



January 31, 2018
42 CFR part 2 Listening Session
Transcription of Proceedings

March 5, 2018



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Introduction

The Substance Abuse and Mental Health Services (SAMHSA) held a public listening session on Wednesday, January 31, 2018 to elicit information concerning the Confidentiality of Substance Use Disorders Patient Records regulation (42 CFR part 2) as required by Section 11002 of the 21st Century Cures Act (P.L. 114-255). The listening session was an opportunity for the public to provide input to SAMHSA concerning the effect of part 2 on “patient care, health outcomes, and patient privacy” as well as potential regulatory changes and future subregulatory guidance.

The event was held live in the Pavilion Rooms at SAMHSA, 5600 Fishers Lane in Rockville, Maryland and was broadcast as a teleconference/webcast via WebEx. Participants included in-person commenters as well as individuals who provided comments through the teleconference/webcast. The proceedings were recorded via WebEx and a transcription was developed. Video recordings of the listening session were made: three videos of approximately 45 minutes each. The following is a transcript of the listening session corresponding to the three videos.

42 CFR PART 2 LISTENING SESSION VIDEO ONE

[TITLE SLIDE]

MITCHELL BERGER: Good morning everyone, both in person and online. We're very pleased everybody is able to participate today. For some introductory comments, I would like to introduce the Director of our Center for Substance Abuse Treatment, Dr. Kim Johnson.

[SLIDE 2: 0:13]

KIM JOHNSON: Thanks, Mitchell. So, this is our agenda for today. I'm going to just do a couple housekeeping announcements. Dr. McCance-Katz, who is the assistant secretary, should be here momentarily and I'll introduce her, and she will have a few words. I'm going to try to be extremely brief on the background slides that I have, because I'm assuming if you are here, or if you're listening, you probably know this maybe even better than I do. But just in case you aren't, I do have a few slides particularly to cover the changes that we've made over the past year.

And then, the rest of the time will be public comments, and really, it is public comments. We're here to listen, so this isn't a dialogue. We're going to listen to you. So, if you ask a question, we'll probably just smile and ask you to reframe it as a comment instead of a question, and then we'll line it up.

[SLIDE 3: 1:05]

So, just a couple housekeeping items. The restrooms are outside the doors and around the corners, pretty easy to find. They're well marked. We're not taking any breaks, so if you need a personal break, please just take it on your own. There's also a cafeteria I'm sure you spotted right across the hall when you came in, so if you need anything to eat or drink, you can do that, again because we're not taking a break, and we're going until 1, if you stay here for the whole duration. If you leave the building, you do have to go through that whole security process again, so we would recommend if you're planning on coming back to not leave the building, but just know that if you do that that's the process.

This meeting is being recorded so that we can capture all of the comments, and we will have a process afterwards where we capture, filter, sort, and organize the comments for any future use. If you have your phones with you, can you please put them on vibrate here in the room, or on mute? And when you do get up to speak, if you are representing an organization, can you state your name, state the name of the organization and your role with that organization? Of course, if you're speaking for yourself, you can speak for yourself.

And if you are on the audio conference, if you're on the webinar, then in order to speak, for those of you that had signed up to speak, you need to press *1, and then you will be prompted when it's your turn to speak, so you press *1 and make sure your own phone is not muted, and you state your name, and you'll get into queue, basically.

[SLIDE 4: 2:43]

So, I would like to welcome Dr. McCance-Katz. Dr. McCance-Katz was appointed as the first assistant secretary for mental health and substance use in the Department of Health and Human Services. In this role, she advises the secretary, the HHS secretary, on improving behavioral healthcare in America, and she leads the Substance Abuse and Mental Health Services Administration.

She is a distinguished fellow of the American Academy of Addiction Psychiatry, with more than 25 years as a clinician, teacher, and researcher. She has served as the chief medical officer for behavioral health in Rhode Island, as a state medical director for alcohol and drug programs in California and was a professor of psychiatry at the University of California San Francisco and at Brown University in Rhode Island.

Dr. McCance-Katz has published extensively in the areas of clinical pharmacology, medication development for substance use disorders, drug-drug interactions, addiction psychiatry, and the treatment of HIV infection in drug users. She served on the World Health Organization committee that developed guidelines on the treatment of drug users living with HIV/AIDS and has been a national leader in addressing the overprescribing of opioid analgesics and in providing consultation on the management of patients with chronic pain and opioid overuse.

We're very fortunate to have Dr. McCance-Katz leading SAMHSA during this critical time when we face the challenges of the opioid crisis and the emerging needs of behavioral health. I would like you all to join me in welcoming Dr. McCance-Katz.

[Applause]

ELINORE MCCANCE-KATZ: Good morning, and welcome to the Substance Abuse and Mental Health Services Administration's public listening session on 42 CFR part 2. As the assistant secretary for mental health and substance use, a psychiatrist with a specialty in addiction psychiatry, and someone who has worked with and treated many people with substance use disorder over the years, I take the confidentiality of patient records seriously. At the same time, I also take the safe and effective care of all who seek treatment for whatever the illness may be seriously. So, this topic is a priority for me and for this agency, and for our administration.

42 CFR part 2 is a regulation that implements statutory positions enacted in 1975 at a time when individuals seeking treatment for substance use disorders faced significant consequences, even legal problems, because they sought help. Since that time, part 2 has been instrumental in supporting individuals seeking help for substance use disorders by ensuring that their confidential information will be safeguarded and shared only for certain reasons specified in statute or with their permission and consent.

As I mentioned, while patient privacy is a critical concern, equally important is the need for individuals with substance use disorders to get the safest and most effective

treatment possible when they experience medical illnesses. This requires that healthcare providers be able to share information and for care to be provided in a coordinated and integrated manner. It is critical that we keep in mind that we aim to protect the rights of individuals with substance use disorders, their rights to privacy, but also the rights to high-quality care in a way no different than for others without substance use disorders seeking treatment. To do less under the assumption of a special need for privacy is itself discriminatory and assures those living with substance use disorders a lower standard of care. My personal view is that we reinforce stigma by making such delineations.

Modernizing 42 CFR part 2 will help bring the treatment of substance use disorders into the mainstream of medical care, and we must do that -- it is time, we must do that -- where these disorders should be, because they are illnesses no different than others such as heart disease, cancer, and stroke. These are just a few examples of chronic conditions needing ongoing care and recovery and rehabilitative services.

With assurance of appropriate protections to prevent misuse of medical information related to substance use, and modification to 42 CFR part 2 to assure the best possible medical and psychiatric care to those living with substance use disorders, we will increase access to care for those in need for all of their medical conditions and healthcare needs.

So, in a few moments, we will have the opportunity to hear from all of you. I thank you for taking the time to let us know what your views are and what your opinions are, and I will hand this back to Dr. Johnson, who will manage the day. Thank you very much.

[Applause]

[SLIDE 5: 7:55]

KIM JOHNSON: Thanks. Okay. I'm going to try and get through these slides in five minutes, even though there's 15 slides, because I want the whole time to hear the comments. So, this session is a requirement of the 21st Century Cures Act. It required us to convene stakeholders to determine the effect of the regulations on patient care, health outcomes, and patient privacy, and so this listening session serves as our meeting that requirement and the law.

[SLIDE 6: 8:33]

So, just very quickly, background, so I'm going to talk a little bit about the actual law and the rules that we just updated.

[SLIDE 7: 8:42]

So, back in '72, Congress noted the discrimination associated with substance use disorders and the fear of prosecution deterred people from entering treatment. They passed the authorizing 42 CFR part 2 to protect the confidentiality of substance use disorder records. People with substance use disorders continue to be, as Dr. McCance-

Katz mentioned, subject to potential negative reactions, including discrimination and legal issues.

[SLIDE 8: 9:11]

So, the statute is the basis for the rules, and we obviously at HHS cannot change that. That's up to Congress to change. And in the statute, it talks about the "records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research," so very broad, "which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall be confidential, may be disclosed as permitted by prior written consent of the patient," and it's "subject to certain exceptions and exclusions."

[SLIDE 9: 10:17]

So, the exceptions are for medical emergencies, so medical personnel to the extent that's necessary to meet a bona fide medical emergency, to qualify personnel for the purposes of conducting scientific research, management or financial audits or program evaluations, and if it's authorized by a court order showing good cause.

[SLIDE 10: 10:39]

The statute does not apply to the VA and the records in the VA, the VHA, and it does not apply to child abuse or neglect reporting. And the penalty is under Title 18 of U.S. Code, and I'm sure someone's going to talk about that, and it instructs the secretary to promulgate regulations, which we have done.

[SLIDE 11: 11:00]

So, just a little bit about part 2 and HIPAA. Part 2 aligns with HIPAA to the extent currently feasible, or that's what we have attempted to do. Substance use disorder patient records and information may be subject to HIPAA as well as part 2, and in some states, they have state laws that are even more restrictive. If both HIPAA and part 2 apply, you're supposed to follow the law that is more stringent, and that's true for state laws as well.

[SLIDE 12: 12:00]

So, before this past year when we revised the regulations, the last update was 30 years ago. And there's been a lot of change in the world in those 30 years, and particularly in healthcare in terms of how we deliver healthcare, how we communicate healthcare information, and just how we manage performance and how we do payments, so a lot of changes that required us to update the regulations. So, our goal was to ensure that patients with substance use disorders have the ability to participate in and benefit from the healthcare models and from electronic data transfer, but to not suffer adverse consequences.

[SLIDE 13: 12:42]

So, this is the history in 2014. We held a listening session much like this, and on February 9th in 2016, we released the regulations, the proposed regulations.

[SLIDE 14: 12:55]

We published a final rule a year ago – almost a year ago to the day – and at that same point in time, we issued a supplemental notice of proposed rulemaking to address some issues.

[SLIDE 15: 13:13]

So, the things that we did last year – that we passed last year – the whole rule was updated to apply to electronic as well as paper records, because 30 years ago we didn't really have electronic records. We changed some definitions and added some new definitions like "treating provider relationship". We addressed some issues under applicability, particularly the language around other lawful holders, and we changed Section 2.13 to add this list of disclosures requirement in order to address the issue of general consent.

[SLIDE 16: 13:50]

So, I think the big thing we did last year was we permitted general consent on both the "to whom" and the "from whom" sections of the consent form, which allows for, with patient consent, a free flow of information back and forth between various providers, and because of that, we required a list of disclosures, so patients could know who got their information. We revised the medical emergency language to make it more consistent with the statutory language and to allow for providers to determine what a medical emergency is and changed some language in the research exceptions so that it more closely aligns with HIPAA and with the common rule, and we changed some language in the audit and evaluation section to permit audits and evaluations that meet CMS requirements.

[SLIDE 17: 14:45]

So, we published the SNPRM (Supplemental Notice of Proposed Rulemaking) – again, this audience probably has already read it, but it was finalized January 2nd, and it will be fully executed, then, February 2nd, so next week, so Friday. So, we published the proposal last year, January 18th. We received comments. The proposal is basically asking for comments based on some feedback that we got in the original NPRM (Notice of Rule Making) around some things that we had not identified and so, therefore, could not really address, but that, given the feedback we had got, that it was important to address, particularly around disclosure of patient identifying information by lawful holders and their contractors and subcontractors, to carry out payment and healthcare operations.

Basically, commenters noted that third-party payors and other lawful holders of patient identifying information and their contractors and subcontractors and legal representatives play a critical role in the provision of healthcare services, and we need

to clarify the ability of those organizations to share information with their contractors, subcontractors, and legal representatives.

[SLIDE 18: 16:00]

So, we obtained additional public comment on these particular things, so we proposed that, consistent with part 2, lawful holders of patient identifying information could be allowed to further disclose the minimal information necessary for the payment and health care operations, and we specified a list that came practically right out of HIPAA's privacy rule under "payment" and "health care operations," although we did exclude a couple items that I'm sure you guys will all talk to me about in your comments.

[SLIDE 19: 16:36]

We proposed some changes to Audit and Evaluation provisions to expressly address further disclosures to contractors, subcontractors, and legal representatives, and to permit those organizations to conduct their work, and we sought comment on whether to add an abbreviated notice to accompany re-disclosure.

[SLIDE 20: 17:00]

So, our final rule that we published on January 2nd permits lawful holders to disclose or re-disclose patient identifying information to their contractors, subcontractors and legal representatives to carry out lawful holder's payment and healthcare operations under the patient's initial consent. It does include an optional abbreviated notice. We changed it slightly from what we proposed in the original SNPRM, so how it reads now is "Federal law 42 CFR part 2 prohibits unauthorized disclosure of these records." It's under 80 characters, so it fits in the free text fields in EHRs (electronic health records). We did finalize the proposed Audit and Evaluation provisions, and we made some minor technical amendments that we had identified in that process.

[SLIDE 21: 17:48]

So, our priorities are that patient privacy remains an important concern, but it's equally important that providers be able to share information to provide good care, that patients can benefit from integrated care systems, that patients, providers, and the overall system can benefit from new technologies, and as we hear duly from everybody else, we want to make sure that we are well aligned with HIPAA. So, we'll be particularly listening for these issues.

[SLIDE 22: 18:19]

We'll hear everything you say, but the things that we're particularly interested in today is how can we revise part 2 to ensure that it adequately addresses "patient care, health outcomes, and patient privacy?" What else might we need to do? What specific changes, if any, should we make to the regulatory text of part 2? What regulatory changes or policy clarifications should SAMHSA consider making to further align part 2 with HIPAA and any other regulations you think are necessary? And what additional subregulatory guidance would be helpful? Now, I know you're still waiting for the initial subregulatory guidance, and hopefully that will be out soon.

[SLIDE 23: 19:00]

So, the guidelines. Now, we'll get to the public comments. We're going to strictly adhere to your three minutes per comment, and our moderators will cut you off, so just accept that. They're not being mean or rude. That's just their role today. We're going to start with in-person comments. We're going to take, I think, 10 and 10, and 10 and 10, so we'll start with the first 10 people in person, and then we'll go to the phones for the first 10 people that have logged in on the phone.

Again, I'll just repeat you should state your name and, if you are representing an organization, the organization you're representing and your title there, or your role there. And if you're on the Web -- and I'll repeat this again after the first 10 people live talk -- but if you're on the audioconference or the Web, to get into queue, to get into line to speak, you have to press *1, make sure your own phone is unmuted, and state your name, and that will put you into the queue to speak.

All the comments, including those here, people who are here physically and those on the phone, can be submitted in writing as well, and we will be accepting written comments, so if you don't get to speak, don't worry. Your voice will still be heard. We'll accept written comments through the rest of February, through February 28, and this meeting is being recorded so that we capture everything that you say and don't miss anything.

Mitchell has a list of people that registered – oh, I'm sorry. Do you have a question?

MALE: Yes. Where are the written comments to be accepted?

MITCHELL BERGER: It was in the Federal Register announcement. They can be mailed, or hand delivered to me, or they can be sent to our privacy regulations (email).

KIM JOHNSON: So, we'll make sure that we have that before the end of the meeting -- that is up on the last slide – before you're all done. So, the question was “where do you submit written comments,” and we'll make sure that that information – it was in the FRN (Federal Register Notice), but we'll make sure that it's available today as well.

SLIDE 24: 21:17 (MICROPHONE SLIDE)

MITCHELL BERGER: Okay. So, what we're going to do is we're going to hear 10 comments from people here in person. Then, as Kim said, we'll switch to the phones. Then, we'll go back to in person and switch to the phones, and just try to accommodate as many people as we can.

Again, if you could please state your name and title, and for those on the phone, we will post these slides after today's event, just because I know there were some WebEx technical issues. So, we'll figure that.

Our first speaker is Nathaniel Counts, Mental Health America.

MALE: He's not here.

MITCHELL BERGER: Okay. So, we'll move to the next person, Dr. Harsh Trivedi, American Psychiatric Association, and please go to one of the row mikes.

HARSH TRIVEDI, AMERICAN PSYCHIATRIC ASSOCIATION: Sure.

MITCHELL BERGER: Thank you.

HARSH TRIVEDI, AMERICAN PSYCHIATRIC ASSOCIATION: Good morning. Hello, my name is Dr. Harsh Trivedi. I'm speaking on behalf of the American Psychiatric Association, a medical specialty society that represents 37,000 psychiatric physicians across the country, to discuss the impact of CFR 42 part 2. I'm also a practicing physician and president and CEO of Sheppard Pratt Health System, the largest private nonprofit provider of mental health and substance abuse services in the country.

I am here today to talk about some of the real-world impacts that CFR has in how we provide care to patients, and what it means for those that are trying to access high-quality care. We very much appreciate the changes that have been made by SAMHSA thus far to better allow us to provide great care. However, part of the difficulty we run into is that the technology doesn't align yet with the changes that have been made. It also further adds to the stigma by segregating an entire class of patients from getting access to the best care that is integrated that we provide.

The comments that I would make regarding the clinical care are: We have worked very hard to provide integrated care, which is functionally, how do we get ourselves to provide psychiatric services within primary care settings? We have an ambitious program with a local hospital, where we have provided a psychiatrist as well as an addiction specialist across every primary care site. While our mental health provider is able to fully integrate onto the team because only HIPAA applies, the addiction specialist that we provide is prevented from documenting within the EMR, has to end up with a sequestered record, but also many provisions of the care then occur, not even within the same parts of the clinic.

The other comment that I would make is, when we have at different times thought about how do we communicate? So, we also run a pretty substantial addiction service where we detox people off medications that they're addicted to. The current barriers prevent us, because we don't always know exactly which doctor's office they will step into, from sharing the right information so that the patient can go through an entire costly detox program, we get them set up in care, they may slip for a moment, end up in an orthopedist's office or their primary care doctor's office, and there will be nothing that the person sees regarding any of that addictions care.

The largest comment that I would make is particularly because of the pretty dangerous nature of the medications themselves that people are addicted to. The other place where we run into lots of difficulty is drug-drug interactions. Many times, it's not simply



that you can't note the diagnosis of the addiction. People have difficulty with which medications will you put on to the clinic summary and what will happen to direct care. And so, what we've run into is we have doctors that are unknowingly prescribing medications that counter or cause difficulty with some of the substances that are being addicted, which can lead to unintentional overdose or other side effects or problems.

The comment that I would make is we have come far in terms of really thinking about depression as just as important as diabetes or heart disease care. We need to now move to thinking about the importance of an addiction as just as important as mental health, as just as important as physical health. And so, I am here today as a representative of the American Psychiatric Association, that, yes, the confidentiality protections are very important, and we want people to be able to access addictions care without fear of prosecutions, or ending up in jail, or any of those types of things, but at the same time, they can't be in a situation where entire states simply choose to restrict addictions' patients from their health information exchanges, where even within the same medical center, physicians are prevented from documenting the actual care that people get, and that actually places people in harm's way.

Anything that you can do to better align part 2 specifically with HIPAA is very much appreciated, and we urge administration to implement regulations that can bring us to that and really allow us to integrate care in the way that we would love to for the benefit of our patients. Thank you.

MITCHELL BERGER: Thank you. Okay. Our next speaker, and feel free to come to the front of the room. Our next speaker is Rebecca Klein, Association for Behavioral Health and Wellness. Yeah, you can come up to the front.

REBECCA KLEIN, ASSOCIATION FOR BEHAVIORAL HEALTH AND WELLNESS: Hi, I'm Rebecca Klein, the director of government affairs for the Association for Behavioral Health and Wellness, and the chair of the partnership to amend 42 CFR part 2. The ABHW is the national voice for payors that manage behavioral health insurance benefits for over 175 million people. Reforming part 2 is a top priority for ABHW and its member companies, and ABHW created the partnership to bring together now 40 like-minded healthcare staple organizations that are committed to aligning part 2 with HIPAA while maintaining patient protections that currently exist in order to provide safe, effective, and coordinated care.

I would first like to speak specifically on behalf of ABHW and thank SAMHSA for taking some steps in the right direction to reform part 2 and its recent final rule. While we still believe this rule does not go far enough to align part 2 with HIPAA for treatment, payment, and operations, we were glad to see that it included a list of 17 operations activities for which disclosures would now be allowed by lawful holders of the information and appreciate that the list is included in the preamble as a way of providing examples.



Of course, while this piece is beneficial to the payment and operation sides of our member companies, other alignment of treatment activities with HIPAA is necessary to truly ensure the coordinated care patients deserve. Additionally, ABHW member companies need the ability to disclose a minor's substance use disorder information to his or her parents, who are fully involved with paying for, and trying to arrange for, their children's substance use disorder treatment.

ABHW and the partnership believe part 2 still needs many more improvements. Overall, it remains an antiquated regulation that severely constrains the healthcare community's efforts to coordinate care for persons with substance use disorders. This can prohibit payors and providers from sharing important information with the healthcare practitioners caring for patients suffering from opioid and other substance use disorders.

Furthermore, persons with substance use disorders are the only subset of healthcare patients whose records are treated separately and, as a result, may not receive coordinated care. Certainly, this aspect alone creates an increased stigma around addiction, as it shows this population is being treated differently.

ABHW and partnership members stress that part 2 is one of the biggest, if not the biggest, barriers to fighting the opioid crisis. part 2 and the final regulations published in the past year all rely on the receipt of patient consent, which can often be impossible or difficult to obtain, and in those instances, the care cannot be coordinated, even though that would be in the consumer's best interest. Individuals with a substance use disorder might not sign the consent form because they do not want others to know about their illness. They may incorrectly assume their addiction record is already being shared in the same manner their medical record is being shared. A patient might be incapacitated due to intoxication and unable to provide consents, or a doctor might not know to ask for the patient's consent. All of these instances would prevent safe, effective, integrated treatment.

In the recent final rule, SAMHSA wrote that it continues to review issues related to aligning part 2 with HIPAA, and we strongly urge you to further examine the detrimental impacts this regulation can have on persons with substance use disorders and their families. When substance use programs are prevented from sharing information about patients' substance use and medications prescribed to treat their substance use with primary care or emergency care providers, dangerous drug-drug interactions can occur, and the risks of accidental death from overdose or fatal drug-drug interactions can be grave.

We welcome the administration's efforts to modernize part 2, as we share the same goal of protecting the confidentiality of patients while improving access to advances in the delivery of health services. We appreciate the time shared with us today, and we'll submit more comments in writing. Thank you.

MITCHELL BERGER: Thank you. Okay, our next speaker is Jack Rollins, National Association of Medicaid Directors.



JACK ROLLINS, NATIONAL ASSOCIATION OF MEDICAID DIRECTORS: Good morning, and thank you for the opportunity to comment. So, I'm Jack Rollins, senior policy analyst for the National Association of Medicaid Directors. Our association represents the individuals who operate and administer the Medicaid programs in the States, the five territories, and the District of Columbia.

We first want to applaud SAMHSA's efforts on the steps that had been made in its rulemaking to date, specifically around streamlining many of the activities the Medicaid agencies conduct to perform their operations and oversight duties.

We specifically want to acknowledge the clarifications at Section 2.33 B regarding the ability for lawful holders to disclose part 2 information with Medicaid agencies and other contracted managed care entities in the performance of healthcare operations. We also wish to applaud the clarifications permitting part 2 data disclosures for Medicaid and shift audits and evaluations to Section 2.53. Those are positive changes to facilitate appropriate Medicaid oversight of the services that they provide.

However, our members do remain concerned with the prohibition on disclosures for diagnosis, treatment, or referable treatment in Section 2.33 B. Medicaid agencies and their partners continue to pursue delivery system and payment reforms to promote coordinated and integrated care across all healthcare needs in the full continuum of care, including social determinants of health, for the Medicaid beneficiaries served.

However, timely targeted sharing of patient healthcare information across care teams is key to these efforts, especially as Medicaid directors and their programs hold their healthcare plans and partners accountable for outcomes of all an individual's healthcare needs, including their substance use disorder and addiction issues. This prohibition inhibits the effective case management, care coordination, and the use of technology to improve care, so we are very much supportive of SAMHSA's efforts to continue aligning 42 CFR part 2 with HIPAA, and we look forward to the opportunity to provide additional comments in writing on these issues. Thank you.

MITCHELL BERGER: Thank you. Our next comment is from Renee Popovits, and I believe Eric Okelbud was going to read comments on her behalf.

ERIC OKELBUD, POPOVITS LAW GROUP: Thank you. I'm reading this testimony on behalf of Renee Popovits, a healthcare attorney from Illinois who has devoted 28 years of her career to the behavioral health field. She writes: "Confidentiality is the cornerstone principle to encourage people to seek treatment, and for no other disease can you lose your liberty. For the last 10 years, I advocated for change to part 2 to increase information sharing among treating providers and care coordination entities to improve patient safety and health outcomes. I have supported alignment with HIPAA with enhanced patient protections. Without balancing the two, my comments and support for change have been taken out of context and misunderstood. If you change

one without the other, the pendulum swings too far. I will share more detailed written recommendations with SAMHSA, but highlighting the following:

- (1) We need to stop feeling constrained by the existing framework and provide one clear rule that patients and counselors understand and all of healthcare can follow. SAMHSA should take the best of part 2 and integrate it into the HIPAA privacy regulations. The integrated rule could, (1) maintain the part 2 stringent court order requirements and include extra protections for substance use disorder records when sought for the purposes other than treating the patient, (2) extend protections for enhanced penalties, breach notifications, procedures, and enforcement by an agency that has a proven track record of enforcement of privacy protections, and (3) establish consistent elements for consents and business associate agreements.
- (2) Secondly, to better address the opioid crisis, we need to integrate information about methadone dosages from central registries into prescription monitoring programs. These PMPs should have restrictions on law enforcement uses and be used primarily for clinical interventions to prevent multiple prescriptions and multiple enrollments. ONC and SAMHSA need to jointly issue regulations on PMPs.
- (3) SAMHSA recognized ambiguities in the 2017 rule and promised subregulatory guidance on 27 items. SAMHSA needs to timely provide this clarity and release binding guidance, especially for new general designation provisions.
- (4) In the 2018 final rule, the payment and healthcare operations definitions of HIPAA were not specifically included in the text of the regulation, only in the preamble. Similarly, lawful holders are not officially defined in the rule. This should be addressed to avoid unfettered discretion, ambiguity and interpretation, and lack of consistent enforcement.
- (5) I question the two-year delay for implementation of an agreement for lawful holders and subcontractors of payors. This translates into two years of pre-sharing with no accountability, oversight, or consequences for these downstream contractors. This is a prime example of the pendulum swinging too far.
- (6) Looking to the future with patient portals and personal health records increasing, OMC and SAMHSA need to address appropriate safeguards of information shared by patients directly.
- (7) Section G of the statute expressly permits regulations to include safeguards and procedures. In addition to existing stringent court protections, I strongly urge SAMHSA to enhance safeguards to include nondiscrimination provisions, exclusion from evidence in criminal, civil, and administrative proceedings, ability for patients to file complaints and pursue enforceable penalties.”

Thank you.

MITCHELL BERGER: Thank you. Our next speaker is going to be Dr. Tim Murphy.



TIM MURPHY, Ph.D. CONSULTING: Thank you. Good morning and thank you for this opportunity to respond to the final rule. I come here today as a psychologist with over 40 years of clinical experience in hospitals, private practice, and the Navy.

As a U.S. congressman, I wrote the law requiring the HHS to review part 2 and offer suggestions. My original bill, the Helping Families in Mental Health Crisis Act, was a combination of years of investigation I conducted as chairman of the Oversight Investigation Subcommittee and the Energy and Commerce Committee.

Our evaluation identified problems across many agencies, programs, and regulations of the federal approach to mental healthcare. H.R. 2646 was amended in the 21st Century Cures Act, signed into law in December of 2016. That bill states, “The Secretary shall convene relevant stakeholders to determine the effect of such regulations on patient care, health outcomes, and patient privacy.” I submit to you today that this mandate was only partially complete.

There are three basic questions that still must be addressed. (1) What is the essential function of the part 2 regulations that is not otherwise covered in HIPAA? (2) Is there any harm caused to patients by the existence of 42 CFR part 2? (3) Since part 2 was written during the Nixon administration, is it outdated? How does it relate to HIPAA, and what else is needed with legislative overhaul?

Regarding the first question, the part 2 rule modifications offered in the rule do not adequately address the issue. That became law 20 years ago after part 2, and several changes have occurred since then, including recent ones in the HITECH Act in 2009. part 2, however, requires separate medical records and an additional requirement for signed consent for every provider within the system. Drug and alcohol records face an additional hurdle by part 2, but these regulations are no longer necessary and, in fact, cause substantial harm.

First, the prescription drug monitoring program, or PDMP, was put into place to allow doctors to track if a patient is jumping to different providers to get prescriptions of opiates. It is essential for the doctor, who otherwise is unknowingly writing prescriptions for someone who may divert or sell their prescription. Methadone, for example, is not included in the PDMP because of part 2 rules. Since drugs are often diverted or resold by a patient, who then uses the money to buy other drugs, it doesn’t make sense that a doctor would not be allowed to know the facts of the record.

Second, an anesthesiologist who does not know a patient has developed a tolerance for opiates may have difficulty titrating the right level of anesthesia or analgesic for a patient.

Third, when the drug treatment medical record is kept separate, a doctor has to remember to ask if it exists, find it, and then seek permission to obtain, read, and review. Use of narcotics affects several medical conditions. The treating provider needs to know this.



Four, in emergency care, the doctor may not have the time to handle this additional layer of red tape. If a patient comes into the ER after an auto accident, and the physician is not aware the patient is in recovery from addiction, the physician may unknowingly put the patient at tremendous risk by prescribing opiates. The recovering patient may be dispensed opiates, relapse back into addiction, or if the patient then takes too many pills, recalling the last time she took the opiate required several pills to feel the effect, she may then overdose, or the patient may end up with an adverse drug-drug interaction.

All of these situations could have been prevented. As Paul Gionfriddo of Mental Health America reminds us, “You cannot treat the whole patient with half a record.” Let’s not forget the fact that one result of this preventable risk is that patients die. Last year, there was more people that died from drug overdose than there are names on the Vietnam Veterans’ Memorial Wall. In how many cases did part 2 contribute to the overdose and relapse or their unnecessary hospitalizations, surgical complications? Is the data even collected to answer these essential questions?

The law required the report to address the impact on health outcomes, but we do not know the morbidity and mortality effect of the rule because it was not reported. HHS needs to go back and gather that data thoroughly and objectively. Until that is completed, this rule is not in compliance with the law.

The rule hints, but does not emphasize, that regulators can only do so much. Hands are tied by the limits of the law. As long as the law is in place, it must be enforced, and I ask HHS to come back and make that point more clear. Is 42 CFR part 2 really necessary? Where does it cause harm? How much harm? How do we reconcile this with HIPAA? And Congress then needs to change the law to meet the demands of what we know today by integrating and coordinating patient care and stop fighting the battles of the 1970s.

Finally, under any other circumstance, if a physician made a harmful medical error because essential facts were ignored in the medical record, there would likely follow a substantial malpractice suit. When federal law requires a doctor to diagnose and treat a patient while remaining blind to essential healthcare information, it is government-mandated malpractice.

It is time to stop this deadly and unnecessary practice, so I call upon HHS to comply with the law to go back and complete the review of 42 CFR part 2 and provide the solid scientific information regarding its impact upon healthcare delivery with information and the impact that it has if it was repealed and concerns are integrated into the HIPAA law. Until that is done, until the law is complied with, this rule is not final. For the sake of saving lives, I strongly urge HHS to go back and complete the task. Thank you.

MITCHELL BERGER: Thank you. Our next speaker is Miranda Franco, Holland & Knight. Miss Franco? Okay. Next on our list is Eric Bailly, Anthem.



ERIC BAILLY, ANTHEM INC.: Thank you for the opportunity to speak with you today. My name is Eric Bailly. I am a CM business solutions director with Anthem and am a licensed alcohol and drug counselor. Anthem and its affiliated plans are proud to serve more than 40 million Americans across our commercial, Medicare, and Medicaid plans, and for several years, we have expanded our capacity to support prevention, treatment, and recovery from substance use disorders. Anthem shares SAMHSA's commitment to quality care and services and the protection of each individual's personal health information.

We commend SAMHSA's efforts to update these regulations to reflect rapidly changing healthcare delivery systems. However, we believe the changes to 42 CFR part 2 fall short. Anthem requests that SAMHSA adopt further amendments to the regulation to achieve alignment with HIPAA. At Anthem, we recognize that our role in the healthcare delivery system is part of a comprehensive team, and we collaborate closely with healthcare providers, addiction experts, and individuals in long-term recovery in an effort to strengthen the network and services for those we serve.

As healthcare system evolve to focus on integration and care coordination, it is imperative that these policies support the ability of payors, providers, and beneficiaries to access information necessary to deliver meaningful and clinically appropriate care in a person-centered and timely manner. By not aligning with HIPAA, as well as excluding case management and care coordination as activities encompassed under healthcare operations, the final rule serves as a barrier to the delivery of quality healthcare.

Monitored approaches to the treatment of substance use disorders require an "all hand on deck" approach. If those involved in overseeing a patient's care plan and prescribing history are not able to transparently exchange information, the patient can be exposed to significant risk of negative drug interactions, overdose, or death. For example, in the context of an electronic medical record, the information-sharing restrictions in 42 CFR set up the scenario in which an incomplete picture could be presented to an attending clinician. Without pertinent substance use disorder information at their fingertips, clinicians are inhibited from making more complete clinical decisions regarding choice of medications and whether or not a particular patient may need an additional layer of support to address an underlying substance use disorder.

Additionally, enforcing two separate sets of privacy rules and regulations for those treated with substance use disorders versus a physical health condition not only conflicts with the intent of mental health parity, but results in confusion, gray areas, and administrative disruptions that can be a disincentive to providing holistic care.

We believe SAMHSA has the authority to amend these regulations to align with HIPAA, and we are heartened that the agency has taken initiative to continue discussions in furtherance of that goal. Should the agency continue to believe they lack the authority to make the changes necessary to achieve alignment with HIPAA, we encourage



SAMHSA leadership to support existing legislative effort such as the Overdose Protection and Patient Safety Act and Protecting Jessica Grubbs Legacy Act.

Once again, Anthem appreciates the opportunity to comment today. The significance and necessity to align with 42 CFR with HIPAA is evidenced in a list of groups who have come together as part of a partnership to amend 42 CFR part 2, many of whom are here today. The diverse coalition includes substance use disorder consumer advocate groups, provider associations, and payors, among others. We all share the ultimate goal of the highest quality healthcare, consistently focused on recovery and resiliency. It is imperative we make every effort to eliminate barriers to treatment and recovery for people experiencing substance use disorders. Thank you.

[END OF 42 CFR PART 2 LISTENING SESSION VIDEO ONE]

42 CFR PART 2 LISTENING SESSION VIDEO TWO

[TITLE SLIDE: 4 SECONDS]

[SLIDE 2: 0.4 – MICROPHONE SLIDE]

MITCHELL BERGER: Our next speaker is Gerard Scheitlin from Orion Health. Mr. Scheitlin?

GERARD SCHEITLIN, ORION HEALTH: Good morning, I'm Gerard Scheitlin from Orion Health. I'm the chief risk officer and vice-president of security risk and assurance. Orion Health is a population health and precision IT medicine provider, so we're in Health IT (HIT). We're a technology company that provides the solutions that a lot of you have used to look at the records to manage what you're managing.

I appreciate what SAMHSA is doing to protect the privacy and rights of individuals. I understand the need for consent. But when you look at what is going on in the electronic healthcare information exchange, when you see what the ONC (Office of the National Coordinator for Health Information Technology) is doing with the Trusted Exchange Framework and the Common Agreement – or TEFCA – there is a discussion about moving this nationwide, about having consent flow nationwide. All right. When you do this, and you take the consent and you put it into that manner, it's becoming more and more difficult to manage. It's becoming more and more difficult to manage electronically, not because we can't say, "Yes, this person's consented," "No, this person has not consented," but because we can't manage the permutations, combinations, and the different rules that are in there. It's going to become programmatically a major challenge.

So, unless we align and simplify, unless we align and come down and align with HIPAA and align with consent across it – because it's no longer managing consent in a specific facility, in a specific organization. It's managing it across states. It's managing it across multiple facilities across multiple states. States have different laws. States have different rules. Opt-in states say you're automatically consented in. Opt-out states say you have to consent in if you want your information exchanged. It's becoming extremely difficult to measure that. And then when you toss in another layer, the sensitivity of data, and if you toss in different layers of sensitivity of data, even when you talk across drug abuse, sexual health, pregnancies, other things, it becomes a very difficult task for any HIT provider.

So, I've listened to some of the comments in here, and I've heard people talk about the health information exchange, that it's not providing the information. The reason is, is the complexity of it doesn't allow the technology organization underneath to provide that information and put those rules in place. Because of the complexity level, it becomes too much of a challenge to even attack programmatically. So, I strongly urge SAMHSA to work with CMS and ONC to understand what they're doing with TEFCA, to understand what they're doing with these laws and consents and simplify it across the nation. Thank you.



MITCHELL BERGER: Okay, great. We're ready to start taking questions over the phone. Can we have our first speaker, please?

OPERATOR: Certainly. Thank you. Our first comment comes from Christine Kerno.

CHRISTINE KERNO, ADDICTION MEDICINE CLINIC: My name is Christine Kerno. I am the supervisor of Addiction Medicine Clinic in Hennepin County Medical Center in Minneapolis, Minnesota. I actually have a couple of questions.

We are moving cautiously to implement the changes in CFR 42 part 2. And so, my questions are, specifically, what is the wording for releases of information so that we can share information to provide integrated care? We're an opioid treatment program located in a very large public hospital, and we're very cautious with this, and we have firewalls even within our own hospital so that medical providers cannot see any of our notes in our opioid treatment program (OTP) or any of our work with patients.

So, my questions are, what exactly is the wording on a release of information (ROI) we can use now? Is the ROI now going to be something we can use for people for integrated care with all providers we come in contact with over, say, a year's period of time inside the hospital, outside the hospital? And also, do we have to add to the list every time we contact or speak with the same outside psychiatrist or case manager? Do we need to immediately put it on the list on the ROI? That's my second question. And is the current change allowing us to think about taking down our firewalls so that medical providers in the hospital, when they see our patients in the ED or on a medicine floor, kind of can immediately see the current treatment situation with the patient? So, are we already at this time given permission, or is it legal, to now take down those firewalls and have other providers in the hospital aware of their OTP treatment to provide a better integrated care experience? Thank you.

MITCHELL BERGER: Thank you very much, and you're more than welcome. As we said at the introduction, we're not really taking questions and answers today, but you're more than welcome to submit those questions to us by email, and we have your questions from the transcript, so we can note those as we look at the outcome of this meeting. We're ready for our second person over the phone, and for the people over the phone, please state your name and title and organization. Thank you.

OPERATOR: Our next question or comment comes from Tom Anderson.

TOM ANDERSON, FRONTIER BEHAVIORAL HEALTH: Yeah, this is Tom Anderson. I'm the HIPAA Privacy Officer with Frontier Behavioral Health in Spokane, Washington. And our question relates to the ongoing issue under 42 CFR part 2 where, when we share information, a client signs an ROI to authorize us to share information with the physical healthcare provider. We're still required, and I don't think the new rules change, for us to include the notice prohibiting redisclosure of that information by the

recipient, which is the physical healthcare provider, to another healthcare provider that's treating that patient.

And the physical healthcare provider is not a part 2 provider as we are, and it really prohibits any kind of integrated care, because our information that we provide is integrated information. We don't have specific separate information around substance use disorder treatment, because so many of our patients that we treat in our behavioral health organization have substance use disorder issues as part of the diagnosis that we're addressing. So, it's an integrated plan, and so, all of our charts, before we can release information, we require folks to sign a part 2 compliant ROI. But the physical healthcare provider is not familiar with that, and it's really not set up very well for them to be able to share to get a separate release before they can share that information with another specialist, and their ROIs do not meet the 42 CFR part 2 restriction prohibiting redisclosure.

So, while we appreciate the fact that the changes have addressed the operations and payment sections related to HIPAA, the treatment sections, it really still is not viable to really call us being able to provide integrated care when the treatment sections under part 2 still prohibit that redisclosure. So, the redisclosure issue is really the main concern that we have that needs to be addressed, or else people that have substance use disorder issues really are not going to get integrated care, and it's really going to be an ongoing problem for any kind of integrated health system. Thank you.

MITCHELL BERGER: Thank you.

OPERATOR: Our next question or comment comes from Karolina Austin.

KAROLINA AUSTIN, OPERATION PAR: Good morning. My name is Karolina Austin. I am speaking on behalf of Operation PAR in Tampa, Florida. We are the largest not-for-profit provider of addiction treatment services for adolescents and adults in the Tampa Bay area of Florida. Our organizational goal is to provide high-quality care and service to the communities within the areas that we serve.

As a provider of substance abuse treatment services, PAR is intimately familiar with the difficulties surrounding compliance with the federal confidentiality regulations. We ask that the following restrictions align more closely with HIPAA.

Authorization restrictions: Under Section 2.31, "Entities without a treatment provider relationship," the new regulation requires the name of the individual to whom the disclosure is being made. We at Operation PAR have many clients who are involved in child custody cases, as well as cases within the drug courts. Many of our clients do not know the names of the caseworker assigned to them until we receive a request for records. Oftentimes, the client's caseworker changes, or the clients can have multiple individuals assisting them with their case or investigations. This new regulation provides challenges and barriers for our agency and clients to release records in a timely manner. Clients oftentimes call us stating they have a new caseworker and need

records sent to them immediately due to a pending court case that they are waiting on. We are unable to assist the clients due to not having proper written consent. Many of our clients do not have transportation to come and complete new authorization forms, or access to a computer. These requests are oftentimes sensitive with little to no time to disclose records. Due to the definition, the Department of Children and Families and drug courts do not fall under a treatment provider relationship. This limits the consents and presents challenges when we are assisting clients to regain child custody of their children or comply with the courts.

We would like to request that changes be made in the regulation under 2.31 to allow the release of records to an entity name and not to the name of an individual for the following agencies: The Department of Children and Families, drug courts, juvenile justice system, and the criminal justice system for probation and parole. This will allow our agency to more effectively assist clients with their open court cases.

Arrest warrants, subpoenas, and court orders under Section 2.61: This regulation presents challenges for part 2 programs. Part 2 programs are unable to consent due to clients no longer being in our programs or obtain consent, or the client is unwilling to sign one. This forces part 2 programs to obtain an attorney to submit a response to the courts. More oftentimes than not, the judge submits a 42 CFR part 2-compliant order releasing the records. For part 2 organizations, this uses unnecessary time, costs, and provides bad business relationship with their requesting courts. This also sets a bad precedence to our clients that they can delay their court cases by refusing to sign a consent for the release of records. Risk of our reputation with the courts, and the courts offering to refer individuals to our services for non-criminal offenses are at risk. The state attorney's offices can take the refusal to release records on a subpoena or a delay to release records as a sign of the part 2 program are trying to hide information and can have a negative consequence against our clients.

We ask that the regulation fall more closely in line with HIPAA, which would allow the disclosure of information without consent if the order is signed by a judge. This would prevent delays, noncompliance, and provide a better rapport with our courts and our affiliates.

We would like the part 2 regulations to become less restrictive. And in conclusion, on behalf of Operation PAR, I would like to thank you for the opportunity to express our concerns over the 42 CFR part 2 regulations. We respectfully request SAMHSA's urgency in addressing these identified issues under part 2 in order to ensure timely and effective care coordination and improved healthcare outcomes for the benefit of our patients in Florida and nationally. Thank you.

MITCHELL BERGER: Thank you very much.

OPERATOR: Our next question or comment comes from Pat Reher.



PAT REHER, HARTFORD HEALTHCARE: Thank you. This is Pat Reher from Connecticut, former commissioner of the Department of Mental Health and Addiction Services, and currently serving as president of the behavioral health network for Hartford Healthcare, the largest behavioral health network in the state of Connecticut.

I agree with most of what has been previously said, that unfortunately the current status of the CFR 42 leave us in the position of not being able to communicate with providers after somebody has left or completed a treatment program, which leaves them at high risk, and one of the issues that I think this highlights in the behavioral health system is, again, the issue of discrimination against people who are seeking treatment and who need continuing care.

In most other medical illnesses – and we know that this is a brain disease and a chronic, relapsing illness – we would not hesitate to communicate to a primary care physician or other treaters about the treatment that the individual has experienced, either in a hospital or in a detox center, or even an ambulatory detox center, and as somebody stated previously, we see people in an active detox program who may still be in a contemplative state and refuse to sign an ROI, and it puts them at high risk of going back to a primary care provider (PCP) or another medical provider, getting a prescription for some sort of opioid, and then overdosing because they've used the same amount as they used prior to admission. So, we feel that the risk is, frankly, high enough so that it can increase the risk of overdose.

In the state of Connecticut last year, we had 247 individuals that died in automobile accidents, and 916 that died from opioid overdoses. Thus, the scope of this crisis is significant enough so that I think that we really have to evaluate the federal laws that, in some ways, keep us from communicating adequately about the individuals that we serve that is so different from the way we communicate about any other medical condition. Thank you.

MITCHELL BERGER: Thank you.

OPERATOR: Our next question or comment comes from Mark Parrino.

MARK PARRINO, AATOD: I'm Mark Parrino, and I serve as the president of AATOD, which is the American Associations of the Treatment of Opioid Dependence. We understand the complexity of what SAMHSA is trying to engage in, and we appreciate it. Literally, we support, as an organization of opioid treatment programs – and there are 1,500 of them in 49 states – the idea of integrating and coordinating care for the patients.

We have some comments. The question for us becomes, Have attitudes shifted so markedly about patients receiving medication to treat opioid disorder since the original confidentiality regulations went into force, as has been said, during the Nixon administration?

The next question becomes, “How are patients treated once the information is disclosed?” Now, I’ve heard the arguments in favor of it, and I understand that SAMHSA is trying to align where it can 42 CFR part 2 with HIPAA. The issues, however, are once information is disclosed about their being on either methadone or even buprenorphine, patients don’t get access to life insurance or disability insurance.

And there’s a question about how the PDMPs handle it. If OTPs are expected to disclose confidential patient information to PDMPs, there would have to be strict enforcement that the PDMP would only share such information with healthcare providers, and there would have to be clear understanding that enforcement authorities could not get this. I give you the evidence of Oklahoma, where the PDMP is directed by the State Enforcement Authority, and they take the view that sharing the information of OTPs into a PDMP should also serve to cross reference any outstanding warrants. That’s not the point of a PDMP.

Additionally, at the present time in Michigan, it’s routine to have patrol cars parked near an OTP, and then, as patients leave treatment, follow them and then pull them over subject to potential DUI. The issue with Virginia is also clear in that if a mining company learns that a patient is enrolled in an OTP and getting methadone, they can’t continue to work, and then the OTP and patient must convert to buprenorphine. For some reason, buprenorphine doesn’t carry the same stigma with coal mining companies in Virginia as does methadone.

So, rather than give you more stories, I appreciate the fact, and we at AATOD appreciate the fact, that you want to do all that you can to integrate healthcare services. And I understand the issue of electronic systems and electronic healthcare records, but still and ultimately, this comes down to how best to protect the interests of the patient, especially at a time when the patient is deciding whether he or she should enter treatment and then remain in treatment. This is especially true for pregnant patients who are wondering, if they enter treatment, will Child Protective Services take the child?

So, as you go through this debate, and I appreciate the sensitivity that SAMHSA has demonstrated in this balancing act, these are all very important points to keep in mind, especially in the evolution of attitudes towards people who seek treatment. I can assure you, the attitudes in many corners are not good, including the medical community.

Thanks for the comments, and I appreciate the difficulty of what you are trying to do at SAMHSA.

MITCHELL BERGER: Thank you. We’ll go back to in person, and my colleagues.

MODERATOR (Suzette Brann): Good morning, everyone. Can we have Deborah Reid from the Legal Action Center?



DEBORAH REID, LEGAL ACTION CENTER: Good morning. I'm Deborah Reid, senior health policy attorney for the Legal Action Center. The Legal Action Center is a nonprofit law and policy organization that fights discrimination against people with histories of addiction, HIV and AIDS, or criminal records and advocates for sound public policies in these areas. Thank you for the opportunity to comment on part 2 and its effect on patient care, health outcomes, and patient privacy.

The Legal Action Center firmly believes that it is important to maintain part 2's core protections and heighten privacy standards for substance use disorder treatment records, since adopting a HIPAA standard would not sufficiently protect people seeking or receiving substance use disorder treatment. We support patients' rights to participate in models of integrated care and the electronic health record systems while maintaining the right to control the disclosures of their records.

Part 2 improves health outcomes in patient care by encouraging people to enter and stay in treatment without the fear that their treatment information will be disclosed. This is the original intent of the regulation. Without part 2's protection, people will be discouraged from seeking treatment for fear that their treatment information will be used against them in criminal proceedings or jeopardize their jobs, housing, or child custody. Considering the current opioid epidemic, these protections are just as important today as they were 40 years ago when Congress passed the original legislation authorizing the part 2 regulations.

Moreover, part 2 gives patients the tools to manage disclosures of their substance use disorder treatment information, because unfortunately stigma and discrimination continue to exist, even in today's healthcare field. Part 2 protects patients from discrimination, which leads to better patient care and health outcomes. Part 2 supports patient privacy and strikes an appropriate balance between maintaining patients' confidentiality and encouraging integration of care. Because the technology already exists to segment data, the appropriate next step should be to bring integrated care and health information systems into compliance with part 2.

We also urge SAMHSA to issue the subregulatory guidance on the topics it identifies in the January 2017 final rule. SAMHSA has made major changes to part 2 that have been in effect for less than a year. In our experience, the programs, vendors, and other stakeholders are still becoming familiar with these changes. For this reason, we are not recommending any further regulatory amendments at this time. Instead, we encourage SAMHSA to issue subregulatory guidance. Further recommendations are set forth in our written comments, which will be submitted for the record. We appreciate SAMHSA's ongoing commitment to protect and promote the health of people who are living with substance use disorders. Thank you.

MODERATOR (Suzette Brann): Thank you. Al Guida, from Guide Consulting Services?

AL GUIDA, GUIDE CONSULTING SERVICES: Good morning, and Dr. Johnson, thank you for inviting us here this morning. My name is Al Guida. I'm with Guide Consulting Services. I'm here in behalf of, and solely on behalf of, Netsmart. We are an electronic health record company that make EHR systems for mental health and addiction providers, psychiatric hospitals, community mental health centers, methadone clinics, and residential treatment facilities for people with opioid addiction.

I want to just briefly discuss some of the technical issues in conjunction with implementing the two rules that SAMHSA has recently issued on part 2, and we thank the agency for its regulatory activism to date in this area. The rules rely upon a data segmentation infrastructure or architecture whereby the patient with opioid addiction will go through their medical record and identify pieces that they will be willing to share with medical providers and those that they will not.

In order to implement both the rules and the data segmentation infrastructure, SAMHSA developed an open source IT platform called Consent2Share. Every hospital system, every primary care practice, every medical specialty practice, every accountable care organization, every health information exchange in the United States would have to adopt this open-source technology in order to be able to operationalize the rules that Dr. Johnson discussed at the beginning this morning.

In order to do that, all of these providers have to modify their existing EHR systems, have to train their staff on how to manage the consent requirements within the Consent2Share platform. They have to train the individual with opioid use disorder on how to use the technology, and there are apparently legal liability issues in conjunction with providing that training to the individual.

So, here's the outcome. An official with SAMHSA participated in the Office of the National Coordinator annual meeting off of Dupont Circle in November 2017. When asked with respect to how broadly part 2 was being implemented, his response was, "Very low." He was then asked about the number of hospital systems that have adopted the Consent2Share technology. The answer was, quote, "Zero," end quote.

So, I think our concern, Netsmart's concern, is that with the inability to operationalize Consent2Share, one of the key objectives that was described earlier, permitting individuals with opioid use disorders to benefit from new care coordination programs and case management systems, is defeated, and this is exemplified by the fact that the only two health information exchanges in the United States, as far as we can tell, actually accept addiction medical records.

One last thing: The last rule appeared to us to suggest that SAMHSA use its discretion in separating out treatment and healthcare operations from medical treatment and care coordination. It's our view that an additional rule is necessary in order to be able to unify these concepts so that addiction medical records can be shared in the manner that was described a few moments ago to ensure proper treatment for individuals with opioid use disorder that have a high incidence of comorbid medical/surgical chronic diseases,



HIV/AIDS, hepatitis C, cirrhosis of the liver, among others, and also to ensure patient safety in prescribing both Vivitrol and buprenorphine, which are FDA-approved products that have a pronounced contraindication profile most prominently with benzodiazepines, anti-anxiety medication. Thank you so much.

MODERATOR (Suzette Brann): Thank you. Teresa Berman, Magellan Health?

TERESA BERMAN, MAGELLAN HEALTH: Thank you. I'm Teresa Berman, senior vice-president, deputy chief compliance officer for Magellan Health. On behalf of Magellan, thank you for hosting today's session. My remarks will address the need for regulatory changes to part 2 to promote individual health, wellness, and recovery via improved care coordination.

Magellan's perspective on part 2 is informed by our experience in managing and administering mental health and substance use disorder treatment and services for health plans, employers, military and government agencies, Medicare and state Medicaid programs. We also contract with more than 80,000 credentialed behavioral health providers and provide services to 1.6 million government members.

For customers and members, Magellan performs case management, care coordination, discharge planning, and related functions, affording us significant direct experience with the impact of part 2. Much of what Magellan does on behalf of our customers and members necessitates disclosing patient identifying information within the healthcare system, interfacing and interacting with providers while protecting privacy concerns of members with mental health conditions and often occurring substance use disorders receiving treatment. Indeed, the Journal of the American Medical Association found 50 percent of individuals living with a serious mental illness also have a substance 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, in effect, prevented from accessing all relevant information necessary to appropriately support his or her needs. Magellan continues to urge SAMHSA to update part 2 to align with HIPAA by adapting a care coordination exemption to the consent requirement. While HIPAA permits such information sharing for treatment and care coordination purposes, part 2 does not, presenting an unnecessary barrier and marginalizing this crucial tool for individuals with substance use disorders.

This meaningful change would retain sufficient protection and confidentiality of the individual's substance use 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. The vast majority of today's integrated care models rely on HIPAA-permissible disclosures and information to support care coordination, that is, without the need for an individual's 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 we arrange for 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 modern electronic infrastructure for information exchange. In an era of electronic medical records, having incomplete records available for providers because substance use disorder information cannot be included without an individual's consent, it disallows providers from supporting their patients holistically. Providers are likely to believe the electronic medical record they have access to includes the member's complete record. In situations where this is not the case, a provider may, for example, prescribe opiates for back pain for a member with a prior history of opiate misuse, which could lead to a relapse.

Access to complete medical information is critical for providers to ensure members' access to care is appropriate to their needs and their clinical histories. To ensure individuals with substance use disorders receive the full benefits of integrated care, Magellan respectfully requests the same care coordination exception as contained in HIPAA be applied to information under part 2. Thank you.

MODERATOR (Suzette Brann): Thank you. Is Amy LaHood, St. Vincent Hospital/Ascension here?

AMY LAHOOD, ST. VINCENT HOSPITAL/ASCENSION HEALTH: Thank you for this opportunity. My name's Amy LaHood, and I'm a family doctor from Indianapolis. I work for St. Vincent and Ascension Health Hospital. I care for an underserved population and have done family medicine for the past 17 years. I know firsthand the devastation addiction causes to families and in communities.

Two years ago, I chose to obtain my Suboxone waiver with the intention of starting a perinatal opioid addiction program. As a family doctor, it was obvious to me that doing prenatal care alongside medication-assisted therapy seemed like an optimal way to treat this vulnerable and motivated group of women. I work at a church-shared care academic center and have the full support of hospital leadership.

I admit, I was naïve about the challenges in providing substance abuse treatment in a traditional healthcare setting. I've spent the past 12 months meeting with hospital leadership, compliance, the best privacy attorneys in town, and our IT department. I didn't even know CFR 42 part 2 existed until two years ago.

My current EMR does not have the capacity to segregate data within a single electronic space. When our program starts this spring to be compliant with HIPAA and CFR, I've been asked to simply have two simultaneous schedules for each patient that comes in, to carry two separate laptops, using two separate names and IDs in every patient room. My nurse will have to do the same. In one electronic chart, the information containing

the prenatal visits will be kept. In the other chart will be the information regarding substance abuse, including urine toxicology results and the buprenorphine prescriptions. The prenatal chart will be accessible to other providers in our traditional EMR. The substance abuse treatment chart will not be available and will be blinded to all other providers in my system.

This required blinding of substance abuse information is counterintuitive to everything I'd envisioned in starting an integrated care model. Today, most experts agree whole-person care is the optimal framework to provide high-quality care. A patient's history or current treatment of substance abuse is a vital part of their medical history, and treating it differently perpetuates stigma of substance abuse. Universal access to this information helps to provide safe, high-quality care in order to minimize risk for future addiction and relapse.

Lastly, my understanding in doing opioid mitigation work is that CFR 42 is one of the reasons why methadone clinics cannot or do not submit data to state prescription drug databases. Treating providers have no mechanism to query whether a patient is on methadone. Methadone is a complex, high-risk drug found in a disproportionately high number of death toxicology reports. Working to make methadone data available through state databases will make patients safer and inevitably save lives.

I am here today to advocate for full alignment of CFR 42 with HIPAA. I remain convinced this change will increase access to treatment, reduce barriers to patients needing treatment, make care safer for persons with substance use disorders, and potentially allow integration of methadone data into state prescription drug databases. Thank you.

MODERATOR (Suzette Brann): Kelly Corredor, ASAM?

KELLY CORREDOR, ASAM: My name is Kelly Corredor, and I am the director of advocacy and government relations for the American Society of Addiction Medicine. ASAM is a national medical specialty society representing more than 5,000 physicians and aligned healthcare professionals who specialize in the treatment of addiction. I'd like to thank SAMHSA for holding this 42 CFR part 2 Listening Session and for its hard work on this issue to date.

ASAM knows that the patient/physician relationship, as the foundation of medical care, is often considered a sacred trust. The uniqueness of this relationship derives from the mutual understanding that the encounter is confidential, that what is said by each party is kept private from all others, with exceptions for a listing confidentiality approved by the patient, and the privacy of medical records documenting addiction treatment is especially important. Part 2 is federal law that requires that documents of addiction treatment be held to higher standards of confidentiality than even psychiatric records, and far higher standards than records of general medical encounters.



With that being said, however, since part 2 was promulgated in 1975, dramatic changes have occurred both in (1) our healthcare system, and (2) our understanding of the disease of addiction. Today, the delivery of American healthcare is increasingly focused on integration of medical services offered by different providers. Disease management of chronic conditions, including coordination of pharmacological treatment and recognition of the patients with the greatest needs, those with multiple chronic conditions, are often associated with some of the highest costs in the healthcare delivery system. Indeed, the advent of integrated healthcare systems and electronic medical records has improved the safety, quality, and coordination of care for patients with other health conditions.

part 2 requirements, however, 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 and the Health Information Technology for Economic and Clinical Health Act.

Perhaps even more importantly, we have learned much about the disease of addiction in the past 40 years. Research has shown that we cannot effectively treat addiction in isolation from other medical conditions. Many psychiatric disorders, infectious diseases, and other chronic conditions frequently co-occur with addiction. Untreated addiction exacerbates these other conditions, and untreated infectious or other diseases complicate addiction treatment.

As a result, ASAM has decided that the barriers that part 2 currently presents to coordinated safe and high-quality medical care cause significant harm and that thoughtful changes to federal law continue to be necessary to mitigate this harm while protecting patient privacy. Accordingly, ASAM has joined other provider associations, patient groups, and health plans to support legislative efforts, which would align part 2 with HIPAA for the purposes of healthcare treatment, payment, and 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 records outside the healthcare system. Moreover, we could use such a legislative opportunity to strengthen protections against the use of addiction treatment records in criminal and civil proceedings as a further improvement to part 2.

In conclusion, ASAM will continue to advocate for the highest treatment standards and the most compassionate care for patients with addiction and seeks to hasten the date when all our patients can easily access state-of-the-art treatment and a healthcare system and a world that do not stigmatize their disease. And despite all good efforts to date, further targeted changes to part 2 remain necessary to realize this goal. Thank you for listening.

MODERATOR (Suzette Brann): Joycelyn Woods, National Alliance for Medication-Assisted Recovery? Joycelyn Woods? William Stauffer, PRO-A?

WILLIAM STAUFFER, PRO-A: Good morning. Thank you for the opportunity to speak today. My name is William Stauffer. I'm the executive director of the Pennsylvania Recovery Organizations Alliance, a statewide recovery organization of Pennsylvania. I'm a licensed social worker, I have 25 years' clinical experience, and I'm also a person in long-term recovery, 31 years in recovery.

I'd like to start by saying I'd like to live in a world where substance use conditions are like other medical conditions. They are not. We are not treated the same, whether we're an airline pilot, a pharmacist, a physician, or a licensed social worker. When we acknowledge that we're in recovery or have an addiction problem, we are treated differently, and we are subject to discrimination.

It is important to note that my first question when I walked into a treatment center in 1986 at the age of 21 was about confidentiality and what was going to happen to the information I shared with my counselor. I trusted the answer I received back then. I know now that such trust is critically important to the fragile therapeutic alliance that must develop for a person to get better. The final rule, as it stands, endangers this fragile therapeutic alliance and may well reduce access to care as a result by making access and use of our information unknowable to the patient.

Recent changes to the rules make informed consent virtually impossible. Information can now go in a myriad of directions once released. If the information is used to discriminate against us, it's impossible from the patient's perspective to know where the violation occurred and who did it. The best example of this is under the use of payment and healthcare operations, which is described in the final rule, and I don't have the time to read through that list of 17 things. Given that long list, as a treating clinician, I would have to tell the client that I have no idea who will get their patient information or how it is used. Under this rule, I would've not entered treatment, or I would've self-edited my disclosures in such a way that it would undermine my own care.

I'm not alone in that. I was talking to an airline pilot the other day that I had to assure multiple times that the information that I shared would not go beyond that. Such a person could still be flying planes I'm flying tomorrow. I think about that stuff.

Please understand that there is much greater stigma around substance use conditions than other kinds of medical conditions. The very acknowledgment of having a substance use condition can open us up to discrimination and, in many instances, place us in legal jeopardy. We face a Hobson's choice when confronted with a consent to release our information under the current rule.

We implore SAMHSA to not further weaken our confidentiality rights. We are concerned that these changes add many layers of complexity and ambiguity to the regulations and will only serve to create further confusion. It is worth noting that many care professionals do not understand that they can access information with a properly



executed consent, while others seem not to care to be bothered to honor our privacy rights.

We understand that SAMHSA is seeking balance between protecting confidentiality of substance use disorder patient records and those who would wish to have expanded access to our personal information. The bottom line is that if consent to release our highly personal information is required for payment or to participate in treatment, we're left with no real choices beyond avoiding care or risking the use of our information to discriminate against us after it flows into our medical records.

We respectfully request that any additional rulemaking would be used to protect us from misuse of our information and to hold those who would use it to discriminate against us as accountable to protect our information. It is the standard that Congress strived for back in 1972, which we believe is just as relevant now, and I will read that: "The conferees wish to stress that their conviction that the strictest adherence to the provision of this section is absolutely essential to the success of all drug and alcohol 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...would 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 who gets it and how it's used. We think that this is a fundamental right and important to quality care and consistent with the original statutes, and we ask that the original intent be honored under the regulation. Thank you.

[END OF 42 CFR PART 2 LISTENING SESSION VIDEO TWO]

42 CFR PART 2 LISTENING SESSION VIDEO THREE

[TITLE SLIDE: 6 SECONDS]

[SLIDE 2: 0.07 – MICROPHONE SLIDE]

MODERATOR (Suzette Brann): Thank you. Fern Wilcox, Daystar Center for Spiritual Recovery? Fern Wilcox? Eric McDonald?

ERIC MCDONALD: Hi, my name is Eric McDonald, and I would like to share my experience with you. I've listened to a lot of different people and studied this online. Up until a few years ago, I didn't know that 42 CFR existed.

I'd like to talk about what happened to me. I had a 10-ton wall strike and crush me for over four minutes. I have lifelong permanent injuries. On day nine of a five-week hospital stay, during a PTSD evaluation, a drug abuse assessment was done without my knowledge. I had almost died, and spoke candidly about my past, not worrying about answers from my youth. I wasn't given informed consent, and being under the influence of pain medication, I wasn't a good historian for my current injuries or my past.

Based on this, they misdiagnosed me with polysubstance abuse, listing it as a current issue though I've been sober for seven years. The practitioner also failed to submit the record as confidential under the 42 CFR, and it affected my entire care. This practitioner was also a counselor at a mental health facility. I called the hospital's main office and was told that they weren't required to adhere to 42 CFR standards, as they weren't a treatment facility. The mental facility did too. A search proved that they did fit 42 CFR part 2 criteria. This was at Providence, Anchorage, Alaska.

These confidential records are still posted to my chart to this day. The failure of this hospital and provider to keep my records confidential has had a devastating effect on my ability to get unbiased care. Every doctor I see pulls up the hospital website and witnesses the confidential diagnosis listed in the open records. It's created an avenue for Work Comp insurance company to deny benefits based on an addiction perspective and has used this as a cross I must bear through the entire litigation process, stating that I'm dishonest and lying about my injuries for financial benefit.

In the three and a half years since the accident, I've used my medication responsibly, although the insurance company has used my pain as a means to demean me, make me feel worthless, and acted as if I wanted a 10-ton wall to slam into me and almost kill me. They have treated me like I'm worth more dead. I live with pain every single day and have never been able to heal emotionally. They took confidential info from the hospital and gave it to every provider I attempted to see.

My bilateral 1st rib fractures ripped into my body, causing a new pericardium and heart damage and a one-liter hemothorax. A heart doctor threw me out of his office, accusing me of lying about my injuries for Social Security benefits, yet I was making over \$12,000

a month at the time of the accident. The culprit? The insurance company's disclosure of my hospital discharge notice, listing the inaccurate polysubstance diagnosis.

The sabotage has been overwhelming. I tried to treat mental issues for being trapped under cement for four minutes. The insurance company gave the mental facility a release but failed to comply it with psychotherapy notes and the privacy rule's federal standards. I discussed my past with this counselor in an attempt to heal, and the notes were used to deny me this much-needed therapy many months after I started.

Even though my entire body was involved in this accident, they have denied these obvious and devastating injuries as a result of this confidential disclosure, a C5 wedge fracture, low back injuries including a traumatic bilateral L5 stress fracture, a T7-8 disk protruding into my spinal column, and all psychological issues, and it made all other injuries difficult or impossible to treat.

I feel that my experience is the exact reason for the establishment of 42 CFR part 2 in the first place. This hospital is a huge company that has many locations in the West and Midwest. I've found their insistence that federal rules don't apply to them is a common occurrence in the hospital and mental health industry, where companies aren't explicitly stated as drug and alcohol treatment facilities. The failure of this adherence is a result of these entities' inability to coordinate with their staff, outside programs, and partner institutions, and the pure and simplest reason, it costs them money to adhere to these rules. Thank you.

MODERATOR (Suzette Brann): Thank you. We'd like to take some comments from the phone now.

OPERATOR: Deborah Kilstein?

DEBORAH KILSTEIN: Thank you. My name is Deborah Kilstein. I am vice-president for quality management and operation support of the Association for Community Affiliated Plans. ACAP represents 61 nonprofit Safety Net Health Plans that predominantly serve the Medicaid population in 29 states. We are also a member of the partnership to amend 42 CFR part 2.

States and federal government have turned to managed care organizations to provide coordinated integrated care for people with Medicaid, Medicare, and CHIP coverage. Many of the ACAP plans also participate in the marketplace. These MCOs assess member needs, identify treatment gaps, engage members, encourage medication adherence, develop individualized care plans, and coordinate care. These programs are particularly important to facilitate integrated physical and behavioral healthcare and social services for individuals with substance use disorder.

Unfortunately, outdated federal regulations that predate current models of care create significant barriers to holistic care for people with SUD. In a coordinated care system, 42 CFR part 2 requirements are excessively burdensome and have the effect of

undermining the delivery of health plan services. While SAMHSA's recently published final rules did make some changes to the consent requirement, those changes did not go far enough. ACAP strongly supports the movement to align 42 CFR part 2 with the HIPAA standard, with additional protections as necessary.

As we all know, HIPAA did not exist when 42 CFR part 2 became effective, but it has now become the well-tested standard for privacy of health information. We understand from the preamble to the final rule that SAMHSA questions whether the agency has the statutory authority to further align with HIPAA standards for information concerning drug treatment. ACAP strongly supports SAMHSA's reevaluation of this position. Moreover, the current designation of care management and care coordination by a member's health plan is not statutorily defined as treatment.

While we strongly believe that the alignment with the HIPAA standard for part 2 services is appropriate and will continue to advocate for this change, we are asking SAMHSA as a minimum to designate health plan care management and care coordination as an operational function, not as treatment subject to the limitations of 42 CFR part 2. Surely, Congress did not intend to make it harder for a health plan to provide care management and coordinate services for people with SUDs and for those with other chronic conditions.

Let me be clear that ACAP strongly supports the healthcare privacy of members who live with an SUD, but we also support the need to allow the flow of information that is necessary to foster care coordination, ensure proper treatment, promote patient safety, and ultimately improve an individual's health status, and thank you very much for the opportunity to comment.

MODERATOR (Suzette Brann): Thank you.

OPERATOR: Amanda Laukant?

AMANDA LAUKANT, BEHAVIORAL TREATMENT SERVICES: Good morning. My name is Amanda Laukant, and I am executive director of Behavioral Treatment Services. BTS is a treatment provider in Colorado providing substance abuse and mental health services to court-mandated clients in the criminal justice system. BTS provides services in halfway houses, county jails, and on an outpatient basis.

I'm here to speak to you today regarding the limitations that the 42 CFR part 2 changes have posed on a day-to-day basis in necessary collaboration with involved criminal justice providers. Working with a range of criminal justice-involved clients always presents a set of barriers, but unfortunately, since the revision of 42 CFR part 2, these barriers have increased. Due to the fact that 90 percent of our clients are court mandated to see us, it is near impossible to provide quality treatment and to ensure community safety if we cannot appropriately communicate.

In practice, the following major barriers have been present: Criminal justice system and private vendors for criminal justice have an overwhelmingly high turnover rate. The changes to 42 CFR part 2 now require us to list one specific person's name in the criminal justice system in order to be able to share clients' substance abuse treatment progress. Due to the turnover rate and the requirement, our clinicians are often found in a position of not having a valid release of information and, therefore, inability to collaborate and educate. Additionally, it is a very rare scenario that a client is only working with one person at a criminal justice agency. When officers are out sick, on vacation or leave, suddenly it is very a common scenario that a new officer needs information quickly in order to ensure community safety and understand the needs of the client. Transportation and access to technology limitations and, therefore, the ability to sign a new release limits our ability to communicate.

Second, clinical staffings are a vital part of several criminal justice populations. Primarily community corrections and specialty courts require that all involved agencies come together to determine the course of action and needs for a specific client. As a clinical provider, it is impossible to know and predict all of the parties that will be present at the table. Again, this can be related to turnover as well as a client's complexity of involvement in the criminal justice system. Clinical staff ensure that they are only sharing the minimum pertinent and necessary information, but again, actual implementation negates our ability to even share this with 42 CFR part 2. This limitation ends up doing the system and the client a disservice due to the fact that there is no clinical advocacy for the client at the table.

I and my agency hold confidentiality of the utmost importance. While this provision was put in place to protect the client's right to confidentiality, the truth is that in practice, all it has done is to take away from our ability to appropriately advocate for the client to their criminal justice provider and to collaborate with the criminal justice system on necessary issues.

I ask you to consider the day-to-day impacts that this rule has on collaboration for the sake of the client. I would ask that this committee consider a revision that allows criminal justice supervision agencies and entities, specifically probation, parole, community corrections, and specialty courts, to be listed on a release rather than an individual name. Substance abuse and criminal justice involvement cannot be seen as two separate issues if we hope to continue to work towards the best interest of the client and community. I appreciate your consideration in the matter in order to best help serve our clients and community safety.

MODERATOR (Suzette Brann): Thank you, Amanda.

OPERATOR: No other questions queueing at this time.

MITCHELL BERGER: Great. We'll go back to our in-person list. The next person on our list is Monica Scott from Misha House.

MONICA SCOTT, MISHA HOUSE: Good morning, everyone. My name is Monica Scott. I'm the executive director of Misha House. We are a very small IOP treatment facility in Baltimore City.

In reviewing the new standards for 42 CFR part 2, I'm in agreement with a lot of things everybody has already said here. But how I'm going to present to you my comment is this: We work in the inner-city Baltimore, where the drug overdose population is very high. In treating these individuals, it becomes very difficult based on the changes that have been made. We have individuals in the criminal justice system who, like others have already talked about, that change agents every two days, ten days, two months, three months, and if that person is engaged in treatment for a period of six months, we may have four different consent forms for that individual, depending on whether or not the individual is willing to provide the name of the new agent, so that kind of prohibits them from getting the necessary treatment and recommendations when you have drug court clients that are mandated for services.

We also have issues with the changes to CFR based on the fact that an individual who comes to us for treatment services, however has not informed us that they're engaged in OMT services once the re-bundling or unbundling of the Medicaid services in Maryland took place. So, you may be engaged in more than one treatment provider at one time, but if they don't notify us or give us consent to contact that organization, then we have issues, because now they're enrolled in two systems within the Medicare system there. We're not being able to bill, they're not being able to be medicated, so it creates a problem, because we can't talk to one another unless the client gives us consent to do so to be able to provide adequate care.

And the last is those individuals who need integrated care, those who are receiving both substance abuse and mental health services in two different locations, or they may be engaged in outpatient treatment. They may be engaged in PRP services and also have a licensed psychiatrist that is prescribing their medication. However, if the client doesn't consent for us to communicate with any of these entities, then we are at a loss for being able to provide holistic care for the individuals.

So, I'm not going to tell you about the rules are wrong. I'm not going to tell you that it needs to be revised. I just think we need to take another look, because we make all of these rules that everybody has to follow, and everybody has to be in adherence to. But who thinks about the individual? Those are the people that we're doing a disservice to and for. We're here to be able to bring people to a place of wholeness and wellness, and we can't do that with new regulations and new laws written by individuals that don't even provide the service to understand what it is that we have to go through in not only dealing with the system but trying to improve the quality of individuals' lives. Thank you.

MITCHELL BERGER: Our next comment is from Jacqueline Madison, PEMS Balance Consulting. Ms. Madison? Okay. Our next comment is from Eric Goplerud in his own capacity, NORC, University of Chicago.

ERIC GOPLERUD, NORC, UNIVERSITY OF CHICAGO: Good morning. My name is Eric Goplerud. Since the original substance use privacy laws were passed in the 1970s, huge changes have taken place in substance use treatment. The laws on which part 2 is based has two requirements that are stricter than HIPAA. Consent is required for releases of patient information, and disclosures without patient consent is prohibited for use in criminal investigations or proceedings, except under tightly circumscribed circumstances.

It is time to go back to the law and rebuild substance use privacy regulations from the ground up, not on the architecture of the outdated 1987 part 2 regulations, an architecture which now runs to over 13,000 words, 95 pages of Federal Register preamble, and still requires 27 areas where HHS says additional subregulatory guidance is needed, but rebuilt from the 737 words of the law, recognizing that the world of healthcare and health information exchange is much different than in the 1970s.

SAMHSA's own data show that twice as many people with substance use disorders receive substance use treatment outside of part 2 programs, and more than 60 percent of patients of part 2 programs are under court supervision with limited privacy protections. The 2017 final report of the President's commission on combating drug addiction and the opioid crisis found that part 2, quote, "acts as a barrier, making it administratively difficult for providers to share information, has ill effects by restraining physicians' ability to make informed healthcare decisions." The commission calls for HHS to, quote, "better align through regulation patient privacy laws specific to addiction with HIPAA and update patient privacy laws such as 42 CFR part 2," end quote.

The law, 42 USC 290dd-2, does not require substance use privacy regulations to be separate from other national HIT privacy regulations. HHS should assess whether the best parts of part 2, the restrictions on the use of substance use medical records in criminal proceedings, could be placed within the HIPAA privacy regulations. We now have regulations, HIPAA and HITEC, which create consistent privacy and security standards for all of healthcare. The law authorizes HHS to promulgate regulations to defined disclosure standards. HHS should adopt the HIPAA disclosure standards, which detail the conditions under which personal health information may be disclosed without prior patient authorization for the purposes of treatment, payment, and healthcare operations. The part 2 law does not dictate the content of patient consents, but the regs sure do.

There should be one standard healthcare consent, and that should be HIPAA's. Moving part 2 under HIPAA could address the significant problems of part 2 enforcement. Unlike HIPAA penalties, which are substantial and enforced, part 2 penalties are small, ambiguous, unenforced, and possibly unenforceable.

Finally, HHS should develop regulations to implement 42 USC 290dd-1, which just precedes the part 2 statute. The statute states, quote, "Substance abusers shall not be discriminated against in admission or treatment solely because of their substance abuse." HHS should craft substance use anti-discrimination regulations and fold them,

along with substance use privacy protections, into HIPAA. Integrating substance use into the medical mainstream is not only the right thing to do, but the law, 42 USC 290dd-2, says you can do it. Thank you.

MITCHELL BERGER: The next person I have on our list is Nanette O'Neal.

We'll come back. Next person is Sherry Sherman, Home Healthcare of Maryland. Okay. Linda McRae, independent consultant? Kim Curtis? Okay.

Gloria Cain, Howard University? Okay. I'll come back to a couple people who we may have passed earlier the first time. Nathaniel Counts, Mental Health America? Miranda Franco, Holland & Knight? Okay. Operator, can we take questions from the phone?

OPERATOR: We have a question from Kirk Kemling.

KIRK KEMLING: Thank you. Good morning. My name is Kirk Kemling. All of my comments are my own. I'm associated with a lot of different organizations, and I just want to make it clear that they do not reflect any of the organizations' views. They are all my own personal views.

I am both a provider and consumer of mental health services, and I have been for over 30 years, so I've seen these regulations built and changed and re-changed. From what I can see from being on both sides of the fence is that there is too much of a gap between sides. I understand, as a provider, we do need to communicate better between providers, but the abuses that go on that I have seen on both sides between patients and on the providers' sides are currently occurring, and if we make them tighter and all, it doesn't really help.

I agree with the previous gentleman's statements saying that things probably should be rebuilt. It's not going to be the most popular way, because it's the long way, but it's probably the right way. We need to keep in mind that, yes, we have to provide services, and we do have to keep the patients' privacy up as the foremost thing. The patients will not seek services if they think that their information is going to be misused. And that's about it. I just wanted to let people think about the patient first. It is a lifelong disease, and just one little slip-up where the information gets out where it shouldn't can affect that person for the rest of their lives, and not just that person, but that person's family and friends and other associates.

All right. Thank you very much for letting me speak, and I know we'll be able to all work this out together if we all work together. Thank you.

MITCHELL BERGER: Thank you. I know we have one person, a Mr. Sperling from NAMI, but after Mr. Sperling, if anyone here in person we didn't call on or thought they were on the list but wasn't would like to speak, we'll give you an opportunity as well. Mr. Sperling?

ANDREW SPERLING, NAMI: Good morning. My name is Andrew Sperling. I'm with the National Alliance on Mental Illness. And I recall immediately, as the late Mo Udall once said in a debate in the House of Representatives, "Everything has been said, but not everyone has said it." So...

[Laughter]

NAMI is the nation's largest organization representing people living with serious mental illness, and their families. Why is 42 CFR so important for NAMI? Well, first of all, we know that a large number of people living with disorders such as schizophrenia, bipolar disorder, and major depression have a comorbid substance abuse problem, and we know that the best way to treat individuals with co-occurring disorders is to have integrated care, and 42 CFR continues to serve as an antiquated, outdated barrier to integrating care and getting better outcome.

I would also note for the record that, as we move toward integrating things under the rubric of behavioral healthcare, that many providers assume that 42 CFR applies to psychiatric treatment records as we have integrated care and moved to single records. So, 42 CFR serves as a barrier even for people who have a serious mental illness and no comorbid substance abuse disorder.

NAMI would also note for the record that we have spent as a field, both mental health and substance abuse, it took us the better part of a quarter of a century to get Congress to pass a parity law, and our message consistently over many, many years was a disorder such as schizophrenia, a disorder such as an opioid problem, the entire basis, the principle of parity was, "Cover us the same way you cover heart disease, cancer, diabetes, COPD, and asthma."

42 CFR was completely contrary to that. To have a regulation that segregates and keeps mental health and substance abuse separate from the rest of healthcare runs completely counter to the arguments we've made for so many years in achieving the Mental Health Parity and Addiction Equity Act. And it is a huge barrier to integrated care, particularly around comorbid health conditions, and it continues to be a barrier that drives bad outcomes, not just for mental health and substance abuse, but the high incidence from these individuals that have comorbid chronic medical conditions that are poorly managed, diabetes, heart disease, COPD, on and on, and deliver those horrific outcomes.

We know that the life expectancy for someone with a serious mental illness in the United States hovers around that of an adult in Bangladesh and is driven by poorly managed, chronic, comorbid chronic medical conditions, and 42 CFR is an enormous barrier to getting integration.

NAMI supports many parts of the rule that SAMHSA came forward with. We believe that more can be done, and we will be offering comments and urge SAMHSA to move forward on subregulatory guidance. But there's one more and very important thing that



the leadership of SAMHSA can do, and it's a recommendation and a plea that NAMI would make to Dr. Elinore McCance-Katz, the assistant secretary for mental health and substance abuse, and our new secretary, Alex Cesar, and that is to get the Trump administration on board in support of HR 3545, NS 1850, the two bills in the House and the Senate that would finally move us toward aligning HIPAA with 42 CFR part 2. We simply cannot have separate rules that govern the handling of these medical records if we're going to achieve the outcomes we need to achieve and overcome the huge barriers to integration that still exist in the system. Thank you very much.

MITCHELL BERGER: Thank you. All right. Next speaker is Ken Martz, a psychologist and independent contractor.

KEN MARTZ: Good morning. I'm Dr. Ken Martz. I'm a licensed psychologist and independent contractor. Thank you for the opportunity to express support for the struggling substance use disorder. Remember that many of these individuals that we're talking about here that are affected by substance use disorder are not here today, nor do they even know that this conversation is occurring thousands of miles away, debating over their rights and their confidentiality protections.

As a licensed psychologist, I've specialized in treating substance use disorder for over 20 years, working in outpatient, inpatient, residential, prison settings, a whole range, and there are three simple points I want you to remember today: Stigma, treatment, and hope.

Stigma: A key reason why people do not seek treatment is stigma. The national survey on drug use and health continues to say that some of the top reasons why people are not seeking treatment today is for fear of stigma, the impact that it will have a retribution from their employment or judgment from their neighbors and friends. You know, we talk about how these are similar to other disorders, but, you know, even today, just as in 1970s, we do not put people in jail for having cancer. We do not deny visitation to your children because you have a heart attack. We do not fire you from your job because you have an ingrown toenail. All medical conditions are not the same. There are certain specialty conditions related to substance use disorder, and treatment is at the center of that.

Treatment occurs in the context of a supportive relationship where an individual feels safe to explore their deepest fears, beliefs, and judgments that lead to the escape into substance use disorder. When I don't have a safe environment, treatment cannot exist. Treatment does not occur. This is the centerpiece of what folks are needing in order to be able to get back out of the world of addiction and into better recovery and long term. If you do not have that safe environment -- that is where recovery can take root and grow -- you will not have treatment, but you lose some of the hope of recovery.

Lastly, impact. SAMHSA's repeated changes to the confidentiality rule creates confusion at a time when patient protections are needed. Every change requires both the retraining of the field as well as an informed consent warning to each and every



patient. Every time a new change comes out, I need to go figure out what it means. I need to train all my staff. I need to then go and connect with each and every patient, explain to them what you had told me yesterday that was private yesterday is no longer private. What I've already released can be released to other people that I didn't agree to you about.

Imagine the look on that client's face for just a moment when they suddenly realize their information is going somewhere that I didn't give you permission to. Think about this. Every change we make, every time we move that bar, it changes the rule of what we can have in informed consent. As a client, I'm agreeing to share my secrets to you under that certain context of confidentiality. When you change and don't inform me about what those guidelines are, or I find out that what I put and confide to you today could be changed next month or next year, it's going to impede folks' willingness to come to treatment and continues to be that concern. Remember that fear of exposure that is the centerpiece of the treatment context and why that privacy is so critical. Every time we weaken confidentiality, we weaken that hope of recovery.

The opioid epidemic has revived some historical attitudes criminalizing substance use disorder with talk of involuntary commitment. You know, we are now trying so hard to get a hold of folks and support them, but now more than ever, these protections are needed for the treatment environment so there's a safe place for someone to begin their recovery.

The final rule as written has gone too far in weakening confidentiality protections, and I urge you to remember that we are the hope of recovery for millions of Americans, and these decisions that we're making about confidentiality mean the difference about life and death. Thank you again for the opportunity to be the voice of some of those who cannot be here today, and to bring the light of that problem of stigma, the solution of treatment, as well as the need for confidentiality protections, a hope of recovery. Thank you.

MITCHELL BERGER: Thank you. Is there anyone else in person that would like to speak that has not yet spoken, or maybe didn't sign up that would like to speak? Okay. Operator, do we have any questions on the phone, I mean, any comments? Great.

OPERATOR: Mark Jones?

MARK JONES: Well, thank you, and good morning to everybody. My name is Mark Jones. I was principal investigator at one of the first HIEs empowered by AHRQ to figure out for the country how to do health information exchange. As a mental health provider, I've spent a lot of time working on that particular issue around 42 CFR. Since that point, we've combined our network with the state HIE, and I've worked with over 20 large mental health centers, their leadership teams, and the medical providers they exchange data with about the issues surrounding the confidentiality of drug and alcohol information.

My comments would be this: I do wonder if we aren't being a little bit too parental. We are essentially designing laws for providers and for patients who don't always understand the consequence of what they're signing, and therefore we are essentially providing protections for them. Our experience here has been that mental health patients very often have their wits about them and can decide for themselves what particular constrictions they'd like to have around their records.

So, what I'd like to throw out here is that, yes, we are trying to figure out whether to do away with 42 CFR or combine it somehow into HIPAA, but listening to all of the providers this morning and users, a lot of people would like to have their data shared, and some would not. So, I do wonder if we could take a look at the idea of allowing the patient to decide whether they want to continue under 42 CFR constrictions, or whether they want to go to HIPAA.

Our experience here is that almost 95 percent of mental health patients are for sharing their data, because they understand, once it's explained to them, the consequences of not sharing it. But there are occasions under which people just really don't want to do that, and maybe by allowing the patient to make the decision, we can get the best of both worlds. Thank you for your attention for this this morning.

MITCHELL BERGER: Thank you.

OPERATOR: Next is Heather Johnston.

HEATHER JOHNSTON, PATIENT ADVOCATE: Hi, my name is Heather Johnston, and I didn't really prepare a speech because I didn't think there would be time for me to speak today, but I'm happy that I can be here from Alaska. I have been a patient advocate for over 15 years, and I'm here to tell you today that discrimination is very much alive for people with substance disorders.

I just want to tell you about a couple of patients that I helped. One was a lady, who went over her handlebars and went to the hospital with extreme neck pain, and they actually determined that she was drug seeking and sent her home with a broken neck without doing any kind of radiology, and she lived in pain until she finally had her neck fused. And then, on a more personal note, my sister went in for a kidney surgery last year, where the doctor operated on the wrong kidney, and it was in a rural area. So, she wanted to go to a major medical center because she was in a lot of pain, and the doctor called ahead to the medical center and said, "This person is drug seeking." So, when my sister got to the hospital, all the doctor could say is, "We're not giving you drugs," and she just wanted something done with the kidney that was supposed to be operated on.

And I'm also Mr. McDonald's significant other. He spoke earlier. And he didn't get to get into a lot of his stuff because of time constraints, but he suffered a heart attack while in the hospital and kept telling them that he was feeling like he was having a heart attack. And once that diagnosis got put on his record, they didn't look for anything else, and ended up leaving the hospital with undiagnosed injuries, including a neck fracture, a

back fracture, and a heart attack. And when looking for the heart attack diagnosis, it came to us, and so when we tried to get more information about it, the doctor accused him of lying about it. And when I went to grab all of my records that I'd taken showing the abnormal EKGs and all of the evidence that we had, he actually grabbed my arm because he didn't want me to see what he was looking at was not any of the heart records, but in fact the drug diagnosis records.

And something needs to be done to protect these people, because it's not only affecting patients, it's affecting families. It's affecting our grandchildren, our children, me. I go to bed thinking about it every day. I wake up thinking about it every day. This has destroyed our lives. And, like the gentleman said earlier, a lot of people don't know that people are sitting here discussing their medical records today. So, that's all I had to say. Thank you.

MITCHELL BERGER: Thank you.

OPERATOR: John Ownby-Hibner.

JOHN OWNBY-HIBNER, RELIANCE eHEALTH COLLABORATIVE: Thank you. So, we have a system we're deploying that uses a common consent model for sharing of the protected information under 42 CFR part 2. But what we're finding is that some communities have shifted to having a crisis center in their area where law enforcement and emergency rooms actually divert patients, so that they can get stabilized and get cooperative care and treatment after they're stabilized. And so, the youth case we're running into is these crisis teams need access to the information, but they don't really fall into an emergency provider role, so we're kind of reviewing legislation and things to see where they fit in.

In a lot of our communities, we've seen a trend where the emergency rooms and law enforcement are kind of diverting these patients to crisis teams or a crisis center. It avoids their entering the justice system and incurring fees and probation and that stigma and cycle. And emergency rooms are trying to use their resources more wisely in more rural areas. So, I think with 42 CFR part 2, it kind of needs maybe expanded with, as healthcare matures and starts creating these youth cases, definitely I think that it needs clarification of some of these roles and who has access.

We did advise them that they could use our system and obtain a consent from the patient, but their response was that sometimes they have law enforcement drop somebody off on their front door that isn't coherent or is still under the influence, and they don't believe that a consent would be valid from that person at that time. So, that's kind of a youth case and what we're running into in supporting our community of providers that want to use our system. Thank you.

MITCHELL BERGER: Thank you. Mr. Hibner, would you be comfortable stating the organization you're affiliated with and location, just for the record?



JOHN ALLENBY HIBNER: Sure. So, I'm with Reliance eHealth Collaborative, and we're in Medford, Oregon.

OPERATOR: Next is Dr. George Patrin.

DR. GEORGE PATRIN: Yes, hello. Thanks for taking my comments on this great session. I'm Dr. George Patrin in San Antonio, Texas. I'm a retired army pediatrician in 2011 and just started a nonprofit called Serendipity Alliance, which is an educational research group who give a voice to the voiceless. This discussion of CFR 42 is so important, as you've heard many callers and speakers today talk about how they haven't had a voice.

But my soapbox as a family practitioner and pediatric, as has been talked about over the years, is that we must have communication, and we all know that's on this call that HIPAA rules and advice is just so we need to keep information private and necessary. I call this group, "Those with a need to know."

My specific mission with Serendipity Alliance is to bring suicide to an end in our culture, our community. And one of the mantras for this, as we go out and speak, is that we must sign releases of information on first visit with our clients -- the clients with substance abuse issues, and the stigma of our culture in society once that information is out that a person's courageous enough to get care, stops them from being able to live their life, is so important.

So, one of the points I make when I speak with the primary care clinics, behavioral health folks -- you should be integrated into primary care with same-day services, that we must sign the releases of information, saying, "Who do you trust?" And I will guard this information as we move on and as a team to provide the care you need.

So, clearing up, this CFR is so important to all of healthcare and further discussion about how we share information. And lastly, I want to say, as a clinician, it is always thought to be the right thing for clients. I agree with an earlier speaker that the rules and the suggestions that we need two separate records, two separate modes of collecting information doubles our cost, and we simply can't afford to keep doing that. We must look at it about how to get this as right as possible, right from the beginning.

I appreciate SAMHSA putting this on and listening to our comments. Thanks.

MITCHELL BERGER: Thank you. Then, Kim, I'll turn it over to you.

[SLIDE 3: 44:25]

KIM JOHNSON: Thank you. Well, thank you, everybody. Thanks to all of you that spoke. Thanks to the folks on the phone that are on the West Coast and got up this morning for this. I know we did this really early for you. And I appreciate everyone's comments, again. Actually, you know, I told them that we would tell them the email box that we should send it to.

[SLIDE 4: 44:55]

So, this is the address, PrivacyRegulations@SAMHSA.hhs.gov that you can submit your written comments to. Or you can use snail mail if you would like, and you see the address up there: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services, Attention Mitchell Berger. Our address is 5600 Fisher Lane, and his room number is – now you know where his office is – 18E89C, Rockville, Maryland 20857.

So, you'll just have to assume that we received your comments if you send them. We're not going to reply – thank you to everybody – but we will include them in our efforts going forward, and I guess that concludes today.

[SLIDE 5 (THANK YOU SLIDE): 46:03]

Thank you, everyone on the phone. Thank you, everyone that's here.

[END OF 42 CFR PART 2 LISTENING SESSION VIDEO THREE]