider:

(1) comfort and knowledge of the proven effectiveness of MAT;
(2) familiarity with evidence-based protocols for treatment;
(3) training in the use of MAT and psychosocial interventions; and,
(4) education and training on pain treatment and management, including effective, alternative/non-opioid therapies for pain management, safe opioid prescribing, and preventing the consequences of opioid misuse and overuse through tapering and other opioid-management strategies.

Building a High-quality Behavioral Health Workforce

(c) Supporting the delivery of medication assisted treatment (MAT) through telemedicine. As discussed in my Written Statement (Page 17), telemedicine may be best suited to improve access to persons living in geographic areas away from SUD treatment providers, and may expand access beyond traditional settings of care. Policies and procedures can be developed to ensure patient safety, delivery of prescriptions for MAT, patients’ connection to psychosocial interventions, and to ensure a system-wide outlook where inclusive of points of access across the full continuum of care over time.

(d) Permanently expanding the pool of qualified buprenorphine prescribers by making buprenorphine waivers available to qualified advanced practice registered nurses (APRNs) with prescriptive privileges, such as nurse practitioners, clinical nurse specialists, certified nurse-Srivastava | Page 6
midwives, certified registered nurse anesthetists, and others (as noted in my Written Statement (Page 17)). (The current law sunsets these privileges Oct. 1, 2021.) A systematic review of the literature on care provided by APRNs concluded these healthcare professionals provide safe and effective quality care in numerous settings, and that, in partnership with physicians and other healthcare providers, contribute to health promotion.12

(c) **Expanding MAT patient panel maximums for APRNs beyond the 30-patient limit for up to 100 patients with OUD.** As part of such an expansion (and the permanent change recommended in (d), above), we recognize inappropriate prescribing is always possible. As for other programs and initiatives, there should be a role for audit and oversight of all DEA-waived practitioners.

(f) **Exploring value-based payment (VBP) initiatives to incent Medicare, Medicaid, Indian Health Services, Veterans Administration, and federally qualified healthcare providers to (a) increase utilization of and access to MAT to treat OUD by providing the appropriate financial support to enable clinicians and care managers to successfully collaborate to treat OUD comprehensively; (b) broaden the coordinated delivery of medication, psychological, and social services, including therapy and psychosocial interventions; and (c) increase the proportion of individuals living with OUD who access and retain treatment. Such VBP initiatives for behavioral health could include emerging payment models, such as the American Society of Addiction Medicine’s Patient-Centered Opioid Addiction Treatment model.

(g) **Advancing a nationally recognized mechanism to ensure accreditation of SUD treatment and services providers, with the future potential to include Center of Excellence (COE) designations and to limit federal reimbursement to accredited providers.** Such COE designations also could tie to VBP initiatives.

Q5: The National Association of Boards of Pharmacy reports that 39 states already mandate use of PDMPs. What has your experience been in using PDMPs to combat the opioid crisis? What is your sense on how providers and dispensers view the usefulness of PDMPs?

In my Written Statement and our March 2, 2018 response to the Committee’s “Medicaid Managed Care Organization Survey,” we discuss our experience using states’ PDMPs as part of our UR programs for Medicaid managed care beneficiaries. Both also discuss current barriers to the fuller effectiveness of these information databases. Specifically, I suggest in my Written Statement (Pages 25-26) that:

> When and where PDMP data can be accessed by the Medicare and Medicaid program and the program’s contractors, data have not been well integrated into health [information technology] systems or into professionals’ and paraprofessionals’, including prescribers’, routines and patient protocols. Compounded by the fact that as many as one-third of primary care physicians may not be aware of these state databases, PDMPs often are underutilized by providers.

To address these unintended limitations on the usefulness of PDMPs, my Written Statement (Page 26) recommends Congress consider the following ideas:

> Magellan recommends all Medicare and Medicaid providers check the prescription drug history of Medicare and Medicaid enrollees through the applicable state’s PDMP prior to dispensing an opioid. We also recommend Congress consider legislative ideas (e.g.,

---

increased FMAP for expenditures related to improving the PDMP in line with such activities for encouraging states to:

(a) allow public payers, including Medicaid and Medicare, and their subcontractors (i.e., Medicaid health plans and PBMs, Medicare Advantage plans, and Part D plan sponsors, and the contractor’s “pharmacy director (or a designee)”), to access the PDMP;
(b) make their PDMPs more easily accessible, including direct access or a daily data feed that can be synchronized with existing Medicare and Medicaid data systems;
(c) ensure data accuracy and availability in as close to real time as is feasible;
(d) better integrate across the country by ensuring state PDMP interoperability with other states;
(e) improve completeness, workflow integration, and interoperability of PDMP reports into EMRs and [health information exchanges] to streamline provider, dispenser, and payer access and usability to allow these entities and supporting providers to have a comprehensive, real-time look at a patient’s clinical history;
(f) partner with medical and professional societies to enhance education and training on availability of state PDMP databases and incorporating provider check requirements into daily routines and patient protocols to encourage real-time reporting; and,
(g) make PDMPs easier to use and report into by allowing prescribers to establish delegate accounts.

Q6: Numerous studies have found that Medicaid enrollees have excessive burdens of chronic pain and are at a much higher risk of SUDs compared to populations with other types of insurance. Similar studies have found that Medicaid enrollees are thus at heightened risk for prescription opioid misuse and were five to six times as likely to die from opioid-related overdose compared to populations with other types of insurance. Because of this, according to the authors of one such study, which I quote: “reducing the number of unsafe prescriptions of opioids in the Medicaid population should be a priority for any drug control policies.” I believe that we have several bills before us today that will help achieve that goal. Our Pharmacy Home Bill, our PDMP Bill, and our DUR bill for example. Do you believe that these policies will help to advance the important goal of reducing the number of opioids in the Medicaid population?

Yes. In our review of the (a) Medicaid Providers and Pharmacists Required to Note Experiences in Record Systems to Help In-need Patients Act (Medicaid PARTNERSHIP Act) of 2018, (b) the Medicaid Drug Review, Utilization, Good Governance Improvement Act (Medicaid DRUG Improvement Act) of 2018, and (c) the Medicaid Pharmacy Home Act of 2018, our initial takeaway is they point in the right direction and the Committee is on the right track. We need to expand capacity for treatment and recovery services and develop programs for at-risk populations that limit access to these highly addictive drugs.

To further support the Committee’s important work, we have specific feedback on each of the bills that we hope is helpful:

(a) Medicaid PARTNERSHIP Act: This bill builds on the constructive efforts of states to implement and promote the use of PDMPs and of state Medicaid programs, Medicaid MCOs, and Medicaid PBMs to use these important information databases, where possible. We support this bill. Because the definition of “managed care entity” differs state-by-state, we recommend the bill include explicit language extending PDMP access to Medicaid MCOs and PBMs.
(b) Medicaid DRUG Improvement Act: This bill builds on the constructive efforts of state Medicaid programs, MCOs and other health plans, and PBMs to implement DUR programs within Medicaid managed care, Medicare, and commercial plans. We support this bill. We suggest clarification may be needed, however, to reflect current rules that disallow the refill of schedule II
opioids (rather, to limit second fills instead). Further, we recommend any requirement for a claims review automated process when opioids are prescribed concurrently with other prescription drugs be evidence based. For example, in Magellan’s experience serving individuals with complex healthcare needs, the combination (or “polypharmacy”) of opioids and HIV treatment drugs is neither uncommon nor inappropriate, particularly dependent on the stage of HIV (i.e., AIDS).

(c) Medicaid Pharmacy Home Act: This bill builds on the constructive efforts of state Medicaid programs and Medicaid MCOs to implement provider- and pharmacy-assignment strategies within Medicaid. We support this bill. We suggest such strategies, however, can be hampered if the MCOs and/or PBMs supporting them do not have access to the state’s PDMP.

These draft bills are critically important components to developing a comprehensive response to this crisis, and Magellan remains committed to supporting the Committee’s legislative efforts.

Q7: The Medicaid HUMAN CAPITAL Act would provide enhanced funding for states to recruit highly experienced Medicaid directors, Chief Information Officers, and Chief Financial Officers. In Mr. Douglas’s testimony, he discusses the importance of strengthening Medicaid’s role as a payer in combatting opioid misuse. He notes “Congress should implement policies that support state recruitment and retention of strong Medicaid executive leadership,” because as he explains, a stable and strong state leadership will be best equipped to respond to the opioid crisis and further public health crises.” In your opinion, is it helpful to improving Medicaid’s role in addressing the opioid epidemic and other public health challenges by helping states secure the most talented, innovative, and experienced leadership possible?

Yes. Medicaid and the Children’s Health Insurance Program are significant healthcare purchasers and their staffs—similar to the Medicare program, and the professional staff within CMS—oversee healthcare coverage, access, and quality of care for a substantial number of Americans. As MACPAC noted in its June 2014 Report to Congress, “[t]he demands on state Medicaid agencies are extensive and diverse and continue to grow as these programs increase in size and scope and seek to increase value and accountability through more sophisticated purchasing strategies.” Specific to the Medicaid HUMAN CAPITAL Act, the report suggests “[i]n-state Medicaid agencies need high level analytic, financial, and clinical expertise to implement and oversee these modernized systems,” and the same is true for specific opioid-mitigation strategies as for these programs overall.

To best support these important programs, as well as specific strategies relating to the opioid crisis, it is important state Medicaid agencies are able to attract and retain high-quality staff.

Q8: I am interested in the draft that proposes a demonstration project to increase provider capacity in Medicaid for treating substance use disorder. States could apply to use the funds to recruit or train current or new providers. However, I do have several concerns with the idea. Given all the funds that Congress has authorized to support provider capacity, such as GME as well as grants from HRSA, SAMSHA, and CDC. Is this idea duplicative? I am also unclear why we would start a new program when those are well established and have staff that understand workforce capacity. Can you comment on that?


14. MACPAC (June 2014), Page 179.
We support Congressional action and legislative ideas to expand capacity for SUD treatment and recovery services in Medicaid and to develop programs for at-risk populations that limit access to these highly addictive drugs. Specific to increasing SUD provider capacity in Medicaid, and as I note in my response to Q4, above, we remain concerned that lower Medicaid provider rates reduce SUD provider participation and capacity. To add color to our concerns, in a forthcoming Report to the Congress, MACPAC is anticipated to share estimates that only 60 percent of counties have at least one outpatient SUD facility that accepts Medicaid and 62 percent of SUD facilities participate in Medicaid, with participation ranges as low as 29 percent to 91 percent.15

While Congress and various federal agencies – such as HRSA, SAMHSA, and CDC – have invested meaningfully in provider capacity development programs, including through the Graduate Medical Education (GME) program, within Medicaid we have a confluence of two challenges: (1) the size of the behavioral health workforce (or provider capacity) and (2) participation in the Medicaid program, specifically. We believe the draft bill (i.e., "to amend title XIX of the Social Security Act to provide for a demonstration project to increase substance use provider capacity under the Medicaid program") begins to address the need to increase capacity and strengthen the behavioral health workforce specific to Medicaid. To further support the goals identified (i.e., (1) and (2), above), my Written Statement (Pages 17-21) and Pages 4-6 herein have outlined additional legislative ideas.

15. MACPAC (April 19, 2018).