

IMPROVING THE COORDINATION AND QUALITY
OF SUBSTANCE USE DISORDER TREATMENT

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED FIFTEENTH CONGRESS
SECOND SESSION

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TUESDAY, MAY 8, 2018

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

The subcommittee met, pursuant to call, at 1:05 p.m., in room 2123, Rayburn House Office Building, Hon. Michael Burgess, M.D. (chairman of the subcommittee) presiding.

Present: Representatives Burgess, Guthrie, Barton, Blackburn, Latta, Lance, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Collins, Carter, Walden (ex officio), Green, Engel, Matsui, Castor, Sarbanes, Kennedy, Eshoo, Degette, and Pallone (ex officio).

Staff Present: Mike Bloomquist, Staff Director; Daniel Butler, Staff Assistant; Zachary Dareshori, Legislative Clerk, Health; David DeMarco, IT Staff; Paul Edattel, Chief Counsel, Health; Ed Kim, Policy Coordinator, Health; Caprice Knapp, Fellow, Health; Drew McDowell, Executive Assistant; James Paluskiewicz, Professional Staff, Health; Kristen Shatynski, Professional Staff Member, Health; Jennifer Sherman, Press Secretary; Austin Stonebraker, Press Assistant; Hamlin Wade, Special Advisor, External Affairs; Jeff Carroll, Minority Staff Director; Waverly Gordon, Minority Health Counsel; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Samantha Satchell, Minority Senior Policy Analyst; and C.J. Young, Minority Press Secretary.

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 recognizes himself for 5 minutes for the purpose of an opening statement.

Over the past several months, this subcommittee has held hearings to evaluate bills to address the opioid epidemic. We have also favorably reported 57 bills to the full Energy and Commerce Committee. Today, we are here to discuss a bill that would make timely reforms to a privacy law that affects patient access to healthcare and creates, in some minds, barriers to treatment: the Overdose Prevention and Patient Safety Act. This hearing is an important opportunity for us to gain a better understanding of Federal privacy laws and how they function in the healthcare system.

As a physician, I believe that it is vital that when we are making clinical decisions, you need all the appropriate information to make the correct determination in the treatment of the patient. Suffering from a substance use disorder should receive the same level of treatment and care as other individuals. Patients affected with substance use disorder deserve to be treated by physicians who are armed with all the necessary information to provide the best of care. I certainly do understand and respect that privacy protection is paramount and should be held to the highest regard. The Overdose Prevention and Patient Safety Act maintains the original intent of the 1970 statute behind 42 CFR Part 2 by protecting patients and improving care coordination. In fact, Mr. Mullin's bill increases protections for those seeking treatment by more severely penalizing those who breach that patient data standard.

The issue of the stigma associated with substance use disorder has been a constant in all the discussions we have had, both in our offices and in hearings. We have dedicated months of our time to putting together legislation to help break the stigma and help individuals with this complex disease gain access to healthcare and support services critical to getting them on the road to recovery. The first step in addressing this problem is admitting that it exists. If we continue to silo the substance use disorder treatment information from a select group of patients rather than integrating it into medical records and comprehensive care models, it is hard to see how we can ensure that these patients are receiving quality care. Physicians, unknowing of a patient's substance use disorder, may prescribe medications that have significant drug interactions, or worse, they may prescribe controlled substances and make the patient's substance use disorder significantly worse. As it currently stands, 42 CFR Part 2 is actively prohibiting physicians from ensuring proper treatment and patient safety while perpetuating stigma.

At our second opioid hearing held this March, we brought this bill up for consideration and openly debated the privacy concerns with experts and expert witnesses and the Health Subcommittee members. Additionally, panelists at our recent roundtable discussion with families who had been affected by the opioid epidemic echoed the need for reforming current law.

As we all know, providing high-quality healthcare is a team effort. Physicians do lead that team, but it is necessary that physicians have the necessary information to adequately coordinate care. We must align payment operations and treatment to allow coordination of both behavioral and physical health services for individuals with substance use disorder.

I recently heard from a hospital in my district that mentioned that there is some likelihood that Part 2, as it currently stands, could be a disincentive for healthcare systems seeking to open additional addiction treatment centers due to the problems that the law creates, particularly the sequestration of patient information from their hospital.

There is a reason why the Substance Abuse and Mental Health Services Administration and most of the health stakeholder community is asking for this change. Clearly, there is an issue here that must be addressed. This crisis, this opiate crisis, is dev-

astating our country. Our action is important to the families and communities and to our constituents who are impacted by this epidemic.

I want to thank all of our witnesses who are here today and look forward to their testimony. And I will yield the balance of my time to the gentlelady from Tennessee.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

In the past few months, this Subcommittee has held three hearings to evaluate bills to address this opioid epidemic. We have also favorably reported 57 bills to the full Energy and Commerce Committee. Today, for the second time, we are here to discuss a bill that would make timely reforms to a privacy law that affects patient access to health care and creates barriers to treatment—the Overdose Prevention and Patient Safety Act. This hearing is an important opportunity for us to gain a better understanding of federal privacy laws and how they function in the healthcare delivery system.

As a physician, I believe that it is vital that when making clinical decisions, I have all of the appropriate information to make the correct determination in the treatment of a patient. Those suffering from substance use disorder should receive the same level of treatment and care as other individuals. Patients afflicted with substance use disorder deserve to be treated by physicians who are armed with all of the necessary information to provide the best care. I certainly do understand and respect that patient privacy protection is paramount and should be held to the highest regard. The Overdose Prevention and Patient Safety Act maintains the original intent of the 1970s statute behind 42 CFR Part 2 by protecting patients and improving care coordination. In fact, Mr. Mullin's bill increases protections for those seeking treatment by more severely penalizing those who share patient data than under the current statute.

The issue of the stigma associated with substance use disorder has been a constant in all discussions we have had, both in our offices and in our hearings. We have dedicated months of our time to putting together legislation to help break stigma and help individuals with this complex disease gain access to health care and support services critical to getting them on the road to recovery. The first step in addressing a problem is admitting that it exists. If we continue to silo the substance use disorder treatment information of a select group of patients rather than integrating it into our medical records and comprehensive care models, how can we ensure these patients are receiving quality care? Physicians, unknowing of a patient's substance use disorder, may prescribe medications that have significant drug interactions, or worse, may prescribe controlled substances that make their patient's substance use disorder worse. As it currently stands, 42 CFR Part 2 is actively prohibiting physicians from ensuring proper treatment and patient safety while perpetuating stigma.

At our second opioid hearing held in March, we brought this bill up for consideration and openly debated privacy concerns with expert witnesses and amongst health subcommittee members. Additionally, panelists at our recent roundtable discussion with victims of the opioid epidemic echoed the need for reforming the current law.

As we all know, providing high quality health care is a team effort. Physicians are leading that team, but it is necessary that physicians have the necessary information to adequately coordinate care. We must align payment, operations, and treatment to allow coordination of both behavioral and physical health services for individuals with substance use disorder.

In fact, I recently heard from a hospital in my district that mentioned that there is some likelihood that Part 2, as it currently stands, could be a disincentive for health care systems seeking to open addiction treatment centers due to the problems the law creates, particularly the sequestration of patient information from their hospital.

There's a reason why SAMHSA and most of the health stakeholder community is asking for this change. Clearly, there is an issue here that must be addressed. This opioid crisis is devastating our country. Our action is important to the families and communities—our constituents—impacted by the opioid epidemic.

I thank all the witnesses here today and look forward to their testimony.

I would now like to yield the balance of my time to the gentlelady from Tennessee.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

And I thank you for having this hearing and for listening to us as we have brought the concerns forward with Part 2. This is something that has become a barrier to many people that are in treatment to get the full access to comprehensive care that they need to be able to fully recover.

And I have spent a good bit of time the past few years doing roundtables and visiting treatment centers and talking with families that are covered—and I come at this as a mother and a grandmother and a friend, and having individuals close to me who have those in their family, in their circle that have suffered from addiction.

So thank you for this. Thank you for the attention to this issue. I look forward to the hearing.

I yield back.

Mr. BURGESS. The gentlelady yields back.

The chair yields back. The chair recognizes the ranking member of the subcommittee, Mr. Green of Texas, 5 minutes for your opening statement, please.

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

Mr. GREEN. Thank you, Chairman, for holding today's hearing on substance use disorder treatment and 42 CFR Part 2.

Ranking Member Pallone and I requested a hearing on 42 CFR Part 2 last month, and I appreciate the majority's willingness to hold a hearing on this important issue.

Title 42 of the Code of Federation Regulations Part 2 are the implementing regulations of the two laws Congress passed in the early 1970s to protect individuals who seek treatment for substance abuse.

According to the Substance Abuse and Mental Health Administration, SAMHSA, the purpose of 42 CFR Part 2 is "to ensure that a patient receiving treatment for a substance use disorder in the Part 2 program is not made more vulnerable by reason of the availability of their patient record than an individual with substance use disorder who does not seek treatment."

I agree with SAMHSA. Americans suffering from substance abuse should not become more vulnerable for doing the right thing and seeking treatment.

42 CFR Part 2 provides individuals receiving substance use disorder treatment with the privacy they need to guard against the negative consequences of unauthorized release of their drug or alcohol patient information, such as the loss of child custody, parental rights, the loss of a job, denial of healthcare, possible exclusion from public housing, possible criminal justice consequences, including arrest and prosecution.

SAMHSA in recent years has revised Part 2 in order to improve coordination among providers providing treatment to individuals suffering from substance abuse. The provisions expand the ability of providers to share information about a patient with a substance use disorder as well as allow new consent options for disclosure but continue to maintain Part 2's core protections.

In 2017, treating provider relationships were allowed under certain circumstances, such as providing information to entities that agree to provide diagnosis, treatment, evaluation, and consultation with a patient.

As we work to balance the privacy needs of the individual seeking substance abuse treatment, we also need to ensure that providers are able to access needed information in order to properly provide them with the treatment they need.

I want to make sure that, in an effort to improve coordination of care, we do not sacrifice the rights of individuals seeking needed treatment for their addiction.

We have spent the past few months working on addressing the opioid crisis and have learned from medical professionals that only a small fraction of Americans suffering from substance abuse seek treatment, in part out of fear that their medical records may be disclosed.

Current law allows for the disclosure of information under Part 2 with regard to internal communications, medical emergencies, special court orders, in the event of a crime on the premises or against personnel on the premises, and entities covered under Part 2, qualified service organization and business associate agreements.

Before our committee moves forward with the Overdose Prevention and Patient Safety Act, H.R. 3545, we need to make sure that the rights and privacy of patients seeking treatment are protected.

I am open to considering changes to Part 2, but these changes need to meet the current standard of protection that protect Americans seeking substance abuse treatment.

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

[The prepared statement of Mr. Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN

Thank you, Mr. Chairman, for holding today's hearing on substance use disorder treatment and 42 CFR Part 2.

Ranking Member Pallone and I requested a hearing on 42 CFR Part 2 last month and I appreciate the Majority's willingness to hold a hearing on this important issue.

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As we work to balance the privacy needs of individuals seeking substance abuse treatment, we also need to ensure that providers are able to access needed information in order to properly provide them with the treatment they need.

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Current law allows for the disclosure of information under Part 2 with regard to internal communications, medical emergencies, special court orders, in the event of a crime on the premises or against personnel on the premises of entities covered under Part 2, and qualified service organization and business associate agreements.

Before our committee moves forward on the Overdose Prevention and Patient Safety Act, H.R. 3545, we need to make sure the rights and privacy of patients seeking treatment are protected.

I am open to considering changes to Part 2, but these changes need to meet the current standard of protection that protect Americans seeking substance abuse treatment.

I would now like to yield one minute to my colleague, Congresswoman Matsui of California.

Mr. BURGESS. The chair thanks the gentleman.

The chair recognizes the gentleman from Oregon, the chairman of the full committee, Mr. Walden, for 5 minutes.

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

Mr. WALDEN. Thank you very much, Mr. Chairman. Again, thank you for your leadership on this and so many other healthcare issues.

Today marks our fourth Health legislative hearing on solutions to address the opioid crisis, an epidemic that knows no geographic, political, or socioeconomic bounds. Throughout this process, part of this committee's approach has been to shift attitudes towards substance use disorder and treatment. As I have stated before, substance use disorder is a medical illness, and we must treat it that way. Removing the stigma of addiction is one of the most important things we, as Members of Congress can do to respond to the national emergency, and it will dramatically change how we prevent and treat this complex issue.

During our work to develop policies to stem the tide of addiction and abuse, an extraordinary array of hospitals, physicians, patient advocates and substance use disorder treatment providers have approached this committee to clearly state that existing Federal confidentiality regulations, known as 42 CFR Part 2, or "Part 2," are interfering with case management and care coordination to effectively treat substance use disorder.

The statute behind Part 2 was enacted more than 20 years ago, 20 years before the Health Insurance Portability Act, or HIPAA, and 40 years prior to the use of electronic healthcare records. The intent behind Part 2 was to protect patients seeking treatment from negative repercussions, such as incarceration or loss of employment, laudable goals. And yet, Part 2 does not even apply to all substance abuse disorder patients, meaning some providers have full access to a patient's medical records and others don't.

For the millions of patients suffering from substance use disorder who are treated by a provider not subject to Part 2, their records are protected by HIPAA. Now, this begs the following question: Is HIPAA protective enough for those seeking substance use disorder treatment or not? If it is not, what can we do to better protect patient privacy and better coordinate substance use disorder treatment? Because, as currently written, the statute behind Part 2 handcuffs providers, and it hurts patients.

Representatives Mullin and Blumenauer have tackled this complex issue and written the Overdose Prevention and Patient Safety Act, which I believe strikes the right balance of maintaining and strengthening patient protections while allowing for the limited sharing of substance use disorder treatment records between healthcare providers, plans, and clearinghouses.

The legislation also includes strong penalties and discrimination prohibitions in statute to protect people seeking and receiving substance use disorder treatment. I have heard from providers in Oregon, from hospitals to healthcare centers to addiction specialists, who believe these changes are critical to their improving treatment of substance use disorder.

In fact, Mr. Chairman, I have a letter for the record from the Oregon Hospital Association commending our efforts I would like inserted, without objection.

Mr. BURGESS. Without objection, so ordered.

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

Mr. WALDEN. So I understand this issue is a sensitive one. There have been a lot of discussions. There has been a lot of confusion, understandably so, about what this bill does or doesn't do, which is why we are having this extra hearing. Privacy law is complex, which is why we are having additional testimony in addition to what we heard in March. So we are here to learn more about this issue, to listen to stakeholders on both sides of the argument. It is important we have a thoughtful discussion and get to the bottom of this.

The Ranking Member has made clear that he will evaluate bills based on two principles: One, whether the proposal improves access to treatment for opioid use disorders; and, two, whether the proposal helps to prevent people from getting addicted to opioids in the first place. I would argue that the Overdose Prevention and Patient Safety Act does both. Treating patients' substance use disorder in isolation from their medical conditions, which predominated care in the 1970s, is not the standard of good medical practice today.

This legislation will arm physicians with all the necessary information to provide the best care, ultimately improving access to treatment and preventing the unnecessary prescribing of substances that may cause patient harm.

With that, Mr. Chairman, I would turn the remainder of my time to Mr. Mullin of Oklahoma, the leader on this issue for this committee.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Today marks our fourth health legislative hearing on solutions to address the opioid crisis, an epidemic that knows no geographic, political, or socio-economic bounds. Throughout this process, part of this committee's approach has been to shift attitudes toward substance use disorder. As I have stated before, substance use disorder is a medical illness and we must treat it that way. Removing the stigma of addiction is one of the most important things we as members of Congress can do to respond to this national emergency and will dramatically change how we prevent and treat this complex disease.

During our work to develop policies to stem the tide of addiction and abuse, an extraordinary array of hospitals, physicians, patient advocates, and substance use disorder treatment providers have approached this committee to clearly state that existing federal confidentiality regulations, known as 42 CFR Part 2 or "Part 2", are interfering with case management and care coordination to effectively treat substance use disorder.

The statute behind Part 2 was enacted more than 20 years before Health Insurance Portability and Accountability Act, or HIPAA, and 40 years prior to the use of electronic health care records. The intent behind Part 2 was to protect patients seeking treatment from negative repercussions, such as incarceration and loss of employment. And yet, Part 2 doesn't even apply to all substance use disorder patients, meaning that some providers have full access to a patient's medical record while others do not.

For the millions of patients suffering from substance use disorder who are treated by a provider not subject to Part 2, their records are protected by HIPAA. This begs the following questions—is HIPAA protective enough for those seeking substance use disorder treatment or not? If it is not, what can we do to better protect patient privacy and better coordinate substance use disorder treatment? Because as currently written, the statute behind Part 2 handcuffs providers and hurts patients.

Representative Mullin and Representative Blumenauer have tackled this complex issue and written the Overdose Prevention and Patient Safety Act, which I believe strikes the right balance of maintaining and strengthening patient protections, while allowing for the limited sharing of substance use disorder treatment records between health providers, plans and clearinghouses.

The legislation also includes strong penalties and discrimination prohibitions in statute to protect people seeking and receiving substance use disorder treatment. I have heard from providers in Oregon, from hospitals to health centers to addiction specialists, who believe these changes are critical to their improving treatment of substance use disorder.

I understand this issue is a sensitive one. There has been a lot of discussion and confusion about what this bill does and does not do. Privacy law is complex, which is why we are having another hearing in addition to the testimony we heard on this issue in March. We are here to learn more about this issue and listen to stakeholders on both sides of the argument. It is important that we have a thoughtful discussion about ensuring that patients seeking these services receive privacy protections, parity and the same quality treatment that is provided to patients with other chronic disorders.

The Ranking Member has made clear that he will evaluate bills based on two principles: One, whether the proposal improves access to treatment for opioid use disorders; or two, whether the proposal helps to prevent people from getting addicted to opioids in the first place. I would argue that the Overdose Prevention and Patient Safety Act does both. Treating patients' substance use disorder in isolation from their medical conditions, which predominated care in the 1970s, is not the standard of good medical practice today.

This legislation will arm physicians with all of the necessary information to provide the best care, ultimately improving access to treatment and preventing the unnecessary prescribing of substances that may cause harm to a patient.

Thank you to our witnesses for joining us today. I look forward to hearing your insights on this important bipartisan legislation, and furthering our efforts to combat the opioid crisis.

Mr. MULLIN. Thank you, Mr. Chairman.

And thank you, Chairman Burgess, for allowing us to have this hearing today and for all the witnesses. Congressman Blumenauer and myself, we don't typically agree on a whole lot, but when we start talking about this, we do agree 100 percent on this issue.

This is about allowing the physicians to be able to see the complete record and be able to treat the patient as a whole, not just part. This is about destigmatizing what addictions really mean. It allows us to bring us back into the 21st century. When Part 2 was first put up there, the medical field looked completely different than it does now. So, without Part 2 alignment, we are going to continue to stigmatize patients with substance use disorder.

I urge all my colleagues today to take a look at how we can bring substance use disorder treatment and the rules and laws governing them into the 21st century. It is simple. We want to take care of the patients. The doctors want to take care of the patients. We need to move forward. This is something that has hit all of us personally.

With that, Mr. Chairman, I yield back.

Mr. WALDEN. And I yield back.

Mr. BURGESS. The chair thanks the gentleman. The chair observes that there are a series of votes on the floor, so we are going to recess while we attend to those votes on the floor. We will reconvene immediately after the last votes and hear from the ranking member of the subcommittee, Mr. Pallone, for his opening statement.

The committee stands in recess.

[Recess.]

Mr. BURGESS. I will call the Committee back to order. When the Committee recessed for votes, we were in the process of hearing opening statements from members, and it is now in order to yield to the ranking member of the subcommittee, Mr. Pallone of New Jersey, 5 minutes for an opening statement, please.

OPENING STATEMENT OF FRANK PALLONE, JR.

Mr. PALLONE. Thank you, Mr. Chairman.

Today's hearing provides a critical opportunity for committee members to better understand 42 CFR Part 2 and the legislative proposal to roll back the heightened protections it provides.

As I noted at the subcommittee markup, we all agree that action must be taken to combat the opioid epidemic ravaging our country, but taking the wrong action because we are not spending the appropriate amount of time to understand the consequences of a proposal could have serious consequences of making things worse. And that is why I requested a separate hearing that just focused on Part 2 and any legislative proposal that would make changes to it. And, as you know, not only is this issue controversial, but it is complicated.

So I thank the chairman for having this hearing, because I think it will help members hear firsthand why the substance use disorder patient advocacy community is united in their opposition to rolling back the protections of Part 2. This is the community that will bear the ultimate burden of this action, and, therefore, we should listen to their thoughts before making any changes that could potentially cause harm. And we will also hear more about why the substance use disorder provider community is split on this issue.

Mr. Chairman, you know we are in the midst of the worst opioid epidemic in our country's history. While I appreciate the bill's sponsors' intention to help build a better healthcare system for the pa-

tient community, I do have concerns with the proposal before us. Confronting the opioid crisis requires identifying strategies that promote more people entering and remaining in treatment for opioid use disorder. This is critically important because major challenges exist to getting people with substance use disorders to enter treatment. In fact, SAMHSA's National Survey on Drug Use and Health found that only about 4 million people out of approximately 21 million Americans in need of substance use disorder treatment received it in 2016, and that is only 19 percent.

And I believe that any action that will potentially prevent people from seeking treatment for any substance use disorder, and particularly opioid use disorder, must be avoided. Unfortunately, the proposal before us I think risks doing just that—reducing the number of people willing to come forward and remain in treatment.

Part 2 generally requires patient consent to share their substance abuse disorder medical records. That is because individuals might not seek or remain in treatment if they are worried about the real negative consequences that seeking treatment can have on their lives. It can mean the loss of a job, a home, or a child. It also could mean discrimination by doctors and insurers or, worse, arrest, prosecution, and incarceration.

Disclosure of substance abuse disorder information has tangible consequences that are not the same as other medical conditions. You can't legally be fired for having cancer, you are not denied visitation to your child due to severe acne, and you are not incarcerated for having a heart attack.

But ensuring strong privacy protections is critical to maintaining people's trust in the healthcare system and willingness to obtain needed health services, and these protections are especially important where very sensitive information is concerned.

So I think we are at a critical moment. At this moment, I believe we should heed the advice of the congressional conferees that negotiated the confidentiality statute that created Part 2, and I am quoting. It said: "The conferees wish to stress their conviction that the strictest adherence to confidentiality of substance use disorder patient records is absolutely essential to the success of all drug abuse prevention programs. Every patient and former patient must be assured that his or her right to privacy will be protected. Without that assurance, fear of public disclosure of drug abuse or of records that will attach for life will discourage thousands from seeking the treatment they must have if this tragic national problem is to be overcome."

Once again, we face a tragic national drug abuse problem, the scale of which our country has never seen. And I believe maintaining the heightened protections of Part 2 remain vital to ensuring all individuals with substance abuse disorder can seek treatment for their substance abuse disorder with confidence that their right to privacy will be protected, and to do otherwise at this time I just think is too great a risk.

I yield the rest of my time to the gentlewoman from California, Ms. Matsui.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Thank you Mr. Chairman. Today's hearing provides a critical opportunity for Committee Members to better understand 42 CFR Part 2 and the legislative proposal to roll back the heightened protections it provides.

As I noted at the Subcommittee markup, we all agree that action must be taken to combat the opioid epidemic ravaging our country; but taking the wrong action, because we are not spending the appropriate amount of time to understand the consequences of a proposal could have very serious consequences of making things worse. That's why I requested a separate hearing that just focused on Part 2 and any legislative proposal that would make changes to it. As you know, not only is this issue controversial, it is complicated.

Ensuring adequate privacy protections is not easy. It requires balancing the needs of patients with regard to the privacy of their medical information with the needs of a coordinated health care system to best serve patients.

I believe today's hearing will provide Members the opportunity to better understand this issue, and hopefully truly grasp the potential unintended consequences at risk to people's privacy. This includes the treatment of medical records under HIPAA's treatment, payment, and health care operations exceptions compared to Part 2, as well as the implications of such differences.

This hearing will also help Members hear firsthand why the substance use disorder patient advocacy community is unified in their opposition to rolling back the protections of Part 2. This is the community that will bear the ultimate burden of this action, and therefore we should listen to their thoughts before making any changes that could potentially cause harm. We will also hear more about why the substance use disorder provider community is split on this issue.

Mr. Chairman, we are in the midst of the worst opioid epidemic in our country's history. While I appreciate the bill sponsor's intentions to help build a better health care system for the patient community, I have serious concerns with the proposal before us. Confronting the opioid crisis requires identifying strategies that promote more people entering and remaining in treatment for opioid use disorder. This is critically important because major challenges exist to getting people with substance use disorders to enter treatment. In fact, SAMHSA's National Survey on Drug Use and Health found that only about 4 million people out of approximately 21 million Americans in need of substance use disorder treatment received treatment in 2016. That's only 19 percent.

I believe any action that will potentially prevent people from seeking treatment for any substance use disorder, and in particular opioid use disorder, must be avoided. Unfortunately, the proposal before us risks doing just that—reducing the number of people willing to come forward and remain in treatment.

Part 2 generally requires patient consent to share their substance use disorder medical records. That is because individuals might not seek or remain in treatment if they are worried about the real negative consequences that seeking treatment can have on their lives. It can mean loss of a job, a home, or a child. But it also could mean discrimination by doctors and insurers or worse arrest, prosecution, and incarceration.

Disclosure of substance use disorder information has tangible consequences that are not the same as other medical conditions. You cannot legally be fired for having cancer, you are not denied visitation to your child due to severe acne and you are not incarcerated for having a heart attack.

Ensuring strong privacy protections is critical to maintaining peoples' trust in the health care system and willingness to obtain needed health services. These protections are especially important where very sensitive information is concerned.

We are at a critical moment in history. And at this moment, I believe that we should heed the advice of the Congressional Conferees that negotiated the confidentiality statute that created Part 2:

"The conferees wish to stress their conviction that the strictest adherence to . . . [confidentiality of substance use disorder patient records] is absolutely essential to the success of all drug abuse prevention programs. Every patient and former patient must be assured that his [or her] right to privacy will be protected. Without that assurance, fear of public disclosure of drug abuse or of records that will attach for life will discourage thousands from seeking the treatment they must have if this tragic national problem is to be overcome."

We once again face a tragic national drug abuse problem—the scale of which our country has never seen—and I believe maintaining the heightened protections of Part 2 remains vital to ensuring all individuals with substance use disorder can seek treatment for their substance use disorder with confidence that their right to

privacy will be protected. To do otherwise at this time is just too great a risk. Thank you, I yield back.

Ms. MATSUI. Thank you, Ranking Member Pallone, and thank you, Mr. Chairman, for holding this hearing today. This is a very important complex issue relating to the opioid epidemic. I feel strongly that we should take action in this space. Patients that are currently receiving treatment may not be getting the best care if their provider does not have all the information necessary.

However, many challenges remain, only some of which might be solved by this bill. Providers still don't always have electronic health records, and even when they do, information is not always shared across providers. We cannot fully coordinate care if substance abuse is not a part of your medical history.

However, we are walking a fine line. As much as we need to reduce stigma and move toward integrated care, we still face technological, medical, and social barriers. Most of all, we do not want to unintentionally harm patients who may still be discriminated against for their addiction.

I look forward to the discussion today, and I thank the witnesses for their testimony.

Thank you, and I yield back.

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

This concludes the member opening statements. The chair would like to remind members, pursuant to committee rules, all members' opening statements will be made part of the record.

Testifying for our first panel is Congressman Earl Blumenauer.

Thank you, Mr. Blumenauer, for being with us today and taking your time to testify before the subcommittee. We look forward to what you have to share with us.

Just as a housekeeping detail, as is the general custom with a Member testifying, we will not do questions, but we will go directly to our second panel of witnesses.

Congressman Blumenauer, you are now recognized, 5 minutes, to summarize your opening statement.

STATEMENT OF THE HON. EARL BLUMENAUER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. BLUMENAUER. Thank you, Mr. Chairman, for your courtesy, and I appreciate the opportunity to share some observations with you to be able to discuss how better to provide high-quality coordinated care for patients with substance use disorders.

And I heard my two colleagues here, and I agree, but we are looking here—I will put it slightly different. We have an antiquated law that prevents lifesaving medical care for patients in recovery for substance use disorders. Originally designed to protect the privacy of individuals in addiction treatment, this decades-old barrier now creates an impediment to the implementation of integrated care.

The Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1972 currently governs how doctors and healthcare professionals share alcohol or substance use disorder records. Under this law, which predates HIPAA of 1996, patient medical records from addiction treatment facilities are segregated from the patient's medical

records. And this can create a life-threatening firewall that prevents medical doctors from knowing their patients' full medical history, which could include treatment for substance use disorders.

The rules that govern this firewall, known as 42 CFR Part 2, or simply Part 2, are more restrictive than HIPAA. It supersedes HIPAA and can only be breached in an emergency or with express written consent of the patient. This consent can often be impossible or difficult to maintain, and in those instances, the care itself cannot be fully integrated. Failure to modernize Part 2 has weakened our nation's ability to respond to the ongoing opioid crisis that is contributing to a record number of drug overdose deaths in 2017 and are continuing.

Our nation's healthcare delivery system has changed and innovated over the last 45 years. As providers shift towards new coordinated models of care, they must rely on shared medical information to improve patient health.

Regulations in Part 2 restrict the providers' ability to access critical substance treatment information, which can result in poor and in some cases tragic outcomes. And I believe the subcommittee has heard some really jarring testimony to this effect. Doctors can't treat a whole patient with half a medical record. And patients have a right to the best medical care available. Along with Representative Mullin, we have been pleased to author this bipartisan Overdose Prevention Act to prevent tragedies such as the committee has heard.

The legislation would treat medical records generated at a substance use treatment facility that relate to treatment, payment, or healthcare operations in exactly the same manner as all other medical records, removing the stigma that has for so long segregated those records from the rest of the healthcare system.

At the current time, persons with substance use disorders are the only subset of the healthcare patients whose records are treated differently and, as a result, may not receive the coordinated care they need.

Now, there is stigma associated with mental health and HIV/AIDS, but both mental health and HIV/AIDS fall under the protections of the HIPAA privacy law. Care is improving for both of those populations, thanks to increased access to public health data and open lines of communication that reduce unnecessary discrimination.

For Americans who are in recovery, our legislation maintains and strengthens Part 2 protections, to prevent disclosure of information. For example, it is currently illegal to share individuals' substance treatment record for an employer, law enforcement, or landlord. That wouldn't change under this legislation. Indeed, we would strengthen the penalties for unauthorized disclosure to make it more secure. As the healthcare system moves forward, more robust, integrated care models, every member of a patient's treatment team needs to understand the patient's full medical history, including substance abuse disorder. Current Part 2 regulations stand as a hindrance to the whole person care, and I think they must be changed to ensure all patients, regardless of diagnosis, have access to safe, effective, high-quality treatment and care.

I deeply appreciate the opportunity to share some observations with you and look forward to your discussions in this area to be able to give people the big picture. Thank you very much.
[The prepared statement of Mr. Blumenauer follows:]

**U.S. Energy and Commerce Committee
Subcommittee on Health
"Improving the Coordination and Quality of Substance Use Disorder Treatment"
May 8, 2018**

Chairmen Walden and Burgess, Ranking Member Pallone and Green, and Members of the Subcommittee, thank you for inviting me to discuss the importance of providing high-quality, coordinated care to patients with substance use disorders.

Simply put, an antiquated law prevents lifesaving medical care for patients in recovery for substance use disorders. Originally designed to protect the privacy of individuals in addiction treatment, this decades-old barrier now creates an impediment to delivery of integrated medical care.

The Drug Abuse Prevention, Treatment and Rehabilitation Act of 1972 currently governs how doctors and health care professionals share alcohol or substance use disorder treatment records. Under this law, which pre-dates the Health Insurance Portability and Accountability (HIPAA) Act of 1996, patient medical records from addiction treatment facilities are segregated from the patient's medical record. This creates a life-threatening firewall that prevents medical doctors from knowing their patient's full medical history, which could include treatment of substance use disorders. The rules that govern this firewall are known as 42 CFR Part 2, or simply "Part 2". This outdated policy, is more restrictive than HIPAA, supersedes HIPAA, and can only be breached in an emergency or with the express written consent of the patient. That consent can often be impossible or difficult to maintain, and in those instances, the care cannot be integrated. Failure to modernize Part 2 has weakened our nation's ability to respond to the ongoing opioid crisis and is contributing to the record number of drug overdose deaths in 2017.

Our nation's health care delivery system has changed and innovated over the last 45 years. As providers shift towards new coordinated models of care, they must rely on shared medical information to improve patient health. Part 2 regulations restrict providers' ability to access critical substance abuse treatment information, which results in poor and, in some cases, tragic outcomes for patients. The story of Jessica "Jessie" Grubb, who passed away from an overdose in March 2016, demonstrates the consequences of providers not having access to a patient's full health history. Jessie, who was in substance use recovery, went in for routine surgery. Providers were informed by her parents that she should not be given opioids except under strict supervision. However, upon discharge Jessie was prescribed 50 oxycodone pills, and the hospital pharmacy filled the prescription because her substance use disorder treatment history was not in her medical record. That night, she died as the result of an overdose. Jessie's father, David, said at the time "she went home with, in essence, a loaded gun."

Doctors can't treat a whole patient with half a medical record and patients have a right to the best medical care available. I, along with Representative Mullin, have authored the bipartisan *Overdose Prevention and Patient Safety Act*, H.R. 3545, to prevent tragedies like Jessie's and will align Part 2 regulations with the existing patient confidentiality protections under HIPAA.

Our bipartisan legislation would treat medical records generated at a substance use treatment facility that relate to "treatment, payment, or health care operations" in the exact same manner as all other medical records, removing the stigma that has for so long segregated those records from the rest of the health care system. Stigma around substance use disorders unfortunately still exists, and it should not be the major reason preventing care coordination for patients with a chronic illness. At the current time, persons with substance use disorders are the only subset of health care patients whose records are treated differently, and as a result, may not receive coordinated care.

Stigma is also associated with mental health and HIV/AIDS; but both mental health and HIV/AIDS patients fall under the protections of the HIPAA privacy law. Care is improving for both of those populations, thanks to the increased access to public health data and open lines of communications that reduce unnecessary public discrimination.

For Americans who are in recovery, our legislation maintains and strengthens existing Part 2 protections that prevent the disclosure of substance abuse treatment records in a manner that might lead to prosecution, discrimination, or loss of employment, housing, or child custody. For example, currently it is illegal to share an individual's substance use treatment record with an employer, law enforcement, or a landlord. That wouldn't change under H.R. 3545. Furthermore, H.R. 3545 will require automatic dismissal of criminal proceedings based upon a substance use treatment record that was improperly obtained using the process currently set forth under Part 2. Finally, current penalties for improperly disclosing or sharing confidential patient information under Part 2 range from \$500 to \$5,000. Our legislation would increase the penalty range to \$100 to \$1.5 million, providing the stronger enforcement standards currently in place under HIPAA.

As our health care delivery system moves towards more robust, integrated care models, every member of a patient's treatment team needs to understand a patient's full medical history, including substance use disorder history. Current Part 2 regulations stand as a hindrance to whole-person care and must be changed to ensure all patients, regardless of diagnosis, have access to safe, effective, high-quality treatment and care.

Thank you for the opportunity to share the importance of the *Overdose Prevention and Patient Safety Act*, H.R. 354, with you. I look forward to continuing to engage with Members of the Subcommittee as you consider these important issues.

Mr. BURGESS. Mr. Blumenauer, thank you for providing your testimony to the subcommittee today. It is a very valuable part of our insight into solving this problem.

Mr. WALDEN. Mr. Chairman, before my colleague from Oregon departs the table—

Mr. BURGESS. The gentleman is recognized.

Mr. WALDEN [continuing]. I would point out that, in 1972, he was winning his first election to the statehouse at the age of either 23 or 24, depending upon when this was written into law. So not that it has been a long time since 1972, but he has had a very distinguished career ever since. On the city council, my father and he served together in the State legislature. Yes, he does go back that far. And then here in the Congress. So we appreciate him being here and sharing this.

Mr. BLUMENAUER. And his father was the real legislator.

Mr. WALDEN. Mr. Chairman, is this where I move to table the bill?

Mr. GREEN. Does the chairman yield? Mr. Chairman, I was also elected in 1972. Are you telling me we are old?

Mr. WALDEN. I would never—no. I am saying the law that was started in 1972 is old.

Mr. BURGESS. The chair thanks the historical perspective that all have provided today.

Mr. Blumenauer, again, thank you for sharing with us.

And we will transition into our second panel. And as we do that, I want to thank all of our witnesses for being here today, and join us at the witness table. Each witness is going to have the opportunity to give an opening statement, followed by questions from members.

Do we have our name placards at the ready?

So, as Zach is placing the names, today we are going to hear from Mr. Dustin McKee, director of policy, the National Alliance on Mental Illness, from Ohio; Ms. Patty McCarthy Metcalf, executive director, Faces and Voices of Recovery; Mr. Jeremiah Gardner, manager of public affairs and advocacy, Hazelden Betty Ford Foundation; Dr. Westley Clark, the dean's executive professor, Public Health Program, Santa Clara University; and Mr. Gerald DeLoss, officer, Greensfelder, Hemker and Gale, Public Corporation.

We appreciate each of you being here today. And, Mr. McKee, you are now recognized for 5 minutes for an opening statement, please.

STATEMENTS OF DUSTIN MCKEE, DIRECTOR OF POLICY, THE NATIONAL ALLIANCE ON MENTAL ILLNESS OF OHIO; PATTY MCCARTHY METCALF, EXECUTIVE DIRECTOR, FACES AND VOICES OF RECOVERY; JEREMIAH GARDNER, MANAGER OF PUBLIC AFFAIRS AND ADVOCACY, HAZELDEN BETTY FORD FOUNDATION; H. WESTLEY CLARK, M.D., J.D., M.P.H., THE DEAN'S EXECUTIVE PROFESSOR, PUBLIC HEALTH PROGRAM, SANTA CLARA UNIVERSITY; AND GERALD (JUD) E. DELOSS, OFFICER, GREENSFELDER, HEMKER AND GALE, P.C.

STATEMENT OF DUSTIN MCKEE

Mr. MCKEE. Thank you, Mr. Chairman.

Chairman Burgess, Vice Chair Guthrie, Ranking Member Green, and members of the Energy and Commerce Subcommittee on Health, thanks for this opportunity to testify before you today on H.R. 3545, the Overdose Prevention and Safety Act. As you all well know, our nation is in the midst of a public health crisis.

Between 2014 and 2016, in my home State of Ohio, 10,383 people died from an opiate-related overdose. One of those people that died during that time was my big brother, Brandon J. McKee. He was 36. He left behind three sons, 4, 11, and 16. Mr. Chairman, Brandon's death was preventable. However, the antiquated provisions of 42 CFR Part 2 prevented his medical professionals that were prescribing him high doses of opiate-based pain medications with multiple refills from knowing that they were treating a high-risk patient with an ongoing history of substance abuse treatment and relapse.

But before I start describing the events leading to his death, I want to tell you a little bit about Brandon. Brandon struggled for most of his life with addiction disorder, but in spite of it, he found success early. My big brother was the best salesman you will ever meet. This guy could sell a double bacon cheeseburger to a vegan. He was a talented salesman that made six figures by the time he was 20 years old selling cars in Mansfield, Ohio, as a sales manager.

But despite two courses of residential treatment and periodic outpatient treatment for substance use disorder, his substance use led to several job losses, multiple DUIs, lots of family strife, and an eventual divorce. After that divorce, he moved into my mom's basement. She was kind enough to let him be there to try and get sober.

One night, he decided to go out and he got into a terrible car crash that crushed a few vertebrae in his spine. He was transferred up to Cleveland Metro Hospital. The orthopedist had no way of knowing he was an addict. So, after the surgery, he was prescribed high doses of opiate-based pain medication with multiple refills. Four months later, interestingly enough, he broke his back again while riding his bike and getting into a wreck. Again, he went to that same surgeon, and, again, he was prescribed high doses of opiate-based painkillers with multiple refills. He didn't sign a 42 CFR waiver. He was an addict. He was about ready to get the holy grail. Those drugs made him feel perfect.

We didn't even know that he was on narcotics until—well, I was the last one to speak with him 3 days before his death. He had burned all his bridges because of the secrets and lies associated with his addiction disorder. He called me that day and admitted that it was more than just the alcohol and that he was taking pills. And I said I was proud of him for telling me about it. Ironically, his phone battery was drained that day, and his phone cut out before the conversation was over. His last words to me were, "I am going to go to that NA meeting tonight, I promise, brother." Three days later, he died of a heroin overdose. He was found alone in his apartment curled up on the floor in the fetal position. It was May 10, 2014.

Mr. Chairman, Brandon's story demonstrates that 42 CFR Part 2 is a significant barrier to integrating care for behavioral health, medical/surgical care, and aftercare. It is also a major patient safety issue. We at the National Alliance on Mental Illness know that siloed treatment for mental illness and addiction is ineffective, leads to negative outcomes. This is common sense.

I would further emphasize that H.R. 3545 takes a very narrow targeted approach that simply aligns 42 CFR Part 2 with HIPAA for the purposes of sharing information only for treatment, payment, and healthcare operations. There is no risk that the records will be shared with outside parties, like landlords, employers, law enforcement, or exposing folks to civil litigation.

These are commonsense policy changes. You can make these changes. The lives of your constituents may just depend on it.

Thank you for this opportunity to testify before you today. I would be happy to answer any questions.

[The prepared statement of Mr. McKee follows:]

Dustin James McKee
U.S. House Energy & Commerce Health Subcommittee
Testimony Re: HR 3545
The Overdose Prevention and Safety Act
May 8th, 2018

Chairman Burgess, Vice Chair Guthrie, Ranking Member Greene and members of the Energy and Commerce Subcommittee on Health, thank you for this opportunity to testify before you today regarding HR 3545, the Overdose Prevention and Safety Act.

As you know, our nation is in the midst of a public health crisis. Opiates are killing more and more people each year. In 2016, my home state of Ohio had the second highest opiate overdose death rate in the nation. According to the Centers for Disease Control and Prevention, 10,383 people have died from opiate overdoses since 2014.

One of the people who died of an opiate overdose in 2014 was my big brother, Brandon Johnathan McKee. He was 36. He was the father of three sons, ages 4, 11 and 16 at the time of his death.

Brandon's death was preventable. However, in part because of the antiquated provisions contained within 42 CFR Part 2, the medical professionals that prescribed him opiate based pain medications were not able to identify him as a high risk individual with a history of substance use disorders, substance use treatment, and countless relapses.

Brandon struggled with addiction for most of his adult life. When he was 17, he fell while attempting a trick on his skateboard and dislocated his shoulder. His ex-wife recalls him frequently saying that the opiate based pain medication he was given intravenously in the emergency department gave him the best sensation that he had ever experienced in his life. It seems as though that incident was the beginning of a long and ultimately unsuccessful battle with substance use and addiction.

Brandon was a talented salesman. By age 21, he was making a six figure salary as a sales manager at a car dealership in Mansfield, Ohio. However, despite his career success, his addictions constantly plagued him. Even after receiving two courses of residential substance use treatment, and ongoing outpatient treatment, his substance use led to several eventual job losses, multiple DUI's, family strife, and an eventual divorce.

After his divorce, Brandon moved into my mother's basement in Wooster, Ohio. He was 35 at the time. Although he was trying to get sober and going to meetings, he relapsed one night. He took his truck to the bar after taking some mixture of tranquilizers and alcohol. He drank until the tavern closed, and then tried to drive his truck home. That night, he passed out behind the wheel and crashed into a large post, shattering several vertebrae in his back.

After the accident he was taken to Wooster Community Hospital and was eventually transported to Cleveland Metro Hospital where he would have back surgery to repair his spine. Because of 42 CFR Part 2, his orthopedic surgeon had no way of knowing that Brandon had a serious opiate related substance use disorder. Brandon did not sign a waiver, nor would he ever sign such a waiver if he had a chance to get a long-term prescription for opiate pain killers. These medications made him feel perfect, and he couldn't resist such an opportunity.

After the surgery, his surgeon gave him a prescription for a high dose opiate-based pain medication, with multiple refills. Four months later, he fell down and broke the titanium screws in his back. This second accident required a second surgery. Due to 42 CFR Part 2, the surgeon was once again unable to see that Brandon was an addict with a long history of substance use disorder treatment. Unsurprisingly, this lack of care coordination led to yet another prescription for a high dose opiate-based pain medication with multiple refills.

After Brandon's pain medication prescriptions were used up, he turned to street heroin. However, until his fatal overdose, none of us knew that he was an intravenous drug user. He was going to work every day, selling cars and living in his own apartment.

Three days before he died, he called me. He finally admitted to me, and only me, that he was struggling with narcotics. He never told me he was addicted to heroin, he was too ashamed to say so. However, he said he'd been taking opiate based pain pills, and had been off of them for a week and a half.

He was crying. He told me he had made it through the "dope sickness" of withdraw, and would be attending an N.A. meeting that evening. Ironically, during our conversation, the battery in his phone was drained and his phone cut off before the conversation was finished. The last words he said to me was "I'm going to go to that meeting brother, I promise", and then the phone shut off.

Three days later, he died of a heroin overdose, alone in his apartment. He was found curled up in the fetal position. It was May 10th, 2014.

Mr. Chairman, as Brandon's tragic story demonstrates, 42 CFR Part 2 is a significant barrier to integrating physical and behavioral health. It is also a major patient safety issue. We at the National Alliance on Mental Illness (NAMI) feel strongly that this barrier to integration and source bad outcomes (for both physical and behavioral health) needs to be updated and brought into the 21st Century.

Individuals diagnosed with a mental health conditions are at much greater risk of abusing substances and falling into the grip of addiction. Additionally, we know that siloed treatment for mental illness and addiction is ineffective and leads to negative outcomes in both an individual's mental health and substance use condition. In many instances, it also creates an even greater risk that individuals will experience poorly managed co-morbid, chronic medical conditions. This is a major contributing factor to the high rates of early mortality for individuals living with mental illness. Numerous studies have found that life expectancy for adults with mental illness may be as much as 25 years less than the general population.

Integrating care across not only mental health and substance use care, but also with primary and specialty medical care, is effective at improving clinical outcomes. It also lowers overall costs across public programs, such as Medicare and Medicaid, and private programs like employer-provided health insurance. However, integration cannot be achieved without the sharing of treatment records among providers. 42 CFR Part 2 remains a significant barrier to the sharing of clinical data and the proper coordination of care. These burdensome consent requirements that are not aligned with HIPAA further

stigmatize mental illness and substance abuse as separate from the rest of the health care system. Parity is necessary across the health care system to ensure that behavioral health records are managed the same as all patient data. 2018 marks the 10th anniversary of this Committee passing the Paul Wellstone and Pete Domenici Mental Health Parity and Addition Equity Act (MHPAEA). This was a huge victory for Americans living with mental illness and substance use disorders. At the same time, we will never achieve full parity until we live by the same rules and standards as the rest of health care. This is especially the case with the sharing of critical health information and the integration of care for the whole patient.

I would further emphasize that HR 3545 takes a very narrow targeted approach that simply aligns 42 CFR Part 2 with HIPAA for the purposes of sharing information for “treatment, payment and health care operations” or TPO. This legislation in no way places treatment records at risk of being shared outside of the context of health care TPO, that is to landlords, employers, law enforcement or civil litigation. In fact, the current draft strengthens existing penalties for inappropriate or illegal disclosure of behavioral health treatment records.

With bipartisan support, this Committee has embraced alternative payment models (APMs) and is moving our nation’s health care system toward paying for “value over volume.” As long as behavioral health records remain subject to separate rules that prevent the sharing of data for treatment, payment and health care operations, mental health and substance use will again be left behind the rest of the health care system. As you advance addiction treatment legislation this spring, I urge you to include the provisions that are in HR 3545 in any bill that is produced by the Committee. This is an important opportunity to improve coordination of care and produce better outcomes for people with mental health and substance use conditions.

Separate is never equal. It is time to align 42 CFR Part 2 with HIPAA and move us toward the goal of true health care integration.

The members of this subcommittee, along with their colleagues in the One Hundred Fifteenth United States Congress have an opportunity to prevent deaths like these. By passing HR 3545 and removing the antiquated barriers to care integration that exist today because of 42 CFR Part 2, physicians with high risk patients like Brandon can be fully informed so they can medically manage the hazards associated with prescribing opiate-based pain medications to people with a history of addiction treatment.

I urge you to make the common sense policy changes in HR 3545 by passing this legislation. The lives of your constituents may actually depend on it.

Thank you again for this opportunity to testify. I would be happy to answer any questions that the committee has at this time.

Mr. BURGESS. Mr. McKee, thank you for your testimony.
Ms. Metcalf, you are recognized for 5 minutes, please.

STATEMENT OF PATTY MCCARTHY METCALF

Ms. METCALF. Good afternoon. And, first, I would like to thank the committee for hosting this important hearing and for inviting me to testify. My written and oral testimony are the result of my experience as a person in substance use disorder recovery, as well as my professional experience as the executive director of Faces and Voices of Recovery.

I am a woman in long-term recovery from alcohol and drug addiction. For me, that means I haven't used alcohol or drugs in over 28 years. And that recovery has allowed me to give back to my community, earn college degrees, own a home, raise a family, pay taxes, establish a career, and become a leading advocate for the recovery community.

As an organized voice protecting the rights of individuals with substance use disorders, Faces and Voices of Recovery is adamantly opposed to dismantling of our critically important 42 CFR Part 2 confidentiality protections. We do not want our highly sensitive personal information shared for the purposes of treatment, payment, healthcare operations, or for any other purpose beyond the current rule without our express written consent.

We agree with the Congress who enacted Part 2 in the 1970s that weakening privacy regulations will discourage individuals who need treatment from seeking it. The dismantling of Part 2 is the antithesis of the principle of patient-centered, integrated care and is largely being pursued by coalitions and entities who hold their own business interests ahead of the rights of the interests of our community. These protections are as critical now as they were 40 years ago and must be maintained to ensure that individuals and families will seek help.

We believe that the interaction between a treatment provider and the client, when discussing specific consents and disclosures, strengthens the therapeutic relationship and builds trust. Patients feel secure enough to know where their personal health information is going and for what purpose. Most often, the treatment provider encourages their clients to provide a written consent, to share information with their primary care physician, but if the client is reluctant to do so for whatever reason, they have an opportunity to weigh the benefits and discuss the options.

We wouldn't be here today discussing Part 2 if it weren't for the fact that we are in the midst of an opioid epidemic. But I want to remind you that the Federal confidentiality regulations are intended to protect the privacy for all individuals with all substance use conditions, not just those with opioid use disorders.

There are an estimated 16 million people like me in the United States that have an alcohol use disorder. And research has repeatedly shown that people with alcohol use disorders experience stigmatization by the public as well as from health professionals more severely than people with mental disorders. This perceived stigma is shown to reduce the probability of using healthcare services and thereby contributes to a decreased likelihood of seeking treatment.

Research also indicates that worries about privacy keep people from seeking treatment. Making these changes to minimize our privacy protections will have long-lasting effects for a wide range of individuals and family members. The potential for negative consequences of stigma and discrimination with regard to employment and education is real for millions of Americans, even after years of sustained recovery from alcohol and drug addiction. And unlike most other medical illnesses, substance use disorders often have criminal and civil, legal consequences, and patients are vulnerable to arrest, prosecution, and incarceration.

Patients may be hesitant to reveal they have been discriminated against, because they would have to disclose the use of illegal drugs as well as the activities that are associated with the use of illegal drugs. The vast majority of persons who will have this happen to them will lack the resources to determine who used their information in an improper way. Even if they did know this, in most cases, they would not take action for the very fact that trying to assert their rights would acknowledge drug use and addiction in a way that would open them up to prosecution and discrimination. Part 2 provides safeguards for patients against potentially disastrous results of unauthorized disclosure.

In conclusion, beyond the significant harm that eliminating Part 2 would do to our communities, it is entirely unnecessary. There is far too much at stake here for those of us depending on these protections in order that we may heal and realize our full potential as productive citizens of this great nation. Many of us have made it clear that we would not have gone to substance use disorder treatment or accepted services if we thought our information would be shared with other entities without our permission or knowledge. We would not have put our careers, reputations, our families at risk of stigma and discrimination if we were not assured that our information about our substance use disorder was safe and would only be shared with our consent. As a person in long-term recovery, a parent, and on behalf of the recovery community, I look forward to working with members of the committee to protect patient privacy.

And thank you for the opportunity to testify and address such an important issue to our community.

[The prepared statement of Ms. Metcalf follows:]



House Energy and Commerce Committee, Health Subcommittee hearing -
"Improving the Coordination and Quality of Substance Use Disorder Treatment"
May 8, 2018

Statement by
Patty McCarthy Metcalf
Executive Director of Faces & Voices of Recovery

First, I would like to thank the Committee for hosting this important hearing and for inviting me to testify on "Improving the Coordination and quality of Substance Use Disorder Treatment." My written and oral testimony are the results of my personal experience as a person in substance use disorder recovery and well as my professional experience as the Executive Director of Faces & Voices of Recovery.

ABOUT ME:

My name is Patty McCarthy Metcalf. I am a woman in long term recovery from alcohol and drug addiction. For me, that means that I haven't used alcohol or other drugs in over 28 years. Recovery has allowed me to give back to my community, earn college degrees, own a home, raise a family, pay taxes, establish a career and become a leading advocate for the recovery community.

I have personal lived experience with substance use disorder ("SUD") treatment. As a teen and young adult, I went to residential treatment three times. The third time, I had just turned 18 years old and was admitted to inpatient treatment for alcohol use disorder and cocaine use. If today I was trying to start college, starting my career, or even buying life insurance, it's likely I wouldn't be telling you this for fear of stigma and discrimination.

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In fact, if I had a drug-related felony and wanted to apply for federal financial aid to go to college or if I wanted to get a license to cut hair, I could be ineligible based on my past history even though I am in long term recovery. The point is that stigma and discrimination are still barriers for millions of people in or seeking recovery from substance use disorders.

ABOUT FACES & VOICES OF RECOVERY:

Faces & Voices of Recovery is a national recovery advocacy organization based in Washington, D.C. Since 2001, we have been dedicated to unifying around key priorities – to gain needed resources for recovery and to end stigma and discrimination against people in recovery. We are working to eliminate barriers to recovery for every American and every family, and to help today’s children and future generations, who often are the biggest winners in the process of recovery.

The Association of Recovery Community Organizations (“ARCO”) at Faces & Voices of Recovery is comprised of over 100 organizations across the nation with hundreds of thousands of individuals engaged in their programs and participating in recovery support services. By organizing and speaking out together, we support and give hope to individuals who are still struggling with addiction and to those who have found the power of long-term recovery.

As an organized voice protecting the rights of individuals with substance use disorders, we are adamantly opposed to the dismantling of our critically important 42 CFR Part 2 (“Part 2”) confidentiality protections. We do not want our highly sensitive, personal information shared for purposes of treatment, payment, health care operations or for any other purpose beyond current the rule without our express written consent or Part 2’s other safeguards.

PATIENT PRIVACY:

The advocacy efforts to eliminate 42 CFR Part 2 have largely been driven by coalitions of hospital associations, insurers, treatment agencies, software vendors and pharmaceutical

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companies, without representation of patient advocacy groups or people in recovery from alcohol and other drug addiction. *Faces & Voices of Recovery agrees with the Congress who enacted Part 2 in the 1970s that weakening privacy regulations will discourage individuals who need SUD treatment from seeking it.* In fact, we believe that the interaction between a SUD treatment provider and the client when discussing specific consents and disclosures strengthens the therapeutic relationship and builds trust. Patients feel secure enough to know where their personal health information is going and for what purpose. We also regularly encounter medical providers who do not understand the 42 CFR Part 2 protections and mistakenly believe it to be a barrier to care because they do not understand how 42 CFR Part 2 works or the recent changes made to them so they work in our 21st century healthcare environment. We believe that resources targeted towards educating the medical field on the current Part 2 protections and to increase understanding of substance use conditions would go far to improve care without eliminating our rights.

An essential element of treatment and recovery includes strength-based approaches that are patient-centered and empower the person to choose who to share their information with and when. Most often the treatment provider encourages their clients to provide a written consent to share information with their primary care physician. If the client is reluctant to do this, they have an opportunity to weigh the benefits and discuss options. In addition, through the updated 2017 Part 2 regulations, patients can now choose to disclose their SUD treatment records in a simplified consent form to their other treating providers in electronic health networks, integrated care systems, as well as treating provider entities (e.g., hospitals, and mental health and other outpatient health centers).

Shared decision-making and whole person care require the participation of the patient. A system that denies patient autonomy and dignity will discourage people from seeking help for a substance use condition. *An integrated, recovery-oriented system of care would not seek to keep persons with substance use conditions from being a partner in their own care.* The dismantling of 42 CFR Part 2 is the antithesis of the principle of patient-centered, integrated care, and is



largely being pursued by groups who hold their own business interests ahead of the rights and interests of our community.

UNINTENDED CONSEQUENCES:

Federal confidentiality regulations are intended to protect the right to privacy for individuals with all substance use disorders, not just those with opioid use disorders. An estimated 16 million people in the United States have an alcohol use disorder (“AUD”), according to the National Institute on Alcohol Abuse and Alcoholism. Research has repeatedly shown that people with AUDs experience stigmatization (by the public as well as from health professionals) more severely than people with other mental disorders. A high perceived stigma in persons diagnosed with an AUD has been shown to reduce the probability of using health care services and thereby contributes to a decreased likelihood of treatment seeking. Research also indicates that worries about privacy keep people from seeking treatment. (*Source: NIAAA, Alcohol Alert, Number 81: Exploring Treatment Options for Alcohol Use Disorders.*)

Making changes to minimize 42 CFR Part 2’s protections will have long lasting effects for a wide range of individuals and family members. For example, my daughter participated in counseling (at a Part 2 program) as a requirement of a diversion program for a possession of malt beverage charge (underage drinking). Without privacy protections, this information would be automatically prominently displayed on her medical record and could negatively impact her for the rest of her life. Had the counseling been related to *illicit* drug use, the harm could be devastating to her future. As a proud parent, I am happy to report that my daughter graduated college with a 4.0 GPA last week. As another example, a truck driver with a commercial driver’s license may participate in counseling and driving under the influence (“DUI”) classes at the advice of his or her attorney after a first DUI offense. If a medical screening is a requirement for employment, as it is for many professions, the physician could potentially disclose his or her substance use disorder treatment history. The potential for negative consequences of stigma and discrimination with regard to employment and education is real for millions of Americans even after years of sustained recovery from alcohol and drug addiction.

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Unlike most other medical illnesses, substance use disorders often have criminal and civil legal consequences. Part 2 provides safeguards for patients against potentially disastrous results of unauthorized disclosure. Unlike individuals with other illnesses or disabilities, SUD patients are vulnerable to arrest, prosecution, and incarceration. Additionally, many people with SUD (who are currently using illegal drugs) are not protected by federal or state civil rights laws that protect people with disabilities from employment, housing and other types of discrimination. Loosened confidentiality protections for SUD patient records can not only discourage patients from seeking treatment, but also subjects them to the risk of experiencing severe negative consequences and discrimination.

SUD patients may be hesitant to reveal they have been discriminated against. Someone using illegal drugs would have to reveal this fact, as well as the activities associated with the use of the illegal drugs. The vast majority of persons who will have this happen to them will lack the resources to determine who used their information in an improper way. Even if they did, in most cases individuals would not do so as by the very act of trying to assert their rights would acknowledge drug use and addiction in a way that would open them up to prosecution and discrimination.

The assertion that 42 CFR Part 2 is a barrier to health care is patently false. Part 2 simply requires that a patient decide if they want to share their personal information with another party. That's all it does. It is not a barrier, because it includes the patient in determining what risk the patient is willing to assume when their personal information is being shared with others. Part 2 as it stands today is a key element of integrated care in the most fundamental way. It upholds the autonomy and dignity of the patient by allowing the person with the substance use condition to decide who gets to get their information. We cannot integrate care by excluding the patient from the ability to make choices about what happens to their information. This is paternalistic and misguided.



There are protections that people would lose if HIPAA becomes the standard for substance use information. Law enforcement authorities could seize patient records with subpoenas and general court orders and use them to prosecute people in addiction treatment programs. The Health Insurance Portability and Accountability Act (“HIPAA”) does not provide significant protections against information in substance use disorder (“SUD”) records being routinely seized to investigate and prosecute patients in substance use treatment. Under the federal substance use disorder confidentiality regulation, Part 2 treatment programs are prevented from releasing patients’ SUD information to law enforcement authorities, and judicial or administrative bodies, without a special court order.

CONCLUSION:

Beyond the significant harm that this proposed legislation (H.R. 3545) would do in our communities, it is entirely unnecessary. It is deeply disturbing to us that organizations who ostensibly support recovery and patient autonomy are supporting the elimination of these rights for our community. Others appear to be signing on for financial gain, convenience, other unknown purposes.

There is far too much at stake here to those of us depending on these protections in order that we may heal and realize our potential as productive citizens of this great nation. Congress was wise in its adoption of these important protections in the early 1970’s when they passed the law. They recognized at that time that these protections were necessary as they were facing a heroin epidemic and they understood that they were important in order to allow people to seek help for their substance use conditions without fear of their information going out further than necessary. As recently as last year, the regulations have been updated to reflect our changing health care system while ensuring our ability to consent to share it. We believe that many medical providers are unaware of these changes. The current Part 2 protections should be given an opportunity to work instead of pursuing these efforts to eliminate our rights.

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While it is true that there are many parallels between substance use conditions and other medical conditions, by its very nature, substance use conditions may involve use of illicit substances which is an illegal activity. The recognition of this fact led to the very protections that this bill seeks to dismantle. These protections are as critical as they were 40 years ago and must be maintained to ensure that individuals and families will seek help.

Many of us have made it clear that we would not have gone to substance use disorder treatment or accepted these services if we thought that our information would have been shared with other entities without our permission or knowledge. We would not have put our careers, reputations, or families at risk of stigma and discrimination if we were not assured that information about our substance use disorder was safe and would only be shared with our consent.

At a time when the opioid overdose crisis claims 144 lives every day, barriers to achieving a life free from the effects of harmful drug use must not be erected. Barriers to recovery hurt not only the individual, but that individual's family, community and the larger society as well.

As a person in long-term recovery, as a parent, and on behalf of the recovery community. I look forward to working with you and the Members on this Committee to advance meaningful legislation while protecting patient privacy. Thank you for the opportunity to testify today and for your commitment to addressing such an important issue that impacts millions of American families every day.

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Mr. BURGESS. Thank you, Ms. Metcalf.
Mr. Gardner, you are recognized for 5 minutes, please.

STATEMENT OF JEREMIAH GARDNER

Mr. GARDNER. Mr. Chairman, thank you for inviting me. I am grateful to you and the subcommittee members for your leadership in addressing opioids and addiction and for this opportunity to testify in support of H.R. 3545.

My name is Jeremiah Gardner, and I am a person in long-term recovery from substance use disorder. I am also a recovery advocate with a master's degree in addiction studies and a counseling license. In addition, I work as a communications professional for the Hazelden Betty Ford Foundation, a nonprofit that has been advocating for patients and helping them overcome addiction for decades.

I believe all of us here today can agree about the need for more coordinated and integrated care, less discrimination against those with substance use disorder, and appropriate patient privacy. We all want to help patients, not harm them. H.R. 3545 is not a question of privacy versus no privacy or coordination versus no coordination or discrimination versus no discrimination, providers versus patients. The very specific question, as the chairman noted, is, does HIPAA provide sufficient enough privacy protection to warrant removing the Part 2 barriers that sometimes get in the way of more efficient, coordinated care.

And as you weigh that choice, I would like to tell you about my mom, who is another illustration of why this topic is so important. At age 59, my mother misused fentanyl patches, Vicodin, and anxiety medications, and died just a couple of rooms away from her husband and 13-year-old grandson.

She had started taking prescribed opioids 20-some years earlier for pain. Eventually, she was on 400 milligrams of morphine a day, which over time led to other ailments, deteriorating mental health, and additional medications, not to mention more doctors. She had lots of them, and lots of medications.

But before her long journey with opioids began, she was treated for alcohol problems at a Part 2 facility. It was a significant fact in her health history that, as far as I can tell, escaped the attention of her later doctors and failed to inform her healthcare moving forward.

Two decades later, at the end, my mom suffered from a complex combination of opioid use disorder, chronic pain, acute pain due to knee surgery, depression, anxiety, arthritis, type 2 diabetes, and other physical conditions. She also had an assortment of social stresses and, because she relied so much on pills for so long, a deficit of healthy coping mechanisms. Her pain was, indeed, profound, manifesting itself like addiction does: physically, mentally, emotionally, socially, and spiritually.

What my mom needed but never got was a good year or more of integrated, coordinated care, and checkups surrounded by support. She needed her multiple care providers to have the full picture of her health and to work together. Instead, they kept prescribing deadly amounts and combinations of drugs to somebody with a substance use disorder. My mom got subpar care.

Could she have done more to actively coordinate care herself? Yes. But as a professional in the field and someone with lived experience, I can tell you that that is a tall order for someone with a severe substance use disorder. Maybe she was too embarrassed or ashamed to acknowledge her condition because of the public stigma. Maybe she didn't understand she was at greater risk, or maybe she did and was not inclined to volunteer information that might prevent her from getting pills for her pain or her anxiety.

She eventually came to know opioids as a relentless monkey on her back, but she also saw them as a solution. And that drive to continue using despite problems reflects the very nature of addiction. My mom needed help recognizing that her constellation of issues tied together, and that substance use disorder was in many ways at the center of it.

My point in sharing is simply that the health of people like my mom can be very complex. Coordinated care is critical and too often absent, and timely relevant information sharing is important.

This bill isn't just about IT or workflows or convenience or efficiency or stigma or cost. It is about knocking down any barriers we can to help ensure optimal care. It is about taking the next step toward parity and bringing the full weight of healthcare to bear against this public health problem. Most of all, it is about people, real people with families like my mom.

There is some fear this bill will discourage help seeking. I certainly don't speak for all patients or family members, but I can tell you privacy laws were not a factor in my own help seeking or my mom's contemplations. And the topic, frankly, is rarely broached by the thousands who call the Hazelden Betty Ford Foundation for help each year. Most want to know, can you help, and how can I pay for this?

I really believe this bill addresses those priorities that patients and their families care about most. I also believe HIPAA is a sufficient and enforceable privacy standard, that discrimination can and must be prosecuted vigorously, and that this is an essential piece of the Federal opioid response and the paradigm shift that began with the 2008 parity law.

Thank you for the opportunity to share. I look forward to answering your questions.

[The prepared statement of Mr. Gardner follows:]

**Testimony of Jeremiah Gardner, MA, LADC, Hazelden Betty Ford Foundation
Before the House Energy and Commerce Committee Subcommittee on Health
On H.R. 3545 – May 8, 2018**

Summary: Mr. Chairman, thank you very much for inviting me to participate in this important hearing. I am grateful to you and the Members of the Subcommittee for your leadership in addressing the opioid addiction crisis, and for the opportunity to testify in support of H.R. 3545.

My name is Jeremiah Gardner, and I am a person in long-term recovery. For me, that means I haven't used alcohol or other drugs in almost 12 years and have been able to build a life, family and career defined by service, community, purpose and gratitude. I'm also the son of a wonderful woman whose life ended three years ago due to her opioid use disorder – one of the hundreds of thousands of Americans lost to overdose in recent years. I am a recovery advocate in my community and nationally. I also have a master's degree in addiction studies and am licensed as a counselor in Minnesota. In addition, I work as a communications professional for the Hazelden Betty Ford Foundation, a nonprofit that has been fighting for patients and their rights for decades.

H.R. 3545 would be a key step in giving those with opioid use disorder greater access to the lifesaving health care they need. The bill would reform the outdated and onerous 42 CFR Part 2 ("Part 2") privacy regulations, which have become a barrier to access and patient safety and deprive patients of the full benefits of modern health care services. Part 2 regulations, enacted in the 1970s, are applied neither fairly nor uniformly, applying only to a small subset of addiction treatment providers. They have never been enforced and actually perpetuate the very stigma that causes discrimination, rather than providing any real extra protection against it. By aligning Part 2 with the Health Insurance Portability and Accountability Act ("HIPAA") for "treatment," "payment," and "operations" purposes – thus allowing the use and disclosure of patient information when needed to facilitate optimal care and protect patient safety – H.R. 3545 will continue Congress's effort to bring much-needed parity between care for addiction and care for physical health conditions. The bill will enable addiction care to become more fully integrated within the broader health care system so patients have multiple access points and can get support for this chronic condition beyond the acute care stage. At the same time, it will strengthen Part 2's protections against discrimination and other potential abuses of information in criminal and civil courts. For all of those reasons, H.R. 3545 is an essential piece of the federal opioid response.

While this testimony is professionally informed, I will focus primarily on my personal experiences as a patient, a person and advocate in recovery, and a son who lost his mom to addiction.

Testimony (Cont.): For whatever reason, Sept. 25, 2006, was my turning point. When I woke up in a hotel at 10 a.m. that Monday – late for work, sick, tired, and crying – I made the fateful decision to stop fighting the reality of my substance use disorder and ask for help. I called a friend and within several hours was admitted to a treatment center. We didn't once talk about privacy that day; it wasn't the slightest factor in my help-seeking decision. I did, however, make some calls before I was driven to the treatment center. I called my boss first. I figured it would be hard to skip work – or in my case, multiple weeks of work – without explaining. It didn't even cross my mind to keep it a secret. I don't even know how that would have been possible. I also called some fellow volunteers to let them know I wouldn't be at an upcoming community event. And I called my girlfriend to let her know, too. And then I got the help I needed at a small, nonprofit facility subject to Part 2.

What sort of message do you think I internalized when I was asked to sign multiple consents at multiple times during my care? It wasn't that my provider or the system cared deeply about me or was trying to protect me. Instead, I was getting the subtle, stigmatizing message that my illness may demand extraordinary secrecy. Before, I hadn't been under the impression that I needed to or could keep my treatment a secret. In fact, getting help had seemed like a good thing. To be sure, nobody wants to go to the hospital, clinic or an addiction treatment center. And there's some confusion and frustration around not being able to get healthy on one's own, born of ignorance about the disease. But I hadn't planned to feel shame for getting help. I can tell you I had also intuitively expected that anyone working with the facility would know about me, and that anyone with my insurance company who needed to know would, too. Why would I expect anything differently? And yet, the unusual culture of secrecy seemed disconnected to the other idea I was learning – which is that I had a health condition, rather than a problem of will or morals.

It's true, of course, that many of us feel guilt and shame over the behaviors that were the symptoms of our health condition. But the idea that getting help and getting well might be a secret we want to keep is an idea that was planted in me. Ultimately, I chose to be as open as I would about any other illness – to be authentic and not establish dual identities – because it felt intuitively like the healthy choice.

Now, had I lost a job after I got back to work because of my treatment, that would have been terrible. It also would have been clearly discriminatory, actionable and wrongheaded. Yes, discrimination happens, and we must prosecute it to the full extent of the law. But if we want to take that next step as a culture, and create an environment that produces less discrimination and addresses addiction more openly, we have to change the laws and institutions that unintentionally validate stigma. We cannot fight discrimination with stigma. And we cannot treat addiction as a health condition unless we do just that – actually treat it like a health condition. It's time for our law to reflect the cultural change we want and need to see. Lives depend on it.

Even if I had tried to keep my illness a secret, Part 2 would not have protected any more than HIPAA against my employer finding out about my treatment. If that information got to my employer without my consent, it would have constituted a HIPAA violation. Indeed, if you examine the privacy breach scenarios most often cited by those concerned about this bill, they are violations already addressed by HIPAA.

It may be true that the more health care and insurance company employees who touch my record, the greater chance there is someone may violate HIPAA. I will stipulate that, conceptually. But is that a widespread problem in the real world? For-profit addiction treatment centers are not subject to Part 2. Is HIPAA failing their patients? I don't think so. Are we seeing more privacy violations at the Department of Veterans Affairs, where patient record regulations are already aligned with HIPAA? Not that I'm aware of.

Congress decided that Part 2 provides no extra protection for our veterans, service men and women, and their families when you exempted the VA from the burdens of Part 2 last year. That legislation was passed without controversy, and the harms warned of by those concerned about H.R. 3545 have not manifested. If HIPAA is sufficient to protect the privacy of our veterans and service members seeking treatment for substance use disorders, why would it not be for civilians?

HIPAA provides sufficient protection, and its violations are rigorously enforced, unlike Part 2 violations, which have never been enforced by a single court – mostly because Part 2 violations are almost always a HIPAA violation, too. It's no surprise the health care system, as an ecosystem, is attuned and geared toward HIPAA compliance. And yet, think of the coordinated care and patient safety we sacrifice for Part 2's illusion of extra protection.

Just three short years ago, my stepfather found my mother dead on her bed at home, leading to the worst phone call of my life. I am the oldest of five kids; she also had seven grandkids and, like a lot of moms, was a towering presence for our entire family. But, in an instant, she was gone. Just 59 years old. Prescription opioids – which she once described as the “monkey on her back” – had finally become something much worse.

My mom had started taking prescribed opioids about 20 years earlier for pain, at the onset of what would come to be known as our national opioid crisis. Like so many, my mom never got off the pills. Eventually, she was taking 400 mg of morphine a day, as prescribed. We kids were mostly unaware. But I did learn in the early-90s, prior to HIPAA, that my mom went to addiction treatment for what I understood to be alcohol problems. I didn't really know or comprehend what having a problem meant at the time, and honestly, it was something that sort of came and went for our family.

But, all the while, my mother's opioid journey continued unabated. I won't pretend to know all the details, but I can't imagine a scenario where her doctors knew about her prior addiction treatment, even though it was a significant fact in her health history. My mom's pain never got better, by the way – only worse. And longtime opioid use eventually contributed to other ailments, deteriorating mental health and additional medications. It was a vicious cycle of problems, more medication, and more problems to justify more medication. Not to mention, more doctors. And, until she opened up to me about this painful history during those final months of her life, my mother's battle was fought mostly internally, quietly and secretly.

In the end, she had a complex combination of opioid use disorder, chronic pain, acute pain, depression, anxiety, arthritis and other physical conditions, an assortment of social stresses, and – because she relied so much on pills for so long – a deficit of healthy coping mechanisms. Her pain, as it is with so many chronic pain patients, was profound – manifesting itself, like addiction does, physically, mentally, emotionally, socially and spiritually.

What my mom needed was a good year or more of integrated, coordinated care and checkups – surrounded by support. She needed her multiple care providers to have the full picture of her health and to work together. Instead, they kept prescribing deadly amounts and combinations of drugs to someone with the disease of substance use disorder. At the very end, while her primary doctor was on vacation, a fill-in prescribed her fentanyl patches to help with the pain that followed two knee surgeries and was complicated by the chronic pain and poor health she had developed over her 20 years of opioid use. My mom misused the fentanyl patches along with Vicodin and anxiety medications, and it killed her just a couple of rooms away from her husband and 13-year-old grandson.

Now, I can't tell you exactly where Part 2 and HIPAA fit into my mom's story. But I can say unequivocally that my mom had a severe substance use disorder and did not get anything close to the coordinated care

she needed. Instead she got subpar care. Could she have been more forthcoming and actively coordinated her care herself? Yes. But as a professional in this field, and someone with lived experience, I can tell you that's an impossible expectation of someone who is in active addiction – someone whose brain is not functioning properly. In reality, there's no way my mom would have volunteered information that would have prevented her from getting pills for her pain – even though she knew the pills were a problem. That irrationality, indeed, is the very nature of addiction – and is all the more understandable in a health care system that may have been prone to just take away her pills; rather than get her the critical care she needed.

Addiction is a disease that has been neglected and marginalized for generations. It's time to bring the full weight of our healthcare system to bear against America's longstanding addiction crisis, which the opioid epidemic has tragically revealed to the masses. Mainstream health care is finally at the table, no longer avoiding this illness and the people who have it, but seeking to treat it on par with other conditions and physical ailments. It's time for primary health care and specialized care providers like Hazelden Betty Ford to work together to address this public health crisis. Part 2 gets in the way with cumbersome regulations and leaves baked into our law the idea that addiction warrants extraordinary secrecy, which perpetuates the very stigma we continue to work so hard to smash.

I have the utmost respect for the folks who have expressed concern for this bill. But please don't think they represent the entirety of the patient community or that patients are unified against this change. I talk to real people every day who are in recovery or still struggling. My organization works on the ground day-in-and-day-out, helping thousands of people a year. We're in the trenches on this, and I'm telling you, when patients are in the help-seeking mode, they generally just want to know: *Can you help? And how can I pay for this?* This bill addresses the questions patients and their families care about most.

More and more people are recovering out loud, and saying “no” to secrecy and shame. There is even now a certain kind of stigma against those who stigmatize people with addiction. In other words, we’ve made good progress, and aligning Part 2 with HIPAA will continue that progress in an important way.

This bipartisan bill is about priorities and the future of addiction treatment in the United States. If you believe patient safety is the most important priority, I urge you to vote for H.R. 3545. And if the future you envision is one with less stigma; open, routine conversations about addiction and addiction care; and more people getting the best possible help on par with other health conditions, I also urge you to pass this important legislation.

Because I work for the Hazelden Betty Ford Foundation, the largest nonprofit provider of substance use treatment, education and prevention services in the world, I also have submitted, as supplemental material, a letter from our CEO and Chief Medical Officer, further highlighting our organizational insights on this bill.

We have arrived at a pivotal point in the history of addiction treatment and recovery. Part 2, once valuable in the absence of HIPAA, is now impeding progress toward the kind of coordinated care that will better protect and ensure patient safety. Maintaining unnecessary barriers to care during the nation’s worst addiction crisis ever would be a missed opportunity and potentially grave mistake.

Thanks again for the opportunity to share my views. I look forward to answering your questions.

Mr. BURGESS. Thank you, Mr. Gardner.
Dr. Clark, you are recognized for 5 minutes, please.

STATEMENT OF H. WESTLEY CLARK, M.D., J.D., M.P.H.

Dr. CLARK. Thank you, Mr. Chairman, Mr. Green, and members who are assembled. Thank you for the opportunity to present to you here today.

I am here as a physician, addiction medicine specialist, and as a college professor. I am here to advocate for maintaining the integrity of 42 U.S.C. 290dd-2 and for keeping those Federal regulations that protect individuals with substance use disorders. Do not discourage them from seeking treatment by stripping away their current right to consent to the release of their personal substance use disorder histories.

There are two contemporary phenomenon that are relevant here: one, the Facebook Cambridge Analytica issue; and, two, the NIH All of Us longitudinal research project. In the case of the Facebook Cambridge Analytica issue, it was clear that the general discourse about the misuse of information, that privacy and confidentiality were important to people and the disclosure of their private information without their consent was a violation. That the information was subsequently used for predictive analytics for the purpose of influencing those whose information had been compromised shows the potential for abuse. This was not a case of data security, but a case of breach of confidentiality and apparent invasion of privacy.

Alternatively, the NIH study will include all data available in the participants' electronic health records, including demographics, visits, diagnosis, procedures, medications and laboratory visits. Pertinent information can include data about mental health, substance use, or HIV status.

What is interesting about the NIH All of Us study and relevant to this hearing is that participants will be asked to consent to release information from their electronic health records. The All of Us study invokes the idea of the comprehensive health record heralded by some EHR vendors, who seek a new generation of electronic information about people, information that includes all sorts of medical and nonmedical information. Thus, the medical record becomes a comprehensive dossier on the individual.

The actual benefit to a patient of integrating all that is known about an individual using the health record as the portal has yet to be determined. Privacy, confidentiality, and consent are important to Americans. If the two vignettes that I have used to introduce my testimony can be understood in the context of the current discussion, then you, as Members of Congress, will understand the importance of maintaining the protections of 42 U.S.C. 290dd-2 and 42 CFR Part 2 to a population that is more vulnerable than those on Facebook or those who agree to participate in the All of Us study.

While the issue of opioid misuse is of major importance, we should keep in mind that 42 CFR Part 2 does not just apply to opioids. The National Survey on Drug Use and Health reveals that 65 million Americans admit to binge drinking in the past month and 24 million Americans admit to being past month users of marijuana.

The critical question today is, how do we get the 28.6 million Americans who are current illegal drug users and the 65 million Americans who are binge drinkers to discuss their substance use with the medical community? We won't do it by compromising their privacy.

It is also argued that substance use is like the flu, diabetes, hypertension, or HIV, and, therefore, should be treated like those conditions with regard to disclosure. The reality is that most substances of misuse are illegal and that disclosure of such information can give rise to harm to the individual affected. These harms include loss of employment, loss of housing, loss of child custody, the loss of benefits, stigma and discrimination, the loss of privacy, shame, and the loss of economy.

The case is often made that healthcare delivery systems need to know about the substance use history of a patient. You don't hear why providers can't simply ask patients themselves about their substance use histories. You hear it is too confusing clinicians know about 42 CFR Part 2 and how to apply the rule. Yet these same clinicians and healthcare systems spend quite a bit of time learning about and executing reimbursement rules, administrative rules, quality standard rules, and all the rules that are necessary to get paid for services delivered to the very people whose agency and dignity are now deemed too inconvenient to respect.

You may also hear that people lie about their substance use, implying that they cannot be trusted. However, since behavioral care is the dominant form of substance use treatment, trust is the cornerstone with behavioral treatment. We should be promoting a patient-provider cooperative relationship instead of encouraging an adversarial one.

The healthcare operations exception found in HIPAA is a loophole in confidentiality that is so large you can drive a Mack Truck through. Neither provider nor regulators will be able to protect those with substance use disorders. The only choice left to those who are vulnerable is not to seek treatment. Remember, 90 percent of those who currently need treatment do not seek treatment. We should be focused on reducing the ratio of those who need treatment versus those who seek treatment from nine to one, to one to nine.

Therefore, I ask you, please do not weaken 42 U.S.C. 290dd-2, and as a result, I ask you to look closely at H.R. 3545. It is not the panacea that it is being marketed as being. Thank you.

[The prepared statement of Dr. Clark follows:]

Testimony of H. Westley Clark, MD, JD, MPH
Dean's Executive Professor of Public Health
Santa Clara University
Santa Clara, California

**Before the Health Subcommittee
of the House Energy and Commerce Committee
May 8, 2018**

My name is Dr. H. Westley Clark. I am a psychiatrist, addiction medicine specialist and a professor. I retired from Federal service after providing clinical care to our nation's veterans for 14 years and after directing the Center for Substance Abuse Treatment in the Substance Abuse and Mental Health Services Administration for 16 years.

I am currently teaching undergraduates about substances of misuse to undergraduates at Santa Clara University, recognizing that the young men and women of this Nation are both at risk for substance misuse and have the potential to changing the cultural dynamic which puts their age cohort at greatest risk for misuse and overdose.

I am here to advocate for maintaining the integrity of 42 USC 290dd-2 and to keeping those federal regulations that protect individuals with substance use disorders who would be discouraged from seeking substance use disorder treatment, because they would be subject to discrimination and legal consequences in the event that their information is improperly used or disclosed.

There are two contemporary phenomenon that I would cite as a prelude to the substance of my testimony: (1) the Facebook/Cambridge Analytica issue, and (2) the NIH All of Us longitudinal research project.

Without venturing into the web of politics associated with the Facebook/Cambridge Analytica issue, it was clear from the general discourse and dialogue about the misuse of information that surfaced from that chain of events, that privacy and confidentiality were important to people, that their sensitive information disclosed without their consent represented a violation of autonomy and sense of self. It was also clear that those violated were not happy about the situation.

That the information was subsequently used for predictive analytics, according to media accounts, for the purpose of influencing those whose information had been compromised showed the potential for abuse. Keep in mind that this was not a case of data security, but a case of breach of confidentiality and apparent invasion of privacy.

I turn next to the NIH All of Us protocol. The NIH is seeking 1 million people to volunteer for an ambitious study that will last 10 or more years. The objective of this study is to build a research resource composed of participant-provided information (PPI), including environmental, physiologic, and health data and biospecimens from 1 million or more research participants.

The NIH Study will include all data available in the participants Electronic Health Records, including demographics, visits, diagnoses, procedures, medications, laboratory visits, vital signs, and physician notes. In addition, the NIH notes that the pertinent information may include data about mental health, substance use, or HIV status.

However, what is interesting about the All of Us Study protocol and relevant to this hearing is that participants will be given the option of providing consent to release information from their electronic health records. In other words, patients will be asked to consent to the use of data from their EHRs. While this is a research protocol and falls under the aegis of research consent and disclosure, the fact remains that consent is a requirement and that the right to refuse consent is respected. The fact that the All of Us study anticipates using additional data from Social Security Death Master Files, pharmacy system data, and health registry data makes consent all the more important, as aspects of study participants health lives will be examined. This research will also provide information about the willingness of participants to consent to have their electronic health information used. Furthermore, formal consent is required because academic scientists, commercial organizations, and interested citizen scientists will be able to request access to the participants' data; thus, the array of inquiring entities will not be given automatic access to this data.

The All of Us protocol invokes the idea of the comprehensive health record heralded by some EHR vendors who seek a new generation of electronic information about people, information that includes social determinants, about what people eat, how much they sleep, if they are obese or live in a food desert, or whether they are lonely.¹ Thus, the medical record becomes a comprehensive dossier on the individual ripe for use or misuse. The hope, of course, is that in coming decades adequate resources will be available to address the convergence of social determinants and health. In the meantime, it has yet to be determined that the necessary linkages and interoperabilities can be fostered to actually benefit the patient rather than simply integrating all that is known about an individual using the health record as the portal.

Privacy, confidentiality, and the consent are important to Americans, and something that should be respected. If the two vignettes I've used to introduce my testimony can be understood in the context of the current discussion, then you, as members of Congress, will understand the importance of maintaining the protections of 42 USC 290dd-2 and 42 CFR part 2 to a population that is more vulnerable than those on Facebook or those who agree to participate in the All of Us Study.

As you well know, we are in the midst of the worse opioid epidemic that this nation has ever seen. And, at the same time, less than 10% of people who need treatment seek treatment. Instead of recognizing that we need to reassure those in need of treatment that they can trust the

treatment community to use the information they disclose, many are calling for severely weakening 42 USC 290dd-2 and 42 CFR Part 2..

It is argued that the opioid epidemic justifies modifying 42 CFR Part 2 to address the opioid overdose deaths and the misuse of opioids. While the issue of opioid misuse is of major importance, we should keep in mind that 42 CFR Part 2 does not just apply to opioids.

Data from the National Survey on Drug Use and Health reveals that 65 million Americans 12 and Older admit to binge drinking in the past month. Of these, 16 million admit to being heavy drinkers. We should also be aware that 24 million people admit to being past month users of marijuana. ⁱⁱ

These numbers alone suggest the magnitude of the issues we are confronting today, as they exceed the 3.4 million people who admit to past month use of pain relievers and the 475,000 who admit to past month users of heroin.

The critical question today is how do we get the 28.6 million Americans who are current illegal drug users and the 65 million people who are binge drinkers to discuss their substance use with the medical community?

“[W]hat should we do about the opioid crisis? First, we must be realistic about who is getting in trouble with opioid pain medications. Contrary to popular belief, it is rarely the people for whom they are prescribed. Most lives do not come undone, let alone end in overdose, after analgesia for a broken leg or a trip to the dentist. There is a subset of patients who are vulnerable to abusing their medication—those with substance use histories or with mental health problems. Ideally, they should inform physicians of their history, and, in turn, their doctors should elicit such information from them.”ⁱⁱⁱ

Although the use of alcohol is legal for those over the age of 21, the medical community should also communicate with their patients about alcohol use. However, as for all psychoactive substances, communications between clinician and patient require trust. Trust is not possible if the function of disclosure is the release of sensitive information into a virtual data storm sewer

It is often argued that substance use should be treated like HIV, the flu, diabetes or hypertension and therefore should be treated like those conditions. Those who make this argument blind themselves to the reality that many substances of misuse are illegal, and that disclosure of such information can give rise to harm to the individual affected.

The harms to which a person who admits to substance use may suffer includes the loss of employment, the loss of housing, the loss of child custody, the loss of benefits, stigma and discrimination, the loss of privacy and the loss of autonomy.^{iv} Medical records can also be used to incriminate a person and subject that person arrest, prosecution, and incarceration.

It is irresponsible to ignore the real harms to which a person with a history of substance use could be subject. It is also irresponsible to ignore the implication that modern electronic health information has for privacy and confidentiality. It is sometimes said that computers have cidetic

memories---they don't forget. Thus, people in recovery from alcohol and drug use who have long since stopped using are still at risk for discrimination and stigma.

The case is often made that the health care delivery systems need to know about the substance use history of a patient. You don't hear why providers can't simply ask patients themselves about their substance use histories. You hear that it is too confusing for clinicians to know about 42 CFR Part 2 and to apply the rules. Yet, these same clinicians and health care systems spend quite a bit of time learning about and executing reimbursement rules, licensing rules, administrative rules, quality standard rules, and all the other rules that are necessary to get paid for the services delivered to the very people whose agency and dignity are now deemed too inconvenient to respect..

Furthermore, there are those in the health care delivery system, including those involved with insurance and reimbursement who are looking for data to inform predictive analytics to anticipate those might be at risk for substance use disorders in order to actuarially determine what course of prospective action should be taken to address those with such possibilities.

Just last week, the USA Today ran a front page article on the evolving image of marijuana, noting that 24 million Americans said that they used marijuana in the past 30 days, 90% for so-called recreational purposes and 10% for medical reasons.^v Clearly, clinicians should want to know why the estimated 2.4 million medical marijuana users choose to use that psychoactive substance to cope with their medical problems. Yet, even though, an estimated 30 states recognize some form of medical marijuana, it remains a Schedule I drug and, thus, not legal under the federal Controlled Substances Act. While marijuana does not carry the morbidity and mortality profile of the opioids, we should want patients to willingly disclose their use of this substance to their health care providers without fear of social or legal repercussions.

I rarely hear or read about concern about the harm to the patient. Instead, I hear concern for the convenience of the delivery system, a concern that creates an adversarial relationship between patient and practitioner rather than respect for and trust from the patient. What appears to underlie the argument for administrative efficiency and systems needs is distrust of the patient, if not contempt for the patient.

Now is the time to welcome people with substance use disorders into the health care delivery system, not with the demand that such individuals concede their agency, dignity and privacy to the administrative convenience of the health care delivery system, but with the old adage of "First, do no harm."

Distrust and Contempt for people with substance use disorders has led to distortions and misinterpretation of 42 CFR Part 2. Emergency room clinicians argue that a patient with an opioid use disorder comes into the ED following an overdose and is unresponsive, 42 CFR part 2 keeps them from getting lifesaving information. Not true, 42 CFR Part 2 allows those emergency room clinicians to access Part 2 protected information kept either by a health information exchange or a substance use disorder treatment program in order to treat the patient in the emergency status.

Internists may argue that it is critical not to prescribe an opioid to an opioid dependent patient who is on methadone. However, they don't establish that asking the patient about their methadone treatment is ineffective. Furthermore, they don't establish that checking the PDMP is ineffective. If the PDMP is ineffective, they don't argue for improving PDMPs by making them real time and regional.

Family members, concerned about the welfare of their opioid dependent adult relatives, are not precluded from getting information when an unconscious adult is brought into the ER following an opioid overdose. Emergency room clinicians under this situation are not prohibited from sharing information with those concerned family members.

It is argued that 42 CFR Part 2 perpetuates the stigma of addiction. This disingenuous argument ignores the laws, regulations, policies and social view about addiction and substance use disorders. It is not illegal to be depressed. It is not illegal to have diabetes. It is not illegal to have a broken leg. It is illegal to use heroin. It is illegal to use marijuana. People with untreated or active diabetes are protected by the Americans with Disabilities Act. People with untreated or active substance use are not. There are no signs posted at the employment office of employers declaring that the workplace is a hypertension free workplace and that all new applicants will have their blood pressure checked; there are no signs saying that anyone with evidence of hypertension shall be denied employment.

The Department of Health and Human Services has already moved to accommodate the modernization of 42 CFR Part 2 through two rounds of rulemaking, including a 2017 Final Rule and a 2018 Final Rule. However, the EHR community and a number of health systems remain restless, impatient and intolerant of those with substance use disorders, suggesting that information sharing is more important than the people about whom that information is shared. Thus, the regulatory efforts to allow patient to provide a general disclosure for substance use disorder information, to offer some flexibility in transmitting substance use data electronically, and to clarify the circumstances in which providers can disclose patient information to contractors and subcontractors for payment and healthcare operations is not enough. The critics of 42 CFR seek to expose those with substance use disorders who seek treatment, making the exercise of treatment a dangerous proposition.

Patient Attitudes toward Treatment

We spend millions of dollars collecting information about the substance use patterns of people in the US. Perhaps we should be concerned about the reality that 89% of people, who meet criteria for needing substance use disorder treatment, did not receive such treatment.^{vi}

Of the 28.6 million people who misused illicit drugs and the 65 million people who were binge drinkers in the past month, only 3.8 million people received treatment in the past year. Of course, mere use does not equate with dependence or needing treatment. However, NSDUH data indicate that over 20 million people 12 or older met criteria for a substance use disorder in the past year in 2016, with 2.1 million meeting criteria for an opioid use disorder.

What is equally interesting is that of the people who met criteria for needing treatment and did not receive treatment, 95.5% perceived no need for treatment. In short, 18.7 million people needed but did not receive treatment; of these, 17.9 million perceived no need for treatment.

Now comes the critics of 42 CFR Part 2, under the flag of bringing integrated treatment to those in need, claiming that it is 42 CFR Part 2 that operates as a barrier to effective and efficient treatment of opioid use disorders, claiming that there is no need for special concerns about substance use disorders, today, never mentioning how they will explain to those actually seeking treatment and those in need of treatment the ramifications of attenuating 42 CFR Part 2.

Changing 42 CFR Part 2 and the Response of Substance Users

It is important to recognize that 42 CFR Part 2 does not apply to most clinicians or most clinical settings. In fact, 42 CFR Part 2 only applies to programs that hold themselves out “as providing, and provides, alcohol or drug abuse diagnosis treatment, referral for treatment or prevention.” Of course, 42 CFR Part 2 governs substance use disorder patient records for those patients who receive, diagnosis, referral or treatment from (a) an identified unit of a general medical facility that holds itself out as providing, and provides alcohol or drug use disorder diagnosis, treatment or referral for treatment or (b) medical personnel or other staff in the general medical care facility whose primary function is to provide those services.

So, it is the patient records of a substance use disorder program (which includes the substance use patient records clinicians who hold themselves out as treating people with substance use disorders in even in non-specialty settings), that are controlled by 42 CFR Part 2. This creates a responsibility for the substance use disorder program to explain to the patient the meaning of confidentiality as it applies to information disclosed to the treatment program.

For the millions of people whose substance use does not meet criteria for protection under 42 CFR Part 2, HIPAA may control. However, HIPAA only controls those health care providers, such as doctors, clinics, psychologists, dentists, chiropractors, nursing homes, or pharmacists that transmit any information in an electronic form in connection with a transaction for which DHHS has adopted a standard. HIPAA’s covered entity standard also applies to health plans and health care clearinghouses. As broad as this covered entity standard is, it does not cover the substance use disorder treatment landscape.

Those seeking changes in 42 USC §290-dd may be attempting to reshape the SUD treatment landscape and to increase the medicalization of SUD treatment. According to data collected by the Substance Abuse and Mental Health Services Administration, private non-profit organizations operated 53 percent of all facilities in its data base and were treating 49 percent of all clients; in addition, private for-profit organizations operated 35 percent of all facilities and were treating 39 percent of all clients. While the focus on opioids is indeed important, the reality is that opioids are not the primary substance treated by SUD treatment facilities. The medium number of clients treated

by non-opioid treating programs in 2016 was 34. In fact, looking at *Opioid treatment programs* certified by SAMHSA for the provision of medication-assisted therapy with methadone and/or buprenorphine, only 8 to 9 percent of all facilities between 2006 and 2016 fit this category. Nevertheless, it is true that the proportion of all clients receiving methadone from any of the over 14,000 programs in the SAMHSA data base ranged from 23% to 30% in period 2006 to 2016; a large minority of patients in SUD treatment, but still a minority of patients.

The dominant forms of therapy provided in SUD treatment are behavioral, not medication oriented. Such treatments as generic substance abuse counseling, relapse prevention, cognitive behavioral therapy, motivational interviewing, anger management, trauma related counseling, 12-step facilitation, dialectical behavioral therapy, rational emotive therapy and other behavioral interventions are the norm.

Furthermore, while 89 percent of the over 14,000 SUD facilities accepted cash or self-payment, only 68% accepted private health insurance, 62% accepted Medicaid and only 34% accepted Medicare. However, with the advent of the Patient Protection and Affordable Care Act and parity laws, there is a push to increase reimbursement opportunities by some. Thus, eliminating the protections of 42 CFR part 2 from current spectrum of SUD treatment facilities, larger, more technology savvy treatment programs would be able to exert greater influence in the SUD treatment market, consolidate business practices and decrease competition. Whether better care would be enhanced is a matter for time to tell. Whether costs would actually rise over time with decreased completion would also be a matter for observation. The ethical question remains, should the privacy of the vulnerable be sacrificed in the service of market dynamics?

We must keep in mind that that HIPAA regulations allow for unconsented disclosure of patient information for, among other things, healthcare operations.

Healthcare operations include:

- Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance)
- Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;
- Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies

- Business management and general administrative activities of the entity, including, but not limited to:
 - (i) Management activities relating to implementation of and compliance with the requirements of this subchapter;
 - (ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.
 - (iii) Resolution of internal grievances;
 - (iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and
 - (v) Consistent with the applicable requirements of § 164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.

Do non-42 CFR Part 2 covered providers explain the width and depth of the health care operations provision under HIPAA? Would patients exempted from 42 CFR Part 2 protections feel that disclosing histories of substance use is wise under HIPAA, even if experimental or rare use of psychoactive substances is involved? Would a patient experiencing a co-occurring disorder of trust and substance use feel comforted knowing that her personal information could be disclosed to the broad spectrum of entities covered under the healthcare operations rubric, especially in small communities? Much of the literature favoring weakening 42 CFR Part 2 or aligning it much more substantively does not discuss this perspective. Ignoring the autonomy of the patient seems to be the prevalent view, diminishing the identity and integrity of the patient is the net effect.

We can learn a lot about the use and misuse of private information from the Facebook/Analytica problem . There, from 50 to 87 million people reportedly had their private data used for political and financial gain without their knowledge or consent. While the spiral of events started out apparently innocently enough, the proprietary interests in predictive analytics apparently overcame whatever promises and safeguards in place. Given the spectrum of exceptions that are inherent in HIPAA's hospital operations category and given the interest of electronic health record vendors and data brokers in predictive analytics, I believe that HIPAA is an inadequate safeguard for those seeking substance use disorder treatment. .

Moving from HIPAA into those programs whose records are controlled by 42 CFR Part 2, it is clear that those with moderate to severe substance use disorders requiring treatment already do not believe that treatment is warranted. How are we going to encourage them to participate in treatment when we propose to broadcast their personal information through networks of uncertain entities with uncertain purpose?

Unfortunately, there are more serious consequences to voiding the patient's right to consent to the disclosure of sensitive information. The unconsented disclosure of sensitive information

resulting in harm to the patient could easily give rise to suicide, relapse to substance use or overdose; these are tragic events that we should be avoiding rather than pretending that the agency and dignity of the patient have no value and can be compromised for the convenience of EHR vendors, data miners and health care operations. Furthermore, we should recognize that many in substance use disorder treatment are at risk for depression, anxiety and other psychiatric disorders, any of which would be made worse by a breach of trust by substance use disorder treatment programs and the health care delivery system.

The loss of privacy due to unconsented disclosure itself is a harm, perhaps not of the magnitude of the loss of a job or of child custody, but a harm nevertheless. Patients have a legitimate liberty interest in their autonomy, in the right to make decisions about their lives.

Blaming the Vulnerable

The Health Information Technology for Economic and Clinical Health Act (HITECH Act) was enacted under Title XIII of the American Recovery and Reinvestment Act of 2009^{vii}. It provided billions of dollars of incentives to an array of primary care hospitals and to physicians to adopt electronic health records and to promote the exchange of health information. However, that same act essentially ignored the behavioral health community; as a result, there were no incentives available for substance use disorder treatment programs to adopt electronic health records. In addition, there were no incentives to the electronic health record industry to develop software and protocols specific to the behavioral health community and the sensitive information generated by behavioral health providers, information of little use to most primary care providers.

At the time of the unfolding of the HITECH Act, I was the Health Information Technology Strategic Initiative Lead for SAMHSA. My team and I met with a number of software vendors in an effort to address the unique needs of the behavioral health community and to compensate for the omission of behavioral health from the promulgated incentives provided to general medicine. We met with little success.

In order to compensate for excluding behavior health from the incentives, standards, and designs for the evolving EHR systems, information exchanges, and the growing recognition that comprehensive health care required addressing behavioral health, efforts were mounted to promote the fiction that behavioral health patient information contained nothing unique and distinct from the general health care environment.

The notion that all health care information is equivalent runs counter to the historical status recognized in the psychotherapist-patient privilege which was justified on the grounds that some personal health information was more sensitive than others. Discussions of mental health, substance use, and sexual health are inhibited unless the patient has certain reassurances that highly sensitive personal health information would remain between themselves and their health care providers. Indeed, “the prevailing legal default and ethical norm in Western nations both

strongly favor the preservation of patient confidence in the absence of compelling grounds to act otherwise.”^{viii}

As Shenoy and Appel point out, the behavioral health record “often combines data related to the patient’s present symptoms, with a descriptive narrative of the patient’s life experience, including sensitive details of psychological trauma, domestic violence, incarceration, sexual encounters, and substance abuse. Much of this information is of great value to a therapist, but not always of clinical use to many other medical providers. The stigma attached to mental healthcare among some individuals and in certain cultural communities even leads some patients to avoid using their insurance for psychiatric care in order to protect their privacy.”^{ix}

While I was at SAMHSA, we recognized the continued sensitivity of behavioral health information, especially for substance use in particular. As a result, we developed an open source code base through a contract that would provide an inexpensive software application for the behavioral health community.^x Unfortunately, due to complaints of unfair competition we discontinued our efforts.

The HITECH Act with its focus on meaningful use and information exchange did not change the unique character of behavioral health information. As a result, we developed Consent2Share, an open-source data segmentation platform that could be incorporated into existing electronic health records to allow patients to be able to consent to the disclosure of highly sensitive patient information.^{xi}

Consent2Share was developed evolved within the Data Segmentation for Privacy (DS4P) initiative within ONC’s Standards and Interoperability (S&I) Framework to improve the interoperability of the plethora of EHRs containing sensitive information that must be protected. The DS4P initiative met its two goals, which were to: Demonstrate how standards can be used to support current privacy policies, including 42 CFR Part 2, for sharing sensitive health information across organizational boundaries; and develop standards that will enable sensitive electronic health information to flow more freely to authorized users while improving the ability of health IT systems to implement current privacy protection requirements for certain Types of health care data, such as substance use disorder patient records.

Unfortunately, the EHR vendor community felt no need to support data segmentation, dismissing the importance of privacy and confidentiality to patients. Furthermore, health information exchanges chose to ignore the importance of privacy and confidentiality to the patients by choosing not to embrace the utility of data segmentation and patient choice. Naturally, without data segmentation and consent management capacities, substance abuse treatment programs operating under 42 CFR Part 2 requirements have diminished capacities to share information with integrated treatment models that ignore patient choice.

In short, SAMHSA was able to demonstrate that patient choice could be respected without compromising the agility and flexibility of required for integrated information exchange.

However, for matters of mere convenience and low market demand, most EHR vendors and health information exchanges chose to support the less expensive and ethically problematic position of eviscerating 42 CFR Part 2..

Economic Disparities, HIPAA, and Confidentiality

What is remarkable about the industry and provider objections to having patients weigh in on whether their private medical information should be disclosed is the loophole in HIPAA that allows rich people or middle income people to have the right to restrict certain disclosures of protected health information to a health plan where the individual pays out of pocket in full for the health care or service received^{xi}. Health care providers, under HIPAA, are required to include such a statement in the notice of privacy practices provided to the patient. Thus, if a patient is rich and can pay for their own treatment in full, including substance use disorder treatment or if they are middle class and can mortgage their home to pay for their treatment in full, they can avoid disclosing the fact that they are in substance use disorder treatment to their health plan. What is amazing is that providers who are committed to doing no harm are willing to sacrifice poor whites, poor blacks, poor Hispanics, poor Native Americans, poor Alaskan Natives, poor Hawaiians, and poor Asians in the service of a fiction of needing highly sensitive personal information without a patient's consent when they could most likely receive that information simply by asking the patient. In situations where a patient refuses consent to disclose sensitive information to entities outside of the treatment situation, that should be the patient's prerogative.

Given the well documented harm that can happen to a person who is an admitted substance users, it should not be EHR vendors or health systems or substance use disorder treatment providers that should decide what sensitive information should be disclosed outside of a substance use treatment process. Financial ability should not be the deciding factor on whether a person retains a modicum of control over their personal information.

Increased Liability for Substance Use Disorder Treatment Programs

Substance Use Disorder treatment programs have a duty to inform patients about the limits of confidentiality. Given the spectrum of entities under the rubric of healthcare operations, it would be difficult for a substance use disorder treatment program to accomplish this with any degree of effectiveness; this would expose the covered program to liability.

Given that the potential harms from inappropriate disclosure of sensitive information garnered during substance use disorder treatment is real, the disclosure of that information may give rise to legal claims including lawsuits for some form of negligence. Unfortunately, since substance abuse treatment programs will be the entities releasing information under the proposed modified 42 CFR Part 2, undoubtedly they will bear the brunt of the legal burden. Increased liability insurance, legal costs, and impaired reputations will ensue. After all, once sensitive information is released into the entity that releases that information has no control over its distribution. The

question would become should substance abuse treatment program that released the information have known that it contained information that could be used to the detriment of their current or past patient.

Substance use disorder treatment programs caught up in lawsuits may have to withdraw from the treatment marketplace. Treatment programs that close under the weight of malpractice claims will only diminish the number of available treatment slots. The cost of care will also increase as treatment programs have to compensate for the increased administrative costs of doing business.

Conclusion:

We cannot adequately address the current opioid epidemic if we remove the protections that 42 cfr part 2 and its authorizing legislation, 42 USC § 290dd-2, offers. We cannot treat those experiencing substance use disorders with contempt by weakening the protections that they currently have. We cannot treat those who experience substance use disorders as a means to an end, attempting to compensate for the lack of public investment in electronic health records for the behavioral health treatment communities following the HITECH Act's focus on primary care.

Efforts to balance the health information technology requirements of integrated systems while preserving a patient experiencing a substance use disorder's right to consent to the disclosure of their substance use treatment history and sensitive matters subsumed under that history have been thwarted by the EHR industry and by health information exchanges. The claim that it would cost too much is overshadowed by the existence of open source strategies that could accomplish the necessary consent management strategies and by the inherent right of a person to determine what happens to sensitive information.

We have contemporary examples of data misuse and data appropriation. The most immediate and germane is the Facebook/Cambridge Analytica experience. We also have an example of an effort to enlist the cooperation and consent of those who participate in efforts to personalize medicine and to collect data on willing participants in the All of Us NIH project; by respecting the consent of its participants, the NIH hopes to engage 1 million people for a longitudinal study. While the All of Us project may yield strategies to support a comprehensive health record on individuals, it is not clear whether the public will be willing to have comprehensive dossiers of their lives hanging in the electronic cloud for the use of those who gain access. The 10 year time line for this research should provide interested parties critical information about the acceptability of comprehensive health records and the utility of predictive analytics that uses information that goes beyond traditional health related data. However, it is premature to adopt such strategies, and certainly inappropriate to use vulnerable populations such as those with substance use disorders as the pilot target groups to vet such strategies.

Unlike the All of Us project, Congress is being asked to conduct a grand experiment, with those who present for substance use disorder treatment functioning as unwitting test subjects and with no suitable IRB or patient advocate. In this experiment, the presumption is that despite laws, regulations, customs and attitudes to the contrary, no harm will come to those currently protected by 42 USC 290dd-2 with its removal. The burden of this presumption falls not on those with assets and not on those with resources to negotiate, arbitrate or litigate, but on the vulnerable.

Congress is being asked to alter the substance use disorder treatment landscape to favor economic models of care that favor corporate entities over local entities, that benefit regional providers over local providers and that decrease competition rather than increasing competition. Again, by sacrificing the informational and decisional privacy of those with SUDs, aggressive market practices would be encouraged without having protected the very objects of those practices.

Thus, despite the chorus of EHR and data vendors, health systems administrators, SUD treatment providers and others who convince themselves that it is appropriate to impose unnecessary risks of harm on those with substance use disorders seeking treatment, Congress should not abandon the commitment to encourage those in need of treatment to seek treatment by stripping away the limited protections offered under 42 USC § 290dd-2.

ⁱ Bernie Monegain, "Epic CEO Judy Faulkner is standing behind switch from EHRs to 'CHRs'", HealthITNews, October 6, 2017, <http://www.healthcareitnews.com/news/epic-ceo-judy-faulkner-standing-behind-switch-ehrs-chrs>, accessed May 5, 2018

ⁱⁱ Source: SAMHSA, Center for Behavioral Health Statistics and Quality. National Survey on Drug Use and Health, 2016.

ⁱⁱⁱ Satel, Sally, "The Myth of the Roots of the Opioid Crisis", Politico Magazine, February 21, 2018, <https://www.politico.com/magazine/story/2018/02/21/the-myth-of-the-roots-of-the-opioid-crisis-217034>, accessed 02/24/2018

^{iv} Lopez, Karla & Reid, Deborah, "Discrimination Against Patients with Substance Use Disorder Remains Prevalent and Harmful: The Case for 42 CFR Part 2," Health Affairs Blog, April 11, 2017, DOI: 10.1377/hblog20170413.059618, accessed 02/25/2018

^v Hughes, Trevor, "The Evolving image of pot" USA Today, 05/03/2018, 36(162), Pages 1A and 2A

^{vi} Source: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2015 and 2016.

^{vii} The American Recovery and Reinvestment Act of 2009, Public Law 111-5).

^{viii} Shenoy, A and Appel, JM, "Safeguarding Confidentiality in Electronic Health Record", Cambridge Quarterly of Healthcare Ethics (2017), 26, 337-341.

^{ix} Ibid

^x <http://www.feisystems.com/what-we-do/learn-about-wits/why-choose-wits-2/>

^{xi} Department of Health and Human Services: 42 CFR Part 2: Confidentiality of substance use disorder patient records; proposed rule. Federal Register 81:6988-7024, 2016.

^{xii} Department of Health and Human Services, 45 CFR Parts 160 and 164: Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules. Federal Register 78 (17: 5566-5702

Mr. BURGESS. Dr. Clark, thank you for your testimony.
Mr. DeLoss, you are recognized for 5 minutes please.

STATEMENT OF GERALD (JUD) E. DELOSS

Mr. DELOSS. Thank you. My name is Jud DeLoss. I am an attorney with Greensfelder, Hemker and Gale in Chicago, Illinois, and I practice in behavioral health law as well as health information privacy and confidentiality.

I represent several behavior healthcare providers that are governed by 42 CFR Part 2 as well as others that are impacted by those provisions and overly restrictive provisions, including the county of Lake County in Illinois, Nicasa, North Central Behavior Health Systems, Stepping Stones Treatment Center, and TASC. Each of these are large and small providers that have had to come to bear and deal with these provisions and these restrictions.

I am here today on behalf of Netsmart Technologies, a technology partner with the behavioral healthcare space, and I am here today to discuss the protections that are provided under HIPAA as well as under 42 CFR Part 2 and the legislation that we are discussing, as well as those protections that would be not only retained but enhanced by H.R. 3545.

At the outset, I wanted to describe those limitations that would remain in place because of H.R. 3545, as amended. As mentioned earlier, the only change that the bill would provide in terms of disclosures without consent would be with respect to treatment, payment, and healthcare operations. We are not talking about disclosures for legal proceedings. We are not talking about disclosures to law enforcement. We are not talking about disclosures to employers, landlords, marketers, et cetera. We are talking about those limited purposes that are the primary types of opportunities and activities that all sorts of healthcare providers engage in.

In addition, and more specifically to address some of the concerns that were raised about operations and the extent and scope of exchanges of information for healthcare operations under HIPAA, the disclosures allowed under the bill would only be allowed to other covered entities.

Covered entities is a HIPAA-defined term. It includes only healthcare providers, health plans, and healthcare clearinghouses, those entities that assist in the reimbursement process. Only those three entities would be allowed to receive Part 2 information under the bill. It would not be fair to say that this information could be shared with third parties. It would not be fair to say that it could even be shared with business associates, strictly reading the terms of the bill. So we would not open up the exchange of information to third parties that have no business. These are parties that need this information in order to carry out payment, treatment, and healthcare operations.

The bill itself provides substantial protections, in terms of the disclosures for civil, criminal, and administrative proceedings. The bill actually enhances those protections that 42 CFR Part 2 previously had in place. So there are increased and heightened types of protections that are available.

I did in my written comments set forth a lengthy review of the protections that are available under HIPAA, those in terms of the

protections, in terms of legal proceedings, employers, also the impact of the Americans with Disabilities Act if any of this information should happen to get into the wrong hands. SUD is a disability under the ADA and is protected as such, as set forth in my written comments. Landlords and housing agencies would also be governed by HIPAA as well as the ADA. The law enforcement and legal proceedings exceptions under HIPAA are very narrow and very stringently enforced, primarily requiring a court order or patient consent in order for the information to be shared for those purposes.

One of the areas that I did want to address is the inability under the current Part 2 regulations to allow for a patient to make a choice in terms of sharing their information for treatment, payment, or healthcare operations, as defined under this law as well as HIPAA.

In addition, I think it is important to note that if a Part 2 program does not want to share information, this bill and HIPAA, more importantly, would not mandate a disclosure without consent. The SUD treatment program has the opportunity to impose higher or more stringent protections against disclosure, not those simply set forth under HIPAA. So there is a choice not only for patients but also for programs or others that might be concerned about disclosure.

To summarize the impact of the bill, a disclosure for treatment, payment, or healthcare operations can only be made to a covered entity. The covered entity, a healthcare provider, a health plan, or a healthcare clearinghouse—would then be bound by these regulations or this law not to disclose that information to anyone other than another covered entity down the line.

So, in conclusion, I wanted to correct some of the misunderstandings with respect to HIPAA, misunderstandings with respect to the scope and impact of this law, and point out that HIPAA itself over the history of its enforcement has resulted in millions of dollars in fines and penalties, a comprehensive enforcement mechanism, where 42 CFR Part 2 has not. Thank you for your time.

[The prepared statement of Mr. DeLoss follows:]

**Testimony of Gerald (Jud) E. DeLoss
Greensfelder Hemker & Gale P.C.
Chicago, IL**

**Before the House Energy & Commerce Committee
Health Subcommittee**

Improving the Coordination and Quality of Substance Use Disorder Treatment

May 8, 2018

My name is Gerald (Jud) E. DeLoss and I am a partner with the law firm of Greensfelder, Hemker & Gale, P.C. in Chicago, Illinois. I am a health law attorney that focuses on health information privacy and confidentiality and behavioral health law. I have extensive experience with HIPAA and 42 C.F.R. Part 2 (Part 2). I have previously served as the Chair of the Health Information & Technology Practice Group of the American Health Lawyers Association (AHLA) and Chair of the Behavioral Health Task Force of the AHLA. I represent several substance use disorder (SUD) treatment programs covered by Part 2 and other behavioral health provider clients including Lake County, NICASA, North Central Behavioral Health Systems, Stepping Stones Treatment Center, and TASC. I am here today on behalf of Netsmart Technologies, a technology partner to behavioral health, substance use treatment, and post-acute providers nationwide.

I am here today to explain the existing protections under the Health Insurance Portability and Accountability Act of 1996 and the Privacy and Security Regulations promulgated thereunder (jointly "HIPAA") and Part 2 and the protections that would remain in place following

enactment of HR 3545 and HR 3545 as amended. I believe there have been misstatements of the law and the protections they provide. My testimony is intended to provide a correct summary of the law and clear up any misunderstandings of the substantial protections in place for the privacy of SUD patient records.

Limited Impact of HR 3545 on Part 2

At the outset it is important to note that the Bill only modifies uses and disclosures of Part 2 SUD patient information for purposes of “treatment”, “payment”, and “health care operations”, each as defined under HIPAA. The Bill does not reduce or remove Part 2 protections against disclosures to employers, landlords, life insurance companies, or in response to subpoenas or discovery requests. Those disclosures are not “TPO” (Treatment, Payment, and health care Operations) as defined by HIPAA. Those disclosures would still be governed by, and protected by, Part 2.

Furthermore, the amended Bill only allows for disclosure “[t]o a covered entity by a covered entity, or to a covered entity by a [Part 2] program” for purposes of TPO. Under HR 3545, as amended, the only disclosures authorized for TPO would be to covered entities, which under HIPAA only include certain health care providers, health plans, and health care clearinghouses. Disclosures to third parties that are not considered HIPAA covered entities would not be allowed. Employers, landlords, life insurance companies, marketers, and the courts are not covered entities. Disclosure to those entities or individuals would not be allowed under the amended Bill.

The definition of “treatment” under HIPAA would allow for the disclosure of health information to a covered entity or a health care provider. Under HR 3545 as amended, health information cannot be disclosed to a health care provider. The disclosure of health information is only permitted to a covered entity. The definition of “payment” under HIPAA would allow for disclosures to third parties for reimbursement and payment-related purposes. Under HR 3545 as amended, health information cannot be disclosed to third parties unless they are HIPAA covered entities. The definition of “health care operations” encompasses many functions and allows for sharing of health information to a variety of third parties. Under HR 3545 as amended, health information cannot be disclosed to third parties – only covered entities. Because health information may only be disclosed to covered entities under HR 3545 as amended, there is no ability for the information to be shared or re-disclosed by a Part 2 program or covered entity to any other recipient unless the recipient is a covered entity. Covered entities would be bound by HR 3545 as amended, by HIPAA, and could not disclose or re-disclose the health information to any other third party, except for other covered entities.

HR 3545 as amended would also not expressly allow for disclosures to or by HIPAA business associates, which are third parties that carry out distinct operations and tasks for covered entities. Disclosures are only permitted to a covered entity. Part 2 allows for disclosures necessary for operations or similar purposes to contractors or agents of the Part 2 program, which are defined as qualified service organizations.¹ Any such disclosures to the qualified service organizations would need to be carried out utilizing a qualified service organization agreement (QSOA) pursuant to Part 2.

¹ 42 CFR § 2.111.

The proponents of maintaining the old Part 2 configuration argue that the Bill will open the floodgates and “eviscerate” the protections available under the law. However, they fail to mention two critical items. First, the Bill only allows for uses and disclosures for treatment, payment, and health care operations purposes as defined under HIPAA. These types of uses and disclosures are typical in the health care world. For example, when a patient is being admitted to treatment, a Part 2 program will require consent to share information with the patient’s insurance company to coordinate benefits and ensure reimbursement. Part 2 provides that a program need not admit a patient until assurances of reimbursement are in place. These types of disclosures are limited, purposeful, and necessary for our health care system to operate. Second, those disclosures relating to life and disability insurance, family law and custody disputes remain unchanged and under the Bill will still require patient consent or a court order.

Legal Protections Provided by HIPAA

In addition to the limitations on disclosures set forth in HR 3545, HIPAA provides stringent protections against the use of health information by employers, for child custody determinations, and by law enforcement. Like Part 2, HIPAA generally prohibits the disclosure of health information to third parties without patient authorization or court order. The arguments advanced by those who support continuing the existing regulations do not take into consideration the stringent legal protections already available under HIPAA and the robust enforcement of HIPAA that dwarfs the little – to no – enforcement that has been undertaken with respect to Part 2.

Minimum Necessary Protections under HIPAA

Under HIPAA, disclosures of health information for payment and operations purposes must utilize the minimum amount of health information that is required in order for the parties to process and pay for claims or engage in the operation.² Further, providers are required by HIPAA to develop and implement policies and procedures that appropriately limit the use and disclosure of health information to the minimum necessary to accomplish the intended purpose, such as obtaining payment from a health insurer for services rendered.³ These minimum necessary requirements are in place to limit the amount and type of information shared for non-treatment contexts, reducing the likelihood and impact of any breach or loss of data.

Employment Protections under HIPAA and ADA

As explained above, the disclosure of health information to an employer would not be considered part of TPO. Any disclosure to an employer under HIPAA would be governed by specific regulations that generally prohibit the disclosure of health information to an employer without an authorization or court order. Under HIPAA, the health care provider must provide the health care service to the individual at the request of his or her employer or as a member of the employer's workforce. The health care service provided must be for medical surveillance of the workplace or an evaluation to determine whether the individual has a work-related injury. Further, the employer must have a duty under the Occupational Safety and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA), or the requirements of a similar State law, to keep records on such information.⁴ Even in that limited situation, the employer must request

² 45 CFR §§ 164.506(e) and 164.502(b).

³ 45 CFR § 164.514(d)(3).

⁴ 45 CFR § 164.512(b)(1).

the evaluation, and the healthcare provider must provide advance written notice to the patient.⁵ In addition, employers who sponsor group health plans are prohibited from using or disclosing health information for employment-related decisions or any other benefit decision.⁶

Generally, under the Americans with Disabilities Act (“ADA”), an employee whose poor performance or conduct is attributable to an SUD may be entitled to a reasonable accommodation and the employer cannot discriminate against the employee based upon the SUD, which is considered a disability. The ADA will not allow for an employee to engage in the use of substances while at work, if the employer prohibited such illegal use. As a result, an employer does not violate the ADA by uniformly enforcing its rules prohibiting employees from illegally using drugs on the job or in the workplace.⁷ However, “qualified individuals” under the ADA include those individuals:

- Who have been successfully rehabilitated and who are no longer currently engaged in the illegal use of drugs⁸
- Who are currently participating in a rehabilitation program and are no longer currently engaging in the illegal use of drugs⁹
- Who are regarded, erroneously, as currently illegally using drugs¹⁰

An individual suffering from an SUD may be protected under the ADA because the addiction may be considered a substantially limiting impairment.¹¹

⁵ Id.

⁶ 45 CFR § 164.504(f)(2)(ii)(C). In addition, the group health plan documents must restrict uses or disclosures to those specifically permitted under 45 CFR § 164.504(f). See 45 CFR § 164.504(f)(1).

⁷ EEOC Technical Assistance Manual on the ADA § 8.3.

⁸ 42 U.S.C. § 12114(b) (1994).

⁹ 42 U.S.C. § 12114(b) (1994). A “rehabilitation program” may include inpatient, outpatient, or employee assistance programs, or recognized self-help programs such as Narcotics Anonymous. EEOC Technical Assistance Manual on the ADA § 8.5.

¹⁰ 42 U.S.C. § 12114(b).

HIPAA and ADA Protections for Housing

Part 2 does not allow for the disclosure of SUD treatment information to a landlord or housing agency without patient consent or a court order. HR 3545 would not alter those protections. HIPAA generally does not allow for the disclosure of health information to a landlord or housing agency without patient authorization or a court order. However, HIPAA would allow for the disclosure of limited types of health information to a landlord or housing agency only if it were a necessary part of the patient's treatment – such as supportive housing.

Generally, under the ADA, a landlord or agency would not be able to discriminate against an individual with a disability and would be required to provide reasonable accommodations for him or her in housing. If an individual is suffering from an SUD, the ADA protections would generally apply and prohibit such discrimination as explained in the section on Employment Protections under HIPAA, set forth above.

HIPAA Protections in Legal Proceedings

Disclosures of patient information where the covered entity is not a party are not considered part of treatment, payment, and health care operations and would not be permitted under HR 3545. The Bill as amended also dramatically increases the protections for SUD information in any criminal prosecution or civil action. Under the HR 3545, a court order or patient consent would be required before:

- Entering the information into evidence in a civil or criminal proceeding
- Forming the part of the record or taken into account in a proceeding before a Federal agency

¹¹ See EEOC Technical Assistance Manual on the ADA § 8.5.

- Being used to conduct an investigation of a plaintiff
- Being used in any application for a warrant

HIPAA also imposes specific requirements for the use or disclosure of health information in legal proceedings, including child custody and family court cases. Where a covered entity is a party to a legal proceeding, such as a plaintiff or defendant, the covered entity may use or disclose health information for purposes of the litigation as part of its health care operations.¹² Where the covered entity is not a party – such as when the patient is involved in legal action with a different party, health information may only be produced in court pursuant to an order by the court or patient authorization. Under HIPAA, health information can only be produced during discovery pursuant to a court order, patient authorization or in accordance with other privacy protections. All subpoenas for records must be accompanied by notice to the patient with opportunity to object, or proof that the litigant sought a Qualified Protective Order.¹³

HIPAA Protections Relating to Law Enforcement

Disclosures to law enforcement are not considered part of TPO, and HR 3545 would not alter the current Part 2 protections and prohibitions in place against those disclosures. In addition, the vast majority of disclosures to law enforcement under HIPAA require patient authorization, a crime, emergency, threat to public health/safety, or court involvement. Similar to Part 2, generally under HIPAA a disclosure to law enforcement requires patient authorization (in limited circumstances) or a court order. HIPAA only permits the following limited disclosures to law enforcement:

¹² 45 CFR § 164.501.

¹³ 45 CFR § 164.512(e).

- By an employee of a provider about the identity of a suspect who had engaged in a criminal act against the employee. Only limited demographic and related information may be disclosed for this purpose.¹⁴
- To report abuse, neglect or domestic violence¹⁵, similar to Part 2's allowance for reporting of child abuse.¹⁶
- Where required by law, in limited situations such as reporting gunshot wounds or other injuries.¹⁷
- Under a grand jury subpoena,¹⁸ or for an administrative request, civil or investigative demand or similar process, provided the information sought is relevant and material; specific and limited in scope, and de-identified information could not reasonably be utilized.¹⁹
- Certain identifying information to identify or locate a suspect, fugitive, material witness or missing person.²⁰
- If the patient is a victim, then after consent or in the event of an emergency, to law enforcement to assist the victim (but never to be used against the patient).²¹
- When the patient has died and the death may have been the result of criminal activity.²²
- In the event of a crime on the premises (virtually identical to Part 2's exception for a crime on program premises).²³

¹⁴ 45 CFR § 164.502(j)(2).

¹⁵ 45 CFR §§ 164.512(b)(1) and 164.512(c).

¹⁶ 42 CFR § 2.12(c)(6).

¹⁷ 45 CFR § 164.512(f)(1).

¹⁸ 45 CFR § 164.512(f)(1).

¹⁹ 45 CFR § 164.512(f)(1).

²⁰ 45 CFR § 164.512(f)(2).

²¹ 45 CFR § 164.512(f)(3).

²² 45 CFR § 164.512(f)(4).

²³ 45 CFR § 164.512(f)(5).

- In an emergency not on the premises, where the emergency medical provider needs to disclose the information to alert law enforcement of a crime.²⁴
- To avert a serious threat to health or safety of the patient or others (“Duty to Warn” exception).²⁵
- In limited circumstances where necessary to apprehend an individual participating in a violent crime or who has escaped from prison.²⁶
- To provide healthcare to inmates and those in custody.²⁷

Part 2 Limits the Sharing of SUD Treatment Information – Even Within the Same Organization

A major flaw in the current Part 2 regulations is the prohibition on re-disclosing SUD treatment information without another consent, court order, or exception under the regulations. Under the newly-created general designation process promulgated under the Final Part 2 regulations, a patient may consent to share his or her information with an intermediary, such as a health information exchange (HIE), accountable care organization (ACO), or other integrated care setting which may then share the information with all members of the integrated care model that possess a treating provider relationship with the patient.²⁸ However, a recipient of SUD treatment information within an HIE or ACO with a treating provider relationship would not be able to re-disclose that information to another participant in the same HIE or ACO without additional patient consent, rendering the new process unusable in practice.

²⁴ 45 CFR § 164.512(f)(6).

²⁵ 45 CFR § 164.512(j).

²⁶ 45 CFR §§ 164.512(j)(1), (2).

²⁷ 45 CFR § 164.512(k)(5). See generally,

http://www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_for_law_enforcement_purposes/505.html.

²⁸ 42 CFR § 2.31(a)(4)(iii)(B).

First, the Substance Abuse and Mental Health Services Administration (SAMHSA) has issued guidance that establishes that “treating providers” in an HIE, ACO, or other integrated care setting cannot directly share SUD treatment information directly with other treating providers inside or outside the integrated setting.²⁹

Under prior versions of Part 2 (pre-2017), an organization with mental health and SUD treatment facilities and clinicians could address the legal restrictions on sharing SUD information by using a qualified service organization agreement (QSOA) between the Part 2 program and the mental health department to share Part 2 information without client consent. The sharing of information would be allowed because it was considered to be for medical services provided by the mental health department to the Part 2 program, consistent with the terms of Part 2 and the QSOA provisions.

The Final Part 2 Rule changes the section addressing QSOAs to no longer allow for disclosures for medical purposes. This revision removes the ability of an organization to utilize a QSOA to efficiently share Part 2 information between a SUD department and other departments which are not covered by Part 2 but are part of the same organization. Under the existing Part 2 regulations, a program would need to obtain individual patient consent for it to share patient information within the same organization that is treating the patient for other conditions – both mental and physical.

²⁹ 82 Fed. Reg. 6052, 6081 (January 18, 2017).

Patient and Program Choice

The adoption of the HIPAA standards for TPO would not mandate that Part 2 programs disclose SUD treatment information to third parties. In fact, under HIPAA, a covered entity may impose additional and more stringent protections of health information, above and beyond what HIPAA requires. It is widely-known that HIPAA only mandates disclosures in two situations: (1) to the patient or individual who is the subject of the information and has requested access; and (2) to the Office for Civil Rights, Department of Health and Human Services (OCR) in response to an investigation or enforcement action (Note that in this latter situation, HR 3545 as amended would prohibit a disclosure to OCR as it would not be a disclosure to a covered entity). A Part 2 program would not have to disclose patient information without consent if it chose to continue to require it. As is the case today, Part 2 programs would still have the ability under law to control who receives that information and how with strict penalties still in place for non-compliance. Opponents of the Bill argue that if HR 3545 is adopted, Part 2 programs would freely share patient data without limitation and without due consideration for confidentiality. This view assumes that Part 2 programs will engage in dishonest and unethical acts with patient information and that to date, they have only acted with honesty and integrity because Part 2 prevented them from deviating. Having dealt with Part 2 programs and clinicians, I know that nothing could be further from the truth and that Part 2 providers are honest, trustworthy, and act with integrity.

HIPAA provides substantial protections for health information. The adoption of HIPAA standards relating only to disclosures to covered entities for TPO will allow for patient choice. Whether and to what extent a patient desires to share any health information, particularly SUD

treatment information, is a decision that should lie with the patient and not with the Part 2 program, the Substance Abuse and Mental Health Services Administration (SAMHSA) or the healthcare system.

Today, a patient cannot share their SUD treatment information freely in an HIE or ACO because consent and re-disclosure requirements imposed under Part 2 are too restrictive. Part 2 now contains a consent process that allows an intermediary, such as an HIE or ACO, to share information with those participants that have a treating provider relationship with the patient.³⁰

However, that consent process under Part 2 does not allow participants with a treating provider relationship to share the SUD treatment information with each other directly, and does not allow participants with a treating provider relationship to share SUD treatment information with another healthcare provider, such as the patient's primary care physician, if that physician is not a participant in the HIE or ACO. This artificial barrier prevents fully-integrated healthcare for patients wishing to include their SUD treatment information.

Any person, whether suffering from mental illness, diabetes, a SUD or multiple co-occurring conditions, should be able to share his or her health information with their healthcare providers, regardless of diagnosis, if they so desire. If someone does not wish to share their data, they should have a clear option to either opt-out or not opt-in to sharing that information.

Under HIPAA, a patient can request a restriction on use or disclosure of health information for TPO. The covered entity would determine whether it can and will accept the restriction and once

³⁰ 42 CFR § 2.31(a)(4)(iii)(B)(3).

it agrees, the information must be maintained in accordance with that restriction.³¹ The covered entity does not need to accept the restriction unless the patient pays for an item or service out of pocket and requests that the provider not share information about that treatment or service with his or her health insurer, in which case the provider must not disclose it to the insurer.³²

The ability to share the information for treatment, payment and healthcare operations under HR 3545 does not mean that Part 2 programs will be sharing SUD information without due concern for patient confidentiality. The Bill will allow for Part 2 programs and their patients to decide whether to share SUD treatment information.

Currently under Part 2, all programs, including those in integrated care settings – HIEs, ACOs and Integrated Health Homes – are required to segment out SUD treatment information from the health record to prevent its disclosure to other treating providers not in the same integrated care setting. Data segmentation is complex and expensive to implement. While some EHR providers, including Netsmart, can segment data, most EHR and HIE providers would need to modify their systems to do so. The cost of modifying all these systems would be significant – well beyond the amount estimated by SAMHSA. Even if mandated from the Federal level, we estimate that a robust system capable of supporting this type of segmented data would not be available for 7-10 more years. In the meantime, most providers and HIEs do not have the resources to modify their systems to support it.

³¹ 45 CFR § 164.522.

³² 45 CFR § 164.522(a)(1).

Breach Protections

The Bill as amended would apply the breach notification requirements of HIPAA to all Part 2 programs. The breach notification provisions will provide additional compliance and enforcement opportunities to ensure patient information is protected.

Under HIPAA, a covered entity must notify OCR if it discovers a breach of unsecured protected health information.³³ If a breach of unsecured protected health information affects 500 or more individuals, a covered entity must notify OCR of the breach without unreasonable delay and in no case later than 60 calendar days from the discovery of the breach.³⁴ If a breach of unsecured protected health information affects fewer than 500 individuals, a covered entity must notify OCR of the breach within 60 days of the end of the calendar year in which the breach was discovered.³⁵

Covered entities must notify individuals following the discovery of a breach. The individual notifications must be provided promptly and no later than 60 days following the discovery of a breach. The notice must include a brief description of the breach, a description of the types of information that were involved in the breach, the steps affected individuals should take to protect themselves from potential harm, a brief description of what the covered entity is doing to investigate the breach, mitigate the harm, and prevent further breaches, as well as contact information for the covered entity.³⁶

³³ 45 C.F.R. § 164.408.

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

These protections will be incorporated into Part 2 under the Bill as amended. The notification requirements of HIPAA already provide more protections and assurance of compliance than existing Part 2 requirements.

HIPAA Enforcement

Since the compliance date of the Privacy Rule in April 2003, the Department of Health and Human Services Office for Civil Rights (OCR) has received over 173,426 HIPAA complaints and has initiated over 871 compliance reviews.³⁷ OCR has resolved ninety-seven percent of these cases (168,780).³⁸

OCR has investigated and resolved over 25,695 cases by requiring changes in privacy practices and corrective actions by, or providing technical assistance to, HIPAA covered entities and their business associates. Corrective actions obtained by OCR from these entities have resulted in change that is systemic and that affects all the individuals they serve. OCR has successfully enforced the HIPAA Rules by applying corrective measures in all cases where an investigation indicates noncompliance by the covered entity or their business associate. To date, OCR has settled or imposed a civil money penalty in 53 cases resulting in a total dollar amount of \$75,229,182.00.³⁹

OCR has aggressively audited, investigated, penalized, and enforced the privacy and security requirements under HIPAA.

³⁷ <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/data/enforcement-highlights/index.html>, last accessed 5/3/18.

³⁸ *Id.*

³⁹ *Id.*

As of this writing, the author is unaware of a single substantive enforcement action taken under Part 2. Although the Final Part 2 Rule will increase enforcement opportunities, historically it has been HIPAA that has been enforced more stringently and more effectively than Part 2.

Conclusion

HR 3545 as amended will allow for the legitimate sharing of health information for specific treatment, payment, and health care operations purposes. The sharing of the information will only be with covered entities – those individuals and organizations that are bound by HIPAA and must have policies and procedures in place, training for their workforce, and agreements that protect the use or disclosure of all health information. Those entities could only re-disclose SUD information to another covered entity. The substantial protections and new rights and antidiscrimination provisions in HR 3545 as amended address the concerns raised by opponents and further the goal of effective, timely, and quality integrated care.

Mr. BURGESS. Thank you, Mr. DeLoss. And I want to thank all of our witnesses for testifying before us today.

And we are going to move into the question portion of the hearing. I am going to begin that portion by yielding my time to the gentleman from Oklahoma, Mr. Mullin, 5 minutes for your questions.

Mr. MULLIN. Thank you, Mr. Chairman.

And thank you for all of our witnesses that are here today.

Since I only have 5 minutes, I am going to get right into it.

Dr. Clark, are all substance disorder providers subject to 42 CFR Part 2?

Dr. CLARK. If they are federally assisted.

Mr. MULLIN. The answer is, are they all subject to it?

Dr. CLARK. Only if they are federally assisted.

Mr. MULLIN. So the answer to that is no. And they are not all Federal assistance, because the VA doesn't fall underneath Part 2. The VA doesn't fall underneath it, and they are Federal assistance.

Dr. CLARK. The VA has its own 38 CFR.

Mr. MULLIN. The question was, do all of them fall underneath 42 CFR?

Dr. CLARK. No.

Mr. MULLIN. So is there evidence that patients that don't fall underneath it, has that been abused?

Dr. CLARK. Well, you invoked the VA. I used to work for the VA, spent 14 years—

Mr. MULLIN. Sir, I said, is there evidence that people that do not fall underneath 42 CFR Part 2, is there evidence that their medical records are being abused and they are being discriminated against?

Dr. CLARK. I couldn't say that there is.

Mr. MULLIN. Because it is no.

Part 2, how many times has it been tried, violators? People that violated Part 2, how many times has it been tried?

Dr. CLARK. It is not a heavily litigated area.

Mr. MULLIN. Heavily. It has never been. It has never been.

Dr. CLARK. It has been litigated, sir.

Mr. MULLIN. No, it is exactly zero. I have the information right here. And I know that you can give your opinion, but we are dealing with facts here.

Dr. CLARK. OK, I am a lawyer also, sir. And so from 1970—

Mr. MULLIN. No, no, hang on, it is my time. You said a lot in your 5 minutes. I am just pointing out holes in it.

Now, underneath HIPAA, how many times has it been tried? 173,426 times since 2003. Because Part 2 is unenforceable. They can't comply with it. It is only a \$50 penalty.

You start talking about discrimination. In your testimony, you said that the harms to which a person who admits to substance use may suffer includes the loss of employment, the loss of housing, the loss of child custody, the loss of benefits, stigma, discrimination, the loss of privacy, and the loss of anonymity.

How would that actually work? How would you do this legally underneath the system that is there? Is that just an assumption that you are making? Because there is no legal way to actually do that. There are laws already that protect the individual from that. Is that not true?

Dr. CLARK. No, that is not true for—

Mr. MULLIN. Oh, there isn't? Well, you are an attorney, so explain that to me then.

Dr. CLARK. OK. If I am an active substance user, the ADA does not protect me. The Americans with Disabilities Act does not protect an active substance user who is using illegal substances.

Mr. MULLIN. So there are not any laws that protect people from being discriminated against? Because as a person that also has several property companies, I can't use that information to deny someone from housing. As an employer, I can't use that to deny someone for employment, because it would be discriminating. So you are making an assumption here that is actually not accurate.

Now, you also said in your testimony that you are comparing my bill to the Cambridge Analytica/Facebook issue. How is adding antidiscrimination language and extra protection for patient information comparable to the Facebook data scrubbing?

Dr. CLARK. The issue is data scrubbing. Just as you said, the healthcare—

Mr. MULLIN. I am not talking about data scrubbing here.

Dr. CLARK. We are talking about data scrubbing.

Mr. MULLIN. Who is scrubbing it?

Dr. CLARK. When you are talking about electronic health records, you are talking about predictive analytics, and you are talking about data scrubbing.

Mr. MULLIN. Yes. But we already show that the only people this covers is essentially Medicare and Medicaid. And when we get into the situation that private payers in VA, that they are not being discriminated against, why is this such a big issue now?

Because you are making a lot of assumptions. And, sir, I know that you are able to make the assumptions. But we are also dealing with people's lives.

Is there anybody in here that doesn't get touched by—this has touched me three different times, and I take it very personal. And when people come here and they want to give their opinion, and it is not based on facts, it really bothers me. I am sure you are a very smart individual. Sir, I am sure you are a very smart individual, but you are coming in here, and you are just giving your opinion.

Dr. CLARK. Well, you wanted to know about, for instance, unemployment. The ADA does not apply to active substance users. That is a fact. That is not an opinion. So I can't help you with that.

And, in fact, there are rules historically for housing. HUD used to have, and still does have, rules that allow you to discriminate against people who—

Mr. MULLIN. What are those rules? What are those rules?

And, besides, by the way, you just mentioned another Federal agency. And this is about Federal protection for those on Medicare and Medicaid. We are talking about the private sector, because that is what you are making comparisons to.

And, sir, I am very serious about trying to protect people's lives here. And I know you are too. But we got to make sure that we are dealing on the same page. And while I respect your ability to give your opinion, I completely disrespect your testimony because it is based on opinion, not facts.

With that, I yield back.

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

The chair recognizes the gentleman, the ranking member of the subcommittee, 5 minutes for questions, please.

Mr. GREEN. Thank you, Mr. Chairman.

I want to thank our witnesses for being here, because this is something that is really important because we have chemical addictions so rampant that we are changing law that provides more protection for someone chemically instead of just a mental or anything else.

And, Dr. Clark, you have read the language in the bill. Is there any way that, as a lawyer, you could suggest other language than what is in the bill that would have some protection there that we still do? Because a number of us have concerns about this legislation. But I also know, under HIPAA, this is much stronger than anything HIPAA has, the bill does.

Is there anything you would suggest that would feel more comfortable to both you but also to Ms. Metcalf? Because I understand, we all have relatives who really don't want to tell us what their issues are. And they have some right to privacy no matter what they have.

Dr. CLARK. Well, the first thing, as a physician, if your patient doesn't trust you, they won't disclose information to you. That is what gets lost in this.

We know that people with mild to moderate conditions that lead to severe conditions don't talk about their substance use. So, if you want to save lives, you do it upstream. You don't wait until the problem is so severe that it is actually quite transparent to everybody in the room. And that is what actually happens. People hide their substance use, and there is no record of it.

All the stories that you hear, how horrible they are and how tragic they are, the stories are that the people do not feel comfortable disclosing what is going on. So 90 percent of the people who meet criteria for an SUD don't discuss that with the healthcare delivery system.

Now, the question is, is there any way to address this? The healthcare operations component of HIPAA, as I said in my 5 minutes, it is so broad that it gives rise to—when you start explaining that to people, if you can explain it to them clearly, they will understand that they really have no privacy, and so they will keep their mouths shut.

And by the time you are aware that their problems are so severe that they need intervention, it will become transparent. Your committee has dealt with physicians who have misused prescribing. We now know we have enough data of using prescription drug monitoring programs and other strategies that we can track what is happening with patients. So it won't be those people for whom prescriptions are written, because now we can track those. We can enhance electronic health records.

There are models being proposed. The gentleman to my left, Mr. DeLoss, talked about working with the her community. I also work—when I was with SAMHSA, worked with the her community. We had developed bridges to allow for patient consent, but the

her community was not interested because there was not enough money in it for them. They had an opportunity earlier in this whole discussion when the HITECH Act was passed, they just were not interested.

I met with the major providers. They were not interested. This was small potatoes as far as they are concerned. Get rid of healthcare operations, and you have got a different bill that at least will allow people to address—

Mr. GREEN. Well, thank you.

And, Ms. Metcalf, I understand from where you are coming from. But we still have this issue that Mr. McKee said that, even as a family member, he wasn't getting information from his brother. And that happens whereas I don't know if HIPAA could be a change. The only thing I could say, as a lawyer, is that a family member gets a guardianship so you take over that oversight. And guardianships are tougher, because it is harder to get. But as a family, that is the only legal thing.

Mr. DeLoss, do you have any other options that a family member could use?

Mr. DELOSS. In order to share the information, correct. The current bill would not allow that direct sharing. It would allow for the sharing only to a covered entity.

As far as an alternative to share that information in that precise situation, there could be an anonymized disclosure. In order to avoid some of the implications of Part 2 that are overly restrictive and engage in a process to warn others. There is no duty to warn exception under Part 2. So, if there is an issue where someone should threaten to kill someone, they cannot inform police or anyone else under Part 2.

So what Part 2 programs have done is to anonymize that disclosure, disclose it in such a way that does not indicate where it came from or who it is about specifically with respect to their SUD diagnosis.

So these are workarounds that SUD programs governed by Part 2 must undertake in order to avoid these overly restrictive requirements.

Mr. GREEN. Thank you, Mr. Chairman. I know I am out of time.

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

The chair recognizes the gentleman from Oregon, the chairman of the full committee, Mr. Walden.

Mr. WALDEN. Thank you, Mr. Chairman. And thanks to our panelists for being here as we work on this very difficult issue.

I have heard from my hospitals in Oregon who are very supportive of what we are trying to do here. They say this regulation makes it very difficult or prevents the sharing of patient information necessary to deliver effective and coordinated care. This conflict forces hospitals and health systems now to go to extraordinary lengths to deliver needed care.

In our panel with the survivors, many of whom lost children, this was an issue they raised. The lack of ability to know what is going on in their kids' lives. We have heard it from others about substance use disorder treatment. I know these are separate issues.

But, Mr. Gardner, patients with substance use disorder who are currently using illegal drugs, I understand to be the case are not protected by civil rights laws, such as ADA, that protect those with disabilities from employment, housing, and other types of discrimination. The legislation before us includes antidiscrimination language, does it not?

Mr. GARDNER. That is my understanding.

Mr. WALDEN. And regarding protections for patients seeking substance use disorder treatment, does this language strengthen or does it weaken the statute behind 42 CFR Part 2?

Mr. GARDNER. Thank you for the question, chairman.

My understanding is that, although I am not a lawyer, it would strengthen protections for the use of such information in criminal proceedings, which I think is important.

Mr. WALDEN. Well, that is my understanding. And like you, I am not burdened by a law degree. I just try and do public policy. No offense to those who have passed the bar or stopped in there.

Mr. DeLoss, can you identify the legal mechanisms, if any, in this legislation for substance use disorder treatment records to get into the hands of landlords, law enforcement, and civil and court judges without patient consent or a court order?

Mr. DELOSS. No, there is no possible way to do so under this bill. This bill would prohibit those types of disclosures. The disclosures would only be allowed for purposes of treatment payment operations. Does not include any of those third parties. Those third parties do not fall under the definition of a HIPAA-covered entity, so those third parties would not receive that information. Only certain healthcare providers, not all healthcare providers, are governed by HIPAA. So not all healthcare providers would receive the Part 2 information under this bill. They would be restricted, health plans and health care clearinghouses.

So, in addition to those restrictions against the third parties receiving the information, as you have mentioned, there are heightened antidiscrimination provisions.

Mr. WALDEN. Heightened. Stronger. More than exists today

Mr. DELOSS. Much more stringent, much more protective than current Part 2 protections with respect to antidiscrimination in housing, in employment. Protections against use of any of this information in any kind of proceeding, civil, criminal, or administrative, all of this is far greater in terms of its protections than what Part 2 currently provides.

Mr. WALDEN. So, if it can't be used to discriminate against you in your employment, your housing, any criminal case, anything else, what is the only thing it can be used for?

Mr. DELOSS. Well, it would primarily be used for treatment. As we have heard, coordinating care is the biggest issue that these SUD programs are facing, is trying to integrate that care with HIEs, health information exchanges, accountable care organizations, any kind of integrated healthcare environment under the Medicaid program. All of this requires coordination.

And with respect to the ability to share that information, the issues that have arisen are so complex in terms of trying to comply with Part 2 that these independent entities, these ACOs, these HIEs, these are not vendors. These are entities that are created to

coordinate care. They have refused to allow Part 2 information to be included.

I have worked with several HIEs or healthcare networks that have refused to include this information exactly because of the Part 2 restrictions. And despite many efforts to create workarounds or ways to address these issues will not include that information.

Mr. WALDEN. So I was in a federally qualified healthcare facility in my district, Klamath Falls, Oregon, last week. And we talked about this very obstacle to quality healthcare. And that is all they care about is the patient and quality healthcare. And they said, "Please, please, please."

I said, "42 CFR Part 2."

And they said, "Yes. You have no idea what an obstacle that is to patient safety and treatment."

And so that is why we are here. We want to get it right. We appreciate all the panelists today sharing their opinions. This is important stuff. It is not easy.

And, Mr. Chairman, thank you for holding this hearing. I think it has been very, very helpful.

Mr. BURGESS. And we thank the chairman.

The chair now yields 5 minutes for questions to the ranking member of the full committee, Mr. Pallone of New Jersey.

Mr. PALLONE. Thank you, Mr. Chairman.

I want to thank all the witnesses for joining us.

And, Dr. Clark, I am interested in learning more about the up-tick of substance use disorder treatment in the U.S., so I am going to start with you.

In your testimony, you note that, of the 28.6 million people who misuse illicit drugs and the 65 million people who are binge drinkers in the past month, only 3.8 million people received treatment in the past year. Could you explain some the reasons people don't receive treatment for substance use disorder? And quickly, because I have more questions to ask you.

Dr. CLARK. Sure.

A number of reasons. The first reason is the ability to pay. The second reason is people don't want to stop. The third reason and fourth reasons are people do have concerns about privacy and stigma. It is an issue that drives people's motives.

And as I pointed out in my 5 minutes and response is that we need to get people early and—before we wind up having to deal with them later in their substance use.

Mr. PALLONE. All right. So, for you and also Ms. Metcalf, could you explain why maintaining Part 2 protections is important to individuals seeking treatment for substance use disorders, including opioid use disorder? Briefly, again.

You could start, Dr. Clark, and then we will go to Ms. Metcalf.

Ms. METCALF. Yes. Thank you.

42 CFR is important to people seeking treatment because they are assured, when they come to treatment, they have that conversation about who will receive their information. And they have a choice to sign it. And it is a simple conversation. And so it is important to actually build—empower those individuals to be part of their care. And it allows them to make that choice that their physi-

cian or the people involved with their medical care can have the information that they are in treatment.

If they choose not, there are many, many, many, reasons why they might choose not to. For fear in small rural communities where they just choose not to share that they have gone to treatment for their alcoholism, been in counseling. Lots of reasons why they may choose to not share that with a small town family physician that is their physician.

Mr. PALLONE. All right. Let me move on.

Under the proposed legislation, patients would lose the right to determine the extent to which their patient record is shared for treatment, payment, and healthcare operations but receive added requirements related to the use of their part D record in criminal, civil, and administrative proceedings as well as discrimination by lawful holders of Part 2 information.

Again, either Ms. Metcalf or Dr. Clark, could you explain why the extra protections included in this proposal do not cure your concerns about eliminating Part 2's patient consent requirements.

I guess he is asking for you to speak, Ms. Metcalf.

Ms. METCALF. The added protections, I think that we are still seeing one of our constituents, a member of Faces and Voices of Recovery, has shared her story about unlawful sharing of her medical records, unlawful redisclosure. The impact on her lifelong is that—an inability to start her small business as a result of the—unable to purchase group health plan for prospective employees based on her health history of substance use disorders; despite being her primary breadwinner, unable to buy life insurance policy to protect her family based on her health history of substance use disorders; and unable to obtain disability insurance due to the same.

So the bill does not protect these individuals from those who the health insurer will share that information with, which includes extensions of the companies that are related to life insurance, disability insurance, and so on.

Mr. PALLONE. All right. Let me ask one more question, Dr. Clark.

Due to the concerns you have expressed with eliminating Part 2's patient consent requirements, what actions can Congress take to allow patients to further benefit from the health system's coordinated care arrangements and still maintain Part 2 protections?

I will ask you that one directly.

Dr. CLARK. One of the things that we would encourage the Congress to do, or I would, is to facilitate the acquisition of electronic health records by the Substance Use Delivery System, which, incidentally, is not primarily populated in hospitals or in doctor's offices. It is primarily populated in small recovery-type oriented behavioral health treatment systems. So, by the time you reach the doctor's office, your problems actually are much more severe. So you could do that.

And one issue that is missing from this is the issue of child custody. There is no discussion about that in the bill. So, while it says you can't use it about a plaintiff, it doesn't say you can't use it about a defendant.

So these are the kinds of things that need to be deconstructed from the bill so that it can enhance the issue of protection if that is what your will is.

I applaud the effort to address these issues. I don't want to suggest that the bill, because of its weaknesses, has got a bad intent. I think it is a well-intended bill, but I think it is inadequate for the purpose that we need to look at these things more carefully. And I really applaud the Congress' interest in trying to correct some of these problems.

Mr. PALLONE. Thank you.

Thank you, Mr. Chairman.

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

The chair would just observe for the record that I did vote against the HITECH Act.

Now I would like to recognize the gentleman from Texas, Mr. Barton, 5 minutes for question.

Mr. BARTON. Thank you, Mr. Chairman.

And I want to appreciate you and Chairman Walden honoring your word at the markup where this bill was not marked up, but you promised to hold this hearing. It is good to follow regular order and try to get more information.

I come at this a little bit differently than most of the Republicans on this committee. I am the co-chairman of the Privacy Caucus here in the House and have been for the last 10 or 15 years.

I want to read a very brief part of the majority memo for this hearing. It is on the second page of the memo, and this is a direct quote: Part 2 regulations provide stronger protections for substance use disorder treatment records than do most other Federal and State health privacy laws, including the standards for privacy of individually identifiable health information, parentheses, privacy rule, under the Health Insurance Portability and Accountability Act of 1996, parentheses, HIPAA. Repeat: Part 2 regulations provide stronger protection than do most other Federal and State health privacy laws.

That is the crux of the issue. Nobody disputes these tragic individual stories. The gentleman from Ohio, the gentleman that I think is representing Betty Ford whose mother had a problem. Nobody disputes that.

But Part 2 provides stronger protections for individuals. Most Federal laws don't. A lot of the so-called privacy protections that we have now in Federal law are jokes. They are information disclosure laws that, when a breach happens, the group that is allowed the breach has to notify you that your data has been compromised. They don't protect privacy. They just require the group that let the privacy be abused to disclose you that it has been abused. And in some cases, especially banking, it is not that it has been breached. They just have the right to use the information however they want as long as they tell you.

So here we have a law that actually does provide privacy protection. And in the name of better healthcare, we are trying to breach it. I am opposed to that.

Now, I am not opposed to some change in Part 2. I understand. But I am opposed to just unilaterally overriding the individual's right to privacy by requiring written consent.

Now, I want to ask the gentleman from Ohio, Mr. McKee. Was your brother, to your knowledge, ever asked to waive his right to privacy under Part 2?

Mr. MCKEE. Not that I am aware of.

Mr. BARTON. OK.

What about you, Mr. Gardner? Was your mother ever directly asked to waive her Part 2 rights?

Mr. GARDNER. I cannot answer for sure.

Mr. BARTON. OK. It may be they were never asked. It may be they were asked, and they refused to. We just don't know.

Mr. MCKEE. Congressman Barton.

Mr. BARTON. Yes.

Mr. MCKEE. With all due respect, how would the physician have known to ask?

Mr. BARTON. What is that?

Mr. MCKEE. How would the physician, how would the surgeon, have known to ask?

Mr. BARTON. Well, if I were treating, and I am not a doctor, but if I were treating your brother, I know, when I go to my dentist, when I go in for any kind of a procedure—I have had gallbladder surgery; I had a heart attack—I have to fill out a form three or four pages long that has asked if I have ever been treated for any of the following occasions. And I believe that, if I were a prescribing physician giving fairly strong pain medication, I would probably either informally, verbally, or formally ask that question.

Now, in fact, every time I go to my doctor, I have to fill out the same form again. And I say, "Well, I just filled it out last year."

"Well, I am sorry. You have got to do it again."

So, there are cases—and my time is about to expire. There are cases where maybe the patient is not mentally able to make a decision. But my guess is a vast majority of the time they are competent, and they choose not to disclose for their own purposes. Now, I don't know that. That is just a supposition.

Anyway, I had two more questions I will submit for the record, Mr. Chairman, since my time has expired.

And thank you all, the witnesses, for being here.

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

Mr. SARBANES. Thank you, Mr. Chairman. Thanks to the panel. I can't see—all the way on the end. Yes.

Mr. DELOSS. Mr. DeLoss.

Mr. SARBANES. Sorry. I lost track of the witness list.

You, I think, were describing, in the new proposed draft of the bill that has been mentioned here today, that there is some anti-discrimination language in there. And I guess that would make it illegal for any entity to use records to discriminate for healthcare, hiring, employment, sale or rental of housing, access to courts, recipient of funds, et cetera. And that gives you increased confidence that facilitated sharing of information that is suggested by the proposed bill would mitigate the occasion for discrimination, therefore, potentially be less stigmatizing. So it goes to addressing that issue. Is that right? Is that the idea?

Mr. DELOSS. That is correct, yes.

Mr. SARBANES. Yes. And I get that.

What I worry about is that—that is well and good. But it is kind of like the cow is out of the barn. In other words, once the data is out there or the information is shared, it may be that somebody misusing it is subject to some kind of penalty or prosecution or what have you. But as we know in life, a lot of times, that kind of discrimination can go unpunished, and at that point, the information is out there. So a better protection is to keep the information safe or in close hands before it even gets out there and you have to test the proposition of whether people are handling it properly.

So I think, I see why people are pointing to that and suggesting, “Well, that should give us comfort,” I am not sure it gives the comfort you are suggesting to a patient who is going to say, “Well, that is fine if someone could get in trouble if they misuse my information, but the chances that it could get misused are still pretty high, and they might not get penalized for it, and there may be no deterrent effect as a result, so the better path for me is to just not share the information, or that puts me in an exposed position.”

So I just wanted to make that point, because I think it is a fair one. And I wanted to turn to you, Ms. Metcalf, and just ask you—

Mr. DELOSS. Could I quickly respond?

Mr. SARBANES. Yes, you could.

Mr. DELOSS. Thank you.

The issue that I see in response to those concerns, which I think are valid, is that the current Part 2 regulations, even though there is a consent process, because they are so overly stringent and technical, it doesn't allow the patient to make that choice, because the recipients, such as HIEs or ACOs or these integrated care environments that are part of the new healthcare model, would not accept that information.

So, even if the patient made the choice to share the information, it couldn't be accepted because those entities would refuse it. In addition, the recipients would have to segment that data if they did receive it so it would not be redisclosed. Again, something that certain electronic health records do not have the current capability to do.

And in addition, with respect to the bill itself, in addition to the antidiscrimination provisions you mentioned, there is a limited set of recipients that could receive this information so it is not going out to third parties. It is not going out to billing agencies. It is not going out to marketers. It is not going out to businesses—

Mr. SARBANES. Let me jump in, because now I am down to 14 seconds. So I won't ask you this question, Ms. Metcalf.

Mr. DELOSS. Thank you.

Mr. SARBANES. My understanding is that, even keeping the key components of the Part 2 regulations in place, that through education, through finding ways of streamlining some of the technical obstacles that people are concerned about, that we could improve the situation for coordinated care without compromising the concerns people have about the privacy of the data. So that is why I continue to have some misgivings about the proposed legislation here that we are talking about.

With that, I will yield back.

Thank you.

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

The chair recognizes the gentleman from Kentucky, Mr. Guthrie, 5 minutes for you questions, please.

Mr. GUTHRIE. Thank you very much, Mr. Chairman. Thanks for having this meeting.

The first few questions are for Mr. DeLoss. I am going to try to ask some on behalf of my good friend from Texas, Mr. Barton.

But, first, Mr. DeLoss, it is my understanding that Part 2 only applies to federally supported providers who identify themselves specifically providing SUD treatment and referrals. Are there health providers, say office-based physicians, prescribing buprenorphine or for-profit providers that do not fall into this category and do not have to comply with Part 2?

Mr. DELOSS. That is correct. There are certain providers that do not have to comply with Part 2 because either they are not federally assisted or do not hold themselves out as specializing in this area.

Mr. GUTHRIE. So what about the Department of Veterans Affairs? And does it make sense that some patients with substance abuse disorders will have this information in their medical records and some will not?

Mr. DELOSS. With respect to the Department of Veterans Affairs, that would be an exclusion from the coverage of Part 2. Part 2 would not apply to those records.

Mr. GUTHRIE. Does it make sense that some would have this information and others would not?

Mr. DELOSS. No. It leaves an incomplete record. Absolutely.

Mr. GUTHRIE. So, while Part 2 is supposed to have stronger protections, Mr. DeLoss, can you discuss the enforcement authority for Part 2 infractions in comparison to the enforcement authority for HIPAA violations?

Mr. DELOSS. Yes.

Part 2 is a criminal statute, so the enforcement, in addition to the Substance Abuse and Mental Health Services Administration, SAMHSA, there would be a criminal enforcement through the Department of Justice. To my knowledge—and I know Dr. Clark had a differing opinion. To my knowledge, there has never been a substantive enforcement action taken for a violation of a Part 2 provision in its history.

With respect to HIPAA, you have the Office for Civil Rights, Department of Health and Human Services, that would engage in a process of audits, reviews, complaint-driven responses, investigations. You have the breach notification provisions which are now part of Part 2 under the bill. I did not mention that earlier. All of that results in a very comprehensive enforcement scheme. And I believe the most recent information I have is that over \$75 million in fines and penalties have been levied against those that have violated HIPAA or not complied completely with respect to the protections that that law requires.

Mr. GUTHRIE. OK. And I am going to ask a question on behalf of my friend from Texas he said he didn't get to, so I am going to read it.

Substance use disorder treatment records—and this is for Mr. DeLoss—has already been subject to data breaches. For example, in August 2016, an addiction treatment provider in Baltimore was hacked, and patient addiction treatment information was put up for sale on the dark web.

In 2017, a data breach of Bronx Lebanon Hospital Center in New York calls the release of at least 7,000 people's records, which included addiction histories.

So, that said, under Part 2, are there currently breach notification requirements?

Mr. DELOSS. Correct. The HIPAA breach notification requirements would require notification not only to the individual patients, probably in the cases you mentioned, to the media as well as the Department of Health and Human Services.

Mr. GUTHRIE. Under Part 2, what are the penalties for an unauthorized disclosure?

Mr. DELOSS. Well, they can range from \$100 for a small negligible type of violation up to \$1.5 million.

Mr. GUTHRIE. So how would the legislation before us help patients whose addiction treatment data has been compromised?

Mr. DELOSS. Well, there would be a requirement and affirmative duty to report any type of breach or violation under the breach notification provisions. Part 2 does not currently require any kind of notification of a violation by a program—or by a provider. So there would be that new affirmative obligation to disclose that, not only to the individual patient but also to the department as well.

So that would obviously bring up the ability—or heighten the ability to enforce the law, because it would impose an affirmative obligation to do so.

Mr. GUTHRIE. Thank you. And I have about a minute.

So, Mr. Gardner, the Assistant Secretary for Mental Health and Substance Use, Elinore McCance-Katz, wrote recently in a letter that, and I will read a paragraph from her letter, the practice of requiring substance use disorder information to be more private than information regarding other chronic illnesses, such as cancer or heart disease, may in itself be stigmatizing. Patients with substance use disorders seeking treatment for any condition have a right to healthcare providers who are fully equipped with the information needed to provide the highest quality of care.

I have 30 seconds, Mr. Gardner. Do you agree with that statement?

Mr. GARDNER. That is a big subject for 30 seconds, but I do believe that, over the course of time, a paradigm of separation and secrecy as opposed to integration and openness does, indeed, create a culture where stigma lives.

Mr. GUTHRIE. Well, thank you, and my time is expired.

And I yield back.

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.

I want to thank all the witnesses for being here today.

Mr. DeLoss' testimony highlights that, under this bill, a Part 2 provider could still require additional consent if it wanted to. There may be a way for this bill to reflect that option more directly. I recognize that Mr. McKee's brother story is an all too common scenario in which the patient may have not chosen to consent even if sharing the information will be in their best interest. However, I think the big question we must ask ourselves is whether we want to completely take away that right to consent.

I think middle ground here is retaining some ability for the patient to consent to whether or not the information is shared. Under current Part 2 law, the patient has a right to consent either every time their information is shared or, under new SAMHSA rules, more broadly if they chose. Under the current bill we are considering, a patient's information would be shared automatically with covered entities for the purposes of treatment, payment, and healthcare operations when they choose to be treated.

What if, upon seeking treatment, the patient retained the right to consent and could choose between privacy protections under 42 CFR or under HIPAA?

Dr. Clark, I will start with you, but I would like to hear from the other witnesses as well.

Dr. CLARK. As I mentioned, I applaud the efforts of this committee to address some of these critical issues, because they are of great concern to our nation's public health and to the citizens of this country.

You raise an important point that, essentially, already exists, has already been acknowledged. You can strengthen 42 CFR Part 2 by strengthening the penalty without abandoning the confidentiality and right to make a personal decision.

There are conflict of laws issues that are raised by the current bill that will have to be negotiated, because, indeed, it attempts to abrogate things like the ADA, the DOT, and Department of Justice kinds of rules.

So then there is the issue of competency of individuals. If you remove an individual's competency in this situation automatically, then what about for cancer? What about for other conditions?

So the right to choose what happens to your own person is an important right. And what we are talking about is creating a slippery slope where we nullify that right for this condition, and then we have to nullify that right for another condition. So I think we need to keep that in mind. Addressing the conflict of laws, addressing the issue of penalties, and making sure that we understand the covered entities.

Ms. MATSUI. OK. Any other comments to this at all?

Mr. DELOSS. I can respond briefly.

Ms. MATSUI. Yes.

Mr. DELOSS. In terms of requiring the consent, I believe that one of the issues would be in what situation would consent be required. Even with the changes that were made in the regulations in 2017 to 2018, there are still issues exchanging that information directly with other healthcare providers because of the limitations that are imposed and because of the complexity of those regulations.

And I think that probably really sums up the critical issue, which is, because of those complexities, that health systems, medical groups, hospitals, and others cannot comply with, the HIEs, ACOs, et cetera, this information is not being included in those exchanges of information for purposes of care coordination. So a consent by itself does no good. But if you add the layers of complexity that are in place currently under the law as well as others that have been proposed by the opponents to this bill, then it makes it extremely difficult, if not impossible, to share that information.

Thank you.

Ms. MATSUI. All right. Now, I realize that both HIPAA and Part 2 protect against information be shared with landlords, employers. But I am concerned that the definition of covered entity under HIPAA may still be too broad such that it increases the likelihood of a breach.

Mr. DeLoss, under this bill, could information only be shared between treating providers, or could it be shared between two covered entities that are not necessarily treating the specific patient?

Mr. DELOSS. The information could be shared for treatment payment or healthcare operations only between two covered entities. A Part 2 program and a covered entity and then a covered entity with another covered entity downstream and definitely, correct.

Ms. MATSUI. I heard differing opinions on whether H.R. 3545 allows for disclosures to business associates.

Are business associates not covered under payment treatment and operations under HIPAA?

Mr. DELOSS. It is my interpretation of H.R. 3545 that the bill would not allow disclosure to business associates because they are not "covered entities," correct.

Ms. MATSUI. OK.

Mr. Chairman, I yield back. Thank you.

Mr. BURGESS. Does the gentlelady yield her time to me?

Ms. MATSUI. Yes, I yield to you.

Mr. GREEN. I thank my colleague.

Mr. Chairman, you and I talked about this. I would like to ask. Mr. DeLoss testified that the bill would not allow information to be shared with business associates. However, a Republican memo states, "the discussion draft will permit said records to be shared between covered entities, healthcare providers, payers, and business associates."

I would like to see if Mr. DeLoss can clarify as to the intent to just include entities, or is it also the intent to include business associates?

Mr. BURGESS. Before we go into that, it is not Mr. DeLoss'—it is not required of him to—

Mr. GREEN. Oh, no. He doesn't have to. I would just like—

Mr. BURGESS [continuing]. To justify what is in the majority memo. He is responsible for his testimony. We are responsible for ours.

You are welcome to address that if you would like. But you are not required to.

Mr. DELOSS. Again, it is my interpretation—I am not familiar with the memo, and I—it is my interpretation that, because it allows for disclosures from Part 2 programs to covered entities or by

covered entities to covered entities, that business associates would not be included. That is my interpretation.

Mr. GREEN. Thank you. I just wanted to get the——

Mr. BURGESS. Thanks. The gentleman yields back.

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

Mrs. BLACKBURN. Thank you, Mr. Chairman.

And I thank you all for your patience in being here today and talking with us about this issue.

As you know, we had quite an extensive hearing prior to your hearing today with the drug distributors and looking at the opioid issue and their participation in it. So this is an issue that we take very seriously.

And as Chairman Walden said, one of the things we have heard from families, from those that are recovering from addiction, that have suffered from addiction, is wanting to have visibility into those records so that they could be there to help their family member or their loved one.

And Ms. Matsui was just touching on the consent forms. And I want to go back to that issue but take a little bit different tack with this. Because I was talking with an attorney yesterday, and we were talking about someone they were trying to get into drug court and a treatment program. And this person had looked at this attorney and said, "You can take me to drug court. They can send me to detox. But I am not going to stop using."

And he talked about the heartbreak. And I think many of us, and you all, Ms. Metcalf, your situation; Mr. McKee, with your brother; Mr. Gardner, with your mom, those are the heartbreaking, heart-wrenching situations that those—as a mom and as a friend to people who have dealt with this, it just tears you apart. And we realize that.

Ms. Metcalf, I want you to just say what would it have meant to you if there was somebody else that had that visibility and, we hear from doctors about compliance or about people maybe telling the truth but not the whole truth when they come in and have a discussion about their health. What would it have meant to you to have somebody with the visibility that could say, "You need to sign this consent form; you need to be truthful and honest about this"?

Just give me 30 seconds on that.

Ms. METCALF. Absolutely. Thank you.

And it meant an awful lot to me. I had a physician and my mother that said—when I was 17 years old, worked together to coordinate my care. And I signed a consent form, because my counselor said that this would be a good thing, to work together as a team. I was prescribed Antabuse at the age of 17, because I was drinking excessively and had been to treatment twice. And so they coordinated together.

It made a lot of sense to me to work together, and I consented and signed that form as a 17-year-old. I would do it again because I was educated in that I was given the opportunity to make a choice.

Mrs. BLACKBURN. Now, as you work with those that are recovering, how do you counsel them?

And, Mr. Gardner, I want you to come in right behind her on that answer.

How do you counsel people on signing a consent form?

And, Ms. Metcalf, you first, and then Mr. Gardner.

Ms. METCALF. I worked as an intake worker in a residential treatment program and had those conversations many, many times. It was a very validating experience to have to say this is what that form is, 42 CFR Part 2. If you would like to share your information with your physician, you can sign it now. Or as you are here in treatment with us, we will revisit this, because you may want to coordinate the care.

I believe that having others make a choice for us or even having this conversation is stigmatizing in a way that says that we don't have the ability or that we are less than, that we don't—we are not capable of making those choices, and we are. There are millions of people that are making those choices every day and consenting to sharing information with their healthcare providers.

Mrs. BLACKBURN. Would you say that consenting to share that information and get that helped save your life?

Ms. METCALF. I don't know that. The prescription that I was given didn't save my life. It didn't work for me. I went on as an adult to treatment.

Mrs. BLACKBURN. OK.

Mr. Gardner.

Mr. GARDNER. Thank you for the question.

I do think those are compassionate conversations. I will say that I don't think patients generally have an expectation, come in with some expectation or knowledge of Part 2, some difference between HIPAA and Part 2. They have some general expectation of privacy, for sure. And I will say that when we come back for repeated consents, in the real world, that is sort of annoying, frustrating sometimes, and can actually raise alarms, like what wasn't I thinking about that I need to be thinking about now?

Mrs. BLACKBURN. OK. I yield back.

Mr. BURGESS. The chair thanks the gentlelady.

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

Ms. ESHOO. Thank you, Mr. Chairman.

And thank you to all of the witnesses.

I have had the advantage of being able to not only listen to your testimony but also to listen to all of the questions from members on both sides. And there are enormous complexities in this. I don't really think there is a tidy answer to this. And I say that because I keep thinking of my first cousin who suffered all of his life from mental health issues, from the time he was in his early 20s until he passed away maybe about 6 months ago. And he didn't really fit into what we are talking about here today in many ways, because if you said to him, "Give consent," he really would not have known what he was talking about. He wasn't in a position to do that.

So I want to thank Dr. Clark. He is a part of a great university in my region, Santa Clara University. It is a Jesuit college with a graduate school, and it is highly regarded for many of its grad-

uates, one of them a member of Congress, a son of the House, Leon Panetta. So thank you for being with us.

What I would like to know is, from among yourselves, Mr. Gardner, what would you and Mr. McKee say to Ms. Metcalf? Ms. Metcalf, what would you say to them?

You believe that Part 2 is necessary, and you told your story, and it is an important one. They told their stories. They are an important one.

What is lacking in HIPAA? Where is the danger going to come from if we change this? So—

Ms. METCALF. Yes.

Ms. ESHOO [continuing]. Maybe the three of you, in a minute, tell me why your case, you believe, is the strongest.

Ms. METCALF. I will go.

And I wanted to say that, we hear these stories, and it is very impactful. I think that when a person with a substance use disorder wants to share their information with a family member, they will. I don't know that signing a HIPAA is going to allow them to— or is going to help that. I think that the family member doesn't have access to that information.

Ms. ESHOO. See, the thing—and what you are saying to me is, and maybe my own experience is discolored by the fact that my cousin really was not capable. If he said so, he sounded and he looked very clear, but he really didn't know what he was talking about a good part of the time. So is that what we are relying on?

Ms. METCALF. I think we have a very misconstrued image of what alcohol and drug addiction is. There are millions of us—23 million in recovery. There are individuals who go on to live and overcome addiction. We are not—

Ms. ESHOO. And this applies only to alcohol and drug abuse? What we are talking about today, it only applies to those two addictions? It only applies to those two addictions?

Ms. METCALF. Yes.

Mr. MCKEE. I would say that by enshrining this distinction between medical and surgical care and substance use disorder conditions that, in the Federal code, we are simply adding to the stigma in a structural way.

There are other health conditions that are highly stigmatized, like sexually transmitted infections, HIV/AIDS. Why are we separating out substance use disorder information?

I work for NAMI. There are a lot of folks that we represent that are seriously mentally ill.

Ms. ESHOO. That is an extraordinary organization. I worked with them for years. They really are outstanding.

Mr. MCKEE. Thank you, Congresswoman. We appreciate that very much. And there are a lot of folks with serious mental illness, like your brother—or your cousin, who simply don't understand this process. And yet their treatment providers of either mental health provision or medical/surgical care are still blocked from seeing these things.

It is almost as if we are—

Ms. ESHOO. Let me give Mr. Gardner just a moment. I appreciate what you are saying.

Mr. GARDNER. Yes. Thank you.

I think in the specialized addiction treatment field, we have recognized for a long time that the way to—one of the big opportunities to improve the way addiction is addressed in America is to get all of healthcare involved and not have it be just us in the specialty treatment field.

And so every opportunity I think we can get to bring healthcare into the fold and get more eyes and professionals on this disease for the people that suffer from it, I think the better. And this seems like an opportunity to do that.

Privacy is important is what I would say. There is no doubt about it. I just think the strategy that we had in the 70s of trying to avoid discrimination is no longer the right strategy. We should be confronting discrimination, and I think we have with—in HIPAA and the newly—the new language around Part 2 that we enforce discrimination and still bring healthcare into the fold.

Ms. ESHOO. Thank you very much.

Thank you, Mr. Chairman.

Mr. BURGESS. The chair thanks the gentlelady.

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

Mr. LANCE. Thank you very much, Mr. Chairman.

And good afternoon to the panel.

I will be introducing a bill that will target new resources for substance use disorder. Health homes, as I understand it, they currently exist in four States: Maine, Maryland, Rhode Island, and Vermont.

Under the model of care in Vermont, for example, the State has markedly expanded access to medication-assisted therapy; reduced the use of alcohol, opiates, and other illicit drugs; decreased the use of hospital emergency room departments; reduced illegal activities and run-ins with law enforcement; and substantially improved family life, housing stability, and emotional health.

However, according to a January 2015 bulletin put out by CMS entitled “Designing Medicaid Health Homes for Individuals with Opiate Dependency: Considerations for States,” one barrier to effective treatment in care coordination identified by Vermont and other participating States was 42 CFR Part 2, and “Collectively, the three States cited Federal confidentiality requirements as a barrier to effective integration of care and sharing of vital information between the health home and other medical professionals.”

And, Mr. Chairman, I ask that the CMS study be submitted to the record.

Mr. BURGESS. Without objection, so ordered.

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

Mr. LANCE. Thank you, Mr. Chairman.

I know that you don’t know the particulars of my bill, but it seems like a way forward. And that would be to align Part 2 with HIPAA. And I think that people on the ground tend to agree with this.

Mr. DeLoss, would aligning Part 2 with HIPAA eliminate the barrier to effective integration of care in sharing of vital information between the health home and other medical professionals? And what sort of improved outcomes for patients could we expect to see if this were the case?

Mr. DELOSS. Well, again, without seeing the bill, but based upon your description, it would appear to me that aligning HIPAA with Part 2 would allow for the free flow of information between those entities as well as substance abuse and substance use disorder Part 2 programs. So that would coordinate the care, allow that information to be shared for the betterment of the quality of the care as well as ensuring that there is any type of drug that could interact negatively with anything that the individuals currently taking in the form of MAT or what they may, as mentioned earlier, as far as their addiction itself.

Mr. LANCE. Thank you.

Is there anyone else on the panel who would like to comment?

Yes, Dr. Clark.

Dr. CLARK. I would like to remind people that most substances don't have medications available to treat them and that we are talking about essentially blaming individual autonomy and rights for the failure of the HITECH Act, the failure of practitioners to be adequately trained to address the issue of addiction. So we are blaming the very people we are trying to help for the weaknesses of the delivery system.

You just had a hearing this morning. You had people throwing large amounts of drugs into the delivery system without question, making money hand over fist, and no one questions that now. We recognize: Oh yes, we should have recognized that large numbers of pills going into a community might be a problem.

We have heard of physicians just writing prescriptions without recognizing that this is an issue.

I treated patients a long time ago, and we always asked: Do you want your family involved? You need your family involved, because this is a family disease. It is not just your own individual disease.

So what we are talking about is not dealing with the system; we are talking about blaming the victim. And I encourage you to look at part J of this bill 3545, which says: to develop and disseminate model training programs for substance use disorder patient records, to get people, to make sure we have enough pilots to prove the point rather than to speculate the point. Because once the horse has left the barn, you can close all the doors you want, but you don't have the horse.

Mr. LANCE. Thank you. Others on the panel?

I commend to your attention the bill that I will be introducing, and I certainly would like you to examine it for your expertise. This is an issue that knows no bounds here in Congress. It is an issue on which we hope to work in a bipartisan capacity and also in a bicameral fashion, because obviously, we want to improve the system together.

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

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

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

Ms. CASTOR. Thank you, Mr. Chairman and Mr. Green, for organizing this hearing today. And I would like to thank all of the witnesses for being here, especially for those of you who have shared very personal stories. Thank you very much.

Ms. Metcalf, I would like to get a better understanding of the importance of Part 2's patient consent requirement. What role does getting patients' consent to disclose their substance use disorder treatment information to providers and other entities play in their treatment? And why is this patient consent requirement important for individuals with substance use disorder?

Ms. METCALF. I would like to respond to that. What we find with people in active addiction is that they are using very little healthcare services for preventive care. They are not getting treated for the conditions that are underlying. They are not doing things that are healthy and seeing dentists or—there are so many things that can be done to help that person.

Once they engage in treatment, that conversation about their health and wellness, taking care of those things to help them live better and longer lives, it happens because the counselor talks to them about the value of sharing that information with their physician. And we have seen, you know, incredible life improvements of people in recovery when they are able to do that.

That is a process that takes place that initially people are not generally—

Ms. CASTOR. Is there data on that? Are there studies you can point on?

Ms. METCALF. I have studies of people in long-term recovery, the Life in Recovery Survey that indicates what recovery does for people. It helps them engage in those medical services where they weren't before. And the services they were using before were the higher cost emergency department services or treatment services versus the preventive care where they could be going to their physician.

Ms. CASTOR. What should providers do if substance use disorder patients refuse to give their consent to disclose their patient information to other health providers?

Ms. METCALF. They should continue to have that conversation with them; and when they are ready and they see the value of that, they will do that in most cases.

Ms. CASTOR. Because the relationship between the patient and the provider is critical, especially with folks with substance use disorder. The cornerstone of the relationship, of course, is trust, which includes trust that the information you give to your provider will be used appropriately and that you know how it will be used.

According to one recent study, two-thirds of adults in America are concerned about a breach in the security and privacy of their personal health information. In addition, the study showed that over 12 percent of patients withheld information over privacy concerns. The more concerned you were about privacy, the more likely you were to withhold information. And I am hearing that this is called your privacy protective behaviors. There has got to be a simpler term for that.

But, Dr. Clark, for people with substance use disorders, all of you know that that relationship is important between the patient and the provider. Would you say that people with substance use disorders are particularly sensitive to concerns about how their data would be used?

Dr. CLARK. That has been my clinical experience. But, as Ms. Metcalf pointed out, the job of the professional in the treatment arena is to encourage individuals to recognize the importance of comprehensive interventions. And that way, they can sample the kinds of reactions that they get. I have heard people in other settings who are in recovery point out that they, in fact, were dropped by practitioners for what appears to be essentially manufactured reasons.

You can't determine whether you have been discriminated against. You just know that these practitioners are unavailable. The problem with the HIE notion is that you may have hundreds of thousands of entities who have access to that information, and they get to decide whether they want to see you or not, and they don't have to see you.

Ms. CASTOR. But Mr. DeLoss I thought made some good points—and I note you are sitting right next to him and heard—that this is very narrow and could be helpful when we are talking about the covered entities. You heard what he said and how narrow it is and why it doesn't—

Dr. CLARK. OK. I disagree with his definition of how narrow it is. Remember, this is your bill, not his bill. So his interpretation won't control. Your interpretation will control. You are making this. He doesn't get to talk about legislative history. He gets to litigate it if that is an issue.

Ms. CASTOR. We are building the record. We are building the record here.

Dr. CLARK. So some of the statements he has made in terms of third-party notification, 42 CFR Part 2 does report third-party notification. You do have to go through extra steps, but it does permit third-party notification. So he was wrong about that, so he is probably wrong about whether the covered entity construct is as limited as he thinks it is.

So we have to think about that collectively rather than just sort of extemporaneously make a declaration.

Ms. CASTOR. I wish I had time to allow him, Mr. DeLoss, to respond, but maybe another member could ask about that.

Mr. BURGESS. I think we should allow Mr. DeLoss to respond.

Mr. DELOSS. Thank you. 42 CFR Part 2, to respond directly to Dr. Clark's statement, does not have a duty-to-warn exception.

Dr. CLARK. It does have a duty-to-warn exception. It does.

Mr. DELOSS. No, it does not.

Dr. CLARK. It does. It permits third-party notification. You should read it a little more closely, sir.

Mr. BURGESS. The gentleman from Texas is correct; the witnesses don't get to debate.

Dr. CLARK. It is not a debate here.

Mr. BURGESS. It is now in order to recognize Mr. Long of Missouri, 5 minutes for your questions, please.

Mr. LONG. Thank you, Mr. Chairman.

And, Mr. McKee, one recent study found that physicians continue to prescribe opioids for 91 percent of patients who suffered a nonfatal overdose, with 63 percent of those patients continuing to receive high doses. Seventeen percent of these patients overdosed

again within 2 years. How will this legislation before us help to stop overdoses and prevent these deaths from occurring?

Mr. MCKEE. Thank you, Congressman. Assuming both of my hands are covered entities, it lets the left hand know what the right hand is doing.

Mr. LONG. A pretty good explanation, I would say. Do you think that allowing health providers to see patients' complete medical record when making treatment decisions would help to prevent such tragedies as in the case of your brother?

Mr. MCKEE. I think it is very likely that improves their odds of surviving.

Mr. LONG. Your brother, you said 36 years old at the time he deceased, three children, divorced, living in your mother's basement. You had fought this, he had fought this addiction, your family had fought this addiction for years and years and years.

What can we do, as Congressmen, what can we do here in Washington, D.C., to prevent another 36-year-old brother deceasing such as yours?

Mr. MCKEE. Thank you, Congressman. H.R. 3545 is a great step. We also have to improve access to prevention, treatment services, ensure that folks are covered, ensure that essential health benefits are maintained, such as those requiring substance use disorders to be covered. And we also have to ensure that we really truly have behavioral health parity in this nation.

Mr. LONG. We have had several panels and discussions on this topic here in Energy and Commerce Committee. And a few weeks ago, we had I believe seven family members that had all—or seven folks that had all lost family members, usually younger college age students and things.

There is one fellow that works here in Washington, D.C. And I was describing at a function one night about how my two daughters, one was 29—I better get this right—and one will be 32 I think in a few more days, but how they had had three friends of theirs that have deceased from opioids. And when we had the panel in here with the seven parents that had lost children and the one lady that was addicted herself and had been since a young, young age.

It had to be extremely frustrating dealing with your brother over the years, trying to help him. We had, as I started to say, one fellow that worked here that had a son, as I was describing at this dinner, about his son had just gotten out of treatment for the third time at Christmastime, and they opened packages, and the boy disappeared. And he told his wife, he said, "Well, you know, we need to check in on him." They hadn't heard—they went upstairs, found him collapsed, as you described, in a fetal position on the floor of the bathroom. In this case, they were able to revive him, got him to the hospital. The next morning, they walked in, and he told his dad, he said, "Dad," he said, "I knew when I got out of treatment I couldn't do the amount of heroin that I had done before," but he said, "My gosh, Dad," he said, "I just had such a tiny bit on the spoon, I could barely melt it."

Is there anything you can enlighten us with that would help these families that are where you were before they have lost these loved ones?

Mr. MCKEE. That is a great point. When Brandon called me, he talked about how he had been off opioids for about a week and a half, and he had gotten dope sick. And then he relapsed. He didn't know about medication-assisted treatment or there was enough stigma around medication-assisted treatment that he didn't access it. He was an all-or-nothing kind of guy.

And I think that when you align things like this, 42 CFR with HIPAA, you are simply showing that this is a disease. These are chronic brain diseases. And the public needs to understand that they are no different than HIV/AIDS, diabetes, cancer. The more we have these discussions, the more we break that stigma, just like with mental illness.

Mr. LONG. Thank you for sharing your story here today. And thank all of you for being here. And the fellow I was talking about, his son has, since receiving the injection that you get—I think it is once a month maybe, and it is expensive. It is a thousand dollars a month, but, for people that can afford it, that is fine, those that can't—but, anyway, thank you.

And, Mr. Chairman, I yield back.

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

The chair recognizes the gentleman from Illinois. Mr. Bucshon, 5 minutes for your questions.

Mr. BUCSHON. Thank you very much, Mr. Chairman.

I was a cardiovascular and thoracic surgeon for many years before coming to Congress, and I just want to describe a few personal experiences—my wife is an anesthesiologist—with what can happen when you have an incomplete medical record.

I will just describe one patient who is a lady in probably her mid 70s who I did an aortic valve replacement on. She was a nice lady. In her medical history, there was nothing about alcohol abuse. However, the second night after surgery, she went into DTs, jumped over her bed rail, landed on her head. And when I subsequently went and talked to the family, they said, "Well, actually, you know, she drinks quite a bit." I am like, "Well, why didn't you tell us that up front?" It wasn't in her record. We had no idea. She had been in Alcoholics Anonymous in the past, relapsed. This is a real problem.

And it is not just alcohol or narcotics. I have patients that take dietary supplements for vascular health. Well, let me just give you a little clue. When you have open heart surgery and you are taking medication for vascular health, you bleed like crazy and you won't stop. We had no idea. I have had three or four patients with that. They didn't tell us. We asked specifically, do you take dietary supplements? Didn't tell us.

And then my wife as an anesthesiologist, and I don't have a specific case, but has routinely had problems anesthetizing patients with narcotic and benzodiazepine-related anesthetic agents, and subsequently has found out from the family, even though the patient denied it, that they chronically use opioids and/or benzodiazepines.

Patients don't tell you these things, and it is a really big problem. We need to know. Physicians, real physicians out there in practice need to know, because it has real repercussions. My pa-

tient who jumped over the rail and hit her head subsequently, after about 2 weeks in the hospital, survived her DTs and her aortic valve replacement and her minor concussion, but they may not.

So, Dr. Clark, in your written testimony, you say: The case is often made that healthcare delivery systems need to know about the substance use history of a patient. You don't hear why providers simply can't ask patients themselves about their substance use histories.

Do you really believe that patients are going to tell you about these things, I mean, every patient is going to tell you when you ask them?

Dr. CLARK. Well, sir, every patient is not going to tell you everything about everything. On the other hand, if, in fact, you take the time or you have a staff person who can take the time to establish the rational relationship between what it is that interventionist is going to do, I think you will get more truth-telling than you are aware.

I have found that asking people things in a carefully designed nonjudgmental way gets a better response than simply reading it in the chart and deciding that you may or may not—

Mr. BUCSHON. Fair enough. So the thing is you are a psychiatrist.

Dr. CLARK. Yes, I am.

Mr. BUCSHON. People come to you because you need to ask—because they have been sent to you to ask questions about mental illness and substance abuse things. Of course, I appreciate your experience, but I can tell you when you are not a psychiatrist and you are just a practitioner, a heart surgeon, an anesthesiologist, in my personal experience, patients do not tell you the full picture.

And it is not a criticism of them. Many people don't know the impact, the potential impact, medical impact of not telling you. You know, for example, why would a dietary supplement be a problem if you are going to have heart surgery? Well, they don't realize the fact that it really does anticoagulate you and you bleed, right, and you have to be transfused. I have had this happen. So I appreciate your experience, but I would argue that the patients don't tell you, and there are real repercussions.

The other question I have is, can you disclose to people's employers or law enforcement people's HIV or mental health status without their consent?

Dr. CLARK. Generally not, but it also depends on the context of the situation.

Mr. BUCSHON. Right. OK. So I get that. And there is some context, right? If they are threatening someone or something like that, there are exceptions, right?

So why would you think if there is a history of substance abuse or alcohol abuse in a patient's medical record already covered by HIPAA, why would you think that there would be a high risk of that being disclosed?

Dr. CLARK. Well, actually, HIPAA's protection is weaker when it comes to such disclosures. I think 3545 makes an attempt to address that. HIPAA does allow administrative police inquiries. So you—

Mr. BUCSHON. Yes, but from what Mr. DeLoss says, you have to have a court—you can answer that, Mr. DeLoss.

Mr. DELOSS. You need a court order; that is correct.

Mr. BUCSHON. What is the requirement?

Mr. DELOSS. You have to have a court order.

Mr. BUCSHON. Or the patient has to authorize it?

Mr. DELOSS. Correct.

Mr. BUCSHON. OK. So, what I am saying here is, look, I appreciate your experience on this issue, but what this legislation is trying to do is, honestly, I think, create parity for patients so that medical providers can provide adequate healthcare.

And the reality is that, without complete information, in my personal experience as a healthcare provider, in a medical record, there are potentially serious ramifications of not understanding a patient's complete medical history.

I yield back.

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

And the chair now recognizes the other representative from Indiana, the gentlery from Indiana, 5 minutes for your questions, please.

Mrs. BROOKS. Thank you, Mr. Chairman.

And thank all for being here and for sharing.

It is my understanding that individuals with opioid use disorder die, on average, 20 years sooner than other Americans. And it is largely because of a strikingly high incidence of poorly managed co-occurring chronic diseases, whether or not that might be HIV/AIDS or cardiac conditions, lung disease, cirrhosis. And in our home State of Indiana, sadly, we have seen an incredibly growing number of Hepatitis C cases linked to the injection drug use occurring in tandem with the opioid crisis.

And so I am interested in each of your perspectives, wouldn't you agree that care coordination, which we have heard a little bit about and which I think Dr. Bucshon was just talking about, is absolutely vital to ensuring better outcomes for those patients with chronic conditions, and in many ways, wouldn't you consider substance use disorder a chronic condition as well? Sir?

Mr. MCKEE. Congresswoman, thank you for that. Care coordination is at the heart of better health outcomes. It has allowed us in Ohio to make significant advances and moving away from volume and towards value.

If we don't have care coordination—part of the reason the mental health system is so broken, especially for the chronically mentally ill, is because we don't have enough care coordination. We are working on that in Ohio. This is simply another step in that direction.

Mrs. BROOKS. And don't we know that those with serious mental illness also often don't have their chronic conditions taken care of, their cooccurring conditions; they have worse other health outcomes?

Mr. MCKEE. Congresswoman, that is absolutely correct. And I would love for you to join as a member of NAMI in Indiana.

Mrs. BROOKS. Thank you. Yes, Ms. Metcalf.

Can you hit your mic, please? Thank you.

Ms. METCALF. Absolutely, we agree that care coordination is critical. We 100 percent support that, not at the expense of taking away our right to choose who our information goes to.

Mrs. BROOKS. Except that we visit often, and I just visited when I was back home in Indiana last week ER physicians at Eskenazi Health. And when people are coming in overdosing, and we have hospitals saving lives each and every day, but those individuals have no ability to share any information about what their condition is.

And so why would we want to tie the hands, particularly of those in our ERs, that are being inundated with people overdosing? Why would we not want them to have access to know what is happening in that individual's life?

Mr. Gardner?

Mr. GARDNER. I was just going to say that addiction treatment is changing pretty drastically in recent years. We are really making an attempt to keep people engaged in care longer. It is no longer you come to a building and you are there for 28 days and you go home.

Mrs. BROOKS. Sure. Outpatient, everything.

Mr. GARDNER. You may go from residential to outpatient. You may go back to your home community. And we are facilitating that ongoing care more and more. Partly, that has been driven by the fact that more and more medication-assisted treatment is taking place, including at our facilities. But you need to link people with prescribers in their home communities and ongoing therapy for this to work. So care coordination like never before has become important in addiction treatment.

Mrs. BROOKS. Dr. Clark, and I want time for Mr. DeLoss.

Dr. CLARK. Care coordination requires patient cooperation, patient compliance. It is not just the prescriber's role.

Mrs. BROOKS. Excuse me. But what if the patient has OD'd?

Dr. CLARK. Well, oddly enough, the emergency room doctor is not controlled by 42 CFR Part 2, and we can enhance that. So we also are dealing with heroin and Fentanyl.

Mrs. BROOKS. But how would the ER physician get access to that individual's substance addiction history?

Dr. CLARK. This bill won't change that. What we are trying to do is encourage people, as Mr. Gardner said, if we can intervene early enough, we don't deal with this. One of the things with medication-assisted treatment is the average length of stay is only 6 months. And so what we are trying to do is trying to foster that longer period of time so that we can facilitate recovery. And that is what SAVR is about, trying to get people to recognize that they remain vulnerable and, just as was previously mentioned, just a small amount of fentanyl, a small amount of heroin—

Mrs. BROOKS. Thank you, sir. I would like to hear from the last panelist.

Mr. DeLoss, would this bill help ensure that an ER physician could get access to a substance abuse record?

Mr. DELOSS. Absolutely. An ER physician is a covered entity and would receive the information under the TPO exemption that is in this bill. So the ER physician would receive all of the information available relevant to the SUD treatment, relevant to the overdose,

and be able to treat that condition and the overdose more effectively.

If I could continue, I would also like to expand on there has been a lot of discussion with respect to other providers in the community trying to coordinate care and provide treatment services or their own medical-surgical services. I would like to speak on behalf of the SUD programs. They want the information from those other providers as well. They want to partner with the physicians. They want to partner with the hospitals, but they can't because of Part 2, because it is too complex, it is overly stringent. That information not only cannot be disclosed by the program, but the program can't go out and ask for that information, because that information would identify the patient as suffering from an SUD. So they are not able to coordinate the care as well.

There are a number of other issues—and I will stop there unless there are other questions.

Mrs. BROOKS. Well, and I think that, on behalf of patients in Indiana, the SUD programs do need to coordinate, particularly with the infectious disease conditions that we are seeing an incredible rise in Indiana.

Thank you, I yield back.

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

The chair recognizes the gentleman from Virginia, Mr. Griffith, the vice chairman of the Oversight and Investigations Subcommittee, 5 minutes for your questions, please.

Mr. GRIFFITH. Thank you very much, Mr. Chairman, I appreciate it. This is one of those difficult issues, and I appreciate you, Mr. Chairman, holding this hearing, because I am trying to figure out exactly what I should do and how I should go on this. And I was not decided coming in here. I leaned towards voting for the bill, because we have had problems for some time. I also have concerns on the privacy side.

So let me go over some of those issues that we have. Last year, we had Brian Moran, the Secretary of Homeland Security and Public Safety from Virginia in. He said, "We got to do something, and it would help us to combat the opioid epidemic and save lives if we could have improved data sharing," and he specifically mentioned Part 2.

And I do think, and Mr. McKee, if I could ask a couple questions of your situation and I know it is painful and I appreciate you being here today to discuss it. Your brother was doing well when he had the accident. Is that correct? Is that my understanding?

Mr. MCKEE. He had had periods of sobriety and periods of relapse, and I am not sure how many relapses and how close together they were.

Mr. GRIFFITH. OK. Fair enough, because he didn't tell you everything. And then he has this accident. And as a part of the accident, they had to do surgery. Was that surgery something that they did immediately upon him having the accident?

Mr. MCKEE. It was not immediate. He was stabilized in Worcester Community Hospital, and then he was driven to Cleveland Metro Hospital.

Mr. GRIFFITH. So here is the question I have, and you may not know the answer. When he stabilized, did they give him opioids for the pain that he was experiencing at that time?

Mr. MCKEE. Absolutely.

Mr. GRIFFITH. And he was not fully conscious, was he?

Mr. MCKEE. No. He was making some jokes about the appearance of the nurse when I came to see him.

Mr. GRIFFITH. OK. So here is what is interesting, and I have this theory. Documentary archeology, you can sometimes go into documents and figure out that people didn't realize what the future would hold. This bill was passed in the early 70s. And what you find in the bill is you have got a section on medical emergencies. Under the procedures required by paragraph C of this section, patient identifying information may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained.

Your brother couldn't give informed consent. Forget his abuse problems; he has just been in an accident. They were probably giving him opioids—and you suspect that and I do too—before he ever gets sent over for the surgery, before he ever gets the prescription. And because of the way the law is written, or at least as it has been interpreted for the last 40 years, nobody knows that he has a substance abuse problem. So they have already given him substances before he ever has a chance to waive. So I recognize that. You see that problem as well, don't you, yes or no?

Mr. MCKEE. Yes, Congressman.

Mr. GRIFFITH. OK, because I am just trying to get to the other side. Now, here is the other side of this. I have got this hypothetical forming in my head where the person who has previously had a substance abuse problem goes to apply for a job, and that job happens to be a covered entity who has access to all this information. And maybe they are not supposed to use it that way, but they have access to all this information. And let's just assume that this person happens to be a medical professional, let's say a nurse, for the sake of argument. And they are going to go to work for, say, an insurance company, working for the insurance company, who is going to provide the health insurance, because that is what they do.

What is the likelihood that, notwithstanding the fact that you are never going to see the fingerprints, Ms. Metcalf, what is the likelihood that that nurse is never going to get that job, that he is going to be excluded, because as they are doing the work-up on the paperwork and so forth, they discover that he has got a prior substance abuse problem. And they will never say why, but all of a sudden, oh, we found out we don't have an opening. What do you think those odds are?

Ms. METCALF. It is a very tight job market out there. Of course, they are going to go with someone that does not have a history of a substance abuse disorder. That is the history of discrimination.

Mr. GRIFFITH. And my colleague says, why would they do that? And, of course, maybe they would; maybe they wouldn't. I don't know. But this is the concern that people with substance abuse problems in their past, and they are on recovery, they are doing well; they worry about these things.

So, Dr. Clark, as my lawyer doctor on this team, here is what we need help on. There are some of us that want to find a balance, because without something as an alternative, I am voting for the bill. That is what I have assessed today, because there is more good than evil. And even though I worry about the privacy concerns and agree with Mr. Barton and others, I don't have an alternative. Now, we got to fix HIPAA at some point too. That is a whole other discussion, Mr. Chairman.

But, right now, I have got a lot of people—nobody anticipated in the early 70s that we would have drugs so powerful that you would be addicted. Six percent we heard earlier somewhere in the studies I have been doing the last week or so, 6 percent on a first use of certain opioids are addicted, 13 percent if you extend that out over a period of time. We are dealing with a whole lot more dangerous drugs than we knew about when this bill was passed. So I am going to vote for this unless I have an alternative.

I don't have any time left. But if you can get me any answers, any advice on how we might be able to make this bill better or an alternative, I would greatly appreciate it. Thank you all for listening and for your input today, and it has been very educational for a guy who was undecided walking in here.

I yield back.

Mr. BURGESS. The chair thanks the gentleman.

I do want to point out to Dr. Bucshon those dietary supplements, they are all natural so it is OK. It is OK, right? They are all natural.

Mr. BUCSHON. They thin your blood.

Mr. BURGESS. I am going to ask the indulgence of Mr. Mullin. I know he is anxious to yield to me for my questions, but could we go to Mr. Carter and hear from him?

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

Mr. CARTER. Thank you, Mr. Chairman.

And thank all of you for being here. And thank you especially for your personal stories. They have been very inspirational.

And, Mr. McKee, I will start with you. I really do appreciate your stories and especially appreciate your work with NAMI. What a great group. I worked with them when I was in the State legislature, and I continue to work with them here, and they truly do some great work, and I appreciate that.

I wanted to ask you, from your perspective, after all you have been through, integrated care can change a patient's trajectory. Do you believe that?

Mr. MCKEE. Absolutely.

Mr. CARTER. And, obviously, you have given an example where you thought in your particular situation where it could have. I am a pharmacist professionally, and I practiced pharmacy for over 30 years, and I have been wringing my mind in trying to think how I can incorporate my experiences into this.

And, having tools in our toolbox is very important, and I am just thinking along the lines that if I had the opportunity to know that someone had a history of substance use disorder, that that would help me in my practice. It would help me help my patients. And that is what pharmacists want to do, they want to serve their patients and help them.

And I am just thinking, I am just trying to figure out what would be the downside of this? I have had the opportunity to be at a number of different conferences and to speak on substance abuse. In fact, one of those conferences was down in Atlanta, the Prescription Drug Abuse and Heroin Conference that Representative Hal Rogers sponsors every year. And I have had an opportunity. And one of the things we talked about at that conference is the stigma, and that is a big problem we have to get over, particularly when we are talking about the opioid addiction. I suspect, and one of the things we talked about at that conference in particular was that we say there are 115 people dying every day because of opioid abuse or opioid addiction. It is probably a lot higher than that. You look at obituaries in papers, and you will see it was a sudden illness, or it was even suicide. And there are families and individuals who would rather say that it was a sudden illness or a suicide than to say it was substance use disorder.

And if I could go to Mr. Gardner and just ask you, I know you mentioned earlier about all these forms you had to fill out and the sense that it just stigmatized you—can you just elaborate on that, what your feelings were with that?

Mr. GARDNER. Well, when I went to treatment myself 12 years ago, before I went—and I am just one person so, again, I am not speaking for all patients. But I called my boss. I called three or four people that I figured needed to know before I went. I wasn't sure how I could keep that secret in the first place, to be quite honest with you.

And I had no assumption necessarily. Of course, I had some embarrassment or shame or frustration mainly about why I couldn't get this under control myself, but I didn't have an assumption that I needed to keep getting healthy or better or getting help a secret. I really truly genuinely believed that that notion was introduced to me in some way by the consent process.

Mr. CARTER. Right.

Mr. GARDNER. Well, not just the consent process. See, I don't want to oversimplify it. Stigma is a much bigger, broader thing. And I just think this overall paradigm of secrecy and separation, separating this particular illness from the rest of healthcare over time is stigmatizing.

Can I say one more thing?

Mr. CARTER. Sure.

Mr. GARDNER. The healthcare industry is one of the places where this has been neglected the most in the past. And so I think things are changing for the better. Healthcare is at the table now, really, in the halls of Congress how much attitudes have changed drastically in the last 5 years, 10 years, and in healthcare.

So, for example, I think if we want to have, as I do, substance use curriculum in medical schools as a part of becoming a doctor—

Mr. CARTER. Absolutely.

Mr. GARDNER [continuing]. Which I think is paramount, I think we need to open these highways to integration and get—

Mr. CARTER. So, in other words, it is time to pull the drapes back. It is time to open it up. And, I am not just talking about patients. It is time for us as a society to recognize—and then we

talked about NAMI. It is time for us to recognize that these are truly diseases here. You know, this is not something someone chooses in a lot of cases. This is something that needs medical treatment.

I have not, during this testimony today, found one reason why I don't support this legislation. I have just simply not. I want to thank the author of the bill for bringing this forward. It is time for us to get through the 70s and get into 2018. So thank you for bringing this forward. And thank all of you again for being here and for your testimony and your work.

I yield back, Mr. Chairman.

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

The chair is prepared to recognize Mr. Mullin if Mr. Mullin will yield to the chair.

Mr. MULLIN. I would yield my time gladly to Mr. Chairman.

Mr. BURGESS. Thank you for that.

And as far as the 70s are concerned, Dr. Clark, you and I are probably about the same vintage in our medical school training. 42 CFR, a product of the 70s. I actually did take during my time in medical school, I was actually partitioned out to a methadone clinic that was state of the art in 1974 for substance abuse treatment. Unfortunately, it is still state of the art, and I don't know that it has improved a great deal, which is the thing that concerns me about our continuation down the path with 42 CFR, a 1972 law. It seems to be an obstacle of prevention from us modernizing our system.

And several people have referenced the panel of family members that we had here a couple of weeks ago. And it was tough, it was a tough afternoon, tough morning listening to their stories.

I appreciate, Dr. Clark, that you say that there are emergency provisions, but I am sorry: I practiced for 25 years. I am not sure that I knew that.

And we had a young woman tell us about a problem she had had in her family, and she talked about her son, and he suffered a fatal overdose and his fatal overdose April 20th of 2016. He had been seen at the hospital and revived with NARCAN seven times over the previous year. Her words, seven missed opportunities to intervene and save this young man's life.

OK, there was an emergency provision that they perhaps could have disclosed the data, but it doesn't do Emmitt any good, does it?

Dr. CLARK. But 42 CFR Part 2 nor HIPAA were relevant to that situation.

Mr. BURGESS. Here is the problem, Dr. Clark, and I am sympathetic with a lot of the points you bring up, but we have created so much confusion that the doctors don't even know.

OK, a high-profile case, a young man flying on his Learjet from one point to another, got some bad Vicodin that caused his respiratory depression. They landed his plane. And it took two doses of NARCAN to bring him back around. And now the emergency room doctor is being sued for not picking up on the fact that two doses of NARCAN was an unusual amount to require. And this in-

dividual, according to news reports—I am not mentioning the name on purpose, but according to news reports, refused a tox screen.

We have got to open up and talk to each other. The siloing of this stuff is what is killing people, in my opinion. And, again, I am just a simple country doctor. But hearing these, story after story after story, we have got to do better than what we are doing.

Mr. DeLoss, I wanted to give you an opportunity to talk about this a little bit. I know that you said, with 42 CFR—of course, 42 CFR, there weren't data breaches, right? Or if there were, we didn't know what they were. We used to call it theft back then.

So there is no protection or duty to inform about a data—there is no data breach notification requirement in 42 CFR, but there would be under the Mullin bill. Is that correct?

Mr. DELOSS. That is correct. There has been historically no breach notification provisions. And the bill does require that.

Mr. BURGESS. So the people who are really, really spun up about privacy, there is actually more protection in what Mr. Mullin has proposed to us than what exists under the 1972 law.

Mr. DELOSS. Agreed, yes.

Mr. BURGESS. Dr. Clark, since you are here and you are a doctor and a lawyer, let me ask you—and, of course, you are never supposed to ask a question you don't know the answer to. And I don't know the answer to it, so I am going to ask you.

Mr. Griffith kind of alluded to it a little bit. I think the situation that he described where an employer is a covered entity, I think that would be running afoul of the law, but just in general, is someone who is in recovery, is that information information that has to be disclosed to an employer, or may it be withheld from an employer?

Dr. CLARK. If they are truly in recovery under the ADA, they can't use it. On the other hand, if the employer has the information, they just don't have to announce it. So, if an employer knows something, they don't have to acknowledge it. They simply penalize the applicant for other reasons.

Mr. BURGESS. So, if they are on medication-assisted therapy, they are going to have a positive chemical test, a urinalysis. Is that correct?

Dr. CLARK. Unless they are under DOT. For instance, if you are on methadone, under DOT, you can't get a safety-sensitive position.

Mr. BURGESS. You can't get what, I am sorry?

Dr. CLARK. Safety sensitive. You can't get a commercial driver's license on methadone. That is not true for people on NARCAN, but those are the kinds of arcane rules that people have to live with.

Mr. BURGESS. But if you wanted to go work in a department store, that information may not be disclosed to the HR personnel at the department store?

Dr. CLARK. It wouldn't have to be.

Mr. BURGESS. Yet, at the same time, if there were something that happened that resulted in liability on the part of the department store owner, would all of that information be discoverable? Again, I am not a lawyer.

Dr. CLARK. It would be discoverable subsequently.

Mr. BURGESS. It would be discoverable?

Dr. CLARK. Depending upon court orders. All information, once it is subject to a court order, including under HIPAA, they would be able to reach it.

Mr. BURGESS. So who bears the liability? Does the department store owner then, who couldn't get the information, are they—

Dr. CLARK. That would be subject to the litigation. And that is exactly—

Mr. BURGESS. And I realize that is far afield. That is not part of the Mullin bill, but it is a question I have had for some time.

Dr. CLARK. It is an important question, sir.

Mr. BURGESS. I need to recognize Mr. Engel for 5 minutes for questions.

Mr. ENGEL. Thank you, Mr. Chairman and Mr. Ranking Member Green.

During our subcommittee's April 12th hearing, I asked Michael Botticelli about H.R. 3545. Mr. Botticelli is currently the executive director of the Grayken Center for Addiction at Boston Medical Center and served as the director of the Office of National Drug Control Policy.

When I asked if he had concerns about altering the protections provided by 42 CFR Part 2, Mr. Botticelli said, "I do, both as a policymaker and as a person in long-term recovery." He went on to say, "Unfortunately, substance use disorders are different from other diseases."

We know that Americans living with substance abuse disorders face stigma and discrimination that people living with other diseases do not, and we know that, as a result, those Americans might be hesitant to seek what could be the lifesaving treatment for fear of discrimination that remains pervasive.

It is our responsibility to ensure that our actions do not make this problem worse, and that is why today's discussion is so important. And I thank all the witnesses for being here and for sharing your insights.

Let me ask Ms. McCarthy Metcalf, I was here before when you gave your testimony and thank you for sharing your story with us. You noted in your testimony that you do regularly encounter medical providers who do not understand the 42 CFR Part 2 protections and mistakenly believe it to be a barrier to care because they do not understand how 42 CFR Part 2 works or the recent changes made to them. So they work in our 21st century healthcare environment. That is what you said.

Could you please describe the sorts of questions you typically get from providers about 42 CFR Part 2 and what kinds of misunderstandings have you seen?

Ms. METCALF. From what we have heard that has been reported to us, providers, medical providers don't understand the rule changing or the updates to the rules. So there is a lot of education that is now being done that SAMHSA is rolling out, and we haven't given that enough time, enough chance to educate medical providers or the community to understand how the new rules fit in with the new healthcare system.

Mr. ENGEL. Let me ask you this: Given what you have said in your testimony, do you believe better provider education would

mitigate the perception that 42 CFR Part 2 creates barriers to care?

Ms. METCALF. Yes. Greater provider education would work to support 42 CFR to protect the patient.

Mr. ENGEL. Let me ask you this: We have heard that requiring patient consent to disclose their treatment records is problematic because it is argued patients won't do something that could keep them from getting certain substances. Could you respond to that argument?

Mr. DELOSS. I am sorry; I didn't understand.

Mr. ENGEL. That requiring patient consent before disclosing treatment records is problematic because it is argued patients won't do something that could keep them from getting certain substances.

Ms. METCALF. It may be hard to get consent to share information about previous substance use treatment, but that is part of that process when they engage in treatment, and that is what the counseling—when they are able to provide that. It is encouraged that they provide that so that they can share that information with their doctors.

Mr. ENGEL. Dr. Clark, can I ask you that question too? I will repeat it. We have heard that requiring patient consent to disclose their treatment records is problematic because it is argued that patients won't do something that could keep them from getting certain substances.

Dr. CLARK. I don't think that is the case. By the time people present to treatment, they have had a number of problems associated in their lives, either with family, with employment, with housing, with the law, and as a result, even if they are ambivalent about treatment, they will be engaged. And it is incumbent upon the professionals to help facilitate that.

You have to keep in consideration that the delivery system is more of a cottage industry delivery system, despite the fact that people are trying to commercialize it. And as a result, it is the lack of electronic health information for the substance use disorder delivery system that keeps information from being shared rather than the patient not being able to share that information.

Mr. ENGEL. Thank you. My time is up.

Thank you, Mr. Chairman.

Mr. BURGESS. The chair thanks the gentleman.

The chair recognizes the gentleman from Florida 5 minutes for questions.

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

First question for Mr. Gardner and Mr. McKee. In your opinion, from your own experiences, do you think the legislation we are reviewing today will discourage people from seeking substance use disorder treatment? First, Mr. Gardner, please.

Mr. GARDNER. Thank you for the question, Congressman. I do not believe that it will discourage people from help seeking.

Mr. BILIRAKIS. That is so important.

Mr. McKee?

Mr. MCKEE. I do not think that it will discourage people from seeking treatment. I think that there are a number of factors that motivate people to move towards treatment. And if they truly are

in a phase for action, confidentiality is not necessarily something that is going to keep them from getting the treatment that they want.

Mr. BILIRAKIS. Very good. I agree.

Again, for both of you, could patients in SUD treatment today be referred to a primary care physician who is unable to view the patient's diagnosis due to 42 CFR Part 2 and be unknowingly prescribed opioids? Mr. Gardner?

Mr. GARDNER. Is it possible to be referred?

Mr. BILIRAKIS. Under the current law, yes.

Mr. GARDNER. To be referred by the SUD provider to a primary care provider without consent?

Mr. BILIRAKIS. Yes. Well, so the primary care doctor would prescribe the opioid, not knowing that this person may have a substance abuse issue. You see what I am getting at?

Mr. GARDNER. I think so, yes. That is definitely possible, yes.

Mr. BILIRAKIS. And we are trying to prevent that from happening with this legislation.

All right, sir, can you answer that question, please?

Mr. MCKEE. Congressman, yes. In the case of my brother, the orthopedist did not have the luxury of a substance use counselor or a psychiatrist in order to build rapport to move them through precontemplation, contemplation, preparation, and action stages that are associated with addiction. They had to give him aftercare. There wasn't time to wait. And they gave a loaded gun to a person who is suicidal.

You are giving opiates to an addict. And there was no time for him to build that rapport in order to get that consent. Bill.

Mr. BURGESS. Would the gentleman yield on that, please?

Mr. BILIRAKIS. Yes, please.

Mr. BURGESS. Just, Mr. McKee, further observation, in the way things have evolved, now you are not even being discharged from the hospital by your orthopedist. It is a hospitalist who probably has never seen you before. And that is an unfortunate derivation.

I am not aware of when your brother was injured, but current practice is the orthopedist, in fact, would then delegate care to the hospitalist, who would be in charge of the posthospital care.

Mr. MCKEE. Thank you for that clarification. And that just underscores the need for better care coordination, which requires some transparency under the protections of HIPAA law.

Mr. BURGESS. Thank you.

Mr. BILIRAKIS. So the next question for Mr. DeLoss. The VA has sorted out a system for gathering a patient's consent to share their full health record across providers, and that benefits the administration for filing claims. They have established a system where the VA consent form is valid for 12 months. And if protocols are followed, the entire record can be shared. This aligns much more closely with HIPAA than current practices for nonveterans.

In your opinion, are veterans suffering from this policy? And I happen to be the vice chairman of the Veterans Committee, so I am familiar with this. So, in your opinion, are veterans suffering from this policy, if you are familiar with the VA?

Mr. DELOSS. I am not very familiar with the veteran system, but with respect to having additional information to treat the veteran, I would assume that yes, they would be treated much better.

Mr. BILIRAKIS. OK. OK. So do you know if we have seen disproportionately fewer veterans seeking treatment as a result of this policy?

Mr. DELOSS. I am not familiar.

Mr. BILIRAKIS. You are not as familiar. Anyone else want to answer that question—who is familiar with the VA, with the system?

Dr. CLARK. I am familiar with the VA. I spent 14 years as an addiction psychiatrist in the VA working with PTSD and other conditions. And the fact of the matter is, clearly, they are better off if there is more information being shared. I won't argue with that at all.

So, with the VA establishing working relationships, because the VA has had her issues in the past establishing relationships with external entities sharing that information, but the receiving entity and the VA, if you are going to use the electronic health record, has to be interoperable. And I can tell you interoperability continues to be a problem.

So often the record is not read because whether the hospitalist has time to read it or not. My mother was just in the hospital, and she went from a skilled nursing facility to the same system. They hadn't read the records.

So we need to be careful about these panaceas, assuming things that will happen that, in practice, actually don't happen. But, if you have got interoperability and you have got a working relationship, you can enhance the care, preferably with the veteran's OK because then the patient doesn't show up if the system is seen as hostile.

Mr. BILIRAKIS. In this case, we get the veteran's consent. So, if it works like it should work, then I think that it is in the best interests of the veteran.

Thank you very much, and I yield back, Doctor.

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

I do want to thank our panel. Seeing no further members who wish to ask questions. Again, we really do owe you a debt of gratitude for being here today and staying with us for so long. There you have it, we are going to have a vote on the floor so we finished right in the nick of time.

I have a lengthy list of statements in support of the Mullin bill that I would like to submit for the record: The Kennedy Forum; Magellan Health; Healthcare Leadership Council; United States Department of Health and Human Services Substance Abuse and Mental Health Administration; America's Essential Hospitals; American Society of Addiction Medicine; National Association of State Mental Health Program Directors; the American Association on Health and Disability; National Alliance on Mental Illness; the American Hospital Association; the Academy of Managed Care Pharmacy; Avera; OCHIN; Pharmaceutical Care Management Association; Shatterproof; Trinity Health; Association for Behavioral Health and Wellness; Mental Health America; the National Association of Medicaid Directors; Oregon Association of Hospitals and

Health Systems; American Health Information Management Association; Blue Cross Blue Shield Association; Association for Community Affiliated Plans; Hazelden Betty Ford; Centerstone; Premier Healthcare Alliance; Catholic Health Association; Information Management; College of Healthcare Information Management Executives; Partnership to Amend Part 2; Confidentiality Coalition; the House of Representatives Rural Relief Initiative; Port Gamble Tribe; American Psychiatric Association; America's Health Insurance Plans; National Association of Accountable Care Organizations; and a joint statement from the National Association of ACOs, Premier, and the American Medical Group Association.

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

Mr. BURGESS. Additionally, Mr. Green had asked unanimous consent for the following letters expressing opposition to H.R. 3545 be in the record. This includes the National Advocates for Pregnant Women; the National Association for Children of Addiction; Opioid Treatment Association of Rhode Island; Ringgold Treatment Center; Victory Clinical Services; Recovery Network of Programs; SC Association for the Treatment of Opioid Dependence; Northern Parkway Treatment Services Incorporated; BH Health Services; Serenity Health; Kentucky Mental Health Coalition; President of the Kentucky Association for the Treatment of Opioid Dependence; People Advocating Recovery; Long Island Recovery Association; Faces & Voices of Recovery; Pennsylvania Recovery Organizations Alliance; Campaign to Protect Part 2; National Council on Alcoholism and Drug Dependence of San Fernando Valley; Opioid Treatment Providers of Georgia; Mid-Michigan Recovery Services; Southwest Carolina Treatment Center; Futures Without Violence; Sally Carr, parent of a son with addiction and representative of Never Surrender Hope; Lauren Wicks, National Independent Family Recovery Advocate; National Association for Children of Addiction; Amy E. Sechrist, addiction educator; Randy Flood, recovery coach, Recovery Coaching Services.

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

Mr. BURGESS. Pursuant to committee rules, I remind members they have 10 business days to submit additional questions for the record. I ask witnesses to submit the responses within 10 business days upon receipt of those questions.

Without objection, the subcommittee stands adjourned.

[Whereupon, at 4:25 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]



April 11, 2018

The Honorable Greg Walden
Chair, Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

Dear Representative Walden,

On behalf of the 62 members of the Oregon Association of Hospitals and Health Systems, I am writing to applaud your efforts to move the bipartisan package of bills aimed at addressing the opioid epidemic. The Energy and Commerce package includes a number of measures that take important steps toward addressing the opioid epidemic in Oregon and other states.

We are especially supportive of one aspect of the committee's work: modernizing outdated substance use disorder privacy policies. Specifically, OAHHS strongly supports aligning the privacy regulations in 42 CFR Part 2 with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of treatment, payment and health care operations.

Coordinating care for patients in treatment for substance use disorder is fundamental to successful treatment. However, the requirements of 42 CFR Part 2 makes it very difficult or prevents the sharing of patient information necessary to deliver effective and coordinated care. This conflict forces hospitals and health systems now to go to extraordinary lengths to deliver needed care.

We urge the Committee to adopt legislation that would fully align the 42 CFR Part 2 regulations with the HIPAA rules. Applying the same requirements for all patient information – whether behavioral or medical – would facilitate appropriate information sharing needed for clinical care coordination and population health improvement, while safeguarding patient information from unwarranted disclosure.

As always, please don't hesitate to contact us if you would like additional information on this issue.

Thank you for your consideration.

Respectfully,

A handwritten signature in black ink, appearing to read "Andy Van Pelt".

Andy Van Pelt
Executive Vice President
Oregon Association of Hospitals & Health Systems



Designing Medicaid Health Homes for Individuals with Opioid Dependency: Considerations for States

By Kathy Moses and Julie Klebonis,* Center for Health Care Strategies

Over the last decade, increasing rates of opioid dependency have become a concern for public health officials, state Medicaid agencies, and the federal government. Increased health care service use and higher costs of care have resulted from the significant morbidity and mortality associated with illegal opioid use. In 2010, roughly 600,000 people in the United States used heroin¹ and 12 million used prescription painkillers, including oxycodone and morphine, for nonmedical reasons.² In 2009, nearly half a million emergency department visits were due to people misusing or abusing prescription painkillers. In that same year, health insurers spent \$24 billion on treatment for substance use disorders, of which Medicaid accounted for 21 percent of all spending.³

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 illness⁴ and could benefit from increased care management.

According to a recent informational bulletin from the Center for Medicaid and CHIP Services, states can incorporate Medication Assisted Therapy (MAT), an evidence-based practice to address opioid use, into efforts to address substance use disorders.⁵ Clinical guidelines recommend that MAT be offered in combination with behavioral health therapies.⁶ Moreover, to ensure that treatment is coordinated with other needed physical and behavioral health services, many state Medicaid agencies are seeking new mechanisms to promote integrated care for individuals with opioid dependency.

The Medicaid health home state plan option offers states one such mechanism. As of December 2014, three states—Maryland, Rhode Island, and Vermont—have approved state plan amendments (SPAs) to implement Medicaid health home models targeting opioid dependence.⁷ This brief, made

IN BRIEF

Although individuals with opioid dependency represent a small percentage of all Medicaid enrollees, they often have significant physical and behavioral health needs that result in high costs of care. States are looking for innovative, cost-effective ways to integrate and coordinate care for this population. Through the Affordable Care Act (ACA), states can implement health homes to provide enhanced integration and care coordination for people with opioid dependency.

This brief, made possible by the Centers for Medicare & Medicaid Services, highlights key features of approved health home models in Maryland, Rhode Island, and Vermont that are tailored to individuals with opioid dependency. It identifies important considerations in developing opioid dependence-focused health homes, including: (1) leveraging opioid treatment program requirements; (2) promoting collaboration across multiple state agencies; (3) supporting providers in transitioning into health homes; and (4) encouraging information sharing.

possible by the Centers for Medicare & Medicaid Services (CMS), shares insights from these three states and outlines key considerations for states in designing an opioid dependence-focused health home.

Comparison of Approved Opioid Health Home Models

Common features across the opioid treatment health home models in Maryland, Rhode Island, and Vermont include: (1) statewide implementation; (2) Opioid Treatment Programs (OTPs)⁸ as a designated provider; and (3) definitions of eligible populations (Exhibit 1). While some program aspects are similar, CMS provides the flexibility for states to tailor programs—within defined requirements and subject to federal approval—to meet the needs of beneficiaries and local providers. Variations across the three state opioid health home models include:

* Julie Klebonis is a former employee of the Center for Health Care Strategies.

- Health home provider structure.** Each state has defined providers differently. Vermont's health home model, for example, refers to its designated providers as "Hubs and Spokes." Hubs are designated providers (OTP programs) that serve clinically complex members and dispense methadone and buprenorphine in an addictions treatment center. Spokes refer to a team of health care professionals (Office Based Opioid Treatment [OBOT]) that is comprised of physicians licensed to prescribe buprenorphine; nurses; and clinician case managers. (For more information, see sidebar *Spotlight on Vermont's Health Home Model* page 5.)
- Type of enrollment.** States must determine if eligible Medicaid beneficiaries will be assigned into the health home with the ability to opt-out, or if beneficiaries must opt-in. Most health home models, including Rhode Island and Vermont, auto-assign beneficiaries, but allow them to opt-out at any time or select among other qualified health homes. Maryland uses the opt-in approach and built beneficiary consent into the opt-in process, ensuring the opportunity to secure the necessary member consent to share critical health care information.
- Team of health home providers.** Each state defines the health home team differently in terms of: (1) required staff positions; (2) education or training requirements; and (3) the ratio of members to full-time equivalent staff. Rhode Island created a shared statewide administrative-level coordinator role to oversee health home implementation at all agencies and act as the liaison to the state agencies supporting health homes. The coordinator strategizes with teams to encourage member participation, identifies potential community partners, addresses implementation challenges, and assists in outcomes evaluation. In Rhode Island, this position is viewed as a trusted advisor to the site-specific health home teams, as well as an excellent resource to the state for ensuring fidelity to the health home model. A key component to this staffing approach is that the state is responsible for hiring the shared administrative coordinator, but funding for the position is shared across all health home sites.
- Approach to payment.** Whereas all three states include some form of bundled payment for health home services, there are three slight variations in payment models: (1) Maryland's per member per month (PMPM) payment is coupled with a one-time payment for initial intake assessment; (2) Rhode Island uses a weekly bundled payment with the rate based on whether the member is enrolled in fee-for-service or managed care; and (3) Vermont has a monthly bundled rate for Hub providers and a monthly capacity payment for Spoke nurses and clinician case managers. The average monthly payment across these three models ranges from approximately \$100 to \$350 depending on the team's cost for providing the service, staffing ratios, and what services are included in the rate.

Medication Assisted Therapy

Medication Assisted Therapy (MAT) uses medication (methadone, buprenorphine or naltrexone) in conjunction with counseling and behavioral therapies. MAT is available in two different provider settings: Opioid Treatment Programs (OTPs) or Office Based Opioid Treatment (OBOT) settings. OTPs are specially licensed treatment programs where patients receive dispensed methadone on a daily schedule. Buprenorphine or naltrexone therapy, which has a less rigorous dosing schedule, is also available through an OTP.⁸ OBOT settings refer to certified providers in general medical practices who are also authorized to prescribe buprenorphine or naltrexone.

Exhibit 1: Features of Approved Medicaid Health Home Models for Opioid Dependency

Feature	State		
	Maryland	Rhode Island	Vermont
Effective Date	October 2013	July 2013	July 2013, expanded January 2014
Geographic Location	Statewide	Statewide	Statewide
Target Population	Medicaid recipients with opioid use disorder and the risk of developing another chronic condition; or one or more serious and persistent mental illness (SPMI)	Opioid-dependent Medicaid recipients currently receiving or who meet criteria for MAT	Medicaid recipients with opioid dependence and the risk of developing another substance use disorder and co-occurring mental health condition
Type of Enrollment	Opt-in enrollment	Auto-assignment, with opt-out	Auto-assignment, with opt-out
Enrollment^a	4,553 (4,038 with SPMI and 515 with opioid use disorder)	2,657	4,436 (2,464 in Hubs, 1,972 in Spokes)
Types of Providers	Designated provider must be one of the following: (1) an opioid treatment program (OTP); and, for the SPMI population, either (2) Psychiatric Rehabilitation Program; or (3) Mobile Treatment Service provider	Designated provider must be OTP licensed by the state as a Behavioral Healthcare Organization	Hub: Designated provider must be a regional specialty OTP Spoke: Team of health care professionals set in OBOT programs
Providers^a	27 agencies with 60 provider sites	Five providers with 12 statewide locations	Five Hub providers; 127 Spoke providers
Key Health Home Team	Health home director, nurse care manager, physician, or nurse practitioner consultant, and administrative support staff ^b	Supervising physician, registered nurse, health home team coordinator, case manager / hospital liaison and pharmacist. Also, three shared positions across health home sites: (1) administrative level coordinator; (2) HIT coordinator; and (3) health home training coordinator ^c	Hub: Registered nurse and master's level licensed clinician case manager, and program director employed by the Hub Spoke: Registered nurse and clinician case manager employed by Blueprint Community Health Team ^d
Payment Model	\$98.87 per member per month (PMPM) payment; and one-time payment of \$98.87 for each member's initial intake assessment	\$87.52 for fee-for-service members and \$52.52 for managed care members structured as a weekly, bundled rate per member	Hub: Monthly bundled rate per member of \$493.37. Note: only 30% of the rate is health-home specific, thus only 30% of the Hub payment is matched at 90% of the federal financial participation rate, or approximately \$148 PMPM. Spoke: \$163.75 PMPM payment

SOURCE: Health Home Information Resource Center and approved health home SPAs.¹⁹^a As of December 2014.^b Staffing based on a ratio of 125 enrollees per team that equates to slightly more than 1.25 FTEs.^c Staffing based on a ratio of 125 enrollees per team of 4.35 FTEs.^d Staffing based on 100 enrollees per team of 2 FTEs.

Health Homes 101

The Medicaid health home state plan option (ACA Section 3763) promotes access to and coordination of primary and acute physical and behavioral health services and long-term services and supports. Health homes may be virtual or located in primary care or behavioral health providers' offices or other settings that best suit beneficiaries' needs. Health homes must provide six core services, linked as appropriate and feasible by health information technology:

- Comprehensive care management;
- Care coordination;
- Health promotion;
- Comprehensive transitional care/follow-up;
- Individual and family support; and
- Referral to community and social support services.

To be eligible for health home services, an individual must be diagnosed with either: (1) two chronic conditions; (2) one chronic condition and at risk for a second; or (3) a serious mental illness. States implementing Medicaid health homes receive an enhanced 90/10 federal match for the first eight fiscal quarters of the health home program.

Considerations for Developing Opioid Health Homes

Interviews with representatives from Maryland, Rhode Island, and Vermont provide additional recommendations for the development of opioid dependency-focused health home models. These include:

1. **Leverage the requirements of OTPs to encompass key health home components.** OTPs, given their responsibility to provide daily doses of methadone to members, have a “captive audience” that is enviable in Medicaid health homes. Thus, the typically challenging task of identifying and engaging members is not an issue in OTP settings. This opportunity in OTPs for daily member contact with medical and other clinical professionals supports health home goals of ongoing care management, care coordination, and consumer engagement.
2. **Invest in multi-agency collaboration to develop opioid treatment health homes.** Overwhelmingly, states cited internal collaboration with other state agencies, such as the Office of Mental Health and the Office of Alcohol and Substance Abuse, as paramount to the success of their opioid health home delivery models. This collaboration requires a significant amount of internal stakeholder engagement to bridge differences in priorities and practices between Medicaid and sister state agencies.

Vermont’s Medicaid agency identified the need for internal collaboration as a key success factor both in the design and implementation phases of its health home. The design of its opioid health home was a result of collaboration between the Department of Health’s Division of Alcohol and Drug Abuse Programs (ADAP), the Department of Vermont Health Access (DVHA) (Vermont’s Medicaid program), and Vermont’s Blueprint for Health (Blueprint)—the state’s health care reform initiative.

In building the health home model, the state leveraged ADAP’s existing relationships with established providers as well as existing provider education mechanisms. The Blueprint for Health, part of DVHA, coordinates the overall administration of the health home effort as well as the PCMH initiatives that are building blocks to the opioid treatment health home model. Blueprint community health teams (CHTs) are being used to provide the additional care management services to Hub and Spoke health homes. Pulling from multiple agencies, Vermont built on each state agency’s strongest attributes to develop a health home model that meets both the goals of the state and the needs of the individuals it serves.

3. **Support providers in transforming into effective opioid treatment health homes.** Offering support and education to providers is vital to the success of health homes for individuals with opioid dependency. The three

Spotlight on Vermont's Health Home Model

Vermont's health home approach is referred to as the "Hub and Spoke" model. This approach builds on existing infrastructure, including: (1) two levels of care for MAT, and (2) the Blueprint for Health (Blueprint), a statewide, multi-payer initiative to improve health care delivery. Depending on the initial determination of complexity and/or appropriate treatment method, individuals are referred to either a Hub or Spoke.

Hubs are based on OTPs, which are highly regulated specialty treatment centers for individuals with complex addictions and comorbid mental health conditions. Medication treatment must be provided in the OTP, and, in Vermont, OTPs may also dispense buprenorphine.

Spokes are based on OBOT programs, which are general medical office settings where physicians are specifically licensed to provide buprenorphine to individuals with less clinically complex conditions. The office settings include primary care, OB-GYN, psychiatry, and other specialties.

Leveraging Existing Infrastructure for Care Management Staffing: Through Vermont's Blueprint, public and commercial payers make additional payments to primary care practices that meet Patient-Centered Medical Home (PCMH) standards and also share in the cost of community health teams (CHT) that provide multidisciplinary support for PCMHs and their patients. The CHTs are staffed with nurse coordinators, clinical case managers, social workers, and other staff. CHTs extend the capacity of primary care practices by supporting patient assessments, coordinating community-based support services, and providing multidisciplinary care. Because the Blueprint is a public-private partnership, CHTs are funded collectively by Vermont's large health insurance payers. Transforming the OTPs and OBOTs to Hubs and Spokes includes adding staff to the CHT infrastructure to provide the core health home services to opioid-dependent individuals and to coordinate patient care across the primary, acute, behavioral, and long-term care systems.

Enhanced Federal Match for New Services: Costs for previously existing opioid treatment services remain matched at Vermont's regular federal match rate. Since new health home staffing at the Hub is approximately 30 percent of overall Hub costs, only 30 percent of a Hub's reimbursement rate is eligible for the enhanced 90 percent federal match. Enhanced Spoke staffing provides all new care management services, therefore, a Spoke receives a 90 percent federal match for all health home costs.

states' approved SPAs include a variety of health home provider education approaches that can be repeated as new providers come onboard or staff turns over. In the three approved SPAs, state options for fostering provider education included:

- **Maryland** used a series of webinars and regional meetings to support information sharing and problem solving among OTP health home teams. The state is also performing outreach to foster linkages with community providers that may collaborate with health homes.
- **Rhode Island** built its education activities upon experience from earlier health home models and substance abuse programs. The state supplemented general health home education activities by adding training on health literacy, motivational interviewing, and emotional trauma in order to enhance provision of care management and care coordination activities. In addition, Rhode

Island is also planning to provide the Whole Health Action Management (WHAM) training program¹¹ developed by the SAMHSA-HRSA Center for Integrated Health Solutions to its peer workforce in order to strengthen their ability to support opioid-focused health homes.

- **Vermont's** ADAP and the Blueprint for Health are sponsoring learning collaboratives and trainings to support OTPs and OBOTs in transitioning to Hub and Spoke health homes. Regional OBOT collaboratives and statewide Hub and Spoke learning collaboratives are designed to: (1) provide education on best practices in care management for individuals with opioid dependence; (2) report on quality measures; and (3) share health home quality improvement efforts (e.g., Plan, Do, Study, Act cycles). The state provides continuing education credits to providers participating in the regional collaboratives.

4. **Encourage information sharing between providers.** Collectively, the three states cited federal confidentiality requirements as a barrier to effective integration of care and sharing of vital information between the health home and other medical professionals. Federal regulations (i.e., 42 CFR Part 2) were established to protect the privacy of individuals with alcohol and substance use disorders by limiting who can access information regarding treatment.¹² Because 42 CFR Part 2 applies to any entity receiving federal assistance that provides an alcohol or substance abuse diagnosis, treatment, or referral to treatment, OTPs are included under this provision.

As more states are moving toward an integrated health care delivery approach, 42 CFR Part 2 poses unique challenges for information sharing. States pursuing an opioid dependency health home program may consider training opportunities that: (1) ensure that health home team members understand privacy laws and what information can be shared between providers absent a signed release; (2) encourage the use of 42 CFR Part 2-compliant release forms; and (3) encourage enhanced support to beneficiaries on the benefits of sharing substance use information with

other providers, including how the information will be used in their health home treatment plans.

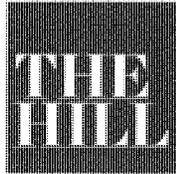
Conclusion

The Medicaid health home option in the ACA affords states considerable opportunity to customize health home services to the unique competencies of providers and needs of beneficiaries. Such considerations are critical for all aspects of program design—ranging from how the population is identified to how providers are qualified and services delivered and reimbursed.

As more states pursue health homes, additional customization for specific target populations, including individuals with opioid dependence, may be expected. The considerations used to shape the opioid dependency health home programs in Maryland, Rhode Island, and Vermont offer helpful guideposts for the development of health home programs in other states, including models that target substance use disorder more broadly. Based on the experiences of these three states, health homes should be considered as an integral model for addressing opioid use disorders in the Medicaid program.

Endnotes

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- ⁵ CMCS Informational Bulletin: Medication Assisted Treatment for Substance Use Disorders; July 11, 2014. Available at: <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf>.
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- ⁷ A state plan is an agreement between a state and the federal government that describes how the state administers its Medicaid program. In it, the state assures that it will abide by federal rules to claim federal matching funds. States submit a state plan amendment (SPA) to the Centers for Medicare & Medicaid Services (CMS) if they wish to make changes to their Medicaid programs. For more information see: <http://www.medicaid.gov/State-Resource-Center/Medicaid-State-Plan-Amendments/Medicaid-State-Plan-Amendments.html>.
- ⁸ Healthcare Brief: Medication Assisted Treatment for Opioid Addiction. Office of National Drug Control Policy. Available at: http://www.whitehouse.gov/sites/default/files/ondcp/recovery/medication_assisted_treatment_9-21-20121.pdf.
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People with addiction issues should be able to control their own health data

BY PATRICK J. KENNEDY AND KEVIN SCALIA, OPINION CONTRIBUTORS — 01/11/18 05:00 PM EST
THE VIEWS EXPRESSED BY CONTRIBUTORS ARE THEIR OWN AND NOT THE VIEW OF THE HILL

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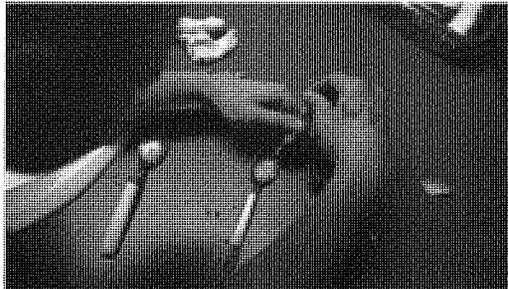
Cambridge Analytica was offered hacked data

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Much of the discussion about the concurrent opioid and suicide epidemic in our nation centers on the need for increased funding and resources. However, another major hurdle we face involves decades-old federal health record privacy regulations containing complicated, cumbersome

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consent requirements that discriminate against and endanger people with a substance use disorder (SUD) or history of SUD treatment.

People with diabetes, asthma, HIV, cancer or a history of heart attack can easily share their health information with doctors. They can also take full advantage of electronic health information exchanges (HIEs) that reduce the risk of potentially deadly medication errors among care teams.

Why should it be any different for a person with a history of SUD? Why are brain diseases excluded from a comprehensive, collaborative approach to care?

The ultimate goal of consent should be to give people the power to share their own health data with healthcare providers, if they so desire. This power of consent should apply regardless of whether a person has a SUD, mental illness, cancer, diabetes or multiple co-occurring conditions. Likewise, if a person does not wish to share her health data, she should have the clear option to either opt-out or not opt-in to sharing that information.

Current federal [privacy regulations \(42 CFR Part 2\)](#), which only apply to people with a SUD, place restrictions on sharing your own health data with a history of SUD. Such regulation puts a burden on patients, their treating providers, and Health information exchange (HIEs), making it operationally expensive — and with today's existing HIE technology — extremely costly, to transfer and manage SUD data.

This makes it very easy for HIEs to just say no, we will not accept your SUD data — thereby denying a person with SUD who wants to share data the same access to care as a person with cancer or diabetes. In this case, the regulations are discriminatory, preventing people with a SUD from benefiting from coordinated, integrated care, and increasing the chance of inappropriate opioid prescribing.

Imagine you are scheduled for outpatient surgery at a local surgery center. You sign a consent form for your SUD treatment program to share information about your addiction to OxyContin with the surgery center. The surgery center makes a note in your health record, but your surgeon,

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who is employed at a separate clinic, isn't permitted to see that part of your health record and prescribes OxyContin post-op for your pain.

Incidents like this happen every day across the nation, and raise several major concerns:

Incomplete health record information

Despite recent updates to regulations by the Substance Abuse and Mental Health Services Administration (SAMHSA), there are still significant complexities in one's ability to consent to release SUD treatment information to treating providers. This data gap prevents doctors and others from seeing a full picture of their patient's health, substantially increasing the risk of treatment and prescribing errors.

Discrimination and lack of parity

Addiction is a disease, not a mindset or a moral failing. Outdated Part 2 regulations are aiding and abetting discrimination against people with a SUD.

Technology limitations

Some integrated healthcare delivery systems, such as HIEs, Medicaid Health Homes and Medicare Accountable Care Organizations (ACOs) won't accept a patient's data (who has a history of SUD treatment) because they lack the technology or financial resources to comply with current consent and data segmentation requirements. Ironically, these entities were designed to provide "whole-person" care that addresses a full spectrum of co-occurring brain and body health conditions, including addiction treatment.

What's the answer?

We are seeing some movement in the right direction. There are indications that SAMHSA may reopen the rulemaking process for further input. Reps. Markwayne Mullin (R-Okla.) and Earl Blumenauer (D-Ore.) have introduced the bipartisan Overdose Prevention and Patient Safety Act in the U.S. House. A bipartisan companion bill, the Protecting Jessica Grubb's Legacy Act (The Legacy Act), has been introduced in the U.S. Senate by Sens Joe Manchin (D-W.Va.) and Shelley Moore Capito (R-W.Va).

These bills more closely align 42 CFR Part 2 regulations with HIPAA, helping to ensure that all clinicians involved in a person's care get the full picture of their health. The bills also strengthen protections and prohibitions against disclosures of SUD information for criminal justice purposes — a legitimate concern of patient advocacy groups.

Most recently, during the fourth meeting of the President's Commission on Combating Drug Addiction and the Opioid Crisis, leaders from the nation's top insurance companies, as well as Commission members, overwhelmingly called for immediate 42 CFR Part 2 reform to stop the horrific cycle of preventable and unnecessary deaths in this country.

Recently, SAMHSA published a final rule that now allows for greater flexibility in the sharing of SUD treatment information by third parties for payment and healthcare operations. The final rule specifically excluded treatment, diagnosis and referral for treatment from the new, more flexible provisions.

Ironically, it's now easier for a person's SUD-related health information to be shared by payers, health plans and other entities for billing, payment, claims management and collections — than with the person's own healthcare providers for fully-informed diagnosis and treatment. The exclusion of treatment from the list of permissible activities for disclosure prevents people with an SUD from benefiting from coordinated, integrated care and exacerbates the stigma often associated with SUDs.

While HIPAA provides substantial protections for health information, it also provides something that Part 2 regulations cannot: patient choice. The decision to share critical health information should lie with the individual, not the Part 2 program, SAMHSA or the healthcare system.

Patrick J. Kennedy is the founder of The Kennedy Forum and former democratic congressman from Rhode Island. He is also a former member of the President's Commission on Combating Drug Addiction and the Opioid Crisis. Kevin Scalia is the executive vice president of Netsmart.

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3/21/2018

People with addiction issues should be able to control their own health data | TheHill



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Electronically submitted via PrivacyRegulations@samhsa.hhs.gov

Feb. 28, 2018

Elinore F. McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
Attn. Mitchell Berger
5600 Fishers Lane, Room 18E89C
Rockville, MD 20852

Re: Confidentiality of Substance Use Disorder Patient Records; Notice of Public Meeting (Docket no. 2018-00150)

Dear Assistant Secretary McCance-Katz:

Magellan Health, Inc. (Magellan) appreciates the opportunity to respond to the Notice of Public Meeting published by the Substance Abuse and Mental Health Services Administration (SAMHSA) in the Jan. 9, 2018 *Federal Register* concerning confidentiality of substance use disorder (SUD) patient records regulations, 42 C.F.R. Part 2 (Part 2 regulations), as noted in Section 11002 of the 21st Century Cures Act of 2016. We further appreciate the opportunity to have attended the Jan. 31, 2018 listening session and have incorporated herein the oral remarks made by Teresa Berman, Magellan's senior vice president and Deputy Compliance Officer, as requested in the course of that session.

Headquartered in Scottsdale, Ariz., Magellan helps millions of Americans live healthier, more vibrant lives. We are committed to connecting behavioral, physical, pharmacy, and social needs with high-impact, evidence-based clinical and community support programs to ensure the care and services provided to the members we serve¹ are individualized, coordinated, fully integrated, and cost effective. Magellan develops and supports innovative ways of accessing better health by combining advanced analytics, agile technology, and clinical excellence, while remaining focused on the critical personal relationships necessary to achieve a healthy, vibrant life.

In addition to Ms. Berman's remarks, our response to the Notice also includes Magellan's experience with Part 2; how Part 2 affects patient care and health outcomes; and recommendations for regulatory action for SAMHSA to consider related to the following, as described further on Pages 5-6:

- Aligning Part 2 with the Health Insurance Portability and Accountability Act (HIPAA) of 1996,
- Relaxing the stringency of the consent requirements to permit a consent form be executed for HIPAA-like purposes, and

1. Included here also are individuals we serve whom are members of our customers' health plans.



- Indicating the permissibility (in response to the opioid crisis) of coordinating SUD care between providers and with providers and clinicians working within managed care entities.

I. Magellan Health's Experience with 42 C.F.R. Part 2

Much of what Magellan does on behalf of our members and our customers necessitates disclosing patient-identifying information within the healthcare system, interfacing and interacting with providers while protecting the privacy concerns of members with mental health conditions and, often, co-occurring SUDs receiving treatment. Indeed, the *Journal of the American Medical Association* found 50 percent of individuals living with serious mental illness (SMI) also have a substance use disorder.² Of those, more than half (53 percent) are a drug-related use disorder, such as opioid use disorder. **As a result of Part 2's restrictions, these members' access to whole-person, fully integrated healthcare can be hampered when providers are prevented from accessing all relevant information necessary to appropriately support individuals' healthcare needs.**

As an experienced specialty healthcare organization, Magellan provides a tailored spectrum of mental health and substance use disorder treatment and services and Employee Assistance Programs for health plans, employers, and various military and government agencies and public healthcare programs, including to active-duty service members and their families, the Medicare Advantage and state Medicaid programs, and individuals dually eligible for Medicare and Medicaid. Magellan also contracts with more than 80,000 credentialed behavioral health providers nationwide and provides behavioral healthcare services to approximately 1.6 million public-sector members through a range of innovative state programs, including the nation's first Medicaid specialty health plan for individuals living with SMI, Magellan Complete Care of Florida. Our subsidiary, Magellan Healthcare, contracts with health plans nationwide and some state Medicaid programs (including Florida, as noted) in order to perform case management and care coordination, utilization review, utilization management, and/or claims adjudication functions on their behalf, and thus has significant direct experience with the impact of the requirements under 42 C.F.R. Part 2. As a contractor and subcontractor, Magellan Healthcare is expected to perform case management and care coordination and related functions on behalf of its customers for its customers' members, including those living with a SUD.

In addition, our subsidiary, Magellan Rx Management, is a full-service pharmacy benefit manager that expands beyond traditional core services to help our customers and members solve complex pharmacy challenges, including through the use of targeted clinical programs, comprehensive member and provider engagement strategies, advanced analytics, and expert specialty pharmacy management capabilities. **Accordingly, much of what Magellan does on behalf of our customers and members – including 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 concerns of individuals living with SUDs receiving treatment and services.**

2. Darrel A. Regier, MD, MPH; Mary E. Farmer, MD, MPH; Donald S. Rae, MS; et al., "Comorbidity of Mental Disorders With Alcohol and Other Drug Abuse: Results From the Epidemiologic Catchment Area (ECA) Study," *Journal of the American Medical Association* (1990) 264, no. 19:2511-2518. doi:10.1001/jama.1990.03450190043026.

For our members and our customers, as well as our customer's members, Magellan performs case management, care coordination, discharge planning, utilization review, claims adjudication, and other related functions, affording us significant direct experience with the impact of Part 2. **This extensive experience informs our perspective on confidentiality and disclosure of substance use disorder patient records, and our response to the Notice.**

II. How 42 C.F.R. Part 2 Affects Patient Care and Health Outcomes

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 treatment details, provider by provider. **Magellan believes it is critical for health plans to be able to assist their members' recovery and relapse prevention by sharing valuable substance use disorder information with members' providers** 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.

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 cannot be included without individualized consent—disallows providers from supporting their patients holistically. **In fact in some case, providers may believe the EMR (to which they have access) reflects the individual's full medical record.** In such situations, a provider may, for example, prescribe 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 members' access to care is appropriate to their needs and clinical histories.

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 more easily be shared 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 over and over again 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, or switches psychiatrists, or begins a new course of treatment with a cardiologist – all of whom need to know about the member's substance use disorder 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 member is in denial about their SUD; is unable to effectively understand or communicate due to their condition; or has other co-occurring conditions (such as SMI) which stymie the consent-collection process.

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 member's discharge from an inpatient detox facility and attempting to locate an appropriate outpatient therapist in the community, the 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 either the:

- Detox facility notifies the therapist of the treatment directly (although they too would first need to obtain written consent to do so as well),
- Therapist asks the member about any SUD history (and that the member responds truthfully), or
- Member is forthcoming enough to inform the therapist proactively.

If none of these occur, the therapist's treatment plan will not address the crux of the member's healthcare needs – their substance use disorder – potentially leaving the member at greater risk of relapse, re-admission, or worse.

Similarly, when a detox facility calls the member's 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. A member with a SUD may not provide the 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 patient care and health outcomes Magellan has encountered in attempting to manage the behavioral healthcare and services of members in compliance with Part 2 include:

- Due to the need to exclude SUD data from the information sharing necessary to successfully coordinate a patient'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.
- **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.

- Denial is an important dynamic in substance use disorders. Individuals living with a SUD may inadvertently rely on denial and not appreciate their own chronic health condition, allowing him or her to hide their condition from clinicians who are attempting to ensure appropriate treatment and services. **Without an easier, more effective way to facilitate transfer of SUD information between providers and health plans, the clinician is left naïve concerning the patient's true healthcare condition, and the SUD diagnosis can go unaddressed and untreated,** further feeding into this difficult, unintended pattern.

In our experience, we have seen multiple member situations and dynamics adversely impacted by Part 2 (as we note above). In further response to the listening session, we would like to share the story of one of our members, and how their care and health outcomes were affected by Part 2:

An adult member was brought to the emergency department by relatives concerned by their loved one's depression and suicidal statements. The member received a complete evaluation, including a physical examination and a psychiatric evaluation. Records from a previous psychiatric hospitalization were obtained from another facility in the community without patient written consent, as permitted by HIPAA.

Three days after admission, the patient experienced a grand mal seizure; it was only then the member shared several years of barbiturate misuse. The member shared they had not wanted the hospital's treatment team to know about this, and thus had denied any history of substance use to staff.

At the previous admission to the other psychiatric facility, the member had been forthcoming about the barbiturate misuse, and had received appropriate detox treatment; however, since a release specifically for SUD information had not been signed by the member, pages of their medical record concerning this previous SUD history had been omitted when the facility provided the patient's records to the emergency department. Since the emergency department's treatment team was deprived of this knowledge, the hospital's inability to correctly diagnose and treat their patient led to a serious adverse incident for this member.

III. Recommended Regulatory Action for SAMHSA to Consider

While we appreciate recent efforts to revisit the regulations, **Magellan continues to urge SAMHSA to update Part 2 to align with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 by adopting a care coordination exception to the consent requirement. While HIPAA permits such information sharing for treatment and healthcare operations, Part 2 does not**—presenting an unnecessary and sometimes even insurmountable barrier and marginalizing this crucial tool for individuals living with SUDs. This meaningful change would retain sufficient protection and confidentiality of individuals' substance use disorder records while also bringing Part 2 into the modern era. Part 2 was created before HIPAA existed and these stringent requirements are incompatible with contemporary advancements in care coordination and electronic information sharing which can



currently be afforded to all health plan members, except those with substance use disorders.

Alternatively, while SAMHSA may be constrained somewhat by 42 U.S.C. §290dd-2, **Magellan believes there is some latitude afforded both in relaxing the stringency of the consent requirements in 42 U.S.C. §290dd-2 (1) and in the exception in section (2) for disclosures “to medical personnel to the extent necessary to meet a bona fide medical emergency.”** 42 U.S.C. §290dd-2(1) notes the content of records “may be disclosed in accordance with the prior written consent of the patient with respect to whom such records are maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).” **The regulations could be modified to permit a consent form to be executed that allows for the use of the member’s information for treatment, payment and healthcare operations – including care coordination – rather than the current requirements to obtain consents specific to each and every provider who is involved in the member’s care in order to coordinate all the various treatments and services the member receives.**

We also believe that, given the significant opioid crisis in our country, which has been declared a public health emergency³, **SAMHSA could indicate in regulation that the coordination of substance use disorder care between providers and with providers and clinicians working at managed care entities and pharmacies would be permissible in response to addressing a bona fide medical emergency.**

To ensure individuals with substance use disorders receive the full benefits of integrated care, Magellan respectfully requests that SAMHSA consider pursuing the proposals discussed above, including either permitting coordination of care without an authorization, or, in the alternative, permitting a member to sign one consent authorizing their information to be used for treatment and healthcare operations purposes, including care coordination, without the burden of naming individual providers.

Magellan would be glad to answer questions or provide further information. Please contact Brian Coyne, vice president of federal affairs, at (804) 548-0248 or bcoyne@magellanhealth.com; or, Claire Wulf Winiarek, vice president of public policy, at (860) 507-1918 or cwulfwiniarek@magellanhealth.com.

Thank you for the opportunity to share our experience and recommendations on this important issue.

Sincerely,

Meredith A. Delk, Ph.D., MSW
Senior Vice President, Government Affairs

3. Office of the Secretary, U.S. Department of Health and Human Services, “Determination that a Public Health Emergency Exists” (Oct. 26, 2017), <https://www.hhs.gov/sites/default/files/opioid%20PHE%20Declaration-no-sig.pdf>.



March 8, 2018

The Honorable Greg Walden
 Chairman
 U.S. House of Representatives
 Committee on Energy and Commerce
 2125 Rayburn House Office Building
 Washington, D.C. 20515

The Honorable Frank Pallone
 Ranking Member
 U.S. House of Representatives
 Committee on Energy and Commerce
 2125 Rayburn House Office Building
 Washington, D.C. 20515

Dear Chairman Walden and Ranking Member Pallone:

The Healthcare Leadership Council (HLC) is writing to you to urge passage of H.R. 3545, the "Overdose Prevention and Patient Safety (OPPS) Act", to enable the appropriate exchange of necessary information among medical professionals who are treating individuals with substance use disorders, including opioid abuse. While HLC commends the U.S. Substance Abuse and Mental Health Service Administration's (SAMHSA's) ruling to amend 42 C.F.R. Part 2 to better align Part 2 regulations within the Health Insurance Portability and Accountability Act (HIPAA) to integrate behavioral and physical healthcare, we believe this ruling does not go far enough to help increase access to relevant health information among patients, payers and providers while concurrently protecting patient privacy.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, pharmacies, post-acute care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach. Through this diversity, we develop a nuanced perspective on the impact of any legislation or regulation affecting the privacy and security of health consumers. We believe access to timely and accurate patient information leads to both improvements in quality and safety and the development of new lifesaving and life-enhancing medical interventions.

Current federal regulations governing the confidentiality of drug and alcohol treatment and prevention records (42.C.F.R. Part 2 (Part 2)) preclude the Centers for Medicare and Medicaid Services (CMS) from disclosing medical information to healthcare providers for care coordination, including those engaged in accountable care organizations and bundled payment organizations. These regulations currently require complex and multiple patient consents for the use and disclosure of patients' substance use records that go beyond the sufficiently strong patient confidentiality protections that were subsequently put in place by HIPAA.

Electronic health records and value-based payment models such as Accountable Care Organizations (ACOs), Health Information Exchanges (HIEs), Medicaid Health Homes, and related Medicare and Medicaid integrated care programs were designed to create a more holistic, patient-centered approach to healthcare where providers work together to coordinate across their traditional silos and in some cases are held jointly accountable for the quality, outcomes, and cost of that care. Critical to making these new models work for patients is having access to the individuals' health records, including those related to substance use disorders. CMS provides participating providers of Medicare ACO and bundled payment organizations with monthly Medicare Parts A, B and D claims under data use agreements that include criminal penalties for misuse. Yet, due to outdated laws mentioned above, CMS is forced to remove *all* claims where substance use disorder is a primary or secondary diagnosis. Patient safety is also threatened with the potential pharmaceutical contraindications that could occur without access to the full medical record. Without this critical information, providers are prevented from understanding the full extent of their patients' medical needs.

We commend SAMHSA's recent rulemaking efforts, and understand the agency has probably gone as far as possible in regards to attempts to modernize the Part 2 Rule. To sufficiently address the need for further reform, Representatives Markwayne Mullin (R-OK) and Earl Blumenauer (D-OR) have introduced H.R. 3545 to ensure healthcare providers have access to the full medical record, including information on substance use disorders, to effectively and safely treat patients suffering from substance use disorders while guaranteeing the privacy and security of substance use medical records. In particular, H.R. 3545 would reinforce and expand existing prohibitions on the use of these records in criminal proceedings.

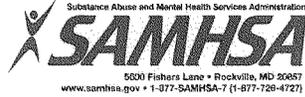
We urge the Committee to consider H.R. 3545 to amend 42 CFR Part 2 and align with HIPAA's treatment, healthcare operations, and payment policy as one of several potential solutions Congress passes to help with the opioid crisis. Thank you for your attention to this important matter. Should you have any questions, please contact Tina Grande at 202.449.3433 or tgrande@hlc.org.

Sincerely,



Mary R. Grealy
President

cc: U.S. House of Representatives



MAR 19 2018

The Honorable Markwayne Mullin
1113 Longworth House Office Building
Washington, DC 20515

Dear Representative Mullin:

Thank you for your correspondence about the revised Confidentiality of Substance Use Disorder Patient Records Final Rule (42 CFR Part 2 or Part 2) and its impact on data-sharing by Medicare and Medicaid programs. Your letter states that the "Centers for Medicare and Medicaid Services (CMS) is forced to remove *all* claims where substance use disorder is a primary or secondary diagnosis," from data shared with ACOs, bundled payment organizations, and others. You also indicate that sharing of information in electronic health records (EHRs) is critical to the success of these new payment models. You suggest that Part 2 is inconsistent with the Health Insurance Portability and Accountability Act (HIPAA) requirements.

The Substance Abuse and Mental Health Services Administration (SAMHSA) is encouraged to see Congress examine the benefits of aligning Part 2 with HIPAA. Patient privacy is, of course, critical but so too is patient access to safe, effective, and coordinated treatment. To facilitate this most efficiently, healthcare providers must have secure access to patient information, including substance use disorder information, in order to provide integrated and effective care. The practice of requiring substance use disorder information to be any more private than information regarding other chronic illnesses such as cancer or heart disease may in itself be stigmatizing. Patients with substance use disorders seeking treatment for any condition have a right to healthcare providers who are fully equipped with the information needed to provide the highest quality care available.

As you note, SAMHSA has taken the steps within our purview to address some of these concerns; however, Congressional action is needed to fully address the issue. The steps SAMHSA has taken include the following:

- SAMHSA's revisions in January 2018 (83 FR 239) permit additional sharing by lawful holders, including Medicare and Medicaid entities, with contractors, subcontractors, and legal representatives for payment and health care operational purposes consistent with those listed in HIPAA's Privacy Rule, as long as initial patient consent is obtained.
- SAMHSA's 2017 final rule (82 FR 6052) notes that entities may ask patients to consent to use of a general designation to share their Part 2 records with all of their current or future treating providers. The preamble to the rule specifically states that "an ACO, pursuant to a [patient's use of the] general designation, may disclose information

Page 2 – The Honorable Markwayne Mullin

described in the “Amount and Kind” section of a consent form [...] to “all my entity treating providers.” The final rule also makes it clear that ACOs may share information in accordance with Part 2 to carry out audit and evaluation activities (§2.53).

Additionally, SAMHSA recently held listening sessions related to Part 2, as required by the 21st Century Cures Act (Section 11002). The vast majority of those who spoke at the listening session expressed their support for further aligning Part 2 and HIPAA and acknowledged that to achieve many of their goals, Congress would need to take action on bills such as yours.

HHS and SAMHSA appreciate your attention to this issue and stand ready to provide any technical assistance you may request on this very significant matter. If you or your staff have any questions, please feel free to contact Brian Altman, Acting Legislative Director, at (240) 276-2009. This response has also been sent to Representative Blumenauer.

Sincerely,



Elinore F. McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and
Substance Use



**Statement for the Record
Committee on Energy and Commerce
Subcommittee on Health**

Combating the Opioid Crisis: Prevention and Public Health Solutions
March 21-22, 2018

Thank you for your work regarding the nation's opioid crisis. America's Essential Hospitals appreciates your committee's dedication in its response to this public health threat, which affects all communities nationwide. Below, we outline the unique role essential hospitals play in addressing the opioid crisis, share issues that impact our hospitals, and comment on several bills before your committee.

America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to providing high-quality care to all people. Filling a vital role in their communities, our 325 member hospitals provide a disproportionate share of the nation's uncompensated care and devote about half their inpatient and outpatient care to Medicaid or uninsured patients. Through their integrated health systems, members of America's Essential Hospitals offer primary care through quaternary care, including trauma care, outpatient care in ambulatory clinics, public health services, mental health and substance abuse services, and wraparound services vital to disadvantaged patients. More than a third of patients at essential hospitals are racial or ethnic minorities who rely on the culturally and linguistically competent care that only our members can provide.

As pillars of their communities and trusted providers for all, essential hospitals have seen firsthand how opioid use disorders have affected individuals and their surrounding communities. Essential hospitals lead in efforts to improve population health and continue to develop innovative programs to prevent opioid misuse among the most vulnerable populations, and they provide treatment to all who need it. As you continue to develop policies to combat the crisis, we urge the committee to consider the unique role essential hospitals play in prevention of opioid misuse, as well as response and recovery for individuals struggling with opioid use disorders.

Essential Hospitals Response to Opioid Crisis

Essential hospitals play a unique and significant role in the opioid crisis. Hospitals are a main care provider for people experiencing opioid-related health problems, like infection or overdose, associated with substance misuse. As a result, hospitals have an enormous role to play in the prevention and treatment of this widespread problem. Essential hospitals have partnered with pharmacies, public health departments, law enforcement, emergency medical services, and other community providers to combat the crisis.

For example, an essential hospital in Massachusetts has been a national leader in fighting the opioid crisis. The hospital runs the largest primary care office-based opioid treatment program in New England. The program was the first of its kind in the nation and has been replicated in

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35 states. It employs a collaborative care model using nurse care managers to provide medication-assisted treatment (MAT) to individuals with opioid use disorder. The program has been tailored to meet the needs of other patient populations, including adolescents and pregnant women. In addition, this hospital created one of the first emergency department (ED)- and urgent care-based opioid treatment programs in the country, and its inpatient addiction consult service has reduced ED visits for participants by 30 percent. In partnership with the state health department, the hospital has pioneered naloxone distribution programs with law enforcement and other first responders and overdose bystanders.¹

Evidence-based treatment programs, which can exist within or outside a hospital system, are a key component of combating opioid use. One of the most commonly used treatment models—MAT—uses counseling in combination with drugs, such as methadone and buprenorphine, to prevent withdrawal, suppress cravings, and support recovery. MAT has proved successful in decreasing mortality, decreasing risk of infection, improving social functioning, and increasing retention in rehabilitation programs. But there are large gaps between MAT capacity and demand. To meet this need, some health systems are developing their own infrastructure and care teams—which include physicians, licensed therapists, counselors, and/or recovery specialists—to treat opioid misuse.² Essential hospitals are deploying protocols that screen for opioid use, provide MAT as necessary, and pair patients with addiction counselors.

Additionally, essential hospitals are deploying targeted improvement efforts to address opioid prescribing patterns and align incentives that promote quality of care. For example, several essential hospitals have implemented new guidelines for prescribing opioids, particularly in the ED. These hospitals urge providers to first provide non-opioid options—ibuprofen and acetaminophen, for example—and then to explore alternative pain management, such as localized nerve-blocking methods. Hospitals engage physicians, pharmacists, and nurses to ensure all staff are committed to providing non-opioid regimens before prescribing stronger medications. Initial evaluations show that such policies reduced by nearly 50 percent the number of opioids prescribed to trauma patients.³

Essential Hospitals Face Challenges

42 CFR Part 2

Although essential hospitals have deployed innovative approaches to treat patients with opioid and substance use disorders, they continue to face challenges. When patients visit doctors and hospitals, most assume providers have a complete medical history and an awareness of addictions or substance use that need to be factored into treatment and prescribing. But that is not always the case, due to an antiquated regulation—42 CFR Part 2 (Part 2).⁴ This regulation limits access to and use of patients' substance use records for certain substance use treatment programs. Obtaining multiple consents from the patient is challenging and creates barriers to whole-person, integrated approaches to care. As a result, many providers often learn of addiction problems only after an adverse event or an overdose. Part 2 regulations also might lead to a physician 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

¹ Susman K. *The Opioid Crisis: Hospital Prevention and Response*. June 2017. <https://essentialhospitals.org/wp-content/uploads/2017/06/Opioid-Brief-1.pdf>. Accessed March 19, 2018.

² *Ibid.*

³ Susman K. *The Opioid Crisis: Hospital Prevention and Response*. June 2017. <https://essentialhospitals.org/wp-content/uploads/2017/06/Opioid-Brief-1.pdf>. Accessed March 19, 2018.

⁴ 42 U.S. Code § 290dd-2.

impedes patients' ability to receive safe, effective, high-quality substance use treatment and coordinated care.

It is crucial that Part 2 is better aligned with the Health Insurance Portability and Accountability Act (HIPAA) so that health care providers can provide comprehensive and coordinated substance use treatment and care. The Substance Abuse and Mental Health Services Administration (SAMHSA) recently released a final rule that takes some steps to modernize Part 2, but it does not go far enough.⁵ Lawmakers must act to modify Part 2 and bring substance use records into the 21st century, allowing for appropriate levels of access for providers to have a complete picture of their patients. However, just aligning Part 2 for treatment purposes is an insufficient approach. Such an approach is inconsistent with HIPAA language on treatment, payment and health care operations, as care coordination activities are not considered a part of a patient's treatment. For Medicaid providers engaging in whole-person care management, it is difficult to separate treatment from payment and health care operations. Also, only aligning Part 2 with HIPAA for treatment activities could preclude a robust prescription drug monitoring program. Without all information about a patient available, it will be challenging to flag patients engaging in drug-seeking behaviors.

IMD Exclusion

Medicaid does not provide reimbursement for inpatient treatment in an institution for mental disease (IMD) with more than 16 beds. As states consider various approaches to combat the opioid crisis, this IMD exclusion has hampered comprehensive treatment approaches. The Centers for Medicare & Medicaid Services (CMS) has encouraged states to pursue innovations and strategies to address the opioid epidemic through Medicaid Section 1115 waiver demonstrations. In a November 2017 update to states, CMS outlined a streamlined approach to accelerate states' ability to respond to the crisis.⁶ Several states, such as West Virginia, Maryland, and Virginia, have used this approach to start comprehensive, evidence-based prevention and treatment programs for Medicaid beneficiaries.

Additional Challenges

The Medicaid program covers MAT services as an optional benefit for states under the Medicaid statute, which has caused available services to vary widely across states.⁷ This limits providers as they identify and employ the best treatment options for their patients.

Essential hospitals also face the additional challenge of a workforce shortage for substance use disorder and behavioral health professionals. There has been a shortage of addiction specialists for decades, and the opioid epidemic only has increased demand.⁸ SAMHSA recognized the serious workforce shortages for behavioral health professionals and funded several programs and initiatives to combat the issue. Essential hospitals operate on slim margins that might hinder them from offering competitive compensation packages to attract needed substance use disorder and behavioral health professionals. Not only do they have financial constraints, many essential hospitals find themselves either in extremely competitive urban markets or in less desirable geographic areas.

⁵ 82 *Federal Register* 6052, January 18, 2017.

⁶ Centers for Medicare & Medicaid Services. *SMD #17-003 Strategies to Address the Opioid Epidemic*. November 1, 2017. <https://www.medicare.gov/federal-policy-guidance/downloads/smd17003.pdf>. Accessed March 19, 2018.

⁷ Medicaid and CHIP Payment and Access Commission. *Medicaid and the Opioid Epidemic*. June 2017. <https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf>. Accessed March 19, 2018.

⁸ Corwin E. *Shortage of Addiction Counselors Further Strained by Opioid Epidemic*. February 24, 2016.

Last, essential hospitals lack adequate reimbursement for integrated care. Overall care delivery is transforming across the health care industry, shifting from fragmentation and care siloes to a more integrated and collaborative system. In responding to the opioid crisis, essential hospitals recognize the complexity and importance of treating behavioral health issues, particularly as they relate to improving care for our nation's most vulnerable patients. Essential hospitals across the United States have dedicated substantial resources to developing innovative programs to improve care coordination among primary care, inpatient, behavioral health, and community-based services for individuals with behavioral health disorders. For example, an essential hospital in Washington state began a behavioral health integration program that incorporates behavioral health care managers and psychiatric consultants at 14 primary care clinics.⁹ Primary care physicians in the clinics conduct routine screening for behavioral health disorders among patients, determine whether further assessment and diagnosis by behavioral health specialists is required, and, when necessary, provide warm handoffs to care coordinators within the same facility. As providers of care to vulnerable populations, essential hospitals are uniquely positioned to implement this kind of care. But funding shortfalls and reimbursement structures pose consistent and significant obstacles to integration.

Legislative Proposals

Prescription Drug Monitoring Programs and H.R. _____, to enhance and improve state-run prescription drug monitoring programs,

Prescription drug monitoring programs (PDMPs) are state-level interventions to improve opioid prescribing and inform clinical practice by tracking the prescribing and dispensing of controlled prescription drugs. Some states have implemented policies that require physicians to check a state PDMP to assess a patient's risk of substance use disorders or nonmedical use of controlled substances as part of the discharge planning and medication reconciliation process. The legislative proposal before the committee would seek to improve PDMPs by authorizing the Centers for Disease Control and Prevention to conduct certain surveillance activities to improve data collection and integration in physician clinical workflow.

We support the goal of reducing prescription drug abuse by increasing provider awareness of at-risk patients. However, the challenges associated with PDMPs—including issues with health IT interoperability, timely data transmission, and privacy and security—make this tool an unsatisfactory option for now. Further, the quality of PDMP data must be validated before its use in the context of a federal program, such as Medicaid. For example, PDMPs do not include data on physician specialty or patient diagnosis, which can make it difficult to distinguish legitimate use, such as higher doses for cancer pain management, from inappropriate use, such as use in pediatrics. Additionally, platforms differ by state, creating a lack of uniformity in accessing PDMP data. More work is needed to mitigate issues of cross-state PDMP data access—e.g., allow prescribers and dispensers to obtain patients' prescription records from across state lines to provide a more complete in-state and out-of-state medication history for at-risk patients. Continued state-level evaluation of PDMPs is needed to identify and evaluate promising practices and to build synergies necessary for application at the federal level. We hope the committee will consider these concerns.

H.R. 5197, Alternatives to Opioids in the Emergency Department Act

⁹ Rangarao S, Susman K. *Behavioral Health and Primary Care Integration at Essential Hospitals*. October 2015. http://essentialhospitals.org/wp-content/uploads/2015/10/BehavioralHealthBrief_FINAL.pdf. Accessed March 19, 2018.

We support legislation that would encourage alternatives for opioid use in hospital EDs. Specifically, we are encouraged by consideration of H.R. 5197, the Alternatives to Opioids (ALTO) in the Emergency Department Act. This legislation would allow hospitals to rein in opioid prescribing by assessing the use of alternate medication options for pain management. This protocol is currently underway at St. Joseph's Health, an essential hospital in Paterson, New Jersey, and is an effective tool to combat opioid addiction.

H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act

Health care workforce shortages present significant challenges. Substance use disorder (SUD) treatment professionals are critical in the fight against opioid addiction, and creating incentives for health care and other social service professionals to treat individuals with SUDs will help to strengthen the workforce in an area with severe needs. Given the financial burden often placed on students training in health-related fields, H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act, will take a step in the right direction to encourage health professionals to work directly on SUD treatment. By offering student loan repayment for these professionals, essential hospitals, who often treat some of the most significant opioid addiction cases, will have greater access to trained SUD professionals and can expand their work already underway to fight opioid addiction.

H.R. 5261, Treatment, Education, and Community Help to Combat Addiction Act

America's Essential Hospitals supports H.R. 5261, the Treatment, Education, and Community Help to Combat Addiction Act, which would support learning institutions that specialize in SUD treatment education to improve how health professionals are taught about SUD and pain management for patients. This bill would help address gaps in educational programs provided to physicians at essential hospitals to ensure SUD patients receive the most comprehensive care for their exposure to opioids.

H.R. ___, Poison Center Network Enhancement Act

The Poison Center Network Enhancement Act would reauthorize the national network of poison control centers, which offer free, confidential, expert medical advice and serve as primary resources for poisoning information. Essential hospitals frequently work in tandem with poison control centers to address public health emergencies, including opioid exposures. Specifically, these centers help lessen the burden on EDs through in-home treatment for opioid exposures. Reauthorizing this network would allow for broader communication between the centers to improve care for those exposed to opioids before they enter hospital systems.

Discussion Draft of H.R. ___, A Bill to Support the Peer Support Specialist Workforce

We support including language to improve the peer support specialist workforce. This provision would expand Department of Health and Human Services grants to peer support specialist organizations providing recovery services. Peer support specialists are individuals recovering from a substance use disorder (SUD) who have received formal training on how to support and mentor other individuals new to the recovery process. Peer support has been a successful tool to support individuals newly diagnosed with a disease or disorder. Essential hospitals have successfully used multidisciplinary approaches to the treatment of individuals with SUDs, and peer support specialists can be a critical tool to an individuals' recovery.

We appreciate your consideration of these provisions and look forward to working with you to improve the legislative package to effectively counter this ongoing crisis.



ASAM American Society of
Addiction Medicine

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March 21, 2018

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Re: 2018 Substance Use Disorder Treatment, Prevention, and Recovery Package

Dear Chairman Burgess and Ranking Member Green,

On behalf of the American Society of Addiction Medicine (ASAM), the nation's oldest and largest medical specialty society representing more than 5,100 physicians and allied health professionals who specialize in the prevention and treatment of addiction, we are writing to offer legislative comments and recommendations as the House Energy and Commerce Subcommittee on Health works on a comprehensive, legislative response to our nation's opioid overdose and addiction crisis.

As you know, the cost of substance misuse, and untreated and ineffectively treated addiction in the United States is staggering, both in economic terms and in terms of human lives lost. During the twelve-month period ending January 2017, the Centers for Disease Control and Prevention estimates there were approximately 64,000 drug overdose deaths.ⁱ Recently, the White House Council of Economic Advisers announced that the cost of the opioid crisis, alone, approached \$504 billion in 2015.ⁱⁱ And while opioid-related overdose deaths may dominate national headlines, the associated costs are a fraction of the total societal cost of substance misuse and addiction. Each year alcohol misuse leads to approximately 88,000 deaths in America.ⁱⁱⁱ Cigarette smoking contributes to another 480,000.^{iv} These costs, however, could be dramatically reduced by utilizing effective substance misuse prevention practices and programs and by addressing untreated, and ineffectively treated, addiction in this country.

Given these alarming statistics, we appreciate your leadership regarding the possible passage of legislation aimed at addressing our country's crisis of addiction involving opioid use. President Donald J. Trump's direction to declare the opioid epidemic a nationwide public health

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emergency on October 26, 2017 was a historic first step, but turning the tide on the current crisis and preventing future crises related to substance misuse and addiction require a new approach to the delivery of substance use prevention, addiction treatment, and recovery support services. Considering all the lives we have lost and all the lives we still risk losing, the time for transformational change is now. Thus, ASAM respectfully offers these comments for your consideration as you embark on the hard work that lies ahead.

Advancing Cutting-Edge (ACE) Research Act (H.R. 5002/S. 2046)

The ACE Research Act would facilitate additional research into treatments for public health epidemics such as the opioid addiction crisis by providing the National Institutes of Health (NIH) with new tools and flexibility to approve high-impact, cutting-edge research. Patients with addiction and patients with chronic pain, like all patients, should have available to them a robust and varied array of treatment options, as no one treatment modality is appropriate or therapeutic for everyone. We support research and the development of non-addictive pain treatment options and additional therapies to treat addiction. These new treatments could not only help save lives but help prevent addiction from taking hold in the first place. ASAM supports the ACE Research Act and recommends that Congress incorporate it into a future legislative package to address the opioid addiction epidemic.

The Addiction Treatment Access Improvement Act (H.R. 3692/S. 2317) / Amendment in the Nature of a Substitute to H.R. 3692

To make a meaningful and sustainable impact on the current opioid overdose epidemic, it is imperative that we build a robust treatment workforce. There are simply too few physicians and other clinicians with the requisite knowledge to meet the needs of the estimated 20.1 million Americans suffering from untreated substance use disorders. The Addiction Treatment Access Improvement Act makes great strides in doing so by codifying the Final Rule issued by the Department of Health and Human Services (HHS) in July 2016 that raised the DATA 2000 patient limit for certain physicians to 275 patients, eliminating the sunset date for nurse practitioners' (NPs) and physician assistants' (PAs) prescribing authority for buprenorphine, and expanding the definition of 'qualifying practitioner' to include nurse anesthetists, clinical nurse specialists, and nurse midwives.

These changes would increase the number of the clinicians to meet the needs of patients who are seeking treatment for their addiction but are unable to find a practitioner who can treat them. It is essential that we increase the treatment workforce, and we urge Congress to include these provisions (or the provisions in the substitute amendment that would also shorten the timeframe to reach the 100-patient limit in certain circumstances) in any legislative package moving forward.

Substance Use Disorder Workforce Loan Repayment Act (H.R. 5102/S. 2524)

In addition to expanding and codifying the eligibility of existing treatment providers, it is imperative that our country make strategic investments to incentivize clinicians to work in programs and practices that specialize in the treatment of addiction. To accomplish this goal, the Substance Use Disorder Workforce Loan Repayment Act helps clinicians who pursue full-time substance use disorder treatment jobs in high-need geographic areas repay their student loans. Many parts of the United States, and particularly rural areas, suffer from a lack of treatment providers. ASAM supports the goals of this bill and its efforts to incentivize clinicians to work in

substance use disorder treatment programs in these high-need areas and urges Congress to include it in any future legislative package to address the opioid epidemic.

The Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse (RESULTS) Act (H.R. 5272)

ASAM is pleased that the House Energy and Commerce Subcommittee on Health is holding a hearing that includes the RESULTS Act of 2018. The RESULTS Act would require grant, loan, and other recipients of funds from the Department of Health and Human Services for a mental health or substance use disorder prevention or treatment program to use evidence-based practices. We also support research and the development of new and innovative treatments for substance use disorders that will contribute to the body of knowledge that is needed for emergent or innovative programs and activities to become evidence-based.

There are many misconceptions about the disease of addiction, and we need a culture change in this country to drive patients to the treatment options that have been proven to be effective at reducing relapse and overdose deaths and supporting patients in remission and recovery. When it comes to opioid addiction, the most effective treatment options we have involve the use of medications in combination with specific psychosocial interventions to support remission and recovery. When we say, "Treatment works," we're not referring to every approach that claims to be treatment. We are physicians and other clinicians who specialize in the treatment of addiction. We're referring to those interventions that have scientific evidence to support their effectiveness.

The RESULTS Act would raise the clinical standard to a level that we demand from all other forms of medicine—to use clinical methods and practices based on evidence—and ASAM is proud to support that goal.

Preventing Overdoses While in Emergency Rooms Act (H.R. 5176)

With the rise in the use of potent synthetic opioids such as fentanyl and carfentanil, the rates of opioid overdoses and emergency department visits due to opioid overdose have increased significantly. Data from CDC's Enhanced State Opioid Overdose Surveillance (ESOOS) program showed opioid overdose rates increased an average of 35% in the 16 states reporting from July 2016 through September 2017. Eight states reported substantial increases (25% or greater) in opioid overdose emergency department visits.^v

People who are admitted to a hospital for a drug overdose and discharged without treatment are at elevated risk to relapse and overdose again. H.R. 5176, the Preventing Overdoses While in Emergency Rooms Act, works to prevent that from happening by authorizing the Secretary of the Department of Health and Human Services to create grants for health care sites with emergency departments to develop protocols for discharging patients who have presented with a drug overdose and enhance the integration and coordination of care and treatment options for individuals with substance use disorders after discharge.

Addiction is a chronic brain disease and evidence shows that treatment is effective at achieving and sustaining remission and recovery. It is past due that we stop discharging patients from emergency rooms without treating their addiction. ASAM is proud to support the Preventing Overdoses While in Emergency Rooms Act and urges Congress to include it in any legislative package to address the needs of patients who have overdosed.

The Comprehensive Opioid Recovery Centers Act of 2018 (H.R. 5327)

Treatment of the disease of addiction, without also addressing associated social externalities such as homelessness, will result in poorer outcomes. The Comprehensive Opioid Recovery Center Act would help to fill this gap in wrap-around care and services, by creating competitive grants to entities to establish or operate comprehensive opioid recovery centers. This policy would accomplish the two-fold objective of increasing access to treatment and ensuring that the treatment is comprehensive - offering a full continuum of clinical, vocational, and educational services to meet the needs of patients. In addition, the grants would prioritize entities in a state or Indian country with high per capita drug overdose mortality rates, so the resources are focused in areas that need it most.

As you consider this legislation, ASAM offers these additional comments:

- Selected centers should be required to ensure that intake and ongoing evaluations meet the clinical needs of patients, including by offering assessments for services and level of care recommendations through independent, research-validated verification processes for reviewing patient placement in addiction treatment settings;
- Independent program evaluators should be required to evaluate program effectiveness; and
- Selected centers should be required to report on a set of pre-identified performance measures.

ASAM applauds this legislation which would make great strides in increasing access to comprehensive treatment and urges Congress to include it in any upcoming legislative package to address the opioid epidemic.

The Treatment, Education, and Community Help to Combat Addiction Act of 2018 (H.R. 5261)

This legislation would amend the Public Health Service Act to provide for regional centers of excellence to enhance and improve how health professionals are educated in pain management and substance use disorder through development, evaluation, and distribution of evidence-based curriculum for health care professional schools. ASAM has recommended for years that medical, nursing, dental, pharmacy and other clinical schools increase curriculum time devoted to addiction screening and treatment, safe prescribing and pain management. We would also encourage you to consider supporting future proposals which would establish an additional pathway for physicians who have had comprehensive training in medical school treating and managing opiate-dependent patients to apply for a DATA 2000 waiver.

We welcome this legislation and urge Congress to include it in any upcoming legislative package to address the opioid epidemic.

Confidentiality and 42 CFR Part 2

The federal regulations governing the confidentiality of drug and alcohol treatment and prevention records, 42 CFR Part 2 (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 physician 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.

The advent of integrated health systems and electronic medical records has improved the safety, quality, and coordination of care for patients with any other health condition. Part 2 requirements prevent patients with addiction from sharing in these benefits, even though electronic exchanges of other health information are governed by strict privacy and security standards set by the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act.

ASAM holds patients' privacy rights in the highest regards but recognizes the barriers that Part 2 currently presents to coordinated, safe, and high-quality medical care cause significant harm, and that thoughtful changes to the law are necessary to mitigate this harm while protecting patients' privacy. Thus, we support changes that would align Part 2 with HIPAA's consent requirements for the purposes of treatment, payment, and healthcare operations. Such a change would allow for the sharing of patients' addiction treatment records within the healthcare system under HIPAA's well-established and modern privacy and security protections, while leaving in place Part 2's prohibition on disclosure of records outside the healthcare system. Moreover, we also welcome changes that would strengthen protections against the use of addiction treatment records in criminal proceedings, a further improvement to Part 2 that we see as essential to protect patients in treatment for substance use disorder.

CARA 2.0 Act of 2018 (H.R. 5311/S. 2456)

We appreciate the leadership of all the CARA 2.0 Act sponsors in filing this major legislative package aimed at addressing the opioid addiction crisis in our country. With that, we would like to respectfully provide comments and recommendations to you on provisions of the CARA 2.0 legislation for your consideration.

Section 3. Three Day Limit on Opioid for Acute Pain.

We appreciate the desire to help reverse the exponential increases in opioid misuse, addiction, and death by limiting initial prescriptions for opioids to three days or less while exempting certain conditions such as chronic pain care and pain being treated as part of palliative care. While this goal is important, a "hard" three-day limit in federal statute is inconsistent with evidence-based guidelines such as the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain (the "CDC Guideline").

According to Recommendation 6 of the CDC Guideline, "[w]hen 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."^{vi} Further, the applicable CDC Guideline narrative reads as follows:

Experts thought, based on clinical experience regarding anticipated duration of pain severe enough to require an opioid, that in most cases of acute pain not related to surgery or trauma, a ≤ 3 days' supply of opioids will be sufficient . . . Some experts thought that because some types of acute pain might require more than 3 days of opioid treatment, it would be appropriate to recommend a range of ≤ 3 -5 days or ≤ 3 -7 days when opioids are needed. Some experts thought that a range including 7 days was too long given the expected course of severe acute pain for most acute pain syndromes seen in primary care.^{vii}

Considering the foregoing, we highlight three observations for your consideration. First, unlike the CDC Guideline, Section 3 of CARA 2.0 is not limited to primary care prescribers. Second, patients with acute pain related to surgery or trauma and for whom three days or less can be insufficient, may have to incur financial costs and bear logistical burdens to obtain additional medically-appropriate opioid medication. Further, such a 3-day limitation would inevitably and disproportionately impact patients with lower incomes and patients living in rural areas located many miles from their prescribers. Third, violating a federal statute can carry significant legal ramifications for prescribers trying to treat acute pain appropriately as compared to deviating from a voluntary guideline, such as the CDC Guideline. Therefore, ASAM strongly recommends that any statutory acute pain limitation passed by Congress incorporate more flexibility for prescribers to meet the medical needs of all their patients and should more closely align with the recommendations of the CDC Guideline.

Section 4. First Responder Training.

This section would provide funds primarily to make naloxone available to first responders to train and provide resources for carrying and administering naloxone. While we know state and local governments would certainly welcome federal assistance for naloxone training and distribution given the increasing cost of naloxone in this country, we urge you to consider enacting policy interventions which would allow the federal government to bulk purchase naloxone at discounted prices to increase access to this life-saving medication. Our nation's Vaccines for Children Program may be an existing model Congress could rapidly replicate to increase naloxone access for first responders, public health departments, and community organizations.^{viii} Such a program, coupled with investments aimed at enhancing the Centers of Disease Control and Prevention's surveillance capabilities for identifying overdose clusters and infectious disease outbreaks, could go a long way in preventing the spread of infectious diseases and death.

Section 6. Building Communities of Recovery.

ASAM supports additional investments in recovery support services for people trying to achieve long-term remission and recovery from the disease of addiction. However, we strongly caution against any statutory language which states that addiction recovery support services can be "in lieu of addiction treatment." Nearly 90% of Americans with addiction do not receive treatment and 80% of individuals with opioid addiction are not treated.^{ix} As many families know all too well, remission and recovery from addiction involving opioid use is often only preceded by evidence-based medical treatment. To put it simply, there is no remission or recovery if you are dead.

Therefore, our nation must come to terms with the difficult reality in which we find ourselves: the current addiction treatment gap will never be closed with the current addiction treatment

workforce. While we want you to support additional investments in recovery support services, we urge you also to prioritize federal funding for Accreditation Council for Graduate Medical Education (ACGME)- accredited addiction medicine and addiction psychiatry fellowship positions and a loan repayment program for students who enter the substance use disorder treatment workforce.^{xi} Additionally, please consider revising the Public Health Service (PHS) Act to include addiction medicine specialists in the definition of “behavioral and mental health professionals” within the National Health Service Corps.

Section 7. Medication-Assisted Treatment for Recovery from Addiction.

ASAM applauds the efforts in Section 7 of CARA 2.0 that would expand access to medication-assisted treatment for remission and recovery from addiction. As previously noted, it is imperative that we build a robust treatment workforce, and this section would make great strides in doing so by eliminating the sunset date for nurse practitioners’ (NPs) and physician assistants’ (PAs) prescribing authority under DATA 2000 and expanding the definition of ‘qualifying practitioner’ to include nurse anesthetists, clinical nurse specialists, and nurse midwives. This section would also give individual states the option to waive the limit on the number of patients a physician can treat so long as the state directs its applicable state regulatory body to adopt evidence-based prescribing guidelines for the use of medication to treat addiction involving opioid use, such as ASAM *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*. This policy change would help accomplish the two-fold objective of increasing access to and the quality of the prescribing medications for the treatment of addiction involving opioid use.

We also welcome the opportunity to work with you and the CARA 2.0 sponsors to improve the innovative “Offer 2 Types of Medication-Assisted Treatment” minimum requirement in Section 7(d) of CARA 2.0. For example, we would recommend that such minimum, two-medication requirement for medications to treat opioid use disorder only apply to residential treatment providers, prisons, and jails^{xii} that receive federal funds for a program or activity offering addiction treatment to people with opioid use disorder, especially if a residential provider is receiving Medicaid funding due to a waiver or repeal of the Institutes for Mental Diseases (IMD) Exclusion within the Medicaid program. We would want to avoid any policy intervention which could result in an unintended consequence of decreasing access to life-saving medications prescribed by individual prescribers treating patients whose health care is federally-subsidized.

Section 13. Require the Use of Prescription Drug Monitoring Programs (PDMP).

ASAM believes that prescription drug monitoring programs (PDMPs) are an important tool to inform safe prescribing. From 2014 to 2016, there was a 121 percent increase in the number of queries by health professionals to state PDMP databases.^{xiii} As a result, we applaud the creative policy innovations outlined in this section - namely that prescribers or their designees be required to query the PDMP upon initial prescription of a controlled medication and quarterly thereafter if treatment continues. Further, requiring proactive reports, increased timeliness of data entry, and de-identified data sets for research and evaluation are also welcomed policy changes. However, requiring state agencies to provide reports to law enforcement agencies and licensing boards “describing any prescribing practitioner that repeatedly fall [sic] outside of expected norms or standard practices for the prescribing practitioner’s field” is troubling as it could have an unintended chilling effect on appropriate prescribing, particularly with respect to disclosures to law enforcement outside of a court-supervised process. PDMP information should be considered what it is: personal health information, and, therefore, should be protected from release like other personal health information.

In addition, we would be remiss not to urge you to fund research and evaluation programs that study best practices for integrating PDMPs into EHRs and clinician workflow in a meaningful, user-friendly manner. While PDMPs now exist in almost every state and practitioners are increasing their use of them, the lack of integration with electronic health records continues to inhibit the effective use of these clinical support tools. Further, in addition to improving and integrating these programs, ASAM recommends that Congress urge the Department of Health and Human Services to support the development of training for primary care providers to know how to engage a patient whose PDMP report indicates he or she may be inappropriately accessing controlled substances. Without such training, many clinicians might simply dismiss patients from their practice without an assessment for substance use disorder or referral to treatment, if indicated. These clinicians are missing an important opportunity to engage patients in treatment and should be equipped to use the PDMP report as a conversation-starter with patients at risk of addiction or overdose death.

Telemedicine

As stated in a [testimony](#) on behalf of ASAM before the House Energy and Commerce Subcommittee on Health, telemedicine provides significant opportunities to reach more patients in urban and rural communities. However, the current restrictions on internet prescribing under the Ryan Haight Act and the seven, specific “practice of telemedicine” exceptions it provides for are of limited utility for expanding access to treatment with buprenorphine for addiction involving opioid use via telemedicine. As you know, the Ryan Haight Act generally requires an “in-person medical evaluation” in the physical presence of the prescribing clinician for the prescription to be considered valid.

The “practice of telemedicine” exceptions to this requirement provide for circumstances in which the patient is being treated by, and physically located in, a DEA-registered hospital or clinic, or in which the patient is being treated by and in the physical presence of another DEA-registered practitioner. It generally does not allow for circumstances in which a patient may have received a medical evaluation by another qualified practitioner but is not physically present in a DEA-registered hospital or clinic or with another DEA-registered practitioner. While *The ASAM’s Standards of Care*^{xiv} and *The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*^{xv} make it clear that patients presenting for treatment of addiction involving opioid use should receive a physical examination by a qualified and appropriately licensed healthcare professional as part of a comprehensive assessment process, they specifically allow for this examination to be conducted by a healthcare professional other than the prescriber, as long as the prescriber “ensure[s] that a current physical examination is contained within the patient medical record before a patient is started on a new medication for the treatment of his/her addiction.”

ASAM recommends that Congress pass legislation to revise the Ryan Haight Act to include an additional exception to the requirement for an in-person physical exam by the prescribing clinician to allow for a current physical exam to be conducted by another appropriately licensed healthcare professional and documented in the patient’s medical record. Additionally, ASAM recommends limiting this exception to the in-person physical exam requirement for patients who will be treated with buprenorphine for opioid addiction only to those physicians who hold “additional certification” or who practice in a “qualified practice setting” per the definitions in the 2016 SAMSHA rule that raised the DATA-2000 prescribing limit.

Additional Recommendations

On March 8, 2018, the Senate HELP Committee held a hearing titled “The Opioid Crisis: Leadership and Innovation in the States.” Hearing participants discussed recommendations from Governors across the U.S. expressed at the National Governors Association annual winter meeting. Toward the conclusion of that hearing, Chairman Alexander highlighted the problem of an “unevenness” in addiction treatment program quality across the country. We would be honored to have the opportunity to meet with Congressional leaders to discuss, in greater detail, possible federal action that could start incentivizing states to continue building out an addiction treatment infrastructure that can consistently deliver quality care for people suffering with addiction.

We know well that as the field of addiction treatment works to integrate more fully with traditional medical care, it is imperative that it “catch up” with other medical specialties in terms of clinical guideline development and quality measurement. Federal efforts to promote high-quality addiction treatment could include support for the following:

- Development and dissemination of clinical practice guidelines for addiction treatment, such as the *ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* and of science-based patient guides, such as the *Opioid Addiction Treatment: A Guide for Patients, Families and Friends*, that include information on assessment, treatment overview (including treatment plans, patient participation, and counseling), and all the medications available to treatment opioid use and overdose;
- Establishment and maintenance of addiction treatment programs that ensure intake and ongoing evaluations meet the clinical needs of patients by offering assessments for all substance use disorder services and level of care recommendations through an independent, research-validated verification process for reviewing patient placement in addiction treatment settings; and
- Implementation of, and related technical assistance for, nationally-recognized and research-validated treatment center certification programs that can provide patients, families, and payers with a reliable indicator that providers are delivering a certain level of care.

Efforts such as these are critically needed to help improve the overall quality of addiction treatment provided in our nation and assure those who are seeking and paying for treatment that they are receiving medically appropriate and high-quality care.

Thank you for the opportunity to make recommendations and offer additional tools that may be helpful to combat this public health emergency. We look forward to working with you to build upon the progress already made and help lay the foundation for a future in which long-term remission and recovery from addiction is not only possible, but probable. If you have any questions or concerns, please contact Kelly Corredor, ASAM's Director of Advocacy and Government Relations, at kcorredor@asam.org or at 301-547-4111.

Sincerely,



Kelly J. Clark, MD, MBA, DFASAM
President, American Society of Addiction Medicine

cc: The Honorable Greg Walden
The Honorable Frank Pallone

ⁱ Provisional Counts of Drug Overdose Deaths, as of 8/6/2017;

https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf

ⁱⁱ White House: Opioid Crisis Cost US Economy \$504 Billion in 2015; <https://www.voanews.com/a/us-opioid-crisis-white-house-report/4126121.html>. [Accessed on 2017 November 27].

ⁱⁱⁱ Stahre, M., Roeber, J., Kanny, D., Brewer, R. D., & Zhang, X. (2014). Contribution of excessive alcohol consumption to deaths and years of potential life lost in the United States. *Preventing Chronic Disease*, 11(E109).

^{iv} U.S. Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014 [accessed 2017 Nov 29].

^v Centers for Disease Control and Prevention. CDC Vital Signs, March 2018. <https://www.cdc.gov/vitalsigns/pdf/2018-03-vitalsigns.pdf>. Updated March 6, 2018. Accessed March 15, 2018.

^{vi} Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. *MMWR Recomm Rep* 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>

^{vii} Id.

^{viii} Vaccines for Children (VFC) Program. Retrieved from <https://www.cdc.gov/vaccines/programs/vfc/index.html>

^{ix} Legal Action Center. (2015). *Confronting an Epidemic: The Case for Eliminating Barriers to Medication Assisted Treatment of Heroin and Opioid Addiction*. Washington, D.C: Legal Action Center. Available at <http://lac.org/wp-content/uploads/2014/07/LAC-The-Case-for-Eliminating-Barriers-to-Medication-Assisted-Treatment.pdf>

^x Saloner PhD, Karthikeyan MPP. Changes in Substance Abuse Treatment Use Among Individuals with Opioid Use Disorders in the United States, 2004–2013. *The Journal of the American Medical Association*. 2015;314(14):1515–1517

^{xi} By way of further background, in 2016, addiction medicine was recognized as an American Board of Medical Specialties (ABMS) subspecialty under the American Board of Preventive Medicine (ABPM). The first ABMS addiction medicine board exam was offered in October 2017. While the board exam will be open to any American physician with a primary ABMS board certification until 2022, after that time, physicians will need to complete a year-long fellowship program to be qualified to sit for the exam. In five short years, the number of accredited and funded addiction medicine fellowship programs and slots will be the limiting factor in determining how many addiction medicine specialists can receive board certification.

It is critical that all stakeholders work to maximize funded addiction medicine fellowship opportunities before their number begins to limit qualified examinees.

^{xii} Green TC, Clarke J, Brinkley-Rubinstein L, Marshall BDL, Alexander-Scott N, Boss R, Rich JD. Post incarceration Fatal Overdoses After Implementing Medications for Addiction Treatment in a Statewide Correctional System. *JAMA Psychiatry*. Published online February 14, 2018. doi:10.1001/jamapsychiatry.2017.4614.

^{xiii} Based on AMA survey and responses from 44 state PDMP administrators. <https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/patient-care/opioid-task-force-progress-report.pdf>

^{xiv} American Society of Addiction Medicine. The ASAM Standards of Care for the Addiction Specialist Physician. 2014. Available at: https://www.asam.org/docs/default-source/practice-support/quality-improvement/asam-standards-of-care.pdf?sfvrsn=338068c2_10

^{xv} Kampman K and Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. *J Addict Med* 2015;9: 1-10.



National Association of State Mental Health Program Directors
66 Canal Center Plaza, Suite 302, Alexandria, VA 22314 (703) 739-9333 Fax (703) 548-9517

Board of Directors

April 6, 2018

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Dear Chairman Walden and Ranking Member Pallone:

The National Association of State Mental Health Program Directors writes to seek your support for the inclusion, within the Energy and Commerce package of legislation designed to fight the U.S. opioid epidemic, of legislation that would align the statute underlying the 42 CFR Part 2 regulations with the disclosure provisions of the Health Insurance Portability and Accountability Act (HIPAA).

NASMHPD is the organization representing the state executives responsible for the \$41 billion public mental health service delivery systems serving 7.5 million people annually in 50 states, 4 territories, and the District of Columbia.

Information-sharing among health care providers treating a patient being treated for substance use disorders is limited under current law because of the restrictions outlined under 42 CFR Part 2 and its underlying statute, 42 U.S.C. § 290dd-2 against the disclosure of records containing diagnosis, treatment, and referral information without specific patient consent.

That statute, enacted in the 1970s, well before HIPAA, and its regulations prohibit the sharing of treatment information—including pharmaceutical treatment involving the use of opioids or opioid antagonists—among treating providers absent specific patient consent. The inability of a patient's other treating providers to access that information automatically, if the substance use disorder patient has not thought or agreed to bring his or her other providers into the treatment loop, raises the risk of adverse prescription reactions, addiction regression, and even opioid overdose. It also prevents the integration of care so crucial for patients who so often have co-occurring substance use, mental, and medical disorders and conditions.

While the Substance Abuse and Mental Health Services Administration (SAMHSA) recently relaxed 42 CFR Part 2 to permit sharing for purposes of operations and payment, the agency specifically prohibited sharing among providers. The agency's legal counsel advises that current law does not permit it to relax restrictions on disclosures among providers. The conduits of any sharing that might be permitted, the Health Information Exchanges, remain reluctant to share substance use diagnosis, treatment, and referral information on their networks, even for the limited purposes permitted, because of ambiguity in what the relaxed regulations mean, the potential legal liability for mistaken disclosures, and the expense and technological difficulty in redacting substance use disorder information from patient information.

H.R. 3545, as originally introduced by former Representative Tim Murphy and now sponsored by Representative Markwayne Mullin, would have maintained the existing statutory prohibition against the use of the subject records to initiate or

substantiate any criminal charges against a patient or to conduct any investigation of a patient, except under court order. Use of those records in criminal proceedings have to be excluded from evidence, and proceedings automatically dismissed where the records were offered into evidence.

In response to concerns expressed by some attorney advocates for individuals with substance use disorders, the amended version of H.R. 3545 offered by Representative Mullin in the Energy and Commerce Health Subcommittee would significantly expand the existing prohibition against use in criminal proceedings to also ban the use of substance use disorder patient treatment information without a court order to initiate or substantiate any civil or administrative charges, claims, or allegations against a patient, or to conduct any investigation of a patient.

The amended bill also requires the exclusion from evidence of any substance use disorder treatment record in any proposed or actual actions or proceedings relating to such criminal, civil, or administrative charges, claims, allegations or investigations that has been used or disclosed to initiate or substantiate any criminal or civil charges, claims, or allegations against a patient or to conduct any investigation of a patient. In addition, absent good cause shown, the use of those records would result in the automatic dismissal of any actions or proceedings for which the content of the record was offered.

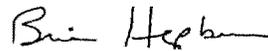
The legislation also responds to the expressed fears of the same attorney advocates by specifically restating the prohibitions against discrimination already prohibited under the existing Americans with Disabilities Act to protect individuals in treatment for substance use disorders – prohibiting discrimination in (i) admission or treatment for health care; (ii) hiring or terms of employment; (iii) the sale or rental of housing; or (iv) access to Federal, State, or local courts.

In summary, the amended bill would facilitate the integration of care and patient safety for individuals treated for substance use disorders, while also increasing the protections against stigma, discrimination, and prosecution, and the use of those records in criminal, civil, and administrative actions. Enabling treating providers to share substance use disorder treatment records would not only help to integrate care for individuals most likely to have co-occurring medical, mental, and substance use conditions and disorders, but would also serve to avoid adverse prescription reactions and substance use and opioid overdoses.

As such, H.R. 3545 constitutes a critically necessary tool in any Congressional toolkit to combat the U.S. opioid crisis. We urge strongly that it be included in the final Energy and Commerce legislative package.

Please feel free to reach out to me by email or by phone at 703-682-5181 or to NASMHPD's Director of Policy and Communications, Stuart Yael Gordon, by email or by phone at 703-682-7552 with any questions regarding this letter.

Sincerely,



Brian Hepburn, M.D.
Executive Director
National Association of State Mental Health Program Directors (NASMHPD)

cc: Kristen Shatynski
Waverly Gordon
Pamela Greenberg



American Association on Health & Disability

110 N. Washington Street Suite 328-J Rockville, MD 20850
T. 301-545-6140 F. 301-545-6144 www.aahd.us

AAHD - Dedicated to better health for people with disabilities through health promotion and wellness

April 7, 2018

Re: HR 3545 – Overdose Prevention and Patient Safety Act

The Honorable Greg Walden
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515
Kristen.shatynski@mail.house.gov
Caleb.gruff@mail.house.gov

The Honorable Frank Pallone, Jr.
Ranking Member
House Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515
Waverly.gordon@mail.house.gov
Tiffany.guarascio@mail.house.gov

Dear Representatives Walden and Palone:

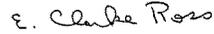
The American Association on Health and Disability (AAHD) (www.aahd.us) is a national non-profit organization of public health professionals, both practitioners and academics, with a primary concern for persons with disabilities. The AAHD mission is to advance health promotion and wellness initiatives for persons with disabilities.

AAHD is a member of the **Partnership To Amend 42 CFR Part 2**. Medical records privacy provisions should be aligned with and fully support integrated whole-person health care. The focus should be on maximizing the health of individuals, consistent with precise patient-consumer-enrollee consent and shared decision-making. Knowledge of all medications currently used by a patient-consumer-enrollee and particularly avoidance of counter-indicated medications should be an important component of individualized whole-person health.

Thus, AAHD supports passage of HR 3545, consistent with the approach of the Partnership To Amend 42 CFR Part 2.

Thank you for your consideration. If you have any questions please contact Clarke Ross at clarkross10@comcast.net.

Sincerely,



E. Clarke Ross, D.P.A.
Public Policy Director
American Association on Health and Disability
clarkross10@comcast.net
Cell: 301-821-5410

Roberta S. Carlin, MS, JD
Executive Director
American Association on Health and Disability
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301-545-6140 ext. 206
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cc. taylor.hittle@mail.house.gov
Kristen.donhefner@mail.house.gov



April 9, 2018

The Honorable Greg Walden
 Chairman
 Committee on Energy and Commerce
 U.S. House of Representatives
 Washington, DC 20515

The Honorable Frank Pallone
 Ranking Member
 Committee on Energy and Commerce
 U.S. House of Representatives
 Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone:

On behalf of the National Alliance on Mental Illness (NAMI), I am writing to offer our strong support for the Overdose Prevention and Safety Act (HR 3545). As the nation's largest organization representing people living with mental illness and their families, NAMI is pleased to support this important legislation to advance the pursuit of integrating care and improving outcomes in behavioral health care.

NAMI believes that 42 CFR Part 2 remains an outdated and antiquated barrier to coordinated care, particularly for individuals with co-occurring mental illness and a substance use disorder. As you both know, individuals diagnosed with a mental health conditions are at much greater risk of abusing substances and falling into the grip of addiction. Additionally, we know that siloed treatment for mental illness and addiction is ineffective and leads to negative outcomes in both an individual's mental health and substance use condition. In many instances, it also creates an even greater risk that individuals will experience poorly managed co-morbid, chronic medical conditions. This is a major contributing factor to the high rates of early mortality for individuals living with mental illness. Numerous studies have found that life expectancy for adults with mental illness may be as much as 25 years less than the general population.

Integrating care across not only mental health and substance use care, but also with primary and specialty medical care, is effective at improving clinical outcomes. It also lowers overall costs across public programs, such as Medicare and Medicaid, and private programs like employer-provided health insurance. However, integration cannot be achieved without the sharing of treatment records among providers. 42 CFR Part 2 remains a significant barrier to the sharing of clinical data and the proper coordination of care. These burdensome consent requirements that are not aligned with HIPAA further stigmatize mental illness and substance abuse as separate from the rest of the health care system. Parity is necessary across the health care system to ensure that behavioral health records are managed the same as all patient data.

With bipartisan support, the Energy and Commerce Committee has embraced alternative payment models (APMs) and is moving our nation's health care system toward paying for "value over volume." As long as behavioral health records remain subject to separate rules that prevent

the sharing of data for treatment, payment and health care operations, mental health and substance use will again be left behind the rest of the health care system. As you advance addiction treatment legislation this spring, NAMI urges you to include the provisions that are in HR 3545 in any bill that is produced by the Committee. This is an important opportunity to improve coordination of care and produce better outcomes for people with mental health and substance use conditions.

Separate is never equal. It is time to align 42 CFR Part 2 with HIPAA and move us toward the goal of true health care integration. Thank you for your leadership on this important issue.

Sincerely,

A handwritten signature in black ink that reads "Mary Giliberti". The signature is written in a cursive style with a large initial "M".

Mary Giliberti, J.D.
Chief Executive Officer
NAMI, National Alliance on Mental Illness



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Two City Center, Suite 400
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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



The Honorable Greg Walden
The Honorable Frank Pallone, Jr.
April 10, 2018
Page 2 of 2

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 pross@aha.org or (202) 626-2677.

Sincerely,



Thomas P. Nickels
Executive Vice President

cc: Members of the Committee on Energy and Commerce



April 10, 2018

The Honorable Greg Walden
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
House Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 2015

RE: H.R. 3545 – “Overdose Prevention and Patient Safety Act”

Dear Chairman Walden and Ranking Member Pallone:

The Academy of Managed Care Pharmacy (AMCP) is writing in strong support of H.R. 3545 – the “Overdose Prevention and Patient Safety Act”. As you know, H.R. 3545 has bipartisan support and was introduced by Reps. Markwayne Mullin (R-OK), Earl Blumenauer (R-OR), Jim Renacci (R-OH), Buddy Carter (R-GA) and Pat Meehan (R-PA). Under your leadership the Energy and Commerce Committee continues its bipartisan efforts to address the opioid epidemic. We applaud your efforts and are especially supportive of your approach to the problem because you acknowledge that it must be addressed on many fronts. To that end, H.R. 3545 is designed to address the issue of patient substance abuse disorder records by bringing those records under the protection of the Health Insurance Portability and Accountability Act (HIPAA).

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government. AMCP is also a member of the Partnership to Amend 42 CFR Part 2, a coalition of more than 40 organizations representing stakeholders across the health care spectrum committed to aligning Part 2 with the Health Insurance Portability and Accountability Act (HIPAA) to allow appropriate access to patient information that is essential for providing whole-person care.

The restrictions implemented by 42 CFR Part 2, under authority granted by a law passed more than 40 years ago, limit the ability of health care providers to implement treatment protocols designed to provide “whole-person” care which includes the use of multi-disciplinary health care provider teams to diagnose and treat patients. Pharmacists, as medication experts, are integral members of those provider teams. However, pharmacists, doctors, nurses and other health care providers do not have complete access to addiction treatment records. Access to a patient’s complete medical record is critical to patient treatment, safety, and recovery.

Of equal concern for patient safety and treatment, is the multitude of unintended consequences of drug to drug interactions, adverse reactions, and even death. Opioids obtained legally, such as those containing oxycodone, and those obtained illegally, such as heroin, may have significant side effects when used with other legally prescribed medications. If a person with an addiction has taken an opioid either legally or illegally and then

receives an additional dose of another opioid, an individual may either experience impairment in their ability to breathe, known as respiratory depression, coma, or even death.

As you know, the opioid epidemic is an ongoing crisis for many patients, their families, the health care system and every state has their "number" of known deaths from overdoses and the mounting toll faced by those suffering from addiction and financial losses resulting from it. By integrating those substance abuse disorder records into a patient's medical records under HIPAA critical information would be available for treatment, payment and operations, yet safeguards and legal protections are also present to assure patients of privacy.

We urge you to support H.R. 3545 as one of the ways to stem the tide of this deadly and costly epidemic. We must continue to work together and if we can provide additional information, please do not hesitate to contact me at 703-684-2600 or at scantrell@amcp.org.

Sincerely,



Susan A. Cantrell, RPh, CAE
Chief Executive Officer



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Fax: (605) 322-4799

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April 10, 2018

The Honorable Greg Walden
Chairman
House Energy & Commerce Committee
2125 Rayburn HOB
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Energy & Commerce Committee
2322A Rayburn HOB
Washington DC 20515

On behalf of Avera Health, a Catholic sponsored health system serving patients in eastern South Dakota and the surrounding states, I am writing in strong support of the Overdose Prevention and Patient Safety Act (H.R. 3545). As the country continues to struggle with how to address the opioid problem, Avera's hospitals and physicians need access to public health data and the patient's full medical record in order to assist in fighting this epidemic. Under current law (42 CFR Part 2) a patient suffering from a substance use disorder is in control of their medical record, unlike every other disease covered by HIPAA. This separate privacy rule is hindering our ability to treat and coordinate care for those suffering from substance use disorder.

As Congress works on the opioid package, which will likely include many proposals such as expanding the utilization of medication assisted treatments, expanding and improving continuing medical education on opioid prescribing, and possibly more funding for states to tackle the crisis, Avera urges the Energy and Commerce Committee to include H.R. 3545, which would align 42 CFR Part 2 with HIPAA so that medical providers can see the full medical record and safely treat patients suffering from addictions.

Sincerely,

Deb Fischer-Clemens, BSN, RN, MHA
Senior Vice President of Public Policy

*Sponsored by the Benedictine
and Presentation Sisters*

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:

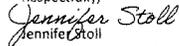
On behalf of OCHIN, Inc., the largest federally-funded Health Center Controlled Network (HCCN) in the nation headquartered in Portland, Oregon, I am writing this letter to convey our strong support of HR 3545 known as the "Overdose Prevention and Safety Act." OCHIN is a collaborative of health care organizations 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 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 and HITECH 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 addiction 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



Statement for the Record

Pharmaceutical Care Management Association

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 millionⁱ 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.ⁱⁱ

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,ⁱⁱⁱ and after the DEA 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.^{iv}

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% (from 60,000/month to 31,000/month).^v 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.^{vi} 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% of prescribed opiates, seeing decreases in all 15 common emergency diagnoses studied.^{vii}



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:

- o \$18 billion to \$37 billion in reduced costs associated with fatalities related to opioid abuse;
- o \$7 billion to \$14 billion saved due to decreased health care costs, decreased treatment costs, workplace productivity gains, and reduced criminal justice costs; and
- o \$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:

- o \$2 to \$4 billion saved due to decreased health care costs, decreased treatment costs, workplace productivity gains, and reduced criminal justice costs; and
- o \$0.5 billion saved from greater efficiencies in physician offices and pharmacies, and increased convenience for consumers.^{viii}

Improve and Integrate State PDMPs 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 (HHS) 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 overuse—patterns far outside the norm, which the OIG says warrant further scrutiny.^{ix} 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).^x 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 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 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, (NCPDP) 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 FDA Commissioner Gottlieb's recent pronouncement that FDA will be "taking a flexible, adaptive approach to the evaluation and labeling of ADF opioids."^{xi}

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.^{xiii} 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.^{xiii} 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,^{xiv} 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 (EHRs), 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.



- ¹ PR Newswire, "PBMs Provide Policy Solutions to Increase Competition, Reduce Rx Costs," Feb 04, 2016.
- ² Script volume figure from Quintiles IMS Institute, "Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021," May 2017.
- ³ See, e.g., Amber Porterfield, Kate Engelbert, and Alberto Coustasse, "Electronic Prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting" *Perspect Health Inf Manag*, 2014 Spring; April 1, 2014. See also, U.S. Department of Health and Human Services (HHS), "Electronic Prescribing of Controlled Substances (EPCS)" November 4, 2016. <https://www.healthit.gov/opioids/epcs>
- ⁴ Imprivata, "State EPCS Adoption Legislation," 2018. <https://www.imprivata.com/state-epcs-legislation>
- ⁵ Geisinger Health System, "Doing Well by Doing Good: Fighting Opioid Abuse While Achieving Cost Savings of EPCS at Geisinger," 2018 Slide Presentation
- ⁶ *Ibid.*
- ⁷ D. Danovich et al. "Effect of New York State Electronic Prescribing Mandate on Opioid Prescribing Patterns," J. Chacko, J. Greenstein, B. Ardolic, N. Berwald Staten Island University Hospital, Staten Island, NY DOI: <https://doi.org/10.1016/j.annemergmed.2017.07.195>
- ⁸ Visante, "Mandatory Electronic Prescribing of Controlled Substances (EPCS) Can Help Combat the Opioid Crisis and Save the United States up to \$53 Billion Annually" Prepared for PCMA, April 2018
- ⁹ HHS OIG, "Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing," July 2017, <https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf>
- ¹⁰ *Ibid.*
- ¹¹ FDA, "Statement from FDA Commissioner Scott Gottlieb, M.D., on Steps to Promote Development of Generic Versions of Opioids Formulated to Deter Abuse," November 21, 2017. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm586117.htm>
- ¹² ICER, "Abuse-Deterrent Opioids: Final Evidence Report," August 8, 2017. https://icer-review.org/wp-content/uploads/2016/08/NECEPAC_ADF_Final_Report_08_08_17.pdf
- ¹³ *Ibid.*
- ¹⁴ C. Bernie Good, Chronis Mancolis, And William Shrank "There's Little Evidence Abuse-Deterrent Opioids Work. Why Should We Use Them?" *Stat News*, August 8, 2017.



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 Recover 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 Stivers (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,

A handwritten signature in black ink that reads "Gary Mendell". The signature is fluid and cursive, written in a professional style.

Gary Mendell
Founder & CEO, Shatterproof
www.shatterproof.org
gmendell@shatterproof.org



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 wellstk@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

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**

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®), Hydromorphone (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 of an opioid it can cause sudden death.**

Other risks include but are not limited to:

- **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://disposemy meds.org/>)
- Follow these steps if you can't find a medicine take-back site to throw out expired, unused or unwanted medicines:
 - Step #1: Mix medicine with used coffee grounds, dirt, or kitty litter.
 - Step #2: Put medicines in a sealed plastic bag.
 - Step #3: Place plastic bag in the trash.
 - 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.



**Association for Behavioral
Health and Wellness**

*Advancing benefits and services
in mental health, substance use
and behavior change.*

April 11, 2018

The Honorable Greg Walden, Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Ranking Member
House Committee on Energy & Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone:

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 Blumenauer, 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

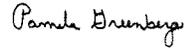
attempting to obtain opioids from several different EDs. Unfortunately, because of Part 2, the health plan was not able to inform the provider that it appeared their patient may be misusing opioids.

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



April 11, 2018

The Honorable Greg Walden
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
House Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone:

Mental Health America (MHA) applauds the House Energy & Commerce Committee for its attention to the nation's opioid epidemic, and writes to urge the inclusion of H.R. 3545, the Overdose Prevention and Patient Safety Act, in any final package passed by the Committee.

MHA – founded in 1909 – is the nation's leading community-based nonprofit dedicated to addressing the needs of those living with mental illness and to promoting the overall mental health of all Americans. Our work is driven by our commitment to promote mental health as a critical part of overall wellness, including prevention services for all, early identification and intervention for those at risk, integrated care, services, and supports for those who need it, with recovery as the goal.

Based on over a century of experience, MHA believes that individuals have a right to control the disclosure and dissemination of their protected health information (PHI). We also believe strongly that separate authorizations perpetuate stigma and lead, perhaps unintentionally, to discrimination and lack of parity in care without giving the individual any more control over their information. They also constitute a significant barrier to integrating treatment. H.R. 3545, the Overdose Prevention and Patient Safety Act would allow for a single authorization for sharing integrated health information while enhancing protections against discrimination as a result of improper disclosures.

The Health Insurance Portability and Accountability Act (HIPAA) requires an individual to sign a form allowing their health care provider to disclose their health information to others, such as other providers or family members. For substance use information, 42 CFR Pt II, an archaic regulation dating back to 1970, requires an individual to sign a separate form in addition to the HIPAA form to allow disclosure of their substance use information. Federal law does not say explicitly that a separate authorization is required for mental health information, but providers often interpret the law regarding substance use to include all other behavioral health information as well. In the absence of statutory clarity, SAMHSA has been unable to conform the two rules.

Separate authorizations contribute to discrimination in care. When an individual goes in for substance use treatment and receives a special authorization form, it implies that they should be wary of disclosure and that they might be doing something others could view negatively. Separate authorizations also complicate the coordination and integration of treatment, because often the behavioral health information does not get transmitted along with other health information. Providers understand that you cannot treat a whole

person with half a health record, and overwhelmingly support action to address this deficiency. We agree. When a special authorization is required for behavioral health information, a provider receiving a record with no behavioral health information in it cannot know whether the person has no behavioral health records, whether they have declined to share them, or whether they were never even asked. This at best contributes to confusion and at worst to poor quality or even dangerous care.

On the other side, MHA has found no evidence that additional formalities actually accomplish the privacy goals of legal advocacy organizations, or guarantee protections beyond those that are inherent in the Americans with Disabilities Act, also enacted after 42 CFR Pt. 2. H.R. 3545 would allow for a single authorization to be used, giving individuals full control over their health information, while promising better integrated care. Individuals will still decide when and to whom to disclose their own PHI, with additional protections from H.R. 3545 for wrongful disclosures.

MHA thanks the House Energy & Commerce Committee's consideration of including H.R. 3545 in the final package, and looks forward to continuing to work with the Committee to address addiction and overdose. Please do not hesitate to contact Nathaniel Z. Counts, J.D., Senior Policy Director of MHA, at ncounts@mentalhealthamerica.net for follow-up or questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul Gionfriddo". The signature is fluid and cursive, with a prominent initial "P" and a long, sweeping underline.

Paul Gionfriddo
President and CEO



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.¹ 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.

¹ Government Accountability Office, “Medicaid: A Small Share of Enrollees Consistently Accounted for a Large Share of Expenditures.” May 2015. <https://www.gao.gov/assets/680/670112.pdf>.



Thank you for your consideration of these comments. Please do not hesitate to reach out to NAMD for additional information on these requests.

Sincerely,

A handwritten signature in cursive script that reads "Judy Mohr Peterson".

Judy Mohr Peterson
Med-QUEST Division Administrator
State of Hawaii
President, NAMD

A handwritten signature in cursive script that reads "Kate McEvoy".

Kate McEvoy
State Medicaid Director
State of Connecticut
Vice President, NAMD



233 N. Michigan Ave., 21st Fl
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April 12, 2018

The Honorable Greg Walden
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
House Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone:

On behalf of 103,000 health information management professionals, the American Health Information Management Association (AHIMA) wishes to express support for H.R. 3545, the Overdose Prevention and Patient Safety (OPPS) Act. The legislation seeks to align the 42 CFR Part 2 regulation with the Health Insurance Portability and Accountability Act (HIPAA) for purposes of healthcare treatment, payment and operations.

AHIMA's credentialed and certified health information management (HIM) members can be found in more than 40 different employer settings in 120 different job functions—consistently ensuring that health information is accurate, timely, complete, and available to patients and providers. The Part 2 regulation presents an operational challenge for HIM professionals working in designated Part 2 programs. HIM professionals working in such programs are often forced to work with paper records. In instances where a Part 2 program may have an electronic health record (EHR), data segmentation functionality is often not available. Lacking such functionality, HIM professionals must keep a patient's addiction records separate from the rest of the patient's medical record—resulting in the creation of two separate medical records. Because such information is kept separate, providers are often unaware of the risks to their patient from multiple drug interactions and co-existing medical problems even though substance use disorders can have a cascading effect on an individual's health and must be carefully managed and coordinated.

The Part 2 regulation is also an impediment to HIM professionals working in states with integrated care delivery models that encourage information sharing to support care coordination and integration of patient care. Despite the fact that state law may encourage information sharing (including substance abuse treatment information), the Part 2 regulation often limits the sharing of both mental health and substance abuse treatment information for purposes of care coordination. In turn, this compromises the intent of integrated care by putting individuals with substance use disorders at a disadvantage over other patients because providers have an incomplete picture of their patient thereby hindering a clinician's ability to deliver informed, coordinated care—the foundation of integrated care delivery models.

A major tenet of the HIPAA Privacy Rule is to ensure that "protections for patient privacy are implemented in a manner that maximizes the effectiveness of such protections while not compromising either the availability or the quality of medical care."¹ AHIMA believes that the same justification should

¹ 67 FR 53181.

hold true for patients receiving substance use disorder treatment in a Part 2 program. Access to an individual's medical record, including addiction records, for purposes of healthcare treatment, payment or operations will help ensure that providers have the information necessary to provide safe, effective, high-quality treatment and care.

We appreciate your leadership on this issue and look forward to working with you and other Members of Congress to advance H.R. 3545.

Sincerely,

A handwritten signature in cursive script, appearing to read "Wylecia Wiggs Harris".

Dr. Wylecia Wiggs Harris, PhD, CAE
Chief Executive Officer
AHIMA



**BlueCross BlueShield
Association**

An Association of Independent
Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4780
Fax 202.626.4833

April 23, 2018

The Honorable Greg Walden
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
House Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

RE: Passage of H.R. 3545, the "Overdose Prevention and Patient Safety (OPPS) Act" to Amend 42 C.F.R. Part 2 and align the Federal Privacy Regulation of Protected Health Information

Dear Chairman Walden and Ranking Member Pallone:

The Blue Cross and Blue Shield Association (BCBSA) is writing to you in support of the passage of H.R. 3545, the "Overdose Prevention and Patient Safety (OPPS) Act." This important legislation would enable the appropriate exchange of information necessary to ensure those suffering opioid use disorders (OUD) and substance use disorders (SUD) obtain safe and effective treatment, gain their most applicable financing and receive their deserved assistance in the form of care management and other healthcare operations.

BCBSA is a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield Plans that collectively provide healthcare coverage for one in three Americans. For more than 80 years, Blue Cross and Blue Shield companies have offered quality health insurance coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare, and Medicaid. Today, Blue Plans are also working with qualified 42 C.F.R. Part 2 treatment programs to ensure that their members with OUD and SUD are provided the care and support to achieve successful health outcomes.

BCBSA commends the efforts of the Substance Abuse and Mental Health Services Administration (SAMHSA) to better align the regulations governing the confidentiality of drug and alcohol treatment and prevention records (42 C.F.R. Part 2 (Part 2)) with the Health Insurance Portability and Accountability Act's (HIPAA) Privacy Regulations. However, SAMHSA's efforts do not go far enough to enable the needed access to relevant health information among patients, payers and providers and balance the protection of individual privacy with individuals' expectations of care.

Current Part 2 federal regulations preclude the disclosure of medical information to healthcare providers for care coordination, including those engaged in alternative payment models. These regulations currently require complex and multiple patient consents for the use and disclosure of patients' substance use records that go beyond the sufficiently strong patient confidentiality protections that were put in place by HIPAA. For example, a health plan or provider should be

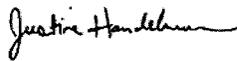
permitted to inform a treatment facility that the individual being admitted was recently released from a different treatment entity's care – information vital to patient safety and quality outcomes.

We are aware that aligning the Part 2 regulations with HIPAA for the purpose of treatment *only* is under consideration. But treatment purposes cannot be separated from payment and health care operations. For payers, treatment, payment, and operations all are interrelated—and the following examples help illustrate future challenges if the alignment is for treatment only:

- Medicaid requires whole-person care management. Payers could not participate in certain prescription monitoring activities without the potential to share information for treatment, payment, and operations. For example, health plans that want to be active in identifying members who are engaging in drug-seeking behavior or providers who are inappropriately prescribing addictive drugs would not be able to send warning letters to the members' primary care physicians and other providers to alert them to the inappropriate prescription activity.
- Health plans might be prevented from partaking in normal customer service activities, like parents calling in about their minor children's authorizations and claims, or family members or friends helping a patient with the financial end of things (claims issues, appeals, questions about coverage).
- Health plans may be blocked from offering significant support to providers in their networks to assist and to help the providers coordinate the patient's entire care. Health plan case management programs, and longer-term data collection, are important pieces of a person's OUD/SUD history and support for them and their family when they are not directly engaged in a program. Most of the time, a patient is at home, with family and friends, and health plans' case management programs offer the supports necessary to assist and to help the providers coordinate all the patient's care.

SAMHSA has acknowledged that the agency has done as much as it can through regulatory efforts under the limitation of the current statutes. Legislative action is necessary in order to modify Part 2 and bring OUD and SUD access regulations to a configuration that supports the 21st Century healthcare approaches and stem the current plague of substance use disorders. BCBSA urges the Committee to include H.R. 3545 to amend 42 CFR Part 2 and align SAMHSA's OUD and SUD regulations with HIPAA's treatment, healthcare operations, and payment policy as Congress passes legislation addressing the opioid crisis.

Sincerely,



Justine Handelman
Senior Vice President,
Office of Policy and Representation

Cc: Kristen Shatynski
Caleb Graff
Waverly Gordon
Tiffany Guarascio
Taylor Hittle
Kristen Donheffner



1155 15th Street, N.W., Suite 600 | Washington, DC 20005
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 John Lovelace, Chairman | Margaret A. Murray, Chief Executive Officer

April 24, 2018

The Honorable Michael Burgess, MD, Chairman
 Health Subcommittee
 House Energy and Commerce Committee
 Rayburn House Office Building
 Washington, DC 20515

The Honorable Gene Green, Ranking Member
 Health Subcommittee
 House Energy and Commerce Committee
 Rayburn House Office Building
 Washington, DC 20515

Chairman Burgess and Ranking Member Green:

On behalf of the Association for Community Affiliated Plans (ACAP), I am writing to express our gratitude and support for the House Energy and Commerce Health Subcommittee's commitment to move a comprehensive slate of bills to address America's devastating opioid crisis. ACAP particularly applauds the Committee's bipartisan recognition of the important role that the Medicaid program has in addressing the opioid epidemic and we look forward to working with members of the Committee and the Administration, as well as the states, to maximize Medicaid's potential to address the opioid crisis.

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. While ACAP supports a comprehensive approach to addressing the opioid issue in America, we want to specifically voice our support for several pieces of common-sense legislation that represent policy priorities for America's safety net health plans. We urge the Committee to ensure these bills are part of any legislative effort that moves through the legislative process. ACAP particularly urges the members of the Subcommittee to support the following:

- ***H.R. _____, Require Medicaid Programs to Report on All Core Behavioral Health Measures***, to require state Medicaid programs to report on the 11 behavioral health measures that are included in CMS's 2018 Core Set of Adult Health Care Quality Measures for Medicaid. This legislation is vital to help federal and state policymakers better understand how state Medicaid programs are addressing the opioid crisis and to provide opportunities to share best practices in this area. ACAP has long advocated for state reporting of the Medicaid core quality measures, we applaud the Subcommittee for this legislation and urge its passage; and
- ***H.R. 3545, the Overdose Prevention and Patient Safety Act***, to align the use of substance use disorder (SUD) treatment records with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of treatment, payment, and healthcare operations. Safety Net Health Plans strongly support the protection of patient privacy and confidentiality. However current federal law and regulation (42 CFR Part 2) creates bureaucratic hurdles to the treatment of and care coordination for health plan members suffering from SUD, including those receiving coverage in Medicare, Medicaid, and through the health insurance exchanges. This legislation will protect patient confidentiality while improving the ability of health plan providers to provide vital health care services to plan members and we urge its support by the Subcommittee.



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John Lovelace, Chairman | Margaret A. Murray, Chief Executive Officer

ACAP recognizes and applauds the Subcommittee's efforts to provide a comprehensive solution to America's substance abuse epidemic and we stand prepared to work with the bipartisan members of this Committee to ensure these bills become law.

Please do not hesitate to contact me or Jenny Babcock, Vice President for Medicaid Policy & Director of Strategic Operations, if ACAP can be of any assistance to you.

Sincerely,

/s/

Margaret A. Murray
Chief Executive Officer

Cc: Members, House Energy and Commerce Committee



April 15, 2018

Chairman Michael C. Burgess, M.D.
 Energy & Commerce Health Subcommittee
 United States House of Representatives
 2336 Rayburn House Office Building
 Washington, DC 20515

Dear Chairman Burgess:

Thank you for your continued leadership on the federal response to the opioid crisis. We are writing to express strong support for the **Overdose Prevention and Patient Safety Act, H.R. 3545**, in its original bipartisan form and to urge against the adoption of the "Amendment in the Nature of a Substitute" drafted by the bill's sponsor, Rep. Markwayne Mullin.

We deeply appreciate Rep. Mullin's leadership on this bill but believe his substitute proposal would fail to solve the significant problems the original legislation set out to address. The original, on the other hand, would be an essential piece of any opioid response package produced by the House this session.

As background, the Hazelden Betty Ford Foundation is the largest nonprofit provider of substance use treatment, education and prevention services in the world. We have provided leadership in the field of addiction treatment for nearly 70 years. In 2017 alone, our organization touched the lives of more than 21,000 people affected by addiction and other co-occurring medical and mental health conditions. We have 17 sites nationwide, serving children, adolescents, adults, families, schools and communities, and all of our treatment facilities are licensed or certified and have achieved accreditation by The Joint Commission.

To address the opioid overdose epidemic and the underlying addiction crisis in this country, we need your help to closely *integrate* addiction care within the broader health care system so patients have multiple *access* points and can get support for this chronic condition beyond the acute care stage. The original H.R. 3545 reforms the outdated 42 CFR Part 2 ("Part 2") privacy regulations, which have become a barrier to access and deprive patients of the full benefits of modern health care services. That's why we support this bill to align the Part 2 requirements with those of the Health Insurance Portability and Accountability Act ("HIPAA"), which apply to all health care providers and allow the use and disclosure of patient information when needed to facilitate optimal care.

Part 2 is outdated and onerous

Part 2 is a 45-year-old law that was created a quarter century before HIPAA specifically to protect the privacy of patients who sought care within the very young and largely un-professionalized addiction treatment industry of that time. When HIPAA was enacted in 1996, Part 2 was left in place, despite providing little to no extra privacy protections beyond those HIPAA began providing for all patients regarding all health conditions, and despite addiction care integrating more and more over time with the rest of health care.

Generally speaking, Part 2 requires many specific, written consents by the patient for his or her substance use-related health records to be shared among doctors, hospitals, specialty care providers like

the Hazelden Betty Ford Foundation, insurers and others who may support the patient's care. HIPAA, on the other hand, allows for streamlined blanket consents that better facilitate needed information sharing. Both laws provide protections for privacy violations, and the federal government regularly prosecutes HIPAA violators. But not a single enforcement case has ever arisen from Part 2, partly because full compliance is a practical impossibility that often poses risks to patient care, and also because legitimate infringements on patient privacy are already well covered by HIPAA.

Part 2 is not fairly and uniformly applied

It's also important to note that, unlike HIPAA, Part 2's unnecessary privacy regulations do not apply to all health care providers who serve patients seeking care for substance use disorder. Generally, Part 2 only applies to the patients of nonprofit specialty treatment providers and those that treat the poor and elderly through public insurance. Most for-profit treatment providers are not subject to the Part 2 regulations; nor are most primary care providers and independent mental health professionals, who increasingly are part of the care continuum for people with a substance use disorder; and nor is the Veterans Administration. As a result, thousands of patients receive treatment services at non-Part 2 providers throughout the country, and their information is protected by HIPAA and state law. The good news is that HIPAA is meeting the needs of those patients just fine, without the barriers that Part 2 poses for patients of Part 2 facilities.

Part 2 is largely unnecessary

Opponents of H.R. 3545 have testified it would create a framework by which, for example, a father in recovery could be denied visitation with his children because he was in addiction treatment, a mother could be threatened with eviction from a shelter because she was being treated with prescribed methadone for her opioid addiction, or a young man receiving worker's compensation could be cleared for work by a doctor but forbidden from returning due to the discovery of a previous treatment for addiction. The fact is that none of those scenarios plays out differently under HIPAA v. Part 2. All would involve disclosures made by the patients themselves, not providers – who would be equally bound under either law. Remedies in each of these situations would be best pursued under discrimination laws.

What is needed for substance use patients is legal protection from discrimination, not laws that impede information-sharing for legitimate treatment, payment and operational purposes. The idea that Part 2 provides extra protection against discrimination is, practically speaking, an illusion. While some have testified that harmonizing privacy laws would discourage people from seeking treatment, neither the law itself nor our experience as a frontline treatment provider supports that assertion.

Part 2 compromises care

In the end, Part 2's costly, onerous rules don't add meaningful protections for patients and, in fact, compromise care by forcing hospitals and doctor's offices to keep records from Part 2 providers on paper or in separate systems from all of the other electronic patient data maintained by their HIPAA-compliant systems. The result of the dual systems is that addiction treatment data are often not shared among doctors. This means doctors may not know if their patients have a history of drug or alcohol misuse or even if they've gotten treatment, and hospitals and doctors in integrated care models can miss crucial information to prevent misdiagnosis and harmful medical interactions for the patient. This separation of the data also makes it difficult for addiction treatment providers to participate in some integrated care models, for which they have to share their patient data. The reality is that the health care system is designed around HIPAA, and now that addiction care is integrating with mainstream medicine to serve patients better, Part 2 poses a dangerous disconnect. The dual policies are simply incompatible with health care today.

As it is, we are faced every day with balancing the impossible requirements of Part 2 with a sacred commitment to our patients, whose care is compromised by the letter of this outdated law.

One example: A recently discharged, hard-of-hearing patient used a relay service interpreter to contact us, a call we cannot legally take without a signed release from the patient for that interpreter. This type of scenario forces us to choose between two risks: breaking the law to help the patient, or abiding by the law and risking patient harm? It's an easy decision in the end, but a double-jeopardy with which we shouldn't even be confronted.

Another example: A patient was prescribed suboxone during residential treatment and returned to his home state. As part of his discharge plan, he was to engage a physician to continue his care. He delayed engaging a physician in his home area, which necessitated a call to the treatment center physician with a request to send his prescription to the local pharmacy. The patient was unable to immediately execute and deliver a written consent to the local pharmacy, however, meaning our physician at the treatment center could not legally call in the prescription refill or consult with the pharmacist.

Anything less than full alignment with HIPAA is problematic

Rep. Mullin's drafted amendment would dial back the scope of his original proposal by aligning Part 2 with HIPAA only for treatment purposes but not for payment or operations purposes. Unfortunately, this further bifurcation of health care records only complicates compliance further and keeps the requirement that dual systems be maintained. It also will hurt patients.

Part 2, as it relates to payment, creates access and quality care barriers, starting with patients' first call for help to determine if they have benefits and if the insurer will issue the necessary preauthorization. These barriers continue through the adjudication of the claim through the insurer as well as the peer review and utilization review processes, and on to any eventual application for disability benefits. The more patients are confronted by barriers like this, the less likely they are to follow through with their intent to access and complete treatment. In serving thousands of patients every year, we know financial impact is one of the most important factors for them — and can be a barrier to access.

Part 2, in fact, requires specific written consent for each person who touches a record within the insurance payment process, and each provider staff member who needs to touch the record as part of day-to-day operations. The average patient at the Hazelden Betty Ford Foundation, for example, is asked to sign about a dozen releases during the course of his or her care. Imagine people who have a heart attack being asked to provide consents to every person in the emergency room, hospital, insurance payment pipeline, and in their health care history who may have information pertinent to optimal care. It's unreasonable and an impossible requirement for Part 2 providers to meet in many cases, but still a federal criminal law. So, responsible organizations like ours do everything we can to comply, at great frustration, expense and harm to care.

Part 2 is a frustration to many patients, not a benefit. Payment alone takes, on average, three to five consents. Having to revisit those conversations throughout the treatment process is a barrier between patients and their care, and often takes an emotional toll on patients. Worse, if mistakes are made at any point, or if anything changes in the process of insurance review, providers often cannot make even the simplest changes without the patient's express consent. And if providers are unable to locate the patient in a timely manner—due to the complicated logistics of obtaining written consents from patients not physically on site, a barrier that does not exist for the rest of healthcare or for non-Part 2 treatment providers—bills end up becoming the patient's responsibility, the stress of which can significantly impact recovery in a negative way. Under HIPAA, on the other hand, presenting your insurance card at the outset provides consent for the whole payment process, a much more patient-friendly policy.

Part 2 institutionalizes stigma

Repeated consents also send patients the signal that the illness for which they're getting care is one that requires unusual secrecy. In that way, Part 2 institutionalizes and exacerbates the very stigma it purports to protect against. We have fought for decades to have addiction viewed and treated as a healthcare condition, and yet Part 2 validates—even if unintentionally so—the stigmatized view that it is instead a moral failing, worthy of hiding.

Part 2 also needs to be aligned with HIPAA for operations purposes. Part 2 programs need to be able to utilize patient information for administrative, regulatory financial, and quality programs. It is impossible for a Part 2 program to obtain consent for every activity and person within the organization that may need to touch patient information for operations activities like fulfilling our licensing and accreditation requirements and performing quality assurance. Some specific examples of operations-related needs include (but are not limited to) utilizing patient information to: examine the most effective treatment options; improve documentation; defend the organization or its partners in a legal dispute; conduct training programs for students, trainees or practicing clinicians; review the competence or qualifications of our multi-disciplinary team of professionals; and evaluate clinical performance.

Alignment supports “parity”

By aligning Part 2 with HIPAA for “treatment,” “payment,” and “operations” purposes, the original H.R. 3545 would continue Congress’s effort to bring much-needed parity between care for addiction and care for physical health conditions. At the same time, the bill would actually strengthen Part 2’s protections against discrimination and other potential abuses of information in criminal and civil courts; we know how important this is because we get subpoenas every day for patient records, which our Legal Department fights strenuously.

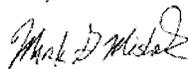
When Part 2 was enacted in the 1970s, there was no insurance coverage for addiction treatment, few states regulated facilities or providers who delivered services, and there were no other federal or state privacy regulations of comparable scope. However, much has changed in the decades since. Thanks to the 2008 Mental Health Parity and Addiction Equity Act, millions of Americans are now able to utilize their insurance benefits. Many states also now regulate facilities and providers, and providers are subject to federal regulations as well – most notably, HIPAA. It’s time to bring about the regulatory changes necessary for providers to meet the needs of our patients.

It is critical that the original H.R. 3545 be preserved to align Part 2 with HIPAA for “treatment,” “payment,” and “operations” and included in any opioid package enacted by this Congress.

We have led the way in advocating for the rights of people with addiction for decades. In this case, the concerns of those opposed to the original bill are not supported by facts or our frontline experience. We feel strongly that maintaining unnecessary barriers to care during the nation’s worst addiction crisis ever would be a missed opportunity and potentially grave mistake.

Thank you very much for your consideration and leadership on this important topic.

Sincerely,



Mark Mishek
President and Chief Executive Officer
Hazelden Betty Ford Foundation



Marvin D. Seppala, MD
Chief Medical Officer
Hazelden Betty Ford Foundation



 CENTERSTONE

April 16, 2018

The Honorable Greg Walden, Chairman
 House Committee on Energy and Commerce
 2125 Rayburn House Office Building
 Washington, DC 20515

The Honorable Frank Pallone, Jr., Ranking Member
 House Committee on Energy and Commerce
 2322A Rayburn House Office Building
 Washington, DC 20515

Cc: Kristen Shatynski
 Caleb Graff
 Waverly Gordon
 Tiffany Guarascio

Re: Support for alignment of Part 2 with HIPAA for purposes of TPO

Dear Chairman Walden and Ranking Member Pallone,

We are very encouraged by Congress's dedication to reversing the opioid epidemic. Centerstone is grateful for all the efforts Congress has made, particularly in the past year, to find ways to better treat patients with substance use disorders. Specifically, Centerstone thanks you for all your work in drafting dozens of legislative proposals to become part of a larger CARA 2.0 package. We appreciate the Committee's continued leadership in working toward well-vetted, high-quality solutions to our nation's opioid challenge. Once again, we reiterate our support for a legislative vehicle to align Part 2 with HIPAA for the purposes of treatment, payment, and healthcare operations (TPO).

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.^{1,2} 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*. 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).

¹ <https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf>

² <http://www.jhconnect.org/wp-content/uploads/2013/09/42-CFR-Part-2-final.pdf>



CENTERSTONE

Substance use disorders can have complicated ripple effects on a patient's health that need to be carefully identified and coordinated.³ The current outdated rule poses a serious safety threat to persons with substance use disorders due to risks from multiple drug interactions and co-existing medical problems. To illustrate this, an example from a Centerstone Indiana patient follows:

A young man was referred to Centerstone from a surgeon who had concerns about depression in his patient. The referred individual had complex medical needs due to an injury. Upon initial referral, it appeared as though the young man had some mental health concerns that were being treated with an anti-depressant and a benzodiazepine, as prescribed by the surgeon. When assessing the young man at our community mental health center for mental health and addiction services, we developed serious concerns about the possibility of overlapping addictive disorders including opiate, benzodiazepine, and alcohol addiction, in addition to a depressive disorder. Due to the severity and combination of drugs the man was using, there were major safety concerns. The young man's support system was shallow - he was not from the area and had no friends or family that lived locally. He had concerns about signing releases of information for any of his family that lived out of town or for any other health care provider because he feared he would no longer be able to hide his addiction from them, or obtain medication from other providers to support his addiction. **Due to the complexity of his medical condition, he was able to easily obtain both opiates and benzodiazepines from separate medical providers. Being honest about his addiction would have resulted in him no longer having access to the drugs that were being legally prescribed to him – ones that were threatening his wellbeing and posing high levels of lethal risk of overdose.**

After consulting with psychiatric staff, we determined he was in need of an additional psychiatric assessment before potentially starting him on Suboxone to aid in staving off his addiction to opiates. The fear remained, though, that he would continue to access benzodiazepines, which, if combined with Suboxone, could be dangerous. As part of the terms of his Suboxone treatment, he had to agree to sign releases of information to his other medical providers so that his psychiatrist could inform them of his full condition, which, if ignored, could be more lethal than any of the other complex conditions he was being treated for. After several months, the young man agreed to be more open about his opioid use, and agreed to involve more and more individuals in his care by signing additional releases of information. Shortly after he signed a release for his mother, he had a significant relapse. Thanks to the ability to correspond with his mother, the treatment team intervened to get him immediate medical attention and follow-up inpatient treatment that led to a longer term residential placement. If the young man had not signed the ROIs for his mother or his other health care providers, his providers would have been extremely limited in how to proactively respond to his needs. **Without an ability to share the young man's full medical history, he would have been at high risk of death.**

SAMHSA recently released two final rules which take some steps to modernize Part 2, but they do not go far enough. Legislative action through **The Overdose and Patient Safety Act (H.R. 3545)** is necessary to modify Part 2 to the full TPO extent. We hope you will consider examples like these in finalizing a CARA 2.0 package to make care safer for all those who seek it. Thank you for your continued attention to these matters.

Sincerely,

A handwritten signature in dark ink, appearing to read "D. Guth, Jr.", written in a cursive style.

David C. Guth, Jr.
Chief Executive Officer
Centerstone

³ <http://www.helpendopioidcrisis.org/>



April 20, 2018

The Honorable Greg Walden
 Chairman
 House Energy & Commerce Committee
 2125 Rayburn HOB
 Washington, DC 20515

The Honorable Frank Pallone, Jr.
 Ranking Member
 House Energy & Commerce Committee
 2322A Rayburn HOB
 Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone:

On behalf of the 3,900 hospitals, hundreds of thousands of clinicians and 150,000 other provider organizations in the Premier healthcare alliance, we thank you for your leadership in finding solutions to address the opioid crisis that is plaguing our communities. We believe critical steps are needed to equip patients, healthcare providers, payers and others in our communities to better deal with the challenges that this epidemic presents and the Committee's role has been instrumental in developing legislation to accomplish this.

As you mark-up your opioid package, we would like to highlight why it is important to include H.R. 3545, the Overdose Protection and Patient Safety Act, introduced by Representatives Markwayne Mullin and Earl Blumenauer, which would align 42 CFR Part 2 (Part 2) with HIPAA's treatment, payment and operation protections. Part 2 was enacted more than 20 years before HIPAA and 40 years prior to the utilization of electronic health care records. When Part 2 was first enacted it played an intricate role in protecting the paper medical record from improper use or seizure by law enforcement for those suffering from substance use disorder.

While these protections were important in the 1970's, Congress went on to enact HIPAA in 1996, which provides strong protections for every medical condition (i.e. mental health, HIV/AIDs, STD's, Hep. C) with the exception of conditions related to substance use covered by Part 2. The enactment of the 21st Century Cures Act then put in motion the transition from paper medical records to interoperable electronic medical records with the aim of connecting our siloed health care system to allow true integrated delivery models that could improve patient safety, quality and outcomes and reduce costs to ensure the longevity of Medicare and Medicaid. Today, many integrated health care providers, such as accountable care organizations, are using electronic health records to better coordinate care for patients among all participating health care providers, including for the purpose of medication reconciliation at the time of diagnosis and treatment.

Premier believes changing Part 2 to align with the HIPAA standard of care for treatment, payment and healthcare operations is essential to ensuring many of the proposals being considered by the

House Energy & Commerce Committee
April 20, 2018
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Energy & Commerce Committee can achieve their intended goals. The opponents of H.R. 3545 cannot provide specific examples how H.R. 3545 would legally allow employers or landlords to access an individual's medical record, as they claim could occur. The bill's co-sponsors have heard them loud and clear and have added protections for substance use data to the bill that go beyond HIPAA's current robust protections. That said, they continue to argue that data breaches happen, but this can be said of any industry in the country, not just healthcare.

The Premier healthcare alliance is committed to helping healthcare providers with their ongoing efforts to reduce adverse drug events, dependence and addiction. Our members are always driving toward continuous improvement and toward finding solutions to this national problem. We are at a point in which the opioid / heroin / fentanyl crisis is moving in the wrong direction, evidenced by the latest CDC reports that show emergency department visits are up 30 percent for overdoses. We are committed to protecting patients' privacy and believe that can be achieved by aligning Part 2 with HIPAA protections. Under current law the penalty for misusing or sharing information covered under Part 2 is \$50 (some argue this may have expired) and only enforceable by the Department of Justice. If Part 2 is aligned with HIPAA, the penalties would range from \$150,000 to \$1.5 million, providing a much stronger recourse if any wrong doing occurs.

First, if we are to effectively care for Medicaid beneficiaries suffering from substance use disorders, wouldn't it be prudent to allow the states to receive much needed public health data to ensure they can identify problem areas in their state and allocate the proper resources to address them? Last year, Virginia's Secretary of Homeland Security and Public Health Brian Moran's written testimony highlighted the need to amend and align Part 2 with HIPAA. He also clearly noted the state of Virginia was flying blind on how to address the deadly opioid crisis.

Second, effective utilization of state prescription drug monitoring programs will require making changes to Part 2. Currently, patients covered under Part 2 will not have their prescriptions reported into the state Prescription Drug Monitoring Program (PDMP). This presents many challenges, especially in regards to preventing patients from doctor shopping for prescriptions, or identifying bad actors in the medical community.

Finally, if we are to expand access to medication assisted treatments for more individuals, shouldn't we ensure that the healthcare community has access to the full medical record? Do we really think it is safe to say that every Part 2 patient is openly and willingly sharing their full medical record with all of their health care providers? As you know, buprenorphine and drugs similar in nature contraindicate with many other drugs patients may be taking. In order to prevent unnecessary adverse events and ensure the best care is being delivered and medications are being safely prescribed, shouldn't the medical community be able to fully reconcile a patient's drug history?

House Energy & Commerce Committee
April 20, 2018
Page 3 of 3

We would welcome the opportunity to share more information about our work to address the opioids epidemic and explore ways in which we can help tackle the problem within the Medicare program.

Sincerely,



Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance



A Passionate Voice for Compassionate Care

April 6, 2018

The Honorable Greg Walden
Chair, Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member, Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

RE: Overdose Prevention and Safety Act

Dear Chairman Walden and Ranking Member Pallone,

On behalf of the Catholic Health Association of the United States (CHA), the national leadership organization of more than 2,000 Catholic health care systems, hospitals, long-term care facilities, sponsors, and related organizations, I am contacting you regarding the opioid crisis affecting far too many of our nation's communities. We have heard from our health systems, hospitals and clinics across the nation how this crisis is affecting their ability to provide health care, and we are pleased to see the variety of legislative solutions being considered in the hearings held by the Energy & Commerce Health Subcommittee.

As the Committee continues consideration of legislation, we wish to express our strong support for the Overdose Prevention and Safety Act as originally introduced (H.R. 3545). This legislation would align current regulations for substance use disorder (SUD) records with existing patient protections for treatment, payment and health care operations, so that SUD and other medical records would be treated in the exact same way. We also support adding provisions to the legislation to ensure even stronger protections for patient privacy and anti-discrimination, as well as appropriate penalties for violations of these protections.

Catholic health providers recognize that each human life is sacred and possesses inalienable worth, and that health care is essential to promoting and protecting the inherent dignity of every individual. We also recognize that supportive and readily available substance use disorder (SUD) treatments are essential facets of holistic, person-centered and effective health care. The first principle in our *Vision for U.S. Health Care* affirms our call to pay special attention to those most likely to lack access to health care, many of whom are in desperate need of SUD services. This commitment is why the Catholic health ministry strongly supports efforts to increase access to these services and ensure that they become fully integrated into our health care system.

CHA supports H.R. 3545, the Overdose Prevention and Safety Act, as an important tool for achieving that integration. Most importantly, H.R. 3545 as originally introduced would allow "use or disclosure" of the content of records to carry out SUD treatment, payment or health care operations as defined under current HIPAA regulations. These three pieces of a



A Passionate Voice for Compassionate Care

patient's record are inseparable in existing electronic health records (EHRs). They enable the essential flow of patient information among providers that is critical to the timely and effective delivery of health care and critical to patient safety and quality. That is not possible when having to maintain and access two separate sets of records for the same patient. For health providers, the alignment with HIPAA for SUD treatment as well as payment and health care operations is essential to providing whole-person care. Full coordination of physical care and SUD treatment, including medical records, is also necessary to minimize the risk of relapse or future addiction among patients. And it is a key component for licensing requirements, accreditation standards and maintaining best practices to ensure that those requiring SUD treatment receive the most effective care possible.

We understand from our member organizations treating substance use disorders that the current system, with separate charts and records for SUD patients, has made the provision of care unnecessarily burdensome and curtailed their ability to expand options for care and treatment even as the opioid epidemic continues. **The full alignment of SUD records with HIPAA across treatment, health care operations and payment settings, as originally provided for in H.R. 3545, is essential to their work, mission and patient safety.**

Thank you again for your attention to the urgent matter of opioid and other substance use disorders. We know that you share the goal of our Catholic health ministry in providing the best possible care and treatment for those who need it, and we look forward to working with you on legislative solutions that can meet the current challenges.

Sincerely,

A handwritten signature in black ink that reads "Michael Rodgers". The signature is written in a cursive style.

Michael Rodgers
Senior Vice President, Advocacy & Public Policy



April 23, 2018

The Honorable Greg Walden
 Chairman
 House Committee on Energy and
 Commerce
 2125 Rayburn House Office Building
 Washington, DC 20515

The Honorable Frank Pallone, Jr.
 Ranking Member
 House Committee on Energy and
 Commerce
 2322A Rayburn House Office Building
 Washington, DC 20515

Re: HR 3545 – The Overdose Prevention and Patient Safety (OPPS) Act

Dear Congressmen Walden and Pallone:

The College of Healthcare Information Management Executives (CHIME) is pleased to support HR 3545, the Overdose Prevention and Patient Safety (OPPS) Act. The legislation would be integral in managing opioid addiction records through seeking to align 42 CFR Part 2 regulation with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of payment, treatment and health care operations.

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 2,500 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.

Recently, in the face of the almost 45,000 lives lost in 2016 to opioid addiction and overdose 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.

When a provider is caring for a patient's health, it is essential that they have a complete medical history with all relevant information that will help them make clinical decisions to the best of their ability. To ensure the highest quality of care possible, information pertaining to substance use disorder (SUD) is pertinent. However, as it currently stands as required by 42 CFR Part 2, SUD treatment and diagnoses are kept confidential from providers which can be extremely problematic when a clinician is attempting to treat someone but doesn't know their prior addiction history. Our members strongly support synchronizing these consent policies and reducing the burdens imposed by these two different sets of rules and facilitating consent for the purposes of treatment, payment and healthcare operations pursuant to HIPAA.



Oftentimes, someone is prescribed an opioid for pain because the physician doesn't have any knowledge of problematic substance abuse history. If they had been able to access this information, they would often have been able to keep those vulnerable for misuse safe from the harm of the highly addictive painkiller. HR 3545 would align 42 CFR Part 2 with HIPAA which would allow the sharing of patient information with clinicians treating the patient, so they can make the most informed decisions possible. By allowing this, the information would still be safeguarded under the rules of HIPAA while giving clinicians electronic access to a broader picture of a patient's health; therefore, resulting in a better care experience for the patient.

We appreciate your continued interest and leadership on this subject. We stand ready to work with you and your colleagues toward the passage of this important legislation, which would help clinicians treat those patients struggling with addiction. Should you have any questions about our position or require additional information, please contact us at policy@chimecentral.org.

Sincerely,

A handwritten signature in cursive script, appearing to read "Russell Branzell".

Russell Branzell, FCHIME, CHCIO
CEO & President, CHIME

A handwritten signature in cursive script, appearing to read "Cletis Earle".

Cletis Earle, Chair, CHIME Board of Trustees
Vice President and CIO Information
Technology Kaleida Health

PARTNERSHIP TO AMEND 42 CFR PART 2

A COALITION OF OVER 40 HEALTH CARE STAKEHOLDERS COMMITTED TO ALIGNING 42 CFR PART 2 (PART 2) WITH HIPAA TO ALLOW APPROPRIATE ACCESS TO PATIENT INFORMATION THAT IS ESSENTIAL FOR PROVIDING WHOLE-PERSON CARE.

April 23, 2018

The Honorable Greg Walden, Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Ranking Member
House Committee on Energy & Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone:

On behalf of the Partnership to Amend 42 CFR Part 2, the undersigned organizations thank you for holding many hearings on the opioid crisis and putting forth thoughtful legislation to address this epidemic. The Committee on Energy and Commerce hearings have covered many challenges facing states and communities, patients, providers, and payors across the country.

As you mark-up your opioid package, we would like to highlight the importance of including H.R. 3545, the Overdose Protection and Patient Safety (OPPS) Act, sponsored by Representatives Markwayne Mullin and Earl Blumenauer. The OPPS Act 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).

Part 2 was enacted more than 20 years before HIPAA and 40 years prior to the utilization of electronic health care records. While different treatment of substance use disorder (SUD) records were important in the 1970's, Congress went on to enact HIPAA in 1996, which allows for the sharing of medical records without an authorization for TPO. Ready access to treatment and efficient payment for health care are essential to the effective operation of our health care system. Additionally, certain health care operations, such as administrative, financial, and quality improvement activities, are essential to support treatment and payment. Aligning Part 2 with HIPAA for purposes of treatment alone would not allow for care coordination, payment to providers, or fraud and abuse detection without an authorization. HIPAA applies to every single illness, including other stigmatized diseases like mental health, HIV/AIDS, and SUD. However, because HIPAA sets the "floor" or minimum protections for health information, the overly-stringent restrictions imposed under Part 2 supersede HIPAA and prevent alignment with all other health care conditions.

The members of the coalition are committed to quality care and protecting patients' privacy and believe that can be achieved by aligning Part 2 with HIPAA for the purposes of TPO. H.R. 3545 maintains all of the protections against the use of SUD records outside of TPO, including in criminal proceedings or investigations, currently in Part 2 and in fact, strengthens them. For example, it currently is not, and is not under H.R. 3545, legal to share an individual's SUD record with an employer, law enforcement, or a landlord. Further, H.R. 3545 will require the automatic dismissal of any criminal proceeding or investigation based upon a SUD record that was not properly obtained using the longstanding court order process set forth under Part 2. Additionally, under current law the penalty for misusing or sharing information covered under Part 2 is from \$500 to \$5,000. If Part 2 is aligned with HIPAA, the penalties will range from \$100 to \$1.5 million, providing a much stronger recourse if any wrongdoing occurs.

We believe changing Part 2 to align with the HIPAA standard of care for TPO is essential in order to integrate care, stop opioid prescriptions from getting into the hands of individuals with a SUD, and to ensure many of the proposals being considered by the Committee on Energy and Commerce can achieve their intended goals.

Sincerely,

Academy of Managed Care Pharmacy (AMCP)
American Association on Health and Disability
American Health Information Management Association (AHIMA)
American Hospital Association
American Psychiatric Association
American Society of Addiction Medicine
American Society of Anesthesiologists
America's Health Insurance Plans
AMGA
Association for Ambulatory Behavioral Healthcare
Association for Behavioral Health and Wellness
Association for Community Affiliated Plans
Catholic Health Association of the U.S.
Centerstone
Global Alliance for Behavioral Health and Social Justice
Hazelden Betty Ford Foundation
Health IT Now
Healthcare Leadership Council
InfoMC
Mental Health America
National Alliance on Mental Illness
National Association for Behavioral Healthcare
National Association of ACOs
National Association of State Mental Health Program Directors (NASMHPD)
Netsmart
OCHIN
Otsuka America Pharmaceutical, Inc.
Premier
The Joint Commission



February 20, 2018

The Honorable Greg Walden
 Chairman
 U.S. House of Representatives
 Committee on Energy and Commerce
 2125 Rayburn House Office Building
 Washington, D.C. 20515

The Honorable Frank Pallone
 Ranking Member
 U.S. House of Representatives
 Committee on Energy and Commerce
 2125 Rayburn House Office Building
 Washington, D.C. 20515

Dear Chairman Walden and Ranking Member Pallone,

The Confidentiality Coalition is writing to you to urge passage of H.R. 3545, the Overdose Prevention and Patient Safety (OPPS) Act, to enable the appropriate exchange of necessary information among medical professionals who are treating individuals with substance use disorders, including opioid abuse. While the Confidentiality Coalition commends the U.S. Substance Abuse and Mental Health Service Administration's (SAMHSA's) ruling to amend 42 C.F.R. Part 2 to better align Part 2 regulations within the Health Insurance Portability and Accountability Act (HIPAA) to integrate behavioral and physical healthcare, we believe this ruling does not go far enough to help increase access to relevant health information among patients, payers and providers while concurrently protecting patient privacy.

The Confidentiality Coalition is a broad group of organizations spanning all sectors of healthcare working to ensure that policies are implemented to appropriately balance the protection of confidential health information with the efficient and interoperable systems needed to provide high quality healthcare. Access to timely and accurate patient information leads to both improvements in quality and safety and the development of new lifesaving and life-enhancing medical interventions.

The Confidentiality Coalition is comprised of hospitals, medical teaching colleges, health plans, pharmacies, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors, pharmacy benefit managers, health information and research organizations, clinical laboratories, and others. Through this diversity, we develop a nuanced perspective on the impact of any legislation or regulation affecting the privacy and security of health consumers.

Current federal regulations governing the confidentiality of drug and alcohol treatment and prevention records (42.C.F.R. Part 2 (Part 2)) preclude the Centers for Medicare & Medicaid Services (CMS) from disclosing medical information to healthcare providers for care coordination, including those engaged in accountable care organizations and bundled payment organizations. These regulations currently require complex and multiple patient consents for the use and disclosure of patients' substance use records that go beyond the sufficiently strong patient confidentiality protections that were subsequently put in place by HIPAA.

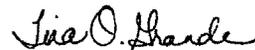
Electronic health records and value-based payment models such as Accountable Care Organizations (ACOs), Health Information Exchanges (HIEs), Medicaid Health Homes and related Medicare and Medicaid integrated care programs were designed to create a more holistic, patient-centered approach to healthcare where providers work together to coordinate across their traditional silos and in some cases are held jointly accountable for the quality, outcomes and cost of that care. Critical to making these new models work for patients is having access to the individuals' health records, including those related to substance use disorders. CMS provides participating providers of Medicare ACO and bundled payment organizations with monthly Medicare Parts A, B and D claims under data use agreements that include criminal penalties for misuse. Yet, due to outdated laws mentioned above, CMS is forced to remove *all* claims where substance use disorder is a primary or secondary diagnosis. Patient safety is also threatened with the potential pharmaceutical contraindications that could occur without access to the full medical record. Without this critical information, providers are prevented from understanding the full extent of their patients' medical needs.

We commend SAMHSA's recent rule making efforts, and understand the agency has probably gone as far as possible in regards to attempts to modernize the Part 2 Rule. To sufficiently address the need for further reform, Representatives Markwayne Mullin and Earl Blumenauer have introduced H.R. 3545 to ensure healthcare providers have access to the full medical record, including information on substance use disorders, to effectively and safely treat patients suffering from substance use disorders while guaranteeing the privacy and security of substance use medical records. In particular, H.R. 3545 would reinforce and expand existing prohibitions on the use of these records in criminal proceedings.

We urge the Committee to consider H.R. 3545 to amend 42 CFR Part 2 and align with HIPAA's treatment, healthcare operations and payment policy as one of several potential solutions Congress passes to help with the opioid crisis. Thank you for your attention to this important matter.

Sincerely,

Tina Grande



Tina Grande
Healthcare Leadership Council on behalf of the Confidentiality Coalition

cc: U.S. House of Representatives



**Statement for the Record of the Port Gamble S'Klallam Tribe
Before the House Energy and Commerce Subcommittee on Health
For the Hearing Record for
"Combating the Opioid Crisis: Improving the Ability of Medicare
and Medicaid to Provide Care for Patients"**

April 11, 2018

The Port Gamble S'Klallam Tribe provides these comments for the record for the Committee's hearing held on April 11 and 12, 2018, entitled, "Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients." These comments communicate the impacts of the opioid epidemic on our Tribe, our response, and what we need from Congress in order to effectively confront this issue. We are proud of the steps our Tribe has taken towards formulating and implementing a multi-faceted, comprehensive approach to respond to the opioid epidemic in our community, and we are pleased to share our experiences with the Committee. We look forward to further opportunities for discussion on this important topic and invite the Committee to contact us with any follow up questions.

I. About the Tribe, our Health Care System and Relevant Programs

The Port Gamble S'Klallam Tribe is a federally recognized, self-governing tribe with 100 percent of its reservation lands in trust. We are located on the northern tip of the Kitsap Peninsula in Kitsap County Washington. The Tribe's Reservation is home to about two-thirds of the Tribe's 1,200 enrolled members. The Tribe is the only Indian health care provider of both primary and behavioral health services in Kitsap County, and proudly provides culturally appropriate health care to our members and approximately 800 other American Indians and Alaska Natives (AI/AN) and community members living on our Reservation.

The United States has a trust responsibility to provide health care to our tribal members, as recognized in our treaty and reflected in numerous statutes. In 1976, Congress amended the Social Security Act to recognize the Federal Government's commitment to honoring tribal sovereignty, upholding the trust responsibility, and recognizing our government-to-government relationship by authorizing Medicare and Medicaid reimbursement for services provided in the Indian Health Service (IHS) and tribally operated health care facilities. The Centers for Medicare and Medicaid Services (CMS) plays an essential role in fulfilling the Federal Government's trust responsibility to Tribes by ensuring access to and the quality of critical healthcare programs and services to AI/AN communities.

Medicaid funds represent 13% of total IHS funding, and provides coverage for 34% of non-elderly AI/ANs and over half of AI/AN children, but that only amounts to a fraction of one percent of total Medicaid funding. Over 44% of patients at the PGST clinic are Medicaid eligible and 28% remain uninsured. Over half of our uninsured patients are tribal members. Medicaid payments represent approximately 20% of our funding in health services.

Medicaid reimbursements are essential to filling the gap created by chronic underfunding of IHS, and are a critical source of funding for self-governance tribes like ours. Our IHS funding alone would not allow us to provide comprehensive primary care services. Our third-party revenue allowed us to hire additional medical staff and support staff, as well as nurse case management and funding for the essential prevention work.

The Tribe joined the Tribal Self-Governance Project, a consortium of self-governing Indian Tribes, in 1990 and has directly provided health services to its members for over 20 years. We fund our health services through a compact with the IHS under the Indian Self-Determination and Education Assistance Act, and operate and manage our entire health system on our Reservation.

Our health system includes primary care, dental, mental health and substance abuse services. We provide our primary care services out of our outpatient primary care health clinic, which is staffed with 2 physicians, a physician assistant, and 4 registered nurses. Our dental building is next door and includes 2 dentists, 1 dental health aide therapist, and a dental hygienist. Our behavioral health clinic is approximately two miles away. It includes 1 physician, 1 Advanced Registered Nurse Practitioner (ARNP), 4 substance abuse counselors, 5 mental health counselors and 2 prevention specialists. It provides outpatient substance abuse treatment, relapse prevention, group, individual and family mental health counseling, psychiatric evaluation and medication management, and Medication Assisted Treatment (“MAT”). Over 98 percent of our behavioral health clients are also served by our primary care clinic. Community Health Representatives and transporters fill an essential role for both clinics, providing clinical linkages to the community and transportation services.

In addition, relevant to the opioid issue, our Tribe operates a police department, which consists of nine officers and places a strong emphasis on community-oriented policing for all residents and visitors. We also operate a Tribal Court with jurisdiction over criminal, civil and juvenile matters. Appeals are heard by our three-judge Court of Appeals.

Our Children & Family Services Department includes our Behavioral Health Division and the Community Services Division and works to enhance the quality of life of our Tribal members and their families through a culturally sensitive approach that encourages living a healthy lifestyle and promotes self-sufficiency. The Port Gamble S’Klallam Tribe operates all eligible programs under Title IV of the Social Security Act; Temporary Assistance to Needy Families (TANF) Part A, Child and Family Services (Part B), Child Support (Part D), and lastly, Foster Care and Adoption Assistance (Part E).

II. Impacts of the Opioid Crisis on the Tribe

In Washington State, the Native American overdose rate is more than twice as high as that of white Washingtonians.¹ The data shows that AI/AN in Washington State die of drug overdoses at a rate of 34.4 per 100,000 people, more than twice the rate of the next highest group (15.1 for Pacific Islanders), and almost three times that of whites at 12.4 and African Americans at 12.3. Other rates are 1.1 per 100,000 for Latinos, and 1.2 for Asian Americans.² For every opioid overdose death, there are 10 treatment admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825 nonmedical users of opioids.³

Further, misuse of prescribed opioids frequently leads to abuse of other drugs such as heroin. According to the National Institute of Drug Abuse, 21 to 29 percent of patients prescribed opioids for chronic pain misuse them, and 4 to 6 percent who misuse prescription opioids transition to heroin. About 80 percent of people who use heroin first misused prescription opioids. The death rate for heroin overdoses among Native Americans has also skyrocketed, rising 236 percent from 2010 to 2014.⁴ That exponential increase is the result of and now a part of the prescription opioid crisis.

The CDC reports that American Indians/Alaska Natives had the highest national drug overdose death rates of any race in 2015, and a 519% increase in the number of non-metropolitan overdose deaths from 1999-2015.⁵ Alarming, approximately 1 in 10 American Indian youths ages 12 or older used prescription opioids for nonmedical purposes in 2012, double the rate for non-Hispanic white youth.⁶

These statistics reflect the heartbreaking reality on the Port Gamble S'Klallam Reservation as we struggle to confront the devastation caused by opioids flooding our community. We have had numerous overdoses and deaths in our community as a result of the opioid crisis, and not only from the vast supply of such drugs coming into our community through the black market. It has been estimated that approximately 60% of

¹ Austin Jenkins, *Inslee Wants Washington State to Declare Opioid 'Public Health Crisis,'* KUOW.org (Jan 12, 2018), available at <http://kuow.org/post/inslee-wants-washington-state-declare-opioid-public-health-crisis>.

² Washington Department of Health Death Certificate Data.

³ National Institute on Drug Abuse. *Opioid Abuse Crisis.* Available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> (last accessed March 8, 2018).

⁴ Dan Nolan and Chris Amico, *How Bad is the Opioid Epidemic?*, PBS.org (Feb. 23, 2016), available at <https://www.pbs.org/wgbh/frontline/article/how-bad-is-the-opioid-epidemic/> (last accessed Feb. 27, 2018).

⁵ CDC Morbidity and Mortality Weekly Report (MMWR), available at https://www.cdc.gov/mmwr/volumes/66/ss/ss6619a1.htm?s_cid=ss6619a1_w (last accessed March 8, 2018).

⁶ National Congress of American Indians, *Reflecting on a Crisis Curbing Opioid Abuse in Communities* (Oct. 2016), available at http://www.ncai.org/policy-research-center/research-data/publications/Opioid_Brief.pdf (last accessed Feb. 27, 2018).

the opioids that are abused come, directly or indirectly, through the standard, “lawful” channels of distribution.⁷

On our Reservation, the deaths include members who were prescribed opioids as pain medication and accidentally overdosed. In the recent past, the Tribe experienced an overdose by a young mother and the death of a toddler, just two years old, who got into his parents’ opioid medication. We have grieving children, parents, grandparents, and great-grandparents who have lost family due to this scourge. Every family on our Reservation has been impacted by this epidemic.

At a government level, these impacts cut across all departments, complicating funding priorities and creating competition for scarce resources. Our Health, Behavioral Health, Children & Family Services, and Housing Departments, as well as our courts, law enforcement, and administration, all have a role to play in responding to this crisis.

One specific example of the impacts we face involves dependency cases that the Tribe files to ensure a child’s safety and well-being. One of the key roles of our Children & Family Services Department is to keep children with their families. However, when the Department is dealing with children who are removed from a home due to abuse and neglect, they need to find alternative care for those children. We have both relative placements and 20 Tribal licensed foster homes. As a result of the opioid crisis, the Department has seen a substantial increase in dependency cases. Ninety-eight percent of all dependency cases are now the result of drug use. In the first eight weeks of 2018, the Tribe filed four new dependency cases, three of which were related to parent(s) opioid abuse. This already surpasses the total new cases filed in 2017. These new cases are in addition to the open dependency cases that the Tribe has already filed. The increased number of dependency cases due to opioid abuse or overdose has overwhelmed our capacity. Opioid abuse impacts the whole family. Our Tribal member grandparents are often raising their grandchildren. In addition to this role, they often struggle to help their own child who is suffering from addiction.

The increased number of dependency proceedings burden existing child welfare services staff and resources, and require additional hires. Every child who comes into the Tribe’s care and custody needs an array of intervention and services, including mental health counseling, medical services, substitute care, and housing. The parents who survive need treatment and counseling as well. Children who are exposed to opioids *in utero* suffer from opioid withdrawal and Neonatal Abstinence Syndrome, and often bear scars that will last a lifetime. These infants are immediately transferred to a neonatal intensive care unit for a period of days, weeks, or even months, frequently requiring emergency evacuation for care to save the infant’s life. Such emergency transportation costs the Tribe thousands of dollars for each occurrence.

⁷ As we have alleged in our lawsuit (discussed below), the practices that the defendant manufacturers and distributors have engaged in by moving massive amounts of prescription opioids into our community are in fact unlawful.

The crisis has forced the Tribe to staff new positions at great expense, including additional substance abuse counselors to deal with the substantial increase in opioid addiction, a nurse specializing in substance abuse disorders for case management related to the opioid epidemic, and physicians to provide Medication Assisted Treatment with drugs such as naltrexone for opioid addiction and abuse.

The Tribe has provided naloxone HCl, also known as “Narcan”, a nasally administered overdose reversal drug, and the training to use it, to all law enforcement personnel. Due to their work in the field in our Tribal community, those officers regularly encounter individuals suffering from opioid overdose symptoms who can only be assisted and saved from death by timely administration of Narcan. The Tribe provides Narcan and training in its use to other members of our community, because the need for such emergency treatment is severe. Approximately 120 Tribal members have been provided with Narcan and trained on how to administer the drug. These steps are necessary, but they also cost money, which affects our Tribe’s budget and priorities for budget spending.

In terms of housing, the Tribe receives federal funding under the Native American Housing Assistance and Self-Determination Act (NAHASDA) to develop and operate affordable housing for low-income Indian families. Due to the substantial increase in opioid abuse, the Tribe has seen a parallel increase in evictions of Tribal members and other Indian families (since NAHASDA requires all leases to have language authorizing eviction for “drug-related criminal activity”). When those families are evicted from the Tribe’s housing they generally become homeless, and as a result they are then in even greater need of social, medical, and child welfare services from the Tribe.

The opioid crisis is overwhelming to our law enforcement and social services programs as they are not presently resourced sufficiently to meet the needs arising from the opioid epidemic. We are working as hard and as efficiently as we can with the resources we have, but additional resources in terms of funding, personnel and authorities are needed to combat the myriad problems the opioid crisis causes.

This epidemic is a complex issue, and there is no quick and easy fix for resolving the problem. Rather, we need a multifaceted, comprehensive approach with tactics that work. Our Tribe has been working to implement such an approach but we need your help.

III. What Port Gamble S’Klallam Tribe is Doing to Combat the Crisis

The Tribe has shown leadership in its aggressive and comprehensive response to the opioid epidemic through our cross-governmental Tribal Healing Opioid Response program, collaboration with Washington State, through participation in the Three County Coordinated Opioid Response Project (3CCORPS), and, most recently, like many other state and tribal governments, by seeking to cut the flow of opioids into our community and seek compensation for the devastation caused by the crisis by filing a lawsuit against the manufacturers and distributors of these drugs for their role in creating this crisis.

A. THOR - Tribal Healing Opioid Response

The Tribe convened two Tribal town hall meetings last year to share the local impacts of the opioid crisis and determine a path forward. The extraordinary attendance at these community events demonstrated the intense and widespread impact of the crisis. Our Tribal Council then met with Kitsap County officials to discuss a response to the opioid crisis. The Tribe recognized that the crisis affects all our members and Tribal agencies and requires a cross-government response. These efforts led to the creation of our Tribal Healing Opioid Response (THOR), a project led by the Tribe's Behavioral Health and Health Services Departments. THOR is now the heart of our opioid response on our Reservation.

THOR has three main goals, and Departments across the Tribe—not just health-related entities—are responsible for achieving them. These three main goals and the associated strategies are:

- (1) preventing opioid misuse and abuse by changing prescription practices, raising awareness of the danger of overdose, youth prevention programs, safe storage and disposal education, and drug supply reduction;
- (2) expanding access to opioid use disorder treatment by training health providers to recognize disorder symptoms, increasing access to treatment, applying treatment practices in the criminal justice system, implementing syringe exchange and overdose prevention/treatment training, and reducing instances of opioid withdrawal in newborns; and
- (3) preventing deaths from overdose by educating the Tribal community in how to recognize and respond to an overdose, and expanding access to overdose reversal medication.

Since January 2017, the Tribe has convened monthly THOR workgroup meetings composed of Tribal Council Members, Department Directors, staff, and other community members to implement the THOR goals. The workgroup is responsible for developing, reviewing and updating the Tribe's local response plan. It reviews the statewide opioid response plan and other best practices, identifies appropriate strategies, and assigns tasks and responsibilities to workgroup members.

Significantly, our Tribe took note of the November 2016 Surgeon General's Report on Alcohol, Drugs and Health which identified prevention as key to the fight against abuse and addiction. We pulled strategies from this report and put them into practice in our effort to get ahead of potential addictions by creating a Prevention Team. Our Prevention Team is responsible for numerous programs that focus on youth and using evidenced-based approaches to keep youth active in the community. The youth services program offers extended hours, a safe space, and education about substance abuse and suicide prevention 6 days a week. Through our Chi-e-chee Tribal Coalition, we collaborate with adults in the community and provide substance abuse education and prevention activities

to adults and families. Chi-e-chee can be translated to “the workers or the do-ers.” The coalition has been active for over 20 years and is identifying and implementing events and activities around issues that are significant to our community.

The Tribe provides education to the community, focusing on pain treatment with exercise, mental health and non-opioid medications. Our ultimate goal through this effort is to significantly reduce the number of opioid prescriptions. Town hall meetings are held quarterly to help educate the community on current issues/topics that are significant to the community and are well attended.

THOR assigns specific responsibilities to each of the Tribe’s departments to reach the THOR goals.⁸ For **prevention**, the Health Department is responsible for promoting best practices in prescribing and promoting safe storage and disposal of prescriptions; the Behavioral Health Department is responsible for awareness programs; Chi-e-chee is responsible for preventing misuse in youth; and the Police Department is responsible for attempting to interdict and decrease the supply of illegal opioids. For **treatment**, the Health and Behavioral Health Departments, along with the Police Department, train providers to recognize abuse, and the Behavioral Health Department, Health Department and Re-Entry Program work together to increase access to treatment and offer syringe and needle exchange. To **prevent overdose deaths**, Chi-e-chee, Human Resources, Behavioral Health and Health work together to educate the entire community to recognize and respond to overdoses, including through the administration of naloxone.

As a tribal government, we are focused on providing culturally appropriate treatment to our members suffering from opioid addiction and the host of health and mental health issues that come with it. These include programs such as our wellness activities, talking circles, and group therapy. The Healing of the Canoe Project is a collaborative project among the Port Gamble S’Klallam Tribe, the Suquamish Tribe, and the Alcohol and Drug Abuse Institute at the University of Washington. Its central mission is to develop a life skills curriculum for tribal youth that includes drug abuse materials. The Project has made its curriculum available and has trained a total of 350 attendees from 46 Tribes and 14 tribal organizations in how to adapt and implement the curriculum.

One of central reasons why our THOR program is so effective is because the Tribe is not only a health care provider for our community, we are also a government with the ability to coordinate with State, County, and regional groups. Our clinics, Police Department and social services departments have the ability to quickly work through bureaucracy for cross departmental collaboration, providing better services to both Tribal members and the community as a whole.

⁸ Tribal Healing Opioid Response Program, <https://www.nihb.org/docs/12032017/Tuesday%20Sessions/THOR%20Presentation.pdf> (last accessed March 11, 2018).

B. Collaboration with Washington State and Accountable Communities of Health (ACH)

Washington State has a Section 1115 waiver under the Social Security Act which funds experimental, pilot, or demonstration projects that are found by the United States Secretary of Health and Human Services to be likely to assist in promoting the objectives of the Medicaid program. These demonstration projects provide states additional flexibility to design and improve their programs with an eye toward evaluating state-specific policy approaches to better serve Medicaid populations. Through its Section 1115 waiver authority, Washington State has created Accountable Communities of Health, which bring together leaders from multiple health sectors around the state with a common interest in improving health and health equity. ACHs seek to align resources and activities to support wellness and a system that delivers care for the whole person. ACHs are also working to shift health care reimbursement strategies away from a system that pays for volume of service to one that rewards quality and outcomes.

Through the Section 1115 waiver and the creation of these ACHs, the Tribe has been able to form partnerships that were not otherwise easily accessible or workable. Now, on the opioid issue, specifically, the Tribe has multiple partners at different levels with whom it can and has been coordinating to develop and implement a variety of tactics to address the many issues arising from the epidemic. The Tribe collaborates with Washington State on the Washington State Opioid Response Plan and, on the regional level, the Olympic Community of Health (OCH) which is implementing the Three County Coordinated Opioid Response Project (3CCORPS).

C. Olympic Community of Health and 3CCORPS

OCH is an Accountable Community of Health whose objectives are to improve patient care, reduce the cost of health care and improve the health of the population in Clallam, Jefferson and Kitsap Counties. Each of the seven Tribal Nations within the three county region, including our Tribe, is represented on the OCH Board of Directors.

3CCORPS, OCH's specific opioid response, was launched in September of 2016 and convened an opioid summit in January 2017. It was not long before this summit that one of our Tribal members died due to missing a dose of naltrexone. This tragedy spurred momentum for our Tribe's active opioid response.

3CCORPS is currently in the implementation phase of its opioid response plan. Addressing the opioid epidemic is a required project in the Medicaid Transformation Project (MTP) of the OCH. 3CCORPS' foundations are the same 3 goals and strategies that the Tribe has adopted and adapted as our own opioid response plan. They also align with the statewide plan. The alignment of goals and strategies allows for quick duplication of evidence-based strategies and the ability to coordinate within the broader regional and state level, and also facilitates evaluation and data collection efforts.

3CCORPS is our work on the regional level with the OCH. Other groups that participate in 3CCORPS are independent clinics, police departments, and social service agencies that serve many different communities.

D. Litigation to Curtail Oversupply of Opioids and to Obtain Compensation for Damages

On March 5, 2018, the Port Gamble S’Klallam Tribe, along with the Suquamish Tribe and the Jamestown S’Klallam Tribe, filed a complaint in federal district court naming various opioid manufacturers and distributors, including Purdue Pharma LP, McKesson Corp., Cardinal Health Inc., AmerisourceBergen Corp. and others. Our complaint alleges that these companies spread false and misleading information about the safety of opioids, negligently created an illicit market for opioids, and failed to control the flow of opioids to our Tribal members. The complaint details the same devastating impacts that we report to you today, and asks the court to find that the defendants broke the law through fraud, negligence, public nuisance, violation of Washington State consumer protection laws, other laws, and racketeering. Through the lawsuit, we seek compensation for the cost of responding to and treating opioid-related addiction and punitive damages. We are also seeking injunctive relief to stop these defendants from continuing these devastating actions. In filing this lawsuit, we join over 400 other plaintiffs across the country,⁹ including state and tribal governments, in seeking to hold these companies accountable for the devastation caused by the opioid crisis.

IV. Lessons Learned and Strategies All Tribes Can Choose to Put in Place

A. Cross-Government Coordination

Through THOR and our 3CCORPS program with the OCH, we have learned many lessons in the fight against opioid addiction and efforts to treat those affected. At the forefront, we learned that coordination and communication across our government is key as well as ensuring that all of our Departments pitch in to the effort however they can. As the opioid epidemic affects all facets of our community, we have taken an “all-hands-on-deck” approach as a government. As explained above, we draw on any and all of our Departments that can help so that we can attack the crisis from many angles. Our monthly THOR workgroup meetings have been key to synchronizing our programs and generating action items to address the opioid problems in our community.

B. Culturally Appropriate Care

Recognizing that traditional healing practices, cultural beliefs regarding approaches to treatment, and differences in interpersonal communication contribute to significant variances in effectively meeting the healthcare needs of AI/AN, cultural competency is an inherent part of who we are, who we serve and what we do.

⁹ “Can This Judge Solve the Opioid Crisis?”, New York Times, March 5, 2018, available online at <https://www.nytimes.com/2018/03/05/health/opioid-crisis-judge-lawsuits.html>, (last accessed March 8, 2018).

C. Abuse Prevention

Prevention is the cornerstone for any opioid response, as the Surgeon General’s Report on Alcohol, Drugs and Health (November 2016) states. We realize that availability of resources is different in different parts of Indian Country. Yet, there are strategies that any Tribe can put into place in its fight against the opioid epidemic. Our Tribe has a “toolkit” which we share with other Tribes in their opioid fight. We are happy to share our “toolkit” with any Tribe who would like access to it. Our “toolkit” includes:

- (1) Our Pain Agreement – used in the clinic for clients with opioid prescriptions for chronic pain;
- (2) Our Narcan Standing Orders & Policy – provides Narcan to any Tribal member or household that requests it, and to any patient with an active opioid prescription; and
- (3) Our Good Samaritan Tribal Code – provides liability protection for those who act in good faith and seek medical assistance for any person who is experiencing a drug-related overdose.

Collaborating with federal agencies has been very helpful in our Tribe’s fight against the epidemic. We suggest that Tribes regularly call upon their regional federal agency officials from IHS, SAMHSA, HRSA, BIA, DOJ, and others. These agencies have resources, technical assistance and connections that they can share. Further, Tribes may find that partnering with their neighboring governments on this particular issue yields a variety of benefits. Accessing additional resources is always a benefit, whether they are financial resources or non-financial resources such as experience, expertise and technical assistance. Brainstorming and sharing ideas with federal agencies and neighboring governments with mutual interest in stemming the opioid crisis can lead to innovation and cooperation.

Our Tribe has benefited from having close collaboration with federal agencies at the regional level. The Acting Regional Director of the Department of Health and Human Services (HHS), and the Regional Director of the Substance Abuse and Mental Health Services Administration (SAMHSA), have both visited the Tribe recently, participating in robust discussions on opioid prevention. As a specific example, our SAMHSA discussion helped clarify 42 CFR Part 2 updates and requirements.

V. Barriers and Needs to More Effectively Fight the Opioid Crisis

A. Funding Needs

There are several barriers that Tribes face in their efforts to overcome the opioid epidemic. We have run into several.

1. Adequate Funding and Direct Funding

Adequate funding to combat this behemoth opioid crisis is, of course, a major barrier. Getting funding out to Tribes for their on-the-ground work is an issue not only in the amounts, but also in the manner in which such monies flow to Tribes. We strongly encourage Congress to not only work on increasing available funding, but to also provide direct funding to Tribes and ensure that any additional funds for opioid crisis response do not decrease services in other areas.

We truly appreciate Congress's inclusion of authorization for \$6 billion over 2 years for opioid efforts in the recently passed Bipartisan Budget Act of 2018. We ask the Committee to advocate for full funding of the authorization and ensure that these funds go directly to tribal governments for them to spend in their own communities. Such funds should not be passed through the States. Direct funding of tribal programs is important as it ensures that funds are available to tribal governments like ours that have culturally appropriate programs and mechanisms in place for fighting the opioid epidemic.

An important bill that includes the requested direct funding mechanism is S. 2270, the Mitigating the Methamphetamine Epidemic and Promoting Tribal Health Act. This bill, introduced by Senator Daines, a member of this Committee, would make Tribes and tribal organizations eligible for direct funding under the 21st Century Cures Act, which provides an allocation to states for opioid prevention and response. S. 2270 would allow such allocation to also be used for prevention and response for other substances, such as methamphetamines, if they are having a substantial impact on the state or Tribe.

2. Full Funding of IHS Budget

Additionally, we ask you to work toward providing sufficient funding to the IHS for opioid treatment and prevention. The FY2019 Budget Request provides \$10 billion in new resources across HHS to combat the opioid epidemic and address serious mental illness. As part of this effort, the Budget Request includes an initial allocation of \$150 million to IHS to provide multi-year competitive grants based on need for opioid abuse prevention, treatment, and recovery support in Indian Country.¹⁰

The Public Health Service Commissioned Corps plays a vital role in providing direct patient care throughout the IHS, and also has a direct role in the work of Tribes combating the opioid crisis. Any restructuring of the Corps should be done in close collaboration and consultation with Tribes.

The FY 2019 Budget Request eliminated both Community Health Representatives and Health Education from the IHS budget. These two line items support the front line work of Tribes and the IHS on both the opioid crisis and daily operations and patient care.

¹⁰ 2019 Budget in Brief <https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf>. As of the preparation of this Statement for the Record, HHS has not released its detailed FY 2019 Budget Justification, including for IHS.

They need to be restored.

3. Full Funding of Contract Support Costs

The FY 2019 Budget Request fully funds Contract Support Costs at an estimated \$822 million and continues the use of an indefinite appropriation, which allows IHS to guarantee full funding of this program. Funding for Contract Support Costs supports the costs incurred by Tribes for activities that are necessary for administering health care service programs under self-determination contracts and self-governance compacts.¹¹ This is an important funding mechanism for self-governing Tribes like ours to administer our opioid prevention and treatment programs.

B. Barriers Beyond Funding

1. Regulatory Hurdles

There are several barriers in the fight against the opioid crisis that are beyond funding. One such barrier relates to funding, but is an administrative limit on accessing already available funding. The Health Resources and Services Administration (HRSA) has behavioral health integration funding available, but it is restricted to rural locations. Kitsap County does not qualify as “rural” and so the Tribe is ineligible for these grants. We recently raised this issue to HRSA, and received assurances that this issue would be addressed. However, it would be helpful for members of Congress to encourage HRSA to reconsider the rural restriction and develop a mechanism for channeling such monies to Tribes. This could be through revising the definition of “rural” to include Tribes regardless of location or “geographic trait” of its reservation.

2. Barriers to Medication Assisted Treatment

We also want to point out certain other barriers to our efforts to combat the opioid crisis. Current regulations impose onerous training and waiver requirements for providers of Medication Assisted Treatment (MAT) prescribing drugs such as buprenorphine, even though no such limitation exists on providers prescribing opioids. This creates barriers to accessing MAT. Medicaid dollars used to fund transportation to opioid services could be reduced significantly if buprenorphine, an opioid addiction treatment drug also known as Suboxone, was easier to access at primary care facilities. Those saved funds could be used for prevention or treatment. In addition, nurse care management as an adjunct to MAT has been shown to be successful and is an evidence-based practice in treating opioid addiction. We need to expand Tribes’ access to this treatment.

3. Physician Access to Medical Records

Federal regulations at 42 CFR Part 2, related to the privacy of substance abuse treatment records, currently prevent the Tribe’s primary care and mental health providers from accessing patient records from dependency providers so the whole person can be treated.

¹¹ *Id.*

This lack of access is a barrier to coordinated, safe, and high-quality medical care and can cause significant harm. 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. The President's Commission on Combatting Drug Addiction and the Opioid Crisis specifically mentioned the need to update 42 CFR Part 2.¹²

In August 2017, Congressmen Tim Murphy and Earl Blumenauer introduced bipartisan legislation that would help align 42 CFR Part 2 with HIPAA rules, ensuring that substance use disorder patients can receive proper care while their data remains secure. The Overdose Prevention and Patient Safety (OPPS) Act (HR 3545) allows access by doctors to patients' full medical records with all the safeguards of HIPAA, but also makes use of such information in criminal investigations unlawful. The Tribe joins others such as the Partnership to Amend 42 CFR Part 2, a coalition of over 20 healthcare stakeholders including the American Hospital Association, in support of HR 3545.

4. The Lack of Co-location of Health Services on Our Reservation

The Tribe is actively working to align substance use disorder treatment with primary care to address a person's overall health, rather than treating it as a substance misuse or a physical health condition alone or in isolation. As stated, our Health Facility and Dental Facility are nearby each other, but our Mental Health Facility and Rehabilitation Facility are some distance away. This causes extra administrative burden and expense of resources. Co-locating these services would improve behavioral health integration, but a new integrated facility for all health services would cost over \$8 million dollars. We suspect other Tribes face similar problems with respect to the lack of co-location of services. We look to Congress for innovative ideas, perhaps through its infrastructure package, for facilitating the construction of co-located health care facilities on tribal lands.

5. The Need to Modernize the IHS's Health Information System.

This issue impacts the ability of Tribes to confront the opioid epidemic. Barriers to integration within the health information system are being addressed at significant cost to the Tribe as we left the Indian Health Service RPMS system for direct patient care documentation years ago, although we continued to utilize that system for Purchased & Referred Care (PRC). The system we use, NextGen, is adequate for primary care, but has limitations for mental health and substance abuse. This has impacted our behavioral health integration work.

The Veteran's Administration announcement that it will pursue a contract with Cerner (a supplier of health information technology) as a replacement for the RPMS Parent system may provide an opportunity for both IHS and Tribes. IHS needs to ensure that the

¹² The President's Commission On Combating Drug Addiction and The Opioid Crisis, at 121-122 (Nov. 1, 2017) available at https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf

replacement of RPMS will include options for non-RPMS tribes and pathways for cost saving programs such as the VA Consolidated Mail Outpatient Pharmacy Service (CMOPS).

6. The Need for Pilot Projects for Residential Post-Treatment Facilities on Tribal Lands.

Our Tribe is particularly interested in initiating a pilot program for residential post-treatment facilities. We would like to provide treatment and support past the prevailing 28-day model, utilizing evidenced-based practices with a robust evaluation component. We have partnerships with Oxford House and Habitat for Humanity to construct and operate such facilities, and we are well positioned to start such a pilot program. We ask Congress to support the establishment of a pilot program by an agency such as SAMHSA, HUD, or IHS to fund residential post-treatment facilities on reservations to be operated by Tribes for their members and families.

7. Lack of Easy Access to Methadone Clinics

Our Tribal Members must travel to Tacoma or the greater Seattle area to a methadone facility to receive such treatment. We are working with OCH to obtain a methadone facility in Kitsap County to save our Members the burden and cost of traveling so far for that treatment. We ask Congress to consider ways it can facilitate the construction and operation of these facilities in locations accessible to tribal and rural communities like ours. Kitsap County, where we are located, has a restriction limiting service to one methadone clinic in the county. This limitation hampers our ability to provide expanded services in the future.

C. Beneficial Opioid Legislation

We have shown leadership by implementing an aggressive and comprehensive approach for responding to the opioid epidemic in our community. However, we still need the help of this Committee, Congress, and Federal agencies to continue our effective efforts to respond to the opioid crisis. We support several pieces of legislation introduced in the Senate with the hope that Congress will enact them and aid our efforts in combating the crisis.

The Opioid Crisis Response Act, a draft package bill in the Senate, is good legislation that will significantly advance the United States' efforts to combat opioid issues. The Port Gamble S'Klallam Tribe generally supports *The Opioid Crisis Response Act*; however, we recommend that the Congress clarify eligibility standards for the new grant program for comprehensive opioid recovery centers and add the necessary language to the bill to ensure that Tribes and their communities will have adequate opioid recovery centers to meet the needs of their members. Furthermore, we respectfully request that Congress include the Indian Country-specific legislation (discussed below) in *The Opioid Crisis Response Act*, or a similar package bill in the House, to make sure that the unique needs of Tribes are addressed in this comprehensive effort.

S. 2270, the Mitigating the Methamphetamine Epidemic and Promoting Tribal Health Act (the "Mitigating METH Act"). This bill, introduced by Committee Member Senator Daines, would make tribes and tribal organizations eligible for direct funding (no set-aside) under the 21st Century Cures Act, which provides funding for prevention and response to opioids, or other substances—such as methamphetamines—if they are having a substantial impact on the state or tribe. The bill would increase the allocation of \$500 million to \$525 million. The Port Gamble S'Klallam Tribe supports S. 2270 because it gives us access to direct funding and important resources for combatting the crisis, in recognition of the government-to-government relationship we have with the Federal government.

S. 2437, the Opioid Response Enhancement Act. This bill, introduced by Senator Baldwin, would also make tribes and tribal organizations eligible for funding under the 21st Century Cures Act but through a 10% tribal set-aside. Like S. 2270, tribes and states could use this funding for prevention and response to other substances threatening public health—such as methamphetamines. Additionally, the bill requires the Substance Abuse and Mental Health Services Administration (SAMHSA) to provide technical assistance to both states and tribes for grant applications, formulating outreach and support efforts, and collecting data. The Port Gamble S'Klallam Tribe supports S. 2437 because it has targeted funding for Indian Country, where Native families and communities feel the disparate impacts of the crisis hardest.

We support direct funding as authorized in both S. 2270 and S. 2437. Adequate direct funding means reliable resources and flexibility for our Tribe to continue implementing our culturally appropriate, multi-faceted, comprehensive approach to abating the opioid epidemic sweeping the community. Additionally, adequate direct funding allows us to plan long term for infrastructure development, program enrichment, and service enhancements necessary for the well-being of our members and local community. We are encouraged by the Sponsors' recognition of the importance for direct funding. However, we note that S. 2437 provides significant increases in funding for a longer period of time. This additional funding is needed and could be put to use by Indian Country to carry out important opioid response activities. Furthermore, we recommend that the *Opioid Crisis Response Act* be amended to fund opioid response activities through a direct funding mechanism to Tribes instead of grants.

S. 2440, the Comprehensive Addiction, Recovery, Education and Safety (CARES) Act. This bill introduced by Committee Member Senator Cantwell—our Senator—would provide law enforcement with more tools to hold drug companies accountable for ensuring that their drugs do not enter the illicit drug market. Specifically, the bill increases civil and criminal penalties on companies that fail to keep proper records or report suspicious opioid distribution practices. Additionally, the bill authorizes funding for the Drug Enforcement Agency (DEA) to investigate suspect drug companies and drug trafficking organizations. The PGST supports S. 2440 because it aligns with our goals in our federal lawsuit to hold drug companies responsible for failing to track orders and for creating an illicit market for their drugs. We also note that the Senator's consultation with

our Tribe for receiving early input about this bill could serve as a model for tribal consultation when developing legislation. Our Tribe supports S. 2440.

S. 2545, the Native Behavioral Health Access Improvement Act of 2018. Recently introduced by Committee Member Senator Smith, this bill aims to help combat the opioid epidemic by creating the Special Behavioral Health Program for Indians (SBHPI): a grant program modeled after the Special Diabetes Program for Indians (SDPI) and administered by the IHS, in coordination with SAMHSA. The SBHPI would provide IHS, tribes and tribal organizations, and urban Indian health programs with access to much-needed resources for addressing mental health needs and substance use disorders, specifically providing \$150 million in annual mandatory funding from FY 2018 to FY 2022. The grants would give tribes needed flexibility to provide tribally driven, culturally appropriate behavioral health care to meet the specific needs of their communities. The bill also provides that IHS, in coordination with SAMHSA, would create a technical assistance center responsible for developing grant-reporting standards in consultation with tribal grantees.

Our Tribe has operated a robust SDPI program for many years and is confident that its use as a model for the SBHPI will be a success. However, we caution against providing Tribes resources through another program funded in the form of grants. As we know from our SDPI experience, grant reporting requirements take away from clinical time and the self-governance model would allow for more administrative efficiency. Additionally, competitive funding pits struggling tribes and local governments against each other for access to limited resources when we should be working together. One of the reasons why our THOR program is so effective is that our Tribe has good relationships with State, County, and regional groups to coordinate on response strategies. The Port Gamble S’Klallam Tribe generally supports S. 2545; however, as an alternative to grant funding, we recommend that self-governance tribes—such as our Tribe—be able to receive funding through their self-governance compacts.

VI. Conclusion

The crisis has ripped the fabric of our community. The loss (through death or addiction) of parents, children, brothers and sisters, uncles and aunts, nieces and nephews, and cousins to this crisis has been devastating, and will impact the Port Gamble S’Klallam Tribe for generations. We are doing what we can to fight it, and we want to work with you to eradicate this crisis once and for all. It will be through your dedication and that of your colleagues to ensure that sufficient resources and authorities are available to tribal governments, as well as to the federal, state and local governments, to stop this scourge on our Nation and communities which takes such a heavy toll on our children and families.

We look forward to working with the Committee to make sure the necessary tactics are implemented to combat the opioid crisis. Our THOR program is an example of one such tactic. We invite you to visit our Tribe to learn more about it and other actions we are taking to do our part in the opioid fight.

Medicaid reimbursements are a critical source of funding for self-governance tribes like ours and play an essential role in fulfilling the Federal Government's trust responsibility to Tribes. Our Tribe respectfully requests that the unique challenges facing Indian Country be considered and addressed in any legislation this Committee puts forward in its efforts to improve the role of Medicaid in combating the opioid crisis.

Thank you again for your work and for the opportunity to submit this Statement for the Record. If you have any questions or would like to discuss this Statement for the Record, please contact our Tribal Chairman, Jeromy Sullivan.



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Washington, D.C. 20024

April 25, 2018

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Health Subcommittee
2336 Rayburn House Office Building
Washington, DC 20515

Rep. Gene Green
Ranking Member
House E&C Committee
Health Subcommittee
2470 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Burgess and Ranking Member Green:

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Tanjaja Gandhi, M.D.
President

On behalf of the American Psychiatric Association (APA), the national medical specialty association representing more than 37,800 psychiatric physicians, we write to offer comments on several of the opioid-related legislative proposals slated for consideration before the House Energy & Commerce Subcommittee on Health. The APA appreciates your leadership on this topic, and as physicians who treat patients with substance use disorders (SUDs), we share your continued concern regarding the opioid crisis' impact on patients, families, and communities. As the Subcommittee moves forward with opioid-related legislation, we offer the following comments for your consideration.

Access to Medication Assisted Treatment (MAT)

Assembly
2017-2018
Theresa Miskimen, M.D.
President
James (Bob) R. Batterson, M.D.
Secretary
Paul J. O'Leary, M.D.
Treasurer
Administration
Saul Levin, M.D., M.P.A.
Chief of Staff & Executive Director

The American Psychiatric Association (APA) supports expanded coverage and access to MAT for patients with substance use disorders. MAT are proven to be an effective treatment for patients with an opioid use disorder, and most effective when combined with psychotherapy treatments. Thus, MAT should be prescribed as a comprehensive treatment plan that includes counseling and participation in social supports. As you know, Congress passed the Comprehensive Addiction and Recovery Act (CARA) in 2016, which expanded prescribing privileges for MAT to qualifying nurse practitioners (NPs) and physician assistants (PAs) until Oct. 1, 2021 by amending the Drug Addiction Treatment Act (DATA). Given its recent implementation, this is an appropriate timeframe to better understand the impact of expanding prescribing authority to certain practitioners under the law. However, we are concerned with the expanded prescribing authority in H.R. 3692, the "Addiction Treatment Access Improvement Act."

As currently written, H.R. 3692 proposes not only to remove the demonstration date for NPs and PAs to prescribe, but to expand permanent prescribing authority to other practitioners including clinical nurse specialist, certified registered nurse anesthetist, and certified nurse midwife. This is a permanent expansion of practitioners who have never had prescribing authority for MAT. Consequently, we are concerned H.R. 3692 is fast-tracking prescribing authority to practitioners without understanding the current environment and the potential impact of the change. Moreover, we are concerned patients may not receive optimal care from an expanded list of practitioners, to include appropriate psychotherapy services, which is a vital component of the effectiveness of MAT for opioid addiction. **Therefore, we recommend the Committee not expand prescription authority beyond the current law of NPs and PAs until more data is available relating to the efficacy of the current prescribing authority and any potential unintended consequences.**

Enhancing Collaboration Amongst Providers

The current patient treatment paradigm, particularly for patients with SUD, is moving towards a system built on effective collaboration amongst multiple health care providers, each practicing in different specialties. However, while APA has always advocated for strong confidentiality protections of patient records, we are concerned that the regulations contained in 42 CFR Part 2 (Part 2) represent a persistent barrier to meeting the whole health needs of patients with SUD.

We were pleased to see the Subcommittee consider H.R. 3545, the “Overdose Prevention and Patient Safety (OPPS) Act.” This important legislation would align Part 2 with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of health care treatment, payment, and operations (TPO). The APA remains committed to the provision of quality care and protecting patients’ privacy and asserts that this standard can be maintained while allowing for patients to benefit from new models of integrated care by aligning Part 2 with HIPAA for the purposes of TPO. H.R. 3545 retains, and in some instances strengthens, current protections against the use of SUD records outside of TPO, including in civil, criminal, and administrative proceedings or investigations. The APA has long supported this legislation and highlights the importance of ensuring that a treating physician has access to a patient’s full medical record. Compartmentalizing various portions of a patient’s record jeopardizes patient safety by undermining a physician’s ability to provide whole patient care. These barriers also increase the chance of complications related to comorbid medical conditions and/or potentially lethal drug interactions.

In addition, preserving the division between SUD records and all other medical records covered by HIPAA only serves to maintain the perception of SUD as something other than a medical condition and impairs a system of effective collaboration amongst providers. Other conditions that carry stigmas—including HIV and mental illness—are nonetheless included in a patient’s medical record and are covered by HIPAA’s protections. ***We urge the Subcommittee to advance H.R. 3545.***

The Subcommittee is also considering Jessie’s Law (H.R. 5009). If enacted, H.R. 5009 would require HHS to develop and disseminate voluntary best practices regarding the prominent display of a patient’s SUD history in their records, but only as authorized under existing law. It does not contain the enhanced prohibitions against the use of SUD records in civil, criminal, and administrative proceedings, nor does it allow a provider to see a patient’s entire addiction record. ***As such, H.R. 5009 does not resolve the underlying barriers to integrated care created by Part 2.***

Supporting Research for Evidence-Based Treatments

The APA supports the Committee’s consideration of H.R. 5002, the “Advancing Cutting-Edge Research Act.” If enacted, this legislation would provide the National Institutes of Health (NIH) with the additional tools and flexibility to support innovative medical research to combat the opioid crisis. The APA supports research on alternatives to opioid analgesics as an important component for addressing the opioid crisis. It is also our hope that the development of non-addictive pain treatment options will help mitigate the likelihood that a patient, particularly those with co-occurring depression or other mental health needs, will develop a concurrent substance use disorder.

Enhancing the Workforce of Substance Use Disorder Providers

Ensuring a robust mental and behavioral health workforce is a critical aspect of any efforts to address the opioid crisis. Unfortunately, there are simply too few clinicians with the requisite knowledge to meet the needs of the the estimated 20.1 million Americans suffering from untreated substance use disorders.

To help meet these needs, we appreciate the Subcommittee’s consideration of H.R. 5102, the “Substance Use Disorder Workforce Loan Repayment Act,” which creates a new student loan repayment program to incentivize an array of health professionals to select career paths that

focus on mental health professional shortage areas. *The APA supports H.R. 5102 and urges the Subcommittee to advance the bill.*

Reducing Barriers to Telemedicine

Treatment of mental health and substance use disorders via telepsychiatry demonstrates similar—and in some cases, superior—outcomes to in-person care, particularly amongst rural communities, certain cultural groups (such as Native American communities), and individuals with certain diagnoses. Telepsychiatry can also help to mitigate the stigma often associated with seeking treatment for substance use disorders and improve access to psychiatric services in a variety of treatment settings.

The Ryan Haight Act generally prohibits the prescription of controlled substances via the Internet, but contains an exception that allows providers to obtain a special registration to prescribe controlled substances via legitimate telemedicine platforms. Unfortunately, because the Attorney General has yet to promulgate regulations concerning this telemedicine registration provision, many telemedicine and telepsychiatry providers remain in a state of limbo with regard to their patients suffering from a SUD. **Therefore, the APA supports H.R. 5483, the “Special Registration for Telemedicine Clarification Act,” that sets a concrete timeline for the Attorney General to issue these regulations, which represents a critical first step in expanding access to telemedicine.**

Further, the APA supports the draft bill, “Improving Access to Remote Behavioral Health Treatment Act of 2018,” which would help to clarify some, but not all, of the telemedicine exceptions to the Ryan Haight Act. Specifically, while the APA supports the expansion of DEA registration to community mental health centers and therefore allow for the administration of controlled substances through the practice of telemedicine into these centers, as detailed in the bill, it does not entirely help to mitigate the persisting issue of lack of access to psychiatrists in response to the epidemic. The APA believes that activating the special registration for telemedicine for individual practitioners—regardless of the originating site of the patient—should also be contemplated in such legislation.

Mental Health Parity and CHIP

Following Congress’ 10-year reauthorization of the CHIP program, we commend the Subcommittee for its additional focus on H.R. 3192, the “CHIP Mental Health Parity Act.” Access to mental health care remains a critical component of the CHIP program, as approximately 850,000 CHIP beneficiaries experience serious behavioral or emotional disorders. Nearly half of

all diagnosable mental illnesses show symptoms by age 14, and 75% begin by the age of 24. Without early intervention services via the CHIP program, these disorders can lead to tragic and costly consequences, such as substance abuse, school dropout, crime, and suicide.

Unfortunately, ten years after the enactment of the Mental Health Parity and Addiction Equity Act, providers of mental health and SUD services continue to experience disparities in reimbursement, while patients experience disparities in coverage for services. According to the 2017 Milliman report entitled, "Impact of Mental Health Parity and Addiction Equity Act," private insurers in 46 states and the District of Columbia offered plans with higher reimbursement rates for primary care office visits than for behavioral health office visits, while patients seeking behavioral health services were four times more likely to receive treatment from out-of-network providers than those seeking medical or surgical services.

CHIP programs are no exception to this phenomenon, and the existing statutory scheme leaves ambiguity as to whether all CHIP plans are subject to parity requirements under federal law. ***H.R. 3192 clarifies that all CHIP plans are subject to mental health and substance use disorder parity laws, and the APA supports its passage.***

Medicaid Institutions for Mental Diseases (IMD) Exclusion

We are supportive of the Committee's efforts to expand residential treatment at institutions of mental disease (IMD) for substance use disorder patients covered under Medicaid with a maintenance of effort on other mental health and substance use expenditures. However, we are concerned that the Committee's emphasis on treating patients dealing with substance use disorders excludes the needs of patients who need to access long-term mental health care. ***We recommend that the Committee expand coverage for both patients struggling with a mental illness and/or substance use disorders to receive treatment at an IMD.***

Prescription Drug Monitoring Programs

The APA supports and appreciates the Committee's efforts to promote information sharing and data transparency efforts among state PDMPs. While we support the expansion of PDMPs and the availability of these programs to share information across state lines, it is important to recognize that PDMPs do not capture all prescription drugs that a patient is taking. If a provider doesn't realize this when they check the PDMP, he or she may inadvertently prescribe contraindicated medication. ***We recommend PDMPs include a notice to providers that clearly states***

the drugs excluded from the program (such as methadone), so they can better understand the limitations of the data collected by the PDMP.

Mental Health Care and the Criminal Justice System

The ongoing discussions concerning the opioid crisis are inevitably tied to issues related to the criminal justice system. 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. According to a recent study, former inmates within a week post-release were over eight times more likely to die from an overdose than inmates within 90 days to a year following their release.

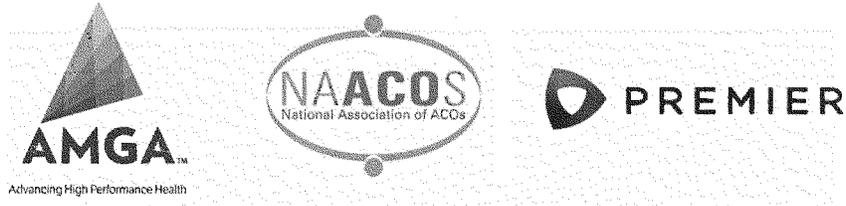
The APA thanks the Subcommittee for recognizing this aspect of the opioid crisis via its consideration of H.R. 4005, the "Medicaid Reentry Act." Under current federal law, medical care—including care for the treatment of mental health and substance use disorders—provided in correctional facilities is categorically ineligible for reimbursement under the Medicaid program. If enacted, H.R. 4005 would allow inmates with SUD to receive evidence-based care within 30 days of their release, thereby enhancing former inmates' ability to successfully re-enter their communities. ***The APA urges the Subcommittee to advance H.R. 4005.***

Thank you again for allowing us to offer our insights on this important legislation, and we look forward to working with the Subcommittee on the development of lasting, impactful solutions. Our Federal Affairs team will follow up with Subcommittee staff on the legislation referenced in this letter. If you have any questions, please contact Megan Marcinko at mmarcinko@psych.org / 202.559.3898 or Mike Troubh at mtroubh@psych.org / 202.559.3571.

Sincerely,



Saul Levin, MD, MPA, FRCP-E
CEO and Medical Director



April 25, 2018

The Honorable Greg Walden
 Chairman
 House Energy & Commerce Committee
 2125 Rayburn HOB
 Washington, DC 20515

The Honorable Frank Pallone, Jr.
 Ranking Member
 House Energy & Commerce Committee
 2322A Rayburn HOB
 Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone:

The undersigned organizations representing accountable care organizations, physicians, hospitals and other healthcare practitioners strongly urge you to include H.R. 3545 in the Energy and Commerce Committee's opioid legislative package to ensure healthcare providers who are engaged in population health initiatives have access to the medical records they need, including information on substance use disorders, to effectively and safely treat their patients.

Current federal regulations governing the confidentiality of drug and alcohol treatment and prevention records (42.C.F.R. Part 2 (Part 2)) preclude the Centers for Medicare & Medicaid Services (CMS) from disclosing such information to accountable care organizations and bundled payment organizations. These regulations currently require complex and multiple patient consents for the use and disclosure of patients' substance use records that go beyond the sufficiently strong patient confidentiality protections that were subsequently put in place by the Health Insurance Portability and Accountability Act (HIPAA). While originally intended to protect patients' privacy, Part 2 now serves to endanger their health. Recognizing the need to revise these laws, the Substance Abuse and Mental Health Services Administration recently testified before your Committee and submitted a letter for the record supporting the intent of H.R. 3545 to align Part 2 to ensure healthcare providers have access to the full medical record.

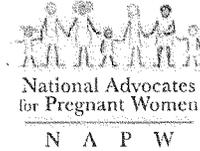
New delivery system models such as ACOs and bundled payments were designed to create a more holistic, patient-centered approach to healthcare where providers work together to coordinate across their traditional silos and are held jointly accountable for the quality, outcomes and cost of that care. Critical to making these new models truly work for patients is having access to the individuals' health records, including those related to substance use. CMS provides participating providers of Medicare ACO and bundled payment organizations with monthly Medicare Parts A, B and D claims under data use agreements that include criminal penalties for misuse. Yet, due to outdated laws mentioned above, CMS is forced to remove *all* claims where substance use disorder is a primary or secondary diagnosis. According to a recent *New England Journal of Medicine* study, this effects roughly 4.5 percent of inpatient Medicare claims and 8 percent of Medicaid claims. Not only does

this pose an alarming patient safety threat in light of potential pharmaceutical contraindications and prevent providers from understanding the full extent of their patients' medical needs, but it is a heavy and costly administrative burden on CMS, which must manually scrub Medicare claims before submitting to ACOs and bundled payment organizations.

We commend you for your leadership on looking at so many solutions to prevent dependency on opioids and related deaths, as well as promoting appropriate access. While these are all urgently needed policy changes and investments, a critical and vital piece to ensuring healthcare providers who are on the front-lines treating those with opioid or other substance use disorders is H.R. 3545, which would provide an unobstructed view of a patients' medical records. Accordingly, we call on Congress to ensure that the Medicare, Medicaid and CHIP data feeds sent to providers that are participating in alternative payment models such as Medicare ACOs and bundled payment arrangements include all claims, including those where a substance use disorder is listed as a primary or secondary diagnosis.

Sincerely,

AMGA
National Association of ACOs
Premier healthcare alliance



April 19, 2018

Representative Greg Walden, Chair
U.S. House of Representatives
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr., Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

**Opposition to H.R. 3545 “Overdose Prevention and Patient Safety Act” and Support
for Preserving and Improving Medical Confidentiality for People Receiving Treatment
for Substance Use Disorders**

Dear Chair Walden and Ranking Member Pallone:

National Advocates for Pregnant Women (NAPW), a non-profit organization advocating for the health and rights of pregnant women, opposes H.R. 3545, the “Overdose Prevention and Patient Safety Act.” H.R. 3545 would eliminate key confidentiality protections in the Confidentiality of Substance Use Disorder Records regulations, 42 C.F.R. Part 2 (“Part 2”). These privacy protections are essential to public health efforts to engage people in life-saving treatment for substance use disorder (“SUD”). Without these protections, people will be deterred from seeking this important health care and will have devastating health consequences. In fact, experience under the existing regulations demonstrate the need to both preserve and enhance the protections of Part 2.

Alternative methods of protecting the privacy of patients with SUD – such as relying on HIPAA, relying on medical ethics guidelines, and relying on health care workers being trained and knowledgeable about SUD and what they may and may not report – simply do not work. NAPW’s peer-reviewed research documented hundreds of cases in which women have been charged with crimes or otherwise punished (e.g. detained, jailed, forced into treatment that is not warranted) in relationship to pregnancy and alleged current or former drug use (including

prescribed medications)¹. Approximately 25% of the pregnant women subject to arrest for crimes including fetal assault, attempted feticide, chemical endangerment of a child, delivery of drugs to a minor via the umbilical cord, and criminal child abuse between 1973 and 2005 were initially reported to law enforcement by doctors and other health care providers, who made those disclosures despite their clear legal and ethical obligations to maintain patient privacy. Since 2005, there have been more than 800 new arrests and detentions², many based on reports from health care providers to police and other public officials. Such reports are not necessarily mandated by any law, violate principles of medical ethics and are contrary to the positions of every leading medical group addressing issues involving pregnant women and drug use.

For example, health care providers in South Carolina played a primary role in reporting pregnant patients who tested positive for certain drugs to police. The U.S. Supreme Court eventually found these violations of patient privacy to be unconstitutional³. Even so, similar violations of patient privacy, particularly of pregnant women, are all too common.

- Since 2006, Alabama health care providers have reported hundreds of pregnant patients who come to them for medical help to law enforcement officials because of suspected drug use⁴.
- Jamie Lynn Russell went to an emergency room in Oklahoma in such debilitating pain that she was unable to move. Because her excruciating pain prevented her from lying down for an examination, hospital staff labeled her “noncompliant,” and called the police. The police discovered that she had two pain pills that weren’t hers. Still in pain, she was released by the hospital as “fit to incarcerate,” arrested for drug possession, and taken to jail, where she died two hours later from a ruptured ectopic pregnancy⁵.

Pregnant women’s experiences when they have specifically sought drug treatment not only demonstrate the continued need for the confidentiality protections of Part 2 but also the need to strengthen it.

- When Rachael Lowe was pregnant in Wisconsin and sought help for her opioid dependency problem, hospital staff failed to ensure her confidentiality. Instead they reported her to state authorities. The result was to undermine medically appropriate interventions that were being put into place; she was, instead, taken into custody by

¹ <https://read.dukeupress.edu/jhpl/article/38/2/299/13533/Arrests-of-and-Forced-Interventions-on-Pregnant>

² <https://thinkprogress.org/criminalization-pregnancy-us-43e4741bb514/>

³ *Ferguson v. City of Charleston*, 532 U.S. 67 (2001)

⁴ <https://www.propublica.org/article/when-the-womb-is-a-crime-scene>

⁵ <https://rewire.news/article/2013/01/14/dehumanizing-pregnant-women-leads-to-real-loss-life/>

police, locked in a mental hospital, put on dangerous medications, and left without prenatal care⁶.

- In New York, a pregnant woman's past treatment for alcoholism was released to state authorities in violation of federal confidentiality protections and used by a prosecutor to support criminal charges against her⁷.
- A Massachusetts public health department policy supports health care providers reporting pregnant women who are receiving SUD treatment – the treatment recommended and supported by the U.S. Substance Abuse and Mental Health Services Administration and the World Health Organization – to the state child welfare agency⁸.
- NAPW recently learned of a South Dakota SUD treatment facility that routinely shares drug test results with law enforcement. Those results are then used to support criminal drug possession charges based on prior use.

Every major medical and public health group in the United States, including the American Medical Association, the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics, supports measures that encourage people to get SUD treatment when needed and opposes measures such as reporting and punishment, precisely because they deter people from seeking help⁹.

For these reasons, NAPW opposes H.R. 3545 and instead supports legislative action that is critical to preserving patient confidentiality and coordinating care between various health care providers. Among these are:

- The Senate's bipartisan "Opioid Crisis Response Act of 2018," providing model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and for training family members and patients on their rights to protect and obtain substance use disorder information.
- H.R. 3331, providing needed incentive payments to SUD and behavioral health providers to obtain certified electronic health record technology.

⁶ http://journaltimes.com/news/local/judge-frees-addict-mom/article_0440a451-4146-565f-9808-e6514865811e.html

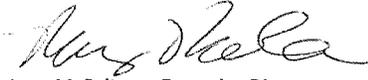
⁷ <https://www.nyclu.org/en/press-releases/court-rules-new-york-state-child-endangering-law-may-not-be-used-punish-pregnant-0>

⁸ <http://www.mass.gov/cohhs/docs/dph/quality/hcq-circular-letters/2013/dhcq-1305586-sen-guidelines.pdf>

- Amending 42 U.S.C. §290dd-2 and Part 2 to provide a private right of action for patients whose SUD information has been improperly disclosed in violation of the federal drug treatment confidentiality law.
- Amending 42 U.S.C. §290dd-2 and Part 2 to clarify that the reporting provision for suspected child abuse and neglect does not create a sex-discriminatory exception to confidentiality protections for pregnant women or new mothers.

Patients in SUD treatment must retain the power to decide when and to whom their records are disclosed.

Respectfully submitted,



Lynn M. Paltrow, Executive Director
Nancy Rosenbloom, Director of Legal Advocacy

National Association for Children of Addiction

... working to eliminate the adverse impact of alcohol and drug use on children and families



May 8, 2018

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and
Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate
Care

Dear Chairman Walden and Ranking Member Pallone:

I am writing to express the National Association for Children of Addiction (NACoA)'s opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. **By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.**

NACoA is the voice for the 1 in 4 children whose parents suffer from substance use disorders. These children are the unaddressed victims in the addiction epidemic that continues to sweep our country destroying families, costing jobs, increasing family violence, and reducing the children's opportunity for a safe and productive life each day addicted parents do not receive treatment and recovery support. This proposed legislation will delay parental help to get well and parental possibilities to obtain gainful employment in early recovery, thus stigmatizing and isolating vast numbers of children from a part of mainstream American opportunity. Fear of losing their children already helps to keep many parents from seeking treatment. H.R 3545 exacerbates that problem.

SAMHSA's amendments to Part 2 in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.

Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society. An important consequence to preserving that power will be the likelihood that their children will have parents who enter and finish treatment and go on to recovery and obtain gainful employment to help support their families, thus giving their children an equal opportunity to succeed.

For these reasons, we oppose H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- **The Senate's bipartisan "Opioid Crisis Response Act of 2018:"** Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you for considering the unintended consequences of H.R. 3545 to already vulnerable children.

Sincerely,



Sis Wenger
President/CEO

Opioid Treatment Association of Rhode Island (OTARI)

Addiction Recovery Institute • Center for Treatment and Recovery
CODAC • Discovery House • The Journey

April 16, 2018

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and Support
for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

The Opioid Treatment Association of Rhode Island (OTARI) writes to express our opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. **By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.**

OTARI members provide treatment and recovery support services to over 5000 Rhode Islanders living with Opioid Use Disorder (OUD) using the three (3) Federally-approved medications – methadone, buprenorphine, injectable naltrexone. Additionally, our members provide treatment and support for other Substance Use Disorders (SUD).

The heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as "Part 2"), are as critically important today as ever. They support care coordination while maintaining patient confidentiality to help ensure that people enter SUD treatment.

Patients have relied, and still rely, on the current protections to assure their ability to enter in to, and receive treatment without the fear of judgement, recrimination, and marginalization. Many continue to find it difficult to find work, housing, and compassionate medical care. Many, particularly those in Medication Assisted Treatment (MAT), have been "abandoned" by their medical provider, terminated from employment, and blamed for their illness. The changes proposed in *H.R. 3545 - "Overdose Prevention and Patient Safety Act"* will expose every person receiving treatment and recovery support for the broad range of Substance Use Disorders (SUD), including but not limited to, MAT, general outpatient for alcohol and other drugs, residential and inpatient treatment.

c/o CODAC – 1052 Park Ave., Cranston, RI 02910 • 401-275-5039 • 401-942-3590 (F) • mrizzi.otari@gmail.com

Opioid Treatment Association of Rhode Island (OTARI)

Addiction Recovery Institute • Center for Treatment and Recovery
CODAC • Discovery House • The Journey

Page 2.

Every person seeking and/or receiving treatment and recovery support will be required to live with the fear and anxiety of unauthorized disclosure of personal as well as treatment information. Many, who might be considering entering treatment may be so concerned about the loss of confidentiality, may choose to forego treatment rather than run the risk associated with these disclosures. As it is, there are enough barriers to treatment. In a time when we are doing our best to get people into life-saving treatment, these proposed changes only add another, unnecessary and life-threatening barrier to access, engagement, and recovery.

Other reasons for our opposition to this bill include the following:

- SAMHSA's amendments to Part 2 by in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.
- Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

For these reasons, OTARI oppose H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- **The Senate's bipartisan "Opioid Crisis Response Act of 2018:"** Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you for your consideration.

Sincerely,



Michael Rizzi, Chair
Opioid Treatment Association of Rhode Island



April 19, 2018

Ringgold Treatment Center LLC
8292 Hwy 41
Ringgold, GA 30736

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and
Support for Other Legislative Proposals to Preserve Confidentiality and
Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

Ringgold Treatment Center writes to express our opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. **By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.**

We are a medication-assisted treatment facility for the treatment of opioid use disorder. We see firsthand the dramatic changes that opioid addicted individuals are able to make in their lives when they participate in comprehensive MAT. But we fear that should H.R.

3545 pass, these individuals will not seek SUD treatment due to the limits on confidentiality. Below are reasons that we oppose this bill:

- The heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as “Part 2”), are as critically important today as ever. They support care coordination while maintaining patient confidentiality to help ensure that people enter SUD treatment.
- SAMHSA’s amendments to Part 2 by in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.
- Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

For these reasons, we oppose H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- **The Senate’s bipartisan “Opioid Crisis Response Act of 2018:”** Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you.

Sincerely,

Vanessa Ruehlmann
Program Administrator
Ringgold Treatment Center LLC

Victory Clinical Services

CARF Accredited

4218 Western Avenue
South Bend, IN 46619
Phone: (574) 233-1524
Fax: (574) 233-1612

April 17, 2018

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and Support for Other
Legislative Proposals to Preserve Confidentiality and Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

We at Victory Clinical Services would like to express our opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. **By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.**

As an accredited treatment provider for Opioid Use Disorder since 1996, we know and have experienced the stigma still present with opioid use disorder and the evidence-based treatment options available to help save lives. Without the protection of confidentiality on treatment records, the trust that Victory Clinic is able to extend to potential patients – to get them off the street, out of crime, and into treatment – would be shattered.

Furthermore, the heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as "Part 2"), are as critically important today as ever. They support care coordination while maintaining patient confidentiality to help ensure that people enter SUD treatment.

SAMHSA's amendments to Part 2 in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.

For these reasons, Victory Clinical Services opposes H.R. 3545 and instead supports the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- **The Senate's bipartisan "Opioid Crisis Response Act of 2018:"** Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you for your attention to our input.

Sincerely,



Erin LaCourt, LAC, ccdp, cade, eadacII
VCS Program Director
AATOD Delegate for Indiana
Vice President Indiana Association for
Treatment of Opioid Dependence

CC: Mark Parrino, AATOD President
David Blankenship, VCS Executive Director



April 16, 2018

Representative Greg Walden
 Chairman
 Energy and Commerce Committee
 2185 Rayburn House Office Building
 Washington, DC 20515

Jennifer Koiakowski
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Representative Frank Pallone, Jr.
 Ranking Member
 U.S. House of Representatives
 Energy and Commerce Committee
 237 Cannon House Office Building
 Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

Recovery Network of Programs, Inc. writes to express its opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. **By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.**

Recovery Network of Programs strives to solve the most difficult social problems facing humanity in order to effect positive, lasting change. It is our mission to save the lives of those ensnared by the hands of addiction as well as individuals who live with mental health disorders. While we fight daily to eradicate the stigma surrounding those suffering from substance use disorders, the reality remains that most of our clients expect 100% confidentiality with regard to their treatment. Client confidentiality is of highest concern when engaging individuals in first time treatment as is protecting against the unfortunate but very real discrimination associated with those labeled as addicts.

Helping people build better lives since 1972

Administrative Office • 2 Trap Falls Road, Suite 405 • Shelton, CT 06484 • (P) 203.929.1954 • (F) 203.929.1279

www.Recovery-Programs.org
 An Affirmative Action / Equal Opportunity Employer

Furthermore, the heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as "Part 2"), are as critically important today as ever. They support care coordination while maintaining patient confidentiality to help ensure that people enter SUD treatment.

Moreover, SAMHSA's amendments to Part 2 by in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.

Finally, patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

For these reasons, we oppose H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- **The Senate's bipartisan "Opioid Crisis Response Act of 2018:"** Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you.

Sincerely,



Jennifer Kolakowski, LCSW
Chief Executive Officer



April 17, 2018

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

The members of SCATOD, the South Carolina Association for the Treatment of Opioid Dependence, write to express our opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. **By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.**

The South Carolina Association for the Treatment of Opioid Dependence (SCATOD) represents 20 Opioid Treatment Programs (OTPs) currently operating in the state of South Carolina. Our programs are on the front lines of treating opioid addiction in our state. We currently serve close to 7,000 individuals with an Opioid Use Disorder (OUD).

Even with the growing awareness that substance use disorders are a disease, the unfortunate truth is that persons with a SUD are still actively discriminated against. This stigma and discrimination is heightened for individuals using Medication Assisted Treatments (MAT), such as treatment with methadone or buprenorphine (best known as Suboxone), to address their OUD. Every day in South Carolina we see examples of discriminatory practices towards the persons we serve. Such as a patient getting dropped by his Primary Care Physician's office and cut off from needed medications for his medical conditions when the physician found out the patient is receiving

methadone for an OUD. Or a baby being taken away from a new mother because she is on methadone for an OUD despite long-standing compliance with her treatment and abstinence from illegal drug-use.

For these reasons we believe the following:

- Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.
- Patients who believe their information may be shared without their consent may not seek treatment. Removing the heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as “Part 2”) will create barriers to persons seeking treatment.
- The regulations under 42 CFR Part 2 support care coordination while maintaining patient confidentiality to help ensure that people enter SUD treatment.
- SAMHSA’s amendments to Part 2 by in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.

As such, we oppose H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- **The Senate’s bipartisan “Opioid Crisis Response Act of 2018:”** Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you.



Christine Martin, LMFT, CACH
President
SCATOD – South Carolina Association for the Treatment of Opioid Dependence
2301 Cosgrove Avenue, Suite F
North Charleston, SC 29405

From: Northern Parkway
To: [Gordon, Waverly](#)
Subject: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care
Date: Sunday, April 15, 2018 12:44:53 PM

Dear Chairman Walden and Ranking Member Pallone:

On behalf of Northern Parkway Treatment Services, I'm writing to express our opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.

- The heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as "Part 2"), are as critically important today as ever. They support care coordination while maintaining patient confidentiality to help ensure that people enter SUD treatment.

- SAMHSA's amendments to Part 2 by in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.

- Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

For these reasons, we oppose H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- The Senate's bipartisan "Opioid Crisis Response Act of 2018:" Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.

- H.R. 3331 - Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui: Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you.

Sincerely,

--
 Babak Imanool, D.O.
 Medical Director and President
 Northern Parkway Treatment Services, Inc.
 3007 E. Northern Parkway
 Baltimore, MD 21214
 Phone: 443-475-0737
 Fax: 410-220-0703
 URL: <http://www.nptreatmentservices.com/>

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This information has been disclosed to you from records protected by Federal Confidentiality Rules (42CFR Part 2). The federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains, or is otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient of this purpose. The federal rules restrict any use of this information to criminally investigate or prosecute any alcohol or drug abusing patient.



Virus-free_www.avg.com



From: Babak Imanoei
To: Gordon, Waverly
Subject: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care
Date: Sunday, April 15, 2018 12:40:26 PM

Dear Chairman Walden :

On behalf of BHI Health Services, I'm writing to express our opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.

- The heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as "Part 2"), are as critically important today as ever. They support care coordination while maintaining patient confidentiality to help ensure that people enter SUD treatment.
- SAMHSA's amendments to Part 2 by in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.
- Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

For these reasons, we oppose H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- The Senate's bipartisan "Opioid Crisis Response Act of 2018:" Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui: Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you.

Sincerely,

Babak Imanoei, DO
 Medical Director and President
 BHI Health Services, Inc.
 450 E. Main Street
 Westminster, MD 21157
 Phone: 410-871-3005
 Fax: 443-293-8711

TEMPLATE FOR COMMENTS OPPOSING H.R. 3545, "OVERDOSE PREVENTION
AND PATIENT SAFETY ACT"

04/15/2018

Serenity Health, LLC
780 W Bel Air Ave, Suite B
Aberdeen, MD 21001

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and
Support for Other Legislative Proposals to Preserve Confidentiality and
Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

Serenity Health writes to express our opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. **By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.**

Some time ago, we had a young lady in our methadone maintenance program that committed suicide. She had several admissions to other levels of care that were unsuccessful, so she entered the methadone maintenance program. She had turned her life around. She was in college, working full-time, owned her own car, was purchasing a house and was no longer using illicit substances. She had to complete

probation for crimes she had committed while she was actively using illicit drugs. Her mother did not know she was in methadone treatment. She did not want her mother to know because her mother did not agree with methadone. The judge found out she was in the methadone maintenance program and disclosed it in a court hearing with her mother present. The judge and her mother insisted that she “get off that stuff”, and she complied only because of the pressure from both to do so. She began abusing illicit substances and participating in illegal activity to obtain those substances. The guilt and shame of returning to what she described as “a life of hell”, lead her to write a suicide note and end her life. If her confidentiality had not been violated, she may have been the one writing this letter. As healthcare providers, we are trained and educated as to the best approach for releasing pertinent health information to assure safe and appropriate disclosure of protected information.

- The heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as “Part 2”), are as critically important today as ever. They support care coordination while maintaining patient confidentiality to help ensure that people enter SUD treatment.
- SAMHSA’s amendments to Part 2 by in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.
- Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

For these reasons, Serenity Health opposes H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- **The Senate’s bipartisan “Opioid Crisis Response Act of 2018:”**
Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive

payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you.

Sincerely,

Nancy J. Turner, RN, MBR, DMP

Nancy J. Turner, RN, MBR, DMP
CEO
Serenity Health, LLC



KENTUCKY MENTAL HEALTH COALITION

April 23, 2018

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and
Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

On behalf of the eighty (80) member organizations of the KY Mental Health Coalition, I am writing to express our strong opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." As you know, we are in the midst of the worst opioid epidemic in our nation's history. It is a time when we must do everything possible to increase the number of people who seek treatment for their addiction. Our grave concern is that H.R. 3545 would not only not encourage individuals to seek treatment, but would actually discourage them from doing so.

H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways. The bill would reduce privacy protections for individuals receiving substance use disorder ("SUD") treatment by allowing disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers, coverage plans and others.

The Kentucky Mental Health Coalition (KMHC) includes every kind of behavioral health professional licensed in Kentucky, as well as public-sector and private-sector agencies and treatment facilities. Our membership also includes advocacy, consumer and family groups who are very clear that protection of personal information is a key requisite of seeking treatment for addictive disorders.

ADVOCACY ACTION NETWORK
120 SEARS AVENUE, SUITE 212 LOUISVILLE, KY 40207
PHONE: (502) 836-4222 TOLL-FREE (877) 894-0222 FAX: (502) 894-0635
WEBSITE: WWW.ADVOCACYACTION.NET

- The heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as “Part 2”), are as critically important today as ever. They support care coordination while maintaining patient confidentiality to help ensure that people enter SUD treatment.
- SAMHSA’s amendments to Part 2 by in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.
- Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

For these reasons, we **oppose H.R. 3545** and instead **support the following bills** that are critical to preserving patient confidentiality and coordinating care among various health providers:

- **The Senate’s bipartisan “Opioid Crisis Response Act of 2018:”** Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you for your attention to this critically important issue. The lives of those with addictions depend on your actions.

Sincerely,

Sheila A. Schuster, Ph.D.
Executive Director

ADVOCACY ACTION NETWORK
120 SEARS AVENUE, SUITE 212 LOUISVILLE, KY 40207
PHONE: (502) 836-4222 TOLL-FREE (877) 894-0222 FAX: (502) 894-0635
WEBSITE: WWW.ADVOCACYACTION.NET

COMMENTS OPPOSING H.R. 3545, "OVERDOSE PREVENTION AND PATIENT SAFETY ACT"

April 21, 2018

Holly Broce, MHA, LCADC
President of the KY Association for the Treatment of Opioid Dependence
Pinnacle Treatment Centers Regional Director
105 Eastside Drive
Georgetown, KY 40324

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

Pinnacle Treatment Centers is writing to express our opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. **By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.**

Working in the field of addiction since 1994, I have witnessed time and time again, patients being dropped from a medical practice or prematurely forced out

of treatment by the criminal justice system. This action is a direct result of a lack of understanding of medication assisted treatment. Forcing patients out of a life-saving treatment, sends them into withdrawal and puts them at greater risk of relapse and overdose.

- The heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as “Part 2”), are as critically important today as ever. They support care coordination while maintaining patient confidentiality to help ensure that people enter SUD treatment.
- SAMHSA’s amendments to Part 2 by in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.
- Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

For these reasons, we oppose H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- **The Senate’s bipartisan “Opioid Crisis Response Act of 2018:”** Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you.

Sincerely,

Holly Broce, MHA, LCADC

President KY Association for the Treatment of Opioid Dependence

Regional Director, Pinnacle Treatment Centers



People Advocating Recovery is a statewide group of concerned individuals working to eliminate barriers to recovery from addiction.

April 22, 2018

PAR-People Advocating Recovery
1425 Story Ave.
Louisville, KY 40206

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and
Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

People Advocating Recovery is writing to express our opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.

PAR-People Advocating Recovery
1425 Story Ave.
Louisville, KY 40206
502-552-8573
www.peopleadvocatingrecovery.org

My name is Mike Barry. I am the CEO of People Advocating Recovery representing over 7000 people in recovery, their families, and friends in the state of Kentucky.

Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

I and many others would have not gone into a treatment program had we thought our information would be shared with others without our knowledge or consent. This could have put our careers in jeopardy since so many people still regard this illness as a moral failure.

For these reasons, we oppose H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- The Senate's bipartisan "Opioid Crisis Response Act of 2018:" Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui: Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you.

Sincerely,

A handwritten signature in cursive script that reads "Michael Barry".

Mike Barry
CEO-People Advocating Recovery
Kentucky



1324 Motor Parkway Suite 102, Islandia NY 11749

April 12, 2018

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and
Support for Other Legislative Proposals to Preserve Confidentiality and
Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

*[I am writing on behalf of the Long Island Recovery Association (LIRA) to express our strong opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. **By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.***

As an individual in long term recovery, when I first decided to go to treatment in 1988 knowing that my presence and related details of my stay were protected provided me

with a sense of comfort and ease that allowed me to follow through on that life altering commitment. Knowing I was able to focus on the task at hand without worrying that my employer and others may know about my medical condition was a big reason I was able to trust the process leading to a sustained life in recovery now approaching thirty years. Had the long standing full provisions of CFR 42 not been in place I am certain I would not have entered treatment at that time. I cannot emphasize enough my belief that that these proposed changes in this legislation, particularly as we face the opioid crisis the number one healthcare issue in America, would have widespread negative impact on individuals in need of treatment for substance use disorders.

- The heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as "Part 2"), are as critically important today as ever; supporting care coordination and maintaining confidentiality to help ensure that people enter SUD treatment.
- Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

For these reasons LIRA opposes H.R. 3545. We support the following bills that are critical to preserving patient confidentiality and care between various health providers:

- **The Senate's bipartisan "Opioid Crisis Response Act of 2018:"** Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you for your consideration and anticipated support.

Sincerely,

Richard Buckman
 Immediate Past President
 Founding Member



April 13, 2018

Faces & Voices of Recovery
840 First Street NE Third Floor
Washington, D 20002

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

Faces & Voices of Recovery writes to express our opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. **By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.**

Faces & Voices of Recovery is dedicated to organizing and mobilizing the over 23 million Americans in recovery from addiction to alcohol and other drugs, our families, friends and allies into recovery community organizations and networks, to promote the right and

840 First Street NE 3rd Floor • Washington, DC 20002
202.737.0690 • Fax: 202.737.0695

www.facesandvoicesofrecovery.org

**FACES &
VOICES**
OF RECOVERY

resources to recover through advocacy, education and demonstrating the power and proof of long-term recovery.

People in or in need of recovery from addiction to alcohol and other drugs face myriad forms of discrimination. Discrimination creates barriers to our full participation in community life. Faces & Voices of Recovery strives to eliminate all policies and practices that discriminate against people and their impacted families based solely on their recovery status. We are very aware of the consequences if the 42CFR Part 2 were to change and as such oppose this bill for the following reasons:

- The heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as "Part 2"), are as critically important today as ever. They support care coordination while maintaining patient confidentiality to help ensure that people enter SUD treatment.
- SAMHSA's amendments to Part 2 by in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.
- Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

For these reasons, Faces & Voices of Recovery opposes H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- **The Senate's bipartisan "Opioid Crisis Response Act of 2018:"** Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive

270

**FACES &
VOICES**
OF RECOVERY

payments to substance use disorder and behavioral health providers to
obtain certified electronic health record technology.

Thank you.

Sincerely,



Patty McCarthy Metcalf
Executive Director
Faces & Voices of Recovery
840 First Street NE Third Floor
Washington, D 20002

840 First Street NE 3rd Floor • Washington, DC 20002
202.737.0690 • Fax: 202.737.0695

www.facesandvoicesofrecovery.org



March 20th, 2018

The Honorable Chairman Greg Walden,
The Honorable Ranking Member Frank Pallone
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

RE: Hearing on Combatting the Opioid Crisis: Prevention and Public Health Strategies - Amendment to HR 3545 the Overdose Prevention and Patient Safety Act"

The Honorable Chairman Walden & Ranking Member Pallone,

Thank you for the opportunity to comment on the proposed Amendment to HR 3545, "the Overdose Prevention and Patient Safety Act." The agency I represent is the Pennsylvania Recovery Organizations – Alliance (PRO-A), the statewide recovery community organization of Pennsylvania founded in 1998. We represent thousands of recovering persons across the state of Pennsylvania. We are dedicated to ending stigma, providing public education about addiction, providing recovery opportunities and to expand access to drug and alcohol services.

We continue to believe strongly that the existing federal confidentiality requirements for substance use conditions information established in 42 U.S.C. § 290dd-2 and 42 CFR Part 2 ("Part 2"), as recently amended twice by SAMHSA, do not require further modifications that would diminish our patient privacy protections in order to achieve the important goal of facilitating the provision of integrated care between substance use disorder information and overall health care.

We remain very concerned that applying the HIPAA Privacy Rule ("HIPAA") standard of allowing without our consent disclosures of our substance use condition records for treatment, payment, health operations or any purpose other than those currently enumerated in Part 2 will result in discrimination against and harm to people living with substance use conditions. The result will be to discourage individuals from seeking SUD treatment even as our number one goal needs to be to encouraging millions more Americans to enter treatment during the worst opioid epidemic in our nation's history.

Section (C) (2) on page 4 of the amendment in the section titled "Use of Records in Criminal, Civil, or Administrative Investigations, Actions or Procedures" identifies a threshold of "absent good cause" for ruling out the use of our information in Criminal, Civil, or Administrative Investigations. This is an ambiguous standard at best and provides insufficient guidance. This will inevitably result in our own information disclosed by seeking help with a substance use condition to be used against us. This will have a chilling impact on the ability of our community to seek help without fear of prosecution.

The Amendment would allow broad access to highly sensitive and personal information. It would be opened up to a vast array of individuals and entities well beyond the counselor treating the person in need and the immediate care provider who need it and can access it under current regulation with our consent.

Additionally, as this information “flows out” to business associates and contracted entities, control over what happens to it decreases while the likelihood of the information being misused or stolen through a breach increases. In instances in which a person has had their information used in a way that caused harm to them, it will become virtually impossible for the patient to determine who was responsible for improperly releasing their information. It is the proverbial wall with a gate open and a pot of gold within.

Our information is that proverbial “pot of gold” and we are deeply concerned about broad dispersal of highly sensitive and personal drug and alcohol related information proposed by the amendment and the lack of clear accountability to us, the patients. It will create conditions favorable to those who would use our information to discriminate against us in a myriad of ways. This includes employment, housing, education and insurance coverage. We have faced the constant drumbeat of the weakening of our protections by business related groups who are perpetually advocating for further weakening and / or elimination of this critically important rule. If one does a google search on medications like “Narcain” or “Buprenorphine” coupled with the term “Life Insurance” one will find how information available within patient records are being used to deny life insurance to people. Turning on the news this week, one is confronted with how Cambridge Analytica used a research clause to gain information on people to use as Kompromat. Drug and Alcohol patient records would be a primary target of other such groups working to gain access to our highly sensitive information. Treatment will become unsafe to participate in.

The sad reality is that there are compelling reasons for entities to obtain and use this information to discriminate against us for their own material gain. The vast majority of persons who will have this happen to them will lack the resources to determine who used their information in an improper way. Even if they did, in most cases individuals would not do so as by the very act of trying to assert their rights would acknowledge drug addiction in a way that would open them up to prosecution and discrimination. In that sense the Amendment has toothless penalties as due process will be un-obtainable by those so harmed.

The Amendment endangers the fragile therapeutic alliance and may well reduce access to care as who gets our patient information becomes unknowable to the patient. It will be no longer possible for the person in care to determine who gets their information and how it will be used (or misused). Information could now go in a myriad of directions once entered into the medical data base. If the information is used to discriminate against us, it is also nearly impossible from the patient perspective to determine how such a violation occurred and who was responsible.

Under this Amendment, as the treating clinician (I have nearly three decades of direct care experience) I would have to tell my clients that I have no idea who will get their patient information, or how it will be used. I will note that I am a person in long term, continuous recovery for over 31 years. *Under this amendment, I would have not entered treatment or self-edited my disclosures in a way that would have undermined my own care.* Without strict protections, I would not have gotten help, obtained an education and have had the opportunity to be a productive citizen. It is quite possible I would not have survived. This is not just my story, this is true for so very many of us in recovery.

Please understand that there is much greater stigma around substance use conditions than other kinds of medical conditions, and the very acknowledgment of having a substance use condition can open us up to

Web site: www.pro-a.org

Twitter Feed: <https://twitter.com/PAREcoveryOrg>

Facebook: www.facebook.com/PaRecoveryOrganizationAlliance/

discrimination and in many instances, place us in legal jeopardy. We will face a Hobson's choice when seeking help under the proposed amendment.

We implore you to not further weaken our confidentiality rights. We are concerned that these proposed changes add many layers of legalese, complexity and ambiguity to the regulations and will serve only to create further confusion. It is worth noting that even with our simpler, current standard many direct care professionals do not understand that they can access all the clinical information they need with a properly executed consent. It is also worth noting that each revision of the standard has made it more complex and harder to understand, which is in and of itself a barrier to care for patients. Others seem to not want to be bothered to honor our privacy rights.

We believe that the patient should retain control over who gets this information and how it is used. It is important to note that substance use conditions are almost always fatal without help, that few people can afford to pay out of pocket for care as a direct result of the condition and that treatment at times can be compulsory. The bottom line is that if information that can harm us is widely available, we are left with no real choices beyond avoiding care or risking the use of our information to discriminate against us after it flows to covered entities and beyond based on "absent probable cause" language, business, research allowances and many other ways.

We believe that expanding access to our information opens it up to misuse and urge policymakers to protect us from the misuse of our information and to hold those who use it to discriminate against us accountable to protect our information. This is the standard that Congress strived for back in 1972, which we believe is just as relevant now:

"The conferees wish to stress their conviction that the strictest adherence to the provisions of this section is absolutely essential to the success of all drug abuse prevention programs. Every patient and former patient must be assured that his right to privacy will be protected. Without that assurance, fear of public disclosure of drug abuse or of records that will discourage thousands from seeking the treatment they must have if this tragic national problem is to be overcome."

We staunchly believe that sharing of addiction and recovery information is an individual choice to be made by the individual who retains control over how it is used and honors the need to limit access to highly sensitive information – we think that this is fundamental to quality care and consistent with the original statutes and we ask that the original intent be honored.

Respectfully Submitted,



William Stauffer, LSW, CCS, CADC
Executive Director

Web site: www.pro-a.org

Twitter Feed: <https://twitter.com/PAREcoveryOrg>

Facebook: www.facebook.com/PaRecoveryOrganizationAlliance/

Campaign to Protect Patient Privacy Rights

March 21, 2018

VIA ELECTRONIC MAIL

Representative Greg Walden
Chairman of the U.S. House of Representatives
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member of the U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: U.S. House of Representatives, Energy and Commerce – Subcommittee on Health: “Combating the Opioid Crisis: Prevention and Public Health Solutions;” Amendment in the Nature of a Substitute to H.R. 3545 - “Overdose Prevention and Patient Safety Act”

Dear Chairman Walden and Ranking Member Pallone:

We, the undersigned national, state, and local organizations *strongly support maintaining the core protections of the federal substance use disorder patient confidentiality law (“42 U.S.C. § 290dd-2”) and its regulations “42 CFR Part 2,”* (referred to collectively as “Part 2,”) to effectively protect the confidentiality of patients’ records. The Substance Abuse and Mental Health Service Administration (“SAMHSA”) recently twice amended the patient privacy regulations in order to facilitate the objective of providing integrative care between substance use disorder (“SUD”) and other health care information.

We remain concerned that using a weaker HIPAA Privacy Rule standard of allowing disclosures of SUD information without patient consent for treatment, payment, health care operations, or other purposes other than those currently allowed by Part 2 – will contribute to the existing level of discrimination and harm to people living with substance use disorders. This will only result in more people who need substance use disorder treatment, being discouraged and afraid to seek the health care they need during the nation’s worst opioid crisis.

We strongly support maintaining Part 2's core protections for SUD information, instead of those of a weaker HIPAA Privacy standard as described in the Amendment (in the Nature for a Substitute) for H.R. 3545 for the following reasons:

1. The heightened privacy protections in Part 2 are as critical today as they were when they were enacted more than 40 years ago and must be preserved.
2. In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase – not decrease – the number of people who seek treatment.
3. SUD is unique among medical conditions because of its criminal and civil consequences and the rampant discrimination people face.
4. With so much at stake, patients in SUD treatment should retain the right to consent when and to whom their records are disclosed, as currently found in Part 2.
5. Effective integration of SUD treatment with the rest of the health care system is critically important, and information exchange in accordance with confidentiality law and current technology is now possible. To facilitate that process, SAMHSA recently amended the Part 2 regulations to further promote the integration of confidential SUD information into general health records.

We respectfully request that the House Energy and Commerce Committee maintain the current confidentiality protections of Part 2 to support individuals entering and staying in SUD treatment and recovery services.

Sincerely,

CAMPAIGN TO PROTECT PATIENT PRIVACY RIGHTS:

A New PATH

Addiction Haven

Addictions Resource Center, Waukesha, WI (ARC, Inc.)

Advocates for Recovery Colorado

AIDS United

Alano Club of Portland

Alcohol & Addictions Resource Center, South Bend, IN

American Association for the Treatment of Opioid Dependence (AATOD)

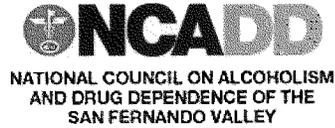
American Group Psychotherapy Association

Apricity
Arthur Schut Consulting LLC
Atlantic Prevention Resources
California Consortium of Addiction Programs & Professionals (CCAPP)
Capital Area Project Vox–Lansing (MI)'s Voice of Recovery
Center for Recovery and Wellness Resources
CFC Loud N Clear Foundation
Chicago Recovering Communities Coalition
Colorado Behavioral Healthcare Council
Community Catalyst
Connecticut Community for Addiction Recovery (CCAR)
Council on Addiction Recovery Services (CAREs), Inc.- Olean, NY
DarJune Recovery Support Services & Café
Davis Direction Foundation - The Zone
Daystar Center
Delphi Behavioral Health Group–Maryland House Detox
Detroit Recovery Project
The DOOR-DeKalb Open Opportunity for Recovery
Drug and Alcohol Service Providers Organization of Pennsylvania
Faces & Voices of Recovery
Faces and Voices of Recovery (FAVOR)-Grand Strand-SC
Faces and Voices of Recovery (FAVOR)-Greenville, SC
Faces and Voices of Recovery (FAVOR)-Low Country: Charleston, SC
Faces and Voices of Recovery (FAVOR)-Mississippi Recovery Advocacy Project
Faces and Voices of Recovery (FAVOR)-Pee Dee, SC
Faces and Voices of Recovery (FAVOR)-Tri-County: Rock Hill, SC
Facing Addiction
Fellowship Foundation Recovery Community Organization
Foundation for Recovery
Friends of Recovery-New York
Georgia Council on Substance Abuse

Greater Macomb Project Vox
Harm Reduction Coalition
Home of New Vision
HOPE for New Hampshire Recovery
Jackson Area Recovery Community-Jackson, MI
Latah Recovery Center
Legal Action Center
Lifehouse Recovery Connection
Long Island Recovery Association (LIRA)
Maine Alliance for Addiction Recovery
Massachusetts Organization for Addiction Recovery
Message Carriers of Pennsylvania
Mid-Michigan Recovery Services (NCADD Mid-Michigan Affiliate)
Minnesota Recovery Connection
Missouri Recovery Network
National Advocates for Pregnant Women
National Alliance for Medication Assisted Recovery (NAMA Recovery)
National Association for Children of Addiction (NACoA)
National Association of County Behavioral Health and Developmental Disability
Directors (NACBHDD)
National Association for Rural Mental Health (NARMH)
National Center on Domestic Violence, Trauma & Mental Health
National Council on Alcoholism and Drug Dependence, Inc. (NCADD)
National Council on Alcoholism and Drug Dependence-Central Mississippi Area, Inc.
National Council on Alcoholism and Drug Dependence-Maryland
National Council on Alcoholism and Drug Dependence-Phoenix
National Council on Alcoholism and Drug Dependence-San Fernando Valley
Navigating Recovery of the Lakes Region
New Jersey Association of Mental Health and Addiction Agencies
Northern Ohio Recovery Association
Oklahoma Citizen Advocates for Recovery and Transformation Association (OCARTA)

Overcoming Addiction Radio, Inc.
Parent/Professional Advocacy League
Peer Coach Academy Colorado
Pennsylvania Recovery Organizations-Alliance (PRO-A)
People Advocating Recovery (PAR)
Pennsylvania Recovery Organization–Achieving Community Together (PRO-ACT)
Portland Recovery Community Center
Public Justice Center
REAL-Michigan (Recovery, Education, Advocacy & Leadership)
Recover Project/Western MA Training
Recover Wyoming
Recovery Alliance of Austin
Recovery Allies of West Michigan
Recovery Cafe
Recovery Communities of North Carolina
Recovery Community of Durham
Recovery Consultants of Atlanta
Recovery Epicenter Foundation, Inc.
Recovery Force of Atlantic County
Recovery is Happening
Recovery Resource Council
Recovery Organization of Support Specialist
Revive Recovery, Inc.
Rhode Island Cares About Recovery (RICARES)
Rochester Community Recovery Center
ROcovery Fitness
Safe Harbor Recovery Center
SMART Recovery (Self-Management and Recovery Training)
S.O.S. Recovery Community Organization
SpiritWorks Foundation
Springs Recovery Connection

Tennessee Association of Alcohol, Drug & other Addiction Services (TAADAS)
The Bridge Foundation
The Courage Center
The McShin Foundation
The Ohana Center for Recovery
The Serenity House of Flint
The Phoenix
The RASE Project
The Recovery Channel
Tia Hart Community Recovery Program
Together Our Recovery Center Heals (T.O.R.C.H.), Inc.
Treatment Trends, Inc.
Trilogy Recovery Community
U MARC (United Mental Health and Addictions Recovery Coalition)
Utah Support Advocates for Recovery Awareness (USARA)
Vermont Recovery Network
Voices of Hope for Cecil County, MD
Voices of Hope Lexington
Voices of Recovery San Mateo County, CA
WAI-IAM, Inc. and RISE Recovery Community
Wisconsin Voices for Recovery
Young People in Recovery



March 21, 2018

Representative Greg Walden
Chairman of the U.S. House of Representatives
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member of the U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: U.S. House of Representatives, Energy and Commerce – Subcommittee on Health:
“Combating the Opioid Crisis: Prevention and Public Health Solutions;”
Amendment in the Nature of a Substitute to H.R. 3545 -“Overdose Prevention and Patient
Safety Act”

Dear Chairman Walden and Ranking Member Pallone:

As a professional alcohol and drug outpatient treatment program, we *strongly support* maintaining the core protections of the federal substance use disorder patient confidentiality law (“42 U.S.C. § 290dd-2”) and its regulations “42 CFR Part 2,” (referred to collectively as “Part 2,”) to effectively protect the confidentiality of patients’ records. Maintaining Part 2’s core protections for SUD information, instead of those of a weaker HIPAA Privacy standard as described in the Amendment (in the Nature for a Substitute) for H.R. 3545 for the following reasons:

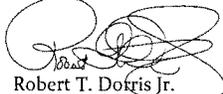
1. The heightened privacy protections in Part 2 are as critical today as they were when they were enacted more than 40 years ago, and must be preserved.
2. Amid the worst opioid epidemic in our nation’s history, we must do everything possible to increase – not decrease – the number of people who seek treatment.

3. SUD is unique among medical conditions because of its criminal and civil consequences and the rampant discrimination people face.
4. With so much at stake, patients in SUD treatment should retain the right to consent when and to whom their records are disclosed, as currently found in Part 2.
5. Effective integration of SUD treatment with the rest of the health care system is critically important, and information exchange in accordance with confidentiality law and current technology is now possible. To facilitate that process, SAMHSA recently amended the Part 2 regulations to further promote the integration of confidential SUD information into general health records.

Like many other professionals in the field of addiction treatment and recovery, we are concerned that weakening the HIPAA Privacy Rule standard of allowing disclosures of SUD information without patient consent for treatment, payment, health care operations, or other purposes other than those currently allowed by Part 2 – will contribute to the existing level of discrimination and harm to individuals and their families suffering with substance use disorders. This will only result in more people who need substance use disorder treatment, being discouraged and afraid to seek the health care they need during the nation's worst opioid crisis.

We respectfully request that the House Energy and Commerce Committee maintain the current confidentiality protections of Part 2 in order to support individuals entering and staying in SUD treatment and recovery services.

Sincerely,



Robert T. Dotris Jr.
President of the Board

cc: NCADD-SFV Board of Directors
NCADD-SFV Management Committee



April 18, 2018

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Privacy and confidentiality of the health data of survivors of domestic and intimate partner violence

Dear Chairman Walden and Ranking Member Pallone:

Futures Without Violence (FUTURES) writes today to support strong privacy and confidentiality protections for the health and behavioral health data/records of survivors of domestic and intimate partner violence (DV/IPV). As an organization that partners with providers and patients, we support a pragmatic approach to care coordination and data sharing that improves care, reduces costs, and protects women and families who experience DV/IPV. Because disclosure of confidential health information can be particularly dangerous for victims, it is imperative that survivors are fully informed about how their data is being used and shared—and that they have control over how, when and with whom.

We are concerned that the changes to the data sharing permissions policies are being hurriedly considered as part of H.R. 3545, the "Overdose Prevention and Patient Safety Act," and do not meet the unique privacy and security needs of survivors of DV/IPV. Careful consideration is required. This is true for substance use and mental health records—and for all health data.

Recent changes to privacy rules, including SAMHSA's amendments to 42CFR Part 2 in 2017 and 2018, have made it much easier to facilitate (with patient consent) the sharing of health information between SUD, mental health and other health care providers in electronic health information systems and coordinated care settings. Until these policies are fully implemented and the full impact of these changes is understood, we recommend no additional changes to the policy to ensure that survivors of DV/IPV—and all patients—have their health data protected.

For survivors, keeping health data confidential is critical both for the immediate safety concerns, and also for survivors' trust of their providers. Survivors may be at risk of violent retaliation or reprisal if an abuser learns about the disclosure of abuse. There also may be legal consequences with an abuser using a survivor's history of mental health or substance use services against them in court or custody proceedings or threatening to do so as a means of coercive control. Survivors also will be less likely to disclose abuse and

seek help if they do not believe their disclosure will be kept private. Survivors must understand who has access to their health data and who may be able to get access to that data, and they should retain the power to decide when and to whom their records are disclosed.

To that end, FUTURES recommends that future policymaking adhere to the following principles:

Robust and informed patient consent

Survivors may have very different needs with regards to their privacy. Some may be comfortable sharing health data with various health care providers and others may choose to exercise more control. The health care system—and all corresponding technology—must be responsive to these different needs and ensure that patients fully understand how their data is shared and be offered the ability to fully consent.

Patient control of data

Patients should be able to choose who can see their records and under what circumstances, and must be offered options to exercise control over these situations. They need to fully understand where their data may go and how their data may be accessed. They must be given the opportunity to opt into (or out of) sharing their health data—and they must be able to control what providers have access to their data and under what circumstances. Technology can support these decisions by allowing survivors to withhold certain information or to prohibit the sharing of certain information. They must be able to easily change privacy settings if their life circumstances change.

Transparency

Survivors must be able to know and be able to track who has accessed their data and when, or when data was shared with others. Providers may be given tools to help survivors protect their data, and the technology must support providers decisions, including education on what data might be sent to outside providers or for reimbursement, or what information might be printed on insurance billing notifications.

Enforceable penalties

There should be strong and enforceable penalties for violations of privacy and consent both in a clinical setting, and across information exchanges. Whether due to negligence or oversight, violations of privacy and consents should be penalized to the fullest extent of the law. The penalties should be strong enough to deter future cases, and they must be enforceable.

We thank you for consideration of these recommendations and look forward to answering any questions or addressing any concerns. For additional information, please contact Kiersten Stewart in FUTURES' Washington, DC office at 202-595-7382.

Sincerely,



Esta Soler
President and Founder
Futures Without Violence

May 2, 2018

Sally A. Carr
502 S. 12th Street
Perkasie, Pa. 18944

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

I, as a parent of a son whom suffers with the disease of addiction, and as a representative of a nonprofit, Never Surrender Hope, write to express my opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.

As I stated above, my son is my main motivation in writing to you today. The stigma attached to the disease of addiction can be witnessed, not only in daily life, but also in those places where people who suffer the same, should feel safe and not judged by their past attempts at recovery or anything else for that matter.. Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

For these reasons, I oppose H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:
The Senate's bipartisan "Opioid Crisis Response Act of 2018:" Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.

H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui: Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you.

Sincerely,

Sally A. Carr

May 2, 2018

Lauryn Wicks
499 Woodcrest Drive
Mechanicsburg, Pennsylvania 17050

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care

Dear Chairman Walden and Ranking Member Pallone:

I write to express my opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. **By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.**

The heightened protections for substance use disorder records in the federal confidentiality law, 42 U.S.C. § 290dd-2 and its regulations at 42 CFR Part 2 (collectively known as "Part 2"), are as critically important today as ever. They support care coordination while maintaining patient confidentiality to help ensure that people enter SUD treatment.

- SAMHSA's amendments to Part 2 by in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.

- Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.

For these reasons, I oppose H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- **The Senate's bipartisan "Opioid Crisis Response Act of 2018:"** Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you.

Sincerely,

Lauryn Wicks
National Independent Family Recovery Advocate

National Association for Children of Addiction

...working to eliminate the adverse impact of alcohol and drug use on children and families



May 8, 2018

Representative Greg Walden
Chairman
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member
U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Opposition to H.R. 3545 - "Overdose Prevention and Patient Safety Act" and
Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate
Care

Dear Chairman Walden and Ranking Member Pallone:

I am writing to express the National Association for Children of Addiction (NACoA)'s opposition to H.R. 3545, the "Overdose Prevention and Patient Safety Act." In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase the number of people who seek treatment, but H.R. 3545 would do the opposite. **By reducing privacy protections for individuals receiving substance use disorder ("SUD") treatment to allow disclosures and re-disclosures of SUD information without patient consent to a wide range of health care providers and plans and others with whom they work, H.R. 3545 would discourage people from entering care out of fear that their treatment records will be used against them in many harmful ways.**

NACoA is the voice for the 1 in 4 children whose parents suffer from substance use disorders. These children are the unaddressed victims in the addiction epidemic that continues to sweep our country destroying families, costing jobs, increasing family violence, and reducing the children's opportunity for a safe and productive life each day addicted parents do not receive treatment and recovery support. This proposed legislation will delay parental help to get well and parental possibilities to obtain gainful employment in early recovery, thus stigmatizing and isolating vast numbers of children from a part of mainstream American opportunity. Fear of losing their children already helps to keep many parents from seeking treatment. H.R 3545 exacerbates that problem.

SAMHSA's amendments to Part 2 in 2017 and 2018 have made it much easier to facilitate (with patient consent) the sharing of health information between SUD and other health care providers in electronic health information systems and coordinated care settings. Unfortunately, many in the health care system do not know what these rules allow, and many SUD treatment programs do not have adequate computer systems to enable them to maintain electronic health records.

Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society. An important consequence to preserving that power will be the likelihood that their children will have parents who enter and finish treatment and go on to recovery and obtain gainful employment to help support their families, thus giving their children an equal opportunity to succeed.

For these reasons, we oppose H.R. 3545 and instead support the following bills that are critical to preserving patient confidentiality and coordinating care between various health providers:

- **The Senate's bipartisan "Opioid Crisis Response Act of 2018:"** Provides model programs and materials for training health providers and compliance staff on the permitted uses and disclosures of substance use disorder information, and training family members and patients on their rights to protect and obtain substance use disorder information.
- **H.R. 3331 – Introduced by Representative Lynn Jenkins and co-sponsored by Representative Doris Matsui:** Provides needed incentive payments to substance use disorder and behavioral health providers to obtain certified electronic health record technology.

Thank you for considering the unintended consequences of H.R. 3545 to already vulnerable children.

Sincerely,



Sis Wenger
President/CEO

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (201) 225-2827
Minority (201) 225-3641

May 24, 2018

Dr. H. Westley Clark
Dean's Executive Professor, Public Health Program
Santa Clara University
Santa Clara, CA

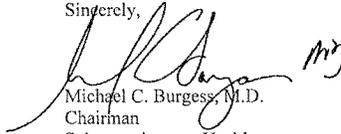
Dear Dr. Clark:

Thank you for appearing before the Subcommittee on Health on May 8, 2018, to testify at the hearing entitled "Improving the Coordination and Quality of Substance Use Disorder Treatment."

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 June 8, 2018. Your responses should be mailed to Kristen Shatynski, Professional Staff Member, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Kristen.shatynski@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 30, 2018

Ms. Kristen Shatynski
Professional Staff Member
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Ms. Kristen Shatynski

At the request of the Honorable Frank Pallone, Jr. and as a result of the Subcommittee on Health hearing on May 8, 2018, I was asked if I was aware of any legal cases involving 42 CFR Part 2 and/or 42 USC 290dd-2. Below you will find a partial list of cases involving 42 CFR Part 2 and 42 USC 290dd-2 and/or predecessor citations. This information was acquired from Google Scholar using the search term "42 USC 290-dd"; this information does not represent all the case involving the indicated statute and/or the indicated regulation. By using Google Scholar, the details and the content of the cases can be verified.

The partial list below involves decision, memoranda, orders or direct reference to 42 USC 290dd-2 and/or 42 CFR Part 2 or predecessor citation. The Federal cases are arranged by Circuit. The state cases are arranged by State jurisdictions.

I hope that this answers Representative Pallone's question.

Sincerely,

A handwritten signature in black ink, appearing to read "H. Westley Clark".

H. Westley Clark, MD, JD, MPH
Dean's Executive Professor of Public Health

Public Health Program, Santa Clara University
500 El Camino Real, Santa Clara, CA 95053-0269
408-554-5422 www.scu.edu/cas/phs

FEDERAL CASES INVOLVING 42 USC 290dd-2 and/or 42 CFR Part 2

First Circuit

18 F.2d 1005 (1987)

Ursula C. WHYTE, etc., et al., Plaintiffs, Appellees,
v.
CONNECTICUT MUTUAL LIFE INSURANCE
COMPANY, Defendant, Appellant.
Ursula C. WHYTE, a/k/a Wendy Whyte, as Trustee
of the S. William Whyte Revocable Trust, Plaintiff,
Appellant,
v.
CONNECTICUT MUTUAL LIFE INSURANCE
COMPANY, Defendant, Appellee.
Nos. 86-1295, 86-1296.
United States Court of Appeals, First Circuit.
Argued September 9, 1986.
Decided May 11, 1987.

95 F.Supp.2d 49 (2000)

UNITED STATES of America,
v.
John Patrick HUGHES, Defendant.

No. Crim.A.99-10405-REK.

United States District Court, D. Massachusetts.

May 12, 2000.

825 F.2d 538 (1987)

UNITED STATES of America, Appellee,
v.
Robert D. CRESTA, Defendant, Appellant.
UNITED STATES of America, Appellee,
v.
John J. GILLEN, Jr., Defendant, Appellant.
UNITED STATES of America, Appellee,
v.
Anthony GRAVALLESE, Defendant, Appellant.
UNITED STATES of America, Appellee,
v.
Guido IMPEMBA, Defendant, Appellant.
UNITED STATES of America, Appellee,
v.
Gabriel CARVAJAL, Defendant, Appellant.
UNITED STATES of America, Appellee,
v.
Ernesto AGUDELO, Defendant, Appellant.
UNITED STATES of America, Appellee,
v.
Richard T. FORD, Defendant, Appellant.

Nos. 85-1010, 85-1022, 85-1024 to 85-1028.

United States Court of Appeals, First Circuit.

Argued September 8, 1986.

Decided July 23, 1987.

(2006)

UNITED STATES OF AMERICA,
v.
CHRISTOPHER SMITH, Defendant.
Crim. No. S-73-B-JAW.
United States District Court, D. Maine.
January 6, 2006.

(2007)

UNITED STATES OF AMERICA, Appellee,
v.
CHRISTOPHER SMITH, Defendant, Appellant.
No. 06-2247.
United States Court of Appeals, First Circuit.
December 21, 2007.

515 F.3d 5 (2008)

UNITED STATES of America, Appellee,
v.
Mark S. SHINDERMAN, M.D., Defendant,
Appellant.
No. 07-1569.
United States Court of Appeals, First Circuit.
Heard November 7, 2007.
Decided January 29, 2008

(2011)
 Richard McEvoy, Shelagh McEvoy, Co-administrators of the Estate of Kevin McEvoy, v.
 Hillsborough County et al.
Civ. No. 09-cv-431-SM.
 United States District Court, D. New Hampshire.
 May 5, 2011.

Second Circuit

899 F.Supp. 933 (1995)
 John DOE and Jane Doe, Plaintiffs, v.
 Naomi MARSH et al., Defendants.
No. 93-cv-0676.
 United States District Court, N.D. New York.

70 F.Supp.2d 225 (1999)
 UNITED STATES of America, v.
 Thomas G. LONGO, Defendant.
No. 97-CR-180S.
 United States District Court, W.D. New York.
 August 5, 1999.

(2005)
 PORT WASHINGTON TEACHERS' ASSOCIATION, AMERICAN FEDERATION OF TEACHERS, LOCAL 2938, NYSUT, AFL-CIO, MARY ANNE CARIELLO, as President of the Port Washington Teachers' Association, and MICHELLE WEIDEN, on behalf of themselves and the female students of the Port Washington Union Free School, Plaintiffs, v.
 BOARD OF EDUCATION OF THE PORT WASHINGTON UNION FREE SCHOOL DISTRICT;
 LAURA MOGUL, NANCY V. COWLES, MARK MARCELLUS, DEAN NARDONE, DR. ROY NELSON, ROBERT SEIDEN, and DAVID STROM, as members of the Board of Education of the Port Washington Union Free School District and in their individual capacities; and DR. GEOFFREY N. GORDON,

as Superintendent of the Port Washington Union Free School District and in his individual capacity, Defendants.
04-CIV-1357 (TCP)(MJW).
 United States District Court, E.D. New York.
 March 22, 2005.

568 F. Supp. 2d 220 (2008)
 Luis SANABRIA, Plaintiff, v.
 Officer Steven MARTINS, Defendant.
Civil No. 3:06cv647 (JBA).
 United States District Court, D. Connecticut.
 March 26, 2008.

(2014)
 MILTON OMAR COLON et al., Plaintiffs, v.
 METRO-NORTH COMMUTER RAILROAD COMPANY et al., Defendants.
Case No. 3:13CV325 (JAM).
 United States District Court, D. Connecticut.
 April 3, 2014.

(2014).
 KEITH RICHARDSON, Plaintiff, v.
 NEW YORK STATE OFFICE OF MENTAL HEALTH, CENTRAL NEW YORK PSYCHIATRIC CENTER et al., Defendants.
No. 6:11-cv-1007 (GLS/ATB).
 United States District Court, N.D. New York.
 August 4, 2014.

Third Circuit

896 F.Supp. 179 (1994)
 John MULHOLLAND and Pamela Mulholland v.
 DIETZ COMPANY and Entwistle Corporation.
Civ. A. No. 94-3517.
 United States District Court, E.D. Pennsylvania.
 December 5, 1994.

933 F.Supp. 485 (1996)
 Clarence CARR, Plaintiff,
 v.
 ALLEGHENY HEALTH, EDUCATION AND
 RESEARCH FOUNDATION
 and Allegheny General Hospital, Defendants.
 Civil Action No. 95-523.
 United States District Court, W.D. Pennsylvania.
 August 9, 1996.

(2005)

GONZALEZ,
 v.
 CITY OF HOBOKEN, et als.
 Docket No. 04-CV-3556 (WJM).
 United States District Court, D. New Jersey.
 June 30, 2005

(2009)

KATHRYN MEGONNELL, Plaintiff,
 v.
 INFOTECH SOLUTIONS, INC. u/d/b/a AVYSION
 IT and/or
 AVYSION HEALTHCARE SERVICES, PAMELA
 HUNTER
 AND LEONARD TOKAR, Defendants
 Civil Action No. 1:07-cv-02339.
 United States District Court, M.D. Pennsylvania.
 November 18, 2009.

(2010)

JIRI PIK,
 v.
 THE UNIVERSITY OF PENNSYLVANIA, et al.
 Civil Action No. 08-5164.
 United States District Court, E.D. Pennsylvania.
 October 7, 2010.

791 F.Supp.2d 383 (2011)
 David BEHAR, M.D., Plaintiff
 v.
 PENNSYLVANIA DEPARTMENT OF
 TRANSPORTATION
 and Allen Biehler, Defendants.
 Civil Action No. 1:09-CV-2453.
 United States District
 March 31, 2011

Fourth Circuit

955 F.2d 914 (1992)
 UNITED STATES OF America, Plaintiff-Appellee,
 v.
 SOUTHERN MANAGEMENT CORPORATION,
 Defendant-Appellant.
 No. 90-2496.
 United States Court of Appeals, Fourth Circuit.
 Argued July 31, 1991.
 Decided February 3, 1992.

(2012)

45. UNITED STATES OF AMERICA,
 v.
 GRACIE BELLOSI-MITCHELL
 Case No. RWT 10er600.
 United States District Court, D. Maryland.
 September 6, 2012.

(2014)

JOHN VANNOY, Plaintiff,
 v.
 THE FEDERAL RESERVE BANK OF
 RICHMOND, Defendant.
 Action No. 3:13-CV-797
 United States District Court, E.D. Virginia,
 Richmond Division.
 June 10, 2014.

(2014)

MICHAEL ALAN CROOKER, Petitioner
 v.
 TIMOTHY STEWART, Respondent.
 Civil Action No. ELH-14-1539.
 United States District Court, D. Maryland.
 December 16, 2014.

(2017).

THOMAS SINSEL, Plaintiff,
 v.
 HITACHI KOKI USA, LTD., Defendant.
 Case No. 7:16-cv-00412-D.
 United States District Court, E.D. North Carolina,
 Southern Division.
 May 31, 2017

(2017)
 MICHAEL J. MORGAN, Plaintiff,
 v.
 RICKY J. SPIVEY, in his individual and official capacities as a Wake County Sheriff's Deputy,
 CASEY L. MILLER, in his individual and official capacities as a Wake County Sheriff's Deputy,
 JOSHUA K. LEGAN, in his individual and official capacities as a Wake County Sheriff's Deputy,
 DONNIE HARRISON, in his official capacity as Sheriff of Wake County, North Carolina,
 THE OHIO CASUALTY INSURANCE COMPANY, individually, and as a subsequent subsidiary of
 LIBERTY MUTUAL INSURANCE COMPANY, as SURETY, Defendants.
No. 5:16-CV-365-FL,
 United States District Court, E.D. North Carolina, Western Division.
 December 8, 2017.

Fifth Circuit

408 F.Supp.2d 295 (2006)
 UNITED STATES of America
 v.
 Diana ZAMORA.
No. CR C-05-746M,
 United States District Court, S.D. Texas, Corpus Christi Division.
 January 10, 2006.

Sixth Circuit

63 F.3d 467 (1995)
 Rick R. ELLISON, Plaintiff-Appellant,
 v.
 COCKE COUNTY, TENNESSEE and David Kickliter, M.D., Defendants-Appellees.
No. 94-5577,
 United States Court of Appeals, Sixth Circuit.
 Submitted April 10, 1995.
 Decided August 24, 1995.

88 F.Supp.2d 753 (2000)
 Gary Wayne FANNON, Plaintiff,
 v.
 Kurt JOHNSTON, Defendant.
No. Civ. 98-CV-72006-DT,
 United States District Court, E.D. Michigan, Southern Division.
 March 24, 2000.

(2011)
 SAMUEL JEFFERSON, Plaintiff,
 v.
 FERRER, POIROT, AND WANSBROUGH, et al., Defendants.
No. 3:10-0754,
 United States District Court, M.D. Tennessee, Nashville Division.
 July 25, 2011.

(2014)
 SAMUEL JEFFERSON, Plaintiff,
 v.
 FERRER, POIROT & WANSBROUGH, et al., Defendants
Case No. 3:10-0754,
 United States District Court, M.D. Tennessee, Nashville Division.
 March 13, 2014.

(2015)
 CARL WATSON RICCHUITE, Plaintiff,
 v.
 JOEY JOHNSON, et al., Defendants.
Civil Action No. 1:14-CV-104-GNS-HBB,
 United States District Court, W.D. Kentucky, Bowling Green Division.
 September 25, 2015

(2016).
 GARDEN CITY EMPLOYEES' RETIREMENT SYSTEM, Plaintiff,
 CENTRAL STATES, SOUTHEAST SOUTHWEST AREAS PENSION FUND,
 Individually and on Behalf of All Others Similarly Situated, Lead Plaintiffs,
 BEVERLY KERN, on Behalf of Herself and Her Siblings,

and as Administrator of the Estate of Donna Kern,
Intervenor,
v.
PSYCHIATRIC SOLUTIONS, INC., et al.,
Defendants.
No. 3:09-cv-00882.
United States District Court, M.D. Tennessee,
Nashville Division.
September 20, 2016.

277 F.3d 969 (2002)
UNITED STATES of America ex rel. Janet
CHANDLER, Ph.D.,
Plaintiff Appellant, Cross-Appellee,
v.
COOK COUNTY, ILLINOIS,¹¹¹ Defendant-Appellee,
Cross-Appellant.
Nos. 00-4110, 01-1810.
United States Court of Appeals, Seventh Circuit.
Argued September 5, 2001.
Decided January 22, 2002.

Seventh Circuit

670 F.2d 702 (1982)
UNITED STATES of America, Plaintiff-Appellee,
v.
Alex J. RAINERI, Defendant-Appellant.
No. 81-1394.
United States Court of Appeals, Seventh Circuit.
Argued September 15, 1981.
Decided February 8, 1982.
Rehearing and Rehearing Denied March 24, 1982

854 F.Supp. 1380 (1994)
In re The AUGUST, 1993 REGULAR GRAND
JURY. (Hospital Subpoena).
Misc. No. 93-63, Grand Jury Subpoena No. KMS-41-
04.
United States District Court, S.D. Indiana,
Indianapolis Division.
May 20, 1994.

168 F.3d 1036 (1999)
Carlos CHAPA, Plaintiff-Appellant,
v.
Jura ADAMS, et al., Defendants-Appellees.
No. 98-1869.
United States Court of Appeals, Seventh Circuit.
Argued January 22, 1999.
Decided February 23, 1999.

(2005)
LISA M. BEARD, Plaintiff,
vs.
CITY OF CHICAGO, Defendant.
No. 03 C 3527.
United States District Court, N.D. Illinois, Eastern
Division.
January 7, 2005.

(2006)
LORA L. STANLEY, et al., Plaintiffs,
v.
CARRIER MILLS-STONEFORT SCHOOL
DISTRICT NO. 2,
and RICHARD MORGAN, Defendants.
Civil No. 05-4203-JPG.
United States District Court, S.D. Illinois.
December 14, 2006.

(2013)
MIRANDA COSGROVE and CHRISTINA
COSGROVE, Plaintiffs,
v.
RODNEY D. McCLURE, individually and as an
agent and/or employee of PIONEER COACH, INC.;
PIONEER COACH, INC., a foreign corporation;
PHILLIP L. CARTER,
individually as an agent and/or employee of JEFFCO
LEASING CO., INC.;
and JEFFCO LEASING CO., INC., a foreign
Corporation. Defendants.
Case No. 3:13-cv-00580-DRH-DGW.
United States District Court, S.D. Illinois.
October 28, 2013.

Eighth Circuit

(2006)

R. KOTESWARA RAO KUNDA and CHICAGO INSURANCE CO., Plaintiffs,
v.
ST. ANTHONY MEDICAL CENTER SELF-INDENTURED TRUST, et al., Defendants.

No. 4:06-CV-0187 CEJ

United States District Court, E.D. Missouri, Eastern Division.

August 22, 2006.

(2017)

MADISON GIROUX by her Attorney-in-fact, JENNIFER GIROUX, Plaintiff,
v.
TOMMI YOUNG BULL BEAR, EMT Director, City/County Alcohol and Drug Program, in her individual capacity;

BRENDA WOOD, Director City/County Alcohol and Drug Program, in her individual capacity;

PENNINGTON COUNTY SHERIFF'S DEPUTY PAUL STEVENS, in his individual capacity;

and PENNINGTON COUNTY STATE'S ATTORNEY SARAH E. MORRISON, in her individual capacity, Defendants.

No. CIV. 16-5003-JLY

United States District Court, D. South Dakota,

Western Division.

March 22, 2017

(2017)

IN RE EMPLOYMENT RECORDS OF JOHN DOES EMPLOYED BY SHARPE HOLDING, INC.,
No. 4:17MC238 RLW

United States District Court, E.D. Missouri, Eastern Division.

December 20, 2017.

Ninth Circuit

879 F.Supp. 1054 (1995)

UNITED STATES of America, Plaintiff,
v.
Gary Lee SNOWDEN, Defendant.
No. CR 94-38-RE
United States District Court, D. Oregon.
February 10, 1995.

146 F.3d 680 (1998)

Donald HALVORSEN, Jr., Plaintiff-Appellant,
v.
Lawrence BAIRD; Jeffrey Kaer; City of Portland; Central City Concern;
Dick Endo; Aaron Beedle; Jeff Mitchell; Joe Brown, Defendants-Appellees.
Donald HALVORSEN, Jr., Plaintiff-Appellee,
v.
Lawrence BAIRD; Jeffrey Kaer; City of Portland; Aaron Beedle; Dick Endo, Defendants,
and
Central City Concern; Jeff Mitchell; Joe Brown, Defendants-appellants.
Nos. 95-35677, 95-35705
United States Court of Appeals, Ninth Circuit.
Argued and Submitted November 5, 1996.
Decided June 11, 1998.

(2010)

LISA LOWEN, as next friend and natural parent of minor B.L., Plaintiff,
v.
VIA CHRISTI HOSPITALS WICHITA, INC. d/b/a St. Francis Campus,
and KIMBERLY MOLIK, M.D., and HENRY B. DOERING, M.D., Defendants.
Case No. 10-1201-RDR
United States District Court, D. Kansas.
November 16, 2010.

(2013)
 MARIA D. CHAVEZ and RENE CHAVEZ,
 individually and as the Successors-in-Interest of
 CHRISTIAN CHAVEZ, Deceased, Plaintiff,
 v.
 COUNTY OF KERN, TOMMY J. ROBBINS,
 JEREMY STORAR, AND DOES 1 TO 100,
 Defendants.
Case No. 1:12-cv-01004-LJO-JLT,
 United States District Court, E.D. California.
 July 9, 2013.

(2013)
 DEBORAH CAHILL, Plaintiff,
 v.
 FRANCISCAN HEALTH SYSTEM, Defendant.
Case No. C12-5829 BHS,
 United States District Court, W.D. Washington,
 Tacoma.
 December 16, 2013.

(2014)
 KETEMA ROSS, et al., Plaintiffs, v.
 JAY INSLEE, in his official capacity as Governor of
 Washington, et al., Defendants.
No. 2:14-CV-0130-TOR,
 United States District Court, E.D. Washington.
 August 4, 2014.

(2016)
 ROBERT DeWAYNE BOSLEY, JR., Plaintiff,
 v.
 M. VALASCO, et al., Defendants.
Case No. 1:14-cv-00049-MJS(PC),
 United States District Court, E.D. California.
 January 8, 2016.

(2016)
 ROBERT DEWAYNE BOSLEY, JR. Plaintiff,
 v.
 M. VALASCO, et al., Defendants.
Case No. 1:14-cv-00049-MJS(PC),
 United States District Court, E.D. California.
 March 25, 2016

(2016)
 Lawrence N. Cherry, et al., Plaintiffs,
 v.
 United States of America, Defendant.
No. CV-15-00236-PHX-PGR,
 United States District Court, D. Arizona.
 August 31, 2016.

(2016)
 CHARLES DES ROCHEs, on his own behalf and on
 behalf of his beneficiary son,
 R.D., and all others similarly situated, and SYLVIA
 MEYER, on her own behalf and all others similarly
 situated, Plaintiff,
 v.
 CALIFORNIA PHYSICIANS' SERVICE d/b/a
 BLUE SHIELD OF CALIFORNIA;
 HUMAN AFFAIRS INTERNATIONAL OF
 CALIFORNIA; and
 MAGELLAN HEALTH SERVICES OF
 CALIFORNIA, INC.—EMPLOYER SERVICES,
 Defendant.
 Case No. 16-cv-02848-LHK.
 United States District Court, N.D. California, San
 Jose Division.
 September 7, 2016.

(2016)
 ANTOINE DOUGLASS JOHNSON, Petitioner,
 v.
 FELICIA PONCE, Respondent.
No. 2:16-cv-1037 JAM.ACP,
 United States District Court, E.D. California.
 December 16, 2016.

(2018)
 ESTATE OF SANDRA VELA, deceased, by and
 through ANNAMARIE MORENO;
 ANNAMARIE MORENO; and BERNADETTE
 ALVERADO, Plaintiff,
 v.
 COUNTY OF MONTEREY; SHERIFF STEVE
 BERNAL, in his individual and official capacities;
 COMMANDER JAMES BASS, in his individual
 and official capacities; SERGEANT ERIKA KAYE,
 in her individual capacity;
 SERGEANT CAROL WHITE, in her individual
 capacity; DEPUTY BARBARA FULKERSON, in
 her individual capacity;

DEPUTY N. QUINTERO, in her individual capacity;
 FORMER SHERIFF SCOTT MILLER, in his
 individual capacity;
 CALIFORNIA FORENSIC MEDICAL GROUP,
 TAYLOR FITHIAN, MD; ELUID GARCIA, MD,
 Defendants.
 Case No. 16-CV-02375 BLF.
 United States District Court, N.D. California, San
 Jose Division.
 January 18, 2018.

(2006)
 CAROL J. HULSE,
 v.
 SUBURBAN MOBILE HOME SUPPLY
 COMPANY, et al., Defendants.
[Case No. 06-1168-WEB](#).
 United States District Court, D. Kansas.
 October 12, 2006.

Tenth Circuit

F.3d 1414 (1998)
 UNITED STATES of America, Plaintiff-Appellee,
 v.
 Frank Anthony OBERLE, Defendant-Appellant.
[No. 96-2275](#).
 United States Court of Appeals, Tenth Circuit.

320 F.3d 1107 (2003)
 CENTER FOR LEGAL ADVOCACY, doing
 business as Legal Center for People with Disabilities
 and Older People, also known as Legal Center,
 Colorado's Protection and Advocacy System,
 P & A System, Plaintiff-Appellant,
 v.
 Michael EARNEST, M.D., in his official capacity as
 Medical Director of Quality Review and
 Improvement;
 Patricia Gabow, M.D., in her official capacity as
 Medical Director and Chief Executive Officer;
 Denver Health and Hospital Authority, also known as
 DHHA, doing business as Denver Health Medical
 Center,
 also known as DHMC, Defendants-Appellees.
[No. 02-1135](#).
 United States Court of Appeals, Tenth Circuit.
 February 25, 2003.

(2006)
 MIKE BOHANNON, Plaintiff,
 v.
 J.M. BAKER, D.O. Defendant.
[Case No. 06-1033-MLB](#).
 United States District Court, D. Kansas.
 October 12, 2006.

(2007)
 JEREMY BUSTAMANTE, Plaintiff,
 v.
 CENTRAL KANSAS MEDICAL CENTER, a
 Kansas Corporation, Defendant.
[Case No. 06-1336-WEB](#).
 United States District Court, D. Kansas.
 May 1, 2007.

(2007)
 JEREMY BUSTAMANTE, Plaintiff,
 v.
 CENTRAL KANSAS MEDICAL CENTER, a
 Kansas Corporation, Defendant.
[Case No. 06-1336-WEB](#).
 United States District Court, D. Kansas.
 May 11, 2007.

(2007)
 LORI PRESCOTT, Plaintiff,
 v.
 TREGO COUNTY, KANSAS, BOARD OF
 COUNTY COMMISSIONERS,
 RICHARD SCHNEIDER, and DENNIS WEAVER,
 Defendants.
[Case No. 07-CV-1008-ITM-DWB](#).
 United States District Court, D. Kansas.
 May 16, 2007.

(2008)
 REBECCA SORTER, Plaintiff,
 v.
 RICARDO ALVARADO, Defendant.
Case No. 07-1401-MLB-DWB.
 United States District Court, D. Kansas, Wichita.
 March 3, 2008

(2008)
 AT WICHITA, KANSAS ROBERT MILLER,
 Plaintiff,
 v.
 E.F.V., minor, and LARRY V. VASQUEZ, father,
 legal guardian,
 and next best friend, Defendants.
Case No. 08-1114-JTM-DWB.
 United States District Court, D. Kansas.
 June 10, 2008.

(2010)
 JENNIFER PRATT, Plaintiff,
 v.
 JOSEPH PETELIN, M.D. and DANIEL PALEY,
 M.D., Defendants.
Case No. 09-2252-CM-GLR.
 United States District Court, D. Kansas.
 February 4, 2010.

(2010).
 GEORGE SPRAGGINS, Plaintiff,
 v.
 SUMNER REGIONAL MEDICAL CENTER
 and DR. LARRY ANDERSON, Defendants.
Case No. 10-2276-WEB/KGG.
 United States District Court, D. Kansas.
 November 3, 2010.

(2010)
 UNITED STATES OF AMERICA, ex rel. ANA
 SANCHEZ-SMITH,
 AMBER HAVERFIELD-CHATWELL, and DANA
 WHITE, Plaintiffs,
 v.
 AHS TULSA REGIONAL MEDICAL CENTER,
 LLC,
 d/b/a TULSA REGIONAL MEDICAL CENTER,
 Defendant.

No. 05-CV-442-TCK-PJC.
 United States District Court, N.D. Oklahoma.
 November 5, 2010.

(2010)
 754 F.Supp.2d 1270 (2010)
 UNITED STATES of America, ex rel. Ana
 SANCHEZ-SMITH,
 Amber Haverfield-Chatwell, and Dana White,
 Plaintiffs,
 v.
 AHS TULSA REGIONAL MEDICAL CENTER,
 LLC,
 d/b/a Tulsa Regional Medical Center, Defendant.
Case No. 05-CV-442-TCK-PJC.
 United States District Court, N.D. Oklahoma.
 November 10, 2010.

(2013)
 NICOLETTE UTTER, Administrator of the Estate of
 CHRISTOPHER UTTER, Plaintiff,
 v.
 DALLAS THOMPSON, et al., Defendants.
Case No. 11-2360-KHV.
 United States District Court, D. Kansas.
 June 7, 2013

(2014)
 SHAWN GIEGERICH, Plaintiff,
 v.
 NATIONAL BEEF PACKING COMPANY, LLC,
 Defendant.
Case No. 13-2392-JAR.
 United States District Court, D. Kansas.
 January 9, 2014.

(2015).
 ANTHONY LOLIN JIMENEZ, SR., Applicant,
 v.
 COLORADO DEPARTMENT OF CORRECTIONS,
 RICK RAEMISCH (Exec. Dir.),
 CROWLEY COUNTY CORRECTIONAL
 FACILITY, MICHAEL MILLER (Warden),
 and THE ATTORNEY GENERAL OF THE STATE
 OF COLORADO, Respondents.
Civil Action No. 15-cv-01006-GPG.
 United States District Court, D. Colorado.
 July 8, 2015.

(2015).

CHARLES EVANS, Plaintiff,
v.
WILLIAM D. MAUCH, M.D., Defendant.
Case No. 2:15-CV-09100-CM,
United States District Court, D. Kansas.
August 26, 2015.

(2016)

FRANKIE T. LYDEN, individually, and FRANKIE
T. LYDEN,
as Special Administrator of the Estate of Michael
Lyden,
deceased, on behalf of the Heirs of MICHAEL
LYDEN, deceased, Plaintiffs,
v.
HOGAN DEDICATED SERVICES, LLC, A
Missouri corporation;
HOGAN TRANSPORTS, INC., a Missouri
Corporation;
HOGAN TRUCK LEASING, INC., dba HOGAN
MOTOR LEASING, INC.,
A Missouri corporation
and MICHAEL DANIELY, a Missouri resident,
Defendants.
Case No. 15-CV-9289-CM,
United States District Court, D. Kansas at Kansas
City, Kansas.
April 4, 2016.

(2017)

MARK RATLEY, Plaintiff,
v.
UNITED STATES OF AMERICA, Defendant.
Case No. 17-4024-DDC,
United States District Court, D. Kansas.
July 20, 2017.

Eleventh Circuit

951 F.2d 320 (1992)
Bill W. DOE, Plaintiff-Appellant,
v.
Anthony M. FRANK, Postmaster General
of the United States of America, Defendant-Appellee.
No. 91-5063,
United States Court of Appeals, Eleventh Circuit.
January 24, 1992.

196 F.3d 1226 (1999)

Raymond D. HICKS, M.D., Plaintiff-Appellee,
v.
TALBOTT RECOVERY SYSTEM, INC. a.k.a.
Talbot Marsh Recovery System or Talbot Marsh
Recovery Center,
Anchor Hospital, Barry H. Lubin, M.D., G. Douglas
Talbot, M.D., Defendants-Appellants.
No. 98-8821,
United States Court of Appeals, Eleventh Circuit.
November 22, 1999

170 F.Supp.2d 1211 (2001)

Gary P. MOSIER, Plaintiff,
v.
AMERICAN HOME PATIENT, INC., Defendant.
No. 4:01CV11-WS,
United States District Court, N.D. Florida,
Tallahassee Division.
November 1, 2001

(2013)

47. IN THE MATTER OF: WILLIAM ARTHUR
ASHCRAFT, D.M.D.
Civil Action No. 2:13-cv-00623-WMA,
United States District Court, N.D. Alabama, Southern
Division.
June 3, 2013.

(2016)

UNITED STATES OF AMERICA, Plaintiff,
v.
XIULU RUAN, M.D., Defendant.
Criminal No. 15-00088-CG-B,
United States District Court, S.D. Alabama, Southern
Division.
April 4, 2016.

DC Circuit

598 F.Supp. 126 (1984)
George L. WHITLOCK, Plaintiff,
v.
Raymond J. DONOVAN and United States
Department of Labor, Defendants.
Civ. A. No. 83-3388.
United States District Court, District of Columbia.
November 6, 1984.

63 F.2d 103 (1988)
Frederick D. JUDD, Appellant
v.
James H. BILLINGTON, Librarian of Congress.
No. 87-5380.
United States Court of Appeals, District of Columbia
Circuit.
Argued November 15, 1988.
Decided December 20, 1988.

**STATE CASES
Involving 42 USC 290dd-2 and/or
42 CFR Part 2**

ALABAMA

773 So.2d 431 (2000)
Ex parte Dr. Walter L. ETHERTON.
(Re Tammy Reynolds Freeman v. Dr. Walter L.
Etherton).
1981962.
Supreme Court of Alabama.
March 17, 2000.
Rehearing Denied June 9, 2000.

156 So.3d 973 (2014)
W.A.A.
v.
BOARD OF DENTAL EXAMINERS OF
ALABAMA.
2121026.
Court of Civil Appeals of Alabama.

ALASKA

89 P.3d 800 (2004)
Diana BRYSON, Petitioner/Cross-Respondent,
v.
BANNER HEALTH SYSTEM d/b/a Fairbanks
Memorial Hospital
d/b/a Family Recovery Center and Guy Patterson,
Respondents/Cross-Petitioners.
Nos. S-10653, S-10673.
Supreme Court of Alaska.
April 23, 2004.

338 P.3d 953 (2014)
John W. PLETCHER IV, Appellant,
v.
STATE of Alaska, Appellee.
No. A-11492.
Court of Appeals of Alaska.
November 21, 2014.

ARIZONA

157 Ariz. 41 (1987)
754 P.2d 1145
Harry A. DANIELSON, M.D., and Jane Doe
Danielson,
whose true name is Beverly Ann Danielson, husband
and wife, Petitioners,
v.
SUPERIOR COURT OF the STATE OF ARIZONA,
In and For the COUNTY OF MARICOPA,
Honorable John Foreman, a judge thereof,
Respondent Judge, Joyce LOPEZ and Richard Lopez,
husband and wife, Real Parties in Interest.
No. 1 CA-SA 200.
Court of Appeals of Arizona, Division 1, Department
A.
December 8, 1987.
As Amended on Denial of Reconsideration March
14, 1988.
Review Denied June 7, 1988.

(2012)
 STATE OF ARIZONA, Appellee,
 v.
 VICTOR PEREZ CANO, Appellant.
No. 1 CA-CR 11-0473.
 Court of Appeals of Arizona, Division One,
 Department B (AUGUST).
 Filed September 20, 2012.

290 P.3d 228 (2012)
 231 Ariz. 34
 STATE of Arizona, Appellee,
 v.
 Terry Wayne TATLOW, Appellant.
No. 1 CA-CR 11-0593.
 Court of Appeals of Arizona, Division 1, Department
 C.
 December 4, 2012

(2013)
 STATE OF ARIZONA, Appellee,
 v.
 DAVID ALAN HOUSE, Appellant.
No. 1 CA-CR 12-0354.
 Court of Appeals of Arizona, Division One,
 Department C.
 Filed January 17, 2013.

ARKANSAS

No Cases in Google Scholar Discovered

CALIFORNIA CASE

(2010)
 MICHAEL MARQUEZ, Petitioner,
 v.
 THE SUPERIOR COURT OF LOS ANGELES
 COUNTY, Respondent;
 ESTATE OF PABLO GARCIA, et al., Real Parties
 in Interest.
No. B221965.
 Court of Appeals of California, Second District,
 Division Seven.
 Filed May 18, 2010.

COLORADO

668 P.2d 3 (1983)
 Stephan D. CLARK, Petitioner,
 v.
 DISTRICT COURT, SECOND JUDICIAL
 DISTRICT, CITY
 AND COUNTY OF DENVER;
 Daniel B. Sparr, one of the judges thereof;
 Estates of Sailas, Respondents.
No. 83SA182.
 Supreme Court of Colorado, En Banc.
 August 29, 1983

944 P.2d 660 (1997)
 The PEOPLE of the State of Colorado Through the
 DENVER
 DEPARTMENT OF SOCIAL SERVICES, In the
 Interest of R.D.H.
 and P.H., Children, Upon the Petition of the Denver
 County
 Department of Social Services, Petitioner-Appellee,
 and Concerning K.L.H., Respondent-Appellant.
No. 96CA0106.
 Colorado Court of Appeals, Div. II.
 May 29, 1997.
 Rehearing Denied June 26, 1997.
 Certiorari Denied October 20, 1997

217 P.3d 841 (2008)
 The PEOPLE of the State of Colorado, Plaintiff-
 Appellee,
 v.
 Anthony Lolín JIMENEZ, Defendant-Appellant.
No. 04CA1098.
 Colorado Court of Appeals, Div. VI.
 October 16, 2008.
 Rehearing Denied December 31, 2008.

[SEE FEDERAL CASE ABOVE]

316 P.3d 4 (2013)
 2013 COA 44
 ADOLESCENT AND FAMILY INSTITUTE OF
 COLORADO, INC.,
 a Colorado corporation, Plaintiff-Appellant and
 Cross-Appellee,
 v.

COLORADO DEPARTMENT OF HUMAN SERVICES, DIVISION OF BEHAVIORAL HEALTH,
f/k/a Alcohol and Drug Abuse Division, Defendant-Appellee and Cross-Appellant.
Court of Appeals No. 11CA2586.
Colorado Court of Appeals, Div. II.
Announced March 28, 2013.

55 Conn. App. 336 (1999)
IN RE JAMES L.¹²
(AC 17869), (AC 18155)
Appellate Court of Connecticut.
Argued June 2, 1999.
Officially released October 19, 1999.
[Footnote 14]

CONNECTICUT

203 Conn. 641 (1987)
STATE OF CONNECTICUT
v.
JEFFREY ROLLINSON
(12814)
Supreme Court of Connecticut.
Argued April 8, 1987.
Decision released June 2, 1987.

263 Conn. 390 (2003)
STATE OF CONNECTICUT
v.
RANDY KIRSCH
(SC 16775)
Supreme Court of Connecticut
Argued February 20, 2003.
Officially released May 6, 2003

DELAWARE

223 Conn. 450 (1992)
CONNECTICUT STATE MEDICAL SOCIETY ET AL.
v.
COMMISSION ON HOSPITALS AND HEALTH CARE
(14456)
Supreme Court of Connecticut.
Argued June 10, 1992.
Decision released August 11, 1992.

683 A.2d 1055 (1996)
STATE of Delaware
v.
Rodney A. BRIGHT, Defendant.
I.D. No. 9412012391.
Superior Court of Delaware, New Castle County.
Submitted: June 4, 1996.
Decided: June 27, 1996.

48 Conn. App. 563 (1998)
IN RE MARVIN M. ET AL.¹³
(AC 16942)
Appellate Court of Connecticut.
Argued November 7, 1997.
Officially released May 5, 1998.

979 A.2d 1138 (2009)
DIVISION OF FAMILY SERVICES, Petitioner,
v.
Ramona REDMAN,¹⁴ John Littleton, Respondents.
No. CS07-02770.
Family Court of Delaware, Sussex County.
Submitted: February 6, 2009.
Decided: April 15, 2009.

54 Conn. App. 663 (1999)
MICHAEL SKAKEL
v.
JONATHAN BENEDICT
(AC 19160)
Appellate Court of Connecticut.
Argued May 27, 1999.
Officially released August 5, 1999¹⁵

980 A.2d 1045 (2009)
DIVISION OF FAMILY SERVICES, Petitioner,
v.
A.B., A.W., Thresholds, Inc., Respondents.
No. CS08-02438.
Family Court of Delaware, Sussex County.
Submitted: December 8, 2008.
Decided: June 25, 2009.

FLORIDA

599 So.2d 749 (1992)
 SERVICE MERCHANDISE COMPANY OF
 FLORIDA, INC., Appellant,
 v.
 John LARSEN, Appellee.
No. 91-2074.
 District Court of Appeal of Florida, Fourth District.
 June 3, 1992.

842 So.2d 177 (2003)
 STATE of Florida, Petitioner,
 v.
 CENTER FOR DRUG-FREE LIVING, INC.,
 Respondent.
No. 5D02-3356.
 District Court of Appeal of Florida, Fifth District.
 March 7, 2003.
 Rehearing Denied April 17, 2003

897 So.2d 501 (2005)
 William N. NELSON, Appellant,
 v.
 LABOR FINDERS, Gallagher Bassett Services, Inc.,
 and Florida Department of Insurance, Division of
 Workers Compensation, Appellees.
No. 1D03-5104.
 District Court of Appeal of Florida, First District.
 February 28, 2005.

974 So.2d 1164 (2008)
 STATE of Florida, Appellant,
 v.
 Meghan D. RUDY, Appellee.
No. 4D06-4924.
 District Court of Appeal of Florida, Fourth District.
 February 20, 2008.

GEORGIA

194 Ga. App. 805 (1990)
 392 S.E.2d 286
 AETNA CASUALTY & SURETY COMPANY
 v.
 RIDGEVIEW INSTITUTE, INC. et al.
A89A1836.
 Court of Appeals of Georgia.
 Decided March 12, 1990.

511 S.E.2d 253 (1999)
 236 Ga. App. 132
 In the Interest of L.H., a child.
No. A98A1720.
 Court of Appeals of Georgia.
 January 28, 1999

521 S.E.2d 199 (1999)
 239 Ga. App. 203
 SLETTTO et al.
 v.
 HOSPITAL AUTHORITY OF HOUSTON
 COUNTY et al.
No. A99A0656.
 Court of Appeals of Georgia.
 July 16, 1999.
 Certiorari Denied October 29, 1999.

717 S.E.2d 190 (2011)
 289 Ga. 881
 BOWLING
 v.
 The STATE.
No. S11A1014.
 Supreme Court of Georgia.
 October 17, 2011.

HAWAII

No Cases in Google Scholar Discovered

IDAHO

No Cases in Google Scholar Discovered

ILLINOIS

764 N.E.2d 1 (2001)
 198 Ill.2d 249
 261 Ill.Dec. 710
 M.A.K., Appellee,
 v.
 RUSH-PRESBYTERIAN-ST.-LUKE'S MEDICAL
 CENTER,
 d/b/a Rush Behavioral Health Center—Du Page,
 Appellant.

No. 90527.
Supreme Court of Illinois.
December 20, 2001.

851 N.E.2d 1243 (2006)
221 Ill.2d 453
James WISNIEWSKI, Appellee,
v.
Reverend Raymond KOWNACKI et al., Appellants.
Nos. 101011, 101014.
Supreme Court of Illinois.
June 2, 2006.

INDIANA

579 N.E.2d 1342 (1991)
TERRE HAUTE REGIONAL HOSPITAL, Inc.
and Hospital Corporation of America, Appellants-
Defendants,
v.
Linda S. TRUEBLOOD, Appellee-Plaintiff.
No. 61A04-9107-CV-223 [1]
Court of Appeals of Indiana, First District.
October 22, 1991.
Rehearing Denied January 13, 1992.

669 N.E.2d 192 (1996)
"Jane DOE", Appellant-Respondent,
v.
DAVIESS COUNTY DIVISION OF CHILDREN
AND FAMILY SERVICES, Appellee-Petitioner.
No. 14A01-9511-JV-361.
Court of Appeals of Indiana.
July 29, 1996.
Transfer Denied October 29, 1996.

694 N.E.2d 1212 (1998)
William F. HURT, Appellant-Defendant,
v.
STATE of Indiana, Appellee-Plaintiff.
No. 82A01-9705-CR-161.
Court of Appeals of Indiana.
May 29, 1998.
Transfer Denied July 8, 1998.

698 N.E.2d 381 (1998)
Larry J. LEY, M.D., and Urological Care, P.C.,
Appellants-Defendants,
v.
Donovan BLOSE and Jean Blose, Appellees-
Plaintiffs.
No. 29A02-9708-CV-553.
Court of Appeals of Indiana.
August 25, 1998.

761 N.E.2d 431 (2001)
Sandra CARTER, Appellant-Respondent,
v.
KNOX COUNTY OFFICE OF FAMILY AND
CHILDREN, Appellee-Petitioner.
No. 42A05-0104-JV-151.
Court of Appeals of Indiana.
November 28, 2001.
Publication Ordered January 14, 2002.

832 N.E.2d 563 (2005)
In the Matter of the INVOLUNTARY
TERMINATION
OF THE PARENT CHILD RELATIONSHIP OF
A.H., L.H., C.H.,
and J.H., Minor Children and Their Mother Annette
Johnston
and Their Father, Jay Haney,
Jay Haney, Appellant-Respondent,
v.
Adams County Office of Family and Children,
Appellee-Petitioner.
No. 01A05-0501-JV-33.
Court of Appeals of Indiana.
August 10, 2005.

IOWA

No Cases in Google Scholar Discovered

KANSAS

272 Kan. 1366 (2002)
39 P.3d 47
STATE OF KANSAS, Appellee,
v.
MICHAEL L. JENKINS, Appellant.
No. 86,320.
Supreme Court of Kansas.
Opinion filed February 1, 2002.

KENTUCKY

No Cases in Google Scholar Discovered

LOUISIANA

638 So.2d 1182 (1994)
 Quelyndreia JACKSON
 v.
 Daniel DENDY, et al.
No. 93 CW 0905,
 Court of Appeal of Louisiana, First Circuit.
 June 24, 1994.

696 So.2d 652 (1997)
 Barry LUGAR
 v.
 BATON ROUGE GENERAL MEDICAL CENTER.
No. 96 CA 1873,
 Court of Appeal of Louisiana, First Circuit.
 June 20, 1997.
 [This case is about breech]

*921 So.2d 1012 (2005)
 Sheri NEWCOMER
 v.
 AMERICAN HOME ASSURANCE COMPANY, et
 al.
No. 2005-C-1242,
 Court of Appeal of Louisiana, Fourth Circuit.
 December 14, 2005

MAINE

637 A.2d 1162 (1994)
 STATE of Maine
 v.
 Ronald W. BOOBAR, Jr.
 Supreme Judicial Court of Maine.
 Argued January 6, 1994.
 Decided March 1, 1994.

MARYLAND

No Cases in Google Scholar Discovered

MASSACHUSETTS

456 Mass. 1003 (2010)
 921 N.E.2d 536
 DWIGHT HIGHTOWER
 v.
 COMMONWEALTH.
SJC-10567,
 Supreme Judicial Court of Massachusetts

464 Mass. 1013 (2013)
 KAREN COUSINEAU
 v.
 COMMONWEALTH.
SJC-11254,
 Supreme Judicial Court of Massachusetts.
 February 20, 2013

MICHIGAN

(2008)
 CAROL JODIS and JAN JODIS,^[1] as Next Friend of
 MIKAYLA GRANGER, a Minor, Plaintiffs-
 Appellants,
 v.
 MICHELLE BRUBAKER, SUE FOWLE, MARY
 STUART, DAVE BABCOCK, NURSE A. VAN
 CAMP,
 DR. DEBRA LUSTY, DR. ALFRED BEDIAKO,
 DR. VERONICA DULA, and
 HILLSDALE COUNTY COMMUNITY HEALTH
 CENTER, Defendants-Appellees, and
 ELIZABETH WARNER and PHILLIP
 BERKEMEIER, Appellants.^[2]
No. 271649,
 Court of Appeals of Michigan.
 January 31, 2008.

PEOPLE OF THE STATE OF MICHIGAN,
 Plaintiff-Appellee,
 v.
 DAVID CHRISTIAN DEJONGE, Defendant-
 Appellant.
No. 295168,
 Court of Appeals of Michigan.
 June 5, 2012.

MINNESOTA

342 N.W.2d 128 (1984)
 STATE of Minnesota, Respondent,
 v.
 David Gerald ANDRING, Appellant.
No. C2-82-294.
 Supreme Court of Minnesota.
 January 13, 1984.

376 N.W.2d 451 (1985)
 STATE of Minnesota, Respondent,
 v.
 Gerry Dean BROWN, Appellant.
No. C1-85-589.
 Court of Appeals of Minnesota.
 November 5, 1985.
 Review Denied December 19, 1985

383 N.W.2d 338 (1986)
 STATE of Minnesota, Respondent,
 v.
 Toby Lynn GULLEKSON, Appellant.
No. C5-85-1647.
 Court of Appeals of Minnesota.
 March 11, 1986.
 Review Denied May 16, 1986.

MISSISSIPPI

No Cases in Google Scholar Discovered

MISSOURI

973 S.W.2d 183 (1998)
 STATE of Missouri ex rel. C.J.V., Relator,
 v.
 The Honorable Michael T. JAMISON, Judge, Circuit
 Court, St. Louis County, Missouri, Respondent.
No. 73917.
 Missouri Court of Appeals, Eastern District, Writ
 Division Two.
 July 31, 1998.

MONTANA

682 P.2d 1365 (1984)
 STATE of Montana, Plaintiff and Appellant,
 v.
 Arthur Leroy MAGNUSON, Defendant and
 Respondent.
No. 83-162.
 Supreme Court of Montana.
 Submitted March 2, 1984.
 Decided June 12, 1984.

NEBRASKA

No Cases in Google Scholar Discovered

NEVADA

No Cases in Google Scholar Discovered

NEW HAMPSHIRE

No Cases in Google Scholar Discovered

NEW JERSEY

239 N.J. Super. 119 (1989)
 570 A.2d 1047
 STATE OF NEW JERSEY, PLAINTIFF,
 v.
 ADAM MARRERO, DEFENDANT.
 Superior Court of New Jersey, Law Division
 (Criminal), Cumberland County.
 Decided November 9, 1989.

NEW MEXICO

No Cases in Google Scholar Discovered

NEW YORK

- 93 Misc.2d 479 (1978)
In the Matter of Doe Children, Alleged to be Neglected. Alic, Respondent.^{1,2}
Family Court, Queens County.
March 7, 1978
- 57 N.Y.2d 399 (1982)
In the Matter of John Short, Respondent-Appellant, v.
Board of Managers of the Nassau County Medical Center, Appellant-Respondent.
Court of Appeals of the State of New York.
Argued October 14, 1982.
Decided November 18, 1982.
- 147 Misc.2d 669 (1990)
Susan W., Plaintiff,
v.
Ronald A., Defendant.
Supreme Court, Queens County.
June 15, 1990
- 149 Misc.2d 200 (1990)
In the Matter of the Guardianship of John D. Alexander, Jr., an Infant.
In the Matter of The Estate of Beverly Clark, Deceased.
Surrogate's Court, Bronx County.
December 12, 1990
- 171 A.D.2d 624 (1991)
In the Matter of David C. Reynolds, Petitioner, v.
Benjamin Ward, as Police Commissioner of The City of New York, et al., Respondents
Appellate Division of the Supreme Court of the State of New York, First Department.
March 28, 1991
- 176 A.D.2d 391 (1991)
In the Matter of Robert J. Shedrick, Appellant, v.
Thomas A. Coughlin, as Commissioner of Correctional Services, et al., Respondents
Appellate Division of the Supreme Court of the State of New York, Third Department.
September 12, 1991
- 180 A.D.2d 866 (1992)
The People of the State of New York, Respondent, v.
Mark Simon, Also Known as Spook, Appellant
Appellate Division of the Supreme Court of the State of New York, Third Department.
February 13, 1992
- 158 Misc.2d 788 (1993)
602 N.Y.S.2d 70
In the Matter of W.H. and Another, Children Alleged to be Neglected. H.H., Respondent.
Family Court, Rockland County.
July 28, 1993
- 163 Misc.2d 373 (1993)
621 N.Y.S.2d 428
In the Matter of Ulster County Department of Social Services, on Behalf of Jane, a Child Alleged to be Neglected. Leslie B., Respondent.
Family Court, Ulster County.
August 23, 1993
- 207 A.D.2d 660 (1994)
616 N.Y.S.2d 38
Jade Napoleoni et al., Respondents, v.
Union Hospital of the Bronx et al., Defendants, and Sushila Gupta et al., Appellants
Appellate Division of the Supreme Court of the State of New York, First Department.
September 1, 1994
- 165 Misc.2d 736 (1995)
630 N.Y.S.2d 850
In the Matter of Brandon A. and Others, Children Alleged to be Permanently Neglected. Claritha P., Respondent. (And Another Action.)
Family Court, Monroe County.
June 15, 1995
- 240 A.D.2d 683 (1997)
659 N.Y.S.2d 495
The People of the State of New York, Respondent, v.
Anthony Rodriguez, Appellant
Appellate Division of the Supreme Court of the State of New York,
Second Department.

173 Misc.2d 879 (1997)
 662 N.Y.S.2d 706
 John Warburton, Claimant,
 v.
 State of New York,¹¹¹ Defendant. (Claim No. 94378-A.)
 Court of Claims.
 August 7, 1997

259 A.D.2d 1047 (1999)
 689 N.Y.S.2d 325
 THE PEOPLE OF THE STATE OF NEW YORK,
 Respondent,
 v.
 GUY LANE, Appellant.
 Appellate Division of the Supreme Court of the State
 of New York, Fourth Department

186 Misc.2d 266 (2000)
 710 N.Y.S.2d 864
 In the Matter of MAXIMO M., a Child Alleged to be
 Neglected.
 ELIZABETH R., Respondent.
 Family Court, Kings County.
 June 24, 2000.

281 A.D.2d 387 (2001)
 721 N.Y.S.2d 383
 JOHN DOE et al., Appellants,
 v.
 JAMES M. INMAN CONSTRUCTION CORP.,
 Defendant and Third-Party Plaintiff, et al.,
 Defendants.
 CATHEDRAL MARBLE AND GRANITE
 COMPANY, Third-Party Defendant-Respondent.
 HARTFORD INSURANCE COMPANY, Nonparty
 Respondent.
 Appellate Division of the Supreme Court of the State
 of New York, Second Department.
 Decided March 5, 2001

188 Misc.2d 470 (2001)
 729 N.Y.S.2d 348
 BRAD H. et al., on Behalf of Themselves and All
 Others Similarly Situated, Plaintiffs,
 v.
 CITY OF NEW YORK et al., Defendants.
 Supreme Court, New York County.
 June 26, 2001.

285 A.D.2d 462 (2001)
 727 N.Y.S.2d 338
 In the Matter of MARLENE D., a Person Alleged to
 be a Juvenile Delinquent, Appellant.
 Appellate Division of the Supreme Court of the State
 of New York, Second Department.

5 Misc.3d 517 (2004)
 785 N.Y.S.2d 292
 THE PEOPLE OF THE STATE OF NEW YORK,
 Plaintiff,
 v.
 PIERRE JOSEPH, Defendant.
 Supreme Court, Kings County.
 September 22, 2004.

71 A.D.3d 1400 (2010)
 898 N.Y.S.2d 742
 L.T., Appellant,
 v.
 TEVA PHARMACEUTICALS USA, INC., et al.,
 Defendants, and
 THE HARVARD DRUG GROUP, L.L.C.,
 Respondent.
 CA 09-01800.
 Appellate Division of the Supreme Court of New
 York, Fourth Department.
 Decided March 19, 2010.

2011 NY Slip Op 50102(U)
 IN THE MATTER OF HAVYN-LEIY "A.," A
 CHILD UNDER THE AGE OF EIGHTEEN YEARS
 ALLEGED TO BE PERMANENTLY NEGLECTED
 BY MORIANNA "B.," Respondent.
 B-xxxx-xx
 Family Court, Clinton County.
 Decided January 20, 2011.

89 A.D.3d 1544 (2011)
 934 N.Y.S.2d 278
 In the Matter of KENNEDIE M. and Another,
 Infants.
 ERIE COUNTY DEPARTMENT OF SOCIAL
 SERVICES, Respondent.
 DOUGLAS M., Appellant, et al., Respondent.
 CHARLES D. HALVORSEN, ESQ., Attorney for
 the Children, Appellant.
 CAF 10-01769.

90 A.D.3d 1224 (2011)
 934 N.Y.S.2d 578
 In the Matter of SIMMONS MACHINE TOOL CORPORATION, Appellant,
 v.
 ST. PETER'S HEALTH CARE SERVICES, Respondent, and JOHN DOE, Respondent.
512534.
 Appellate Division of the Supreme Court of New York, Third Department.
 December 8, 2011.

90 A.D.3d 1655 (2011)
 936 N.Y.S.2d 825
 In the Matter of SHIRLEY A.S., an Infant.
 ERIE COUNTY DEPARTMENT OF SOCIAL SERVICES, Respondent; DAVID A.S., Appellant.
CAF 11-01027.
 Appellate Division of the Supreme Court of New York, Fourth Department.
 December 30, 2011.

NORTH CAROLINA

IN THE MATTER OF: G.D.C., Minor Child.
No. COA06-140
 North Carolina Court of Appeals
 Filed November 7, 2006
 This case not for publication

NORTH DAKOTA

361 N.W.2d 232 (1985)
 HEARTVIEW FOUNDATION,
 a corporation, and Sherman Sandbo, Petitioners,
 v.
 Gerald G. GLASER, Judge of the District Court,
 South Central Judicial District, and Keith Conrad,
 Respondents.
Civ. No. 10849.
 Supreme Court of North Dakota.
 January 18, 1985.

488 N.W.2d 879 (1992)
 JANE H., Petitioner,
 v.
 The Honorable Cynthia A. ROTHE,
 Judge of the District Court, Cass County,
 East Central Judicial District, Thomas L. Herzog.

Jerry J. Baldwin, and Fargo Clinic, Ltd., a.k.a.
 MeritCare, Respondents.
Civ. No. 920101.
 Supreme Court of North Dakota.
 August 21, 1992

631 N.W.2d 159 (2001)
 2001 ND 137
 Interest of R.O., V.O. and J.H.
 Keith BERGER, Director Grand Forks County Social Services, Petitioner and Appellee,
 v.
 F.O., Respondent, and
 L.H., Respondent and Appellant.
 Interest of R.O., V.O., and J.H.
 Keith Berger, Director Grand Forks County Social Services, Petitioner and Appellee,
 v.
 F.O., Respondent and Appellant, and
 L.H., Respondent.
Nos. 20000305, 20000307.
 Supreme Court of North Dakota.
 July 20, 2001.

OHIO

11 Ohio Misc. 2d 1 (1983)
 PACHECO
 v.
 ORTIZ,¹⁴
No. 54159.
 Court of Common Pleas of Cuyahoga County.
 Decided November 4, 1983.

154 Ohio App.3d 301 (2003)
 2003-Ohio-4847
 The STATE of Ohio, Appellee,
 v.
 PULASKI, Appellant.
No. 19790.
 Court of Appeals of Ohio, Second District,
 Montgomery County.
 Decided September 12, 2003

2005-Ohio-4243
 State of Ohio, Plaintiff-Appellant, (Cross-Appellee),
 v.
 Brandon Johnson, Defendant-Appellee, (Cross-
 Appellant).
No. 04AP-539.
 Court of Appeals of Ohio, Tenth District, Franklin
 County.
 Rendered on August 16, 2005

5 N.E.3d 100 (2013)
 2013-Ohio-5540
 Rebecca R. GENTILE, Plaintiff-Appellant,
 v.
 David D. DUNCAN et al., Defendants-Appellees.
No. 12AP-1023.
 Court of Appeals of Ohio, Tenth District, Franklin
 County.
 December 17, 2013.

14 N.E.3d 470 (2014)
 2014-Ohio-2508
 OHIO STATE DENTAL BOARD, Petitioner-
 Appellee,
 v.
 HEALTHCARE VENTURE PARTNERS, LLC et
 al., Respondents-Appellees,
 (Dr. J.W., D.D.S., Appellant).
No. 14AP-165.
 Court of Appeals of Ohio, Tenth District, Franklin
 County.
 June 10, 2014.

OKLAHOMA

No Cases in Google Scholar Discovered

OREGON

993 P.2d 152 (1999)
 164 Or. App. 369
 In the Matter of Chelsea West, a Minor Child.
 STATE ex rel. JUVENILE DEPARTMENT OF
 MULTNOMAH COUNTY, Respondent,
 v.
 Dion WEST, Appellant.
(9707-82066; CA A100350).
 Court of Appeals of Oregon.
 Argued and Submitted May 10, 1999.
 Decided December 15, 1999.

99 P.3d 748 (2004)
 195 Or. App. 431
 William E. MITCHELL, Respondent-Cross-
 Appellant,
 v.
 MT. HOOD MEADOWS OREG., Limited
 Partnership, an Oregon limited partnership;
 and Mt. Hood Meadows Development Corp., an
 Oregon corporation, Appellants-Cross-Respondents.
0005-05389, A116119.
 Court of Appeals of Oregon.
 Argued and Submitted July 22, 2003.
 Resubmitted July 14, 2004.
 Decided October 6, 2004.

283 P.3d 930 (2012)
 251 Or. App. 395
 STATE of Oregon, Plaintiff-Respondent,
 v.
 William Delray TOLAND, Defendant-Appellant.
 State Of Oregon, Plaintiff-Respondent,
 v.
 Larry Alan Fricano, Defendant-Appellant.
07C51659, 07C51658; A141030 (Control), A141047.
 Court of Appeals of Oregon.
 Argued and Submitted June 9, 2011
 Decided July 25, 2012

PENNSYLVANIA

No Cases in Google Scholar Discovered

RHODE ISLAND

644 A.2d 309 (1994)
 In re CORY C.
No. 93-690-Appeal.
 Supreme Court of Rhode Island.
 May 18, 1994.

SOUTH CAROLINA

455 S.E.2d 693 (1995)
 Shirley McMAKIN, Respondent,
 v.
 BRUCE HOSPITAL SYSTEM, Petitioner.
No. 24208.
 Supreme Court of South Carolina.
 Heard January 3, 1995.
 Decided February 27, 1995

458 S.E.2d 439 (1995)
 John DOE, Appellant,
 v.
 NORTH GREENVILLE HOSPITAL, Respondent.
No. 2345.
 Court of Appeals of South Carolina.
 Submitted April 3, 1995.
 Decided May 8, 1995.
 Rehearing Denied June 29, 1995.

343 S.C. 471 (2000)
 540 S.E.2d 484
 MacKennon WATSON, a Minor, by his Guardian ad
 Litem, Susan WATSON, Respondent,
 v.
 David CHAPMAN, M.D., Appellant, and
 Susan Watson and Don Watson, Respondents,
 v.
 David Chapman, M.D., Appellant.
No. 3272.
 Court of Appeals of South Carolina.
 Heard November 8, 2000.
 Filed December 18, 2000.
 Rehearing Denied February 12, 2001

SOUTH DAKOTA

No Cases in Google Scholar Discovered

TENNESSEE

194 S.W.3d 457 (2005)
 Morris M. DICKSON
 v.
 CITY OF MEMPHIS CIVIL SERVICE
 COMMISSION.
 Court of Appeals of Tennessee, Western Section, at
 Jackson.
 August 23, 2005 Session.
 November 2, 2005.
 Permission to Appeal Denied April 24, 2006

(2010)
 STATE OF TENNESSEE,
 v.
 JOHN COTE AND SARAH COTE.
 In Re: DR. SANDRA ELKINS.
No. E2008-02483-CCA-R9-CD.
 Court of Criminal Appeals of Tennessee, at
 Knoxville.
 August 25, 2009 Session.
 Filed September 28, 2010.

(2012)
 CITY OF MEMPHIS CIVIL SERVICE
 COMMISSION,
 v.
 STEVEN PAYTON.
No. W2011-02501-COA-R3-CV.
 Court of Appeals of Tennessee, at Jackson.
 July 19, 2012 Session.
 Filed November 7, 2012.

TEXAS

142 S.W.3d 574 (2004)
 In the Interest of K.C.P. and J.D.P., Children.
No. 06-04-00009-CV.
 Court of Appeals of Texas, Texarkana.
 Submitted July 28, 2004.
 Decided August 9, 2004.

UTAH

No Cases in Google Scholar Discovered

VERMONT

648 A.2d 652 (1994)
 In re B.W., Juvenile.
No. 93-263.
 Supreme Court of Vermont.
 July 1, 1994.

659 A.2d 1137 (1995)
 In re B.S., Juvenile.
No. 94-036.
 Supreme Court of Vermont.
 March 31, 1995.

VIRGINIA

No Cases in Google Scholar Discovered

WASHINGTON

9 P.3d 840 (2000)
 STATE of Washington, Respondent,
 v.
 Brenda Rochelle ANDERSON, Appellant.
No. 43590-6-1.
 Court of Appeals of Washington, Division 1.
 August 7, 2000.
 Publication Ordered August 31, 2000.

76 P.3d 280 (2003)
 118 Wash.App. 435
 STATE of Washington, Respondent,
 v.
 Scott Warren WHEAT, Appellant.
No. 28413-8-II.
 Court of Appeals of Washington, Division 2.
 September 16, 2003.

94 P.3d 407 (2004)
 STATE of Washington, Respondent,
 v.
 Catherine Christine CASSILL-SKILTON, Appellant.
Nos. 29710-8-II, 29714-1-II.
 Court of Appeals of Washington, Division 2.
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