TRANSCRIPT OF PROCEEDINGS

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Listening Session)

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UNITED STATES DRUG ENFORCEMENT ADMINISTRATION

In the Matter of:)
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TELEMEDICINE)
)
Listening Session)

700 Army Navy Drive
Arlington, Virginia

Wednesday,
September 13, 2023

The listening session was convened, pursuant to notice, at 9:00 a.m.

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P R O C E E D I N G S

(9:00 a.m.)

MR. STRAIT: Good morning. For those of you who are returning, welcome back. For the new faces here with us today, welcome to DEA'S 2023 telemedicine listening session.

I am extremely thankful and appreciative to everyone who has taken time out of their busy schedules to participate in person and virtually in this two-day event.

I am also appreciative for those who are watching the live stream for this event from the DEA Diversion Control's website, www.deadiversion -- all one word -- .usdoj.gov.

Let me now introduce the person who is sitting next to Administrator Milgram and Administrator Milgram herself. Administrator Milgram was sworn into the DEA as Administrator on June 28 after being confirmed by the U.S. Senate by unanimous consent on June 24. As the DEA Administrator, she leads the Agency of nearly 10,000 public servants who work in any one of our 334 offices nationwide.

Next to her is Tom Prevoznik. Tom is a career Diversion Investigator with 34 years of public service, I believe, and he serves in the role as

Assistant Administrator to the Diversion Control Division.

Thank you, Tom and Anne, for being here today.

My name is Matthew Strait. I am a Deputy Assistant Administrator in Diversion, and I oversee an office known as the Office of Diversion Control Policy. This is the office responsible for the regulatory drafting efforts of the DEA which impact those authorized to handle controlled substances for legitimate medical and scientific purposes in the United States. I will be serving as the moderator for this listening session event.

This listening session I want to say is novel for the DEA in that we have not generally held public meetings to inform our regulatory drafting efforts. I hope that this effort underscores our sincere desire to improve upon our information-gathering capabilities to better inform this important work. At no time has this novel approach been more logical and more appropriate. And why do I say that? Because these regulations will impact the delivery of healthcare for every American in the United States, and, frankly, we need to make sure that we get it right.

We've structured this event so that we could hear from stakeholders who could either be here in person or participate virtually. We issued a Notice of Meeting in the *Federal Register* on August 1 and then gave the public until August 21 to register for the event. We received a total of 1,308 registration requests for those who wanted to participate. Of that list, 186 people requested authority to present their comments either in person or virtually.

Due to the structure of the event and our decision to let each commenter provide up to 10 minutes of remarks, we curated a list of commenters with diverse views on a number of issues of interest to the DEA. Twenty-nine were offered the opportunity to participate in person, and 32 were offered the opportunity to participate as virtual presenters.

Yesterday, we heard from half of our 61 presenters both in person and virtual, and today we will hear from the remainder of our presenters. Thank you all for being here.

Because we are transcribing the event and that transcription will be part of DEA's administrative record, our presenters were advised that they could not use visual aids. While we know that some of our presenters and, indeed, those who we

could not accommodate wish to provide written materials during this event, we will continue to encourage those folks to provide written materials when all interested parties are invited to respond to a forthcoming proposed rule on the subject.

For the folks who registered to attend this event in person as an observer, I'm happy to report that we were able to accommodate all of you, and I'm thankful that you all chose to join us here today.

Okay. Let's now go over a quick run of show. This morning, our first block, our morning block, will consist of as many as 15 virtual presenters. I will call Virtual Commenter 1 shortly, and that individual's image will be displayed on the screen up here on the stage. Virtual commenters will be asked to state their name and their affiliation, and then they will be asked to spell their first and last name.

Once we have heard from all virtual presenters, we will take a break, and this should take us to sometime around lunchtime, around the noon hour. We will take a recess and begin our afternoon session at 12:40 p.m., where we will then hear from as many as 14 of our in-person presenters who are up in the first two rows.

For all presenters, at the nine-minute mark, commenters will hear a chime, and that will be their cue that one minute remains. When our countdown clock gets to 10 minutes, commenters will then hear a gentle buzz, which will be an indication to wrap up your remarks. Upon completion, we will pause in the event that Administrator Milgram or Assistant Administrator Prevoznik have any clarifying questions for our presenter.

Before we begin, I want to just lay out a couple of our ground rules. For our in-person and virtual presenters, I ask that you make comments that are related to the nature of DEA's rulemaking and refrain from providing remarks which are not germane.

As moderator of this event, if I believe that your comments stray substantially from the scope of our rulemaking, I will interrupt your presentation and remind you to keep your comments to the practice of telemedicine relating to controlled substances.

For our folks in the audience, you are welcome to get up and use the facilities at any time, but we do require our visitors to be escorted. So, if you need to use the facilities at any time, please exit the door in the rear of the auditorium. There will be DEA staff there to escort you around the

corner to the restrooms.

If you need to leave the building perhaps for a quick bite in our noon hour, please know that you will have to return through the visitors center that you came in through this morning.

And also for our folks in the audience, much like the DEA is in listening session, so are you. There are, unfortunately, no opportunities for questions and answers, and we ask that everyone stay silent during the session. This will not only improve the quality of our transcription but the quality of our simulcast for those who are watching virtually.

Also, please keep your phone on silent. If you need to take a call, feel free to exit again the rear of the auditorium and take that call in our lobby.

Second to last point. In the unlikely event that an audience member is disruptive, as moderator, I will ask our security team to escort you out of the building. Of course, I do not anticipate this to be the case here today.

Last point. Please recognize that Administrator Milgram and Assistant Administrator Prevoznik may need to step away from this event for potentially significant periods of time in order to

attend to their duties. Should that be the case, you may see senior personnel from either the Diversion Control Division and/or the Office of the Administrator sitting here in their stead.

Last, before we begin, I do want to acknowledge that as you walk in the courtyard between these two buildings today you may see our flags flying at half staff. That is to acknowledge the passing of Howard Safir on September 11. He was a distinguished member of the DEA family whose federal law enforcement career began in 1965 with the agency that actually preceded DEA. He served in several capacities at DEA and then later with the U.S. Marshals Service.

Howard went on to serve in roles as the Commissioner of the New York Police Department and Commissioner of the New York Fire Department. His connection to DEA always remained strong during this time, and in our great tradition, we will always remain forever grateful for his service and the enduring mark that he left on the DEA and the law enforcement community at large.

So, with that, let me go ahead and say I will now request Virtual Presenter No. 1 to be displayed.

MS. JANTOS: Good morning. Thank you for

allowing me to testify. My name is Laura Jantos, spelled L-A-U-R-A, J-A-N-T-O-S. I'm a Healthcare Technology and Digital Healthcare Management Consultant, having more than 25 years of experience in the field, a two-time traumatic brain injury survivor, and a patient advocate. I'm also the parent of two kids diagnosed with ADHD. I'll be speaking from a personal perspective today.

My testimony is focused on Methylphenidate, which I understand to be a Schedule II drug. I've been disabled due to TBI since 2012. After that incident, I was able to concentrate for 45 minutes twice a day. Making it to medical appointments and following provider directions was a significant effort, as were most activities of daily life, and I'm left with chronic headaches, cognitive fatigue, and a host of other symptoms because your brain basically controls everything. Essentially, the effort of getting through my healthcare was all I could accomplish.

Methylphenidate oral was the medication for pain management prescribed to me after a second TBI in 2018 and helped me establish a platform for cognitive recovery, which has taken years to accomplish and has allowed me to be able to work again enabling

organizations to leverage technology to improve healthcare outcomes and reduce disparities.

Telemedicine was a significant factor in my recovery because it eliminated the need for complex and time-consuming travel, navigation, parking costs, and other interactions that reduced my ability to improve and focus on more important tasks, yet every month refilling medications for myself and my children presents a significant challenge and burden with hurdles imposed by strict regulation, occasional and unpredictable pair determinations, lack of access to providers, and medication shortages.

For one of my children, this is further complicated by attending college out of state and being subjected to different laws requiring providers in both locations and different processes and time frames virtual and face-to-face for filling prescriptions, which often results in medication gaps.

The impact of TBI and other cognitive disabilities is often misunderstood and downplayed. Again, think about what your life would be if you could only focus for 45 minutes twice a day. It isn't just about being able to perform well on tests. It can be staring at a grease fire in your kitchen and trying to remember if you put that out with water or

if that's exactly what you're not supposed to do. It's a difference between being able to work or not.

There are also documented interdependencies between ADHD, anxiety, gastrointestinal disorders, that can be so crippling it's difficult to work, leave the house, or participate in daily activities.

Consistent access to Methylphenidate is critical to managing part of this triangle, and the anxiety caused by not knowing if this month's refill process is going to be simple or not can be crippling. Often, the process of refill itself results in delays in access and lags that then require recovery.

So the key points I'd like to make today with respect to telemedicine and e-prescribing are that, first of all, our existing certified EHR systems, which we have spent billions of dollars implementing over the past decades, our data exchange standards provide sufficient documentation to track prescribing provider, dosage, frequency, dispensing pharmacy, and patient information.

Our business intelligence tools and artificial intelligence are available to mine this data and identify aberrant patterns without requiring undue or additional burden on patients.

Having face-to-face encounters with

providers is, from my perspective, unnecessary. Needs are sufficiently met by telemedicine either through video or audio, and it's important to recognize that audio-only telemedicine visits are critical from an equity perspective.

Refill processes for Methylphenidate are overly complicated and archaic. They include very short windows to call for that refill before you run out, the provider verification process, again, state variability, limited quantities, and payer denials and prior authorizations. And for someone with limited cognitive abilities, this is a substantial burden that manifests and causes significant physical issues.

People frequently travel between states for a variety of reasons, and I would like to see federal law enable more consistency wherever possible so that patients are not caught off guard by varying regulatory issues.

I'd urge that regulation support the needs of the majority of individuals who are being aided by appropriate use of these medications and not subject everyone to compensate for the activities of a small number of bad actors.

Thank you very much for your consideration.

MS. MILGRAM: Good morning. If I could ask

one follow-up just to clarify. You talked about the electronic health records system and the technology and digital systems around that that would be available for data mining and other sort of information-gathering.

I think two questions. One is I read you as suggesting that as an existing and potential safeguard for misprescribing and abuse or diversion.

And then the second is, are you suggesting that some of that information should be shared with DEA and, if so, what information?

MS. JANTOS: I think there is potential for that information to be -- yeah. I think there is certainly potential for that information. Again, it already exists. From a patient perspective, you know, personally, from my experience, I know how much information is in those systems, yet day to day I'm asked to repeat that every time I go to a visit. We know it's stored. We have that access to that information. It certainly is possible to have access, for the DEA to have access for that to mine it.

MR. STRAIT: Yeah. And thank you, Ms. Jantos, for those comments. I do want to say that I think, as kind of a clarifying nature question to Anne's point specifically, you know, there are a lot

of perceptions that we actually have access to that information. We presently don't. And I think that's the point that Ms. Milgram was trying to make, is that it sounds like you're saying -- and we certainly take the point that that information does exist. The question is whether or not it's available to those of us who are charged with tracking diversion and misuse.

Thank you very much for your comments.

Before we go on to our second virtual presenter, I did want to acknowledge that we have sign interpreters that are here with us today, and those are for the folks that are here in the audience. So, if there are folks that are hearing-impaired and you need to move closer to see our sign interpreters, feel free to move at any time if that ends up being beneficial for you. And I thank you all for being here today.

Okay. Let's move on to Virtual Presenter No. 2. You are ready to go, Dr. Bailey.

DR. BAILEY: Oh, I'm sorry. Hi. Good morning. My name is Dr. Felicia Bailey. I am a family nurse practitioner. I am representing Avaesen Healthcare in Frederick, Maryland.

My presentation will be coming from the perspective of a family nurse practitioner who also

provides addiction and psychiatric services, and I would like to share some of my experiences with the population that I serve, which generally are a population with severe substance use. They typically need to be housed in inpatient units and things of that nature and developing life skills for the community.

One of the recommendations, and I will have to say that there are a large population of my clients who are very good follow-through clients who usually follow the diversion or criterias for prescribing and things of that nature, they attend their appointments, they follow up with their primary care providers.

One of the concerns that I have with the other half of my population is some of the common things that I've seen with potential diversion. And as a provider, it has been a challenge to make sure that these clients stay in compliance and also take care of their health. Some of the things are selling prescription drugs.

Also, doctor shopping, which some providers may have multiple controlled substances from multiple providers, and some clients may have frequent drug theft reports.

In that population, I would certainly

recommend that the DEA have more access to clinical documentation, and some of that clinical documentation may be screenings from other providers, a way that it does not put the burden on a family or addiction specialist to have to call a psychiatrist and verify what medications a client is on.

That database could possibly include other measures to evaluate their medical health, their physical health, and just making sure that we as providers understand whether it's pain, whether it's substance use concerns, that they're also being addressed with their medical providers as well, and my recommendation would be for a collaborative relationship between the providers and primary care.

Some of the examples that I would recommend is making sure that, for example, some of those medications that are commonly misused would be the categories of benzos, stimulants, pain medication versus the substance use medications. If that information was readily available, it would help providers in prescribing.

Also, making sure, and I'm not sure this is possible, but there has been a challenge identifying those clients who are on methadone. I have just noted this over the COVID transition, that there's not a lot

of clients reporting that they're on methadone. Most of them are just on Suboxone, which is good. It's a good thing that they are seeking some type of help, but the barrier that I've seen is that methadone doses are not there.

I have seen some clients who, when I requested them to come to the office, then I realized that they are on methadone, or they have been prescribed Vivitrol or a medication to treat their substance, but they're not showing positive for those substances. My concern is mainly, again, making sure that data is available for all providers, making sure that we address population health.

We do understand that there are certain individuals that they have resorted to abuse of substances because of their healthcare behaviors. Having a provider guide those behaviors to improve those behaviors certainly helps with the population.

What we perform in the primary care environment that I work in is we actually do HIV testing, Hepatitis C testing, and we refer to treatment. Referring to treatment also helps with our children, their children, just to make sure that we maintain treatment with that environment.

I would certainly say that laboratory tests

would actually help us even as a substance use provider initiate or encourage that client to continue to treatment.

One of the other things that I've realized is the frequency of this population, and I say again this population may be those with chronic medical conditions and multi substance use concerns.

If there were emergency room data, this population circles the emergency room very frequently. A lot of times they may not reveal to their family provider that they just had an overdose two days ago, unfortunately, but at least having that information so that we can probe the patient and see if we can manage their care a little bit more efficiently.

The other recommendation is to make sure that there is some type of point-of-care information inside of our databases so that we can use that information to apply treatment and counseling and recommendations for further services.

So I ask for these things with all respect just to address the population again that I serve, which I think is very common but missed, overlooked or underserved population, and that way we collaboratively care for our population and those with substance use disorders.

MS. MILGRAM: Thank you so much. Just a couple of follow-up questions. To clarify, when you were talking about the medications that you see being abused, can you just go through that list again? I missed maybe the couple at the end.

DR. BAILEY: Sorry, I didn't hear you.

MS. MILGRAM: I'm so sorry. Can you hear me now?

DR. BAILEY: Yes.

MS. MILGRAM: Okay. Great. Just to clarify, you went through a list of some of the medications that you see being abused. I didn't catch all of them. I was wondering if you could just list those again, the ones that you see most frequently being abused.

DR. BAILEY: Usually, this population has a combination of pain medication, anxiety medication, stimulants. I have noticed in the COVID era that there's a lot more individuals with that combination, and it could be any category of medication that's controlled, but I've noticed there are a higher amount. And not to the fact that I don't believe that they need it. I believe that maybe a face-to-face evaluation to just really hone in on what the body is saying to the provider would be very helpful.

MS. MILGRAM: Thank you. The other thing, and I don't -- I'm just trying to make sure I'm pulling together some of the threads that I was hearing. It sounded to me like you were talking about having some sort of national database that providers could access that would give you information on the prescriptions that somebody's on, the provider visits, the emergency room data. So the first question is, did I get -- is that part right? Is that an accurate reflection of what I'm hearing?

DR. BAILEY: Yes, that is accurate. And I will give an example. I live within 30 to 45 minutes of three states, Pennsylvania, West Virginia, Virginia, and Delaware, so I'm sorry, four states. If there is an opportunity for a client to drive within an hour, I think it would be very beneficial for a provider to have access to that data.

MS. MILGRAM: Is there anything else that you would put in that data that a provider should have, list?

DR. BAILEY: Emergency room visits. Those are key indicators that the client is going through a crisis. And I'll make sure I clarify because I do respect those clients who do what they're supposed to do and they have no intentions of misuse. You will

see cycles because the consistency is not there. These clients may be under-insured. These clients may be purchasing their medication from another patient. And they have more frequency emergency room visits.

MR. PREVOZNIK: With that system, would you also want the pharmacists to have access to that as well?

DR. BAILEY: Absolutely. That would be a great idea. Great idea.

MR. STRAIT: Okay. I think we are done with follow-up clarifying questions and comments, so thank you, Dr. Bailey. And we will move now on to Virtual Presenter No. 3.

DR. BAILEY: Thank you.

MR. STRAIT: Dr. Bassi?

DR. BASSI: Hi. I'm Bruce Bassi, B-R-U-C-E, B-A-S-S-I. I'm with Telepsych Health. Good morning, everyone, and thank you for inviting me to speak. I want to first thank the DEA for holding these listening sessions. Thank you for trying to find the right solution that is least burdensome but also maximizes patient safety.

We heard a lot of great ideas yesterday, and what struck me was the incredible diversity of practices and disease types that we all use controlled

substances to help treat. Treating substance use versus chronic pain, versus hospice, versus ADHD are all very different, and this emphasizes the great challenge the DEA has in trying to apply a simple blanket policy across all disciplines in the entire country.

All speakers were correct in their own right because the decision to prescribe or not prescribe should be one that's made between the clinician and patient. So the question becomes how to prevent bad actors from taking advantage of a very lenient system to prevent what happened during the COVID health emergency when we essentially had a trial period for how this would go. I think some of my recommendations would address that.

Let me introduce myself. I am Board-certified in general psychiatry and addiction psychiatry. I'm the sole owner of the private practice Telepsych Health, which is mostly virtual and accepts commercial insurance and Medicare. We have an office for in-person appointments in Jacksonville, Florida, as well. Despite being a virtual practice, we do not expect to profit at all by more lenient regulations in this regard because we prescribe a very low percentage of controlled substances overall.

I have a DEA license in states where we have partnerships with certain facilities, the most notable of which is with our partnership with a prison re-entry program, where we primarily evaluate substance use disorders and prescribe buprenorphine to some of those individuals. In the year 2022, we had a total of 32 patients prescribed buprenorphine.

The vast majority of our patients do see us for general psychiatric reasons, and I run a virtual group therapy as well. During COVID, we wrote for controlled substances for people with severe anxiety, insomnia, and ADHD, and this comprised an additional 34 patients in 2022. In total, we sent in 15,000 different prescriptions that year, 406 of which were for controlled substances, for an overall rate of 2.6 percent of prescriptions sent.

Before I prescribe any controlled substance, there are a number of factors that I consider clinically before deciding if this is an appropriate choice. First, have they completed a written consent form that outlines our clinic policies of expectations. For example, they may be asked to obtain or collect a urine drug screen randomly to be done at their local lab within two days or at a facility that they’re affiliated with.

Also, that the medications need to be locked and out of reach of any other person to prevent diversion and accidental diversion from any children or teenagers in the home.

Simultaneously, during the appointment, I'm considering a number of other important factors, such as, one, the patient's age and history of substance abuse. If the person has a history of drug abuse, I'm thinking about other co-occurring conditions, where they are in the recovery, do they have a sponsor, how much support do they have, are they going to groups, et cetera.

Secondly, I'm considering family history of substance abuse. We know there's heritability of addictive disorders not only through genetics and epigenetics but through its impact on childhood trauma.

Third, I'm considering the duration of the prescriptions. Is it a bridge to starting another medication, or is there no discernible end point to the prescription?

Fourth, I'm considering escalating doses and early refills, which I would find by checking the PDMP, which I think is extremely important and I do before prescribing any controlled substance.

Fifth, what is the addictive potential of the medication I'm prescribing. We know that not all schedules are the same, and I consider what is the time release rate of the formulation that I'm prescribing.

In 2022, of the 66 patients who were initiated on controlled substances remotely with no in-person visit, 93 percent of them were continued without an issue. Of the 7 percent, we treat each breach of contract on a case-by-case basis to try to figure out what was the underlying intent of the relapse or if they intended to manipulate and deceive us. If needed, I can expand more on how we might approach those cases.

In an informal Facebook poll of physicians in preparation for this talk, 64 percent stated that clinicians should be able to use their best judgment in prescribing controlled substances virtually and without any regulations; 32 percent stated patients should be required to see somebody in person first, and only 2 percent agreed that there should be a telehealth registry.

Therefore, the vast majority felt prescribing controlled substances should be a decision made between the physician and patient. In my

opinion, I don’t see a one-time in-person examination reducing the risk of abuse, nor do I see it materially altering the potential for diversion, nor would it add to me substantial information to a psychiatric appointment that I could not gather virtually. None of the five other clinical concerns I stated earlier would be changed if some arbitrary person saw them once previously.

Furthermore, it’s important to point out online notaries have existed for a number of years now. Thus, verifying an individual's identity virtually has been legally acceptable. An in-person requirement would also unfairly burden rural patients, those without transportation, and those without childcare.

Like I mentioned earlier, the new rules should take into consideration that there are practices that have a high volume of controlled substances and pose an overall greater risk to the public versus those who do not. I noticed during the COVID emergency there were a number of companies that popped up with their entire business model predicated on solely prescribing controlled substances. Given the addictive potential of controlled substances, this presents an unethical conflict of interest wherein

profit is inextricably linked to prescribing and, thus, prescribers are partially incentivized to starting and continuing these medications.

Therefore, I think the upcoming DEA policy should attempt to reduce the potential corporate entities can profit off lenient prescribing rules but without putting an excessive burden on those who are thoughtful in their prescribing. One way to do this is by having increased oversight on telehealth prescribers who choose to prescribe a large number of controlled substances per month. There should be transparency about what those cutoffs would be and what additional oversight would be.

I would suggest a cutoff of more than 200 controlled substances per month, which can be tracked through the PDMP, and I do support a national PDMP as well. That was suggested earlier.

For all Schedules II to V, I would recommend the following apply to all clinicians regardless of reaching the cutoff: (1) prohibit direct-to-consumer and social media advertising for prescribing of controlled substances, in particular for buprenorphine or ADHD solely; (2) require that the clinic obtain a copy of the patient's government-issued ID and that the telehealth visit must include a real-time

interactive video evaluation, not just a review of questionnaires and symptom checklists that were completed by the patient; (3) require that patients complete a written consent form outlining risks, benefits, and alternative treatment options, safekeeping of the medication, and clinic policies and circumstances in which the prescriptions would be discontinued; (4) allow clinician reporting to the PDMP when a prescription was discontinued by the clinician due to an aberrant behavior or breach of clinic policy. This would allow other clinicians to see that the patient previously breached a contract with that practice and take appropriate next steps to perhaps reach out to that practice to get more information.

If the prescription was labeled to be made via telehealth, I fear this would add unnecessary scrutiny and fear by the pharmacists and add more barriers to the patients receiving the medication. Also, for clinicians' safety, the prescription should not publicize their home address if they’re working from home. The prescriber should only need a DEA license in one state where they’re physically present and not have an office and DEA license in every state. Sixth, allow for one-time refills by covering staff in

the same practice.

Regarding the increased oversight beyond the cutoff, I would suggest: (1) the practitioner be registered for a high-volume DEA registry to cover administrative costs for additional supervision by the DEA; (2) the practitioner should be required to complete additional continued education for recognizing and treating addiction and diversion; and (3) be subject to increased audits of recordkeeping to ensure they're following the standard of care in their prescribing practices.

In regard to the recordkeeping, I would recommend all practitioners to document: (1) that they verified the patient's identity with a government-issued ID and a correspondent to that video image; (2) that they have obtained the written consent form talked about earlier from the patient outlining clinic policies and diversion mitigation steps; (3) that they've checked the state PDMP prior to issuing the prescription; and (4) in addition to documenting the standard medical history and current medications, the practitioner should have evaluated for static and dynamic patient risk factors for substance misuse and abuse, including family history of addiction, any aberrant behaviors, such as a rapidly escalating dose,

lost prescriptions, early refills, and any actions taken by that clinician to address these issues.

Thank you for your time. I was honored to be invited today, and I welcome any opportunity to be part of the ongoing conversation and collaboration. Thank you.

MS. MILGRAM: Thank you so much.

Could I ask you to expand a little bit on the -- you mentioned you could talk a little bit more about the 7 percent that relapsed or had fraud. Could you just tell us a little bit about --

DR. BASSI: Yeah, absolutely.

MS. MILGRAM: -- you know, how did you identify that --

DR. BASSI: Like some --

MS. MILGRAM: -- what did you do?

DR. BASSI: Like somebody mentioned yesterday, I try to not take a punitive approach. Stopping the prescription and sending them to another practice makes that disease state become another clinician’s issue and they have no background information off which to work with.

I would try to use the situation as a way to rehabilitate the individual, promote honesty and reducing shame of withholding information in the

future. Some people make impulsive mistakes and they need to learn from those. It doesn't help them in the long term either to deceive us for certain scripts.

So, first, I would get confirmation testing of the UDS before jumping to any conclusions. I would also start to reduce the quantity of prescriptions that the pharmacy would be dispensing, increase the frequency of appointments, and maybe perhaps implement more peer support. There's a lot of virtual online peer support as well that we could require of that patient. Request that they obtain a sponsor and follow up with what they're working through with that sponsor, and then also require that we perhaps obtain additional collateral information from family members to help keep them accountable for what they say they're doing in the clinic.

MS. MILGRAM: And how did you identify that 7 percent?

DR. BASSI: It was primarily through other clinicians who had reached out to us to let them know, like therapists, and also positive urine drug screens that led to a conversation about their relapse.

MS. MILGRAM: Sorry. Sorry, I'm going to give it to Tom in one second.

You talked about an audit checking the state

PDMP. One of the questions just to sort of ask you to expand on that a little bit is, if we're talking about a national -- you recommended a national registry for telehealth or, you know, not having multiple registries. How would you go about identifying or understanding whether or not there was a prescription in another state?

DR. BASSI: So the PDMPs have expanded quite substantially over the last year, two years even where you can add additional states, and that has been extremely helpful. We know patients travel quite frequently and they might live on a border, like another presenter alluded to.

So many of them -- I'm registered with the PDMP in all the states that I have DEA licenses, and in most of them now, you can add up to 30, 40 different states. I do think that while that's progress in the right direction, it still leaves for the possibility that you don't check off those additionally. It should just be by default that you're seeing that across the country.

And also, I would add the previous presenter mentioned a couple other additional points that could be included in that PDMP, which is a great database we already have that we can just improve upon, is

identifying, okay, I'm seeing this patient who has recently gotten a prescription over the last three months from three different doctors. What does that mean? Let's try to reach out to them.

Like somebody mentioned, you often call an office and you get a call center. Well, one way we can resolve that is by marking down that this was discontinued due to a breach of contract. That way, I know, okay, this wasn't due to doctor shopping, but they actually had to travel for some reason or they got stuck where they ran out of medication early or they have an issue medically where they need a higher dosage and that wasn't an aberrant behavior and so I shouldn't look additionally into this versus something that was done with malicious intent where they were trying to actually deceive and withhold information from their previous prescribers.

MR. PREVOZNIK: Could you help clarify -- I think you said and please correct me if I'm wrong -- that you did not want the prescriptions to indicate that it was telemedicine. However -- is that correct?

DR. BASSI: I think I'm torn on that after hearing from the previous pharmacists yesterday. I really understand they are burdened with trying to identify if this is a legitimate relationship between

doctor and patient when on the spot they don't have enough information to make that determination. And, right now, there's so much stigma attached to whether or not it was a telemedicine visit that those patients are placed under increased scrutiny in particular states and particular pharmacies due to the excessive overabundance of prescribing habits that we've seen during the COVID emergency.

So it could include that it was telehealth if there was less fear among the pharmacists that it's not up to them to establish whether or not it was a correct relationship because they're not in the doctor/patient appointments and it's not possible for them to police that. It should be the prescriber's responsibility, and there shouldn't be additional barriers where the patient needs to hop around to 10 different pharmacies and identify which pharmacy is known for allowing them to give them their prescription, which has happened in certain cities that we've experienced.

MR. PREVOZNIK: Okay. Thank you. But, to further -- another point that you made was for us or, yeah, for I guess DEA to identify the telehealth companies to take the stance against the corporations. How would we do that if we don't know what the

prescription -- where it's generated from if it's telemedicine, so how would we -- do you have suggestions on how we would do that?

DR. BASSI: Right. The PDMP can include that it was made via a telehealth visit and then that way they can monitor if that prescriber is approaching or exceeding the cutoff that was already demarcated by the DEA, and then they can apply for additional registry. I think the burden should be on those individuals -- the increased regulation burden should be on those individuals who are high-volume controlled substance prescribers where they undergo those three additional recommendations that I made, having a registry solely for those individuals kind of like for buprenorphine previously, with varying levels for each prescriber depending on their level of experience. I think that that makes a lot of sense to me and that's the only way that I can think of that would start to separate those bad actors who are essentially becoming the "pill mills." I hate to use that colloquially, but that's essentially what they've become known as.

MR. STRAIT: Okay. Thank you, Dr. Bassi.

I will now move on to Virtual Presenter No. 4.

DR. ARMITAGE: Good morning. My name is Dr.

Alex Armitage. I'm a supportive nurse, supportive palliative care nurse practitioner at Baylor Scott & White Health in Texas. My name is spelled A-L-E-X-A-N-D-R-A, last name Armitage, A-R-M-I-T-A-G-E.

The assistant director of supportive palliative care at Baylor Scott & White has asked that I testify on behalf of our entire service line. Palliative care at Baylor Scott & White consists of 13 interdisciplinary teams covering 18 facilities scattered across about a third of Texas. Most of our patients come from the 11 million people living in the service area, but we also draw patients from New Mexico, Oklahoma, Arkansas, and Louisiana.

Our 13 supportive palliative care teams include 64 Board-certified hospice and palliative care physicians and advanced practice providers. In fiscal year 2023, we provided over 63,000 total patient encounters, with over 6,000 outpatient encounters.

Early palliative services allow patients to be embraced holistically and cared for in the most humane possible way at a time when they are most vulnerable and most in need of care. Early delivery of palliative care reduces unnecessary hospital admissions and the use of unhelpful health services. In other words, palliative care patients are less

likely to receive non-beneficial treatments.

To demonstrate some of the challenges that our patients face, let me share a clinical vignette. Sally is a 36-year-old runner and mother of two children who I served since shortly after she was diagnosed with stage 4 breast cancer three years ago. Chemo and radiation therapy was initiated by her oncologist, who also referred her to my clinic for help managing her physical and temporal pain.

As with most patients newly diagnosed with metastatic cancer, she was not a hospice candidate as her cancer was being actively treated and she had a projected life expectancy of over six months. Her pain was so great that traveling the two hours to my office was not imaginable to her. Due to COVID, I had already been tasked with establishing telehealth video services, full palliative care at Baylor Scott & White, and so I was able to set up such a visit with her.

On our first video visit, Sally’s pain was so intense that she could not sit up in bed due to metastatic lesions through her spine and pelvis. She was literally reduced to tears because of her pain. I was able to complete a comprehensive evaluation and we explored her goals of care. Sally and I agreed on

what an acceptable level of pain would be, and she started on a combination of methadone and morphine. Over the following months, we titrated her pain medications not to complete absence of pain but to a level of pain control that would allow her to resume at least some of her activities of daily living and possibly get out of the house for a short period of time. I am proud to say that we've been successful.

On her most recent video visit last week, she was out of bed and dressed. She had improved enough to take a short trip to the hairdresser, which made her proud as her hair was growing back after chemotherapy. She was even able to get up and cook a simple meal for her family.

Yet she still struggles with traveling long distances in the car. I'm not in her shoes, but I cannot imagine her being comfortably able to travel to my clinic, nor do I think it necessary. We know and, more importantly, she understands that she will never be a hundred percent pain-free and that eventually her cancer will return. But she, her oncologist and I are thrilled at the moment that she no longer lives immobile in a bed of pain.

In case it's not clear from my story, I have yet to meet Sally in person, but the treatments that

I've been able to provide to her via video have given her her life back, and I thank the DEA for the suspension of the in-person rule during COVID, which allowed us to relieve her suffering.

As many know, palliative care and hospice services are frequently confused, and when that happens, referrals come late, which diminish benefits to patients, their families, and healthcare providers alike. To help alleviate that problem, Texas law recognizes and my health system recognizes two types of palliation. The first and more familiar to the public is hospice for which enrollment requires the patients to forego attempts to treat their primary disease. There are over 570 hospice agencies in Texas serving less than 1 percent of us who will die in any given year.

Hospice typically provides services for days to weeks before death. My patient, Sally, was not hospice appropriate as she was actively undergoing cancer treatment and had a prognosis of greater than six months.

The second type of palliative care is what Texas law and Baylor Scott & White refers to as supportive palliative care. Our patient population is seriously ill, the sickest of the sick. Like Sally,

they often have extremely high symptom burden, including some of the worst pain imaginable.

Although we would not be surprised if any of our supportive palliative patients were to die in the coming year, annual mortality rates are in about the 50 percent range, clearly not hospice appropriate and, like Sally, our patients wish to maintain disease directed treatment. Thus, unlike the typically short service time for hospice patients, in support of palliative care, we serve patients for months to years, most commonly in a hospital or clinic setting.

Unfortunately, in Texas, supportive palliative services are not as available as hospice. For example, the most recent data available suggests that only 154 of the 262 hospitals in Texas offer supportive palliative care services and most of those are hospital-based only. Even in our system at Baylor Scott & White with 13 supportive palliative care teams, we are only able to staff six outpatient clinics. In addition, unlike hospice, we do not receive a per diem fee and do not have the staffing available to send professionals to the patient's home. This means that if we are unable to provide telehealth services, our patients must come to us.

Hopefully, all can understand how

challenging such travel is given the symptom burden and the distances involved, distances which can grow to hundreds of miles in some cases.

I have set up two telehealth clinics in the last few years servicing hundreds of sic patients. I could tell you many more clinical vignettes like that of Sally, but we don't have the time.

In closing, my supportive palliative colleagues and I recognize the need to protect the broad population from opioid abuse, but we believe that such protection must not impair effective pain treatment and other symptom management for the seriously ill, the sickest of the sick patients with life-limiting illness.

Our patients cannot always travel to see a medical provider in person because of the distances involved and because of the severity of their symptoms. For some patients, obliging them to do so would effectively be denying them care. We advise against placing any regulatory hindrance in front of the barriers already created by their life-limiting illness and all the geographic distances required to reach our limited clinics.

We believe that the Drug Enforcement Administration was correct in suspending the

requirement for the in-person visitation for opioid therapy during COVID, and we recommend that at least for patients of supportive palliative care professionals that this humane suspension be maintained. We recommend that the DEA carve out Schedule II prescribing rules for prescribers in support of palliative care and allow such prescriptions via telemedicine visits alone, thus negating the severity of illness and travel distance barriers that I have shared with you today.

Thank you for the opportunity that you've provided us to testify. My colleagues and I would be happy to participate in any further dialogue.

MR. STRAIT: No? Okay. Thank you, Dr. Armitage. I think we have no questions, so we will now move on to our Virtual Presenter No. 5.

DR. TYROCH: Good morning. Is my audio okay?

MR. STRAIT: Yes, it is.

DR. TYROCH: Thank you. My name is Roxanne Tyroch. I live in El Paso, Texas, and I am an Internist at Intellimedicine PA. As a primary care physician in an office setting, I prescribe controlled substances on a regular basis. The most common ones are for adult attention deficit disorder, which are

Schedule II amphetamines.

During the pandemic, it was reasonable to drop the regular safeguards when there were no COVID vaccines nor treatments. Now that the pandemic no longer poses these risks, there is little valid justification to extend this laxity in safeguards against diversion and health-related hazards.

Our clinic has urine drug screening for the use of controlled substances. The patients must have their first visit in the office always and have annual in-office physical examinations and wellness visits. And, monthly, they have the option to do their drug screen in the office and then have it at the same time as an in-office encounter, or they can do a telemedicine visit and do the urine at their convenience.

If there are any concerns during a telemedicine visit as far as safety, say they have chest pain or some symptom of concern, then the patient comes to the office and we can do a physical exam or whatever is needed to do to remedy the situation ensues.

In October 2022, the FDA announced a shortage of amphetamine mixed salts, pointing to ongoing intermittent manufacturing delays at Teva

Pharmaceuticals, a major supplier of Adderall amphetamines.

Due to the Adderall shortage, my patients now have to call around to pharmacies in order to get verbal confirmation that there's adequate supply, and then we hold their visit right away so they can get to the pharmacy within hours of it being written, and even this fails, and they'll have to find supply elsewhere.

By returning to proper safeguards of only prescribing to patients that have had an in-office evaluation, we are ensuring that the medication is directed to people who are appropriate to receive the medication. There are many other benefits to this procedure. The physician ensures cardiovascular safety with the use of amphetamines with an electrocardiogram and physical exam. Any concerns found on drug screening can be addressed in a personal setting.

The American College of Cardiology published guidelines on the topic in April 2015, and this was an expert analysis with 28 references outlining the challenges of prescribing these medications even in a proper setting, such as an office.

The package inserts for stimulant drugs warn

against use in patients with pre-existing heart disease or cardiac structural abnormalities due to risk of sudden death, stroke, or myocardial infarction. Furthermore, the FDA issued a safety announcement in 2011 stating that stimulant products in such areas should not be used in patients with serious heart problems or for whom an increasing blood pressure or heart rate would be problematic.

There have been reports that such errors have induced life-threatening Long QT Syndrome. It's recommended that Methylphenidate amphetamine-containing drugs be avoided in patients with congenital Long QT Syndrome. Package inserts for Modafinil and R-Modafinil warn against use with patients with a history of left ventricular hypertrophy or those with mitral valve prolapse.

The final summary of this document emphasized how proper assessment of clinical benefits and risks should be made on an individualized basis when therapy is warranted. Monitoring of cardiovascular parameters is in order and should be limited to the lowest effective safe dose.

On an additional side note, my daughter is a college student and I asked her, what have you noticed about people's use of amphetamines in school? And she

noticed that after the pandemic, when this change took place, that just anecdotally it was noted more diversion of stimulants in the college student setting has been identified.

And I understand the potential motive of prescribers that seek to lower standards for telemedicine only prescribing of controlled substances. If no brick-and-mortar building is required, overhead plummets and profit will rise.

And I would submit to you that this is not a good enough reason to allow for telemedicine only prescribing of controlled substances in a setting of drug shortages. All patients deserve the safeguards and personal care that I've outlined. It's simply incomplete to not have those options available when needed. Handheld cardiac devices and do-it-yourself heart monitoring in my experience has not been adequate to screen for arrhythmias.

I wish to thank the DEA for having this listening session and demonstrating that you want to have as much information at hand with these important decisions. Thank you very much.

MR. STRAIT: Okay. Thank you, Dr. Tyroch. I don't see any questions, so we will proceed on to Virtual Presenter No. 6.

DR. GUILLE: Great. Thank you so much. My name is Dr. Connie Guille. First name is C-O-N-N-I-E. Last name is G-U-I-L-L-E. I'm from the Medical University of South Carolina. Again, just wanted to say thank you very much for having us here today and the opportunity to speak with you all.

As I mentioned, I'm from the Medical University of South Carolina, where we're one of two federally recognized and funded National Telehealth Centers of Excellence by the Health Resources and Service Administration. Our center has over 300 telehealth programs throughout our state, on average about 800 telehealth visits per day, primarily to rural and underserved areas within our non-Medicaid rural state.

Since 2015, I specifically have been working in the space of treating pregnant and postpartum women with opioid use disorder using telehealth modalities and particularly prescribing Suboxone via telehealth.

My comments today are actually very specific to the pregnant and postpartum populations and recommendation to not require an in-person visit prior to prescribing Suboxone for the treatment of pregnant women with opioid use disorder and postpartum women.

Just to highlight a few things that I think

are relevant, in the United States, our rates of maternal mortality, which is death during pregnancy and the postpartum year, is higher than any other developed country, and the leading cause of maternal mortality in the United States is due to mental health conditions, primarily due to suicide and drug overdose, and the overdose deaths are primarily related to opioids and they occur typically later in that postpartum year.

I think it's just important to note that since 2010 to 2019 we've had about a 190 percent increase in pregnancy-associated deaths just due to drug overdose. The most recent data shows an 81 percent increase in those pregnancy-associated deaths due to drug overdose from 2017 to 2020.

The vast majority of these deaths that we know from our state's maternal morbidity and mortality review committees are actually preventable, and they're preventable by providing better access to care and, particularly for opioid use disorder, life-saving medications such as Suboxone.

There have been a number of studies, those including JAMA Psychiatry, of over 200,000 Medicaid recipients that have shown that telehealth expands access to treatment for opioid use disorder. It

results in improved retention and treatment and reduced rates of overdose deaths. And, furthermore, utilization of this during the pandemic was associated with improved retention and treatment of opioid use disorder and decreased overdose deaths in comparison to our pre-pandemic cohorts when we required an in-person visit.

Our concern today is that any progress that's been made towards improving access to evidence-based treatment for opioid use disorder and reducing opioid overdose deaths will be reversed by requiring a proposed in-person visit before we can prescribe Suboxone for the treatment of opioid use disorder.

I just want to add that where we are in South Carolina we've had firsthand experience of the detrimental impact of resuming the in-person visit requirements. In April of 2022, South Carolina announced a return to pre-pandemic state regulations for prescribing controlled substances via telehealth. As a result, that has resulted in an increase in no-show rates to the in-person visit and unsuccessful treatment engagement despite actually an investment in outreach and additional personnel to try to engage people in the in-person visit.

We were given 180 days to transition all of

our patients from the pandemic requirements to coming in for an in-person visit. We were really unsuccessful in doing that, and a number of patients dropped out of care and were no longer retained in treatment, which retention and treatment is what predicts a reduction in overdose deaths.

So I want to highlight that in our clinical practice, when we see pregnant and postpartum women with opioid use disorder, we can accomplish everything that we need to to safely manage that disease without having an in-person visit. Using telemedicine, I can make an appropriate diagnosis of what is happening with that person. I can look for signs and symptoms of intoxication and withdrawal. I can check my state prescription drug monitoring program. I would like to be able to check other states' prescription drug monitoring programs in order to determine if there's any other prescribers on board or multiple medications being prescribed to this patient. In that, I'm able to safely prescribe these medications.

The only thing that the in-person visit does is it actually creates additional barriers to these patients' accessing treatment and prevents a lot of people from accessing these treatments. We've had the firsthand experience of requiring the in-person visit,

resulting in delayed care and an overdose death of a pregnant woman, and, you know, to continue to have that happen is not acceptable.

I agree with a lot of the presenters before in terms of the safeguards that can be put in place with reducing drug diversion but just want to be very clear that that in-person visit does not increase our chances of reducing drug diversion.

With that, I will stop and just say again thank you very much for your time today and our ability to present this information to you.

MR. PREVOZNIK: I have a question. You keep saying inpatient, not having the inpatient visit. Are you --

DR. GUILLE: In-person.

MR. PREVOZNIK: -- is your practice two-way or is it audio only? I'd like to hear your perspective of audio only as an initial visit or two-way. Get your perspective on that.

DR. GUILLE: Yeah. So sorry for not being clear on that. When I say telemedicine and a visit with a patient, it's using audio and visual telehealth. The only thing I'm suggesting is that they don't come in in person to meet with us before we prescribe medication, that we can achieve all of that

using audiovisual telehealth, synchronous encounters.

MR. PREVOZNIK: And, excuse me, you talked really fast in the beginning. When you were talking about the medical university, you indicated that it got some sort of certification? Could you explain what that process -- what the certification is and what was the process for you to get that certification?

DR. GUILLE: Sure. So HRSA, Health Resources and Services Administration, is a -- HRSA is a organization that has federally recognized and funded MUSC, or Medical University of South Carolina, as a National Telehealth Center of Excellence. And so what we are tasked with within the Center of Excellence is advancing telehealth and demonstrating the effectiveness of telehealth programs in terms of providing greater accessible and effective care via telehealth in our state.

MR. PREVOZNIK: Do you know what the process was for you to get that gold star of excellence?

DR. GUILLE: Yes. HRSA puts out a call for proposals. There were many proposals throughout the United States, and they only designated South Carolina and Mississippi for that recognition as a Center of Excellence.

MR. PREVOZNIK: Okay. Thank you.

MR. STRAIT: Okay. Thank you, Dr. Guille, for your time today. And we will now move on to Virtual Presenter No. 7.

MS. GILLOOLEY: Thank you. My name is Caitlin, C-A-I-T-L-I-N, Gillooley, G-I-L-L-O-O-L-E-Y. I'm the Director of Behavioral Health and Quality Policy at the American Hospital Association.

And on behalf of our nearly 5,000 member hospitals, health systems, and other healthcare organizations, as well as our clinician partners, the AHA appreciates the opportunity to provide input on the way forward for telemedicine prescribing of controlled substances.

And we recognize and appreciate the DEA's efforts to support safe prescribing of controlled substances via telehealth during the COVID-19 Public Health Emergency. Indeed, during the COVID-19 PHE, the DEA enacted certain flexibilities to ensure that patients could continue to receive life-saving medications via telehealth while minimizing exposure and preserving provider capacity.

However, we are deeply concerned about the DEA's refusal to implement a special registration process for telemedicine prescribing of controlled

substances, and we disagree with the direction of the two proposed rules issued this past March. The rules would impose burdensome restrictions and administrative requirements that we believe are overly burdensome on providers and patients which we are concerned will adversely impact access to medically necessary treatments.

So we have several recommendations in response to the proposed rules. We expressed these in our written comments on the rules. We'll reiterate them today.

Our primary recommendation to the DEA is to develop and implement a special registration process in lieu of the proposed regulatory guardrails contained in the aforementioned rules.

First, we urge the DEA to expeditiously set forth a special registration process and establish a pathway to waive in-person evaluations prior to the prescribing of controlled substances for practitioners who register with the DEA. Indeed, the Ryan Haight Act required that DEA establish this process nearly 14 years ago, and the Support for Patients and Communities Act reinforced this requirement and applied a clear timeline for the process's development by 2019.

In the March 2023 proposed rules, the DEA noted that it had determined a special registration process would be overly burdensome for providers. However, as I will elaborate upon later in this testimony, the provisions proposed by the DEA would certainly add significant burden for providers.

Further, we believe that a special registration process would simply be complementary to the existing DEA registration process rather than a new and distinct process that prescribers would have to go through on top of their current licensure.

For example, practitioners, hospitals, clinics, pharmacies, and others are currently required to complete applications for registration and renewal of registrations for prescribing controlled substances, namely, Forms 224 and 224A.

The process has already established guardrails that build upon state medical licensure processes and Medicare reporting, so rather than creating a novel and separate process or form, DEA can add fields to those forms that providers already use. This way, the special registration process would include key elements that providers already report, like their contact information, their employer, practice address, state medical licenses, liability

history, et cetera, and could add unique attestations on patient identification verification via telemedicine, drug monitoring, diversion control, and emergency protocols.

We would encourage the DEA to not require reporting of home addresses if practitioners are administering telehealth from their home address due to privacy concerns.

We would welcome the opportunity to assist further in developing a proposed special registration process and establishing appropriate guardrails.

Next, we appreciate that the DEA has recognized the need for additional time to consider creating a special registration process and has extended the COVID-19 pandemic-era rules through this coming November for new patients and November 2024 for existing patients.

However, considering the enormous volume of comments received on the rules this spring as well as the wealth of information that is being shared during these listening sessions and the additional comment period announced yesterday, we believe that the Agency will have to further extend public health emergency waivers to ensure that people who need access to appropriately prescribed controlled substances can get

them, and that should be the case regardless of whether they're a new or established patient.

So the DEA has already exercised its authority to extend PHE waivers of the in-person visit requirement. We believe they should exercise this same authority to create an additional provision that would allow for extensions of the waiver for prescribing buprenorphine for all patients, including those who did not begin their OUD treatment during the PHE. Buprenorphine is a unique substance used for a specific life-saving purpose, and the Agency has the authority to extend PHE-era waivers to ensure continued access to this treatment while we work to develop a permanent framework.

Alternatively, the DEA can use authority granted under the public health emergency for the opioid crisis, which was renewed most recently on April 1 of this year to extend these waivers. Just as DEA used its authority to allow for the initial evaluation to be conducted via telemedicine during the PHE for COVID-19, the Agency has the discretion to use the same authority under the opioid-specific PHE to allow the practice of telemedicine when it is being conducted during a public health emergency declared by the Secretary under § 247(d) of Title 42.

So we urge the DEA to act under this PHE as intended to innovate and implement a variety of actions to combat the opioid epidemic, such as a special registration process for the telemedicine prescribing of controlled substances including but not limited to buprenorphine for the treatment of OUD.

So this process would be an efficient and effective way to allow practitioners in good standing to appropriately prescribe controlled substances for legitimate clinical purposes.

Conversely, the provisions proposed by the DEA in this March's rules would be overly burdensome to providers and would erect unnecessary barriers between patients and evidence-based therapeutics.

So, in those rules, the DEA proposed that prescriptions administered via telemedicine would not be able to exceed a 30-day supply without an in-person visit. We are concerned that these limits are arbitrary, unnecessarily burdensome, and will reduce access to critical care. There is no scientific evidence suggesting that 30 days is the appropriate interval for patients undergoing treatment with controlled substances to be evaluated by their physicians. The 30-day limit would require patients to complete an in-person evaluation before obtaining

more medication. For many patients, it may be impossible to get an appointment with a practitioner in just 30 days, such as patients who live in geographically remote areas, who have childcare limitations, or who have conditions that make traveling to appointments physically painful.

While some patients may benefit from a periodic in-person evaluation, the need for an in-person evaluation should be left to clinical judgment rather than enforced through a general requirement that ignores individual needs.

Telemedicine encounters are designed to use the extremely limited availability of healthcare professionals the most efficient way possible, and, thus, requiring superfluous interactions with little benefit negates those gains. So we recommend removing any supply limit and instead allowing clinicians to determine the frequency of in-person exams.

The proposed rules issued in March would also impose significant administrative burden for recordkeeping requirements of prescribing practitioners, their referring providers, or other providers physically present with the patient during a telemedicine visit and their staff. We urge the DEA to reconsider what type of information is truly

necessary and whether it can be gleaned more easily from other sources, like claims and medical records, before imposing recordkeeping tasks on the already overburdened workforce.

In the rules, the DEA states that the additional recordkeeping requirements are necessary to mitigate the risk of diversion. However, the Agency did not provide data demonstrating that the proposed requirements are associated with decreased diversion, In fact, during the COVID-19 PHE, when practitioners were allowed via waiver to prescribe controlled substances, specifically buprenorphine, for the treatment of OUD via telemedicine, the proportion of opioid overdose deaths involving this substance did not increase, suggesting that the risk of diversion did not increase absent additional guardrails.

So practitioners who prescribe controlled substances already keep detailed medical records. These additional recordkeeping requirements would not provide further protections.

Now, although many of our comments specifically refer to the prescription of buprenorphine for the treatment of OUD, we should not lose sight of the longer list of use cases for other controlled substances. Because the rules focus

separately on buprenorphine and all other controlled substances, we are concerned that DEA is unaware of the myriad appropriate clinical use cases for these medications.

The proposed rules issued in March would limit telehealth prescribing of controlled substances without a prior in-person visit to Schedule III through V non-narcotic medications and buprenorphine only. The rule states that prescribing any Schedule II or narcotic substances via telemedicine would pose too great a risk to public health and safety. The Agency relies on a general assumption that because controlled substances can be misused, an increase in access would result in increased risk for diversion. The assumption not only overstates the risk of diversion, as I previously mentioned, but it also fails to consider the millions of Americans who may be adversely impacted from an inability to access medically necessary medication through virtual prescribing.

A few examples of the circumstances, and I'm sure you've heard these today already, where prescribing of Schedule II controlled substances and narcotics may be clinically appropriate may include a homebound palliative care patient receiving opioids

for pain management; a person with cancer with transportation limitations; a person with epilepsy living in remote areas receiving anti-seizure medication; a child receiving ADHD medication virtually due to a lack of pediatric psychiatrists in the immediate service area. So we recommend that DEA add circumstances under which Schedule II and narcotic medications can be eligible for telemedicine prescribing without an in-person exam.

Circumstances which are worth waiving the in-person requirement could include certain diagnoses or disease burdens, like hospice and palliative care, and/or the inability to travel to in-person appointments.

And, again, we are happy to assist with the development of these provisions, and we thank the DEA again for the opportunity to provide comment and would welcome further dialogue on our recommendations.

That's all I've got.

MR. STRAIT: Okay. Thank you, Ms. Gillooley, for those comments. I do see that Tom does not have any follow-up questions, so I will go ahead and go to Virtual Presenter No. 8.

DR. BERGER: That me? I'm not sure.

MR. STRAIT: Yes, Marc, you're up.

DR. BERGER: All right. Yeah, okay. I'm having a hard time finding what was just there a minute ago. Join us in Zoom now. Okay. I don't have my televideo working. I'm having problems with that now, but -- oh, there we go. Can you hear me and see me?

MR. STRAIT: Yes, sir.

DR. BERGER: Okay. Good. Fine. I am Dr. Marc Berger. I am an old-fashioned, real general practitioner family medicine doctor, and I have a few comments from my personal experience and also from some of my beliefs.

One of the first ones is, when I was practicing, I used to do controlled drug substance both in my practice individually and also as a takeover physician for a narcotic clinic. At the time, we were doing real visits once a month with them, and I thought that was very good.

There are some interesting things I noted. One, telehealth, I feel very strongly opposed to it for Controlled II narcotics, but I am perfectly in support of telehealth, telemedicine for Controlled II non-narcotics, particularly the ADHD drugs. I do prescribe them on occasion. It has been a difficult burden. This is a chronic condition that is unlikely

to change, ADHD, Attention Deficit Hyperactivity Disorder, on Ritalin, Adderall, et cetera. And I feel that that would be very reasonable to do through telemedicine.

However, controlled drugs, particularly Controlled IIIs and Controlled Iis -- I'm talking about hydrocodone, which used to be a Controlled III -- I find very difficult to perform telemedicine, and I'll give you some examples.

I do telemedicine for medical marijuana in the State of Florida. This has been off and on. It has been exceedingly difficult to perform telemedicine because there is no physical examination possible, and many of the conditions require a reassessment of the severity and the appropriateness of the continued use of the drug. For things such as chronic pain, there is no alternative to a physical examination to determine if the pain is still severe enough to continue with medical marijuana.

For some of the other conditions, that might not be unreasonable, but for some things, you do need a physical exam. I have in the past suggested that telemedicine for the purpose of any visit which traditionally requires point-of-care testing or physical exam is substandard of care. I do not see

how you can diagnose sinusitis through telehealth. I do not see how you can assess back spasm, chronic pain, back pain, acute post-operative pain, or any other issue by telemedicine. I believe that since ADHD is primarily a psychological condition and there are screening tools and it is a talk that it is reasonable to prescribe telemedicine for non-narcotics.

Some of the missed opportunities I have noticed, there is an inability to do a random drug screen or a true drug screen when you do not have an in-person visit. My practice was to do an in-person drug screen. We did occasionally find people who had made mistakes, had cheated, had used marijuana, had other drugs. Some of them were counseled, some of them were discontinued. Sometimes I required extra testing. I've had people who have had random testing that was false positive, and when they came to visit me, I did a supervised high-quality liquid chromatography test and proved that was not the case.

So the point-of-care lab, especially urine drug screens, cannot be done through telemedicine adequately in my opinion. Physical exam cannot be done. I routinely do examine my patients. I have found at least three people who I think I've saved

their lives from medical marijuana. Non-telehealth, re-certification, established patients, finding suspicious-looking moles, a new atrial fibrillation arrhythmia, and one other diagnosis.

I've also made suggestions for alternative treatments that I have seen. I can't evaluate a post-operative scar. I can't evaluate a CT scan, an MRI report, a real film at telemedicine, and sometimes that does change my prescribing, particularly for medical marijuana, but even for controlled drugs.

I have had patients on controlled drugs for a temporary period post-operatively when the surgeon did not do an adequate job. I've had patients on chronic pain medication for many years. And, again, the opportunity to see them in person means that I can perform real medicine and not just a simple re-certification and a reissue.

The other thing that -- okay. The other problem is you cannot actually touch the patient. You cannot do neurological testing. You cannot listen to their heart and lungs. You can't do vital signs. You can't see if their pulse oximetry is low. So, again, I do not feel that it is within the standard of care for a controlled drug, opiate, Controlled II, to have telemedicine. I used to do telemedicine for

Controlled III. It was unsatisfactory.

And in addition, at the VA, Controlled III drugs were occasionally done by pharmacists, their certification. I'm also concerned that paramedical professionals are really not qualified to treat patients for chronic opioid use, and yet different states are relaxing the standard such that in Florida nurse practitioners can prescribe up to seven days for acute conditions. They can prescribe for hospice patients. Physician assistants can prescribe. There is no requirements for supervision by an M.D. They are independent practitioners. So I do not believe they have the training and experience to perform telemedicine.

The other issue I would say, oh, actually, I used to also do non-medical -- non-drug therapy. I would occasionally do joint injections, refer for physical therapy, and do other treatments, such as implementing muscle relaxers, anti-spasmodics, et cetera, topicals, which I don't feel comfortable doing over telemedicine because I can't examine them.

One of the last things in terms of diversion, I have done two things in my practice to prevent diversion which I think should be publicized. One, for fentanyl patches, I have required patients on

fentanyl patches, once they take a patch off, to slap it on a piece of paper and date the date they removed it. When they come in for re-evaluation, they are to present me the paper, which should have eight fentanyl patches on it that should be dated. Although this is not perfect, it shows that they have not diverted the patches to someone else or they're really sneaky and took the patches back from who they diverted it to put them back on the paper. So, if they don't have eight fentanyl patches back on the paper, I get very suspicious that they may be diverting fentanyl patches.

The other suggestion I have which has not been approved is to allow pharmacists to do weekly partial drug fills. Not re-certification, not renewal, but to allow voluntary, the pharmacist and the physician, to allow the patient to only get a one-week supply of medication at a time and be able to come back every week to the pharmacist without seeing the physician to get the next week's supply.

The requirement is already available, but the pharmacist cannot bill the $2 and so dispensing fee, what makes it difficult. It would be advantageous to the pharmacists. They would have a better idea of who's coming in because they would

expect the next three weeks of a four-week prescription to be there.

It would cut down the number of drugs in the house, on the street, for any given patient by three-quarters. They would only have one week's supply of controlled drugs at any given time, which makes it harder to divert, harder to steal, harder to overdose.

In addition, they get extra supervision by the pharmacist, and for the pharmacy, they also have the added benefit of having to walk through the pharmacy and possibly buying other things from the pharmacist.

So I think encouraging partial weekly drug fills, I write a prescription for 120 percocet. The first week, the pharmacist gives 30. The patient comes back next week, he gets another 30, the third week another 30, the third week another 30. The pharmacist will keep the records. I don't have to do it. My prescription is still for one month. So I think partial drug fill weekly would significantly help the overdose possibility and get a large number of prescription drugs off the street and encourage patients to come into the pharmacy more often. They still have to come into the pharmacy even with

telemedicine. But the opportunities that are missed, including drug screens, physical examinations, alternation of treatment, review of other practitioners, particularly surgery, physical therapy states, and the opportunity to do point-of-care labs.

Again, I have had at least four patients die from drug overdose. One was deliberate where he had three different physicians prescribing three different drugs. That was not found easily at autopsy. Another one had an incidental possible overdose that was botched on autopsy. The other two were never investigated properly. So I've had that. I've had patients on various drugs.

So, in summary, I am opposed to telemedicine renew of medications that are Controlled II narcotics, but I encourage the telemedicine review and re-prescribing of Controlled II attention deficit disorder drugs and other psychoactive non-narcotic drugs. Thank you.

MR. STRAIT: Thank you, Dr. Berger. I'm looking over at Tom. I do not see that he has any follow-up questions, so thank you.

And we will now move on to Virtual Presenter No. 9.

MR. HEAPHY: Hi. Good morning, everyone.

My name is John Heaphy. That's spelled J-O-H-N, H-E-A-P-H-Y. I am the Deputy Director of the New York State Bureau of Narcotic Enforcement. I have the privilege of speaking to you today as the voice of New York State on behalf of the New York State Department of Health, the Office of Addiction Services and Support, and the Department of Mental Health.

I would like to thank the DEA for providing stakeholders with the opportunity to contribute to the discussion regarding the telemedicine prescribing of controlled substances.

The pandemic precipitated a rapid expansion of telemedicine, which has benefitted many across the country. These practices have contributed to health equity for many underserved populations, and we believe there is a role for continuing telemedicine prescribing of some controlled medications.

Evaluation should continue, and the Centers for Medicare and Medicaid Services should issue guidance with particular attention to health equity as there remains a risk that some more vulnerable populations may be inadequately served.

With that said, the Drug Enforcement Administration had posed several questions regarding the practice of telemedicine, and I will address those

now. The first asks, what framework would be recommended if telemedicine prescribing of Schedule III through V medications were permitted in the absence of an in-person medical evaluation?

It's important to begin by addressing medications for opioid use disorder. The clinical significance of both buprenorphine and methadone in the treatment of opioid use disorder has been well established. While there are currently limitations on the prescribing of methadone for this indication, which New York State believes should be re-evaluated, we have seen success in telemedicine-initiated buprenorphine.

This practice should continue as it did during the pandemic to allow synchronous audio and audiovisual interactions. Best practices are still evolving, and we believe these should be shaped predominantly by evidence-based medicine.

If telemedicine prescribing of Schedule III through V medications other than buprenorphine were permitted in the absence of an in-person medical evaluation, New York State recommends the following.

Practitioners must be registered to deliver, distribute, dispense, or prescribe controlled medications in the state where the patient is located,

and they must maintain compliance with federal and state laws when delivering, distributing, dispensing, and prescribing the controlled medication.

The United States Department of Health & Human Services should be called upon to issue guidance on which conditions can be managed appropriately by telemedicine as the diagnoses and treatment of those conditions will rely on history rather than physical examination.

The primary safeguard in the practice of medicine is appropriate documentation, and the federal government could standardize this component. The telemedicine consultations should be synchronous or audiovisual with the exception of continuing the option of initiating buprenorphine allowed through synchronous audio-only consultation.

However, it is important to consider the potential risks of permitting audio-only telemedicine against the possibility of creating further health inequities or an increased risk of self-medicating due to lack of access to buprenorphine, and this is especially dangerous considering the increased presence of counterfeit medications currently available.

Prescriptions should be issued in electronic

format to reduce the risk of fraudulent prescriptions. The Prescription Drug Monitoring Program should be consulted prior to prescribing to reduce the risk of duplication or the issue of interactions. States should monitor the Prescription Drug Monitoring Program for changes in prescribing patterns and monitor data on morbidity and mortality related to medications obtained pursuant to telemedicine encounters.

DEA posed a similar question as it pertains to Schedule II medications as well. If telemedicine prescribing of some Schedule II medications were permitted in the absence of an in-person medical evaluation, we have the following recommendations and considerations in addition to those previously stated.

Stimulant treatments for use with ADHD should be considered. National data on youth mental health show poor mental health outcomes and increased school disconnectiveness.

Restricting access to evidence-based treatment for ADHD is likely to further increase poor outcomes. Additionally, while the federal government is making significant investments in school-based mental health, there are not enough child psychiatrists, pediatricians, and other prescribers to

provide in-person services.

Allowing for stimulant prescribing for youth with ADHD with a complete psychiatric evaluation by audiovisual telehealth will have a tremendous impact in ensuring that youth receive timely and appropriate treatment while expanding access to care.

Safeguards should include obtaining guardian consent when prescribing to youth and possibly limiting the types of practitioners who may prescribe by telehealth, for example, limiting it to Board-certified child and adolescent psychiatrists or pediatricians or other practitioners that have a supervisory relationship with Board-certified child and adolescent psychiatrists.

And, lastly, DEA should include a component covering stimulant prescribing and stimulant use disorder in the required eight-hour course which was instituted by the Medication Access and Training Expansion Act of 2021.

The final two questions posed pertain to data collection by practitioners and pharmacies. There is a great deal of data collected on Schedule II through V medications, including prescription drug monitoring program data, insurance company data, as well as private companies that collect health

information and make it available at a cost.

Practitioners and pharmacists should not be asked for more data specific to these medications except for the following: The National Council for Prescription Drug Programs, or NCPDP, script standard includes a field to indicate that a prescription was issued by telemedicine, and this field should be utilized.

The DEA has historically issued location-specific DEA registrations to practitioners. Continuing this practice will indicate the practitioner's location where that telemedicine prescription is issued.

Telemedicine practitioners could be required to submit the name of the telehealth practice or company that they are representing. Additionally, we do not see a role for requiring registration beyond the current standard DEA registration.

The former X waiver DEA registration illustrates why this isn't necessary. History shows that the requirement for a practitioner to have a special registration to provide buprenorphine was a deterrent to sound medical practice and to our knowledge did not provide useful safeguards or data.

However, if a telemedicine registration is

required, then we do recommend that telemedicine-registered practitioners should submit accurate data on the number of prescriptions in each schedule and/or medication class prescribed. This, of course, should not include line-level patient-specific data due to confidentiality concerns.

In closing, we recommend that further regulatory changes be considered beyond today's discussion. As mentioned previously, access to methadone for the treatment of opioid use disorder is currently limited solely to opioid treatment programs, and, as such, research on the ability to prescribe methadone for opioid use disorder is limited.

New York State encourages new pathways be explored to increase research on this issue and allow for improved access to utilize methadone for opioid use disorder.

Thank you again for your time and the opportunity to speak today.

MR. PREVOZNIK: Could you elaborate on -- you made the comment that the states would monitor. So you talked about the EPCS format, the PDMPs, and then you said states should monitor morbidity and mortality. What would that monitoring be, and who would -- like, what is that report going to do?

MR. HEAPHY: We believe that if states were to utilize prescription monitoring program data in coordination with vital statistics, such as morbidity and mortality, we would be able to analyze the impact that telemedicine prescribing of controlled substances is having on fatal overdoses and overdoses in general.

MR. PREVOZNIK: But you did say that you don't feel that there needs to be a special registration. So how would you know that it was a telemedicine encounter plus --

MR. HEAPHY: I indicated in my talk that the PDMP field should be utilized which indicates the origin of the prescription, which would be telemedicine in this case.

MR. PREVOZNIK: And how would that be marked on the prescription?

MR. HEAPHY: There is a field that is transmitted through electronic prescribing in the NCPDP script standard which would indicate telemedicine prescription. That data would be captured, could be captured by the prescription monitoring programs if that field is required to be submitted.

MR. PREVOZNIK: So this data that would be collected, this would be just monitored by the states.

There would be -- would there be any coordination with DEA or law enforcement?

MR. HEAPHY: That would be up to DEA purview. Our current recommendation is that it's collected at the state level.

MR. PREVOZNIK: Okay. Thank you.

MR. HEAPHY: Thank you..

MR. STRAIT: Okay. Thank you, Mr. Heaphy, for your comments.

And we will now move on to Virtual Presenter No. 10.

DR. MOORE: Hello. My name is Philip Moore. I'm the Chief Medical Officer for Gaudenzia. My background is internal medicine, addiction medicine, and medical toxicology.

Gaudenzia is the largest nonprofit provider of treatment for people with substance use and co-occurring disorders in the Northeast. Gaudenzia has been treating people for the past 54 years in 50 locations, and we have a hundred programs in Pennsylvania, Maryland, Delaware, and Washington, D.C.

Our largest footprint and our corporate office is in Pennsylvania. Last year, we served over 15,000 people, and our stance, Gaudenzia strongly endorses the permanent integration of telehealth for

Schedule III to V drugs which was established during COVID.

The way we were able to, you know, develop these telehealth programs, our facilities created the infrastructure where our patients would come in for counseling, they'd come in for urine drug screens, and they would receive injectable medication, such as extended-release buprenorphine, and they would receive this from nurses when a physician or advanced practitioner was not onsite. We were able to create a rotating schedule where a prescriber rotated around between multiple sites.

And we offer telemedicine using encrypted audiovideo platforms with multifactor authentication. And what our program allowed us to do was to bridge MAT and mental health treatment until our patients could transition from our residential facilities to community providers or would allow us to really maximize who we could see at our rural locations that may not have a licensed prescriber five days a week or seven days a week.

We were able to pair the MAT with counseling instead of just offering counseling alone at, you know, a significant, you know, increased number of facilities. So we were able to reduce barriers to

care for people living in rural areas without consistent convenient access to care. We were able to increase the accessibility for people with disabilities who have reduced access to consistent substance use care. We were able to maximize access to physicians for vital medication-assisted treatment induction and maintenance in both our residential and outpatient settings.

More about the residential is that telehealth allowed us to expand access to start MAT for individuals starting treatment. Our facilities are 24-hour, and, you know, we might not have a prescriber in the facility all 24 hours of the day. So, if someone comes in in the evening, we have a small window of time before they start going into withdrawal, and telehealth really helped us to improve our retention in treatment so that people were staying, you know, much longer than 24 hours.

So, you know, our endorsement is rooted in a belief that vital substance use disorder treatment, including medication-assisted treatment, should be available for all those who seek it and when they seek it.

We've found that there's a small window of time to start these medications when someone requests

help. This is because modern drugs and their use have been associated with the development of withdrawal symptoms faster than what historically occurred.

Most recent data from the NIH and CDC reveals a concerning statistic. Just one-fifth of nearly two-and-a-half million adults grappling with opioid use disorder received medication-assisted treatment in 2021.

Returning to the pre-COVID regulations, which mandated in-person evaluations, could significantly compound access challenges, especially in rural and underserved areas, which leads to increased relapse and overdose rate.

During the pandemic, it really underscored the significant value of remote care, especially with substance use disorder treatment. Gaudenzia's outpatient sites in particular harness the flexibility and accessibility to telehealth to increase MAT services to the majority of the agency's outpatient sites and facilitate access to MAT for over 450 outpatient clients since May of 2020.

We were able to add 10 additional outpatient sites in the last year and a half because of telehealth. So telehealth has permitted the flexibility, improved access. It has not jeopardized

safety and accountability with counseling and nursing staff playing an essential role in monitoring and ensuring continued engagement and treatment.

We understand that these changes can only be made permanent with a meaningful framework, which is what we strongly, you know, encourage, is that telehealth is only offered by facilities that have the appropriate infrastructure to monitor for diversion and safe prescribing.

Considering the patient's safety concerns and the imperative of preventing controlled substance misuse, Gaudenzia recommends enhancing patient identification, verification, and monitoring protocols alongside establishing tailored guidelines and standardized training specific to telemedicine practices.

And we recommend continuing the access to telehealth care that includes all forms of MAT treatment when it's closely monitored, and we feel this will continue to improve necessary access to these life-saving medications and care for persons with both substance use and co-occurring disorders who might not be able to access healthcare in the traditional methods.

Removing this much-needed flexible tool

could have significant negative effects on the opioid and addiction epidemic which we're all working so hard to stop.

In summary, telemedicine should be a vital option for facilities and prescribers that have demonstrated a capability to safely manage with the appropriate infrastructure to minimize the diversion for Schedule III through V medications.

I really appreciate the opportunity to speak today.

MR. PREVOZNIK: Could you expand on your thoughts on the patient ID, either what you do or what you are suggesting on that?

DR. MOORE: So, using telehealth, if they're using multifactor authentication and if they're, you know, using their appropriate, you know, their corresponding name on that, that helps make sure that you are speaking to that individual.

And then also, once they're on the line, have, you know, a way to confirm their identity, their name and something like, you know, a code word or, you know, last four digits of a number, something so that you're allowed to or that you're able to more accurately verify it is who you're supposed to be speaking with.

Similarly to when someone comes into an OTP and you're, you know, verifying their identity by looking at a picture that's been scanned into the system and you have a copy of their driver's license and, you know, they give you a four-digit number or some kind of word to also help identify who they are, that's what we try to build into our telehealth platform.

MR. PREVOZNIK: And, medically, what else do you see as this meaningful framework that a provider would do in their evaluation?

DR. MOORE: As far as, like, what structure we built that they're evaluating during the initial and follow-up visits?

MR. PREVOZNIK: Specifically, the initial visit. Like, what medical steps is that provider taking to ensure that they know they're assessing the patient properly?

DR. MOORE: So all our patients, we have a workflow for intake, and the intake or admission assessment is completed by multiple individuals. So part of it will be in a facility. Part of it could be remote by telehealth, but, you know, the same things are completed as far as demographics, obtaining a copy of their insurance, their photo ID. You know, we

complete an insurance verification. We complete things from a Depression Screener to Columbia's Suicide Risk Assessment. There's a nursing bio-psycho-social. There's also a counselor or clinician intake.

The prescriber would review all of these documents and then individually confirm a history, you know, of course, their identity and then with all this information, which could also include a urine drug screen, which we require to be collected within seven days of an admission in our outpatient program, and as well as checking a Prescription Drug Monitoring Program report, so, with all that data, our licensed physicians or advanced practice practitioners would make a decision about the appropriateness for outpatient treatment, or, in some circumstances, they might recommend residential to start, then eventually stepping down to outpatient.

Does that answer your question?

MR. PREVOZNIK: Yes, thank you.

MR. STRAIT: Okay. All right. Well, thank you very much, Dr. Moore.

I am being told by the production crew that we have two more virtual presenters for our morning session. So we will now move on to Virtual Presenter

No. 11.

DR. EHRENFELD: Thank you very much. I'm Jesse Ehrenfeld, Dr. Jesse Ehrenfeld, an anesthesiologist and President of the AMA. It's Jesse, J-E-S-S-E, Ehrenfeld, E-H-R-E-N-F-E-L-D. The American Medical Association really appreciates the DEA hosting this public listening session to help inform your regulations on prescribing controlled substances via telemedicine. We want to commend the DEA for taking additional time to ensure that your rules provide an appropriate balance between advancing patients' access to care via telemedicine and ensuring patient safety.

I want to first comment on Schedule III through V. The COVID public health emergency demonstrated telemedicine prescribing of Schedule III through V medications with and without an in-person evaluation help patients with many medical conditions begin and maintain necessary care. Whether it was audio-only, audiovisual, or in-person care, the physicians provide-high quality, evidence-based care that relies on thorough assessments and sound decision-making.

So, for example, during the COVID public health emergency, audio-only and audiovisual

telehealth induction with buprenorphine for opioid use disorder was extremely helpful for maintaining continuity of care and preventing relapse for those currently receiving treatment with medication for opioid use disorder. We strongly urge the DEA to ensure that access to medications for opioid use disorder is not interrupted through new requirements that might impose a barrier to care.

There are many safeguards that currently exist through state law as well as the Controlled Substances Act that provide a sufficient framework to help ensure patient safety and prevent diversion. The professional, the ethical, the legal obligations that govern the practice of medicine and pharmacy can and should be trusted to provide ample safeguards for ensuring patient safety. If a prescription is not issued for a legitimate medical purpose, it should not be dispensed. This applies regardless of the modality used for patient evaluation leading to the issuance of the prescription.

Another key safeguard is that every state requires controlled substances to be entered into the state prescription drug monitoring programs when they are dispensed. This information provides physicians and pharmacists with helpful clinical information,

including whether patients are obtaining prescriptions from multiple prescribers and pharmacists. If the dispensing pharmacist has questions regarding whether a prescription for a scheduled medication is for a legitimate medical purpose or has other questions, it is common for the pharmacist to talk with the patient, contact the physician, or seek other information to try and resolve the questions or determine that the prescription should not be dispensed.

These processes and relationships help ensure patient safety as well as protect against diversion. The framework for prescriptions issued based on a telemedicine encounter must also allow patients sufficient time to schedule an in-person visit when clinically appropriate. The AMA urges that following an initial telehealth encounter the patient be afforded at least six months to fill and renew prescriptions before being required to have an in-person visit. This can help ensure that the patient is stable on the course of medication therapy so that the in-person visit can be a seamless transition.

Having at least six months as a part of the framework for prescribing Schedule III through V controlled substances via telemedicine addresses

multiple current barriers. These barriers include health insurance network inadequacy; functional limitations that can make access to in-person services difficult; long travel times; racial disparities in access to buprenorphine versus methadone treatment; long wait times for treatment; the need for a caregiver to accompany the patient; stigma within the medical community regarding drug users; and patients experiencing unstable housing and lack of transportation or childcare. Telehealth visits for opioid use disorder have helped many patients access treatment, including buprenorphine.

Now let me mention Schedule II medications. The AMA continues to support telemedicine prescribing of Schedule II controlled substances in the absence of an in-person medical evaluation when clinically appropriate. A telemedicine prescription can help ensure that the patient receives timely therapy without delay, including for patients with chronic medical conditions, cancer, in hospice, those living in remote or underserved area, or other situations.

The AMA does not support sham practices that have no assessment, evaluation, or other markers of legitimate care, but the COVID public health emergency demonstrated that physicians can and do thoroughly

assess a patient via a telemedicine encounter. This includes determining whether a prescription would be clinically appropriate during an initial telehealth visit or, for current patients, telemedicine can allow a physician to conduct pill counts, monitor toxicology screens, and ensure medication adherence or identify aberrant behaviors requiring a change in therapy.

For situations where an in-person evaluation would result in a delay in care that could lead to patient harm, the AMA urges that telemedicine prescribing of Schedule II medications be permitted. When a telemedicine visit is scheduled or started, the physician does not know how complex the patient's illness or injury is or what medication or medications may be most appropriate to treat the illness or manage its symptoms until the visit's been completed.

It's equally true that not all care could be provided via telehealth, a lesson we have learned well. If a physician determines during a telehealth visit that the patient needs to be seen in person, that should be the next step. The AMA cautions DEA about making new rules allowing only some controlled substances to be prescribed based on telemedicine visits. If at the end of a telemedicine visit the complexity of a patient's medical condition warrants a

prescription for a medication that is not on some approved telemedicine list, the physician's options will be to prescribe a non-optimal treatment or to attempt to arrange an in-person appointment so they can prescribe the appropriate medication. This includes Schedule II medications.

The AMA urges a targeted enforcement strategy to deal with illegal online practices rather than new rules that would adversely affect practices that provide high-quality evidence-based care to patients with medical conditions benefitting from Schedule II controlled substances.

Safeguards already exist in the Controlled Substances Act and state licensure governing medical and pharmacy practice. The AMA recommends that where it is suspected that the standard of care is not being met and diagnostic integrity and accuracy may be compromised, medical boards pursue focused oversight to ensure appropriate patient care in prescribing of controlled substances. If there is illegal activity, law enforcement intervention may be necessary as well.

The COVID public health emergency forced physicians to adopt new ways to ensure evidence-based high-quality continuity of care and increased access to care for patients with chronic conditions. We met

that challenge. Our patients benefitted. We supported the Administration's efforts to extend the PHE flexibilities, and we similarly urge DEA not to reverse practices that are now helping patients.

Let me just mention a few other data points. The framework moving forward should avoid a new burdensome recordkeeping requirement. We are concerned about the DEA's proposal regarding records being maintained for investigation purposes. Current DEA requirements for records related to prescribing and dispensing of controlled substances should be sufficient if the DEA needs to conduct an investigation. The DEA already receives a tremendous amount of data from manufacturers, distributors, pharmacies about controlled substances in the supply chain. These entities are required to provide DEA with suspicious order reports to help identify potential problem areas.

State PDMPs contain personal health information regarding individual prescribers and patients that's clinical in nature and should not be shared or disclosed to law enforcement without probable cause. DEA has the ability to seek judicial approval for accessing a PDMP or conducting other surveillance activity. We do not believe the DEA

needs more data to strategically target illegal activity, and we would be concerned if DEA proactively sought state PDMP data as a part of data mining or routine surveillance activities.

Thank you very much for the opportunity to provide these comments on behalf of the American Medical Association.

MR. PREVOZNIK: You mentioned a targeted enforcement strategy. What does that mean?

DR. EHRENFELD: It means when you have a signal that there's a problem that you look at those practices that have an aberrant strategy going on and you look at them with scrutiny.

MR. PREVOZNIK: Okay.

DR. EHRENFELD: As opposed to taking a blunt approach through a regulatory framework that ultimately causes more harm than good.

MR. PREVOZNIK: And the -- where did I have it here? I missed one of your -- after the six months you're -- the framework that you had, I had check insurance, travel times, long wait times, and I didn't get that -- what was the fourth one? It was -- stigma was the one after that.

DR. EHRENFELD: So, when I was mentioning the framework, there are a lot of barriers to people

accessing in-person care. So health insurance network inadequacy, functional limitations that can make access to in-person services difficult, long travel times, racial disparities in access to buprenorphine versus methadone, long wait times for treatment, the need for a caregiver to accompany the patient, and stigma within the medical community regarding drug users and patients experiencing unstable housing, lack of transportation, childcare are the barriers that we wanted to highlight.

MR. PREVOZNIK: Okay. Thank you.

MR. STRAIT: Great. Thank you, Dr. Ehrenfeld. And I do want to just make a point of clarification and it bears emphasis because I know that this, I think, is a fundamental assumption or perhaps misunderstanding about our rule or the draft rule that was published in March. And as Anne Milgram mentioned on day one in her introductory remarks, the Ryan Haight Act amended the CSA and required an in-person visit be established and then created an exception to that requirement when the practice of telemedicine was occurring. All right? And then the statute then listed seven or eight different circumstances that constituted the practice of telemedicine.

So one thing that we made clear in our rule and the nature of our rulemaking forthcoming is that when there is already an in-person relationship that has been established, this rule does not in any way, shape, or form somehow impose a new requirement on the types of controlled substances that could be prescribed, the duration of the controlled substance that is prescribed, and the instance in which a patient must then come back and visit the practitioner. And it just bears emphasis because I think we don't want to lose in our translation the fact that this rule is not being applied broadly to all telemedicine encounters across the entire spectrum whether that in-person relationship has been established or not. So I just wanted to make that clarification.

I appreciate Dr. Ehrenfeld's comments. And we will now move on to Virtual Presenter No. 12, which I believe is our last presenter for our morning session. Thank you.

DR. HUANG: Hello, everyone. My name is Delphine Huang. That's D-E-L-P-H-I-N-E; last name is H-U-A-N-G. Thank you so much for taking the time to hear some of my thoughts and comments. I'm coming as a representative of CalMHSA, which is the California

Mental Health Service Authority. We're a joint power of authority where we work with MediCal counties across the State of California as collaborative multi-county projects that improve behavioral and mental health for patients that are Californian and for MediCal. We work together with them to pool county resources, think about partnerships in leveraging the technical expertise, and think about the strategies.

My particular role, I'm a medical director of innovation and design. While a physician, I'm actually responsible for thinking about the user experience and how different services or technologies are implemented.

Today, I wanted to share just some perspectives and mostly raise some questions around for just us to think about where I'm curious when it comes to prescribing I think, along with other colleagues that I've heard here today, prescribing our resource-limited populations, which many of our MediCal patients are facing, so we want to understand better from the DEA what are some issues around prescribing controlled substances in a telehealth environment and the impact for vulnerable as well as resource-limited populations, especially in rural

areas, where there are really limited numbers of doctors available.

In some of the MediCal counties that are rural, we actually only have one to two child psychiatrists or two to six adult psychiatrists that will be serving the entire county, and they use telehealth as the only means to have the expansive reach that they do.

We are also seeing a workforce crisis in mental health currently where we have declining numbers of doctors and/or prescribers due to other competitions, you know, for doctors working in private or for Medicare, as well as an aging provider population. This actually makes it very difficult to recruit and retain talent. We have several counties that have difficulty even recruiting their one child psychiatrist because they actually as a MediCal county will be required to provide in-person services and therefore must hire locally.

So we're curious to hear from the DEA, you know, what support if moving forward for these requirements, what are the HIE and data-sharing access that they're going to support, especially around flags and notifications. Currently, CalMHSA has an EHR that we rolled out in July across 22 counties as a

semi-statewide EHR, and other counties are also coming on board.

We have taken upon ourselves to create fields where we can track whether or not doctors are reviewing CURES and they can report that, but we're curious to hear because many of the things that they are also requesting for in the EHR is ways in which they can integrate with CURES and get notifications as well as kind of local and population health in order to support their work, which they believe is in accordance of tracking prescribed controlled substances. We have also created ways within the EHR to think about med reconciliation as well as identification of the patient.

I'm curious to hear from the DEA what exceptions might be made, especially around some of the things that folks are raising here, which is around given the patient population, especially our MediCal population, which may have difficulties both with transportation and getting themselves into an in-patient appointment.

Really, where we see some of the issues are when it comes to how patients are using their controlled substance is really around that piece around data, how data is captured between the visits.

If you think about the visit being only a 15-minute moment of time, what is happening between those visits are actually more important when it comes to patient safety, patient outcomes.

A second area that we would love to understand better from the DEA is understanding around CF42 and both the need to respect privacy, patient privacy, but also the need for data-sharing transparency for making decision-making about prescribing controlled substances, especially around Substance Use Disorder providers, SUD, and the mental health and medical.

So, as I mentioned, with the EHR that we have launched across our 22 counties and expanding more, there has been a lot of discussion around CF42 and how this has led to siloed prescribing. And so thinking we want to understand better from the DEA how they consider the CF42 that currently exists and what it means when it comes to telehealth and data-sharing across different providers. We do think it's really important when it comes to especially controlled substances given the risk to maintain that transparency in order for providers to be able to have clarity on the diagnosis, the clinical decision-making, as well as the medication.

So, once again, thinking about what it means when it comes to HIE and data-sharing when it comes to these prescribed controlled substances and then thinking about how you're tracking patient movement across different siloed systems that currently exist, given that while we are moving towards having a universal EHR, this is still very difficult when we are not necessarily connected to the medical side and then, therefore, if we are thinking about it from a telehealth perspective, these patients may be coming and may have difficulty coming to their appointments, and, therefore, follow-up is very tough to get that information from the patient.

That's all my comments here today. More so providing kind of questions to the DEA to learn more around the CFR 42, as well as thinking about how we build accessibility for resource-limited populations that also have very limited access to a small workforce. Thank you.

MR. STRAIT: Thank you, Dr. Huang. And I believe that we may have a question, or do you have a question, Tom?

Okay. It does not appear that we have a question for you, so thank you for making time for us.

And I think we are now going to conclude our

morning session. We will resume our afternoon session at 12:40. I do know that Administrator Milgram will be back for the 12:40 session. I thank everyone on the virtual side for presenting, and those that are watching the livestream, thank you for attending, and, of course, all of you that are here in the audience today. We'll see you at 12:40.

(Whereupon, at 11:14 a.m., the listening session in the above-entitled matter recessed, to reconvene at 12:40 p.m. this same day, Wednesday, September 13, 2023.)

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A F T E R N O O N S E S S I O N

(12:40 p.m.)

MR. STRAIT: Okay. Welcome back from lunch everyone. Thank you to our in-person commenters who were here early and so patient waiting as we walked through our virtual comments from our morning block.

As I indicated, we will now be starting our afternoon block of in-person presenters. I'm happy to report we have Administrator Milgram back for our afternoon presentations as well as Assistant Administrator Prevoznik.

So without further ado we will go ahead and call to the stage commenter number one. I'll just give a friendly reminder to all our commenters, if you would, state your name and your affiliation and then spell your first and last name for our transcribers.

MS. VAETH: Welcome back everyone. My name is Danielle Vaeth. That's spelled D-A-N-I-E-L-L-E. Last name V-A-E-T-H.

Thank you for the opportunity. I represent QbTech, a privately held medical device company that has dedicated the last 15 years to providing FDA cleared evidence-based tools to improve assessment and treatment monitoring for clinicians dealing with ADHD.

I stand here today in alliance with DEA,

ATA, AMA, ABHW, ATA, an ADHD patient advocacy group with more than 6,000 adult members and many others for the importance of data-driven and equitable access to telehealth services.

We stand that telehealth is health, but mental and behavioral care is health care. And to reiterate Kyle Zebley's comments, that all -- should be regulated on a level playing field regardless of whether in-person or virtual.

We appreciate the opportunity to promote better safeguards for telehealth and in-person visits particularly when it comes to prescribing medication.

I've been at QbTech for just under a decade and personally have heard from hundreds of clinicians and want to reiterate that the thousands of people including patient stories particularly that of later in life adults like Dr. Teddy or mom Lori, who we've heard from over the last few days, are not unique.

I must highlight that ADHD access is a public health issue, not just a private one, and was reminded by expert in the field Dr. Tony Rothstein this morning that none of the science and effort in advancing the field is truly meaningful without access.

Based on our experience with over 12,000

clinicians globally we believe that companies and clinicians should consider adding a level of protection for practices that is not yet widespread in the U.S., leveraging data, better informs treatment and enhances patient outcomes which include those receiving care for ADHD, a most treatable behavioral health condition.

My aim is to share how prescriptions via telehealth along the care continuum can be considered alongside FDA-cleared objective measurements in sharing precise dose optimization and mitigating over treatment.

Quality measurable data that can safeguard virtual prescribing practices is currently available and utilized by thousands of clinicians nationally.

By way of introduction Qbtech, an FDA cleared medical device has been available to U.S. practitioners since 2012. It offers a simple and computer-based test that measures hyperactivity, attention and impulse control. The test can be conducted at home or in a clinic and is interpreted by a trained, qualified health professional.

By comparing a highly visual report, incorporating robust data against age and sex controls, clinicians can ensure that the right

patients receive the care that they need.

The same test is used to measure symptom changes before and after treatment of any kind, often as we know with Schedule 2's, to ensure effective symptom improvement.

Our experience has been that many patients, parents and clinicians alike certainty, confidence an clarity when it comes to both their diagnosis and decisions around treatment. It is often a misunderstood condition both over and under-diagnosed. It is a condition that is underserved in medical training programs. For example 93 percent of psychiatry residency programs do not include formalized training in ADHD.

Ill-prepared to accurately assess these patients, clinicians search for objective data to aid diagnostically as well as to quantitatively measure response to treatment and to better titrate medication dose.

I not only represent Qbtech but the clinicians we partner with including a clinical and community advocate team, the ADHD Expert consortium. This group created a call to action statement for increased clarity, advanced education, tools and resources for which they have almost 900 signatures.

Their statement underscores the critical need for data-driven care. The group includes the likes of pediatrician James Wiley in Alabama who while educated and resourced on the topic struggled to find an accurate assessment for his own daughter who was initially incorrectly diagnosed with a learning disability.

These clinicians add objective data to their care pathway because ADHD is a chronic, prevalent condition. It is one of complexity where management takes nuance.

A study by Vogt, Shameli showed that Qbtech computerized objective data could not only identify treatment response in 84 percent of patients, but could also separate those with a partial response from those who are non-responders.

This is a pivotal moment in our history where we can continue to provide equitable access, evidence-based tools, and safeguards that have been extended in an already overburdened system.

We believe hybrid models of patient care are necessary but need to keep in mind that ADHD has a unique burden in this model as a chronic and complex condition with high prevalence rate. Treated commonly with Schedule II medications, this is a condition

which can be missed.

Today we hope to shed light on the role FDA cleared technologies and ensuring that quality ADHD care can be delivered regardless of the delivery model.

Measurement based tools are providing clinicians with objective data on symptom severity and treatment response, better informing clinical practice, providing accountability and facilitating safer prescribing practices without the need for an in-person visit.

Prescriptions based on data points looking at efficacy as well as time of day help to add safeguards around controlled substance dispensing and to standardize a more step-wise process.

Our success extends globally. We have a proven track record in countries that are already prioritizing evidence-based objective data into their pathways. Our testing system is now a standard of care within the National Health Service in England where 70 percent of NHS clinics are routinely using Qbtech testing which after three years of study and 70,000 patients we received a nice appraisal this past March.

We now serve over 4,000 clinicians in the

U.S. in varying size and geographic locations from FQHCs and universities to health systems and private networks. We know the need for mental health care virtually has increased since the pandemic. ADHD evaluations and treatment especially among adults surged 400 percent since 2020 while the supply of qualified health care providers remains stagnant or sadly decreased.

After five years of study, Qbtech launched an FDA cleared remote testing platform, ensuring that quality of ADHD evaluations and medication monitoring remained uncompromised for remote patients. So clinicians like Heather Brannon, a doctor in rural South Carolina, could continue to monitor medication efficacy without compromise just because her patients were receiving care remotely.

To date we have tested more than 70,000 patients using our virtual Qb test. Our robust quantitative data and highly visual reports are incorporated into clinical interview and patient report symptoms. Qualified health care professionals are trained by our masters level mental health clinicians.

In 2023 we conducted over 6500 training episodes in the U.S. ensuring that clinicians are well

equipped to interpret and utilize our data effectively. These clinicians all use testing as a part of their assessment process.

Additionally, when it comes to initiating a treatment protocol, particularly for Schedule II medications, many clinicians will conduct a repeat testing on treatment to monitor results over time. Depending on the type of treatment and time of day, the clinician may be looking at efficacy, type, dose, class or consideration of wear-off. This data is then utilized in context of interview and self-report to guide next steps.

FDA cleared objective measurements ensure precise dose optimization and can mitigate over-treatment. Objective data should be recorded at each medication change as available, along with evidence of patient benefit efficacy and to mitigate diversion.

Many clinicians monitor effectiveness long term every six months to look at changes over time or across the day, both with subjective self-report and objective testing data.

We have examples and study data that similarly confirm the efficacy of Qbtech's objective data in measuring treatment response. A study published in 2022 out of North Carolina where patients

completed a self-report and/or testing, were followed up with their clinician at six months. When looking at the patient self-report data alone, 36.6 percent of adults reported improvement. Yet when analyzing their Qbtech results, 85.5 percent showed a measurable change on their treatment, demonstrating that self-report alone misevaluated over 50 percent of patients, or 50 percent or patients were missed with self-report alone when it came to treatment response measuring. Meaning that when employing FDA validated tools, were leaving less subjectivity when it comes to measuring if treatments are working. This could lead to clinicians and patients agreeing on changes in dose or medications that were unnecessary.

Our data shows that Qbtech when used to monitor treatment response can distinguish a treatment effect within hours of pharmacological treatment if prescribed a stimulant, meaning clinicians and patients have additional data around treatment decision-making and can further be used for monitoring long-term treatment effect.

Pediatrician Dr. Melinda Wellingham, a member of our expert consortium who also serves as a representative for the AAP on the Committee for Federal Government Affairs, who uses Qbtech to serve

an unserved community outside out of Atlanta she describes as a care desert, shared this. In today's evolving health care landscape, telemedicine presents a unique opportunity to harness rich patient data, to advance precision care. By considering data as a vital component in both assessment and treatment response, we empower health care providers to tailor interventions with greater accuracy, elevate the standard of care, and ultimately improve patient outcomes.

In conclusion, telehealth is health care and is providing more people with necessary care. We have the ability to provide equitable and objective approaches to care and ensure accurate screening, monitoring and clinical confidence, especially in virtual visits as a safeguard. Together we can earn clinicians with objective tools and enhance the quality of care for those living with ADHD.

I thank you for your attention, and I thank you for your caring. I hope together we can achieve what we've dedicated our lives to in making a difference.

MS. MILGRAM: Thank you. If I could ask one question.

You talked a little bit about, I think you

talked about and I just want to make sure I'm tracking and asking you to expand correctly. You talked a little I think about the guidelines for prescribing and I think I would love for you to expand a little bit on are there sufficient prescribing guidelines for ADHD for children? And are there sufficient prescribing guidelines for ADHD for adults?

MS. VAETH: I think I'll leave that up to the clinical community to comment more. I know that AAP and SDBP, the Society for Developmental behavioral Pediatrics, have clinical care guidelines around treatment. The adult guidelines are being built right now by ABSARD which is an organization I'm a member of. But I think there is clarity.

MR. PREVOZNIK: Could you expound on, you said there was research platform testing of 70,000 patients. Could you --

MS. VAETH: No. We've tested over 70,000 patients in our virtual platform.

MR. PREVOZNIK: Are there results of that testing? What has it shown?

MS. VAETH: Those are the number of people who have had access to our testing via virtual. The data, if you have specific questions about the data and treatment response, we've got 15 studies looking

at treatment response measurement varying in terms of length and duration, time, from looking at efficacy, time of day, for instance, wear-off, those types of things.

MR. PREVOZNIK: Okay, thank you.

MR. STRAIT: Commenter No. 2. Thank you.

DR. MARTIN: Good afternoon. Thank you very much.

My name is Stephen Martin. S-T-E-P-H-E-N. Last name Martin, M-A-R-T-I-N. I'm with Boulder Care, and I will also spell that because it is B-O-U-L-D-E-R Care.

Thank you so much for this opportunity to share comments on behalf of Boulder Care.

We are a joint commission accredited telehealth organization caring for people with opioid and alcohol use disorders since 2017. I have served as Boulder's Medical Director for research, education and quality since early 2019.

After attending medical school at Harvard and residency training at Boston University I became a family physician and addiction medicine specialist. For nearly 20 years I have provided in-person primary care in rural Massachusetts, where I'm also a professor of family medicine and community health at

UMass Chan Medical School.

I came to DEA headquarters today knowing of your memorial and photographs for some of the people who have been lost to opioids, especially Fentanyl. In my rural office above my desk I have my own photos of health center patients we have lost to overdose as well. I still care for their grieving families.

I begin my comments sharing this mutual respect for those we have lost with you and recognizing we are here together to find the best way forward to help everyone in need.

Almost 20 years ago in 2004 I was in my residency training at South Boston Community Health Center. An internist faculty member had just begun prescribing Buprenorphine which was recently approved and his panel maximum was 30 patients. When that number went to 29, people in the community knew about it before we did. People were desperate for this lifesaving medicine. Desperate. And we were essentially running a lottery for people to survive addiction to Oxycontin.

Twenty years later we now have a lottery for people to survive addiction to Fentanyl. A major reason is that American primary care cannot take on the complexity of this type of care at the scale that

is needed. The numbers speak for themselves. People can't even establish primary care let alone access just in time expertise to care for this life threatening condition.

Even with the X waiver eliminated, researchers and practitioners both acknowledge this is unlikely to change the basic calculus of available treatment.

If people can't access Buprenorphine through primary care, what are their choices? The outcomes for Naltrexone continue to be disappointing to the point that people have voted with their feet. It is used less than one percent of the time compared with the other two FDA approved medications.

Access to Methadone in the U.S. is the most tightly controlled in the developed world and has its own well described and entrenched obstacles that are doing harm. Unfortunately, they aren't likely to change in the near term.

If Methadone is not increasing in availability and Naltrexone isn't useful, we are left with Buprenorphine.

As a matter of policy, if this medication isn't readily accessed in primary care, where can it come from? A relatively small number of the estimated

7.5 million Americans with opioid use disorder end up at the emergency department where even when they are seen for an overdose they are prescribed Buprenorphine less than ten percent of the time.

Twenty years after the scarcity of treatment I saw in South Boston, the scarcity continues.

But we're here together because there is a proven solution of telehealth. Let me tell you a bit about Boulder care.

Since the suspension of an in-person visit in March of 2020, our clinical team has conducted over 50,000 visits on secure video and engaged in 600,000 secure telecommunication touch points with several thousand patients. Almost 90 percent of our patients have Medicaid coverage -- the most underserved population in substance use disorders and who have the greatest needs.

Over 30 percent of our patients live in HRSA designated rural areas and the vast majority lack transportation.

Despite the challenges of being in remote areas, our rural patients have parity in outcomes compared with those who are located in suburban and urban locations as has also been found by other telehealth providers.

Sixty-four percent of our patients who responded to a March survey said they have significant barriers to in-person care, lacking access to transportation, a nearby health care facility that can treat substance use, or a primary care provider, or a combination of all three.

Hundreds of patients reported that they fear losing their privacy and anonymity if forced to seek services locally, particularly those residing in small towns. There is shame and humiliation associated with in-person addiction treatment and there are related risks of losing employment, child custody and social standing.

Boulder care is relentless about using data to improve our work, publish research, and share insights freely with others who may benefit. We are held accountable for quality care by dozens of health insurers who reimburse based on outcome metrics.

Between 2021 and 2023 through grant funding by the National Institute on Drug Abuse we conducted a prospective cohort study with our research partner Oregon Health and Science University, reporting our findings this past June.

We found that telehealth only clinics, glocoms (phonetic) were the same or better than

treatment as usual. The study found Boulder Care's six month retention to be approximately 90 percent -- three times the national average for office-based opioid treatment.

Another analysis of our clinical outcomes found that patients who stay in care with us for three months have a 50 percent chance of staying with us for more than two years.

Our data is consistent with a body of peer-reviewed research including recent reports from the CDC and NIH that indicate telehealth only Buprenorphine care is safe, effective, valuable to society in the midst of a worsening national opioid crisis.

This research also finds that an in-person evaluation is not representative or a proxy for quality health care.

I can understand the inclination to associate in-person with increased quality of care, but having been in health care for over a quarter century there is a lot of terrible in-person care and a lot of excellent care at a distance.

Having two warm bodies in the same room has nothing to do with safer quality care. Everything one would want from a public policy perspective --

improved equity, health, quality of life and help for vulnerable populations -- is being done with telehealth only care.

As practitioners with decades of clinical experience treating patients and prescribing controlled substances in-person and through telehealth, we'd appreciate sharing some recommendations about policies that will impact our ability to provide Buprenorphine treatment for adults.

We echo prior comments about minimizing burden place on patients and have ample evidence that a mandatory in-person visit of any type presents a significant barrier many patients will not overcome.

We concur with sentiments that regulating a clinical entity is preferable to adding requirements for patients.

We caution against adding new forms of patient surveillance not supported by medical evidence or deemed necessary by the treating provider, having seen these protocols deter patients and providers for decades. Examples include prescription dosing limits, short term prescriptions and frequent drug tests.

We ask that the DEA consider the extensive local, state and federal oversight already in place to regulate practice standards for practitioners.

Practitioners are already required to report copious information to licensing boards, state authorities, insurers and accreditation bodies in order to practice. The DEA can make use of existing data sources for clear quality indicators and warning signs to identify and root out the potentially few bad actors.

A special registration, if enacted, should not create unnecessary administrative burdens on telehealth providers with multi-state practices and avoid exacerbating existing challenges to providers. As stated by previous commenters, providers should not be required to maintain physical addresses or locations in multiple states.

Lastly, telehealth prescriptions should not be labeled or red-flagged. Pharmacies, particularly certain large chains, have discriminated against and refused to fill valid prescriptions from telehealth clinicians as described during a SAMSA two-day meeting last year. Any requirement to label a prescriptions as telehealth will further stigmatize and restrict patient access to medication.

Pharmacist colleagues from around the country are allies in supporting telehealth based care and do not see a need for such labeling.

Earlier this year we received hundreds of comments from our patients about the hardships an in-person visit would present for them or future patients. With their permission, I appreciate bringing in their patient voice to this listening session.

Patient one. To get the medication I need to live a better life, my 75 year old mom was actually driving me and another disabled individual almost every week to our Last Mat program. Not only would it be traumatic to see a new doctor I'm not familiar with as a war veteran with PTSD and dual diagnoses, it would disrupt the continuity of treatment.

Patient two. The care I am getting at Boulder is available 24-7. I've utilized their on-call doctor in the middle of the night and to reach my peer support all week. My peer calls back within an hour. My doctor answers my messages within seconds. They have helped me live a safer, better life helping others and living up to my potential. We should be trying to ease patients' fears and trepidation about getting clean and sober, not making it more difficult.

Patient three. I've been with Boulder going on two years. Suboxone care through telehealth has saved my life. My doctor's amazing. Although it is

through telemedicine we have a personal relationship and I have an attachment to her, a real connection. She has supported me more than just through addiction and my eight month old baby has her mom back.

Making quality treatment accessible ensures that the right thing to do is also the easiest thing to do. The alternative, purchasing Fentanyl on the street for $3 by sending one text message should scare and inform us. We can prevent diversion and overdose by giving people an immediate link to treatment as soon as they are ready. Telehealth uniquely makes this possible.

Lastly, very few health care interventions actually scale, maintain quality and improve equity. Telehealth for opioid use disorder does each of these. It Is truly a medical miracle and it is the only demonstrated solution that can help this administration meet its goal of dramatically expanding quality care for opioid use disorder.

We ask that you please ensure conscientious telehealth providers can continue to readily offer and expand this lifesaving care as they have for the past three years.

Thank you for your time and consideration.

MS. MILGRAM: If I could, just a couple of

questions.

DR. MARTIN: Please. Thank you.

MS. MILGRAM: Thank you so much. To clarify, and I was taking notes --

DR. MARTIN: Oh, certainly.

MS. MILGRAM: -- but I might have missed this. So you were talking about the expans -- the removal of the X waiver --

DR. MARTIN: Yes.

MS. MILGRAM: -- and the expansion of the number of providers --

DR. MARTIN: Yes.

MS. MILGRAM: -- for Buprenorphine but I believe you were saying that American primary care can't take on Buprenorphine.

DR. MARTIN: Yes.

MS. MILGRAM: I would love to have you expand on that a little bit.

DR. MARTIN: Oh, I have a textbook I'm writing -- I'm very dedicated to primary care. I think it is probably the best source of care for this kind of work.

In Massachusetts right now if you're in Boston you can't get primary care for six months, and that primary care is not likely to know what to do

with opioid use disorder.

In other settings over the country, those data are worse. If you have MEDICAID, worse. If you have no insurance, worse. Again, fewer than 5 percent of primary care providers have an X waiver showing interest prior to the removal of the waiver.

The complexity -- this is not hypertension. It really is very different. People are living with a life threatening illness and we have a dedicated phone number for people on Suboxone so they can get right to a knowledgeable nurse that hour, that day, that minute.

Primary care, unfortunately, isn't built to do that these days, and I wish it were. I hope to see it do it some day, but we don't have time.

I hope that helps.

MS. MILGRAM: Thank you. It's very helpful. The guardrails, you talked --

DR. MARTIN: Yes --

MS. MILGRAM: -- a little bit about --

DR. MARTIN: Please --

MS. MILGRAM: -- available data --

DR. MARTIN: Yeah.

MS. MILGRAM: -- but it would be helpful to have you talk a little bit about what guardrails you

think should exist around telehealth providers.

DR. MARTIN: Oh, certainly.

I've been through the generation that came to the prescription monitoring programs and the data that are available there are quite robust. People can tell what Steve Martin is prescribing in any given month to any given set of people in any given location. That's a lot of information to work with.

I do think the tracking mechanisms that are available currently can let DEA evaluate not only number of prescriptions but also types of prescriptions and forms Buprenorphine that are prescribed.

There are certainly cases where a monoproduct of Buprenorphine is in somebody's interest. But I do understand the policy concern about that becoming a majority of prescriptions for any given provider.

MS. MILGRAM: So we had this conversation yesterday. DEA does not have access --

DR. MARTIN: I apologize.

MS. MILGRAM: -- to the PDMP. So I think the way to ask you to expand is, would you --

DR. MARTIN: I would. Yes. I would think that a national PMP makes more sense, and I heard that

comment yesterday, I believe. The fragmented approach right now is very difficult. If I have someone in Vermont I have to press a separate box. If I have someone -- and I don't know there what they're counting. Massachusetts looks like Gabapentin, but others don't.

Again, I think because the relative downside is relatively low but the upside is that DEA would essentially have a passive collection of information that wouldn't require another degree of surveillance. Thank you.

MR. PREVOZNIK: Could you expand on your perspective of audio only and two-way?

DR. MARTIN: Yes, yes. Audio only, yes. Boulder, my company, does not do audio only. For good reason, I think. We're in a new terrain, we're not really sure how this will be evaluated. But I have been advocating in Massachusetts on behalf of patients for what we have in Massachusetts which is now law to compel the use of audio only payments. The reason is very clear. Mass General came out with a study very early on in the pandemic showing that the people who are excluded from telehealth care are predictably brown and older people, if video is required.

There is no data to show that video is any

more helpful in any part of medicine other than neurologic conditions such as Parkinsonism.

The barrier to entry with video is so difficult and highly technical people can't get me on video and vice versa, no matter how hard we try. And it seems to me -- I'm hesitant. It's almost a fetish, this idea that video adds value. It doesn't. It often detracts, unfortunately, and it detracts for people who can least afford to lose care.

I hope that helps.

MR. PREVOZNIK: It does.

How do you evaluate that patient, because clearly this is a very difficult, OUD's a very difficult thing to assess. So how do you assess that on the audio-only call?

DR. MARTIN: Certainly, certainly.

In my experience, patients present to me the kind of patient that they think I'm looking for, and I try to dispel that as quickly as possible because I want to know who they are as a person.

I don't think that's any different with video. I don't think that's any different in person and not with audio.

If someone called me and said that they had a Fentanyl disorder and they needed help, I would take

that at face value.

If someone wanted all the constraints and difficulties of getting Buprenorphine and taking it, there are far easier things that they could do in their lives.

But I think I've been finding that these diagnoses are less difficult to make when someone calls and said I overdosed and was in the ER yesterday. Can I get some help? Hearing that over the phone would work just as well.

MR. PREVOZNIK: Thank you. Thank you very much.

MR. STRAIT: Okay. Commenter No. 3.

DR. RAMTEKKAR: Good afternoon. My name is Ujjwal Ramtekkar, spelled as U-J-J-W-A-L, last name R-A-M-T-E-K-K-A-R. I'm a double-Board Certified Psychiatrist. Administrator Milgram and Assistant Administrator Prevoznik, I really thank you for holding these listening sessions, but as a psychiatrist, I would also say thank you for very thoughtful commenting and very reflective clarifying questions. It just shows your attention, your interest, and your enthusiasm in doing the right thing, so we appreciate that.

I stand before you today as my role as the

Vice President and Executive Medical Director for Quartet Health and Intertel Telepsychiatry. We are a URAC accredited behavioral health company committed to expanding access to high-quality mental health and substance use treatment for marginalized under-served populations across rural, urban, and frontier communities.

We have been operating for almost a decade now, treating hundreds and thousands of patients across 31 states and Washington, D.C., across several settings, whether it's health systems, federally qualified health centers, community mental health centers, and more recently, in their homes, as well.

For almost a decade we have delivered this very vital mental health service to people struggling with all acuities, including serious mental illness and substance use disorders as well. I'm also the Adjunct Clinical Professor of Psychiatry at University of Missouri - Columbia, and a consultant and faculty for several programs across the country that are geared towards building capacity in providing mental health access through primary care, as well, ranging from statewide programs like Missouri Child Psychiatry Access Projects, to learning collaboratives nationally like Project Echo for primary care and mental health.

It has been a great privilege, honestly, to look at the evolution in the one-and-a-half decade or so that I've been involved with telemedicine, particularly telemental health, and as being a part of American Academy of Child and Adolescent Psychiatry and American Psychiatric Association on their telepsychiatry committee, on the quality committee, developing some of the standards of care as to how to deliver high-quality and safe telemental health and telepsychiatry for more than a decade.

We have enough data that it definitely increases access, reduces no-shows, improves overall outcomes and quality of care as well, when it's done appropriately within the standards of care, which are, really, already established for more than a decade there, as well.

I would like to share the Quartet Health's recommendations today in front of you for the special registration of prescribing controlled substances for the reasons of mental health treatment and substance use disorders.

And let me also make a note that this has been the collective voice and expertise, with three other national large telebehavioral health companies: Array Behavioral Health, Iris Telepsychiatry, and

Talkiatry as well. In addition, we have been very fortunate for getting input, expert guidance from a lot of professional organizations like APA, ACAP that represent thousands of clinicians across the country, as well.

So, I thank you again for this listening session because it's not just about prescribing via telemedicine; it's also about equity. About 50-to-70 percent of patients across the country do not have access to physical psychiatrists or a child psychiatrist.

I remember the days where I dreaded getting sick because if I would be out-of-commission for a day, I had nowhere to place those young patients, for about nine months, when kids with autism who have to drive with their parents four hours, in the heat, while they're trying to save the gas money and therefore cannot put the air conditioner on, they're miserable when they cannot afford to find some accommodation or food for a 30-minute visit for a psychiatrist.

That's miserable. And that is never a reflection of what is the true state of the child or that adult is, from a mental health perspective. It really makes more sense to see them, evaluate them,

and partner with them in what makes sense for effective and safe treatment in their own equal systems.

There are so many stories that we have heard around thousands of patients who would have not had any care at all if not for telemedicine. In the last two-and-a-half years, there are so many stories that we heard that they had a diagnosis, they had a treatment, that they had to discontinue.

And the only reason they were seeing me or my colleagues is because there was an option of telemedicine, which they were connecting through their local library's Wifi, with their permission, because they could not even afford that.

We have had several stories of patients in frontier and underserved areas where their wait time was three-to-six months and only because of telemedicine it came down to two-to-three weeks. It really is an issue of equity, access, and public health.

Unfortunately, last year we logged some of the highest numbers of suicides -- about 50,000 -- and someone told me it's about 3500 large plane crashes is what it is. In one year. That's dark. Something is wrong, and we are really in a mental health crisis.

If we have blanket restrictions that also affect mental health access, then that will be really a problem for the society and for this country. So, at the same time, we really understand and share the DEA's concern about potential diversion, and that's why we are going to put some of these recommendations for effective and safe prescribing of controlled substances Schedule II-V via telemedicine.

And this will be for legitimate, appropriate prescriptions through telemedicine, without any in-person care, when it's appropriate. Telehealth, in our general framework, is not inferior than in-person care. Telehealth is not necessarily just a modality; it's a setting in which we deliver care.

And sometimes that setting is not appropriate, and that is totally up to the clinician and patient's judgment about that setting being right or not and referral to any in-person care needed -- just as we do not force somebody who needs inpatient treatment to be treated in an outpatient setting.

There is no clinician who would say you need in-person care or higher level of care but we still are going to treat you with telemedicine. That just does not happen. That is not the standard of care.

So, as the general framework, we would

recommend that DEA implement a special registration for telemedicine, for the short-term, until the agency is satisfied with the longitudinal data of safety and impact on potential diversion of these medications.

And we hope it will go away in a few years like the ex-members did. It will be a new registration that would allow a provider to prescribe controlled substances via telemedicine in absence of in-person evaluation of referral, and this would be separate than the existing general statewide DEA registration.

However, we recommend that the agency allows the clinicians to have one, single national special registration so that the clinicians are not required to have registration in each state as long as they have one statewide regular DEA registration, or they don't need to have any physical location to store and dispense the medications either, because all of this is happening through telemedicine.

Well, in response to the agency's questions for guardrails, we definitely do have some specific recommendations for the safeguards. And again, these are based on already-established clinical standards that we do, no matter whether we are delivering care in telemedicine or in-person.

We would schedule the prescribing through the special registration without in-person care in telemedicine to Schedule II and non-narcotics III, IV, and V. We may require providers to evaluate their patients at least once every 90 days, but should be, again, left to the clinician's discretion around the stability and the safety of the patient. It could be more.

But generally for a controlled substance treatment, we could suggest a 90-day restriction, for timing. We can require the providers the capability to furnish a fully HIPAA-compliant audio-video synchronous visits, as well.

Now, this would be really important, probably, in our mental health treatments for the initial visits, but it certainly is a burden for a lot of people who may not have access to technology or the other means to make that happen, so follow-up cares, again, could be with audio.

But again, it should be at the discretion of the clinician who wants to assess more or want to look for some other signs that requires video, that probably should be left to the discretion of clinician for any follow-up visits. The initial visit, although, could be required for audio and video.

We should be prohibiting from requiring, recommending, or referring to a specific pharmacy or pharmacy chain unless it comes up from the patient, because there may be only one pharmacy in their town and that's their option, so that's reasonable.

We would like to suggest excluding ketamine from the list of medications that can be prescribed under special registration because, again, per standard of care, it requires about four hours of in-person observation with the physician on-site.

We should be authorizing prescribing medications, but not necessarily storage or dispensing of the medications as well, as a part of this safeguard. And then, limiting the prescribing of Schedule II and non-narcotic medications like stimulants for the treatment of mental health conditions by a physician.

That includes primary care providers because now it has become a competency, through their training and their professional organizations, to appropriately train them in that; or with advanced-practice nurse practitioners or physician assistants who have a certified qualification in psychiatry as well.

We know that a lot of prescribing happens outside of these specialties, and that's purely a

reflection on access, demand, and supply, and that's really a much-needed thing. But if you were to do it safely, we would recommend that anybody who does not have these certifications as an APRN or RPA, we recommend a one-time eight-hour training requirement by an approved State Medical Board on prescribing controlled substances, not necessarily about particular condition.

We obviously cannot manage what we cannot measure, so in response to the DEA's request for additional safeguards, we could propose placing a limit on the number of prescriptions per provider per month.

Again, this would be totally based on what would be the average full-time provider who sees patients in an ambulatory setting with a mix of emergency room consultations and, occasionally, probably covering for their physician colleagues who work in the same practice, as a bridge prescription.

And, we could also suggest potential data reporting, but with the caveat that the resource-constrained not-for-profit organizations and the providers practicing there be exempt from that, as well.

So, from the number perspective, it would

suggest possibly 500 controlled substance prescriptions per provider per month, but its specific circumstances if the provider exceeds that because it is truly their specialty or it's really the specialty population they're treating, that we provide them with an opportunity to write a statement of justification for exceeding that one, rather than automatically red-flagging it, because that might provide us some insights into some legitimate reasons as to why that happened.

Second, we suggest the providers to maintain data, and if required, provide the data in non-PHI format, and that would include things like DEA registration number of the healthcare entity, the name of the medication, the, possibly, NDC number of the medication, the number of prescriptions written, and the date of the prescription.

Now, I would also mention here that these are the data elements that could be automated and appropriately stored in the electronic medical records without any specific intervention from the provider, because it's already a huge administrative burden for the providers, who often -- myself included -- do not get time to eat lunch. We are doing charting or often working in the evenings, just to complete the charts.

On top of that, if you are given this administrative burden, it would be difficult, for sure, and it might inadvertently reduce access because then providers don't want to engage in that, at all.

However, we definitely recognize the need for measurement and data, as some of the previous speakers have already said, and I would echo, that the only prescription that is at-risk of diversion is the prescription that is filled.

And so, the real source of truth for that kind of information is the pharmacy data. We also have PDMPs, but we understand that either DEA does not have access to that data, or there's a variability between states about how that is managed and run and there's not really a national system. So this would be a wonderful opportunity for DEA to lobby for creating a national database similar to PDMP to support and access any of those data, as well.

We have over two decades of evidence that high-quality mental health services can be safely delivered through telemedicine in-accordance to the standard of care. And so, imposing an in-person requirement for patients seeking these mental health treatments will certainly impede access to psychiatric care and worsen the crisis.

On behalf of Quartet Health and our partners, I want to thank you for your consideration for our recommendations for the special registration and what we believe to be a good, collaborative path forward that will allow DEA to maintain some important controls on diversion, but will also ensure that practitioners can continue to furnish a very high-quality and safe mental health to the patients when they need it, how they need it, and where they need it. Thank you.

MS. MILGRAM: Can I ask a few follow-up questions? Thank you so much. I just didn't hear this clearly; you said DEA could lobby for the creation of a national database like -- and then you had a bunch of initials. I apologize. I missed that.

DR. RAMTEKKAR: Oh, like the state PDMP programs. Correct.

MS. MILGRAM: PDMP --

DR. RAMTEKKAR: Correct.

MS. MILGRAM: -- okay. When you talked about a potential guardrail of requiring an evaluation of a patient every 90 days, I assumed you were talking virtually?

DR. RAMTEKKAR: Correct. Correct.

MS. MILGRAM: Okay, thank you. Just wanted

to make sure. Thank you. And could you just expand a little bit on ketamine and why you think that should be excluded? And also, are there other things like ketamine that you would have similar concerns over?

DR. RAMTEKKAR: Correct. So, the rationale for that statement is that it's still a newer treatment, it is a very effective treatment, but we still are looking for more and more safety data, and currently there's a requirement of observation, in-person, with a physician on-site.

If the physician is on-site, then there's probably no reason to prescribe it virtually, either, because we are really observing them. And so there could be other potential newer treatments that are still not fully tested in masses and has not really become a standard of care that could include some of the psychedelics, for example, as well.

I'm not saying that -- it may not change. That's the good thing about science and evidence of space that it changes, and as it evolves, we evolve our standards of care and safety protocols as well.

MR. STRAIT: Thank you so much. And I see Commenter No. 4 coming to the stage, now. I'm going to take a five-minute break at the conclusion of her remarks, just for us to stretch legs, and get out and

use the facilities, if anyone needs to do so.

So, I welcome Commenter No. 4 to the stage.

MS. NATOLI: My name is Christa Natoli. C-H-R-I-S-T-A, N-A-T-O-L-I. I'm the Executive Director of CTel, the Center for Telehealth and E-Health Law. We're a 501-C3 non-profit telehealth research institute focused on policies and regulations that impact the delivery of virtual care. We are bipartisan and not beholden to any particular stakeholder.

I would like to express the deep gratitude of CTel for the opportunity to provide comments today concerning the crucial role played by the DEA in the prescribing of controlled substances via telehealth. CTEL stands alongside the DEA in its commitment to safeguarding our communities from drug abuse, diversion, while supporting policies that promote quality medical care and legitimate patient access.

As a research institute, we aim to present evidence supporting the long-term viability of the DEA flexibilities implemented during the COVID-19 public health emergency waivers. Dr. Yael Harris and her team have collaborated with CTEL as impartial third-party researchers.

In these remarks, we will present data that

reinforces the ongoing use of telehealth for prescribing life-saving treatments. It's my pleasure to introduce my co-speaker, Dr. Yael Harris, the CEO of Laurel Health Advisors. Dr. Harris has been an invaluable independent researcher for CTel, gathering and analyzing data from across the United States to evaluate the effects of telehealth.

MS. HARRIS: Thank you, Christa, thanks for this opportunity. My name is Yael Harris. That's Y-A-E-L, H-A-R-R-I-S. I am the CEO of Laurel Health Advisors, which is a health services research company focused on using data to drive health equity and access.

As a health services researcher, I have over 25 years of experience, half of that with the Federal Government Department of Health and Human Services. As a researcher, I love data, so I always look at what the evidence shows me before I endeavor into doing any new research.

So, according to the Journal of Drug and Alcohol Dependence, before the pandemic, in most instances, diversion was associated with a real need for treatment among those unable to access a provider or obtain medication.

This is a really important finding. Even

though there was illegal diversion taking place, the root cause was access, not abuse or misuse. With the implementation of the DEA's public health emergency waiver, data reported by the American Psychiatric Association provides substantial evidence that the expanded use of telehealth, despite unprecedented growth in telehealth use, did not lead to an increase in diversion.

According to data from NFLIS, the National Forensic Laboratory Information Systems, during the pandemic, there was a decrease in buprenorphine diversion. A March 2023 study in the Journal of American Medical Association of Psychiatry confirmed that the increase in telehealth provision of medications for opioid use disorder was associated with a reduced risk for fatal overdoses.

Research studies and peer-reviewed journals, including the Journal of Addiction Medicine, Journal of Substance Use and Treatment, and the Journal of the American Academy of Child and Adolescent Psychiatry have evidence that the ability to initiate and renew prescriptions for controlled substances via telehealth increased access to critical vulnerable populations, which include children and young adults struggling to focus and succeed in schools, families of whom are on

either low-income, rural, and lacking proper fusion, which would make it difficult and devastating to take a day of leave from work to get their child care.

Pain management for individuals unable to leave their home and seek treatment, and access to medications as a treatment are met for individuals living with a substance use disorder. Also, access to medically necessary Schedule IV anxiolytics for individuals living with some serious mental illness.

There's research presented by the Journal of Substance Abuse Treatment points to the fact that, in the absence of telehealth, we would have seen lower levels of compliance for substance use disorder. According to the National Council for Well-Being, many individuals experienced long wait times to get into insurance-covered programs for behavioral health, even those that live in areas where there is a psychiatrist.

Access to in-person medical care is a privilege that many Americans with socioeconomic disadvantages, or experiencing mental and physical disabilities, do not have. According to the Commonwealth Fund, as of March 2023, 160 million Americans live in areas with behavioral health professional shortages, with over 8,000 more

professionals needed to ensure an adequate supply.

CTel's research has shown that, at the state level, all states accept telehealth to establish the patient-provider relationship, and according to recent data collected by the National Council for Mental Well-Being, the national average wait time for behavioral health services is 48 days. That's nearly seven weeks.

Among those seeking treatment for substance use disorder, this wait is untenable. If you ask a substance use specialist, they will tell you that when a person that is living with a substance use disorder is ready for treatment, even a 24-hour wait may be too much.

Without the benefit of being able to promptly prescribe buprenorphine to this at-risk population, many individuals who may have benefitted from that therapy will go without. According to the South Dakota Department of Social Services, limited access to MADD is associated with a reduction in relapse and overdose, and greater access reduces the risk of criminal activity and transmission of infectious diseases.

Data from the American Academy of Pediatrics shows significant persistence shortages. Wait times

for pediatric Sub-specialists often exceed two weeks, and according to the Children's Hospital Association, families wait an average of almost 15 weeks to see a developmental behavioral pediatrician.

As a mother of children with ADHD, I know firsthand the importance of timely diagnosis and treatment. While my children were struggling in school, many pediatric psychiatrists were not taking new patients. As any parent knows, weeks can mean the difference between academic success and failure for your child, affecting their self-esteem, their confidence, and their mental health.

And I was fortunate. According to the Centers for Disease Control and Prevention, less than half of children with ADHD even receive treatment. Enabling patients to see providers virtually, as well as receive prescription medications virtually, is a critical component for improving our healthcare system.

Research published in the Journal of Substance Abuse Prevention and Policy demonstrated the impact of how increased enforcement to avoid harm associated with controlling substances has actually led to fear and unintended consequences.

These include high rates of diversion of

opioid agonists; greater fear of disciplinary action against opioid prescribers, resulting in forced tapering and under-prescribing; and providers refusing to take on patients who legitimately require opioids.

The Controlled Substances Act proposed establishing a special registration process, with the key objective of increasing access to needed medications safely. The rationale provided for this registry was to prevent illegal prescribing and potential harms associated with diversion and inappropriate use.

As I mentioned by my peers earlier today, less access is actually associated with more misuse. Let me turn it back to my colleague, Christa.

MS. NATOLI: CTel is in support of any policy change that will eliminate unnecessary administrative burden on prescribers, while improving access to quality healthcare interactions and curtailing illegal diversion activities.

These changes may include the use of existing electronic data sources, including the Prescription Drug Monitoring Programs in every state, or creating a national program.

Use of pharmacy data to track and red-flag certain prescribing activity, and enhanced use of

electronic health records to evaluate and end improper prescribing activity, as well as incentivizing legitimate prescribers to flag inappropriate conduct.

We understand DEA is seeking input on potential guardrails and safeguards. Those that already exist include medical exam requirements. It is already necessary for the standard of care be met for medical examination evaluation. High quality of care does not require proximity. Physical examination does not always happen with in-person treatment, either.

It's a standard of medical care independent of the virtual issue. This is a process independent of whether the exam is done via telehealth, in-person, or from collateral sources.

Number two: identity verification. The in-person advantages of identity verification, vitals verified in-person, drug screens, do not need to be completed by a DEA-registered provider and can be done by another team member, such as a nurse, medical assistant, therapist, or case manager, in-conjunction with a licensed medical provider -- either in a brick-and-mortar or in-home.

They can also be done via biometrics or in a facility at a point of entry where no DEA-registered

provider is in the building. And finally, number three, prohibiting prescribing based solely on a medical questionnaire.

While diversion was an issue even before the widespread use of telehealth, limiting access to prescription medications via telehealth is not going to solve the issue of diversion, but may, in fact, exacerbate it by limiting legitimate prescribing encounters while failing to root-out those diversion activities that have persisted for years.

Experience shows, any new burdens are likely to lead to great public health and safety concerns when patients aren't able to access needed medications in a timely manner. As patients and prescribers alike have gotten accustomed to the regulatory flexibilities implemented as part of the COVID-19 public health emergency waivers, our data shows that diversion activity has not necessarily increased.

Therefore, restricting these flexibilities is an unnecessary step that will impact patient care, will not preventing problems DEA has identified.

To recap, CTel supports the continuation and permanency of telehealth flexibilities made available during the public health emergency wavier, the creation of the special registration, and guardrails

to protect against inappropriate prescribing, while increasing access to life-saving care.

On behalf of CTel and the telehealth community, we appreciate your attention to these important matters. Thank you.

MR. STRAIT: Thank you, both. Okay. I see that it is now 1:38. We'll just take a five-minute leg stretch or use of the facilities. Thank you.

(Brief recess.)

MR. STRAIT: Thank you for that short break. I am now pleased to call-up Commenter No. 5 to the podium for his remarks. Thank you.

MR. WELLS: Thank you. I got it all written down here. Hello. I'm John Wells, J-O-H-N, W-E-L-L-S, and I'll forego, you know, the typical academics list of, you know, various accreditations and things like that. I'll just say, I'm an Associated Professor of Clinical Psychiatry at LSU-HSC, so Louisiana State University Health Sciences Center, in New Orleans where, at least in part, I specialize in providing integrated and mental behavioral healthcare to remote and rural federally qualified healthcare centers, which we'll call FQHCs, as well as training residents to do so.

Now, in Louisiana, we have, you know, quite

a few very rural and remote populations. I have no financial conflict of interest to report. Really, I'm primarily a clinician and a teacher.

The focus of my comments today really are to advocate, you know, irrespective of the other concerns which have been spoken about already in terms of specifics around buprenorphine prescribing, you know, things like that -- stimulants for children.

The focus of my comments today is really to advocate for special rules in regard to FQHCs and primary care clinics under that aegis -- so the look-alikes as well. These clinics provide longitudinal and, often, really intergenerational patient care.

And I've been really fortunate to be able to immerse myself into some very well-functioning FQHCs and see maybe, you know, a vision of what things could be, or maybe it's only nostalgia for what things used to be and things are really moving in a different direction.

Clinicians in these settings, they really know their patients very well. They know their patients' families and neighbors. They know their livelihoods and, you know, these clinicians really share the unique economic and geographical challenges

of those patient populations in these FQs.

Our patients generally like to attend clinic in-person. It's not always universally the case, but, you know, at times in their lives, they experience limitations on their ability to do so, hence, you know, telemedicine has been such a valuable, sort of, additive tool in general.

For a variety of reasons, these remote and rural communities have been profoundly affected by, you know, Schedule II-V controlled substance diversion overprescribing and mis-prescribing, and in particular, benzodiazepines and stimulants are particular areas of concern, you know, for our teams, which is why I'm a little bit hesitant, you know, to see things opened-up too much.

And so in that sense, perhaps this is a bit of a cautionary note. One of the most difficult tasks that we, you know, are faced with embedded in these really rural and remote communities is what I call "de-prescribing" -- and certainly I'm not the one who coined that notion -- but especially when our patients have been able to access remote providers who are not invested in their community, you know, we are kind of left to mop-up the mess that's caused.

And this is not unique to telemedicine; it

certainly existed before telemedicine. People would drive to Texas and, you know, go get medications in places where they knew they could access them. But telemedicine prescribing of controlled substances certainly made it a lot easier.

You know, so, benzodiazepines, opiate narcotics, right, stimulants and now cannabis, where these patients are really getting the prescriptions remote, geographically and culturally, from, you know, the place where really their primary care is housed and where they live.

I know as a country we're facing a crisis in primary care and we struggle to really incentivize clinicians to work in these areas. That's one of the reasons why I bring the residents out with me, you know, to try to get them interested.

On the other hand, many of the providers who end up, you know, physically practicing in these places came from these places and really have a vested interest in maintaining the strength of those and health of those communities that they're from.

They know these populations better than anyone else can, and really share in, you know, the joys and losses and pains of these communities that they serve. So, there certainly is a problem

recruiting people, but when it works, it does work well.

So, during the pandemic, telemedicine exploded, as we all know, for a variety of reasons. Telemedicine had, before the pandemic -- and still retains -- a critical role, really, as a tool, you know, for the provision of primary care in these communities.

But the community providers in these FQs certainly expressed to me that they are worried about, kind of, a free-for-all of remote providers. It takes away their business, you know, makes their clinic less resilient, and then like I'd say, then we are often left with, you know, mopping-up prescribing that has not been so clean when provided by providers who are not embedded in these communities.

Our patients, you know -- just to paint a little bit of a closer picture to home of where I work, you know -- they're fishers, they're off-shore operators, boat operators, you know, they really don't often have access to the same sorts of time scales that we've talked about.

You know, like, a month is a very arbitrary thing for somebody who works offshore for weeks at a time or has to travel, you know, many, many miles to

find work and may be there for several months or, you know, who has to fish every hour of every day, you know, during, say, the shrimping season.

And so, you know, for that reason, telehealth has really been, as I'd said, a critical tool to help these primary care clinics maintain, you know, their ability to really treat their patients in the best possible way. You know, these clinics are really trusted.

And so, you know, I do think that providing mechanisms for scheduled substances, you know, to be prescribed by telemedicine should be expanded and, essentially, made frictionless in a lot of ways.

I also do think that, you know, there are some problems with it being opened-up, sort of, willy-nilly. And that's why I like, you know, I like the idea, at least in my own mind, of utilizing, you know, systems that are already in-place like the FQHC system to help ensure that, you know, diversion, misprescribing, safe prescribing, are able to be, you know, to be monitored.

So, you know, in this context, I guess I put together some specific recommendations. I think that many of the people who came before me, you know, have, sort of, more sophisticated ideas and better

understandings of what, you know, the national sort of the push is for national providers and large-scale providers.

We've talked a lot about the PMP. There are problems with the PMP, and I'm in complete agreement with everyone else who's spoken about that as a resource, really one that should be, you know, expanded to be a national database.

You know, we often find problems with reporting from pharmacies and things like that, and presumably -- and also, you know, different types of medications which are not listed in certain states. So those things have all been mentioned.

In the FQHC setting, you know, in particular, I mean, we like in-person visits, and we really, you know, like to know our patients. And so, you know, it wouldn't be remiss, from my perspective, you know, to have some controls around whether or not people should be seen in-person, at least at some point early in their course of, you know, being prescribed a controlled substance, whether that's before they are seen in-person or whether maybe it's shortly after they're seen in-person.

But, you know, I guess what I would mostly push for is, I think that, as people have pointed out

before me, there are very few bad actors when we're talking about primary care doctors and, you know, community psychiatrists, and so really allowing a lot of discretion in terms of what's the interval at which a patient needs to be seen in-person, you know, should be allowed and should be just documented within the clinical reasoning, which presumably physicians are already, you know, doing.

And that would include also, you know, the in-clinic toxicology testing and screening, again, you know, at the prescriber's discretion, because in this FQHC context, right, we really are concerned about, you know, sort of, a panel of patients who live nearby us.

And then, you know, finally, I guess, as I've alluded to earlier, the restrictions on, you know, the length of time, you know, 30-day supply, that sort of thing, can be very onerous, especially, you know, in addition, in my patient population, we have a lot of people worried about hurricanes and things where at a moment's notice they might be required to evacuate immediately.

And so, a 30-day, you know, supply of controlled substances, the inability to reach your doctor or to have them be able to send, you know, a

stimulant across state lines sometimes can be very problematic.

So I understand I'm not, you know, giving really clear guidelines; I just wanted to point-out some issues that I thought maybe hadn't been brought up. Thank you for the time.

MS. MILGRAM: Can I ask? Trying to articulate this in your words, a little bit; you talked about tox screens, how often patients should be seen, whether there should be a time limit, and I would just ask you to expand a little bit on a, sort of, I think, related question, which is: when we start talking about deference to physicians and prescribers, when we start talking about standards of care when it comes to prescribing some of the medicines you talked about, should there be specific standards of care related to telehealth prescribing?

I may not be articulating this well. If you have someone coming into your office, you're doing a tox screen on a certain basis. If someone's virtual, would you have that be the same timing, or different? You know, would that change how you would see the standard of care if it's a video relationship?

MR. WELLS: Thank you for asking that. I think that, you know, my perspective -- at least the

one, you know, that I'm illustrating today -- is somewhat different because I'm not, sort of, advocating for a national, you know, group that would provide it really across state lines, but really, the health of community clinics.

And so, to answer your question, you know, all of the primary care doctors that I work with -- all of the psychiatrists and other people that we have embedded in these clinics -- they know their patients. And so, really, telehealth, for us, whether it's telephonic, whether it's with video, whether it's in-person, it's the continuity of care across, usually, multiple generations.

And so, you know, that's a little bit of an artificial question because it's no different to me if I've seen a patient for the past 20 years and I have to talk to them on the phone and they're going to be gone, right? I mean, I feel comfortable.

But if they go to somebody who they just contact at 12 o'clock at night because they feel anxious and that person is three-states-over, I think that's a different situation. So I'm really advocating for this community health clinic.

MR. PREVOZNIK: Actually, that's the last point that you just made is what I'd like to ask you

to expand on. How do you see dealing with that issue of, you know, the patient three-states-away getting it and now you have to mop it up, as you called it.

Like, I mean, I'm sure you've had these discussions, and so I'm just trying to pick your brain on what those discussions were on.

MR. WELLS: Yeah, I mean, you know, it's a larger problem than I can certainly -- I mean, I deal with it at a granular level so, you know, that's why I really hesitate to advocate for just, sort of, an opening-up of prescribing, you know, for -- and in my world really, it's less, I'm not talking about, you know, treatment for substance use disorders so much as benzodiazepine and stimulant prescribing, okay, which are hugely problematic in these remote and rural settings.

And so, you know, I spend a lot of time really saying to people, "You don't need to be on," you know, "six milligrams of Xanax a day that that other good doctor gave you," right? Of course, you're seeing me, not that good doctor anymore, for whatever reason -- whether they've been, you know -- I mean, there's a whole myriad of reasons why they would not longer be seeing them.

So, I don't know if that quite answers your

question, but that's sort of the concern on-the-ground in community clinics, I think.

MR. STRAIT: Okay. We'll now invite Commenter No. 6.

DR. HINCAPIE-CASTILLO: Okay. Good afternoon. I am Dr. Juan Hincapie-Castillo, spelled J-U-A-N, last name H-I-N-C-A-P-I-E - C-A-S-T-I-L-L-O. I am an Assistant Professor of Epidemiology. I'm here representing the National Pain Advocacy Center, or NPAC. As a researcher, I am at the intersection of pharmacoepidemiology and injury prevention.

I leverage real-world data to evaluate and promote evidence-based policymaking, and my primary focus is on improving prescribing policies and the provision of equitable pain management.

Like I mentioned, I'm here today on behalf of the National Pain Advocacy Center, or NPAC, where I currently serve as President of the Board of Directors. NPAC is a non-profit organization that takes no industry funding and advocates for the health and human rights of people living with pain.

This means that I'm here today representing the 50 million Americans who live with chronic pain, the 17-to-20 million Americans with persistent pain so severe that it regularly prevents them from

participating in life activities and work, and millions more with acute or episodic pain.

Chronic pain is the chief cause of long-term disability in the United States, and pain frequently accompanies other disabling conditions. The explosion of telemedicine and the shutdowns related to the COVID-19 pandemic and the related PHE proved transformative for countless patients with pain and disability who were otherwise unable to access care.

For these vulnerable patients, telemedicine extended a needed breach to critical care, one that the DEA must not now resign. Regarding the prescribing of Schedule II substances for pain, NPAC is chiefly concerned with the continuity of care for patients with long-term pain who currently take opioids. Today, these patients face substantial barriers to care that pose an imminent risk to their health and lives.

As public health agencies from the CDC to the FDA have acknowledged, many such barriers stem from government actions like those the DEA considers today. Two studies by Laqyzetti (phonetic) colleagues published in the Journals of Jaman Edward Copeland (phonetic) in 2019 and Pain in 2021, for example, found that upwards of 40 percent of primary care

doctors will refuse to treat a new patient who uses opioids to manage pain.

An NBC news piece recently highlighted the plight of a patient who called 150 different providers, desperately trying to arrange care. Disruptions in care are deadly. Many studies show that opioid disruption places patients at increased risk, including a three-to-five-fold increase risk of overdose and suicide.

Studied by Plants and Jaman Edward Copeland in 2019, James in the Journal of General Internal Medicine in 2019, Ed Levi (phonetic) in 2020, Ognoli (phonetic) in JAMA 2021, Fenton in Jaman Edward Open (phonetic) in 2022, and La Rachelle (phonetic) open both in 2022, all found a heightened risk for death, overdose, or suicide with opioid disruptions.

Even destabilization of dosage carries risks that continues for up to two years after dose is destabilized, according to the study I mentioned by Fenton and colleagues in 2022.

Opioid disruptions are associated with other risks as well, including the increased need for emergency medical care and hospitalization, according to Mark and colleagues in the Journal of Substance Abuse Treatment in 2019, and Magnum (phonetic) and

colleagues in the Jaman Edwards Copeland 2023.

This life-threatening and health-destabilizing problems affects a substantial number of people. As many as 8 million Americans use opioids to manage pain long-term -- more than three-times the number with a diagnosed use disorder.

The DEA has seen the effects of patient abandonment and opioid disruptions firsthand. When the DEA suspended a doctor's license in California, for example, three people died, two of them by suicide. Another, a wheelchair user with dystonia, was able to prevent withdrawal by using a methadone clinic, but the medication did not manage her medical condition. She suffered persistent spasticity that continuously knocked her out of her wheelchair for several months until she was able to arrange alternative care that required her to travel to another state in that condition.

The threat to life is not limited to overdose or suicide. Canermest (phonetic), for example, a quadriplegic living in Colorado who recently testified in the Colorado Legislature had a heart attack and woke up on a ventilator after an opioid disruption.

At a moment when the street supply is

especially dangerous, when the CDC is warning especially about deaths from counterfeit pills, and when overdose deaths continue to escalate, surpassing 107,000 in 2021, making policy decisions to roll-back a proven avenue for care, and one that puts people in harm's way, is reckless.

In order to protect continuity of care for this population, our suggestion in-alignment with the questions asked in the DEA framework is as follows: the DEA should allow telemedicine prescribing for continuity of care in these patients by permitting an established opioid dose from a previous in-person prescriber to be continued using telemedicine.

This approach is analogous to guess-dosing permitted by SAMSA in an opioid treatment program, or OTP, and is similarly protective of treatment continuity. This is a preferred action, and would leave in-place existing avenues for care for this population.

Alternatively, the DEA could allow 60-to-90-day initiation via telehealth by a new provider, with appropriate documentation that accords with relevant state medical board rules and procedures. The DEA should also consider allowing a 60-day initiation via telehealth, even for new

prescriptions via telemedicine for pain in situations when people cannot otherwise physically access care.

Often, a physical examination will precede a Schedule II prescribing for a new opiate prescription, but care deserts in the United States are vast, and in-person care is a poor proxy for a bona fide healthcare relationship.

According to the Health Resources and Services Administration, nearly 100 million Americans live in areas with a shortage of health professionals. Rural areas where many clinics and hospitals have shut down are especially burdened.

A 2022 systematic review on the barriers to access to pain care for other adults in rural areas, conducted by Sontay (phonetic) and colleagues and published in the American Journal of Palliative Care, for example, identified transportation-related issues as a major access barrier to pain and palliative care -- precisely the type of barrier mitigated by telemedicine.

All impediments to care and continuity of care are likely to be borne disproportionately by people with disabilities, racialized populations, and people living in rural areas or other healthcare deserts.

Disparities in pain experience biases in pain assessment, and inequities in prescribing for pain based on race, gender, gender identity, and disability are all well-documented.

In regard to prescribing for Schedules III-V, the timeframes proposed by the DEA for Schedules III-V medications are out-of-sync with the realities of the U.S. healthcare system. According to a large survey of wait times for doctor's appointments in the 15 largest metropolitan areas, conducted by AMN Healthcare, for example, found that the average wait times to arrange primary care was 26 days, with some cities reporting 45 days.

For rural areas who are especially scarce, the wait times are longer. The DEA should extend telemedicine to prescribing all controlled substances in areas where patients lack realistic access to in-person providers.

Doing so would likely require DEA to abandon existing geographic limitations, which reflect an anachronistic pre-telemedicine world. These considerations are extremely important, considering the continued increase in drug-related overdoses in the country. Patients living with opioid use disorder also need to have access to life-saving medications

that can be prescribed by telemedicine.

Now, regarding the Government's interest in protecting against diversion and the evidence of success of telemedicine prescribing amid COVID-19, importantly, the flexibilities that allowed for telehealth prescribing during the PHE do not appear to have resulted in documented harm.

A rise in prescription-related drug overdose deaths is not evident in provisional data from the National Centers for Health Statistics. On the contrary, studies that have examined the impact of telehealth prescribing during the PHE found, not surprisingly, that telemedicine prescribing reduced overdose mortality.

Notably, three major studies focused on buprenorphine prescribing via telemedicine showed, including a major study in which the lead author was Christopher Jones, the former Director of the National Center for Injury Prevention and Control at the CDC and current Director of the Center for Substance Abuse Prevention at Samsung (phonetic), telehealth prescribing reduced overdoses, providing a literal lifeline to patients who experience lapses in, and barriers to, care.

Finally, with regards to the additional

question DEA asked in its framework about appropriate guardrails, should the agency extend teleprescribing of controlled medications. The best solution is for prescription drug monitoring programs to be modified to include the mode by which the dispensed medication was prescribed to identify telemedicine prescriptions.

Nevertheless, any such modifications should be accompanied by an explicit avowal from the DEA that telemedicine prescriptions are not inherently inferior, nor suspect, to avoid their being denied by pharmacy chains -- something that we saw happening during the pandemic by major chains in buprenorphine dispensing.

A separate recordkeeping system for providers is not a good idea. It raises cost, burden, and security concerns. A duplicative system increases risk of error that may ultimately endanger patient safety. Thank you for your time and for your consideration.

MR. STRAIT: Okay. And we're calling Commenter No. 7.

DR. ULAGER: Absolutely. Hello, everyone, my name is Dr. James Ulager, J-A-M-E-S, U-L-A-G-E-R. I'm the medical director for a company called Pursuecare that provides addiction treatment

primarily, but not exclusively, by telehealth. While I'm certainly here on Pursuecare's behalf, I'm also first -- as a physician, I always think of myself as a human first, a physician second, and then my affiliation third.

As such, my mission in life is not to sit here and defend telehealth as an ideology. My very mission in life is to make sure the patients that I take care of every day don't end up on the fentanyl board that's out here because that made me really sad. It's hard to go to the bathroom here because you have to walk right by that. So that is my purpose, and telehealth is the tool.

I would have never in a million years thought when I started a career in medicine that I would be, number one, practicing addiction medicine and, number two, doing it by telehealth. I went through a bit of a conversion and I want to, in two minutes or less, give you insight into that, and really what happens when we're treating a patient with an addiction disorder with buprenorphine. That's really important.

Buprenorphine is life saving medicine. The meta analysis of half a million patients published in 2019 found people were eight times less likely to

overdose if they were in an NAT program. That could be buprenorphine, Naltrexone, or methadone, but those latter two have their own challenges. So eight times.

And compared to other chronic diseases and part of my agenda is to help people understand that the opiate use disorder is a chronic disease of the brain, as defined by the American Society of Addiction Medicine, just like asthma is a chronic disease of the lung or heart failure is a chronic disease of the heart. This is the same thing.

We do not have other pharmacologic treatments in chronic care that reduce the risk of death by eightfold. If we can get to a twofold reduction in mortality, that is hitting it out of the park. The fact that we have a medicine that can decrease overdose death by eightfold is astounding. It's astounding, and it's so amazing that it starts to become concerning to me not that we're rather than asking what safeguards we put around it -- and the safeguards are important and I'll get to that in a moment -- but how do we get this to everyone?

It's also life saving medicine because you need to know when you sit across from a patient, whether it's on telehealth or in a room -- and I've done both -- and you watch them coming in ready to

detox off fentanyl, and you watch the transformation that they undergo physiologically, emotionally, socially, in 72 hours, and I'm generalizing but you can see it, in 72 hours, their hair is combed, their teeth are brushed, they're wearing clean clothes. In four weeks from then they have a job. Three months from then they have their kids back. That is why it's life saving medicine.

I think most of us know this but this is so important to start the -- there's still this perception that people who are using buprenorphine are still getting high. Most people I've seen who get -- by the time they come to me they haven't been high in years, they're just trying to feel normal, and they can't go to work if they don't feel normal, and they can't take care of their kids if they don't feel normal.

The problem is buprenorphine is not available. In December there was a publication that 13 percent of Americans with OUD get treatment, and it's worse in rural areas. That makes it sound like we're a developing country who doesn't have the resources in place to take care of the chronic needs of its patients, and the reason it sounds that way is because that's true. We don't have the resources in

place we need to give people access to this life saving medicine.

Why is it worse in rural areas? A lot of my patients don't have cars. They can't afford cars. They live at the end of the dirt road in eastern Kentucky. If they did have a car, they couldn't drive it because they lost their driver's license. I see many patients with one pharmacy and maybe one doctor's office in their town.

And I love the FQHC, whoever it was, and my heart is very much -- I was a rural family doctor for over 10 years before I started doing this on telehealth. Again, a big change in my life. But a lot of them don't want to, or can't, go to those places because they may have burned bridges or they may be too ashamed of what they're facing.

Other reasons for access. People have to go to work. So when we're seeing somebody in the buprenorphine program, we're seeing you a lot. At first we see you weekly, sometimes even more, and then after three or six months we might go to monthly, but we're never seeing you less than monthly.

My patients tell me, like, my boss wants to know where I go every second Tuesday of the month. And, you know, having been an in office primary care

doctor in a small town for a long time, you could not get into and out of my office in less than two hours, I promise you. And I wish that were true, or different rather. I wish it were different, but it wasn't.

And so it was a half day affair for people who are trying to get their kids back, stay at work, keep a job, and then it got worse because we want to monitor patient safety, and when people aren't doing this, well, you see them more often. So then that person whose boss wants to -- I said this is a real conversation. Look, my friend, I've looked at your drug screen. I'm concerned about what's going on. I'm just going to give you a week's worth of medicine.

Doc, I can't do a week. I'm going to get fired. I'm going to get fired. And we could talk as much as we want about protecting with an ADA or protecting employment, but it still happens. So people need to go to work.

And then we just don't have providers in rural areas. So most of the care I provide is in rural areas, and our company provides are in rural areas. There are no providers. Part of the reason I left my rural community in Vermont, where I still live, by the way, that I still practice there, is, and

I would never say that Vermont has it all figured out because we don't, but I knew there was a place in the country that needed the resource more.

I'm not going to live in eastern Kentucky and West Virginia right now, but that's where the epidemic of overdoses is worst and the need is greatest. I love seeing my patients in eastern Kentucky. People have been talking about personal relationships. I have very personal relationships with my patients over telehealth. I see most of them way more often than I ever saw any of my primary care patients, and that's very important.

So telehealth is a very important part of the solution, but it needs to be safe. I have a number of nurse practitioners I work with and we talk a lot and they ask, say, Dr. Jim, how are we going to keep our patients safe? And then I say we're going to do -- all of the same things that we do in a face to face clinic we're going to do on telehealth. If you're worried about somebody, you see them more, you check the PDMP before every prescription, you check their toxicology.

We have developed some unique ways of improving toxicology and getting toxicology. I would say we haven't developed them. We're working with

people who have developed them. We're developing in corporation would be a more adequate way of saying it.

We're doing all the same things, and, in fact, some of those things are easier to perform by telehealth than they are when somebody's face to face in my clinic. You could put on a good face when you come to my clinic. When you're at home, I see what's going on at home. I've found people in domestic violence situations. I've realized that people are homeless. When they come to your clinic you don't always find out that they're homeless. When you see where they're calling you from you know they're homeless.

And that's all what contributes to what we might call an aberrant thing. You know, not all aberrancy is diversion, but it is always a cry for help, and you can see that so clearly. And my patients who are trying to keep their jobs, they log in with me on their lunch break from their car, during a 10 minute coffee break. Doc, I'd be happy to see you. We have providers who see people into the night because we don't have to staff the clinic. We have people who work second, third shift. I need to see you at 9:00. No problem. We do that.

So what about the numbers? And the numbers

are important. It's important that we not think about -- I've heard people talk about telehealth as something scary or whatnot. Let's look at the outcome. And somebody else, I think it was Dr. Martin shared -- forgive me if it was somebody else -- it was retention data. Retention is a great surrogate marker for success. Not a perfect one, but a very good one. Our 90 day retention is 85 percent, which is not quite twice the national average for brick and mortar clinics. I think there's many reasons that that's true.

And by the way, not all retention is good. We certainly look for people who, you know what, maybe this person isn't the right person for telehealth. I will also say I've stretched my notion of what is appropriate for telehealth, not because I'm devoted to telehealth, because I'm looking at the alternative. So when people are advocating for in-person care, the alternative is often not, well, do they have telehealth or in-person care, the alternative is nothing. If we can't get the medicine on the end of their dirt road where they don't have a car, their dealer will.

So my simple request is just that -- two -- is that it's recognized that, as a telehealth

provider, we're real people. If there's a mess, we need to help somebody clean up, we can be called. There's a phone number on the prescription of who prescribed your medicine. You can get a hold of us. We deeply care about our patients.

I watched, I trained in the opioid epidemic in some of the crises of the mid-2000s. I nearly left medicine because of how awful it was. Watched how my fellow colleagues, myself, and my staff were treated in a small town that was getting eaten alive by the opioid epidemic. I do not want that to happen because of buprenorphine I'm prescribing, but buprenorphine and telehealth together are part of the solution to that. And we want to be held accountable in the same way any brick and mortar clinic would be. Thank you.

MS. MILGRAM: Thank you. If I could ask just a couple follow up questions.

DR. ULAGER: Of course.

MS. MILGRAM: You talked about you are using unique ways to check the toxicology. Could you just elaborate a little bit?

DR. ULAGER: Yeah. We use an oral swab. We use saliva. I actually don't do it, it's our great staff that does it, so they could speak to that, but there's a number, and they watch the patient put it

in, they read the number, they seal it, and you could tell if they unseal it, and so it's an observed screen that then gets overnighted and gone to the lab.

What's beautiful about it is that most urine screens are not observed and this is. This is observed. It's online. Is there a way to cheat? I've watched ways to cheat every drug test I've been able to come up with, sadly, but it's pretty good. It's not bullet-proof, but it's very good.

MS. MILGRAM: Could you elaborate a little bit, whether or it's your organization or what you've seen, in terms of is your prescribing done by physicians? Is it done by nurse practitioners? Physician assistants? And there have been some commenters who've suggested potentially requiring additional training for some prescribers that aren't physicians or family docs. Just curious if you could expand.

DR. ULAGER: We're primarily a nurse practitioner practice. So, we need to normalize the prescription of this medicine. And it's totally appropriate that my colleagues who are nurse practitioners and physicians' assistants are providing this care. If we didn't have that, access would be terrible.

And we could spend a half day seminar on this: what appropriate collaboration supervision looks like is -- and that's very near and near to my heart -- a much longer answer, but I think that's where the money is.

MS. MILGRAM: Last question. You talked about just buprenorphine generally, how do we get this to everyone? You asked the question but you didn't answer it, so can I in one or two minutes ask you to offer your --

DR. ULAGER: Yeah. So I do think telehealth is part of the solution. We remove as many barriers as possible, is how we do it. The message I was intending to send is I think the burden of proof is on the people -- people. I don't want to personalize us. The burden of proof. Show me -- If we have something that's eightfold effective in mortality, show me that telehealth is dangerous. I'm being a little provocative by saying please don't show me that telehealth needs to be saved. I'm flipping the burden of proof a little bit.

And I don't entirely believe in that, by the way. It's more of a rhetorical question, because I do think we have a burden of doing no harm in everything we do. So I'm not being overly provocative. How do

we get it to people? We train more people. We normalize it. We normalize. We normalize.

One concerning statistic I've heard a few times today is a red flag that a certain clinician prescribes -- X number of percent of their prescriptions are buprenorphine. I will save you the time. It's almost all of my prescriptions because that's what I do for a living.

We would never tell an oncologist that they're prescribing too much chemotherapy. Why is all your medicine chemotherapy? Why is it all asthma, not (sic) COPD medicine? That's not a thing. Of course most of my prescriptions are going to be for buprenorphine, because that's what we do. That's my specialty. We need to normalize it, like any other chronic disease.

MR. PREVOZNIK: I would just like to get your thoughts on -- we had a presenter yesterday who was in Tennessee and he said he couldn't even think of the last time he had someone that came in just suffering from OUD because of the methamphetamine, because of benzos. Are you seeing that?

DR. ULAGER: Yes, we do. And that's a good example of some of what I think is appropriate and inappropriate for telehealth. The benzodiazepine use

disorder is very difficult to manage by telehealth because with withdrawal you have to check blood pressure, you have to check pulse.

And, by the way, in two years, if there's a way -- or there are ways to do that by telehealth now, but if they're more available and they're easy to do, I would retract that statement. Right now the way we do, so if somebody says, oh yeah, and I find that, look, there's benzodiazepines in your tox screen, I would love to take care of you on our telehealth platform, but that's not where we're going to be able to help you.

Methamphetamine is different. I wish we had better medicine for methamphetamine use disorder. We have some. They're not the best. And we need to be with people while they're on their journey with meth while we're keeping them safe on opiates. So those people we do retain in our practice. We see them a lot more often. We see them weekly instead of -- you know, they don't get to that month long thing. Thank you.

MR. STRAIT: And we now have Commenter No. 8 to the stage. Thank you very much.

DR. CRISSMAN: DA Administrator Milgram and Deputy Assistant Administrator Prevoznik, thank you

for the opportunity to testify today. My name is Dr. Halley Crissman, H-A-L-L-E-Y, C-R-I-S-S-M-A-N. I use she/her pronouns. I serve as the associate medical director and director of gender-affirming care at Planned Parenthood of Michigan, an affiliate of Planned Parenthood Federation of America.

Planned Parenthood is the leading advocate for high quality, affordable sexual and reproductive healthcare for all people in the United States. As healthcare providers, Planned Parenthood's nearly 600 affiliate health centers prescribe patients medication as medically necessary and appropriate, which includes controlled substances, like testosterone, which will be my focus today.

I am a Board-certified obstetrician-gynecologist, and I have a Master's degree in public health. In my role at Planned Parenthood I get to oversee gender-affirming hormone care for more than 2,200 patients across 13 health centers and via telemedicine. My clinical work focuses on reproductive and sexual healthcare for gender diverse people.

I've published numerous peer-reviewed journal articles related to gender diversity and gender affirming reproductive healthcare, and I've

trained more than 20 advanced practice providers in gender-affirming hormone care. I also serve as adjunct clinical assistant professor in obstetrics and gynecology at the University of Michigan where I see patients both in-person and via telemedicine for gender-affirming care.

Today I am proud to testify about the critical need for testosterone to remain available through a telemedicine prescription without an in-person evaluation requirement. Gender-affirming care refers to a range of services provided to support transgender, nonbinary, and gender diverse people. It includes care related to physical, mental, social health needs, and well-being, all affirming a patient's gender identity.

Medically necessary gender-affirming care includes mental health counseling, non-medical social transition, and, most relevant for the DEA's work, gender-affirming hormone therapy. Gender-affirming hormone therapy, as well as other forms of gender-affirming care, is the evidence-based standard of care.

Appropriate recipients of this necessary form of treatment are identified on a case by case basis with their healthcare provider. Gender-affirming

care is life saving care. It has implications that are incredible for mental health and well-being. My clinical experience has made it clear that testosterone can be safely and effectively prescribed via telemedicine and that this path is essential for patient access.

Since the DEA waived an in-person evaluation requirement, providers have developed thorough standards and protocols for attuned and high quality medical care via telemedicine. Every day via telemedicine, patients and providers expect and build full patient-provider relationships. Telemedicine has proven essential for my patients to access gender-affirming care, many of whom began treatment during the COVID pandemic because telemedicine care made it possible for them to access care.

In Michigan where I practice, telemedicine has played a crucial role in expanding access to gender-affirming care, allowing the concentration of healthcare providers in the southern portion of the state to expand their reach to the northern portion. Requiring even a single in-person visit to access testosterone could mean that many of my patients will be prevented from accessing gender-affirming therapy, a potentially catastrophic result for their health and

lives.

In the months since the declaration of the end of the public health emergency, which should be a good thing, I have fielded countless calls and messages from patients worried they won't be able to travel for an in-person visit, terrified they will lose access to the care that has been a literal lifeline.

Gender-affirming hormone care with testosterone is incredibly well-suited to telemedicine care. Testosterone is a non-narcotic Schedule III substance for which safety and diversionary concerns are notably low. Testosterone is not an addictive substance. In my years as a clinician, I have not seen a patient abuse or intentionally misuse prescribed testosterone.

I understand the DEA's interest in ensuring there is a diversionary framework in place, but an in-person evaluation is neither the only, nor the best, solution. Moreover, the DEA's diversion goals are advanced by providers reviewing recent PDMP, or prescription drug monitoring program, data.

For testosterone, blood labs are typically the only important information for safely initiating and monitoring testosterone therapy that cannot be

obtained directly during a telemedicine visit. Thankfully, healthcare providers are well-accustomed with protocols for having patients obtain labs locally and are not reliant on labs obtained concurrently with an in-person visit.

Instead of an in-person visit requirement, healthcare providers can instead order blood labs which can be obtained at a healthcare facility or commercial lab local to the patient and then transmitted to the ordering provider for review. These avenues for obtaining lab results allow healthcare providers prescribing testosterone to make their own assessment of the patient, while being equipped with information about the patient's physical state via review of pertinent lab results.

An in-person evaluation for testosterone requirement is medically unnecessary and burdens patients that would be disproportionately impacting individuals affected by systemic and institutional forms of oppression.

Planned Parenthood centers, including those I oversee, provide inclusionary care, but many members of the LGBTQ+ communities, particularly trans and nonbinary individuals, face discrimination and forms of violence when seeking healthcare, including

misgendering, invasive, unnecessary questioning, unwanted touching, and abusive language. A recent survey found that approximately half of transgender and nonbinary respondents reported having at least one of these kinds of negative experiences with a doctor or healthcare provider in the last year.

A particular vitriolic discourse now runs rampant in some state governments and local jurisdictions, compounding longstanding access issues. Gender-affirming care is healthcare. It has clear support from all major American medical professional associations, including the American Medical Association and American Pediatric Association, but numerous states have severely restricted access to gender-affirming care.

In 2022, state legislatures across the country introduced more than 100 anti-trans bills. In 2023, there's been a dramatic expansion of anti-trans legislation. Almost 500 anti-LGBTQ+ bills have been introduced in state legislatures this year. Roughly 130 of these target trans healthcare. These bills are extremely harmful. People of all gender identities deserve civil and human rights -- I shouldn't have to say that -- including the right to high quality, affordable, and non-judgmental healthcare. These bans

actively impede access to care and stigmatize those who seek it.

In this climate, telemedicine access for testosterone is essential. An in-person evaluation, or a referral for one, is, for many people, simply unattainable. A return to in-person evaluation requirements would interrupt patient care and, for some, present insurmountable barriers to accessing prescriptions for testosterone that they need, particularly for patients who are young, live in rural areas, are working to make ends meet, or live at the intersection of multiple of these.

With respect to practitioner record keeping, providers' record keeping obligations and practices are already robust. For provider privacy and personal security, and because records could be misused by hostile lawmakers to target individuals who have obtained gender-affirming hormone therapy, providers should be required to document only their city and state during a telemedicine appointment and maintain any records at the registered location of their dispensing registration.

Planned Parenthood's concern about the risk of entities hostile to gender-affirming hormone therapy misusing prescribing records to criminalize

patients and/or providers, like me, who receive and provide this medically necessary care, extends to all data keeping requirements, as well as to the DEA's consideration of a special registration.

Planned Parenthood strongly urges the DEA to exercise caution in deciding how to implement such a registration. It is imperative that it be maximally protective of patient and provider safety and privacy, and does not burden access to care.

In sum, because testosterone prescriptions made via telemedicine are safe and effective, because an in-person evaluation requirement would severely interrupt care for patients who need access to testosterone, and because there are alternatives the DEA could utilize to ensure a satisfactory diversionary framework, Planned Parenthood strongly advocates for the DEA to permit telemedicine prescription of testosterone without burdening patients with an in-person evaluation. Thank you for the opportunity to testify.

MS. MILGRAM: So a question, and I'm going to ask you a general question that a number of folks raised the same issue yesterday around provider privacy and not wanting to have the specific address. You just mentioned, I think you mentioned, city and

state. What about zip code? If you could just sort of expand a little bit about where you think that line might be, that would be helpful.

DR. CRISSMAN: I don't know if I can comment on a specific line in the sand without seeing something written, and I know we would be happy to submit written comments, but what I would say is if the DEA thinks that a national registry is necessary, or that collecting more details of location are necessary, we urge adequate protections of this highly sensitive medical information and urge cognizance, in particular in relation to gender-affirming care, of the hostility and real dangers that patients and providers may face if this information is in hostile hands, including of regulators who are anti-trans. Thanks.

MR. STRAIT: And we now have Commenter No. 9 coming to the podium.

MS. RIGSBY: Good afternoon. My name is Jessica Rigsby. That's J-E-S-S-I-C-A. Last name Rigsby, R-I-G-S-B-Y. I am the head of legal compliance at Ophelia Health. I'm a licensed attorney as well as being certified in health care compliance.

I've been in the OUD treatment space for many years. Initially with a typical brick and mortar

clinic organization and now in telemedicine. I can say from experience the additional privacy and ease of access in telemedicine helps patients get in and stay in care well beyond what is standard in-person treatment.

I'd like to start by thanking the DEA for this opportunity to speak about the special registration. I'm here today on behalf of Ophelia, our clinicians and our patients.

Ophelia provides medical treatment via telemedicine for opioid use disorder and mental health care under a team-based medication and counseling model. Our mission is to make health high quality, evidence based MOUD care safe, affordable and accessible to all.

I want to highlight that it's important to understand that we believe telemedicine is a complement to and not a total replacement for in-person care. Telemedicine adds to the treatment ecosystem improving access, outcomes, satisfaction and reducing costs.

During the last three years, Ophelia has navigated through state and federal level regulations an PHE flexibilities and at the same time proven that telemedicine MOUD care is safe and effective.

We've seen telemedicine decrease the treatment gap which is one of the main drivers of the epidemic of opioid overdose deaths. More than 80 percent of our patients had not received any type of OUD treatment before coming to us, demonstrating how clearly telemedicine creates access.

We've also spent time publishing studies to demonstrate and share what we've learned, including a study that showed high treatment retention rates, irrespective of patient geography and race or ethnicity. We've learned that 80 percent of patients stay in care for at least six months if they can use their in-network insurance benefits, but that some insurance plans are skeptical of contracting with us due to the uncertain future of telemedicine controlled substance prescribing.

I won't spend my time today reiterating all the wonderful points others have made at these sessions about how much telemedicine increases access, reaches populations otherwise unserved, et cetera, et cetera. Ophelia submitted a lengthy comment in March to the proposed rules which outlines all of that.

Instead I'm going to talk about some basic best practices for telemedicine in general, follow up with best practices specific to telemedicine MOUD,

discuss a few misconceptions about at-home urine drug screens, and also some truth about Buprenorphine.

All telemedicine prescribers regardless of the conditions that they treat should be adhering to basic best practices and regulatory requirements. This is a non-exhaustive list, but maintaining clinical licensure and of course DEA registration in good standing. Compliance with all state and federal laws including state-level controlled substance registrations and any collaborative or supervision requirements for nurse practitioners and physician assistants.

We should all be abiding by clinically appropriate policies and procedures specific to the care that we provide. And we should have established processes for assessing patients for appropriateness for telemedicine care and be prepared to refer patients to in-person care either initially or at any point during treatment when it becomes indicated clinically or becomes patient preference.

We should have protocols for detecting and managing emergencies and protecting confidentiality. Telemedicine providers should be willing to participate with major insurance plans including public and private payers. And we should all be

addressing commonly occurring medical and psychiatric comorbidities.

Clinicians prescribing Buprenorphine for OUD via telemedicine should additionally be adhering to requirements like using synchronous audiovisual clinical visits as a standard. Diversion prevention and detection protocols to include the use of all the tools available to us. Things like PDMP checks before every single prescription, real time UDS screen protocols, film or pill counts when clinically indicated, and advising patients on safe medication storage.

Clinical leadership and supervision should be done by qualified addiction medicine or psychiatry specialists and should conduct internal clinical oversight like clinical case reviews and clinical support for monitoring controlled substance prescribing.

Clinical models should include minimum standards of care such as obtaining patient medical and psychiatric history, collaborating with outside providers like a patient's primary care physician or other specialty care providers. Real time audiovisual clinical evaluation starting with higher frequency and decreasing as patients stabilize with a minimum of at

least one clinical visit per month per patient. A treatment agreement with the patient and a documented clinical treatment plan as well as periodic UDS and maintaining comprehensive medical records of treatment and medication accounting.

OUD telemedicine clinicians should build referral and consultation relationships with treatment programs in communities where their patients live. These relationships should include primary care and specialty care services as well as other in-person OUD care options including OTPs and residential addiction care. Often OUD care is a patient's first meaningful connection with health care and we should be using this opportunity to connect them to other crucial preventative and comprehensive health care.

Before I move on, a few things about diversion management.

We prevent diversion the same way in-person care does, by establishing good relationships with patients, assessing their progress, and maintaining open communication. All that in partnership with regular documented PDMP review and urine drug screens.

The topic of urine drug screens has come up a number of times in these sessions. Anyone who has been in health care for any time at all has heard a

wild story about a patient's attempt at faking a UDS. Interestingly, though, a 2022 study found very low rates of falsification of urine drug screens among patients of OUD receiving treatment via telemedicine.

Our own study at Ophelia which included close to 3400 patients which were monitored for at least 180 days was recently published in JAMA. It showed that it is feasible to conduct regular urine drug screening in a remote setting with very low rates of unexpected results such as being negative for Buprenorphine or positive for other opioids.

At-home UDS kits are simple to use, screen for multiple substances, include built-in tampering prevention such as temperature readings and indicators of adulteration. These results are easy for clinicians to obtain and view during a clinical audiovisual visit with the patient. Every Ophelia patient has at least one if not more sealed UDS kits on hand at all times. We can also refer patients to local labs such as Quest if more sensitive or comprehensive testing is indicated. We have detailed UDS protocols and keep extensive records on the collection and results of each UDS.

Now onto Buprenorphine.

We understand the DEA's concern about

diversion in telehealth in general, but Buprenorphine is different from other controlled substances. It has a much different risk-to-benefit ratio.

Buprenorphine isn't a recreational drug. It blocks the opioid receptors in the brain, minimizing cravings associated with OUD without producing a high when used as prescribed.

Studies have repeatedly found that diverted Buprenorphine is an attempt by individuals to initiate OUD treatment they don't have access to on their own. Studies also indicate that 70-90 plus percent of people who use illicit Suboxone report using it to prevent cravings and withdrawal.

A recent study by health authorities found that despite increases in Buprenorphine prescribing after the onset of COVID, there was not a correlating association with the prevalence of Buprenorphine among overdose victims. This study replicated findings from an earlier study in New York City showing that Buprenorphine was incredibly uncommon in the toxology reports for overdose victims, speaking to its risk protective profile.

Our data speaks for itself. At Ophelia we've treated over 10,000 patients during the past three years with only 10 overdose related deaths

reported to us. That is one-tenth of one percent and it's well below the incredibly high rate of mortality otherwise observed among individuals with OUD which is typically 1 to 2 percent annually, possibly higher at this point with dangerous Fentanyl exposure.

Many individuals treated with Buprenorphine are alive today because they were able to access this treatment via telehealth. We firmly believe that every patient in care is one less person seeking diverted opioids. We reduce diversion not just among our patients with our internal monitoring protocols, but by reducing the number of customers in the market for diverted opioids.

SAMSA's own publications show that patients who discontinue OUD medication generally return to illicit opioid use within just a few weeks or months. Low barrier of access to quality Buprenorphine care prevents diversion.

One final point. The opioid PHE is still in effect and has been for six years. We would ask the DEA to repeat the flexibilities and extend it to all controlled substances during the COVID PHE to Buprenorphine under the opioid PHE for as long as it lasts.

In closing, we are directly addressing the

root cause of the opioid PHE one patient at a time. We like to think we are your partners in the fight against diversion and not the cause of it.

On behalf of our current patients and all those still looking for an answer to their OUD, thank you for taking the time to listen to our recommendations. We appreciate your care and your attention.

MR. STRAIT: Thank you.

I'm going to ask Commenter No. 10 to pause before coming up. We're going to take just a five minute leg stretch break. So we will come back at 2:55. Thank you.

(Brief recess.)

MR. STRAIT: Let's get started.

I am happy to call Commenter No. 10 to the podium.

MR. FERNANDEZ-VINA: Marcelo Fernandez-Vina, M-A-R-C-E-L-O F-E-R-N-A-N-D-E-Z hyphen V-I-N-A. I'm with the Pew Charitable Trusts.

Good afternoon. I'm Marcelo H. Fernandez-Vina appearing today on behalf of the Pew Charitable Trust Substance Use, Prevention and Treatment Initiative.

Pew works with state and at the federal

level to address the nation's opioid overdose crisis by developing solutions that improve access to timely, comprehensive evidence-based and sustainable treatment for opioid use disorder.

The Pew Charitable Trust through its Substance Use, Prevention and Treatment Initiatives recommends that the pandemic flexibilities allowing for Buprenorphine prescribing by all DEA registered practitioners via telehealth without an in-person requirement be kept in place permanently.

Overdose deaths have reached unprecedented levels in recent years with over 100,000 overdose deaths occurring in 2022, the majority of which involved opioids.

In light of the public health crisis we face, access to Buprenorphine should not be restricted. Therefore, Pew urges the DEA to take steps to maintain access to Buprenorphine in order to curb the overdose epidemic. Allowing health care providers to prescribe Buprenorphine remotely during the pandemic helped more patients start and stay in treatment without increasing overdose deaths.

The pandemic telehealth flexibilities helped veterans, people experiencing homelessness, individuals involved in the criminal justice system,

those living in rural areas, and racial and ethnic minorities access Buprenorphine via telehealth with audio-only visits helping many of these patients access care.

Allowing Buprenorphine to be prescribed via telehealth decreases challenges associated with the transportation and geography and helps patients with work and child care responsibilities. Telehealth improved access to care for rural and hard to reach populations, reduced wait times, and worked around challenges with child care, work, transportation and stigma.

Under DEA's pandemic flexibilities, Buprenorphine was safely and effectively prescribed via telemedicine and reached more people including people that traditionally face challenges accessing Buprenorphine by centering patient access, comfort and empowerment and reducing barriers to treatment.

DEA's pandemic flexibilities improved access to Buprenorphine by allowing patients to start lifesaving medication via telehealth without having to see a provider in person.

In multiple studies both patients and prescribers report positive experiences with telehealth for Buprenorphine prescribing, including a

greater sense of ease, flexibility and autonomy for patients.

Earlier this year researchers at Harvard Medical School found that providing OUD care via telehealth may be comparable to in-person OUD care and no evidence indicates that telehealth for OUD care is unsafe or over-used.

A study published in JAMA Psychiatry found that Medicare beneficiaries who received telehealth services related to OUD were more likely to stay on medication and less likely to experience an overdose.

Similarly Veterans Health Administration patients using telehealth for Buprenorphine treatment were more likely to stay in treatment than patients being seen in person.

Based on this information additional requirements for prescribing Buprenorphine via telehealth including a special registration impose arbitrary, non-evidence based barriers to lifesaving treatment.

During the pandemic all prescribers were able to utilize telehealth with no special registration requirement. Given the administration's and this agency's commitment to prioritizing meaningful interventions that address substance use

disorders, DEA should carefully consider the effects special registrations can have on restricting access to Buprenorphine treatment.

Both DEA and the National Institute on Drug Abuse agree that increased Buprenorphine prescribing decreases diversion. DEA has previously stated that it's actually lack of access to Buprenorphine that drives Buprenorphine diversion, and that increasing access to medication may be an effective way to prevent diversion.

The National Institute on Drug Abuse has also stated that as Buprenorphine access increases, Buprenorphine diversion decreases.

An assessment of telehealth impact on adverse outcomes found no data indicating evidence of increased diversion for patients receiving care via telehealth. Rather, Studies found that virtual Buprenorphine access led to few adverse events.

There are existing robust safeguards in place to prevent Buprenorphine misuse and diversion. Prescribers of controlled substances are already registered with the DEA and licensed through their state boards, meaning they have to meet specific standards of health care delivery to practice or they risk losing their license.

In addition, most states require prescribers to use their prescription drug monitoring programs or PDMPs to track prescriptions for controlled substances in Schedules II through V. Most PDMPs update their data on a daily or weekly basis and participate in interstate data sharing.

In our view, additional data collection by DEA is unnecessary. Under DEA's pandemic flexibilities Buprenorphine was safely and effectively prescribed via audio-only and audio video telemedicine without additional data collection measures, and prescribers in the future should not be subject to additional arbitrary requirements which can reduce access to lifesaving medication.

I'd also like to note that CMS already collects data on the use of telehealth by requiring Medicare practitioners to use a modifier for telehealth claims and Medicaid and other insurers track telehealth claims.

Buprenorphine is extremely safe and the overdose risk on Buprenorphine is extremely low as the drug has a ceiling effect, meaning its effects will plateau and not increase even with repeat dosing.

It's notable that as Buprenorphine prescribing increased during COVID, overdose deaths

involving Buprenorphine did not increase.

The evidence is clear. Buprenorphine is safe, effective and saves lives. Buprenorphine access plays a vital role in reducing Buprenorphine diversion and there are major benefits to public health and safety that the pandemic flexibilities provided to patients with OUD.

The Pew Charitable Trust strongly recommends that the pandemic flexibilities allowing for Buprenorphine prescribing by all DEA registered practitioners via telehealth without an In-person requirement be kept in place permanently.

Given the overwhelming evidence base in support of our recommendations today, Pew urges the DEA to finalize a rule for telehealth prescribing of Buprenorphine without an in-person requirement as soon as possible.

To avoid reductions in access to treatment during the rulemaking process, we urge DEA to extend the existing temporary rule or use the already designated opioid public health emergency to keep the pandemic flexibilities in place for Buprenorphine prescribing via telehealth.

Thank you for the opportunity to offer comment on behalf of the Pew Charitable Trust and for

your attention to these matters today.

I'm happy to respond to any questions you may have.

MR. STRAIT: No questions. Thank you.

We re now calling Commenter No. 11.

MR. GOLDEN: He just told me not to worry about the ten minute time limit, just do what I need to do and go as long as I can.

(Laughter).

MR. GOLDEN: Everybody here's been extremely courteous for the last two days, but it is the driest event I've ever attended in my life. I mean honestly, the people that's been here yesterday and today are changing the world. It's an emotional thing and I hope I can hold it together. All of my friends and family are watching, but I'm passionate.

I've heard of doctors, lawyers, scientists, professors from Yale, Harvard, Johns Hopkins University, pharmaceutical representatives, representatives from the government. And I'll tell you who I am. I am rural America.

My name is Dan Golden, G-O-L-D-E-N. For further clarification I'm Commenter No. 11 which so E-L-E-V-E-N. See, we're smiling and having fun.

In all seriousness, I do represent rural

America. We have East Coast Telepsychiatry and our provider is Amy Farr. She's a 29 year nurse practitioner who is passionate about the care of her patients.

When the telehealth thing went in chaos at the end of March we panicked. Everything that we own, we put into doing a telehealth business to provide care for people, and people don't understand in rural America the numbers are different.

Washington, D.C. and the DEA is not America. America that I live in -- I live in Northumberland County, Virginia. There are two stop lights in the whole county. Twenty-three miles apart. And those two stop lights are twice as many items that there are providers. There are not two providers in the county.

The closest hospital does not accept psychiatric patients because they have no psychiatric doctor that works at VCU, Tapahanock Hospital in Virginia. So obviously the statistics are there. Rural America needs help. Rural America needs telehealth, they don't need restrictions that punish the patient.

Basic statistics that I'm going to try to cover everything -- I want to talk like the micro-machine guy from the commercials back in the '80s.

By 2034 the American Medical Colleges report there will be a shortage of 124,000 providers in the United States. Another statistic that I don't know that people are aware of, telehealth visits increased from 2019, from 840,000 to 52.7 million telehealth visits in one year. From 2019 to 2020. According to the United States Census Bureau, in the last four weeks the survey was done in February, in the last four weeks, 23 percent of all adult Americans had attended a telehealth appointment.

Many hospitals have no psychiatric providers. There are providers available but the average wait time, according to a study from Virginia Tech School of Medicine and Medstate (phonetic) in the State of Virginia, only 18 percent of psychiatrists were available to see new patients. The median wait time was 67 days for in-person appointment, yet only 23 for Telepsychiatry. The crime factors, if the patients don't get the medicine from providers, we prescribe a lot of Adderall conserved to Ivans (phonetic

I can walk out probably on the corner of this property and get that item from illegal drug sellers, so we need to ensure that people are taken care of by proper care.

In 2008 the White House mandated that the DEA create special exemptions. Fifteen years later we're sitting here trying to do so. One thing that I want to make very clear. I think the DEA liked having everyone here yesterday and today, getting this input, and hopefully doing a lot of the work for them because they can't think of all of the things that providers, prescribers, doctors, pharmacists deal with on a day-to-day basis.

I think one thing that is very important is that the DEA needs to build a team of providers, pharmacists and any other key parties to meet virtually, maybe every 90 days or six months, because the decisions that you make in the next few months are going to be outdated in two years. Technology is going faster than we can even fathom.

One thing that I do think is important that's not been addressed, I do think a telehealth visit should be done by a person, not an AI bot, because that is going to be a factor probably within nine months, sooner, or may already be happening. So those are things that need to be looked at.

The PMP Awareness Program, everybody has mentioned it and I'm going to strive that that thing is crucial. We had a patient last fall, she scheduled

an appointment the first of November. She was determined to have ADHD. She was prescribed Adderall. She returned for a follow-up visit a month later. She had obtained the exact same medication from four more providers, all within a 30 day period.

The PMP system needs to be federal. If it's state level, they're all going to have their own quirks and additions. It needs to be one shot. So when I click in and the guy just moved from San Antonio, Texas to Lottsburg, Virginia, I can see what he got over the last year, what medications he's been on.

Talk about flagging providers and pharmacists. The patients need flagged.

If I put in a prescription or our provider, Amy Farr, puts in a prescription for a patient and they pick up that medication, the problem is with PMP that's not been mentioned by anybody, it is hugely flawed. And if the government picks up on the PMP today it will be an utter failure because pharmacists put on the fill date of a medication. If I prescribe, my buddy Pierre gets prescribed maybe Vyvanse, and we send in the prescription electronically today and the pharmacist has time to fill it this evening, he enters into PMP that it's filled and he hangs it on the rack

in the little plastic bag for people to come and pick up.

Well, Pierre may not pick his medicine up until next Monday or Tuesday. So then when he comes for his follow-up in 28 to 31 days, he's getting his medication a week early. So now he's got extra Adderall laying around where he can sell those seven pills or he's not taking the medication properly.

Every patient that we see, and I do think this should be something added on to providers, every patient, every visit there should be a PMP check pulled and stuck in their file for review. For the simple fact that it prevents people from drug shopping. It prevents pharmacists from giving out the pills, even though somebody's gotten four different prescriptions for Adderall 20mg in the last three weeks. And something else the lady from Medicaid yesterday mentioned there's fraud being done in the EPCS. A federal PMP program would also eliminate that because Amy Farr can say I didn't prescribe these three medicines. So she can report, hey, somebody's hacked my account or done whatever. You know, there's multiple safeguards that can take place there.

This is a common sense thing to me. That's why I'm glad I'm here and I don't have all those

degrees. I'm rural. I'm the country dude. I built decks for 25 years. I have no medical background until my wife decides we need to open a practice to take care of people. She's been a nurse practitioner for 29 years, and is passionate. And the rules that are currently in place could devastate every penny we've ever spent. And I know these rules are changing. That's why we're here. It's just a matter of lining up the dots and getting things done. So we're thankful.

And this gentleman mentioned earlier, you know, the grandfather thing. It's already in effect. Don't worry about your current patients. The current wording when you pull up on the DEA website is that exemption was placed from March until this November, but for previous existing patients it's active until 2024.

That needs to change immediately, and any pre-existing patients and cases the wording needs to say when somebody Googles it, they are grandfathered forever. There's no reason that you have a patient coming to us for the last 2.5 years and then November 2024, I have to say I'm sorry, I can no longer prescribe your medication. I'm sorry about your anxiety.

What's going to happen to a person with anxiety if they can't find a provider within two months? And they can't get to an office? It provides undue stress.

So the people that we have, they don't need to be limited to 2024. The patients we have now, we have the right to keep those patients and they have a right to choose and leave if they want to.

Drivers license, state ID or passport. In my opinion if a person is getting a controlled substance they have to produce that to the provider and they have to produce it every time they pick up a prescription. It's not Motrin, it's not some simple cold remedy, it is a controlled substance.

Video visits versus telephone. A video visit should be mandatory for at least the first visit. Put eyes on the person so when the driver's license comes in you at least know you're talking to the same person. After that, go to a telephone.

The same care can be given on a telephone. We don't like to do it. We require video visits. On rare occasions we do the telephone. Just for the fact you can lay eyes on the people. They may tell you they're perfectly fine, but they may have tears coming down their face. They may have physical problems.

They may have meth marks. You know, things that people need to see.

So video's important. If it's done by telephone only, that's okay, but the first visit I think we need to establish yeah, this is John Doe because that's what his driver's license says.

Let me see if I have anything else. I know my time is ticking.

The DEA is worried about the future. The future happened two years ago when the United States was put into a pandemic, so it's too late.

You need to fix these rules now and you need to ensure that you do things to continuously change things as they need changed. Don't wait 20 years to address this topic again because it's not happening. You will be left behind in the technological dust.

So with that I'd like to thank everybody for my time and putting up with my passion.

MR. STRAIT: No questions.

We are now welcoming Commenter No. 12 to the stage.

DR. SIMON: Thank you to the Commenter No. 11, given the time that we're at.

My name is Dr. Kevin Simon. Kevin, K-E-V-I-N. Simon, S-I-M-O-N. I am here from the City

of Boston. I appreciate the Pew acknowledging study from our group with regards to opioid use and telehealth.

I'm here today representing dual roles. I serve as the first Chief Behavioral Health Officer for the City of Boston. And professionally I am one of these rare child and adolescent and adult psychiatrists. I'm also board certified in addiction medicine and operate or work through the Adolescent substance Abuse and Addiction Program, also known as ASAAP at Boston Children's Hospital.

I get to care for families, youth. A mother emailed me today with regards to her son who is 14. I met him when he was 12. He had to go to the ED in part because he used to be in DYS, the Department of Youth Services, the Juvenile Justice Service. Got discharged on Friday and today is Wednesday or Thursday. In school he was vomiting in part because he's engaged in Percocet and other opioids.

So telehealth is critical. It is a lifesaving measure that we've demonstrated through our group. Particularly when we were thinking about adolescents, and this hasn't yet been mentioned. I'm going off the cuff and not really with my remarks here.

In reference to -- for all the adult patients that we're talking about, 90 percent began their substance engagement before 18. So in terms of who we really should be trying to target, it's those who are adolescents. The reality is, adolescence has prolonged itself over time because socially you get to be on your parents' insurance until 26. The average age of marriage, back when my parents got married it might have been 21. That's not the case anymore.

So in terms of how do we ensure appropriateness of care, we do it with our group. We meet yes with the patient, but adolescents don't really like to share information all that much, but because they're under 21, or really under 18, we also meet with their parents or their guardian. The reality is, you have access to collateral information to ensure the patient that you may not be able to see visually, somebody else is able to see that person.

So I want to talk about two fictitious but real patients. Anna, from rural America; and Jason from urban America.

The reality is Anna, although she's not from a city like D.C. or New York, she's not safeguarded by having a condition like autism spectrum disorder which 50-60 percent of patients with autism have ADHD.

Patients that have ADHD, 20-30 percent of them have autism. They're going to need medication.

If we're talking about Jason who lives in let's say East Brunswick, it's really close to Jersey. It's really close to New York City. But complicated factors, neighborhood disorder, make it such that he's experiencing life in a health condition, substance abuse engagement, pre-addiction. The fact of the matter is unless we're providing telehealth services, we're going to miss a whole host of people and it's actively happening now.

So of that 90 percent of adults that began engagement with substances before 18, the truth of the matter is less than 15 percent, the data here depends on the source, but less than 15 percent actually received evidence informed treatment. Now there's treatment, but then there's evidence informed treatment.

The fact of the matter is telehealth allows clinicians to reach that population.

So I totally understand that the DEA is required to do safeguards and practice and want to ensure that there's no diversion. I practice cautiously myself. But the truth is, as that gentleman said, you probably should convene a group.

And I get that we have a two-day convening here, but I know that there's -- I know that there's working groups that are in the DEA in the health fraud division that are trying to find bad actors, because the reality is there are often bad actors. But just trying to take away something that you've given to many patients, the genie's out of the bottle. It's hard to put the genie back in.

So in reference to proposed rules, the registration, I know it's been on the books. It has yet to actually be enacted. You have a whole host of people who are prescribing actively to try to get them to actively do eight hour training will be difficult. We've seen removal of the X waiver has not shifted the amount of people who actually should be prescribing Buprenorphine. I prescribe it. But literally I have colleagues in hospitals that say well, I'm not comfortable. So I'm not really sure what adding an additional layer of mandated requirements is going to do. It's probably just going to stem people from actually engaging.

So the reality is that as the person I think Commenter 10, some research from our group identified that those that have substance abuse problems, mental health conditions, particularly that are adolescents,

actually do engage pretty well with regards to telehealth services, and the key part about our study was they were very willing to come in after being established vis-a-vis telehealth. So I don't necessarily think you need a mandate.

The reality is, if you're with a provider that you trust and it's been three months or six months and you make the suggestion to come in, it's very likely that they will actually come in. And if we're talking about those who are minors, if they can't some in, some guardian can come in because they're potentially not unhoused.

So when we're thinking about this idea of the rural and the urban individual, the truth is you have tools that are at your disposal. Yes, the PDMP. You don't have current engagement with it. I'm sure that would be very difficult to do for the fact that it's technically I think 49 states. I'm not sure if Missouri has added it yet.

So the truth is, this is a very complicated issue. I greatly appreciate that you're attempting to resolve some of the issues. I do think if we're going to go back to the 2008 and try to do a special registration there has to be some subset of criteria in terms of who can prescribe. Again, there's less

than 8,000 child psychiatrists. I'm one of them. You should take a photo of me because there's not many of us. But we're not the only ones who can prescribe stimulants, not the only ones who can prescribe Buprenorphine. But again, even those that can, aren't.

In terms of setting some kind of standardization, just like every year for every state that I'm licensed in, I have to get a renewal. So if you're going to have a special registration there needs to be a renewal process. And physicians and prescribers are already used to a renewal process because we already have to do that for the respective states that we're in.

In terms of routine monitoring, I just don't know what the jurisdiction is of the DEA in terms of trying to set up some regular monitoring. The current monitoring that I think is happening, there's somebody who's a good whistleblower and says hey, something's going on here. Then you guys go in and search. But I don't know that you have the capacity to set up some kind of monitoring system. That would be ideal.

Again, this tech integration doesn't yet exist, but if it could that also would be ideal.

I know you've listened to many people and I

can see my time's winding down. The reality is the special registration, that would be great. But the problem that we're trying to figure out exceeds two days of listening. And those of us at Boston Children's, Children's Hospital Association, all of the advocacy groups that you heard from will gladly partner in trying to figure it out. But literally, as I'm standing here there's a patient of mine that I'll see vis-a-vis telehealth tomorrow because I'm here and they're in Massachusetts. So it's going to be very hard to curtail something that you've given to millions of people over the last couple of years.

I'll stop there. Thank you for the opportunity to be engaging here.

MR. STRAIT: Okay. We are going to be bringing up our 13th commenter. I will say that we had up to 14 today and I don't believe that Dr. Kolodny is here yet if at all. So I will say that assuming that we have no one after Commenter 13 we will then go back to one in-virtual commenter who could not join us in the morning and that will be our last presentation for the day.

So, Commenter No. 13, welcome to the stage.

DR. REDDOCH: I have significant presbyopia, so I can't work off of a small device. I bring up a

laptop.

MR. STRAIT: Absolutely.

DR. REDDOCH: And I use, like, 16 point, and, hopefully --

MR. STRAIT: Wonderful.

DR. REDDOCH: -- I can capture this. Thank you.

Good afternoon. I'm Dr. Shirley Reddoch, S-H-I-R-L-E-Y, Reddoch, R-E-D-D-O-C-H, a Board-certified pediatrician and pediatric hematologist/oncologist with 40 years experience in direct patient care and as a pediatric residency and pediatric hematology and oncology fellowship program faculty. Currently, at the latter part of my professional life, I have a part-time faculty appointment in Pediatrics at Johns Hopkins, a continuing appointment at Johns Hopkins School of Medicine, where I serve as Clinical Teaching Attending in the Children's Hospital.

Thank you for the opportunity to speak at this DEA listening session centered on the subject of telemedicine prescribing of controlled substances and the role or necessity of in-person medical evaluations by the prescriber.

Today, I speak to you as an individual concerned physician and not representative of Johns

Hopkins or any other healthcare organization or general medical or specialty associations, although, like other presenters, I am a member of several specialty organizations. To name some, the American Academy of Pediatrics, the American Society of Pediatric Hematology Oncology, and the American Medical Association.

Before specific comments on the current question, I'd like to give you a little bit more of my background, experience, and observations over time in medicine.

I started my residency training in pediatrics in 1981, entering the Army on active duty after completing medical school in the civilian sector. Subsequently, I served as a general pediatrician in an Army community hospital and clinic before doing my pediatric hematology oncology fellowship training at then Walter Reed Army Medical Center.

Following fellowship, I served as Peds Heme Onc and on pediatric residency faculty at two other Army medical centers before transferring to this area, Fort Meade, Maryland, in a healthcare admin role as Deputy Commander for Clinical Services at Kimbrough. I then returned to Walter Reed, first leading the

Department of Health Plan Management, then returning to full-time Peds Heme Onc practice and on pediatric residency and fellowship program faculty, with clinical faculty appointment at Uniformed Services University of Health Sciences. Those were my first 24 years of practice and were within the military healthcare system, which I understood the beneficiary population well as a member with a family in that beneficiary community as well as a physician.

Given the size of our program and resource allocations, we all practiced in the inpatient and outpatient setting, so knew our patients in both those environments.

In those years prior to formal telehealth programs, all care was considered in-person, though telephonic communications were frequently made and documented, with only occasional non-controlled substance prescriptions associated with a telephonic communication with a patient, again, already seen and followed by a physician or service team of physicians.

It's important to know medical students, residents, fellows in training at that time, at this time, understood and were engaged in the continuity of care between inpatient and outpatient settings and direct communication between primary care and

specialty care.

Leaving practice in the military healthcare system and affiliating with Johns Hopkins Pediatrics, Pediatric Hematology, now 18 years ago -- I'm feeling older by the minute as I read this -- I recognized the challenges of much larger socioeconomically diverse patient referral populations not only geographically spread but often with primary care or other specialty care outside of the Hopkins medical system.

As with any such system, there are those patients who are well known to the service but many others with only infrequent encounters within the system and sometimes more in the emergency room or inpatient setting than out. Various insurance coverages and/or no coverage further separated accessible or covered sites and sources of care and services.

Establishment of a sophisticated electronic records system with expanding capabilities helped connect different electronic record sources via the Health Information Exchange in the state, and PDMP helped in monitoring certain controlled substance prescriptions, but still the weaknesses interpreting that information were often revealed when patients were seen for their in-person visits.

Although I cannot speak to all areas of Hopkins medicine, as I recall now, outpatient telehealth visits were just being implemented by my service colleagues at or around the time the COVID-19 pandemic hit. My activity was in patient care at that time, but our service case management discussions ensured awareness of in-person and telehealth encounters and often covered opioid use and pain management of conditions like sickle cell disease with complications involving acute and chronic pain.

Formal video telehealth visits, video visits with the ability to prescribe controlled medications have greatly facilitated continuity of care of established patients, but periodic in-person care, advisedly outpatient but also evident with episodic inpatient care managed by the same service team, is still the practice.

We should also remember that during this time, these last few years, there were severe restrictions placed on outpatient in-person visits and limitations set on who and how many members of the care team and which members could even see patients on the inpatient services directly and the level of PPE required for a provider to wear to see patients in either setting, medical trainees, students, residents,

fellows, were getting a very different learning experience from those prior to the pandemic years and immersed in such removed evaluations and care of patients with their rapidly developing facility and comfort with telehealth care.

It is my concern that this may heighten the risk just in general for overuse of, overconfidence in, or misapplication of telehealth, with emphasis or preference for virtual care on the part of practitioners as well as patients.

Following my further conversations with physicians across the country, to include hospital-centered and community-based hospice and palliative care programs, psychiatry, and a chronic opioid use pain management program, and listening to presentations last day, my considered conclusion is there still should be an inpatient evaluation that is proximate in time and related to an initial telehealth visit for prescribing controlled substances, and, ideally, that visit should be with that prescriber. I said ideally.

Ongoing telehealth prescribing of controlled substances by that prescriber should be within appropriate disease and condition management that warrants such prescribing, with the telehealth

prescriber trained and appropriately certified in such fields as substance use disorder or medical specialties covering specific diseases, conditions requiring frequent or chronic medications in the schedules of controlled substance or hospice and palliative care medicine.

The telehealth prescriber must be licensed for telehealth in the state where the patient resides and if by chance is so geographically removed from the patient that the prescriber cannot see the patient in person, there should be a primary referring practitioner in room with the patient simultaneously communicating on video platform, video visit platform, with the consulting provider or specialist. Documentation of such a visit must be adequately reflected in both the primary provider and consulting provider's records system.

If the disease condition management with prescribing of controlled substances is continued by the remote-only telehealth consultant specialist, there should be a documented primary care or referring provider relationship established to facilitate future video, tandem video visits, in person as initially established.

If the primary care provider with the

ability to do periodic in-person evaluations assumes responsibility for prescribing of controlled substances following the specialty consulting provider care plan, there should be follow-up recommendations with frequency and whether in-person or telehealth, acceptable follow-up as stated and understood.

If the consultant specialist who is accessible only via video visits assumes continuing prescribing responsibility, it should be so documented.

Exceptions to this process can be codified outlined in policy established state by state with involvement of the state practitioners' licensing boards, with consideration of the healthcare needs of the population, with attention to the underserved.

States should be cautious about permitting any out-of-state practitioners organizations only licensed for telehealth in the state to develop an independent telehealth practice independent of any in-person direct healthcare service or working with such a direct healthcare service residing within the state as this may directly compete with and undermine the work of such similar services that may exist within the state that I heard alluded to in visits in presentations last day and with the in-state services

appropriately serving the state's populace.

Quality of care, adherence to care, outcome measures should be tied to telehealth. Only exception programs as well as those that offer in-person visit capability. This again requires additional insights as may be ascertained from state medical societies, licencing board, health departments, nonprofit healthcare organization, independent practices, and FQHCs within the state.

Codification of policy at federal level for exceptions to visits may also need to be reviewed regarding programs that serve DoD and federal institutions.

All controlled substances at high risk for diversion, abuse, or overprescribing should be reported on a standard PDMP platform that can communicate across state lines essentially nationally, as many others have recommended.

And with such tremendous input and some concrete recommendations that have been presented by in-the-trenches providers in these two days who have identified specific risk mitigation measures to be taken, including qualifications of providers teleprescribing and particularly in psychiatric and behavioral health only, telehealth-only practice would

suggest that DEA specifically look at those recommendations made.

But I would also recommend reassessing adequacy of education on controlled substance use and prescribing for practitioners and pharmacists in telehealth environments and a more robust standardized education surrounding prescribing of controlled substances in various settings, patient settings, electronic prescribing, and telehealth platforms be formally incorporated in and across all graduate medical education before upcoming physician transitions from care oversight within residency programs to widely varying and increasingly narrower focus of independent clinical practice settings.

This speaks to not just specializations in care but sites of care, like ambulatory only, hospital only, emergency medicine practices, where one can easily narrow patient care focus to their environment of care and can decrease attention to patients' overall healthcare which requires access to other settings of care.

And believe it or not, my final concern to raise is actually the primary one that brought this listening session to my attention. It is that of legal lethal dose prescribing of single or combination

of medications prescription that can involve one or more controlled substances or clearly off-label toxic use of non-controlled medications. This type of prescribing was legalized in several states via end-of-life option or medical-aid-in-dying legislation and offers the most protection of those prescribers, no protection of patients or transparency to family and other non-medical-aid-in-dying-involved providers.

There's likewise no real monitoring of adherence to minimal documentation requirements, thresholds for investigation, and no consistent way to identify if and/or when the prescription is taken as patients could have died of underlying qualifying diagnoses before taking medication, delayed taking prescription, gotten better, changed their minds.

There are no particular skills or training required of a prescriber to prescribe a killing dose of any medication. One would say this is not chronic care or continuing medication risk, but telehealth visits in lieu of in-person for this prescription consultation promotes too-easily-obtained prescriptions, no assurance of any care for the patient by the prescriber who is not otherwise involved in the patient's care if the patient chooses not to take or delays taking medication.

Such telehealth providers must be licenced in the state of the patient's residence and should not be able to violate visit prescribing rules of that legislation if not enacted in the patient's state.

There is ample opportunity to obscure illegal prescribing as in illegal in certain states, as in still the majority of states.

As I am not engaged in telehealth directly with associated controlled substance prescribing, this particular DEA request for input in listening sessions did not actually get my attention or many of the other people I consulted who practice good medicine in their fields with good documentation of telehealth and prescribing. But my antenna went up when I heard that A Death With Dignity, that Death With Dignity sent out alerts to their followers requesting and eliciting approximately 10,000 comments by their count of your 38,000 comments to the DEA supporting telehealth-only prescribing. I realized then that there's an underappreciated risk that lay in this ongoing expansion of telehealth, so I bring that to your attention.

And, subsequently, I was sent a copy of a letter that I think may have already been sent to you from concerned organizations opposing assisted

suicide. So this is always on people's minds, and the potential of this kind of use of telehealth actually further undermines reliance and trust of those providers involved in care of hospice and palliative care.

And one final comment speaking to what a prior speaker, a recent prior speaker just raised is that the specter of AI as threat to integrity of telehealth. I think that is very real, and with so much imitation, you don't know sometimes will it get so good that you won't even know if you've got a real patient in front of you? Not just the provider but the patient. So we need to move away from dependency on this or any other singular encounter type as we may need to pivot as we've had to so many times in medicine.

Thank you very much.

MR. STRAIT: Any questions?

(No response.)

MR. STRAIT: Okay. Thank you so much.

Okay. And we will now, like I said earlier, go to our Virtual Presenter No. 13. Thank you.

DR. SPENCER: Hello. My name is Dr. Sarah Spencer, S-A-R-A-H, S-P-E-N-C-E-R, and I'm representing myself today. I'm an employee of the

Ninilchik Tribal Council and the head addiction medicine consultant for the Alaska Native Tribal Health Consortium. I'm here today to speak on telemedicine regulations of buprenorphine for the treatment of opioid use disorder and to speak against the requirement for an in-person visit.

I'm a Board-certified addiction medicine physician, fellow of the American Society of Addiction Medicine who has provided care for patients with opioid use disorder in rural Alaska for 13 years, and I've been offering telemedicine for OUD for years prior to COVID.

To remind you of the vastness of Alaska, we are, of course, more than twice the size of Texas, and there are over 200 Alaska native villages spread over 660,000 square miles, most of them off the road system.

I work in tribal health and I'm one of the only addiction medicine specialists in the state that provides treatment of OUD via telemedicine for any Alaska native person regardless of tribal affiliation.

I work on the rural southern Kenai Peninsula and I'm the only addiction medicine specialist in our 25,000-square-mile borough. The next nearest addiction medicine specialist and the nearest

Methadone clinic are over 200 miles away in Anchorage.

In 2021, Alaska suffered the greatest increase nationwide in our overdose death rates with fentanyl-related deaths up 150 percent, and the overdose rates in Alaska native people are triple that of white Alaskans. In fact, indigenous Americans nationwide are among the populations with the highest overdose death rates.

Buprenorphine has been shown to reduce mortality related to OUD by over 60 percent. However, many remote areas in Alaska still have no local access to this medication. Most of the 170 tribal village clinics are off the road system, meaning patients can only get in and out via boat or plane, and they are staffed only by community health aid practitioners, with licensed providers, such as doctors, NPs, or PAs, visiting just a few times a month or sometimes less than once a month, and there are huge tribal regions, such as the 115,000-square-mile Arctic slope and Norton Sound region, that have zero prescribers of buprenorphine.

Historically, fear and stigma around diversion or misuse of sublingual buprenorphine, as well as the challenges in monitoring the use of this medication in remote areas, have caused many rural

tribal clinics to shy away from offering this medication altogether.

Monthly long-acting injectable buprenorphine has less stigma surrounding its use and it could potentially dramatically expand treatment availability. But, unfortunately, due to DEA restrictions, it cannot be shipped to a remote village clinic staffed only by a community health aid practitioner because it can only be shipped to clinics that have a resident DEA licensed provider. So, unfortunately, this medication is also not accessible to patients living in remote native villages.

Most of the tribal organizations who do offer MOUD offer medication options that can be limited, and many only provide in-person care and they require patients to travel from their remote home villages to the hub clinic to attend in-person visits.

I am one of only two physicians in the State of Alaska with the Indian Health Service Internet Eligible Controlled Substance Provider exemption to allow for buprenorphine prescribing without an in-person visit.

However, that exemption requires that the patient be present at the remote village clinic site to receive services, and merely obtaining this

certification does not ensure the cooperation of the distant tribal health organization. And I have personally seen multiple incidences of patients refused telemedicine access from their home tribal clinic to access buprenorphine therapy.

Within these large tribal health organizations exist many individual tribal clinics, all with different tribal councils, different administrations, and some have policies against providing buprenorphine therapy, and they may refuse to collaborate with an outside clinic offering the service and refuse to host telemedicine specialty consultation appointments originating at their clinic. Patients may also be unable or unwilling to access care through their local clinic due to very legitimate privacy concerns in these very small villages.

Since the Internet Eligible Controlled Substance Provider exemption does not apply to patients being seen in their homes, I cannot provide treatment to native beneficiaries living in these underserved areas or to non-native patients living in any remote native village if an in-person visit is required.

The Alaska Native Medical Center in Anchorage is the specialty care referral hub of the

state for native beneficiaries, but it does not have an addiction medicine department and has no system in place to offer buprenorphine therapy via telemedicine for remote patients. So uninsured native beneficiaries living in remote villages, lacking a buprenorphine prescriber locally, essentially have no access to this treatment.

When patients do need to travel for in-person visits, the cost can be astronomical. The cost for a patient to get from a remote village in northwestern Alaska to my specialty clinic for an in-person visit could easily exceed $1500.

Even for non-natives who live on the Kenai Peninsula, the majority live more than 20 miles from my clinic, and the nearest pharmacy is 35 miles from my clinic. Ninety percent of our patients have Medicaid, and most either don't own an operational vehicle or they don't have a valid driver's license, and even if they do have those things, many may not be able to afford the gas for the 70-plus-mile round trip.

These patient costs were not adequately accounted for in your cost impact analysis of this regulation. Our clinic is the only one on the Kenai Peninsula of Alaska offering low threshold

buprenorphine treatment. We offer telemedicine to all patients for their intake appointment, and this has dramatically reduced our no-show rates. It also allows us to offer a more flexible open access schedule so patients can get same-day telemedicine appointments for urgent care.

To assist with medication monitoring, patients who are not able to travel to the clinic may choose to participate in drug testing through local clinic labs or through mail-order oral fluid tests with virtually observed collection. We utilize random medication counts conducted by video when needed. And the patients also have the option of demonstrating medication compliance through video directly observed therapy when appropriate for their care plan.

Most of our patients do a mix of telemedicine and in-person care, and this flexibility has greatly increased our ability to support our patients' retention in treatment as well as improve patient satisfaction.

Most of our patients self-refer for monthly injectable buprenorphine. However, it's not unusual for patients to have to take sublingual buprenorphine for more than a month prior to being able to travel to the office for their first injection. In fact, I've

had a patient that had to drive 250 miles one way to get his first injection.

Also, there are many patients who struggle and fall in and out of care in those first few weeks and months, and they may need multiple follow-up telemedicine appointments over several months to motivate and enable them to attend that first in-person visit.

Buprenorphine interruption such as would occur if a patient had not attended their first in-person visit by the end of 30 days is dangerous. After buprenorphine discontinuation, 50 percent of people return to use within a month, and one in 20 experience an overdose event the following year.

The Ryan Haight Act was intended to reduce the inappropriate prescribing of medications such as prescription opioids that increase the risk of overdose. Buprenorphine, however, is a very safe medication since it does not induce respiratory depression and it dramatically reduces mortality risk in patients with OUD. So it's not surprising that overdoses involving buprenorphine did not increase during the pandemic despite its increased availability via telemedicine.

In August '22, a JAMA Psychiatry study

looking at 175,000 Medicare beneficiaries who received telemedicine for buprenorphine therapy, the use of telemedicine to access buprenorphine was associated with a reduced overdose risk and improvement in treatment retention.

Additionally, data that is gathered from in-person visits such as urine drug testing has not been shown to improve treatment outcomes or to reduce diversion.

In summary, requiring an in-person visit to prescribe more than 30 days of buprenorphine for OUD treatment will only result in further exacerbating the already disproportionately reduced access to treatment suffered by our most vulnerable and most affected populations, including Alaska natives and American Indians, low-income patients, and those living in rural areas.

The arbitrary decision to require an in-person visit at 30 days has no basis in evidence to improve patient outcomes, while we have strong evidence that uninterrupted access to medication for OUD is critical to reduce mortality.

I strongly believe that the requirement for in-person visits for buprenorphine prescribing will do more harm than good and recommend it to be removed

from the proposed telemedicine regulation.

Thank you for the opportunity to speak today, and I welcome any questions.

MR. STRAIT: Okay. Thank you, Dr. Spencer. My understanding is there are no follow-up questions, so I want to thank you for participating and for being our last presenter.

And I will say that by purposes of concluding remarks, again, thank you for everyone who took time out of your busy schedules to be here on either one day or two days.

I want to give a special thanks to Administrator Milgram and Assistant Administrator Prevoznik for taking time out of their schedules to also listen. I think and I hope it demonstrates to you and the public and those that are watching us virtually that we really do care about trying to get this right.

So, with that, I will say again thank you. Safe travels. And enjoy the rest of your week.

(Whereupon, at 3:55 p.m., the listening session in the above-entitled matter adjourned.)

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REPORTER'S CERTIFICATE

DOCKET NO.: --

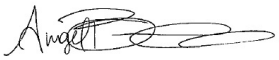
CASE TITLE: DEA Telemedicine Listening Session

HEARING DATE: September 13, 2023

LOCATION: Arlington, Virginia

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Drug Enforcement Administration.

Date: September 14, 2023



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