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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 22202

Tuesday,
September 12, 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 and welcome to this session. I am extremely thankful and appreciate to everyone who has taken time from 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 of this event from the DEA Diversion Controls website. You'll hear me say it a couple times, www.deadiverson.usdoj.gov.

I would now like to introduce Administrator Anne Milgram. Administrator Milgram was sworn in as DEA Administrator on June 28th, 2021, after being confirmed by the U.S. Senate by unanimous consent on June 24th. As the DEA Administrator, she leads an agency of nearly 10,000 public servants who work in DEA'S 334 offices across the globe.

It is with honor and respect that I now welcome Administrator Milgram to provide opening remarks.

(Applause.)

MS. MILGRAM: Thank you so much, and good morning. I want to start by thanking all of you who are here with us today both in person and online, and

a special thank you to all of our presenters. It means a lot to us to have all of you with us today as we embark on these listening sessions.

I also want to say my deepest thanks to Diversion Control, our head of Diversion Control, Tom Prevoznik; our Deputy, Matt Strait, and the whole team that has worked tirelessly on this day, today and tomorrow, as well as the whole team at DEA who has really given their all to make this day, and tomorrow, a success.

We are very eager today to hear your perspectives as we propose a path forward on telemedicine. Before I turn things over to our moderators, who will tell you about the ground rules for the next two days, I want to speak generally about telemedicine, and telehealth.

We recognize the importance of telemedicine in providing Americans with access to needed medications. DEA has been, and remains, committed to expanding access to telemedicine in a way that puts patients and their safety first. That means a final set of rules that is simple to understand and apply that reflects technological advancements, and that is consistent with the lessons that we have all learned during the COVID public health emergency, and that

also recognizes and understands the ongoing opioid epidemic.

Those in person with us today walked past our faces of Fentanyl exhibition, and saw the nearly 5,000 faces of American lives lost to the opioid epidemic, and in particular to Fentanyl. It has wrought a devastating impact on our country.

Let me tell you a little of what these rules do not cover to make that clear from the outset, and maybe let me start with a little bit of background on telemedicine, and what we mean when we say it.

The telemedicine regulations that we are going to discuss today will be issued under the Ryan Haight Act. That act was named for a California high school student who died from a prescription drug poisoning. Ryan had obtained those drugs after receiving a prescription for a controlled substance from a rogue online pharmacy.

Before obtaining that prescription Ryan had never seen that prescriber in person. Those are the concerns that the Ryan Haight Act confronts, prescribing of controlled substances via telemedicine when a practitioner has never seen a patient in person.

That background should help to explain why a

final set of regulations will not affect practitioner/patient relationships if an in-person medical evaluation has occurred at any point during that relationship. Once there has been an in-person evaluation of a patient, that practitioner/patient relationship is not considered to be telemedicine anymore under the Ryan Haight Act.

So as a patient if you have seen your doctor in person before, whether it was a month ago, or a year ago, the regulations we are discussing today will not apply.

In addition, DEA regulations issued under the Ryan Haight Act only apply when there are prescriptions for controlled substances. This means the final regulations will not apply to Telehealth visits that result in no prescriptions at all, or that result in prescriptions for noncontrolled medications like antibiotics, insulin, birth control.

In sum, the final telemedicine regulations will impact only a subset of practitioner/patient relationships, those in which a practitioner is prescribing controlled substances via telemedicine, and has never seen that patient in person.

Finally, let's turn back to where we are in the process, and where we're headed. This past March

in concert with the Department of Health and Human Services DEA issued two sets of proposed telemedicine regulations. Those regulations would have allowed for telemedicine prescribing of certain controlled substances subject to safeguards, and would have imposed an initial limit on telemedicine prescriptions to a 30-day supply. To prescribe more, an additional supply to a patient, the prescribing practitioner generally would have been required to evaluate the patient in person.

We received over 38,000 public comments in response to those proposed regulations, and we read every single one. We believe that is among the highest number of comments we have gotten in DEA'S history.

A significant majority of those comments expressed concerns that the proposed regulations placed limitations on the supply of controlled substances that could be prescribed prior to an in-person evaluation.

After evaluating these comments DEA wanted to reopen this conversation about telemedicine prescribing, and to allow for a public listening session. We are now holding these listening sessions to gather information from stakeholders in this space,

including patients, practitioners, pharmacies, and others.

We're going to hear from as many as 61 individuals over the next two days representing a wide range of interests about a pathway forward. We will also have another comment period this fall for written comments before any telemedicine regulations are finalized.

So to those who applied to present today, but were not selected, thank you for your interest in this issue, and we are looking forward to receiving, reviewing, and responding to your thoughts as well.

Finally, to conclude, I want to thank the presenters again, and to all the folks who are with us today in person and online, for taking this opportunity to provide us with additional valuable input. We are looking forward to hearing from you as we consider regulations in this important space.

As I say all the time here, eventually we are all patients, and so this matters very much, and doing this well matters very much to all of us at DEA. Thank you.

(Applause.)

MR. STRAIT: Thank you for your remarks, Administrator Milgram.

Let me now introduce the person who is sitting next to her on her right, Assistant Administrator Tom Prevoznik. He's a career Diversion Investigator, and oversees the work of the Diversion Control Program. Thank you, Tom, for also being here today.

My name is Matthew Strait. I'm a Deputy Assistant Administrator, and I oversee the Office of Diversion Control Policy. This is the office responsible for the regulatory drafting efforts of the Diversion Control Division.

I will be serving as the moderator for this listening session event, and over the next two days we will have, as Anne mentioned, as many as 61 presenters both in person and virtual providing their unique views and opinions on important regulations impacting the practice of telemedicine with controlled substances.

This event is being transcribed, and will be part of the administrative record relating to DEA'S rulemaking in this space. This listening session 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

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. Why? Because these regulations will impact the delivery of healthcare for every American in the United States, and frankly, we do need to make sure 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 1st, and then gave the public until August 21st to register for the event. We received a total of 1,308 registration requests for those who wanted to participate. Overwhelming majority are people who wanted to be here and listen virtually.

We received a total of that list 186 people requested authority to present their comments either in person, or virtually, and due to the structure of the event, and our decision to let each commenter provide up to ten minutes of remarks, we curated a list of commenters with diverse views on a number of issues that are of interest to the DEA. 29 were offered the opportunity to participate in person, and 32 were offered the opportunity to present as virtual

presenters.

Because we are transcribing the event, and that transcription will be part of DEA'S administrative record, our presenters were advised that they should not use visual aids. While we know that for some of our presenters, and indeed, those who we could not accommodate who wished to provide written materials during this event, we will continue to encourage those folks to provide those written materials when all interested parties are invited to respond to our forthcoming proposed rule.

For the folks who registered to attend this event in person as an observer, I'm happy to report that all were given the opportunity to be here today.

Okay. So let's go over the run of show, and then after that we'll lay out some basic ground rules.

This morning our block will consist of as many as 15 in-person presenters all seated here in the first two rows. Presenters will speak in the order in which they arrived this morning.

I will call commenter number one to the podium. I will ask that individual to state their name and their affiliation. Our transcribers have asked me to make sure that presenters spell their first and last name. That way we have a better

transcription of the event.

Each presenter will then have up to ten minutes to provide remarks. At the nine-minute mark commenters will hear a gentle chime letting them know that one minute remains to their comments.

When our countdown clock gets to ten minutes you may hear a gentle buzzer. Yes. Upon completion we will pause in the event that Administrator Milgram, or Assistant Administrator Prevoznik, have any clarifying questions.

We will continue to call each of our in-person presenters one after the other. This should take us some time to just about before the noon hour. We will take a recess, and begin our afternoon session at 12:40, where we will hear from as many as 17 virtual presenters.

I will call virtual Commenter No. 1, and the individual's image will be cast onto the screen up here on the stage.

I will ask our virtual commenters to, again, state their name and affiliation, and again, ask them to spell their first and last name. Once we've heard from all virtual presenters we will wrap up day one.

Okay. So now onto a couple little ground rules and housekeeping matters. 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, if there are comments that stray substantially from the scope of our rulemaking, I will politely interrupt the presentation, and ask you to keep your comments related 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 that visitors be escorted. So if you need to use the facilities, please exit the door in the rear of the auditorium. There will be DEA staff at the door to escort you around the corner to the facilities.

If you need to leave the building maybe for a quick bite at our session -- in between sessions, please know that you will have to return through the visitors entrance that you came into this morning.

Also for our folks in the audience, much like the DEA is in listening mode, we ask that you stay so as well. There are, unfortunately, no opportunities for questions and answers as part of this event, 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 us virtually.

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

Second to last point, if an audience in the unforeseeable situation where we have an audience member who is disruptive, as moderator I will ask our security team to escort you out of the building. We don't anticipate that happening, but I just want to say it for the sake of clarity.

Last point, and 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 normal 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.

Okay. That's the end of my remarks, and I think it's time for us to get started, so I will now invite Commenter 1 to step up to the podium. And again, as a friendly reminder, please spell your first and last name, and state your affiliation.

MS. KRAYN: Hey, everyone. My name is Robert Krayn, R-O-B-E-R-T, K-R-A-Y-N. I'm the cofounder and CEO of Talkiatry.

Administrator Milgram, I'd love the opportunity to shake your hand quickly before I get started.

Talkiatry is a nationwide psychiatry group. We directly employ over 300 Board-certified psychiatrists across the country. We employ five nurse practitioners, all of whom are Board-certified in psychiatric mental health. We treat hundreds of thousands of patients annually.

The average cost per visit for a Talkiatry patient is on average less than $30. We operate at the pinnacle of quality. Each psychiatrist is directly overseen by a chief psychiatrist, who spends 90 percent of their time on administrative duties. They oversee a cohort of no more than 50 doctors at a time.

We have been accredited to issue continuing medical education much like a large academic institution or health system. We partner with every major insurer in the country, including Medicare, to off expand access to care on an in-network basis.

I would also like to introduce my cofounder,

and Talkiatry's Chief Medical Officer, Dr. Georgia Gaveras.

Let me be clear, we have no subscription fees, we have no pharmacy affiliations, and we see our patients on average once per month for 30 minutes.

MS. GAVERAS: Hi. I'm Georgia Gaveras, G-E-O-R-G-I-A, G-A-V-E-R-A-S.

So I want to talk a little bit more about what I do just so you can understand why I'm up here with Robert. I'm a triple Board-certified psychiatrist. I'm Board-certified in child and adolescent, in addition to general psychiatry.

And I'm also an addiction medicine specialist, so I'm Board-certified in addiction medicine. So my clinical career before starting Talkiatry with Robert was treating teenagers with substance use disorders in addition to psychiatric disorders.

I was the Director of Training and Education in Child and Adolescent Psychiatry, and I ran the two emergency rooms, mostly notably the one in Kings County Hospital in Brooklyn, and if you know Kings County Hospital in Brooklyn, it's a very, very busy emergency room with a lot of substance use disorders, and children.

I've also had a long academic career as well, which I'll spare you the details. Robert?

MS. KRAYN: Listen, I think that you're going to be hearing from a lot of people today, and they're going to be asking for a lot of things. They're going to be asking for access; they're going to be asking for no limitations, and they're going to be asking for less restrictions, all of which, I think, are valid requests.

But what I think you won't hear is you won't hear a lot of specifics. You won't hear the hard stuff, the guardrails, the specific framework for how this can actually be put into operation. You won't hear who can prescribe what medications, and for what. What number of medications are they allowed to prescribe.

These are the things that I think the DEA asked us here to present, and provide data behind why we're presenting these specific guardrails. And that's exactly what Georgia and I are going to do here today.

We stand before you representing some of the highest quality Telepsychiatry practices in the United States: Talkiatry, CORE Telehealth, and Inova Telepsychiatry, ERA Behavioral Care, and Iris Telehealth, some of which are also speaking today.

Together we directly employ over 1,600 clinicians, and we treat over one million patients annually. We have worked with practitioners of all types, and all care settings, to balance safety, diversion controls, and expansion to access of care.

We've created a joint recommendation, and we've spoken to a lot of other associations to get their input, including the American Telemedicine Association, the American Academy of Child and Adolescent Psychiatry, the American Psychiatric Association, and the American Hospital Association.

Before I get into specifics, let me provide some background. In 2016 I was the subject of a brutal home invasion. A friend suggested I go and speak to someone. Their wife is a psychiatrist. In the largest city in our country, with the most number of psychiatrists, I couldn't find anybody.

You email 20 doctors, and whoever responds is the doctor you go and see. It's a very high likelihood that that's not the right doctor for you, and an even higher likelihood that you're not the right patient for that doctor.

For me it was a basement office with eight doorbells on the side of the wall with tape underneath each one. I assume it's linked to a bell in a

doctor's office to let them know I'm here. In person visits do not equal quality care.

The Flexibilities that Administrator Milgram has afforded America over the last three years have fundamentally changed access for millions of Americans. You should be incredibly honored and proud of the work that your team has done.

Make no doubt, we're on the precipice of history. I say we. I'm including myself in that. And I think that we have the opportunity to resolve a special registration process under this Administration that's been evading multiple Administrations for decades.

MS. GAVERAS: So I want to talk a little bit about quality because I think that's where -- when we talk about in-person we look at what's the quality of the medical care. At Talkiatry we're honored actually to have been selected by the Department of Health and Human Services to provide psychiatric care to migrant children in desperate need while they're here in the United States.

We also work with large organizations such as HCA, one of the largest hospital associations, and NYU Langone, who have selected us to be their partner providing psychiatric care to patients they need to

refer.

We've done studies of our patients. We're running a little short, so I won't go into details, but we've shown significant reductions in symptoms purely by a means of Telepsychiatry.

Our studies are not yet published, but they will be, where we have thousands of patients we've reviewed. We've reviewed their symptoms. We've done evidence-based research on the treatment via telemedicine, and we've shown incredible reductions in their anxiety and depression.

When it comes to ADHD, I think that's really the hot topic when it comes to controlled substances. We found that patients that came to us with the chief complaint of ADHD only 40 percent after psychiatric evaluation were actually diagnosed with ADHD.

I think what happens a lot of times is a patient will come to us saying I have ADHD when they're really saying I have attention problems, and what it really takes, again going into quality, is of somebody that knows what ADHD is, what psychiatric illnesses are, to evaluate them, and really to determine is this ADHD, and then treat them appropriately.

About 25 percent of patients that we have

seen who we have diagnosed with ADHD are actually successfully treated with medications that don't fall under the controlled substance umbrella, and we're able to do that successfully.

For people on controlled substances we've also shown significant reductions over time in the prescriptions, and even discontinuation of treatment for patients. These medications are an important part of psychiatric care, and have evidence-based and FDA-approved uses.

MS. KRAYN: Now, onto the proposal we're here to share with you today with the limited time that we have remaining.

We propose two paths for the DEA to allow the prescription of controlled substances. One, the existing registration, including the proposed notice of proposed rulemaking that was issued on March 1st, 2023, to allow a path for referrals.

And second, the one we're actually here to discuss, a new special registration which will allow qualified practitioners to prescribe Schedule II-N nonnarcotic III, IV, and V medications via telemedicine without an in-person visit or a referral. This predominantly impacts large provider groups that see patients exclusively, or predominantly via

telemedicine without an in-person evaluation.

We will propose exemptions from certain requirements for A, providers at not-for-profit organizations, for those at hospitals for profit and not-for-profit, and for Buprenorphine prescriptions.

Some overarching points before we get into the nuance. So long as a practitioner holds at least one DEA registration in any state only one special registration will be required to prescribe controlled substances in all 50 states, D.C., and its territories. Providers would not need a separate registration for each state where they practice; only a medical license in that state.

Providers would not be required to maintain a physical location, or to physically store records in each state where they practice. Providers can store records electronically in common spreadsheet formats, or certified electronic medical records.

And lastly, providers can prescribe controlled substances under the authority of the DEA registration, or the special registration, depending on the setting in which the care they treat the patient.

MS. GAVERAS: And some other specific guardrails that come out of clinical experience in

discussion with our very extensive clinical team. We believe that requiring providers to evaluate the patient at least once every 90 days to continue to provide controlled substances is adequate. For controlled prescriptions, prohibit telemedicine practitioners from requiring, recommending, referring, or suggesting a patient utilize a specific pharmacy unless the patient requests a recommendation for a pharmacy.

Another guardrail we propose is excluding Ketamine from the list of medications that could be prescribed under this special registration. Already the intranasal formulation of this Ketamine requires observation by a healthcare professional during its administration. And we also believe that the at-home prescribing of a substance that does have huge promise for depression also has very significant diversion risks, and we believe that it should be regulated further.

We also recommend to limit Schedule II and II-N nonnarcotic medications, and as far as we're concerned, to the treatment of psychiatric diagnoses, and require prescribers to satisfy one of the following: either be a physician, and when it comes to -- we're talking about psychiatric medications, a

physician, a certified nurse practitioner with Board-certification in psychiatric or mental health from the American Nurses Credentialing Center, a P.A. with a certification qualification in psychiatry from the National Commission of Certification of Physician Assistants, or complete state licensing medical board medical education on specifically the diagnosis and treatment of ADHD.

MS. KRAYN: And there was just a couple more. We also propose an exemption for hospitals, and things like that, but I feel like there's some additional folks in this room who can speak to that.

We also believe that for entities that aren't not-for-profits, or hospitals, or prescribing Buprenorphine, we believe that a limit on the number of prescriptions that can be prescribed in terms of controlled substances may be appropriate. Our proposed limit is 275 patients at a time, or 500 prescriptions in one month.

With our background we believe that our doctors, the largest number of controlled substance prescriptions that anyone of them has ever written in a month is about 320, and the most patients that any of our doctors have ever actively had on a controlled substance is 220. And so we believe these limits are

appropriate, and these are predominantly psychiatrists who treat children, or treating military veterans, for example, and it can be done in a high-quality way.

We also believe that there are some data reporting requirements that are really needed to ensure that the DEA has the information needed to go after and stop diversion before it starts, and we propose supplying to the DEA on a quarterly basis the prescriber DEA registration number; healthcare entity the prescription was affiliated with, for example, Talkiatry; the name of the drugs prescribed; the number of prescriptions for each drug, and the date of prescriptions.

It's important to note that the data reporting requirements in patient limitations in our proposal would not apply for hospitals, for profit, or not-for-profit, or for doctors who are seeing patients in a not-for-profit setting, or prescribing Buprenorphine. So any of those restrictions I just mentioned on those two things would be excluded in that framework.

That concludes our remarks today, but if there's any questions, we would be happy to take them from a clarification standpoint.

MS. MILGRAM: So thank you on that for your

presentation. Sorry. Sorry. Thank you for your presentation. I really appreciate it. And as Matt said, we're only able to ask clarifying questions, so just a couple of quick clarifying questions.

Who is conducting the studies? You mentioned some studies of your work.

MS. GAVERAS: Yeah. We analyzed our data from our patients. So we have a National Director of Clinical Quality, who is a physician. She's a psychiatrist. She is the one that ran the study, and it's an IRB-approved study.

MS. MILGRAM: If you'd be comfortable sharing any of that with us.

MS. GAVERAS: Sure.

MS. MILGRAM: And obviously I know it's not done, but we always like to see --

MS. KRAYN: Of course. Yeah.

MS. GAVERAS: Sure.

MS. MILGRAM: -- that kind of information. It's very helpful.

MS. GAVERAS: It's the Government, I'll tell you.

MS. MILGRAM: Thank you. Can you tell us a little bit about your payment model?

MS. KRAYN: Yeah. So we're entirely in

network, so we do not have any subscription-based models, fees. It's just like any other doctor. You come to Talkiatry, and we have a contract with your I insurance company, or with Medicare, or in this case actually with HHS for migrant children, and we will go ahead and bill them a contractually-obligated rate. And so it's in accordance with your insurance plan, so deductibles, coinsurance, just like a primary care physician.

MS. MILGRAM: And could you just expand a little bit on why you don't think that hospitals or nonprofits should have to have data requirements?

MS. KRAYN: Yeah. I mean, I think that they have limited resources, specifically on the not-for-profit side. And I think that when you look at the potential for diversion it really stems from people who are gaining a profit from making the prescriptions, and a lot of not-for-profits it's just simply not the case.

It's also understandable that creating a regulation that applies to everyone makes sense, but I think that I'd be remiss if I stood here and said that a not-for-profit has the same resources as Talkiatry.

The data reporting requirements are cumbersome. They are not as easy as they might sound.

Certain doctors who work at multiple not-for-profit organizations treating many patients, those records are scattered everywhere. They do not have the money, the resources, or the technology know-how to a certain extent to make this an easily reportable component.

I think Buprenorphine, for example, should be treated separately just because of the Opioid crisis if you will, and we just got rid of the ex-waiver right, so adding those pieces of information back might not be appropriate, but I think, we learn something good that it could be valuable.

And so people like Talkiatry, who operate on the for-profit space, is happy to take on that burden, and report that information up front to the DEA so that you guys have everything that you need to spot diversion, or spot trends, and go in and take a look at it. We've got absolutely nothing to hide, but we also have more resources than other folks.

MS. MILGRAM: Thank you so much.

MS. GAVERAS: I have the information now if you want, the data points.

MS. KRAYN: Yeah. The information that you asked for.

MS. MILGRAM: Thank you.

MS. GAVERAS: So the study that we did our

end was 1,800 patients over a median treatment length of 96 days, and the median number of visits was five visits. Over this period 26 percent of patients in this study who came with either moderate or severe anxiety no longer showed symptoms, and 51 percent had a greater than 50 percent reduction in symptoms. 28 percent of the patients in this study who came with moderate or severe depression no longer showed symptoms, and 53 percent had a 50 percent or greater improvement in their symptoms, and all this was 100 percent telemedicine.

Thank you, guys, very much.

(Applause.)

MR. STRAIT: Okay. I'd like to next invite Commenter No. 2 to the stage.

MS. KHAN: Good morning. I'm Shabana Khan, S-H-A-B-A-N-A, last name Khan, K-H-A-N. I'm a physician that specializes in child, adolescent, and adult psychiatry, and I'm speaking on behalf of the American Psychiatric Association, and the American Academy of Child and Adolescent Psychiatry.

I'm an assistant professor and Director of Telehealth for the Department of Child and Adolescent Psychiatry at NYU Langone Health of the NYU Grossman School of Medicine. I chaired the Telepsychiatry

Committee of the American Psychiatric Association, and I cochair the Telepsychiatry Committee of the American Academy of Child and Adolescent Psychiatry.

The American Psychiatric Association, APA, and American Academy of Child and Adolescent Psychiatry, ACAP, really appreciate DEA'S time in conducting this listening session, and we welcome the opportunity to collaborate with the DEA on our mutual goals of ensuring access to care, preventing diversion, and promoting public health.

APA is a national medical specialty society that represents over 38,000 psychiatric physicians and their patients, and ACAP represents 10,000 child and adolescent psychiatric physicians, many of whom treat adults and transitional age youth age 18 and above.

We understand that the DEA has renewed interest in exploring the public safety of the legitimate prescribing of controlled substances through telemedicine, as well as a potential special registration as an avenue to expand access to clinically appropriate remote prescribing of controlled substances.

Our recommendations focus on balancing commonsense safeguards for DEA enforcement of legitimate controlled substance prescribing without

decreasing access to lifesaving treatments.

First, to provide some perspective on psychiatric practice as it relates to telemedicine prescribing. In a survey of psychiatrists that was conducted by the APA in April and May 2023, 97 percent of the over 1,600 respondents noted that they conduct telemedicine visits.

Most clinicians maintain a physical practice location where they're capable of seeing patients as-needed, but many do not have any physical locations in every state in which they carry a medical license, and currently can see patients.

Respondents report medical necessity is the primary factor determining their clinical decisions, and they see the lack of clarity around telemedicine regulations as the primary barrier to the ability to serve their patients. Many particularly noted restrictions around controlled substance prescribing both at the federal and state level.

Respondents appreciate the opportunity to use telemedicine to serve their patients with health-related social needs, including mobility, transportation, childcare, and other caregiving barriers that prevent them from traveling to psychiatric appointments, especially in the 55 percent

of U.S. counties that have no psychiatrist, and 70 percent of U.S. counties that have no practicing child psychiatrist.

As DEA has heard in APA and ACAP's comments to their 2023 proposed rules, telemedicine has not been shown to increase diversion, decreases no-show rates, and increases access to care. Prescribing practitioners are able to accommodate social determinants of health and other barriers to in-person care, such as employment hours, family care situations, stigma, violence, reducing flexibility in modalities of care, increases in equity, forcing practitioners to cherry-pick patients that have the ability to travel to in-person care.

Rather than a mandatory blanket requirement, the need for an in-person examination of a patient really should be left to the clinical discretion of a practitioner who has the knowledge, skills, and experience to make that decision.

I've been practicing telemedicine for over a decade, and I'd like to describe what a typical initial telemedicine visit that may result in appropriate prescribing of a controlled medication would look like. For example, a child, adolescent, or adult diagnosed with ADHD who may be prescribed a

stimulant.

Similar to in-person care, the identity of a patient seen by telemedicine is verified. Appropriate consents for treatment may be obtained as required by state payer or organization rules.

The patient's location is confirmed as the general rule is that a practitioner is licensed where the patient is at the time of the visit; the practitioner has obtained a DEA registration; the practitioner is registered with the patient's state's prescription drug monitoring program, the PDMP; the practitioner insures malpractice coverage for the care that's being provided; a thorough clinical assessment is completed through telemedicine, just as it would be in person; all the clinical data needed to properly assess and diagnose a patient is obtained before a treatment plan is developed.

If the clinical assessment indicates that the patient may benefit from the prescription of a controlled medicine, it's prescribed for a legitimate medical purpose, and within the usual course of practice, and scope of practice of the telemedicine practitioner.

Prescribing is not based solely on an online questionnaire, so it's a thorough clinical assessment

just like we would do in person. Relevant assessments are completed, and data such as vital sign measurements as-needed can be obtained for a telemedicine visit, just as they are in person.

We can conduct a complete mental status examination via video. We can assess for potential side effects of the medications we prescribe; home monitoring devices can be used to obtain vital signs like blood pressure, heart rate, weight. If needed, we can also collaborate with primary care doctors, school nurses, and other clinicians locally to ensure that we have all the information that we need, and the necessary data is obtained for an assessment.

Safety protocols are outlined prior to initiating services. So for example, what steps will be taken if a crisis or safety issue arises, or if there's a technology failure during the telemedicine visit.

Whether care is provided in person or through telemedicine there are already the existing processes and requirements I described that provide a high level of oversight, and accountability of prescribing practices.

Along with these existing requirements a telemedicine special registration could allow

practitioners to affirm their adherence to the processes, along with additional key elements, including having a plan in place if a patient may need to be assessed in person at some point.

The special registration potentially would allow care to be completely remote, but if a patient needed to be assessed in person, what would be the plan; whether the telemedicine practitioner could see them in person, that may not always be feasible, or they can collaborate with other clinicians locally who are not necessarily DEA-registered. But they possess the capability to capture and convey necessary physiologic data as-needed to make appropriate clinical decisions.

Required checks of the PDMP, the prescription drug monitoring program. While this is already required in most states, clinicians would need to be able to access the PDMP in any state in which their patient is located.

PDMP access data in time could be included in the notes section of their prescription. Improved interoperability of the PDMPs across states would be helpful, so that practitioners can access PDMPs across states should -- the data from PDMPs should be shared across states, and that should be a policy commitment

across federal agencies.

Required reporting by pharmacists, other medical practitioners, or organizations. If prescribers have a pattern of high-risk prescriptions based upon the pharmacists or other providers check of the PDMP defined as prescribing multiple scripts of higher dosages than are recommended by clinical guidelines, and/or duplicate prescriptions from multiple providers for the same medication. Reports would trigger an investigation, which may not result in penalty or enforcement action.

One caveat there is that, let's say, you have a specialist that specializes in a condition diagnosis where controlled medicines are commonly prescribed. They may have elevated rates that are appropriate, but elevated rates of prescribing, so that's just something to keep in mind there.

The special registration should not be limited to a particular diagnosis or a condition. In the longer term we believe that DEA should enhance collaboration with healthcare agencies to integrate data sources, and develop better algorithms, and access to identify bad actors.

DEA should convene clinical subject matter experts to the subspecialty level to develop

appropriate enforcement frameworks by Subspecialty patient population, and other clinical considerations. Any DEA audits should also incorporate appropriate clinical expertise to assess appropriate prescribing practices.

DEA should also work with federal health agencies and state PDMPs to create a national database for PDMPs, and electronic prescribing of controlled substances, EPCS, data for population-level monitoring and enforcement.

A national special registration we believe should not require a physical location in each state as this would more closely mirror the current process for state medical licenses.

Medical licensure should continue to be required for DEA licensure in that state. The special registration could require reporting of the prescriber's employer to hold telemedicine employers accountable as necessary.

Registration should also document the states in which the clinician is licensed, registered, and plans to practice telemedicine.

Registration can also collect key considerations for the practitioners telemedicine practice, including the patient population, or

conditions that they typically serve. In applying for a national special registration the prescriber would be agreeing to additional accountability and oversight by the DEA.

To respond directly to DEA'S existing proposals in March 2023, the 30-day initiation period would not be adequate given the current wait times, given the shortages as I mentioned, 70 percent of counties with no child psychiatrist; 55 percent with no psychiatrist, would not be adequate for evidence-based medicine.

Notating prescriptions as telemedicine increases pharmacists' hesitancy to fill the medications without good reason. We are already finding this in our practice, so adding that telemedicine indication on there could potentially make it even more difficult for our patients to access care.

Schedule II-N should be carved into all new allowances as high quality assessment and care can be done virtually in the same way as they are done for other controlled medicines using clinical discretion.

I do worry that if the proposed rules are finalized, and they are very restrictive, just as an example, child psychiatrists may choose not to provide

telemedicine into these communities that don't have care. So now we're not only limiting access to ADHD treatment, but we're limiting access to all psychiatric care in the context of our current mental health crisis.

On a practical note, practices and clinicians are already scheduling several months out for appointments. If the DEA waits to issue updated rules much longer, there is a risk of disruption of an abrupt severing of patient care.

Our recommendations reflect a shared commitment across mental health services to providing evidence-based, high quality, equitable care that uses every tool in our toolbox to address the opioid and the mental health crises in our country.

Thank you for your consideration of these comments.

MS. MILGRAM: Just a couple of quick sort of follow-up --

MS. KHAN: Sure.

MS. MILGRAM: -- expansion questions. You talked about the clinical data that you collect as part of -- when you gave the example of a telehealth patient experience that you have.

Can you just say -- expand on what that

clinical data looks like that you would be collecting in your sort of average telemed?

MS. KHAN: Absolutely. So, if I am seeing a child or adult who may have the diagnosis of ADHD and a stimulant medicine is clinically indicated, we measure vitals, such as blood pressure, heart rate, height, weight periodically particularly for children and adolescents. If the patient during the telemedicine visit is home, then we can use home monitoring devices and provide guidance to the patient on how to accurately check. There is the option of also working with school nurses to collect that data or primary care doctor, pediatricians. So we just have to get a little creative. But, if there were any reason why we thought that we didn't have the information that we needed before prescribing a medicine, we would have a plan in advance of whether we don't prescribe or have the patient go in to see someone locally to get more information.

And then, if -- since most situations we have electronic prescribing of controlled substances, there's data that's automated that's already tracked in terms of number of prescriptions, dosages, pharmacies where they were filled, that interoperability among PDMPs across states would be

very, very helpful. I know New York. There are only a certain number of states that I can check, but there are many that I don't have access to. And then, with electronic medical records as well, there's a lot of data from a payor perspective, certain clinical items that we track and that we document.

MS. MILGRAM: Great. Just one more follow-up. You talked about following clinical guidelines on prescribing. What do you use for ADHD now?

MS. KHAN: The American Academy of Child and Adolescent Psychiatry has practice guidelines for assessment and treatment of ADHD, so that would be one of the guidelines that we would use.

MS. MILGRAM: How about for adults? Do you have the same?

MS. KHAN: American Psychiatric Association as well.

MS. MILGRAM: Thank you.

Tom?

MR. PREVOZNIK: Yeah. Could you please explain how you verify the identity? I know you mentioned, like, you confirm the address and things, but could you actually walk me through step by step how you identify that that is the patient and then do

you -- how do you assess that that is the patient the next time you see him?

MS. KHAN: Sure.

MR. PREVOZNIK: I know we're talking children, but I'm just trying to get --

MS. KHAN: Yeah.

MR. PREVOZNIK: -- a better understanding of that.

MS. KHAN: So it would vary by practice. Some practices may get a copy of the patient's state ID or federal ID. Some patients -- some practices may use biometric screening as well to verify patient identity, so it would vary. We would -- in my practice, we are collecting data, getting an ID verification.

MR. PREVOZNIK: Okay. And how -- what do you do about the address? How do you verify that?

MS. KHAN: So it would be on the ID or a patient would self-report their address as well.

MR. PREVOZNIK: Okay. So -- but you're not doing any other check to ensure that that's the -- that's all -- I'm just trying to clarify that. Okay. Thank you.

MS. MILGRAM: Thank you.

MS. KHAN: Thank you.

(Applause.)

MR. STRAIT: Okay. We will now proceed to Commenter No. 3.

MR. HOFFMAN: Good morning. Let's step back from ADHD for a moment and talk about pain. When Congress passed the Food, Drug & Cosmetics Act in 1932, they could not have been contemplating restriction on access to pain medication for terminally ill patients, and neither should the DEA. I appear before you today to urge the DEA --

MR. STRAIT: May I ask you to state your name and affiliation? Sorry.

MR. HOFFMAN: Thank you. David Hoffman, D-A-V-I-D, H-O-F-F-M-A-N, Columbia University and the Completed Life Initiative.

MR. STRAIT: Thank you.

MR. HOFFMAN: I appear before you today to urge the Drug Enforcement Administration to acknowledge the dramatically different circumstances society confronts when regulating access to narcotic pain medication for terminally ill hospice patients versus the same medications for people with treatable chronic or acute pain conditions.

I'm here wearing several hats. I am an assistant professor of bio-ethics at Columbia

University, where I teach courses on law and bio-ethics and organizational ethics and compliance, among others. I also serve as a clinical ethics consultant for a large urban hospice organization and, importantly, for the purpose of today's discussion, as hospital counsel and compliance officer for a group of community hospitals in the rural northern-most part of New York State, where you can literally see Canada.

But most importantly, I am proud to be the Vice President and Secretary of the Board of the Completed Life Initiative, an advocacy organization dedicated to expanding access to the greatest range of services for patients at the end of their lives. That said, the opinions I express today are exclusively mine.

It is with these positions in mind that I urge the DEA to adopt a policy of bifurcation of its regulatory initiatives. Treating access to pain medication through telemedicine consultation for the terminally ill is a wholly different and unrelated circumstance than treating those who are non-terminal.

The causes of the opioid crisis we face are many. We all know that. The Sackler family and Purdue Pharma have significant responsibility, but so do the very well-meaning American Pain Society and

U.S. Veterans Administration, which in 1996 and 1999 respectively declared pain to be the fifth vital sign, very well intentioned, but that suggested to many that no one should experience untreated pain. The problems of overprescribing and diversion can be traced back to these and other triggers.

In end-of-life care, we often frame our discussions about care management in terms of missing the window of opportunity for a variety of interventions, including medical aid in dying and palliative care. Lack of access to a provider can cause that window to be missed.

In the case of terminally ill patients who lose the ability to travel, access to care can be impacted by their physical limitations and geographic location. The problem is particularly acute for patients transitioning, as so many patients do, from oncology care to palliative care.

Sadly, many oncologists I know do not consider themselves even qualified to manage pain at the end of life. For those patients in that circumstance, it is important that prescribing clinicians be afforded the respect and latitude to decide whether it is safe and appropriate to prescribe narcotic medication solely through the modality of

telemedicine consultation. This is especially urgent in rural areas because of the profound shortage of physicians generally and of pain management specialists in particular.

Medical education is, of course, not the responsibility of the DEA. I understand that. But, as part of its regulatory intervention, it must consider that this physician shortage is borne of the failure by medical education organizations and, indeed, the federal government to acknowledge and respond to the current physician shortage, which was publicly acknowledged by the American Association of Medical Colleges and the Accreditation Council on Graduate Medical Education at least as early as 2005. Rural hospitals need expansion of the number of residency slots, at least enough to keep up with the growth of the number of Americans in need of high-quality end-of-life care, including palliative care.

Now we know it's relatively easy to solve a single-variable equation. And if all the DEA had to be concerned about is elimination of opportunities for drug diversion, then the proposed ban on telemedicine for first prescribing of narcotics might make some sense. But the interests of patients in need of

relief from pain and suffering, particularly those patients with terminal illnesses and, therefore, limited ability to travel to doctor appointments, must be considered a strong balancing consideration by the DEA.

I therefore urge you to assess your responsibilities more broadly than simply limiting access to narcotics, grounding DEA policy instead in a broader view of its obligation to protect patient well-being, which is what the Food, Drug & Cosmetics Act requires. While more difficult than just focusing on diversion, it is nonetheless more responsible and humane.

Both goals can be achieved by using enhanced tracking of CPT codes for pain management of terminally ill patients and by expanding use of CPT code modifiers to create easier tracking of narcotic use by hospital patient -- by hospice patients, excuse me, and generation of exception reports from e-prescribing systems to detect multiple clinicians writing prescriptions for the same patient.

We have just incredible amounts of data locked up in all of our electronic medical record systems, more than enough information for DEA to be able to monitor and easily readily detect the presence

of overprescribing for patients experiencing end-of-life pain, such as is experienced by patients who have cancer conditions and are required to transition from their oncologist to a pain management specialist if they can find one.

There's no question drug diversion is a real problem, particularly in rural areas, but the solution should not come at the expense of patients who want to squeeze out every possible day of comfort at the end of their lives. Thank you.

(Applause.)

MS. MILGRAM: Can I -- I'm sorry -- can I ask you just a follow-up?

MR. HOFFMAN: Absolutely.

MS. MILGRAM: In your recommendation, you talked about enhanced tracking of CPT codes and expand some of the CPT code modifications. Could you expand on all those recommendations?

MR. HOFFMAN: Absolutely. The billing methodology for healthcare services is elaborate, would be a polite way of describing it, but it provides many useful tools, and the CPT codes tied to hospice care and pain management more generally are useful for keeping track of which patients are at the end of life.

We have the opportunity to add modifiers so that a clinician could clearly identify a patient who transitioned from oncology care to palliative pain management care so that you could, in effect, remove them from the set of clinical encounters that you need to be most concerned about from a diversion perspective. You asked one of the earlier speakers about the availability of data to identify who is getting what modality of care, even within either treatment for ADHD or pain or any number of other conditions.

We can create CPT code modifiers that will specifically identify, for example, patients who were under the care of an oncologist and then transitioned to the care provided by a palliative care or a pain management specialist so that, again, you would be able to identify those circumstances where a first encounter with a clinician prescribing narcotics wasn't, as you described earlier, Administrator Milgram, the circumstance where someone out of nowhere seeks a prescription from an online resource where they have no contact, no prior involvement, no introduction by a clinician, we will be able to identify for your easy access the circumstance where a patient was being treated by an oncologist often for

months or years in person. That oncologist was no longer comfortable managing that patient's care because there was no longer any curative care possible and that patient, at the most vulnerable and often most burdened moment in their lives, is scrambling to find someone to find pain medication.

And those people are incredibly hard to find, especially in rural areas, so that we have pain management specialists who of necessity are managing hundreds and hundreds of patients because we are in this odd moment in the baby boom -- and I can talk about the baby boom because I'm part of it at the very tail end -- we have doctors retiring from practice just as people of their age are showing up in record numbers looking for cancer care and end-of-life care, and we have fewer and fewer people to take care of them.

I don't expect you to solve the problem of the physician shortage. I do ask that you acknowledge that it is part of the challenge we face in the clinical community and do what you can to write regulations that are sensitive to that particular circumstance.

MR. PREVOZNIK: Yeah, could you just expand a little bit on the consultation?

MR. HOFFMAN: Right. So, when a patient is finishing up some other course of treatment for an acute or chronic condition, including conditions that wind up being terminal, we can arrange a handoff from that clinician who's providing curative care, whether that's a physician, nurse practitioner, PA, clinical psychologist, any other professional, to a virtual prescriber for pain management and other palliative care services without the necessity of a patient at the end of life who may be in their living room in a hospital bed having to physically travel to that alternate provider.

The consultation can, because of the quite remarkable capabilities of electronic medical records, involve the transfer of treatment records. The key is that we need people who are willing and able to prescribe pain medication that in a patient who has an acute treatable or chronic condition might be problematic from a diversion perspective. I think, when we have these controls in place and when we are utilizing the CPT code and modifier data sets to track these consultations, we can provide substantial assurance on the provider clinician side, doctors and hospitals and nurse practitioners, that there is a warm handoff, albeit a virtual warm handoff.

MR. PREVOZNIK: Thank you.

(Applause.)

MR. STRAIT: Okay. I'm inviting now Commenter No. 4. Thank you.

MR. ZEBLEY: Administrator, Assistant Administrator, my name is Kyle Zebley, K-Y-L-E, Z-E-B-L-E-Y. I serve as Senior Vice President of Public Policy for the American Telemedicine Association, also known as ATA, and Executive Director of ATA Action, which is the ATA's affiliated trade association focused on advocacy.

We advance policy to ensure all individuals have permanent access to telehealth services across the care continuum, and we represent a broad coalition of healthcare providers in over 400 organizations. It is a guiding principle of the ATA that telehealth is health, and healthcare practice should be regulated on a level playing field regardless of whether in person or virtual and regardless of virtual platform.

We have submitted a very comprehensive letter to the DEA in advance of this meeting just last week and which is available to the public on the ATA's website summarizing our recommendations in detail regarding a special registration process for the remote prescribing of controlled substances, and my

testimony today will summarize those recommendations we shared last week.

We appreciate DEA's responsibility to write rules that provide effective controls against diversion and protect public health and safety, but we believe that a requirement that a patient see a clinician in person is not an effective control against diversion and instead simply limits access to legitimate healthcare.

During the COVID-19 public health emergency, DEA has used its emergency authority to waive the prior in-person requirement. This has enabled providers to safely prescribe controlled substances remotely using telemedicine, increasing access to clinically appropriate medications.

After the initial experience of the pandemic, a report found that over 70 percent of providers surveyed reported that telehealth made patient continuity of care better or much better and that overall level of care provided via telehealth was better or equal to that of in-person care.

We cite additional research regarding the effectiveness of telehealth services for different conditions in our letter and, of course, are happy to work with DEA to provide further available clinical

research.

Mandating an in-person evaluation prior to prescribing a controlled substance via telemedicine only results in reduced access to care and does not enhance DEA's ability to do its job of limiting drug diversion or pursuing illegal actors.

Every state allows a clinician and a patient to establish a valid patient-provider relationship via telehealth, and that relationship is just as legitimate as one established in person.

While in-person requirements may be intended to reduce diversion and illegal activity, they will likely, in fact, do the opposite. As access to legitimate healthcare is restricted, illegal online drug sellers will fill the void.

We urge DEA to reject the notion that an in-person visit is necessary prior to a telemedicine visit and instead pursue other mechanisms to prevent inappropriate access to medication via the internet.

And now I'll just do some recommendations that will lay out how the DEA can do that, and we will turn to our recommendations regarding a special registration process for telemedicine. And we really do so appreciate, as everybody in this room and everybody watching online does, DEA's consideration of

public input on the best approach.

We believe that if implemented without undue burden or restrictions on providers, a special registration process can be an appropriate mechanism for DEA to fulfill its mission of preventing diversion while allowing legitimate telemedicine to occur.

ATA Action urges DEA to consider two principles when regulating telemedicine prescribing of controlled substances. One, clinical practice should not be limited by non-clinical decision makers, and, two, telehealth is not a type of care but a modality of care. Rules should take into account the unique nature of the use of technology as a modality without arbitrarily restricting its use.

ATA Action's recommendations for DEA for a special registration process include seven tenets, which I'll spend the remainder of my time describing.

First, the special registration process should work in conjunction with the existing registration processes. We recommend special registration should be an optional supplemental form associated with the existing registration process and should result in a modifier on a practitioner's DEA number, such as a T at the end, to indicate that the provider has a special telemedicine registration.

Second, telemedicine providers should not be required to maintain local addresses in every state where they practice. The value of telemedicine by nature is only fully captured through the ability to practice across state lines. Providers are already required to obtain state licenses and authority in the states where they practice. Thus, many telehealth providers hold multiple state licenses.

However, the most significant limiting factor to a multistate practice and the most counterintuitive is the requirement to have a physical location in every state where you practice. Having a physical location in each state defeats the purpose of serving patients remotely. Medical boards do not require physicians to have an in-state brick-and-mortar address in order to obtain a medical license, and the DEA should follow suit with the same approach in the special registration process for applicants with multistate telemedicine footprints.

Third, special registration should include the elements DEA needs to monitor for illegitimate practitioners and illegal prescribing practices. We outline specific elements that DEA could require in a special registration, including business information, state authority to practice, and attestations that DEA

could ask of providers.

Fourth, special registration should not be limited to any specific specialty or treatment condition. Schedule II prescribing could involve additional oversight but should not have additional restrictions.

Clinical judgment should be left to the clinician. There are not distinctions for prescribing of controlled substances for different conditions or treatments for in-person providers, nor should there be for telemedicine providers.

However, we do, of course, understand that Schedule II medications are classified as more dangerous than Schedule III through V and recognize DEA's interest in particularly limiting diversion of these medications. Therefore, we recommend the same general special registration process for all Schedule III through V medications but with some additional information required on the same form of registrants who indicate interest in prescribing Schedule II medications.

Fifth, dispensers. Pharmacies and pharmacists should be able to identify legitimate prescribers who have a current special registration. When a pharmacist receives a prescription from a

provider who has an active DEA special registration for telemedicine, they should have confidence that if the prescription originating from a geographic location that is not near the pharmacy or near the patient, that it is not a red flag. A part of the purpose of telehealth is to reach patients that are not in the provider's geographic area. We recommend that DEA make clear that the addition of the T modifier to the registration number should explicitly indicate to the pharmacist that geographic red flags should not be considered.

Sixth, the location of the patient should not require any registration. Patients should be able to receive telemedicine services from their home or any other location. Those locations where the patient is during the visit should not be required to have any controlled substances authority. The prescriber prescribing the controlled substance and the dispenser dispensing it should have the controlled substances authority, not the location of the patient, when they see the prescriber remotely.

And, finally, the special registration process should not place any arbitrary limits on a clinician's ability to practice within the scope of their authority. Prescribers should not be limited to

treating an arbitrary number of patients in our perspective. They should not be limited to issuing prescriptions for an arbitrary time period. DEA should not arbitrarily limit which clinician types have which authorities or privileges, and prescriptions should not be limited to FDA-approved indications as off-label use of medications is legal and, of course, common.

Thank you for the opportunity to provide comments today. We urge the DEA to consider realistic timelines when implementing these new processes. We note that if DEA proposes a new rule regarding special registration that the current pandemic flexibility should be extended beyond November 11 to ensure care is not interrupted.

We emphasize that following a final rule DEA should allow adequate time for the healthcare community to accommodate new clinical and administrative procedures and update systems. We look forward to providing further feedback on our recommendations and otherwise assisting in this process.

On behalf of the entire telehealth community and our patients that those in the telehealth community are serving, we thank you so much.

(Applause.)

MR. PREVOZNIK: Yeah, just to follow up on you mentioned that the registration, keeping the same registration process that we have, but we could add additional questions to those that are interested in Schedule II.

MR. ZEBLEY: That's right.

MR. PREVOZNIK: Could you be a little more specific on what you're suggesting that we might be asking?

MR. ZEBLEY: Well, I know, on existing DEA license forms, there is a clarifying question as to whether or not you will be prescribing Schedule II, and those have received higher scrutiny from our understanding from clinicians in the field. So modeled perhaps on that process of providing additional information as needed. It is in the letter, and we can definitely follow up with you on those specific questions.

MR. PREVOZNIK: Okay. Thank you.

MR. ZEBLEY: Thank you.

MR. STRAIT: Okay. Thank you very much. I will now invite Commenter No. 5.

DR. HUGHES: Good morning. My name is Dr. Helen Hughes, H-E-L-E-N, H-U-G-H-E-S. I am the

Medical Director for the Office of Telemedicine at Johns Hopkins Medicine. And I'm honored to be able to comment today.

In addition to my role as Medical Director of Telemedicine, I'm also Assistant Professor of Pediatrics in the Johns Hopkins University School of Medicine and a practicing pediatrician in east Baltimore.

It's my pleasure to comment today on telemedicine prescribing of controlled substances without an in-person medical evaluation. I'll be making the following three key points in my comments: First, there are many clinical situations which require telemedicine controlled substance prescribing without an in-person visit. Second, arbitrary one-time in-person evaluation requirements do not prevent abuse and diversion. And, third, the current proposed requirements will be operationally and technically burdensome to implement, especially for complex health systems like our own.

Johns Hopkins Medicine, headquartered in Baltimore, has seen a digital evolution in care delivery spurred by the pandemic. We had fewer than 800 total outpatient telehealth visits prior to the pandemic. We've had an Office of Telemedicine since

2016, and due to a number of barriers, it was very slow getting things off the ground. But, since March 2020, our providers have completed more than 1.8 million telehealth visits to over 470,000 unique patients. This care represents over half of our outpatient care during the early months of the pandemic and 13 percent of outpatient care over the last 12 months at our institution.

And this care spans a wide variety of specialities, from psychiatry, genetics, neurology, surgery, and oncology, and this rate has been steady over the past one-and-a-half years with about 30,000 visits per month, and we consider this to be our new normal.

Although we've seen telemedicine used across all specialties at our institution, we found it particularly impactful to increase access to mental healthcare. At Johns Hopkins Medicine, 65 percent of our outpatient psychiatry visits were conducted via telemedicine in 2022, and 40 percent of the provider-patient relationships in psychiatry were maintained exclusively via telemedicine over the past three years with no in-person visits.

Leveraging telemedicine in our view is the only realistic pathway to achieve the goals of

President Biden's mental health strategy seeking to connect more Americans to mental healthcare.

We feel strongly that the Drug Enforcement Agency should not interfere with reasonable clinical decision-making. Telemedicine controlled substance prescribing happens in a variety of settings across Johns Hopkins Medicine, often without a previous in-person encounter.

And I want to provide three specific examples from specialties across our institution. In child psychiatry, Adderall prescribed during an in-person second -- sorry, telemedicine prescribed in a second opinion ADHD telemedicine visit with a patient who lives in rural Maryland and cannot travel in person to Johns Hopkins. In neurology, anti-seizure medication prescribed in a telemedicine visit by a neurologist who is unanticipatedly covering while her clinical partner is out on maternity leave. In palliative care, opioids prescribed to a terminally ill patient receiving virtual palliative care services.

In each of these cases, the ability for these providers to prescribe controlled substances and to use their medical judgment over telemedicine without a prior in-person visit allows patients to

receive clinically appropriate essential care via a convenient and patient-centered modality.

And we strongly believe the in-person medical requirement should be removed in its entirety. While the proposed rule would prevent or limit prescribing in the above scenarios, it does nothing to prevent a provider who saw a patient one time in person even 10 years ago from recklessly providing controlled substances via either telemedicine or in-person care. And we've seen no evidence to suggest that telemedicine controlled substance prescribing over the past three years has led to patient harm or increased inappropriate prescribing.

We would support several alternatives or amendments to the current proposal. Our strong preference, as I stated, would be to remove any in-person requirement and to instead develop a streamlined telemedicine special registration that would allow the DEA to perform centralized recordkeeping, prescription checking, and data monitoring it needs to police prescribing practices and prevent drug diversion and abuse.

This special registration process, without other prescribing limitations, would provide an avenue for practitioners who are willing to make this extra

effort to complete a second application in order to provide the care they deem necessary for their patients when their patients need it.

If telemedicine prescribing of Schedule II medication is restricted as proposed, we recommend that DEA consider adding Schedule II non-opioids or to end the exception or to allow for treatment of mental health conditions, such as ADHD and other medical conditions. This would be particularly important, as has been previously mentioned, for pediatric populations, where there is an even more significant mental health workforce shortage that can be addressed through telemedicine.

The burdensome operational and recordkeeping requirements as proposed are not beneficial and difficult to the doctor-patient-pharmacy relationship which already relies heavily on IT interoperability, which can sometimes cause confusion.

Our electronic health record does not currently attach information to prescriptions regarding the modality of an originating encounter and the location of the provider or the location of the patient at the time of healthcare delivery.

At a minimum, for the safety of our clinicians, we recommend the DEA remove the

requirement of the practitioners to report their physical address during the telemedicine encounter, especially if the provider is located at home, which is a common practice location for our providers.

If any new prescription or recordkeeping requirements are implemented, healthcares and pharmacies should be given at least six months to a year after finalization to implement these operational and technically difficult requirements as many of them involve changes to our electronic health record and interoperability with pharmacies.

It's also unclear whether the proposed rule applies to a number of common prescribing scenarios. For instance, does the proposed rule apply and/or address refills obtained from telephone calls or electronic portal messaging? Does it apply to or address providers who may provide refills while on call or covering for someone else in their practice group? More time will allow us all to navigate these important questions together.

In summary, we truly appreciate the DEA's careful attention to this important matter. Telemedicine is now a routine care delivery tool for providers across the country and at our institution.

We support the use of tools to track,

analyze, and intervene in cases of inappropriate controlled substance prescribing both for telemedicine and for in-person care. However, we find that the proposed rule arbitrarily limits clinically appropriate care during telemedicine visits without addressing abuse and diversion.

Thank you so much for the opportunity to provide comment today, and we welcome any future collaboration and discussion.

MS. MILGRAM: Thank you so much.

(Applause.)

MS. MILGRAM: If I could just follow up and ask you to expand on you talked about a streamlined special registration with centralized registration, tracking of prescribers, and additional data tracking. Could you just go through each of those three and give a little more detail?

DR. HUGHES: Sure. We certainly support what Mr. Zebley and the ATA put forward earlier. We do not want to make this much more burdensome for our providers. We found at least with the cross-state licensure process that processes that are expensive and/or result in a lot of additional paperwork are difficult for our providers to keep up. So we would want whatever special registration process is

available to really sync up with the processes that providers are already doing for the DEA.

In terms of analyzing and data tracking, you know, through the prescription monitoring program, you know, in Maryland, we have CRISP, which is a state health record. I think anything we can do to have nationally available records of prescribing practices and to analyze those will be more impactful to catch those who are inappropriately prescribing than limits on needing to have an in-person visit first. I think that is -- was there one more?

MS. MILGRAM: You just talked a little bit about not expanding what doctors do beyond the DEA process. Can you talk a little bit about information that doctors already provide to payers that might be available here or used here?

DR. HUGHES: Well, I mean, claims data. So, certainly, at a Medicare level, I imagine Medicare would have a lot of information about prescriber practices.

For claims data for commercial insurers, I think it would be more complicated, but I think, for most states, there is sharing. I'm not sure on the technical, if that information comes from pharmacies or from payers. But I think the data do exist, and

the more there is interoperability through ONC and other groups, you know, I truly believe it is possible for us to understand at a national level some of these prescribing practices. Thanks very much.

MR. STRAIT: Thank you.

(Applause.)

MR. STRAIT: Okay. I will now invite Commenter No. 6 to the podium.

DR. CLEAR: Good morning. I'm Brian Clear, B-R-I-A-N, C-L-E-A-R, and I'm a family physician, addiction medicine specialist, and I'm Chief Medical Officer at Bicycle Health and speaking on behalf of the organization today.

I directed in-person OUD care programs for about five years prior to beginning telemedicine work with the onset of the COVID public health emergency. Through the flexibilities permitted by the waivers, at Bicycle, we've come to employ 80 addiction medicine specialist providers and treat over 11,000 patients with opioid use disorder across 37 states.

When I began this work in 2020, like most of our providers, I initially assumed that telemedicine would be limited compared to in-person care. In some ways, it is. But like all effective treatment settings, it also has advantages, and these have been

so significant. They've enabled us to expand access and improve outcomes in ways that have exceeded expectations from in-person experience.

We see a 90-day retention rate of 70 percent compared to in-person norms of about 50 percent. We're able to see and begin treatment for over two-thirds of new enrollees within 24 hours of their initial outreach. Nineteen out of 20 patients who begin care with us achieve their initial effective treatment dose within seven days, and 80 percent of our patient population completes a drug screen in any given month.

These outcomes would indicate an extraordinary program in any setting, and we've achieved them broadly at scale through telemedicine. So why are we initially skeptical of telemedicine in OUD care? We recently used a qualitative research design to survey our own provider team to find out, and we find common themes of initial hesitance around starting telemedicine work that come from the newness of the setting as it establishes credibility, regulatory uncertainty, and also from assumptions about who patients with OUD are, which leads to doubt about telemedicine's ability to serve them well.

This third hesitation comes from a common

misconception. If you look at a typical population of an in-person OUD care program, you might assume that the average person with opioid use disorder is unemployed, has few or no family obligations, has a high likelihood of being unsheltered, and has limited access to technology and perhaps little ability to use it reliably.

It would be wrong to extrapolate that to the larger OUD population. Traditional OUD care programs serve 10 percent of the population who need their services and tend to design their programs for the most severely affected 10 percent. As a result, the majority of those with opioid use disorder, even if there is a nearby in-person program, often don't access it either due to conflicting obligations or perception that the program is not intended for them.

Our survey results support that despite initial skepticism, after beginning telemedicine practice, our team feels effective and rewarded in their role. Providers observe that we can effectively build relationships with patients in the telemedicine setting. We can see into patients' homes, we can meet their families, we can see them quickly on their lunch break when they can't get off work.

Our team also notes the ability to reach

rural patients and treatment naive patients, which has been especially rewarding; 18.2 percent of our patients are rural, 67 percent are employed, and over 20 percent of new patients have not engaged with any medical opioid use disorder treatment program before. We're reaching patients who have not previously been reached. As a result, like our patients, our providers also tend to stick with us and stick with telemedicine. We consistently see a less than 1.5 percent quarterly provider turnover rate.

Another element of telemedicine OUD care that invites curiosity and skepticism is how drug testing is performed. We utilize a randomized at-home drug testing program that prompts patients on average once every 30 days to complete a urine drug test.

Test results are submitted through a series of timed photographs of the at-home kit, and we also utilize video-observed saliva drug screens when necessary. We know that sample falsification rates at in-person programs range from about 5 percent to 18 percent in the literature.

To get a sense of our own sample falsification rates, we ran a study that required a cohort of patients to submit a one-time sample by mail to our research partner, and following that

submission, we collected a buccal swab under direct video observation for genetic matching to the previously submitted urine sample.

Among submitted samples, only 2.3 percent were found to contain exogenous or spiked buprenorphine or other evidence of adulteration; 0.8 percent were determined to be human urine from a source other than the patient. These observations support a high rate of drug screen adherence among participants who completed the study, and full findings are pending publication later this month.

When we do determine that a patient is struggling to use their medication as directed, we now have a new tool that I'd like to mention briefly. Previously, if non-adherence continued following our best interventions, our only option would be to refer to an in-person program for sublocade or for daily observed treatment.

More recently, we can now use sublocade via telemedicine in some areas which has been administered directly by a qualified pharmacist. Sublocade is a once-per-month injected extended-release buprenorphine depo. For some patients, it can solve medication adherence issues and it's essentially impossible to divert. It's not a magic bullet. It's still very

costly and access is limited, but it is a promising new resource that we've used now for several patients and look forward to continuing to scale as more pharmacies begin to offer the service.

The next experience I'd like to offer this group is what happened when an in-person mandate was implemented in the State of Alabama in July of 2022. In July, Alabama enacted a law requiring that for any controlled prescription to be issued on the basis of a telemedicine encounter, the prescriber must have seen the patient in person at least once within the preceding 12 months.

When this law was enacted, we'd been operating in Alabama and were treating just over 500 patients via telemedicine. In response, first, we successfully supported 20 percent of those patients and transferring to in-person programs, but that left about 400 who were either unresponsive to the effort or were unable or declined to find an accessible in-person provider.

To try to retain these 400, we sent a team of two physicians and support staff to Birmingham to offer a weekend pop-up clinic. All patients were asked to travel to the pop-up clinic to see our physicians in person and satisfy the mandate for one

year.

One hundred and sixty-two patients were able to complete the visit. Over 200 patients did not and were lost to follow up. Of the 162, 160 recently completed their second annual in-person visit this past July, and 158 also completed an experience survey. Of these, every one of them arrived by car, none by public transit. Mean travel distance was 86 miles; 25 percent missed work to attend even on the weekend, and 16 percent needed to find childcare to attend.

Patients disagreed with the following two statements on a 1 to 5 Likert scale with a median score of 2. One, seeing my provider in person improves my care or my ability to succeed in treatment, and second, I have other resources for opioid use disorder care in my community.

In Alabama, we saw the in-person mandate selected for the most resourced and engaged patients. We know that almost everyone who completed the requirement once went on to do it again a year later. But we'd be foolish to assume that the in-person visit itself had anything to do with achieving that 98 percent one-year retention rate. In fact, it created a filter which removed the most vulnerable 60 percent

of patients from our treatment program, and we don't know what happened to them. By any measure, it was a disaster.

Telemedicine OUD care has been highly successful at expanding access and improving quality of OUD care. Also, we've seen that improvement is as vulnerable as a person in early recovery from OUD, particularly in the face of hasty regulation.

My ask is that in designing a permanent regulatory framework, we consider that we need it to work for the majority, not just for the more resourced and motivated minority.

For patients, we should understand that any new barrier to patient access will discourage that access, and regulating requirements for a patient, no matter how seemingly small, it should already be a universal component of good OUD care or it becomes a barrier to good OUD care. A bonafide physical exam, whether in person or via telemedicine, does meet this standard, and so does maintaining a valid form of patient identification. An in-person requirement does not.

For providers, those us currently braving telemedicine OUD care are highly motivated and willing to accept risk and expense for public health and for

the field. The majority of providers won't be as eager to sign up for new costs and risks unless there's an offsetting benefit.

If special registration is the pathway chosen to enable telemedicine OUD care, it won't be successful if its net effect is a burden and an expense. My group would prefer for telemedicine OUD care to be enabled through regular rulemaking as opposed to the addition of a new special registration process.

However, special registration could potentially be a net benefit to multistate telemedicine OUD practice if it offers a single national registration pathway rather than state-by-state registration.

For effective OUD care, it would only need to permit the prescribing of Schedule III through V medications that are FDA-approved for the treatment of OUD. And, presumably, it would not authorize any onsite medication storage or dispensing.

It would also be reasonable as a condition of receiving special registration to require attesting to certain practice elements that are established as universal in good-quality telemedicine OUD care, such as PDMP reviews, a formal medication adherence support

or diversion control policy, and a formal drug screen monitoring policy based on published standards of care endorsed by a reputable professional society.

It would also be reasonable to require e-prescribing. I strongly discourage requiring any arbitrary dose, duration, or formulation requirements in any framework.

Finally, I urge DEA to design any new process to improve your ability to oversee and audit prescribing patterns and to intervene when exploitative practice is identified but to avoid attempting preemptively to control or limit clinical practice through regulation.

It's been my pleasure to participate in this forum. Thank you for organizing this event and for this opportunity.

(Applause.)

MS. MILGRAM: Thank you so much. Just a couple quick questions. You know, you talked a couple times about protocols around drug testing.

DR. CLEAR: Sure.

MS. MILGRAM: What are those protocols that you follow currently?

DR. CLEAR: Certainly. So every one of our patients, when they first begin treatment with us,

they're mailed a set of three at-home urine drug screen kits. They're also mailed a saliva drug screen kit and a home pregnancy test. Patients agree to complete one of these drug screen kits anytime they're randomly prompted to do so through text messaging or through our app. The providers control the average interval at which these prompts are sent. They're sent no less often than every 30 days. Patients typically complete the first test within the first three days of treatment for opioid use disorder. They usually complete a follow-up test on a weekly basis until they get their first favorable test. Then it's at provider discretion thereafter.

We can do a video-monitored saliva screen where the test is completely within the frame of the video throughout the duration of taking the sample and also developing it. So that controls for potential sample substitution or adulteration. It's not a good baseline test because it's much less sensitive for buprenorphine or other drugs of abuse, but it is a good deterrent for sample substitution that helps preserve the integrity of our urine drug screening system.

MS. MILGRAM: Thank you. You talked a little bit about research that's ongoing. We'd love

to see that when it's available. You can connect with our folks. Anything you can share we appreciate.

DR. CLEAR: Absolutely. We've got two publications that just finished peer review. They're pending publication. We'll send them your way.

MR. PREVOZNIK: Can you just expand just a little bit on, at the very end, you talked about a new process of auditing. What is your vision of what that would look like?

DR. CLEAR: I understand from I believe informal comments that I have heard from DEA in certain forums that one problem with auditing multistate telemedicine practice has been that records are dispersed throughout different practice locations. Some of them are even unstaffed. It may just be a computer in a room with a receptionist.

I would imagine that a consolidated special registration process that's based around the primary, single, primary practice location would make it easier for DEA to require that all records of their entire national or however many states they're practicing in practice to be kept at that one location so that DEA can be sure that you're getting a full picture of that provider's practice with one audit rather than multiple state-by-state audits.

MR. PREVOZNIK: Thank you.

DR. CLEAR: Thank you.

(Applause.)

MR. STRAIT: Thank you. I will now call up Commenter No. 7.

MR. MILAM: Thank you. My name is Thomas Milam, T-H-O-M-A-S, Milam, M-I-L-A-M. I am the Chief Medical Officer at Iris Telehealth.

Good morning. As I said, I'm Tom Milam and I'm honored to be -- to have been invited to speak to this DEA listening session, and I thank the Administrator and Assistant Administrator and the staff and colleagues that are here today for the time and attention given to this important matter.

By way of introduction, I have been a Board-certified psychiatrist for over 25 years and for 12 of those years have been involved in developing and delivering telebehavioral health solutions for underserved communities and healthcare systems throughout the U.S.

As I said, I'm currently Chief Medical Officer for Iris Telehealth. I'm President of our medical group there, and I serve as Associate Professor of Psychiatry and Behavioral Medicine at Virginia Tech Carilion School of Medicine in Roanoke,

Virginia.

Iris Telehealth is a Joint Commission accredited healthcare organization that focuses exclusively on providing behavioral healthcare virtually to underserved community mental health centers and primary care clinics, hospitals, emergency departments, and residential treatment centers. We currently employ nearly 450 U.S.-based psychiatrists, psychiatric nurse practitioners, and therapists in hundreds of care sites across 40 states. Iris has been delivering care since 2013, well before the pandemic, and over the years, we've had many constructive conversations with DEA on various topics like we are addressing today.

I want to say up front that I believe it is imperative that we enable the prescribing of Schedule II medications virtually via telemedicine and without in-person requirements as long as proper safeguards are in place to ensure patient safety and prevent diversion. In my upcoming remarks, I will discuss the numerous safeguards already in place, as well as some that could and should be added or strengthened.

Ultimately, if in-person requirements are mandated for controlled medications, particularly Schedule II medications, simply as a means of

diversion control, which is an important effort, it will lead to unnecessary delays in care and the prolonging of significant human suffering for legitimate patients seeking legitimate treatment from legitimate DEA registered providers.

I think it's important that DEA understand what safeguards are already in place to ensure patient safety and prevent diversion when prescribing controlled particularly Schedule II medicines, whether such medications are prescribed by in-person or telemedicine providers.

First, before prescribing any new controlled substance for a patient and periodically thereafter, healthcare providers review the prescription monitoring program for the state in which the patient resides as well as numerous surrounding states when that data is available.

While prescription monitoring programs vary from state to state, they are a good initial safeguard against the overprescribing of controlled medications by multiple different providers and in quantities and combinations that may prove dangerous or lethal.

Brandeis University's prescription monitoring Center of Excellence issued a brief in 2012 stating that evidence is accumulating that

prescription monitoring programs are effective in reducing diversion of controlled substances, improving clinical decision-making, and assisting in other efforts to curb the prescription drug abuse epidemic.

While DEA does not have carte blanche access to prescribing data from each state's prescription monitoring program, most programs do permit interstate data exchange and thereby provide collaboration and early stage processes for preventing and stopping aberrant and illegal prescribing practices.

Rather than create new additional recordkeeping and reporting requirements for controlled medications that put additional burdens on providers and clinics, who are already working hard to manage heavy caseloads for the patients they see, I encourage the DEA to continue working closely with state legislators, the Federation of State Medical Boards, the National Association of Boards of Pharmacy, SAMHSA, and other reputable national organizations to expand the security, privacy, and reporting of existing controlled medication prescribing data. We do not have to create a whole new reporting system de novo.

The second safeguard for ensuring patient safety and preventing diversion of controlled

substances involves the effective use of controlled medication contracts. Whether in brick-and-mortar or virtual care settings, patients who are prescribed controlled medications, especially controlled Schedule II medications, are required to sign contracts that indicate under which circumstances those controlled medications will or will not be prescribed. Those contracts include items such as drug screening requirements, refill contingencies, pill counts, and the use of prescription monitoring programs to track patient prescriptions. Patients and providers are expected to adhere to the tenets of those contracts as long as those controlled medications are prescribed.

A third safeguard for ensuring patient safety and preventing diversion involves e-prescribing controlled medications. Healthcare providers are expected to use DEA's certified electronic or e-prescribing platforms that require two-factor authentication, that only allow registered legitimate pharmacies to be listed, and that have hard stops to prevent exceeding quantity and refill limits. Most e-prescribing software is already incorporated into commonly used electronic medical records, rendering easily forged paper prescriptions obsolete.

E-prescribing controlled substances directly

links providers with legitimate pharmacies which allow patients to choose convenient local or mail order pharmacies. Because these pharmacies are the nexus between patients, providers, and controlled medications, prescribing and dispensing is best limited to data from pharmacies that take on maintaining and reporting controlled substance prescription data.

As I've said before, creating a new provider or clinic-based reporting structure would be cumbersome and would unnecessarily duplicate existing reporting structures and safeguards.

In regard to the circumstances in which telemedicine prescribing of Schedule II medications should be permitted in the absence of an in-person medical evaluation, the COVID-19 pandemic exposed what many of us in the mental health field already knew to be true: There is an incredibly dire and worsening shortage of psychiatrists and many other mental health professionals in the U.S. and worldwide.

DEA and CMS took bold steps during the pandemic to help patients get access to the providers and medications they needed to treat their physical health, mental health, and substance use disorders, and I applaud DEA and CMS for the steps that they

took. They were the most amazing that I had seen in 25 years of practicing medicine. But the mental health and opiate crisis have continued to expand with little to no end in sight despite incredible effort.

So what can we all do to make sure patients continue to have access to the care and medications they need, including Schedule II medications, to get and stay well while ensuring patient safety and preventing diversion? First, DEA and Congress could select an add federal and state-funded nonprofit healthcare organizations to the list of those exempted from the Ryan Haight Act. Community mental health centers, FQHCs, rural health clinics, and other nonprofit front-line health and addiction treatment centers should be afforded the same exemption from the Ryan Haight Act that Indian Health Services and veteran clinics received.

You might say there already is an exemption for DEA registered hospitals and clinics, but that exemption is not as clear as it sounds. Companies like Iris Telehealth work with hundreds of nonprofit clinics and hospitals in communities across the U.S. that remain very confused and don't understand if they are or are not a DEA registered organization. That leads to confusion and patients not getting the

medications they need.

Second, for providers who choose to practice and treat patients 100 percent virtually without regard to an in-person examination and requiring one, the long-awaited special registration referenced in the Ryan Haight Act is imperative. Providers granted special registration with the DEA could be identified by the letter T and incorporated into their DEA number in a manner similar to that done for X-waivered providers who sought to prescribe buprenorphine to help curtail the opiate epidemic. Such T waiver providers could undergo FBI background checks and other federal and state clearances so they could prescribe for patients they treat in any U.S. state without being required to have physical locations in the state where they treat patients. Special registration should not be simply granted by filling out a Form 224 or 224A and paying a fee but should come with requirements including additional and meaningful training on patient safety and diversion.

Finally, regarding ADHD and Schedule II stimulant prescribing, as a psychiatrist with 25 years' experience practicing in community and academic centers, hospitals, and emergency departments, I can assure you that ADHD is a very serious developmental

and learning condition. It is often diagnosed in childhood, but it can emerge and become disabling under the progressive demands of early and middle adulthood. I'm glad to provide clarity on that from my book chapter, "Attention Problems," published in the 2014 edition of Essential Psychopathology Casebook.

Ten percent of children and 5 percent of adults struggle with ADHD, especially in rural, underserved, and ethically and racially diverse communities across the country. It is very hard for a lot of these folks to get the physical and mental health and addiction treatments they need and deserve, and they never will get it unless we implement progressive community-oriented telemedicine reform at the state and federal level without the encumbrances of pre-pandemic geographic reimbursement and controlled medicine prescribing practices. There is no need to further frighten millions of children and families and adults who fear losing access to their medications and their telemedicine prescribers in our efforts to prevent diversion control.

We can inform and transform the healthcare landscape and ensure patients get the physical, mental health, and substance use disorder treatment they need

virtually anywhere. Thank you.

(Applause.)

MS. MILGRAM: If you'll just pause there for one second, I'd like to clarify. Thank you. Just to clarify quickly, I may not have accurately heard this. You recognized that DEA does not have access to a lot of the PDMP data. Did I hear you say that you did not think DEA should get access to the PDMP data? I wasn't sure.

MR. MILAM: Yeah. No, that's a great question. It's my understanding that they have access to the data but can only use the data in a limited scope for seeking criminal behavior or investigating complaints, but not carte blanche access to all the data in prescription monitoring programs.

I think they should have access to that data and work with the organizations that I mentioned for a collaborative effort that you all get the information that you need to prevent diversion control, work -- that's helpful to us and to communities, but it doesn't burden patients with going through a lot of additional steps to get the medications they need to be refused medications for legitimate prescriptions at pharmacies when they present them just because they're prescribed by telehealth. There should be access to

data that is very transparent so that some of this confusion around legitimacy is clarified.

MS. MILGRAM: Thank you.

MR. MILAM: All right. Thank you.

MR. PREVOZNIK: You're not off the hook yet.

You mentioned about our 224 and 224A form, but then you went on to say that there could be perhaps another -- I'm not really sure what you were striving for, but other requirements that we could ask. Could you expand on that?

MR. MILAM: Sure.

MR. PREVOZNIK: Like, what you're thinking?

MR. MILAM: FBI background checks, which are a routine part of our own credentialing process for all of our providers, and that could include state and federal checks to make sure people are who they say they are, that they are not -- have been accused of -- or found guilty of criminal activity.

Educational processes, I think that's something we can all work together on, having meaningful substantive required education courses, one hour, three hours, eight hours, kind of like what was done for buprenorphine prescribing in early days, something like that that's not onerous but meaningful, that people can have when they new or renew their DEA

registration or special registration and that could be updated regularly so that providers, clinics, and others are getting regularly updated data about diversion control efforts because we don't hear a lot about that and about meaningful prescribing patterns, best practices, things like that so that you all know that the people that are providing legitimate prescriptions are educated at a level that's meaningful to you as well.

MR. PREVOZNIK: Thank you very much.

MR. MILAM: All right. Thank you.

(Applause.)

MR. STRAIT: And I'm now inviting Commenter 8.

MS. MELVILLE: Thank you. Good morning. I'm Melanie Melville, M-E-L-A-N-I-E, M-E-L-V-I-L-L-E. I'm a psychiatrist by training, and I'm the Medical Director of the Department of Behavioral Health at Legacy Community Health. I oversee a department that has over 140 clinicians, including 40 psychiatrists. We're very thankful for the opportunity to be in front of the DEA and represent the hundreds of thousands of underserved patients that we care for every year.

Legacy is the largest Federally Qualified Health Center, or FQHC, in Texas. We're the tenth

largest FQHC in the country, and we serve nearly 200,000 community members across southeast Texas. We have 54 widely dispersed clinics across the state. Thirty-four of those are school-based health clinics, and we provide services for all patients independent of their ability to pay. Most of Legacy's patients are at a significant economic disadvantage. Ninety-three percent of our patients are at or below the income level of $200,000 of the federal poverty guidelines, and 69 percent of our patients are living in poverty. Thirty-three percent of our patients are uninsured, and 49 of them are on Medicaid.

We quickly worked around the clock in 2020 to develop procedures that were safe and appropriate to implement telemedicine into our practice even though Legacy has been providing behavioral health services in Texas since the mid-'90s. Though we're definitely not rookies in the practice of psychiatry and therapy, this was definitely new ground for us.

Once we were able to establish telemedicine and we didn't need to put our psychiatrists in brick-and-mortar clinics, we were able to triple the size of our department. We were able to finish 19,000 more appointments from 2019 to 2022; 19,000 more appointments were completed.

Through the pandemic, we all saw an increase in depression. We also saw an increase in anxiety. We saw an increase in academic difficulties for youth returning to in-person school and even still doing virtual care -- virtual learning. Sorry. We all saw the negative effects of social isolation, and we also saw even an increase in OCD behaviors relating to the concern about transmitting an unknown virus. But you all know this already. We all know that psychiatry care now more than ever is needed.

So we ask the DEA to remove any red tape and make it as easy as possible to intervene and prevent costly interventions, such as ER visits and hospitalizations that happen when these illnesses are not treated in a timely manner. We believe that the most responsible, most excessive and -- accessible, sorry -- and appropriate need of meeting these increased demands is through telemedicine.

At Legacy, we also understand that the administration, we have very real concerns about the legitimacy of telemedicine for prescribing controlled medications. For this reason, I also ask that we note that psychiatry is different than other disciplines in medicine. I'm not throwing shade to other disciplines, just pointing out the obvious.

Psychiatrists treat conditions that often don't necessarily need a physical exam to be diagnosed and treated. We treat psychotic disorders. We treat mood disorders, insomnia, ADHD, anxiety disorders. All of these are appropriately treated through a virtual exam and telemedicine follow-ups. In fact, sometimes we can even learn more about our patients when we see them in the comfort of their home. I can give you an example of one of our patients who had actually been seen in person by us several times, and the first time that we saw them via telemedicine we realized that this person actually met criteria for hoarding disorder. We would have never been able to catch that and treat it appropriately with medication and psychotherapy if we had not been able to see this patient in the comfort of their home.

Because we knew that at some point the waivers were going to go away, we actually implemented a procedure internally at Legacy trying to see all of our patients that were being seen via telemedicine in person at least once a year since last August. I'll give you an example of one of my patients that I started seeing via telemedicine.

This is an autistic patient who also has ADHD. Without the use of Vyvanse, which is a

stimulant -- as you all may know, it's a controlled medication -- he's unable to participate in school. He becomes aggressive. His hyperactivity and impulsivity prevents him from actually participating meaningfully in school. His mother had to take the entire day off. His grandmother also had to take the entire day off to take care of my patient's sibling because they had to drive four hours each way so that they could come and see me so that I could say, check, I've seen this patient in person, I can continue to prescribe. That's two adults and a child missing of their daily activities and incurring in the cost of time, effort, and resources of a four-hour drive each way to see me for 20 minutes so that I can check this box. And we're not even started, right? This is not even already a requirement. This is something that internally we try to be prepared for.

We also ask that the Administration consider the availability of providers and specific characteristics of each state. For example, Texas experiences a severe shortage of mental health providers in 248 of the 254 counties. In 2023, Forbes identified Texas as the worst state for mental health in the U.S. and notes that it's the state that has the highest percentage of uninsured adults with mental

illness. Those are my patients. Those are the people that I see.

We also ranked highest in the percentage of adults with cognitive disability who could not see a doctor due to cost and highest percentage of youth who had a major depressive disorder in the past year and did not receive treatment. Psychiatry is one of the hardest disciplines for us to fill positions. We have a clinic in Beaumont, which is a hundred miles away from our central clinic in Houston. That position was open for three years. Three years we did not have a psychiatrist in that clinic. As of yet, we have not found a child and adolescent psychiatrist to provide services in that clinic.

Before telemedicine was an option, we were forced to meet the needs of our patients by hiring a psychiatrist in Houston and they would drive twice a week to see the patients in Beaumont. Of course, this clinician burned out after two years after driving, you know, twice a week to Beaumont and she eventually moved to a clinic in Houston. We couldn't fault her.

Note that Texas is extremely large. Transportation is one of the main barriers that our patients have for attending their visits. When we started doing the requirement of an in-person visit

every year, which again was an internal requirement to make sure that we could meet whatever requirement was set out in the future, we saw an increase of 30 percent in no-show procedure -- in no-show appointments even though we told our patients, hey, it's very likely that if I don't see you in person I'm not going to be able to continue to prescribe, and yet they couldn't make it to their appointment. They didn't have a ride. They didn't have childcare.

All of our locations are along a bus line, but even if the patient has access to a bus, oftentimes they have to change up to three buses in order to make it to our clinics. Our wait list is 8,000 people. So, if I have a patient who doesn't show because they didn't have transportation, that means that I wasn't able to see another person either, right, and I wasn't able to get these patients in. We get 19,000 referrals a year for behavioral health services.

In short, please, we ask the DEA to allow clinicians to use their best judgment in determining when a patient needs to be seen in person and when they can continue to be seen via telemedicine. As my colleagues have stated before -- and thank you for the shout-out for us FQHC peeps -- an in-person visit

doesn't preclude someone from practicing inappropriately. It also doesn't mean that we can see the patient for the whole person that they are, which sometimes telemedicine actually allows us an opportunity to do that.

That's all I have.

(Applause.)

MR. STRAIT: Thank you so much.

MS. MELVILLE: Yeah.

MR. STRAIT: Hold on one second.

MR. PREVOZNIK: I have one follow-up.

MS. MELVILLE: Sure.

MR. PREVOZNIK: In the beginning, you said that in 2020 you started your safe procedures on what your guidelines would be, what your protocols were.

MS. MELVILLE: For telemedicine?

MR. PREVOZNIK: For telemedicine.

MS. MELVILLE: We started in 2020.

MR. PREVOZNIK: 2020.

MS. MELVILLE: Yes.

MR. PREVOZNIK: Could you expand on what it is that -- what were those protocols?

MS. MELVILLE: Yes, of course. So, in -- I don't know if you're familiar with Texas law, but Medicaid actually did not cover telehealth in Texas up

until our organization, our -- over here, helped us prepare the white paper that helped change the law.

So we did not provide -- we provided telemedicine only for that Beaumont clinic that I was talking about, and that was the only telemedicine that we did. And to give you an idea, we knew that we were not going to get any reimbursement from those appointments, but we still hired a psychiatrist to do telemedicine to Beaumont because we needed -- we knew that those patients needed care.

So we had to very, very quickly determine procedures and find a telehealth platform because our electronic health record -- again, we're an FQHC, so our electronic health record is not the fanciest one -- so that we could start providing care for our patients.

So, in a matter of two weeks, we were able to go fully telehealth with our patient -- with our clinicians in the clinic, and two weeks later we were able to send all those clinicians home. And one of the reasons for that also is because, including behavioral health clinicians in the clinic where I practice, the traffic of people is 400 people a day, you know, so can you imagine how scary that was in the middle of the pandemic. So, by removing half of that

patient population, we were actually able to protect not only our patients but also our primary care colleagues, who were seeing patients in person because they didn't have the option of telemedicine.

MS. MILGRAM: Sorry, just to follow up, you said you have 140 clinicians, 40 psychiatrists. Who are the other clinicians in that group?

MS. MELVILLE: They're psychotherapists, integrated behavioral health consultants, and psychologists.

MS. MILGRAM: Great. Thank you.

MS. MELVILLE: Mm-hmm.

MR. STRAIT: Okay. Thank you.

(Applause.)

MR. STRAIT: And in perfect succession, we've got Commenter No. 9 coming to the stage right now.

MR. RECK: Hi. My name is Dan Reck, D-A-N, R-E-C-K, from Matclinics.

So, as I said, my name is Dan Reck. I'm the CEO of Matclinics. We're the largest based opioid treatment group in Maryland. On behalf of our employees and our patients, I'm pleased to share our thoughts on this proposed rule.

Each year, Matclinics treats over 3,000

people suffering from opioid use disorder, and the primary treatment modality we employ is the prescription of buprenorphine products, often through the use of responsible telemedicine.

In addition to prescribing a critical medication, we offer our patients broad behavioral health services, including case management, substance use counseling, mental health therapy, and psychiatry.

And while we appreciate the DEA's attempt to balance access to care with responsible prescribing of controlled substances, we are concerned that the proposed rule does not go far enough to control diversion and the misuse of buprenorphine. If rules around prescribing are too permissive, it is likely that we will see a repeat of many of the excesses that ultimately led to the over-enforcement and restrictions on high-quality care in other areas of medicine.

Unlike most well-intentioned public policy, where we are often surprised by unintended consequences, the negative consequences of this proposed rule are likely to be all too predictable.

Buprenorphine is a controlled substance that the DEA itself has described as "capable of producing significant euphoria" while adding that it is "gaining

popularity as a heroin substitute and is a primary drug of abuse."

A robust illicit market for buprenorphine exists. Diversion is an existing problem that implementation of the proposed rule will inevitably compound. The results of diversion should not be minimized. Patients actively using illicit substances can fund their use by selling their prescribed buprenorphine typically for $500 to $1,000 per month.

Most patients who are prescribed buprenorphine, however, find it to be incredibly effective at relieving symptoms of physical dependence on opioids. These patients take their medication as prescribed and progress through treatment in a constructive and healthy way.

We know this because, by deploying an objective scoring methodology that we developed in conjunction with scientists at NIDA, we can categorize patient adherence to treatment into one of five trajectories. I brought some visuals that I'd be happy to share afterwards, but you're going to, I guess, have to just put up with me trying to describe the graphs with words.

Almost 80 percent of patients are stable from the start of treatment or quickly achieve

stability. There are, however, a meaningful minority of patients who struggle in treatment. If the purpose of treatment is to reduce illicit drug use and adherence to buprenorphine, these patients need closer attention from providers, not less. Without persistent, reliable definitive drug testing, how would a tele-only provider ever be able to distinguish amongst their patients?

We have firsthand experience when adequate controls are missing in the prescribing of buprenorphine. In two situations over the last five years, we inadvertently ran two natural experiments.

Experiment No. 1. In February 2018, Matclinics began to accept Maryland Medicaid and watched our patient census increase dramatically as people learned that they could access buprenorphine without paying anything out of pocket.

Simultaneously, we added definitive urine toxicology testing to each of our Mat patient visits. While we were gratified to see our patient census increase over the first few months, we were shocked to see how many patients were adulterating their urine.

As you would have seen in another graph I brought, during those first few months, growth in patient urine samples with unnatural levels of

buprenorphine and/or missing Norbuprenorphine, the metabolite that is generated by normal liver processing, grew to more than 5 percent.

We quickly set up to minimize the potential for adulteration, and now we see fewer than 4 in 1,000 samples with signs of adulteration, a more than 12 times drop. Had we not intervened to control adulteration, it seems likely that we too would have gained a reputation as a place to access uncontrolled buprenorphine prescriptions.

Experiment No. 2. In May of 2020, we heeded the advice of state and federal health agencies and started conducting all patient visits via telemedicine only. For those four weeks, we could not collect urine samples and reverted to asking our patients what we would find if they provided us with a sample. The vast majority of patients who had recently presented with opioids in their system reported that if they'd give us a urine sample we would find only buprenorphine in their urine. However, after moving to a COVID-safe and in-person system for collecting urine samples, most of those same patients tested positive for opioids and many were missing buprenorphine in their urine.

It seems highly unlikely that these same

patients were adherent to treatment protocols only during the time when they were not required to provide a urine sample.

We urge the DEA to reconsider its proposed rule and strike a better, safer balance between increasing access to medication to treat addiction and ensuring that treatment is both safe and of high quality.

Buprenorphine prescribed judiciously is an effective medication in treating OUD and a central part of an effective response to the opioid crisis. However, without proper oversight of patients prescribed controlled substances, including regular in-person visits combined with definitive toxicology testing, there is no reason to believe that some telemedicine-only providers won't become buprenorphine mills just as pain pill mills once flourished.

We are concerned that the consequences of unregulated buprenorphine will contribute further to the already deadly opioid epidemic.

Thanks for your time today. Happy to answer questions.

(Applause.)

MS. MILGRAM: You talked about protocols you put in place to control the adulteration and you're

now down to four in a thousand. Can you just talk about what those controls were?

MR. RECK: So what most patients -- so not all patients who adulterate are there to divert. A lot of patients adulterate because they're afraid of the consequences, because they're afraid that they might be maybe thrown out of treatment or not be allowed to go on because they've somehow relapsed.

And so what we've worked really hard with our staff on doing is to make sure that if we see evidence of adulteration that that patient is told that, like, we can only treat them if they give us an actual sample. It's the only way we really know what's going on with them. We're not going to take a punitive stance against them. That has helped a lot in terms of making patients more comfortable with giving legitimate samples.

But we also, of course, if patients are being prescribed a medication for which there's no evidence that they're taking it, over time, we just can't -- that's not a patient who should be prescribed buprenorphine anymore, and those patients are usually, if they're using other illicits, they are -- you know, we're just not sufficient, right? We're the lowest level of treatment. We're outpatient level. Those

patients probably need a higher level of care, and we work to get them to those higher levels of care.

MS. MILGRAM: In the recommendation of what you would sort of suggest, you said regular in-person meetings, regular toxicology. Could you just elaborate if there's anything else you would put on that list?

MR. RECK: I mean, just I think that the toxicology bit is nuanced. So a lot of what people call urine drug testing are just, you know, like what are called presumptive or screening tests, and those don't have the sophistication to sort of see whether or not the people are actually taking their medication or not.

People can put buprenorphine directly in their urine. You can't see whether or not they're actually processing it through their system. So I do think that there just needs to be, and I can't speak to all controlled substances, but just on the buprenorphine side, we have a lot of experience with this. There just needs to be some amount of in-person collection so that we can see what the temperature is of the urine to make sure that it's actual, like their sample coming from them, and then go through a definitive tox. We think that is -- it's the easiest

way that we know of to distinguish amongst patients.

And while there's a lot of history of abuse of toxicology, but what we find is it actually reduces total cost because, as we talked about, most patients actually don't need to come in very often, right? Most patients are very stable, react very well to the medication. And so, by doing intermittent definitive tox tests, we then can allow them to space out their appointments over a much greater length of time. It allows us to focus our attention on those who actually need more attention.

MS. MILGRAM: And we'd love to get the visuals if that's okay.

MR. RECK: Sure. Yeah.

MS. MILGRAM: Thank you.

MR. STRAIT: Thank you.

MR. RECK: Okay. Thank you.

(Applause.)

MR. STRAIT: And we now have Commenter No. 10 coming to the stage.

MS. MARTINI: Hello, everyone. My name is Dori Martini. That's D-O-R-I and Martini like the drink, M-A-R-T-I-N-I. And my affiliation today is with Circle Medical.

Like I said, my name is Dori Martini. I am

an operations expert with 20 years of experience, and I most recently had the honor to be the Vice President of Operations and Regulatory Affairs for Circle Medical.

Circle Medical is a comprehensive, tech-enabled, adult-only primary care practice. Established its first brick-and-mortar clinic in 2015 in San Francisco. And through a lot of hard work, a lot of perseverance, and, more importantly, the commitment to the practice of ethical and evidence-based medicine, we have gone from serving what used to be hundreds of San Franciscans, mostly coming through our brick-and-mortar location, to now serving upwards of 50,000 patients per month in 23 different states.

A big part that facilitated this growth was the fact that we were tech-enabled and we were able to scale very quickly as a result of the secure mechanisms that we had in place with our own in-home-grown electronic health record system that really allowed us to expand as soon as the Ryan Haight Waiver lifted.

Now I do want to mention that we did kick off with COVID, obviously, the pandemic, and I would say for the first nine months of the pandemic we were

essentially a COVID clinic offering services nationwide.

Early in my career, I had the privilege of leading compliance and expanding access to care initiatives while working for some of the top-performing early qualified health centers and medical managed care health plans in the State of California. Once I transitioned to the private health sector seven years ago, I left my public health work with the heart-wrenching notion that I would no longer have the opportunity to serve the underserved.

But much to my surprise, my most recent firsthand experiences have led me to hypothesize that, in fact, the majority of Americans, even those technically above the federal poverty levels, are also incredibly underserved.

One segment of the population that is chronically in need of being served is the more than 9 million adults in America that are diagnosed with ADHD and the millions more that fail to obtain diagnosis due to the systemic access issues and the stigma associated with this condition all because evidence-based medicine dictates that the most effective first-line treatment for most patients that meet this diagnostic criteria is a stimulant

medication, which, as we know, is a controlled substance.

Because of the stigma and difficulty in accessing treatment, many of these people obviously go without, and the results are devastating. The distractability, the impulsivity that come with ADHD lead to the extensive burden on our health system as undiagnosed or inconsistently treated ADHD individuals result in co-morbidities such as obesity, diabetes, heart disease, risky sexual behavior, suicide, and substance abuse. They get into more car accidents, and when they do, they're more likely to be fatal. When you add it all up, ADHD leads to a reduction of life expectancy between nine and 13 years.

Ladies and gentlemen, ADHD is real and it is a problem, and potentially the lack of consistent treatment can lead up to another really big public health emergency, which, of course, we're all here together today to try avoid.

I understand and I care so much about these 9 million Americans because I am one of them. When I think back to how I ended up in healthcare, I find it to be fairly ironic. As a first-generation Mexican-American growing up in Santa Barbara County in California, even as a middle-class family, Western

medicine concepts were not regularly sought in our household, but rather we relied on a variety of culturally influenced home remedies and other alternative treatments.

To be frank, it actually was not until the pandemic, due to the increased isolation that I personally experienced, along with the rest of the world, that I for the first time ever came to a realization of, like, maybe I need help. Maybe there's something wrong with me because my entire life and process had been disrupted in terms of how I did my work, and that routine had basically shifted very aggressively and was broken.

It is true that the dramatic shift in social norms really accelerated public dialogue around the widespread need for behavioral health. As studies have shown, in the height of the pandemic, 40 percent of adults reported symptoms of anxiety or depression, compared to only 11 percent in a pre-COVID world.

Fortunately, I did not hesitate at that point in seeking care. I was able to connect for the first time with a medical provider over a two-way video audio visit. The security I felt in being able to access this type of intimate and really scary treatment and care for someone that historically

didn't think anything was ever wrong with them, being able to do that within the safety of my own home really made seeking out this help a no-brainer for me.

And I can't help but remember that maybe I put it off for so long not only because of this unknown diagnosis but also because of the regular daily barriers of daily life you kind of tend to deprioritize if it's not something that's basically preventing you from doing what you believe are your daily activities of daily living.

Being diagnosed with ADHD in my mid-30s made me realize how underserved I had personally been through my childhood and young adult life, and I couldn't help but wonder, what if I would have been diagnosed earlier? Would my academic experience have been different and maybe a little easier and not so hard? Building social relationships, familial relationships, could they have been easier?

However, finally being treated for ADHD has had a vast impact on my life, and I would be remiss not to share that in a way, a big part of my life's personal work and professional work collectively has really unknowingly brought me here, cross country, to be speaking in front of all of you today.

During my time as Vice President of Circle

Medical, I also authored and submitted a detailed 24-page letter to the DEA in response to the proposed rule for the remote prescribing of controlled substances, which is also available to the public through Circle Medical's website.

I'd like to spend the remaining part of my time addressing the critical questions raised by the DEA regarding telemedicine prescribing of controlled substances, focusing specifically on Schedule II-N medications, non-narcotic medications, patient safety, and proactive diversion strategies.

The first question, should telemedicine prescribing of Schedule II medications be permitted in the absence of an in-person medical evaluation?

First, let's consider the necessity of in-person evaluations. The expansion of telemedicine during the pandemic has shown that safe and effective care can be delivered remotely. In the last three years, over 500 Board-certified Circle Medical practitioners conducted hundreds of thousands of real-time two-way video/audio telehealth appointments, demonstrating that safe evidence-based care remains consistent irrespective of the modality.

However, what has been key in being able to safely and effectively deliver this care are the

safeguards that we have put in place, which brings me to our second question. What safeguards would you recommend for telemedicine prescribing of Schedule II medications? Safeguards for prescribers such as checking the PDMP are imperative. This should be a requirement for all prescribers of all controlled substances at the federal level and, at a minimum, a best practice to validate this prior to issuing any controlled substance over telemedicine.

Establishing a controlled substance agreement between the prescriber and the patient allows for the correct expectations to be set up front so then that way the patient understands that they are going to be held accountable to being seen through a telemedicine visit every single month and being able to disclose if they have any other conditions and/or if they end up taking another medication, having to divulge that information immediately to their prescriber.

We understand the importance of ensuring that clinically the recommended dosage and usage guidelines provided be followed and believe this is where the DEA and practices like Circle Medical can stand to work together to help solve for diversion at the point of patient entry as opposed to at the point

of treatment because, when you're dealing with a patient that is in need of treatment and has a diagnosis, a legitimate one, it is so disruptive to the care to be able to have to kind of stop because they cannot get their treatment medication.

For example, Circle Medical has implemented advanced patient ID verification mechanisms that require the patient's ID to be electronically scanned prior to being able to book an appointment. In other words, this technology can actually tell if a fake ID is being uploaded into our system, among many other things that could indicate the potential for someone attempting to access our services fraudulently.

One could argue that this level of verification is not being done today in most in-person clinical environments alone as it is customary for most patients to simply present their ID and it gets usually photocopied by a front desk person for the medical chart and for billing purposes.

As a result, our tech-enabled practice, we have had significant documentation and data that we have been actually able to share with the DEA in one specific incident where there was a criminal attempt, essentially, of this individual who was going around to various practices, both in-person and through

telemedicine, to try to obtain as many controlled substance prescriptions as possible. And the fact that we had the level of data and all of the information and all of the attempts and all the fake ID attempts from this patient really allowed the DEA agent in this particular case to be able to make a charge.

We believe that this is one example of many where technology can really help safeguard patients who are truly in need of medically necessary treatment while also supporting the DEA's ability to help implement the necessary guardrails that will lead to safer prescribing and de-risk diversion.

There is definitely something that we need to talk about and that is Question No. 3, which is, what telemedicine prescription data should be collected, maintained, and reported to the DEA?

Today, the Electronic Prescribing of Controlled Substances, known as the EPCS, is an existing mechanism that is already in place that can enhance prescription legitimacy, and I strongly urge the DEA to consider revisiting this program as a way to streamline additional information that can be collected about the prescriber at the point of prescription in real time as this is a device that

they have to interact with in order to be able to electronically prescribe.

Associate Administrator Thomas, I know that you have been asking throughout today's presentations what are some of those very specific questions that can be asked as part of the special registration application. I would say something that the DEA could look into is the actual process for an application-type question that is asked by a malpractice carrier. Malpractice carriers will ask physicians very specific questions about their practice, such as what percentage of your care is delivered via telemedicine versus in-person? What kind of patients and/or populations are you serving? What are the main areas of care that you're actually providing care for? And taking it a step further because this would be specific to prescribing, asking what are some of the most frequent medications specifically by name.

Many of these telemedicine practices have been able to adopt very specific clinical guidelines where they will not deviate from them, so more than likely, you would be able to have a very strong view of how they're practicing.

The other thing that I would really mention

is that I think the DEA should really consider evolving its technological stack and develop some sort of universal plug-in for electronic health records so that prescribers have direct access to report whenever they come into contact with potentially a questionable individual over a telemedicine encounter.

Going back to that case that I had the opportunity to work on with the DEA, that was one of the questions that the agent had asked me, are you proactively reporting any of these individuals that are maybe trying to tamper with your system or upload these IDs, and when she walked me through what that process would actually consist of, we both kind of agreed that it's fairly rigorous and it's a little challenging and that there's probably a better way there.

My final question that I would like to quickly address is, what telemedicine prescription data should pharmacies collect, maintain, and report to the DEA? Folks, I cannot stress enough that if we were to wave a magic wand and come up with the most amazing, perfect process special registration today, walk out of here, our work is done. It does not mean that the patient is going to get that medication at the pharmacy.

Pharmacies need guidance on their responsibilities in verifying prescription information. The pharmacist has no way of knowing without extensive communication with prescribers and a lot of back-channeling whether all rules have been "followed." To address this, one option is to establish a more collaborative agreement between the prescriber and the pharmacies. This is something that is done today a lot within cancer centers where they're working in tandem and in partnership when it comes to really knowing the inner workings of the patients that they're serving.

There's always a lot of mentions from pharmacies when we speak to them because we have an average of about 400 patients a day at Circle Medical that report their inability to access their legitimate treatment at the pharmacy level. The two top reasons that they list that they're refused that prescription is shortages and the second one is that it was prescribed through telemedicine and, therefore, there is a discomfort by the pharmacist to dispense that medication.

And it's understandable that they're uncomfortable because there is a lack of clarity around these "red flags." The pharmacists should know

to what degree they are going to be held responsible for and at what point does their due diligence basically exhaust so that they can be confident that they're not going to lose their pharmacy licenses, their pharmacist licenses, at the point of dispensing a legitimate medication.

Moreover, it's crucial to factor in the administrative and financial burden imposed on clinical practices and practitioners. Given the current physician burnout crisis, we must also provide sufficient time to streamline these types of operations and prevent dangerous disruptions in care. So no matter what it is that we try to do here, it's really, really important that we have the time to implement these things as well so that we don't end up in a crisis-like state.

I really thank you for your time, and I'm incredibly optimistic of bringing us all together here. I think this is a great move in the right direction, and I'm excited to see where it goes.

Thank you.

(Applause.)

MS. MILGRAM: Thank you. Could I just ask one clarification question?

MS. MARTINI: Mm-hmm.

MS. MILGRAM: You just talked a little bit about a lack of clarity for pharmacies around red flags. Could you just specify what information you think pharmacies would need to be able to fill prescriptions?

MS. MARTINI: Yeah. So part of the inconsistency stems from the fact that the pharmacy says all of this data, it looks the same. We don't know if the prescriber is legitimate. We don't know if the patient is legitimate.

I've had the opportunity to speak to some of the bigger pharmacies, and some of the feedback that I got was, you know, it would be really great if we could even just get more access to some of the patient data and patient information. For example, when was the last date of service? When were they seen? How were they seen? What is some of the ongoing treatment?

There are some states that have adopted the need to actually enter, you know, ICD-10 codes in the notes section. But it's a systemic problem. It's very inconsistent. The systems that power these electronic prescription services should really be required to, you know, universally list some pre-approved fields so that those changes can be made.

Circle Medical has gone even as far as to pilot what we call kind of a brief medical chart version. It's a one-pager just kind of giving the pharmacy a snapshot of everything that they, you know, would hopefully need to see. Also with a direct telephone number to a dedicated phone team that is only taking the phone calls from the pharmacists because, you know, if they have any follow-up questions, they should absolutely be able to ask them.

And so being able to also provide them with that type of support is also incredibly important. But I will say that the feedback has been having a faxed single medical chart is very, very cumbersome for them to handle operationally on the receiving end.

Thank you.

MR. STRAIT: Thank you very much.

MS. MARTINI: Thanks.

(Applause.)

MR. STRAIT: Okay. I do want to say we have three more presenters for our morning session. I'm calling up Commenter 11 now. But just in the way of expectation management, we have three left to go, and then we will make our switch to our afternoon virtual session. So, without further ado.

MS. USCHER-PINES: Good morning, everyone,

and thanks for bearing with us. My name is Lori Uscher-Pines, that's L-O-R-I, U-S-C-H-E-R, P-I-N-E-S, and I'm a health services researcher at Rand, which is a nonprofit research organization. I represent a team of researchers and clinicians from Harvard and Rand that have been conducting research on telehealth for opioid use disorder for about a decade now, and today my comments are going to focus on prescribing of buprenorphine via telemedicine.

First off, we applaud the DEA for reconsidering a special registration process that would allow some clinicians to prescribe buprenorphine without an in-person medical evaluation.

In our research, we have shown that telemedicine was used for about 15 percent of all buprenorphine inductions in the early pandemic, and greater use of telemedicine for opioid use disorder has not resulted in inferior outcomes.

Our research, as well as the research of others, has shown that permitting telemedicine to start patients on buprenorphine can improve access to care without obvious negative impacts on patients.

We also recognize that the DEA is concerned about a new framework that fundamentally expands access to a controlled substance, and DEA wants to

ensure the permanent flexibilities to prescribe buprenorphine via telemedicine does not result in greater diversion.

The DEA is looking to strike the right balance between an overly restrictive system that limits patient access and an overly lax system that results in more diverted buprenorphine, so, you know, looking for some guardrails to really strike that important balance.

I'd like to start today with a few overarching principles that can inform the design of a special registration process, and then I'll talk about some specific guardrails that the DEA can consider incorporating into that process.

The first principle is to limit the special registration process to higher-volume clinicians, such as those who start more than five patients per year on buprenorphine via telemedicine. This focus on the higher-volume prescribers would limit administrative costs and focus regulation on clinicians in a position to have the greatest negative public health impact. So clinicians who only treat a handful of patients via telemedicine would not have to register under this model or be subject to additional guardrails, but we believe that their likely impact on public health

would be small even if a minimal amount of diversion were occurring.

According to our estimates using Medicare claims data, in 2022, about 25 percent of buprenorphine prescribers started at least one patient on buprenorphine in that year via telemedicine. Excuse me. So 25 percent started at least one patient. However, only 1 percent started five or more. So, if you limited a special registration process to the 1 percent versus the 25, that would greatly limit the administrative burden for DEA and for registering clinicians.

The second principle is that when selecting guardrails, the DEA should try to avoid burdening patients who already face numerous barriers to care, and we've heard a lot about that today. When choosing between a guardrail that creates additional hurdles for patients or for clinicians, choose to inconvenience the clinician.

Third, the DEA should avoid guardrails that interfere with clinical decisions and require that clinicians play the role of police. This can have negative impacts on care quality and on therapeutic alliance.

Fourth, the DEA should not interpret small

increases in diversion that may be associated with new prescribing flexibilities as problematic, and this point is a little bit new and key, I think. It's important to emphasize that diversion is very common with in-person care, and telemedicine did not create this problem.

For example, a JAMA article, a recent on, showed that buprenorphine users misused buprenorphine about 30 percent of the time or 30 percent of users misused it before the telemedicine flexibilities were put into place in 2019, and another study found that buprenorphine diversion has been increasing over time with increased buprenorphine use. So it's probably impossible to increase access and use of buprenorphine through telemedicine or through any other means without increasing diversion.

The DEAS should not be asking are new prescribing flexibilities increasing diversion if it's doing that through the mechanism of improved access. Rather, the question that you should ask is whether the rate of diversion is higher with telemedicine prescribing versus in-person prescribing, and to our knowledge, there is no evidence yet that this is the case, that when high-quality clinicians deliver telemedicine there's more of a risk of diversion.

So this final principle not to interpret small increases in diversion as a result of greater access as a failure is important as the DEA evaluates the impact of a special registration process and works to improve it over time.

So now I'd like to pivot and present a set of specific guardrails that can be incorporated into a special registration process that align with some of the principles that I just mentioned. We recommend that the DEA consider implementing a few of these in combination rather than all of them, and that is the case because, at some level, too many barriers are just going to prevent clinicians from offering telemedicine as a treatment option, and too many guardrails will yield diminishing returns with respect to diversion risk.

Further, the DEA should gather feedback on the acceptability of some of these different guardrails from a range of stakeholders before making any final decisions.

The guardrails that we recommend, as well as some more concerning guardrails, are detailed in a health affairs article that our team published on September 1 in preparation for this discussion today. We recommend that you take a look at the full list

that's published there for additional context.

So, for the guardrails, first, DEA could consider requiring electronic prescribing, that is, prohibit the use of paper scripts.

DEA could require registered clinicians to accept insurance. This could prevent the growth of cash-only pill mills.

Third, DEA could require that all registered clinicians submit a diversion mitigation plan that really outlines organizational policies to prevent diversion. For example, registrants could discuss their policies around urine drug screening and how results that may indicate diversion or misuse will be used to inform treatment decisions.

Fourth, the DEA could require that clinicians take steps to verify the identity of the patients they're treating, especially in the case that these clinicians are delivering audio-only visits without that face-to-face component.

Fifth, DEA could require clinicians to use prescription drug monitoring programs before prescribing and at regular intervals.

Sixth, DEA could require that organizations or clinics doing telemedicine inductions are certified by an external entity, such as the Joint Commission or

NCQA.

Seventh, DEA could require that organizations doing telemedicine inductions involve an addiction-trained clinician in some sort of supervisory role or perhaps on the leadership team.

Eighth, DEA could require additional training for clinicians on why diversion is a problem, detection, and how to respond. A 2018 survey showed that while approximately 80 percent of prescribers report that they assess patients for diversion, specific practices differ. So the goal of training, additional training, would be to ensure that all prescribers, not just 80 percent, do this and do this routinely and that they accept the responsibility of partnering with the DEA to prevent diversion.

Ninth and finally, the DEA could require that clinicians only prescribe buprenorphine naloxone, as opposed to buprenorphine mono-product, unless the patient is pregnant or has a documented naloxone allergy because of decreased risk of diversion associated with combination treatment.

So it's important to emphasize that there are guardrails that others have discussed in the literature or have been applied to in-person care in the past that we don't recommend because they're

likely to reduce access to care by burdening patients or could even undermine promising care models that have emerged in the past few years.

For example, one guardrail we recommend against is limiting the length of the prescription, for example, only allowing up to two-week prescriptions for the first two months of treatment. Another we recommend against is requiring observed dosing via telemedicine. Both of these are burdensome for patients and may reduce the likelihood that they remain in treatment.

So one final thought before closing. DEA and public health stakeholders sometimes seem to be speaking different languages. In the public comments, thousands spoke about the critical role of telemedicine in increasing access to controlled substances like buprenorphine given the many communities' lack of prescribers and there's stigma associated with opioid use disorder.

In announcing the listening sessions, DEA expressed concern about the very thing the public health stakeholders are so excited about, and that is a new policy environment that fundamentally expands access to controlled substances.

Greater access either represents something

to strive for or cause for alarm depending on where you sit, and this doesn't need to be the case. In summary, we believe that there is a potential compromise. DEA can implement a special registration pathway with a few select guardrails that apply to a certain population of prescribers. This can incorporate important checks against diversion and increase access to this life-saving medication.

Thank you for your time.

(Applause.)

MR. STRAIT: Stay right there just in case we have some questions for you. Any questions?

(No response.)

MR. STRAIT: Thank you so much.

Okay. We are getting close to the end of our morning segment. I'll call up Commenter No. 12.

MR. LEWIS: Good morning. Thank you very much for joining us. I especially appreciate the Administrator and Deputy Administrator being here in person. It shows your true commitment to getting this problem -- getting this solution right for all of us, and I really appreciate your consistent commitment to that in your role as Administrator and then also with our interactions with DEA.

My name's James Lewis. I'm here on behalf

of the American Society of Consultant Pharmacists. We represent thousands of pharmacists who specialize in senior care and medically complex care, practicing in a number of settings around the country, including long-term care facilities, skilled nursing facilities, assisted living, group homes, home and community-based care, as well as individuals who are incarcerated. So we've got the whole setting.

And so my comments today are focused on two main points: one, ensuring appropriate, safe, and accessible access to care; and two, a series of questions that were enumerated in our formal comments to the Agency on the role of pharmacists in implementing whatever DEA regulation is put forward.

So I'll start with the first piece. Having read the rules, they are great and they put forward great ideas, but they are very, very focused on the ambulatory setting. From sort of top to bottom, it is envisioned that this individual may or may not be able to even go to a physical office.

In our setting, while we do have patients in front of practitioners the entire time, we do leverage telemedicine to connect them with specialists, especially addiction medicine specialists and geriatric psychiatrists, both of which we have very,

very few of in this country, and so the use of telemedicine for us in our setting is especially important to get our patients access to those individuals who have the specialized care and training for their needs.

So I just sort of encourage the Agency as it's looking at those issues to think about those patients who may be in front of a practitioner but may not be in front of the right practitioner and that telemedicine can solve those problems.

In the rulemaking, there is the proposal for a non- sort of -prescriber to make the referral that would allow for this to occur. We do have sort of questions and concerns about that as well. In particular, the definition of practice of telemedicine proposed in the rules could be artificially restrictive to pharmacists given especially the fact that in many states -- California, Idaho, Montana, Washington, Massachusetts, North Carolina, Ohio, Tennessee, and Utah -- pharmacists are authorized to prescribe certain substances and in many states aren't prescribed to initiate buprenorphine treatment.

Additionally, we are concerned as well, getting back to the need, that this telemedicine prescribing would be limited to specifically what's on

the FDA label. As discussed, our pharmacists specialize in the care of the medically complex. Oftentimes, we are forced to use medicines off label because it is the right choice for that patient, that patient's needs, and that patient's setting.

So, again, as we look at this for sort of patients in the non-ambulatory setting, you know, will there be sort of greater flexibility to allow a physician or prescriber to make the appropriate choice for that patient based on their training and expertise regardless of the FDA label.

And then finally, just, you know, on the concept of some sort of new waiver, I worked on the Hill before joining ASCP. I remember all of the consternation around the X waiver and the thought for years of trying to get rid of it. Congress finally took action and did it. Are we just going to create another waiver that's going to create another series of artificial barriers between people who know they have a problem with opioids and those people seeking and getting the care they need to get clean and sober?

Finally -- so this is moving into the second part -- you know, I do appreciate the Agency's efforts for the incorporation of ACPS. You've gone a lot further than some of the other federal government

partners on that, so we really appreciate that.

But ACPS will not solve all of the concerns that pharmacists have. We've already heard from other speakers that pharmacists are already hesitant to dispense medicines via telemedicine because there is a severe risk that they could be held accountable for that.

So our questions remain, you know, is a pharmacy responsible for verifying that an in-person visit was conducted, or if this is a referral, that the appropriate in-person evaluation for the referral was conducted? Is the pharmacist responsible for verifying the national provider number and DEA registration number of each, also understanding that a lot of times our patients are coming in from a hospital transfer or another transition of care? Does that transition of care from another setting -- a hospital, acute care, or home-health agency -- qualify as that telemedicine referral? And, finally, will a pharmacy be responsible for verifying the DEA registration in two states if the prescriber is not in the same state as the prescribee?

So, again, I thank you for your attention to this. We have submitted our formal comments, which goes into greater detail about all of these concerns,

but in particular, I just want to stress the need of two things.

One, we've got to make sure that we are taking care of all of our patients, not just the 90 percent of our patients who operate in the ambulatory setting. There are a lot of patients who have a lot of need, and we are seeing increased demand from buprenorphine treatment in our long-term care facilities.

And second, I encourage the Agency to continue to think about what is going to happen at the state levels with either state scope of practice, collaborative care, or expansion of care teams, that the rules should not artificially prohibit a provider with the training, expertise, and blessing of their state to carry out something within their state's scope of practice. Thank you.

(Applause.)

MR. STRAIT: Pause right there if you would just to see if we have any questions for you.

MR. LEWIS: Any questions?

(No response.)

MR. LEWIS: Thank you.

MR. STRAIT: Thank you so much. All right. And we have Commenter No. 13 here. Welcome.

MR. ADAMEC: Chris Adamec with the Alliance for Connected Care. The Alliance appreciates the opportunity to testify to this listening session on DEA's regulations on the prescribing of controlled substances via telemedicine.

As a way of introduction, the Alliance is an organization dedicated to improving access to care through telehealth and remote patient monitoring. Our members are leading healthcare and technology organizations from across the spectrum, representing health systems, health payers, technology innovators, and others. The Alliance works with an advisory board of approximately 50 patient and provider organizations who wish to better utilize the opportunities created by telehealth.

We appreciate the DEA's quick response during the COVID-19 pandemic to allow prescribing via telehealth. This was also a hugely meaningful expansion for many Americans who had other barriers to accessing care. These include individuals who are frail, home-bound, or lack transportation, who live in areas with provider shortages, and caregivers of all kinds whose responsibilities serve as a barrier to care.

We strongly support the development and

implementation of a permanent policy for the prescribing of controlled substances through telehealth to ensure that these individuals do not lose access as these are not challenges which will go away.

As others have noted, mental health and substance use disorder visits continue to represent a growing share of all telehealth visits due to several factors, including growing needs for mental health services and well-documented workforce shortages across the nation.

Americans rely on access to telehealth, with mental health representing 62 percent of all mental health treatments last year. I also want to note that while mental health is the predominant condition, there are many others that are relevant, including access to end-of-life care for home-bound patients.

We believe future DEA actions to preserve access to this care will be a crucial pillar in supporting President Biden's mental health strategy, which seeks to connect more Americans to mental health care through the widespread use of telehealth.

In our testimony today, the Alliance will discuss the importance of a special registration as the primary guardrail to identify and mitigate risks

of diversion in the prescribing of controlled substances through telehealth and will discuss implementation concerns with any proposed regulation.

We'd like to begin today by recognizing the importance of DEA's work in preventing the diversion of controlled substances and zeroing in on exactly what needs to be accomplished in this rulemaking. As you guys know, the DEA's mission includes both protections against the diversion of controlled substances and ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

We do recognize that there have been highly public instances of inappropriate prescribing demonstrated during the emergency, and these demonstrate the need for a regulation. These examples emphasize the need for a regulation that allows good actors to differentiate themselves from those engaging in questionable medical practices.

They should also give the DEA very clear insights into what types of practices may require additional oversight, as explained here. These are our preferred solution rather than a blanket restriction on telemedicine.

As noted in its mission, it's crucial that

DEA balance their concerns around diversion with the huge number of Americans who are relying on the leaders at DEA for an uninterrupted supply to medication for legitimate medical needs.

We believe that the regulation proposed this spring failed to kind of strike that balance because it did not create a pathway for practitioners to treat patients through telemedicine without having had an in-person interaction, effectively ending access to care for many who have the highest needs.

We do think that the special registration outlined by Congress laid a strong foundation for the right balance between empowering the DEA to identify and address diversion while not inappropriately interfering with the practice of medicine and medical decision-making, best left to practitioners and patients.

For healthcare providers, this special registration process should be an opportunity to subject themselves to a higher level of scrutiny, share additional data with DEA, and in exchange, have greater flexibility to prescribe without an in-person requirement, without prescribing time limits, and with the ability to prescribe a wider range of substances.

Having met these criteria, they should not

be subject to other burdensome guardrails. We strongly believe that the registration itself is the protection and does not need to be accompanied by restrictions on the practice of medicine.

For DEA, the special registration should be a tool that allows for the tracking and understanding of who is prescribing controlled substances in what manner so that the DEA can effectively act in its capacity as a law enforcement agency, using this data to identify and investigate potential bad actors, as we all agree is needed.

As noted, we support data-driven decision-making on documented abuses of controlled substances where they exist. We believe that rather than creating overbroad restrictions on the practice of medicine, there can be a targeted solution.

Turning to more specific recommendations, when considering a rigorous special registration process that allows the prescribing of telehealth without an in-person visit, DEA should consider the ability to streamline implementation of that registration process alongside the existing DEA registration in order to eliminate regulatory burden for both DEA and practitioners.

One example of this would be the use of a

single special registration number in conjunction with the appropriate regular DEA registration number to prevent pharmacies and others from having to store multiple special registration numbers for prescribers.

Building on this thought, the ability to have the special registration clearly cited on prescriptions issued from a telehealth visit, along with the appropriate regular DEA number associated with the state where the patient is being treated, would help address pharmacy-related barriers to medication access.

As has been noted today, there have been widespread documentation of pharmacies hesitating to fill controlled substance telemedicine prescriptions as the public health emergency has come to an end. And we believe that consistent documentation clearly endorsed by DEA will resolve many of the concerns that have led to additional barriers to patients receiving access to their medications.

While documentation is important, we do want to note that DEA should take care to maintain the confidentiality of a telehealth prescriber's home address, noting that many practitioners work from home today, and release of this information would create a safety risk for the healthcare provider and their

family if released publicly in any way. Prescribers should be allowed to use a prescribing address that may be a physical practice location or a corporate address if appropriate.

As also discussed today, DEA should work to partner with the CDC, states, and others to obtain telemedicine-related data that may be reported to a PDMP. We think that would strengthen the work.

With a strong registration in place, we believe it would be appropriate for DEA to continue its flexibility when it comes to individual registrations for each state where a provider prescribes to patients. We think the special registration framework in particular would be ideal for addressing multistate telemedicine provider registrations, and we request that the DEA offer additional clarity and streamline how providers with a multistate practice can meet registration requirements efficiently.

Finally, I do want to flag that DEA must allow an appropriate amount of time for the healthcare industry to make system updates and accommodate for the final rule and promote ongoing compliance. This is not only healthcare providers but also the many systems that support them, such as electronic health

records, pharmacy dispensing systems, licensure verification systems, et cetera.

Finally, we do want to flag that we urge DEA not to finalize some requirements that were proposed this spring. Specifically request that you do not finalize any provision that requires an in-person visit prior to the delivery of a telehealth visit.

The primary challenge with an in-person referral mandate is the limitation it creates for millions of Americans seeking treatment for a condition for which there are significant barriers to access. These can include stigma, provider shortages, long distances to see providers, and many other barriers.

There is no reliable guarantee that patients who found access to care through telehealth over the last few years will be able to obtain a meeting with an in-person practitioner who is able to make an examination referral.

Please do not omit Schedule II and non-narcotic substances from the rulemaking. The public health emergency demonstrated almost three years of evidence for the prescribing of Schedule II and non-narcotic controlled substances via telemedicine.

In the broader interest of continuing to prevent substance use disorder, we make specific note that proper treatment of a condition like ADHD with a controlled substance can be crucial to lowering the likelihood of a future substance use disorder.

Finally, please do not add other restrictions, such as the 30-day limits on prescribing, which interfere with the practice of medicine and create barriers to high-quality care. Building on that specific example, if we think about this restriction in practice, it means that a telehealth clinician will be pressured to prescribe a medication to a patient without a clear knowledge of whether that patient will be able to complete the full treatment regimen. Many other restrictions would have similar challenges for the practice of medicine.

Thank you so much for this opportunity to comment. We continue to believe it's both reasonable and possible for the DEA to protect Americans while differentiating between higher-risk business practices and the normal provision of medicine through telehealth.

We urge DEA to continue working with stakeholders, as you are now, and find a nuanced approach to diversion that allows ongoing

relationship-based care between patients and their virtual providers. Thank you so much.

(Applause.)

MR. STRAIT: Thank you. Just hang here for one second.

MR. ADAMEC: Yup.

MR. STRAIT: Any comments? Tom, any comments for you?

(No response.)

MR. STRAIT: Okay. Thank you so much. Appreciate it.

Okay. Well, we are at the conclusion of our morning block of in-person commenters. I want to say thank you to all 13 individuals and the organizations they represent for coming all this way to be here. I think we got a lot of great information.

As I alluded to at the onset, we are going to break until 12:40. 12:40 is when our virtual presenters are all going to be lined up, so we do kind of want to start on time.

For those that are planning to stay for the virtual event, you'll basically have between now and then to potentially go to use the facilities or to go outside and get something to eat. I will just remind you that if you do have to go and leave the building,

unfortunately, you will be asked to go right back to that visitor entrance to go back through our magnetometers, which is just kind of protocol, so I apologize for that.

Again, thank you so much, everybody, and we'll see you at 12:40.

(Whereupon, at 12:02 p.m., the listening session in the above-entitled matter recessed, to reconvene at 12:42 p.m. this same day, Tuesday, September 12, 2023.)

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

(12:42 p.m.)

MR. STRAIT: I know we didn't have a significant amount of time to go out and grab something to eat. I hope everyone who was able to or wanted to get something was able to do so.

We have our panel back here with Assistant Administrator Prevoznik and Administrator Milgram. Thank you all for joining us.

As I mentioned at the outset, we are now going to begin a virtual block of comments. So as I started saying earlier today, I believe we have up to 17 virtual presenters. I'm told we will have a total of 14, or at least at this point we have 14 confirmed. And I am going to basically be sitting here as moderator, but most of the comments and the conversation will be coming and being displayed on the screen here. We'll do just like we did earlier at the end of our virtual commenters' remarks, we will pause and give Administrator Milgram and Assistant Administrator Prevoznik the opportunity to ask any clarifying questions.

So without further ado, let me now call up Virtual Presenter No. 1.

MS. LINDERBAUM: Thank you.

Hi, my name is Elizabeth Linderbaum, spelled Elizabeth, E-L-I-Z-A-B-E-T-H. Last name Linderbaum, L-I-N-D as in Dog, -E-R-B as in Boy, -A-U-M as in Mary. I am with the National Association of Community Health Centers, otherwise known as NACHC.

I just want to say thank you so much for selecting us to discuss the importance of teleprescribing and how it decreases barriers to accessing crucial medications for the vulnerable patients that health centers serve.

Just a bit about NACHC. NACHC is the national membership organization for federally qualified health centers, also known as FQHCs or health centers.

Health centers are federally funded or federally supported non-profit community, directed provider clinics that serve as the health home for 31.5 million people including one in six Medicaid beneficiaries and over three million elderly patients. It's the collective mission and mandate of over 1400 health centers across the nation that provide access to high quality, cost effective primary and preventive medical care as well as essential behavioral health and pharmacy services and other enabling or support services that facilitate access to care to individuals

and families located in medically underserved areas regardless of their insurance status or ability to pay.

We see teleprescribing as a health equity issue. It really helps reach patients who otherwise may have difficulty obtaining a prescription in-patient due to social drivers of health.

Health centers serve some of the most vulnerable people. Sixty-six percent of health center patients are at or below the federal poverty level, the FPL, and 90 percent live under 200 percent FPL.

Additionally 80 percent of health center patients are uninsured or publicly insured. Furthermore, health center patients have always had complex care needs and these needs have grown increasingly complex in the past few years.

From 2013 to 2017 the percentage of health center patients diagnosed with substance abuse disorder grew 73 percent, and patients diagnosed with depression grew 39 percent.

We see access to medications to treat conditions like these via telehealth as a lifeline for these health center patients. Teleprescribing is also a harm reduction strategy. For example, when discussing substance use and the readiness to change,

we see the best time to intervene is when the patient is ready, not when they can get a ride to the clinic. If the goal is to minimize risk associated with use such as HIV, Hepatitis C, syphilis or overdose, then allowing individuals to have access to a prescription without additional barriers to engagement is very important.

So both adults and children were able to continue accessing medically necessary controlled substances via telemedicine by waiving the requirement that the patient have a prior in-person visit regardless of their location during the PHE, and we were very supportive of that.

I just want to echo some of the comments that we put in our previous comment letters, that we are not just concerned about the potential negative impact that an in-person medical evaluation or requirement may have on a patient's ability to receive subsequent prescriptions and their ability to maintain continued access to necessary controlled medications.

We see the in-person requirement potentially affecting and impacting myriad types of patients that health centers serve. For example, patients who face transportation barriers, parents with young children at home, older adults, patients who started on a

controlled substance during the pandemic and then subsequently became bed-ridden or homebound, unable to come to the clinic for care. People with disabilities and people experiencing homelessness. All of these patients can face significant obstacles to meeting that in-person requirement, and NACHC is concerned about the negative health implications of that proposal.

We also think that an in-person requirement could affect some special populations that health centers serve. For example, health centers that serve the LGBTQ population. They often report that these individuals come from outside of their service area to seek services from the health center via telehealth because in their community there's a lack of access to affordable services that truly take into account the unique clinical needs of the LGBTQ population. This in-person requirement could create disruptions and care for patients who choose a certain health center based on the services available, which may not be located in close proximity to them.

Having an in-person requirement could also negatively impact the health care workforce which is already struggling to recruit and retain staff.

NACHC released a recent survey that found

that 68 percent of health centers lost between 5 and 25 percent of their workforce in early 2022 with a majority citing financial opportunities at a large health care organization as the main reason for departure.

Health centers have reported extreme difficulty in retaining behavioral health staff like psychiatrists and licensed clinical psychologists, and many health centers have tried to fill the gap by utilizing telepsychiatry providers for psychiatric needs. Even so, some health centers have reported a limited supply of psychiatric prescribers, resulting in longer wait times for patients to see prescribers.

We also think that having an in-person requirement could disproportionately impact the workforce for health centers and their patients specifically in rural areas. Nearly 400 health centers operate 5600 service delivery sites in rural communities and health centers serve 1 in 5 Americans living in these rural communities.

Many providers live in major cities and they're unable to physically travel to these remote cities and therefore, they see their patients via telemedicine.

Rural providers also use telehealth to form

partnerships with providers in urban and larger cities to expand their network, to reach more patients.

By enforcing in-person requirements many patients might not be able to continue seeing their providers, especially in regions with less access to care.

For instance, one state primary care association told us that 40 percent of their health centers from their main site located (technical interference) areas, and we see that as very critical that health centers are able to maintain their ability to provide care to the most vulnerable patients and use telehealth to meet the patients' needs in the least burdensome way.

The in-person requirement could also increase wait times for appointments. The average wait time for a physician appointment across the country is 26 days, with specialty medical appointments with an even longer wait list for in-person appointments. And these wait times can result in more patients going without proper assessment and treatment because of an in-person requirement and that could likely add to the burden on the hospital systems. Patients may seek treatment in different forms such as emergency rooms and urgent

care centers where their needs will most likely not be met.

We really appreciate the DEA's time and consideration of our comments. For health center patients the ability to access vital controlled substances via teleprescribing really enhances health equity by breaking down barriers to care and better meeting patients where they are. Teleprescribing possibilities given during the pandemic really ensured continued medication regimen and ensured that care plans were not abruptly disrupted, and we hope that this can continue.

Thank you so much for the opportunity to speak, and I'm very happy to answer any questions.

MR. STRAIT: Okay, okay. Thank you so much for your comments. I have paused, the Administrator and Assistant Administrator Prevoznik are saying there's no questions.

So what we will now do is cue up Virtual Presenter No. 2.

MS. COPE: Thank you. My name is Michelle Cope spelled M-I-C-H-E-L-L-E C-O-P-E. I'm with the National Association of Chain Drug Stores or NACDS.

NACDS represents chain pharmacies that operate as traditional drug stores, supermarkets, and

mass merchants with pharmacies. Chain pharmacies operate over 40,000 pharmacies throughout the nation and fill over three billion prescriptions yearly. Thank you for the opportunity to share NACDS member perspectives related to telemedicine prescriptions.

It is imperative that DEA work to ensure that any requirements the agency establishes for telemedicine prescriptions do not inadvertently and unnecessarily stifle patients' ability to benefit from telemedicine by unduly burdening pharmacies attempting to fill telemedicine prescriptions. Any new or special requirements for controlled substance prescriptions issued via a telemedicine encounter must be workable for pharmacies to implement.

NACDS previously submitted comments to DEA on the NPRM's addressing telemedicine prescribing. From our prior comments we want to reiterate and emphasize the following points relevant to the focus of today's listening session.

Number one, there's a strong likelihood that controlled substance prescriptions issued via a telemedicine encounter will be electronically prescribed. Thus DEA must provide adequate time for system vendors, practitioners and pharmacies to update their EPCS systems to accommodate any new information

that DEA might require on a telemedicine prescription. Such as a special prescriber notation or, as we've heard referenced today, as special new DEA telemedicine prescriber registration number.

Such an endeavor will require coordination across the entire health care system and will likely take years to complete.

Number two, DEA must make it clear that any requirements for practitioners related to prescribing via a telemedicine encounter do not increase obligations under pharmacists' corresponding responsibility. Pharmacies don't have access to prescribers' electronic medical records or progress notes to verify prescriber compliance with all of DEA's standards for telemedicine prescriptions. Anecdotal reports indicate it can sometimes be difficult for pharmacies to contact telemedicine prescribers at the number listed on the prescriptions which sometimes leads to an automated message advising pharmacies to fax in any questions.

Number three, DEA should allow telemedicine prescriptions for all Schedule 3, 4 and 5 and should not impose any limitation based on a status of a narcotic versus a non-narcotic drug. This might lead to confusion among health care providers which is

unnecessary because controlled substance schedules are already stratified by risk.

For today's listening session DEA asked for feedback on number one, what pieces of data to include or exclude if pharmacies are required to collect, maintain, and/or report telemedicine prescription data to DEA; and number two, what data pharmacies already report to federal and state authorities, insurance companies, and other third parties.

With respect to any potential requirements for pharmacies to report telemedicine prescription data to DEA, we have significant concerns with DEA imposing such a requirement on pharmacies. Any requirement for pharmacies to report telemedicine prescriptions to DEA would be administratively burdensome requiring pharmacies to shoulder the burden of weeding through and supplying DEA with prescription data that DEA will presumably use for practitioner investigation and enforcement purposes.

Furthermore, requiring pharmacies to report telemedicine prescription data to DEA would be akin to a DEA establishing and maintaining a national data repository for telemedicine prescriptions, much like a nationwide PDMP. If this is DEA's intent, we ask DEA to clarify the agency's statutory authority for such a

requirement.

To support DEA's investigation and enforcement activities, we think the agency should follow the same processes it uses to investigate and enforce with prescribers who issue controlled substance prescriptions to patients on the basis of an in-person encounter.

However, if DEA remains intent on relying upon pharmacy data for its enforcement efforts and requires additional information to identify prescribers issuing telemedicine prescriptions for its investigation and enforcement purposes, then NACDS recommends that DEA develop a separate, special registration for practitioners that is used only when prescribing a controlled substance via a telemedicine encounter.

Additionally, DEA should require that the transmitted prescription information clearly identifies any affiliated telehealth entity.

With respect to any potential requirements for pharmacies to collect or maintain new prescription data unique to telemedicine prescriptions, e.g. a telemedicine notation or a telemedicine DEA registration number, as previously stated, accommodating new prescription data elements would

involve substantial changes to data transmission standards and to electronic prescribing and record keeping systems across the entire health care system that would likely take years to complete.

Currently states, insurance companies and other third parties do not require pharmacies to identify or distinguish telemedicine prescriptions for record keeping purposes or to process pharmacy claims. So pharmacies don't collect, maintain or report such data. Electronic prescribing and record keeping systems changes would be needed to support this.

With respect to telemedicine prescriptions issued electronically, we've now mentioned several times that systems updates are needed to facilitate the distinction or notation of a prescription issued via telemedicine encounter.

The topic gets very weedy and technical, so for the sake of time and clarity, I'm going to refer DEA to NACDS' past comments on the 2023 NPRMs for telemedicine prescriptions that really kind of dig into this.

I'd also encourage DEA to consult with the National Council for Prescription Drugs Programs. That was the standard-setting organization that developed health data transmission standards that

facilitate the data exchange for electronic prescribing of controlled substances, prescription and pharmacy related health care claims, and other information exchange.

But in short, if DEA officers require new information on prescriptions to delineate telemedicine prescriptions, pharmacies as well as EHR and pharmacy system vendors would need adequate time to implement system changes to support the transmission of these data points so that pharmacies could record and maintain any new required prescription information in their records.

Lastly, to further support DEA's ability to identify telemedicine prescribers and assess prescriber compliance with the originally proposed rules, we encourage the inclusion of two additional data elements on controlled substance prescriptions that are issued via a telemedicine encounter.

Number one, the practitioner's state license number and the state into which the telemedicine practitioner is issuing a prescription. And number two, if the prescriber issuing a telemedicine prescription is part of a larger dedicated telemedicine practice, the name of that company or group.

Thank you again for the opportunity to speak today, and I'm happy to answer any questions you might have.

MS. MILGRAM: Can I follow up with a couple of questions?

MR. STRAIT: Absolutely, yes.

MS. MILGRAM: Thank you so much.

When you talk about being part of a larger telemedicine practice, what would the delineation be for that sort of size?

MS. COPE: We do not have at this point a specific recommendation for how many practitioners would be under that practice, but I think what we're kind of getting at is the large telemedicine groups that have hundreds of prescribers. I understand that DEA will be inviting further comment on that, so that's a point that I'm happy to bring up with our membership and to provide further insight on.

MS. MILGRAM: Could you expand a little bit, in terms of you talk a little bit about what data the pharmacists and the pharmacies are already collecting. Could you give an example in one sort of prescribing situation, could you expand on what that data looks like that you collect today?

MS. COPE: Sure. It's what's required to

process a claim or to meet DEA's existing record keeping requirements or state-level record keeping requirements, right? So it's the name of the patient. It's all of that information that's delineated in the DEA rules and laws that specify what goes on the prescription. So what is required, that's what pharmacies are maintaining. That's limited.

With respect to the data points that we have heard brought up or that we saw raised in the rule, currently, originally DEA had proposed a notation of a telemedicine prescription for prescriptions that were issued via a telemedicine encounter. And that's not something that is collected now. Without jumping into the NCPDP scripts standard, that's not something that there is a dedicated implemented field for transmitting that information to. So that's not currently reported.

And if there would be a new DEA registration number that would, that potentially would be something that would have to be accommodated to.

So I think I answered the question, but, you know --

MR. PREVOZNIK: What data is there -- I know the Administrator just asked this, but a little bit of aside, what data is there that could currently be used

to leverage, to identify this?

MS. COPE: I did cut that out but I'm happy to jump into that.

So what exists now is -- and we're thinking like in terms of the e-prescribing, right? Because most of this is going to very likely be an electronic prescription and not an in-person encounter.

What could be used now and immediately is the prescriber place of service and the usage of last office visit. But that being said, that's not something that's commonly sent to pharmacies. The standard exists and that can support the transmission of that information, but EHR systems, prescribers' EHR systems are going to have to be updated to transmit that. You know, it's a whole sort of trickle-down effect.

So the standard has something to support it, but it's not commonly sent and I don't believe that may prescriber systems are set up to send it just now.

MR. PREVOZNIK: Good.

MR. STRAIT: Okay, Michelle. Thank you so much for your comments.

I will now go to Virtual Presenter No. 3.

DR. RANSONE: Good afternoon Administrator Milgram and Deputy Assistant Administrator Prevoznik,

DEA representatives and leaders. My name is Dr. Sterling Ransone. Spelled S-T-E-R-L-I-N-G R-A-N-S-O-N-E.

I'm a practicing family physician in a small clinic located in rural Deltaville, Virginia on the coast of the Chesapeake Bay. I'm the immediate past president and am serving currently as the board chair of the American Academy of Family Physicians, or AAFP. I'm honored to be here today representing the 129,600 physician and student members of the AAFP.

Family physicians provide comprehensive person-centered primary care to patients across the life span forming longstanding relationships with our patients and serve them across all practice settings. We are often our patients' first call for chronic care management, acute illness, emergency care, and increasingly mental health concerns. Our training and uniquely broad scope of practice enables us to be responsive to the needs of our patients, their families and our communities including offering telehealth visits and providing treatment for opioid use disorder or OUD.

During the COVID-19 pandemic family physicians like me found that telehealth services help us improve access to care for our patients by removing

transportation and other barriers that prevented them from getting in to see us in the office. The longstanding relationships I have with my patients have enabled me to determine whether a telehealth or an in-person office visit was most appropriate for their condition. Such as when a patient needs hands-on care or a new or renewed prescription for a controlled medication.

Unfortunately, we also have observed how appointments conducted by telehealth companies without these preexisting relationships led to fragmentation of care and at times lower quality care.

That's why the AAFP recommends permanent telehealth prescribing regulations that prioritize established patient/physician relationships while also facilitating equitable access to care for our patients, millions of whom live in health professional shortage areas and are facing months-long waits for chronic disease management via an in-person appointment.

To achieve this, we strongly recommend that DEA not impose additional telehealth prescribing restrictions for controlled substances on physicians who have already established the patient relationship through an in-person visit.

As family physicians we want to support our patients by providing them time and flexibility to overcome issues caused by transportation costs, child care, stigma, distance, and other barriers to treatment.

Many of my patients are quite elderly and find it difficult or physically painful to visit the office. Telehealth has allowed them to receive the care that they need with the physician they trust in the privacy of their own home.

A majority of my current telehealth visits are in the behavioral health sphere. It allows me to visit the patient at home, at work, or in their school dormitory. It allows me a peek at their social situation as well, so I can give better care and maintain the important bond between the patient and their physician as they heal.

I call telehealth the house call of the 21st century. It's vital for the DEA to partner with us in supporting our patients' access to care, and telehealth prescribing is key to maintaining that access.

Second, DEA should allow prescribers to manage a known patient's condition via telehealth for six months before requiring an in-person exam.

Family physicians believe six months of telehealth only prescribing with Schedule 3 through 5 medications achieves the appropriate balance of facilitating access to care and protecting patients' safety. With long appointment waits in many communities like mine, a shorter time limit will create operational challenges for physician practices and for patients alike, and ultimately exacerbate health disparities.

Third, we recommend DEA permanently allow telehealth-only prescribing of Buprenorphine for the treatment of opioid use disorder.

Studies conducted during the public health emergency found that telehealth prescribing of Buprenorphine improved treatment access and retention as well as improved patient satisfaction wile reducing illicit opioid use. Given the robust evidence in support of telehealth OUD treatment, limited access to OUD treatment providers and low rates of Buprenorphine divergence, we strongly encourage DEA not to finalize any proposal that would require an in-person visit and exam for prescribers of Buprenorphine for OUD treatment.

As family physicians we stand with the Biden administration in strongly supporting expanded access

to OUD treatment through telehealth.

Finally, we urge DEA to focus on addressing diversion and improving oversight of telehealth companies instead of imposing complex burdensome regulations on physicians. While we have advocated to permanently expand coverage of payment for telehealth services and strongly support our patients' ability to access telehealth services from their usual source of care, the AAFP has also repeatedly shared concerns that services provided by direct to consumer telehealth companies may drive care fragmentation and pose significant patient safety risks.

Most helpful for family physicians would be increased agency oversight on telehealth provided by companies that are not a part of a patient's usual source of care. Better, more targeted oversight will be more effective than burdensome reporting mandates and duplicative licensing requirements for telehealth prescribing of controlled medications within an established patient/physician relationship.

Physicians are already overburdened, particularly in small and rural practices like mine and we encourage DEA to work with other agencies to harmonize licensing requirements for prescribers. We urge DEA to focus its efforts on addressing diversion

and stopping bad actors through law enforcement activities, not health care regulations.

In closing, family physicians are uniquely positioned to safely offer comprehensive care that integrates telehealth as a tool to help us provide better care without additional burdensome requirements that prevent us from serving our patients as they need, or risk negatively impacting their outcomes.

We look forward to partnering with DEA to uphold safe prescribing practices and to ensure patients' continuous equitable access to care after the PHE era flexibilities end.

Thank you for the opportunity to provide this testimony. I look forward to answering any of your questions.

MR. PREVOZNIK: Doctor, thank you for your testimony.

I have a question in regards to what your experience has been with audio only or two-way?

DR. RANSONE: The biggest thing that I've noticed is a lot of my older patients, especially those over 75, when we do a video teleconference or a video visit, almost all of them have either an assistant, a caretaker or a family member to help them work the technology.

Audio only telehealth services for my practice have been -- and the ability to be paid for those services, has been a boon because most of my old folks know how to use a telephone. Unfortunately, they don't feel as comfortable in using a computer and video available services.

So I have used quite a bit of audio only telehealth services.

The other problem is where I am, many of my patients don't have broadband access. In order to access some of the more advanced telehealth services in my electronic health record, they can't get in because they don't have broadband access.

So availability of a telephone really has allowed me to reach them.

For my practice, most of my patients I've known for 20-30 years, and when I speak with them on the phone I can get a lot, just telling how they are over the phone. So I personally have been quite pleased and it has benefitted my practice to have the availability of the audio only services.

MS. MILGRAM: Can I just follow up on the audio only.

DR. RANSONE: Sure.

MS. MILGRAM: My sense from how you're

describing it is that you don't have an identity verification component because you have longstanding relationships with that patient, but I don't want to make that assumption. Is there an ID --

DR. RANSONE: That's true for most of my patients. Most of these folks, when I do audio only, they're folks that I know. And usually I know their voice or I know their family members and things like that.

As far as proving identity when we speak, most of mine is experience.

I would have to defer to the AAFP for any other physicians' experience for those who don't have these longstanding relationships.

MS. MILGRAM: One last question.

You talk a little bit about some concerns with the telehealth companies that were doing appointments with some of your patients. Can you just elaborate on that a little bit? Give us some examples, maybe.

DR. RANSONE: Yes, ma'am. I practice in a rural area with my wife who's a pediatrician. And we frequently will have patients come in to see us for followup after a visit that was a telehealth visit with one of these companies where we have not received

the data, i.e. diagnosis or treatment plan or treatments from those companies when the patient sees us for followup.

Very frequently, for something that might be a viral infectious disease, we'll see these folks coming in on antibiotics or other substances which we personally wouldn't have used because we know these patients and we know the things that they get and where they've been. Plus we know the bacteria that are in our area, we know the sensitivities and resistances of folks in our area, or of the diseases in our area which folks who aren't in this area might not know it.

So the biggest concern is probably the fragmentation of care. Unfortunately, when patients come in and I ask well, what did they do? Well they put me on a white pill. Do you have it with you? Usually they don't bring it. Then I'm scrambling trying to figure out what medication they were placed on so that I don't do harm by out-prescribing a medication that might interact with the drug that they've been given, and I don't have the data to know what it is that the patient's been treated with.

So that fragmentation of care has been quite concerning for us.

MR. STRAIT: Great. Thank you, Dr. Ransone.

And I am just going to add as just a point of clarification, I know Administrator Milgram mentioned it at the outset and it just deserves an assurance that we're providing clarity. Dr. Ransone has specifically been talking about his experience as a family medicine practitioner in his rural community where he knows and has treated many of those patients in person in the past. Our telemedicine regulations, we're seeking to create a situation where that in-person medical evaluation had not previously been coordinated. So I just want to throw that out there.

In the instance of an existing patient that a doctor is treating, once that in-person medical evaluation or that in-person treatment has been established, which could have been years back or relatively recently, the requirements of what we were proposing in our regulation would not exist because that in-person relationship's already been established.

Okay. With that, let me pull up Virtual Presenter No. 4.

MS. KESIC: Good afternoon. My name is Anna Kesic, that's A-N-N-A, K-E-S-I-C, and I am the CEO of Empower, located in Florida. We are a non-profit

behavioral health organization in-operation since 1994. We serve over 9,000 individuals a year in our various programs, and I have been blessed to be in this role with the organization over the last 15 years.

Empower's primary care client base consists of Medicaid recipients and members of the uninsured or the underinsured population. Our goal is to provide access to quality treatment for those in-need of behavioral health services.

It is well-documented that if patients have telehealth access to behavioral healthcare, they are more likely to initially engage in treatment and more likely to remain in treatment. Since the inception of telehealth treatment at Empower's psychiatric clinic, patient appointments have more than quadrupled in number.

Within the first year alone, a 60 percent pre-telehealth no-show rate for in-person dropped to 12 percent via virtual telehealth. Empower has built a very robust and safe telemedicine practice which is predicated on clinically sound treatment and a fully compliant face-to-face secured virtual platform.

With over 210,000 telehealth services conducted since the PHE in 2020, Empower considers

itself experts in telepsychiatry in the state of Florida, and many of our state employees and telehealth associations agree with that.

Telehealth treatment has exponentially increased each year. Please let me provide you with some of our statistics. We are currently serving 489 individuals that are underinsured or underinsured in our clinic. For all of our funders from April 1 through August 31 of this year, the agency provided 8,177 psychiatric services, of which 7,539 were medication management and 638 were psychiatric evaluations.

During COVID, October 1, 2021 through May 31, 2023, 500 individuals were served at our clinic at Empower. A total of 7,332 behavioral health services were provided to all of our clients during this time. Nationally, prior to the COVID-19 pandemic, less than one percent of all behavioral health visits were performed via telehealth.

However, in the second quarter of 2022, that number rose to 32.8 percent, and in the same quarter, 63.8 percent of all telehealth visits were for behavioral health. According to a new analysis by Truliant Health, telehealth-delivered behavioral health services jumped 45-fold since the inception of

the pandemic, demonstrating a critical need for such services.

The pandemic helped to lift the stigma for receiving behavioral health services. It has also contributed to an increase need to many of the individuals who have lost loved ones, jobs, personal related health issues, et cetera. We are only beginning to see the aftermath of the toll the pandemic has taken on individuals' mental health well-being and put it in jeopardy.

Under the definition section in your rule, it states that, "CMS recognized that for many mental health services, visualization between the patient and the clinician may be less critical to the provision of service. Mental health services are different from other services because they principally involve verbal exchanges between the patient and the practitioner."

For these services, face-to-face visits are not necessary to provide sound and quality treatment. Empower's mission to serve the uninsured and underinsured population of Florida -- there is a national critical shortage of psychiatric providers, and this data is mirror here in this day. There are even fewer psychiatric practitioners willing to work with our population, and even fewer Child

Psychiatrists than the national average.

For these reasons, it is even more critical to utilize telehealth to meet the need. Without telehealth, this large segment of the population will not and cannot be served. Regrettably, the flexibilities outlined in the DEA proposed language are construed too narrowly to appropriately address the needs for the behavioral health population, especially for lower-income clients without transportation, children of families in the child welfare system, individuals in rural areas, and individuals residing in provider-impoverished areas.

Instead, the proposed language is highly focused on narcotic medication and does not give the same credence to behavior health patients who have a longstanding, valid doctor-patient relationship via telemedicine and are in need of non-narcotic controlled substances for psychiatric treatment.

In fact, the majority of telehealth visits pre- and post-pandemic have been for the treatment of behavioral health conditions. In the DEA intent of proposed language, it states, "More than 75 percent of all counties in the U.S. are classified as mental health shortage areas, and 50 percent do not have mental health practitioners."

Behavioral health practitioners and organizations are left to ask: how will the in-person requirement help patients who need non-narcotic controlled substances for their mental health? The simple, and direct, and honest answer is: it doesn't. Rather, it will create unintended discriminatory hardships on mental health patients who are not abusing medication, and impedes timely access to care and continuity of their treatment.

Empower's referrals for these services mainly come from school systems, family members, corrections, diversion programs, the judicial system, juvenile justice, and the child welfare system. Rarely are they referred from primary care physicians, and although having a primary care medical home is a best practice, many of these clients do not have access for a variety of reasons.

Furthermore, the language seems to focus principally on the enforcement component of DEA and not the practical solutions. The vast majority of medical practitioners are not, and have not contributed to the misuse and abuse of prescribing controlled substances.

This is particularly true for behavioral health practitioners. With such a focus, these

individuals that truly need services and have access to care issues are being penalized, as well as the dedicated practitioners who provide these services.

Behavioral health providers propose that an exception be made for the prescribing of Schedule II non-narcotic medicines for the treatment of ADHD, and Schedule IV substances for the treatment of anxiety. In fact, because of our advocacy at Empower, the State of Florida Board of Medicine recognized the importance of this, and in March of 2017, enacted the following language.

And I quote, "Controlled substances shall not be prescribed with the use of telemedicine except for the treatment of psychiatric disorders." The DEA intent of proposed language states that the Ryan Haight Act, or RHA, intended to address threat to public health safety caused by physicians who prescribe controlled medications via the internet without establishing a valid doctor-patient relationship through such fundamental steps as performing an in-person medical evaluation of a patient.

It is important to point out that when the RHA was implemented initially, telehealth did not exist as it is at all today. In fact, it was vastly

different. This is especially true for behavioral health providers.

The proposed language is overly focused on the opioid use disorder and does not consider mainstream psychiatry and the essential need for non-narcotic Schedule II and Schedule IV medications. The proposed language creates a greater risk that non-specialty behavioral health practitioners without specific current knowledge of psychiatry will prescribe controlled substances during their in-person examination, rather than defer and refer patients to specifically trained psychiatric practitioners.

It is important to note that PCPs write 79 percent of all antidepressant prescriptions and 45 percent of antipsychotic medication, and may inadvertently contribute to overprescribings of these drugs nationally.

In summary, longstanding non-profit organizations such as Empower have been the backbone of behavioral health treatment from the uninsured and the underinsured for years. We have figured out how to do best and to meet the needs of those populations to keep them safe, out of higher levels of care, and ensure they have access to the services they need to live their best quality of life.

Empower has always done that and will continue to prioritize quality while working to eliminate unnecessary barriers to care. For these reasons, Empower is here requesting that the DEA carve-out an exception to the face-to-face requirement for behavioral health services in which non-narcotic controlled substances are prescribed.

We ask that there be a provision in the rule that allows for telehealth behavioral health entities to be vetted, particularly longstanding practices and non-profit organizations, and be exempt from the in-person requirement. I thank you very much for your time, and I'm happy to answer any questions.

MR. STRAIT: Okay. Thank you, Anna. We actually have just been told there are no follow-up questions, so we will now move onto Virtual Presenter No. 5.

DR. PLUMER: Hello. My name is Dr. Robin Plumer, spelled R-O-B-I-N, P-L-U-M-E-R and I'm an end-of-life physician in New Jersey. When I first heard about the proposed restrictions regarding the prescribing of controlled substances by telehealth, I was extremely alarmed, and my first thought was, "Wait, I think they forgot about the end-of-life community."

Individuals who are at the end of their lives often rely on controlled substances to relieve what can otherwise be debilitating pain and unbearable shortness of breath. As a hospice physician, my patients rely on me to be able to prescribe these medications in a timely manner, and I rely on telehealth to help care for them.

Deeply concerned for my patients' access to the medications necessary to relieve their suffering, I, along with representatives from Death With Dignity and the Completed Life Initiative, went to D.C. in April of this year to advocate for the judicious use of telehealth to prescribe controlled substances for end-of-life patients.

We visited the DEA headquarters in D.C. to personally deliver boxes containing over 10,000 letters from concerned members of the end-of-life community regarding this issue. These letters represented 25 percent of the total letters sent to the DEA asking for reconsideration of the proposed rule.

Clearly, there are many highly concerned end-of-life practitioners, patients, caretakers, and loved ones who realize just how devastating the DEA's proposed regulations and the loss of telemedicine

would be to this vulnerable group of patients.

I am uniquely positioned to appreciate the DEA's intention to implement safer prescribing practices for controlled substances amidst the opioid epidemic, as I was an emergency physician for 30 years before shifting my practice to end-of-life care.

As an ED doctor, I saw firsthand the devastating impact of opioid misuse, abuse and dependence, and I applaud the DEA for trying to develop strategies to address the opioid crisis and acknowledge the value of an in-person clinical assessment when prescribing controlled substances for the population at-large.

However, having spent the last eight years caring for individuals at the end of life, I rely on opioids and other controlled medications to relieve my patients' suffering. These patients are often weak, homebound, bed-bound, and they lack transportation to attend a clinic visit in order to obtain their needed medications.

Hospice fills this role admirably by providing patient-center care in the patient's home. Prior to the COVID pandemic when I worked as a hospice medical director, the standard of care was that a hospice nurse would see a new patient in the community

and then phone the hospice doctor to give a report about hospice eligibility and the patient's needs.

Based on that, the doctor would order initial comfort care meds, which generally included liquid morphine and Ativan. Now, with the new proposed rules, the DEA is, perhaps incorrectly, sending the message to hospice patients and workers that they want to go backward and destroy the system that has served hospice patients for years.

Not only are terminally ill patients on palliation, not to worry about in terms of drug abuse or illegal activity, but they should never be forced to suffer extended pain and lack of access to necessary medications in their final days of life.

Let me tell you a story about John. John was an elderly man suffering from severe pain in his abdomen and bones from end-stage cancer. He was bed-bound, weak from being unable to eat, and short of breath from fluid in his chest and abdomen. He required oxygen to breathe.

His wife, who was his primary carer, was herself frail and elderly, and certainly would not be able to get him to a clinic visit. The ability to use telehealth so I that I could assess his condition and prescribe the right medications to treat his symptoms

has been an amazing advance to make both of their lives easier.

Most people in such a situation would want this kind of patient-centered care in the comfort of their own homes for themselves or their loved ones. Mandating in-person visits prior to prescribing controlled medications in this unique population would create a devastating burden to these patients, and it would delay their ability to obtain these medications in a timely fashion.

At worst, many individuals would go without the medications necessary to mitigate their pain and ease their breathlessness, and instead, their last days would be devoid of comfort and dignity.

Some hospices care for hundreds of patients, and this is, and has been the model of care across the U.S. A change to the current procedure, requiring the hospice doctor to visit every new patient in-person, would be completely out of the question due to the number of patients that would need to be visited.

There are simply too many dying people and not enough doctors, especially in rural areas. Currently in my own end-of-life practice, I am able to care for patients who live anywhere in New Jersey. Some are three hours away, and it would be impossible

for me to spend six hours round-trip to see a new patient in order to prescribe for them.

Some of these patients live in rural areas where they would simply lose access to care if telemedicine were not an option. The terminally ill patients I care for don't just live in cities near major medical centers. We all know the challenges our healthcare system has in delivering quality care to rural areas.

For the terminally ill, this problem is even worse, for they lack easy access to specialized physicians who can provide the care they need. Telemedicine has become so accepted in general medical practice since COVID that the thought of withdrawing this option seems like a giant step backwards. It certainly will not enhance compassionate care for terminally ill patients.

Our goal as medical practitioners is to reduce suffering, and provision of needed medication is a huge part of this. This group of patients is at very low risk for abusing controlled substances, and will undeniably suffer if we limit their access to pain-relieving medications.

Their legitimate need for opioid medications at the end of life is not disputed by anyone in the

medical community, and I hope that the DEA can protect this specialized population and exclude end-of-life providers from unnecessary and cumbersome restrictions.

Please do not further complicate our patients' final days by limiting their access to the medications which are carefully prescribed to minimize their suffering. The CDC realized the critical need for hospice and palliative care patients to receive adequate symptom relief by specifically stating in their guidelines for prescribing opioids that their recommendations to not apply to pain management related to palliative care or end-of-life care.

I hope the DEA will make a similar thoughtful exception to these well-intended proposals regulating controlled substances by excluding those individuals at the end of life. Thank you.

MR. STRAIT: Thank you, Dr. Plumer. Do we have any comments? Tom? Anne? Okay. Thank you very much. We will now move onto Virtual Presenter No. 6.

MS. SULLIVAN: Hi. My name is Jodi Sullivan, J-O-D-I, S-U-L-L-I-V-A-N, and I represent the Investigations Medicare Drug Integrity Contractor. We investigate part D drug fraud cases. Part D is the main drug coverage for Medicare and covers over 51

million patients.

So, as part of our daily activities, we do investigate both drug diversion and telehealth fraud cases, so our input is relative to the DEA in terms of minimizing diversion and improving patient safety as part of an enhanced registration.

So, we do appreciate the time and collaboration here, and we would be willing to participate in any future discussions with the DEA regarding this. So, the main points we want to bring up are some of the things we see in our investigations. One is, with embracing this, we really need a Federal standard as to what a true telehealth visit would require for controlled substances.

As discussed by some of the other speakers, there is a variety of different types. In our cases, we sometimes see unlicensed personnel taking medical histories -- call center employees, for example -- so it is very important that the DEA establishes a Federal standard for this as part of an enhanced registration.

State laws vary greatly and we may have a prescriber, a pharmacy, and a beneficiary all in three different states that we are trying to evaluate as

part of a diversion case and telehealth case. There's two other components to a standard that should be evaluated.

One is: how do you monitor and evaluate these patients without the inpatient visit, and what would be a minimum that would be required? And this might vary depending on what type of patients and therapeutic area you're addressing.

But in medical record review with bad actors in this space, we do often see that the need for controlled substances initially and ongoing is poorly documented. So, we would need to have some sort of standard to help us evaluate and determine what would be inappropriate and should be referred to law enforcement.

Urine drug screens are another important tool that we often find are problematic in these patients' medical records reviews and often lead to patient harm from the inaction to accuse of misuse, abuse, and addiction by providers.

So, when we evaluate these, how are we going to monitor these in a remote environment? There's a variety of discussion out there, including sending packages to patients and having them return them. We do see falsification, a lot of times -- samples that

are not consistent with human urine -- and so you need ways to prevent tampering for that.

So, the DEA should endorse some ways to appropriately remote monitor patients with urine drug screens that would not be subject to tampering by patients with drug use issues.

Confirming a valid relationship. This is really important for a couple of aspects. One is, patients. We see very often in telehealth scams that patients do online searching for their own medical care that's very common these days, and they are often bait-and-switched into a scam to get their medical information and to prescribe and dispense medically unnecessary prescriptions that may not at all address the patient's medical need, and so there's a variety of patient harms that can come from that, as well as the financial harm to a payer like Medicare.

So, that is something that's very important. A patient should be able to see if an organization or a prescriber has this valid registration, something like an internet page symbol or a national lookup where you could verify and say my prescriber is enrolled and I know they're valid, as well as a way for a patient to submit a complaint.

If they have had someone misrepresent their

status, then the DEA should be able to get that complaint and investigate it. Pharmacists should be able to verify these claims, especially when they're remote. They don't know this prescriber, so they need to be able to verify that, and I think a few pieces of information added to the prescription would be key to that.

One would be the fact that it is a telehealth prescription. A lot of times we do see that prescribers do this practice on top of another practice -- a day job -- so it is important to be able to discern the two different patterns sometimes and what is legitimate and is not legitimate.

ICD-10 codes would be another thing that would be helpful, particularly if the DEA did the enhanced registration specific to only certain areas like hospice or mental health. Being able to determine that it was related to those and not outside of scope for a virtual visit would be important for pharmacies, pharmacists, as well as insurers.

Those information should be added to electronic prescription drug claims so payers could have access to that as well. Medical records. Although those are onerous and time-consuming for people to provide and to review, sometimes they're

warranted for investigations, and we do find they're difficult to get from drug diversion and telehealth cases a lot of times, typically because the medical records do not meet minimum standards for a medical record or evaluation and management services for Medicare, and they have not been charged Medicare; they have been done through cash payments or other payments.

So, when we evaluate these, you really do have to consider whether medical records can be obtained. So, medical records should be obtainable with reasonable requests. If not, that should open a pathway to the DEA for revocation of the registration.

Payment of services should be transparent. We do find that financial interests by the telehealth company or pharmacies can often lead to kickbacks and also drug fraud, so it does need to be transparent who paid for the medical services if they were not submitted to the insurer.

In controlled substance investigations, patients who are drug seekers often pay cash to get around insurance utilizations and to seek out physicians or prescribers who will enable their drug diversion, their drug misuse.

Data sets. I would like to bring up state

PDMP. These are very helpful data sets. They aid patient safety and they assist dispensers and practitioners, prescribers, in providing appropriate patient care and preventing drug use and misuse.

With enhanced electronic prescribing of controlled substance and now virtual prescribing of controlled substance, I think we are at a point where we need Federal PDMP. Every program is state-level, and I honestly do not feel they're sufficient, either from an insurer payer or from a practitioner standpoint, to really support a Federal prescribing system like we're talking about here with enhanced registration.

We do appreciate your time and consideration. On behalf of CMS and the investigations medic, and I'll be happy to answer any questions at this time.

MR. STRAIT: Thank you, Ms. Sullivan.

MS. MILGRAM: Thank you so much. Could I just ask you to expand a little bit on the idea of a Federal PDMP? What would you want to see in that? Would you see it being identically structured to the current State PDMPs?

MS. SULLIVAN: I think payment type is very important, as I talked about. I think the

transparency of that has definitely been shown with controlled substance investigations. If it's not through insurance, I think was it paid by the patient or not, and I think that's a little bit different for telehealth compared to regular State PDMPs, but I think that would be something that would be very helpful.

I also think having access by insurers and payers. In certain states, somebody like myself, an Investigations Medic, cannot access that system, although I can access it as a pharmacist if I'm dispensing it as a prescription to that patient. But we may be equally trying to determine diversion in those patients.

A payer may be looking at evaluation for a lock-in program. They may be trying to look at case management of a patient to prevent harm, and reasonable access may be limited to certain fields, but that reasonable access to that Federal system would greatly assist payers like Medicare Part D sponsors and the Investigations Medic in their work.

MR. PREVOZNIK: Tom, we've talked a lot this morning and this afternoon about drug screening. Could you give examples of good things that you've seen with drug screening, how it's done, and also

maybe some examples of where it's not been so good?

MS. SULLIVAN: Sure. So, on the good side, I would say people who screen with some unpredictability, you know, not just at a visit but also random drug screens as well. You can do a, sort of, broad-based test, you know, but you do want to go definitive for if you have abnormal results or atypical findings.

So, things where it's unexpected, you do not see the drugs prescribed in the urine, anything consistent with tampering of the urine or falsification of urine samples, as I was talking about. Those things should be acted on. And then also, unexpected positive findings. So, if there's illicit drugs, for example.

I don't know if it's been mentioned in others' talks, but many of the overdoses we see are with illicit drugs now. We've moved away, a bit, from a prescription drug overdose problem to one that contains illicit drugs.

So, many of the overdoses we investigate with medical records, facility records, and toxicology reports as well as autopsies, do note illicit drugs, such as methamphetamine, for example, or cocaine. So it's very important if a provider has seen that in a

drug screening to act on it. It could save a patient's life. I hate to be overly dramatic, but that's absolute truth.

On negative sides, what we see very frequently is failure to do any urine drug screens, or sometimes excessive drug screens where they're billed to Medicare, and there's also failure to act on any of the results. So, we see that very often or where people are turning a blind eye to multiple problems.

We had a review recently where someone just kept noting, "Will re-order drug screen and then opine on results," and there was no changes to the prescription and that patient was somebody who did overdose and did suffer harm because the misuse and abuse was not acted upon by the prescriber.

So, the other thing is just ignoring those signs of tampering. I mean, a urine drug screen done by a lab will note if a sample is not consistent with urine, if the temperature was off, if the creatinine was off, if there was evidence of spiking, for example, where there's no metabolites of that drug so it looks like they weren't taking it -- they just inserted some in the urine.

So, all of those factors are noted by reliable labs, so that's something that if it's there,

they should act on. And it is important to utilize a true lab test for some of those reasons, at least on occasion, even if screening is done, in doctors' offices, for example -- random dipsticks and things like that.

But you do need that full lab test to give you some of those information, sometimes.

MR. STRAIT: Okay. All right. Well, thank you, Ms. Sullivan. We are actually going to take a 10-minute break, so if folks need to get up and stretch their legs or use the facilities, please feel free. We will start and resume our virtual presenter, starting with Virtual Presenter No. 7, at 1:57, okay?

(Brief recess.)

MR. STRAIT: Okay. We are now back. We'll welcome Virtual Presenter No. 7 to the screen. And Mr. Duane, at your convenience.

DR. DUANE: Thank you. My name is Kevin Duane, K-E-V-I-N, D-U-A-N-E, and I'm a community pharmacist in Jacksonville, Florida. I own and operate two pharmacies in the Jacksonville area, along with my wife, who's also a pharmacist.

During the COVID-19 pandemic, we saw firsthand the flexibilities in prescribing of controlled substances, and really, the explosion of

telemedicine in general. But it was the flexibilities that were taken-up so quickly that surprised us.

While we understood that the unprecedented situation called for loosening regulations to ensure that people could continue on with their medications, we also believe that the pandemic is well-past us now and we need to carefully strike a balance between our previous rules and regulations and the kind of Pandora's box that's been opened up now in the interim.

So, I appreciate the opportunity to provide insights and some recommendations on the evolving landscape of telemedicine, especially as it concerns prescribing of controlled substances.

And while I recognize that there is some significance to establishing a secure set of guidelines that uphold the integrity of the practitioner-patient relationship and then the pharmacy-patient relationship, we also need to be adaptive to technological advances.

Regarding existing regulations, we have found in our practice that the rise of audio-only telemedicine has presented some challenges for us, and by that I mean that it has become very difficult for us to validate that the person that worked with or

spoke with the practitioner to obtain the prescription is actually the person whose name the prescription is being presented for and that that is the same person that is actually receiving the prescription.

So, we believe that while there may be some cases where audio-only interactions are acceptable, we believe that audio-only interactions should really be the exception, rather than the rule, and that they should not be approved in a blanket way.

And we also believe that it's imperative that, at some point, the patient is seen physically by a healthcare provider. I know that we've all heard stories about how, you know, the pandemic and a reduction in the access to physical exams has led to progressions in cancers and other incidental findings -- or non-findings, as it may be.

But in the case of controlled substances, the physical exam and having seen someone at some point physically will help to cut down on some of the issues that I described earlier with audio-only telemedicine.

As far as the Notice of Proposed Rulemaking, I'll first limit my comments just to the general telemedicine Notice of Proposed Rulemaking, and then I'll address the buprenorphine comments separately.

I firmly believe that a separate registration process should be in-place so that there's a separate DEA number that's used for telemedicine encounters, and that's because, as I think was probably mentioned earlier, there are some practitioners that, kind of, moonlight and will do their normal day job and then do telemedicine on the side, or something like that.

But for pharmacies, it's very difficult to understand where this prescription's coming from. Is it coming from their live practice, or is it coming from a telemedicine side-gig or something like that? And so the scrutiny or the corresponding responsibility that we undertake in order to discern whether or not the prescription is issued for a legitimate medical purpose in the usual course of professional practice is different.

And so we need to, as pharmacists, be able to understand which silo that this is coming from. And we do believe that all practitioners -- in the state of Florida, practitioners are required to check the PDMP before issuing prescriptions, but for practitioners that are doing telemedicine outside of our state, you know, their state laws can be different than ours, so just standardizing that would help us to

understand, you know, where that prescription's coming from.

We also think that there should be ancillary data provided that is not required to be provided right now, such as a diagnosis code. You know, for example, a benzodiazepine that's being prescribed for a reduction in, you know, a large amount of seizures per day is much different than a benzodiazepine that's being given to someone for anxiety or for sleep first-line.

We also advocate against allowing the prescription of narcotic-based drugs just solely based on a referral, unless that referral to telemedicine is from an in-person practitioner exam and those two practitioners are part of the same health system. We think that otherwise it creates a kind of perverse incentive for a kickback scheme or other kind of referral scheme that can distort the actual relationship.

We also think that the grandfathering provision that allows for care that was established during the pandemic to continue without a physical exam should be sunsetted. At some point, you know, we believe that patients do need a physical exam because although we're seeing them in the pharmacy, we don't

know that that means that, you know, the physical exam is catching things that need to be caught.

As far as buprenorphine goes, we think that, again, there should be a separate registration for telemedicine prescriptions for buprenorphine. I also think that particular care should be given to the type of MAT that is given. We have seen in our practice that, you know, prescriptions for buprenorphine contained with naloxone, and then prescriptions that are for buprenorphine sublingual tablets without naloxone.

Our law enforcement here have, you know, made it very well-known that, you know, buprenorphine without naloxone is as much more readily obtained on the streets and is used or misused often.

So, telemedicine prescriptions, as far as some of the new questions that were proposed, should really be limited, possibly, to psychiatric evaluations if there's going to be no in-person evaluation at all, or perhaps terminally ill patients or patients in hospice care.

I can't see another scenario where Schedule II medications, outside of psychiatric evaluations or terminally ill patients, should be prescribed, especially not for conditions like chronic

non-malignant pain. That's a huge problem that we've seen here in the state of Florida.

I think that the DEA should require the collection and reporting from practitioners of demographic data, such as patient zip codes, patient ages. I think, that way, they would be able to quickly identify outliers and practitioners that may be, you know, well-beyond what a typical telemedicine practitioner is doing.

Also, recording things like the number of referrals or the number of exams that are done and then referred to by the same practitioner-telepractitioner set, and other types of patient-practitioner relationships would be helpful to identify certain patterns that may be indicative of diversion.

And then, I think documenting and reporting the number of telemedicine visits that that practitioner performs that does or does not result in the prescribing of a controlled substance, and then I think that, in the absence of the ability to compel PDMP data nation-wide, that there should perhaps be voluntarily disclosure of all practitioner prescriptions that are sent so that the DEA can use those to examine them and then look for any outliers.

Supplying data to the pharmacies I think is very important because we are charged with this corresponding responsibility but we don't often have or cannot easily obtain all of the data necessary to do that.

I think that providing urine drug screen results when they're performed would be very helpful to pharmacies, just to understand if there is a positive that shouldn't be there or if there is a negative when a positive should be there, that helps us, kind of, understand where the patient is at in their therapy.

And then, to have a full and complete list of diagnosis codes -- I have seen prescriptions that lack diagnosis codes. It's impossible for me to know whether it's for oncologic-related pain, end-of-life-related pain, or chronic non-malignant pain -- you know, acute pain versus non-acute pain. So the obligation to provide those will simplify and streamline the ability for us to perform our corresponding responsibility when it comes to controlled substance medications.

And then, of course, while Florida does require it, it does not require the practitioner to endorse to the pharmacy that they did check the PDMP,

so we're kind of left in the dark as to whether or not they are performing, you know, their part of their obligation.

The last thing that I'll say is, you know, we've seen a lot of fraudulent prescriptions come with the advent of electronic prescribing. We had hoped that electronic prescribing would lead to less fraudulent prescriptions, but it's just that the crime is getting more sophisticated.

So, understanding who we are looking at, especially when it comes to mid-level practitioners and practitioners like podiatrists and dentists will help us understand where they are in their practice. And again, that separate registration will also help us to understand, you know, what they do as far as telemedicine and the non-telemedicine portion.

So, I believe, in closing that the suggestions do balance the need for innovation in healthcare, but also the imperative of patient safety and the prevention of drug diversion. Thank you for your consideration, and I'm happy to answer any questions that you all may have.

MS. MILGRAM: Thank you so much. Just a follow-up: could you expand a little bit on what type of fraud you're seeing with the electronic

prescriptions?

DR. DUANE: Yeah, sure. So, yeah, it's actually been very incredible, to me. We've seen very sophisticated fraud where completely EPCS-certified prescriptions are coming through. From what we understand, bad actors are obtaining credentials of DEA-registered providers and then reaching out to electronic health record systems.

I believe probably the breakdown is that the electronic health record systems are not rigorously enough vetting the persons that are purporting to be the practitioners, and so these bad actors are able to obtain credentials in the name of -- most commonly I see mid-level practitioners and dentists, and then they use them to, you know, send prescriptions to pharmacies.

The good thing, I think, is that you could stop this very easily. Like for example, in Jacksonville, we had one where there was a doctor that was a dentist that was out of Chicago that was rapidly sending prescriptions for promethazine with codeine to different pharmacies in Jacksonville.

And so, you know, there were prescriptions being sent for a patient, from what we ascertained, you know, 20 or 30 patients within the first hour of

the day that pharmacies in Jacksonville were open. So it's like, you know, any time an EHR saw that kind of data so rapid-fire, different kinds of controlled substance prescriptions are the same for many different people, you know, that should raise red flags.

But it becomes more difficult for the pharmacy to determine whether or not those are legitimate prescriptions. You know, back in the olden days, we could tell, oh this handwriting is much too neat, or this prescription looks photocopied or tampered with somehow, but, you know, the prescriptions that we're seeing now are "legitimate" -- quote-unquote -- prescriptions from EHR that pass all of the normal EPCS regulations because they're simply just issued -- the credentials are -- to bad actors who have not been properly vetted that they are the practitioners that they say that they are.

MS. MILGRAM: Thank you so much. Could you say a little more; you talked for a minute about some of the issues you've seen with chronic pain. You just mentioned in-passing talking about telemedicine prescribing. You were talking about psychiatric care, patients in hospice care, or terminally ill, and then you raised a concern around chronic pain patients.

Can you just expand a little bit on what you've seen related to telemed?

DR. DUANE: Sure. You know, as a pharmacist, I think that it requires more due diligence on our part when we see a prescription for chronic non-malignant pain. Number one, the State of Florida requires it in the statute, but also, you know, someone spoke earlier about end-of-life care, and I think that, you know, it's pretty obvious when a patient, or patient who's being seen by hospice, and the need for opioid therapy.

And that's not to say that all chronic non-malignant pain patients do not have an obvious need for opioid therapy either; it's just that, especially during the pandemic when there was no differentiation via a different DEA registration number or something like that, it's impossible for me to know, okay, is this a patient that was seen in-office, you know, had hands laid on them, you know, was face-to-face with a person to understand not just, you know, what their problems are but their body language, their mannerisms, the way that they're presenting themselves.

Or, was this a patient that was seen via telemedicine and, you know, to my other point, like,

audio-only telemedicine, or are the standards for audio-visual being enforced by the practitioner when they're being seen by the practitioner.

So it just puts an extra burden on us to understand, you know, whether the practitioner was in the office that day or whether they were seeing patients from home, or if this patient was being seen by a practitioner that was in the home, was the patient seen in the office and was still oriented by the nursing staff or a mid-level practitioner but then seen via telemedicine by the physician, as a pharmacist, you don't know all of those things.

So because you don't know all of those things, you know, you have to look in other places to understand, you know, was this prescription issued for a legitimate medical purpose in the usual course of professional practice. And as we expand telemedicine and people are referred to physicians or mid-levels that are outside my state or outside of my city, it becomes even harder to understand.

You know, I may only see one prescription from that physician or mid-level per day, but is that one of, you know, a thousand prescriptions that a quote-unquote "pill-mill" telemedicine operation was issuing that day? I don't know anything, you know, to

know that, so I think that, to my point about the DEA being able to collect data like that, you know, a physician that uses his or her telemedicine registration to see a few patients per day to augment their existing practice or to see patients that are homebound or otherwise they wouldn't be able to see -- maybe they're in a rural area or something like that -- that's much different than a practitioner that's issuing hundreds of prescriptions per day.

But as a pharmacist, I don't know a prescription coming over, which bucket that one may go into, so it just presents a, you know, increased difficulty in that sense.

MS. MILGRAM: Thank you so much. One other follow-up on -- you mentioned a couple of times -- individuals who have day jobs and then, sort of, moonlight with telehealth or other organizations. Can you just expand on that, a little bit, of what you're seeing?

DR. DUANE: So, I mean, I think I'm referring to, like, the Cerebral and the Done type prescriptions for, you know, Schedule II stimulants, and so I think that, you know, if with these proposed rules that type of ability to issue prescriptions for psychotropic medications like amphetamine-type

stimulants or even benzodiazepines for the treatment of anxiety or other psychiatric-type conditions, I think it will become more in-vogue or prevalent for physicians to lend their credentials, or mid-levels to lend their credentials to some of these services.

And I worry about the continued erosion of, you know, is there a robust and satisfactory patient-practitioner relationship that exists before these prescriptions are issued. If we saw anything with, like, you know, the whole ADHD stimulant issuance via telemedicine, I think the answer was, at least at first, no.

So, as a pharmacist, how do I know that the patients that are coming in that are being evaluated by these practitioners -- you know, it's much different if there's a practitioner who devotes their practice solely to only, you know, anxiety or other psychiatric conditions solely via telemedicine.

It's quite another if they're someone who is looking to make a little bit of extra money so they want to see a few extra patients via one of these telemedicine referral services in addition to, you know, the day job that they work as a primary care physician with a health system, or something like that.

While that certainly is allowed, it just makes it more difficult for us to understand, again, is the practitioner-patient relationship robust enough for us to be able to say that this is a prescription that was issued in the usual course of professional practice.

MR. PREVOZNIK: Just to follow up on the one statement that I really would like you to expand on, you said it's obvious when someone's being seen at the end-of-life. Can you explain that?

DR. DUANE: Yeah, no, by that, I mean -- I'm sorry -- it's obvious in some cases, but not in all cases. Like, for example, the hospice that we have, it presents directly on the electronic prescription that the patient is being seen with, you know, XYZ hospice, so it will say, like, County Hospice Program so I know that that patient is being seen by a practitioner in their capacity as a hospice practitioner, you know, performing end-of-life care.

So, I mean, when I say "prescription" that comes over, and it's from a doctor that I know is a hospice doctor or it's from a nurse practitioner that has on there that, you know, they're affiliated with Haven Hospice, or something like that. Then I know that the prescription's being issued for that purpose.

Or, I mean, it could be as simple as an ICD-10 code that is consistent with end-of-life care, and so when I see something like that, I understand that, you know, Florida regulations regarding chronic non-malignant pain are much different than Florida regulations that have to do with oncologic-type pain or end-of-life or palliative care.

So, having those things available to us -- some practitioners choose to transmit those to us freely; some do not -- so when we have those transmitted to us, it's much easier for us to perform our corresponding responsibility.

But when we do not, it can lead to delays in care when I'm doing what I'm obligated to do by, you know, State and Federal Law to ensure that the prescription's being issued properly but I can't because I don't have those, you know, ICD-10 codes or other things readily available.

And, you know, like hospice, for example, some of the prescriptions may come in at odd hours of the day and so I'm not able to easily, you know, reach into and connect with those practitioners to be able to perform that corresponding responsibility right away.

MS. MILGRAM: How often are you

connecting-in with practitioners, would you say? Is it frequent, rare?

DR. DUANE: I'm sorry, could you repeat the question? I wasn't able to hear.

MS. MILGRAM: You mentioned a couple of times the ability to, sort of, connect-in with practitioners if you have questions. Is that something that you do routinely? If you could just elaborate a little bit on that?

DR. DUANE: Sure. So, I would say that I do it routinely, but I would say that my experience is not typical. I mean, Panama Pharmacy has been here in the Jacksonville area for 100 years. We're very well-known in the community, so I think that practitioners know what we're capable of doing and the great work that we provide for the community.

And that being said, you know, a lot of practitioners have my cell phone number. They're able to text me, or call me and reach out, and that's fine. But like I said, that's not typical, and I think that most employed pharmacists, especially at large chains, do not enjoy the time ability to be able to have those kinds of, and cultivate those kind of, relationships with practitioners.

And I think the other side of the coin of

that is -- and especially as telemedicine proliferates -- you know, I see a telemedicine prescription; I have no idea how to get a hold of a practitioner, you know, in, you know, California, and you get an 800-number. It's a call center. Someone screens it. And that's not unique to telemedicine.

I mean, there's a large academic medical center that's here in Jacksonville that has the same thing; they have a call center that screens all calls. You almost never get to talk to a practitioner. It's always very time-delayed. So the more information that we can get proactively along with the prescription will allow us to perform, you know, a more robust and satisfactory, you know, corresponding responsibility compared to having to chase down practitioners from apps, or in the case of healthcare systems, you know, navigate through a call center or something like that.

But, you know, I know that NCPDP standards are trying to improve to where pharmacies are able to message practitioners in the same way that practitioners can send electronic prescriptions and pharmacies can send electronic refill requests, but that technology isn't mainstream yet and it really hasn't hit the prime-time.

So, until it does, while we can at my pharmacy, I would say that that's not typical, and I wouldn't expect that kind of relationship to duplicate at most employed pharmacies and chain pharmacies that see the majority of these types of prescriptions that we're referring to.

MR. STRAIT: Okay. All right. Well, thank you very much, Dr. Duane. Appreciate your comments and your follow-ups there.

DR. DUANE: Absolutely.

MR. STRAIT: We will go ahead and move to Virtual Presenter No. 8.

(Technical issue.)

MR. STRAIT: Okay, Teddy, we'll get you back online. Let's move to the next presenter, Ms. Clark. K. Clark.

DR. CLARK: Hi, I'm Dr. Kelly Clark. K-E-L-L-Y C-L-A-R-K. I'm speaking on behalf of ASAM, the American Society of Addiction Medicine.

Good afternoon. I'm a physician board certified in addiction medicine and have practiced medicine for over 30 years. I'm a recognized expert on issues related to opioid use, addiction and treatment as well as illegal prescription substances.

I currently serve in several leadership

positions including as co-chair of the Telehealth Working Group of the Actions Collaborative on Countering the U.S. Opioid Crisis of the National Academy of Medicine. I'm also a past president of ASAM, or the American Society of Addiction Medicine.

ASAM is a national medical society representing over 7,000 physicians and other processionals who specialize in the prevention and treatment of addiction. Today I speak on behalf of ASAM.

ASAM has determined that the recent calls for a special registration process to prescribe Buprenorphine without an in-person evaluation while well-intentioned are misguided.

In the March 2023 Notice of Proposed Rulemaking for the induction of Buprenorphine, the DEA and HHS got this part right. I'd like to thank the DEA for hosting us with these public listening sessions.

To truly address addiction and overdose in this country it's critical that federal agencies take the time to understand the disease of addiction when developing policy, and especially policy governing the prescribing of medications, whether in-person or via telehealth. Such a policy will have immediate and

direct impact on access to evidence-based addiction care for tens of thousands of Americans.

Addiction involving opioid use is a treatable chronic medical disease. People with moderate to severe opioid use disorder or OUD, use opioids despite harmful consequences because of complex interactions on brain circuits, genetics, the environment, and their individual life experiences.

Happily, there are evidence-based treatment approaches for this disease which are generally successful as those for other chronic medical conditions. Like diabetes hypertension, OUD generally requires treatment by a health care professional often with medication and is best managed with a combination of medication, psychosocial treatments and lifestyle changes that are maintained over the long term. However, this is not the way we have historically approached addiction treatment in this country.

We now struggle to find our way out of an ongoing and devastating overdose crisis because we're still too often trying to solve a medical and public health crisis with outdated treatment models and haphazard policies, burdensome regulations and requirements that give too few Americans access to evidence-based care.

Compounding this is the fact that addiction treatment has historically been segregated from the rest of medical and mental health treatment, and therefore many clinicians don't even consider it within their purview.

So while we do have scientifically based treatments such as safe and effective medications to treat addiction involving opioids, alcohol and nicotine, they're still gross under-utilized.

Thus with a better understanding of both addiction and our history of marginalizing appropriate addiction treatment, we must now be willing to advance older policies including codifying telemedicine policies that will bring care to where it's needed and save more lives.

Specifically, regarding the telemedicine initiation of prescriptions of Schedules 3 to 5 medications which includes Buprenorphine, for medications that are approved in the -- excuse me.

(Pause.)

MR. STRAIT: I see that Ms. Clark needed to step away. Are you good now?

MS. CLARK: Sorry, I'm back.

I can't control my environment back here.

So regarding the telemedicine initiation of

prescriptions of Schedule 3 to 5 medications including Buprenorphine which are approved for the treatment of substances disorder, ASAM urges the DEA and HHS to use the authority found in 21 USC 802-54g to finalize a rule that codifies a bonafide examination requirement, not an in-person exam requirement. As well as certain common sense guardrails that will inappropriately impact patient access to care.

Those common sense guardrails are prescription drug monitoring checks, proper documentation around audiovisual and audio only initiation, and required electronic prescribing.

As outlined in ASAM's comment letter submitted earlier to the DEA this year, a bonafide medical evaluation to prescribe Buprenorphine for OUD via telehealth occurs when the prescriber obtains information from collateral sources as well as the patient through audio and/or visual examination which is sufficient to make or confirm a diagnosis of OUD and determine that the benefits of treatment outweigh the risks. The latter is made on a patient by patient basis, and that's important to keep in mind.

While there are recommended clinical standards for performing a bonafide initial examination to prescribe Buprenorphine for OUD, there

are no reasonably defined and accepted approaches for building a new special registration process for medical practice to utilize this lifesaving medication.

For example, some people recently called for the special registration to initiate prescribing of Buprenorphine, suggesting guardrails like requiring telemedicine clinicians to accept Medicaid which often has very inadequate payment rates, or restricting lengths of dosing or maximum daily prescription doses. But these proposals would cause profound barriers to patient access by placing extraordinary barriers and burdens on the providers who are at the front lines of these crises and cause a mismatch with regulations and the national practice guidelines as well as emerging strategies in the age of Fentanyl and similar synthetic opioids. Ironically placing these burdens on providers may actually increase Buprenorphine diversion by decreasing access to legitimate medical treatment for OUD.

Establishing such a special registration process would also disproportionately address Buprenorphine diversion concerns by reducing access to a treatment that provides benefits to both the public health and public safety.

The rate and disparities in overdose deaths increase where there is a lack of access to treatment with maintenance medications for OUD.

Research has repeatedly demonstrated that the most common reason for Buprenorphine diversion is likely self-treatment and lack of access to prescribers.

Additionally, there's no evidence that there's a threat to public health or safety due to failure of the DEA's existing methods to track and identify Buprenorphine diversion.

It's important to note a recent report by the National Forensic Laboratory Information System, a program of the DEA, which systematically collects the drug identification results submitted to forensic laboratories and drug places. It found that while Buprenorphine reports had increased from the first half of 2013 to the first half of 2019, they then decreased through the first half of 2022 -- at the very time that full telehealth flexibilities for Buprenorphine initiation were in place.

So the published science is clear. The Ryan Haight Waiver for Buprenorphine initiation has not increased widespread Buprenorphine diversion but has instead improved access to treatment.

So in sum, recent calls for special registration for telemedicine prescribing of Buprenorphine are misguided. We don't need another X-waiver. The DEA should be cautious about codifying a final rule which requires authorizing the phrase "legitimate need" when it comes to Buprenorphine which is a statutory requirement for implementing a special registration process, and cautious about a final rule that disadvantages local or hybrid addiction medicine practices that are more likely to be dissuaded by additional administrative burdens.

The DEA should codify a modified examination requirement, not an in-person examination requirement.

When and whether an in-person eval occurs should remain a clinical decision between the prescriber and the patient. Not rigidly dictated by DEA regulations. This would inevitably result in some clinically appropriate treatment being considered a federal crime.

Prescribing of Buprenorphine for OUD, whether telemedicine or in-person care, must remain at the professional discretion of the clinician. The common sense guardrails of prescription drug monitoring checks, proper documentation around audiovisual or audio only initiation, and required

electronic prescribing can be included within the DEA's final rule test, using the authority in 21 USC 802-54g. That statuary authority allows the DEA and HHS to specify the circumstances under which telemedicine prescribing has effective controls against diversion, is otherwise consistent with public health and safety, avoids the erecting of barriers to providing critical treatment with a special registration process for which there is no reasonably defined or accepted approach.

So during the midst of this worst overdose crisis in American history, those of us who work in the field of addiction medicine have the responsibility of bringing treatment to where patients are, and to close this addiction treatment gap.

Front line clinicians need the DEA to take a pragmatic approach and codify a telemedicine rule that puts its thumb on the scales in favor of addiction medicine and the public health so that we can reach more Americans with addiction who are not currently receiving care and save more lives.

Thank you.

MR. STRAIT: Thank you, Dr. Clark.

It does not appear that we have any questions for you, so we will move on to Virtual

Presenter No. 9.

MS. WEATHERSBEE: My name is Teddy Weathersbee. That's T-E-D-D-Y W-E-A-T-H-E-R-S-B-E-E. My pronouns are she/they, and I'm here today speaking as a patient advocate, and not affiliated with a specific organization.

I'm also a PhD social science and public health researcher, but today I'm here to share my personal experience as a person living with a neurodevelopmental disability, Attention Deficit Hyperactivity Disorder, and to talk about how my life was saved after establishing a telemedicine only doctor/patient relationship with a psychiatrist who specializes in ADHD and eventually starting on a Schedule II stimulant medication during the COVID-19 public health emergency. I appreciate this opportunity to share my experience to help inform the agency's regulations on prescribed and controlled substances via telemedicine.

I'll start with some background and a trigger warning. I'm going to briefly mention my history of post traumatic stress disorder and suicidal ideation.

I'm 61 years old and I've been in and out of psychotherapy since age 25 after disclosing to family

members that I had experience severe, long-term childhood sexual abuse by my paternal grandfather. Not surprisingly I'd experienced severe anxiety and low level depression from a young age. I was severely bullied for being a skinny introvert who when I did speak sounded different from my peers. I was also called a space cadet who walked into walls, oblivious to time and space, always seeming to be thinking about something else.

I was in the gifted program, but never turned in homework and still managed to get all A's. I was not, however, motivated like my over-achieving younger sister, which my parents variously attributed to laziness and my refusal to properly apply my high intelligence to reach my full potential. Statements that I continued to hear from family, teachers, friends and partners into my 20s, 30s, 40s, and 50s.

As a teen and young adult in the '70s and '80s, I often self-medicated in an attempt to get relief from the constant noisy distraction in my head, and the feeling that something was really broken in me and in need of fixing. Along with the intense shame and fear of others finding out, that became so overwhelming at times that I longed to just not exist.

I also have a near phobic fear of death

which was at least part of what kept me alive, along with the constant thoughts of a new business, job, relationship, state or country to live in as I reinvented myself over and over again in a desperate attempt to find someone or something that would click.

In my mid-20s I began to believe I could possibly succeed in college, which started a winding journey over the next two decades as I earned my bachelor's degree and eventually landed in a very competitive PhD program where at age 44, sober for more than a decade, yet another therapist tried to diagnose and treat my anxiety and depression with a now growing list of failed medications with awful side effects. Until one day the therapist gave me a five-minute screening questionnaire, diagnosed me with ADHD, and sent me home with a prescription for a controlled stimulant, which I was terrified to take and eventually discarded.

Weeks later a professor asked me to meet with him after one of my qualifying exams and she flung the paper at me across her desk and angrily asked do you have a disability or something?

I was intensely ashamed and admitted maybe, but then I went back to trying harder to just be normal which I desperately wanted to be.

I defended my dissertation four years later and earned my PH.D. months after starting my first job as a social science researcher, but my life continued to be very difficult and my health was always precarious.

Fast forward to November 2021, now 20 months working from home in a new job I had started eight months before the COVID-19 public health emergency. I was alone at 59 years old, no family or friends nearby. My mother had died somewhat unexpectedly ten months earlier, and I reached a very dark place that I'd never really experienced before.

I did have enough spark left to wonder if maybe I really did have ADHD and maybe I could at least find a place to meet other people who could understand me because no one else ever seemed to. I had long lost trust in therapists and psychiatrists so I started looking for a meet-up group where maybe I could find some peer support.

Then I stumbled across an educational webinar by a psychiatrist who specialized in diagnosing and treating ADHD. I was actually surprised how familiar all the symptoms sounded and I emailed him the next day, saying in part that I wasn't even sure if he was for real or if he would answer my

email, but I was desperate for help.

He sent back a very empathetic reply the next day and agreed to set up an appointment and then proceeded to evaluate me over multiple video-based telemedicine visits before finally confirming the ADHD diagnosis and discussing a treatment plan, but emphasizing this wasn't about fixing me. This was about helping me to be more my authentic self and achieve my goals while living in the neurotypical world.

I was still terrified to try medication, but my doctor continued working with me, always discussing the full range of therapies and support and encouraging me until enough trust had been built and I decided I wanted to at least try a small dose of Adderall which I did.

It was like someone had finally turned the loud radio down that had been playing in my head for 59 years, and severely distracting me from being able to live a normal life.

My severe anxiety nearly immediately disappeared, which was very surprising to me. And has never returned, including severe panic attacks which I was having over many years.

Over the next weeks and months my

psychiatrist worked with me to find the best medication dose and now 21 months later, my quality of life has measurably and vastly improved, along with dramatic improvement in my mood and neurocognitive functioning.

I've achieved goals now that I've only dreamed of before, like successfully managing my household alone. Preparing all my own meals and enjoying going out, visiting with friends, having hobbies, while also working as a PH.D researcher.

Without these telemedicine visits I would not have the access I need to the high quality specialty care and medication that saved and continues to save and enhance my life.

I've met hundreds of people now with similar stories -- patients whose lives and families have been saved and improved because of telemedicine only access to high quality ADHD care and treatment that includes Schedule II medications.

We are also all concerned about patient safety and potential threats to public safety, but believe there are mechanisms such as DEA special registration for practitioners and other state boards that are consistent with public health, safety and effective controls against medication diversion.

These include things like enhanced patient identification and medical history review, video consultations where possible, patient education and follow-up appointments, secure electronic health record systems that are integrated with state-run prescription monitoring programs, evidence-based clinical guidelines for prescribing Schedule II medications via telemedicine, and also clinician training with clear protocols for handling emergencies, adverse reactions, or cases where in-person evaluations become necessary.

So thank you again for your time. That's all I have.

MR. STRAIT: Thank you, Dr. Weathersbee. And I am looking over and I do not see any follow-up questions, so thank you very much. We will now move on to Virtual Presenter No. 10.

DR. ARMAH: Dr. Tichianaa Armah. T-I-C-H-I-A-N-A-A.

I want to begin by just thanking you Administrator Milgram and Assistant Administrator Prevoznik for permanent vision for safe and effective prescribing of controlled medication in telehealth, and allowing me to speak today. I spent many sleepless nights this spring preparing for the worst

while praying for a message that came halting the implementation of the initial proposal.

I'm a assistant clinical professor in the Department of Psychiatry at Yale School of Medicine, but the two roles most relevant today are my positions as Chief Psychiatry Officer at the Community Health Center Incorporated, and as President of a 600-member district branch of the American Psychiatric Association, the Connecticut Psychiatric Society which holds as its core mission advocating for patients' access to quality mental health care. That's why I'm here today.

For our patients like my EJ, not her real initials, who speaks only Spanish, suffers from chronic pain, and tells me each time we have a telephone visit, the fight for her to get the care that she needs without limitations.

She requires audio-only synchronous visits.

Prior to COVID because of mobility, transportation, support issues, she would miss more visits than she would attend, and would often go unassessed for long periods, falling out of care, and would be without her medication which included a controlled medication for debilitating anxiety and it caused her and her family to suffer.

Today her children are needed to help her get on video, but they work so many hours they can't commit the time to bring her for visits with me in person or by video, any time between the hours of 7:40 a.m. and 7:00 p.m., which is when I see clients.

But she can pick up a phone.

Now despite being here today advocating for it to become permanent today, I secretly hoped there will be no permissions to provide telephone visits because I assumed they would be sub-par care. Soon after it was allowed and I provided the care and got feedback about it individually and through our formally conducted surveys, I realized that lives were saved and I had to eat my words. Even with patients on controlled medication.

But here is why these two connected points are so important. EJ reflects the trend I see early on that highlight that the current proposal would have disproportionately negative effect on patients of color, both Latino and mono-lingual Spanish speakers, and black patients and most of the economically disadvantaged patients.

At Community Health Center Incorporated, we are a federally qualified health center and I've been practicing psychiatry, providing bilingual care for

now over a decade, and you may know that federally qualified health centers are the nation's largest safety net setting located in designated high need communities, caring for 28 million patients annually. And CHC is among one of the largest. And we treat everyone, regardless of their ability to pay, taking Medicaid, Medicare, all kinds of insurance, self-pay, and over the course of a year we've served over 100,000 patients in over 600,000 visits, and our behavioral health staff provided about 250 of those visits, and our 34 psychiatrists and psychiatric APRNs saw 5,000 patients in over 30,000 visits.

Now despite all but two of my staff returning to the office and all patients being offered in-person appointments, only six percent of those visits were through telemedicine because patients are feeling like they're better able to attend and being in-person wasn't clinically necessary. Wherever we feel that it really is, that's what we insist on.

But during the pandemic no-show rates really dropped from the national averages in behavioral health around 26. In our organization we were around that national average, but it dropped to 18 percent by phone, and 28 percent, a rise of 28 percent in person. And since May when we got the call, we sort of really

started to, we saw that proposal, we started to push harder for in-person because we just thought at any moment this may be snatched away.

What we saw is that in this time, since May, 14 percent no-show rate per phone -- 26 percent no-show rate for in-person; 26 percent no-show rate for video. But the interesting part comes when you break it down by race and language spoken.

We did an IRB approved study that we would be happy to share when published, and we looked at over 23,000 patients attending behavioral health visits in a little under two years. Only 43 percent had been seen in behavioral health prior to the pandemic. So speaking to those patients who, those first-time visits having to be in-person.

What we saw from the trends were non-white patients -- Hispanic, Latino, Spanish-speaking preference, Black, African American, Native American, Asian and other races -- were more likely to attend virtual-only visits. We also saw that with our older patients. This was corroborated as well by a study after I saw these trends, and started to look and see if other people were seeing it, a study by Simon (phonetic) and Sanchez that saw the same. They were looking at the impacts of eliminating audio on the

disenfranchised and really looking beyond Buprenorphine telehealth accessibility. They found the same.

So here's the thing. Telehealth is a delivery modality and it's not the enemy to bad care. I mean to good care.

I just want to highlight one of my concerns as I was looking through the proposal and we were starting to strategize how we're going to deal with it. What I saw was a lot of potential for arbitrary, routine paperwork. That concerned me. I think anytime you do that, you lead to greater stigmatization by taking care of folks with mental illnesses. So stigmatization of mental health and mental health care. You're decreasing the time interacting with patients and assessing them, and you're leading to a less efficient use of psychiatric expertise, fewer psychiatry providers ending up being willing to offer telemedicine at all, and the few who are, then really offering fewer of those visits because it becomes a hassle.

So a real danger is present -- the dangers present prescribing powerful controlled medication through telemedicine, by phone or video, are the same dangers present when prescribing in-person.

So I ask that you not sort of be distracted by vilifying telemedicine or those who practice it as an enemy to good care. I think the real enemy to safe and effective mental health care are less time available to see patients, less time to self-audit, less communication, and time between systems. So those electronic health records. Less support in monitoring patient medication adherence and safety. Also less time for supervision. And less accessible hours from psychiatry providers.

I think some of this can be remedied by working with other governmental agencies like EPSA around mental health parity because of the cost associated and the low payments for behavioral health providers, I think it definitely adds to it.

So supporting internal auditing and reporting I think is one of the solutions for outpatient clinical administrators. So most administrators who are clinical see patients, you've heard my story, and so the time can be more limited. So as much support as agencies can get in dedicating time of those administrators with their expertise and being able to look at the safety is crucial.

Increased support for incentives for the use of the PDMP and the integration of EHRs. I will tell

you that it's hands-down different since we integrated and have the PDMP coming up into our EHR. It skyrocketed for psychiatry providers, how many of them were really just getting in there as much as possible.

Creating easy reporting systems as well, for employees who are worried about organizations that may be pushing unsafe practices, as well as supporting quality care, allowing for the supervision and adequate visit lengths. And really incentivizing high quality, and those internal oversight time expectations.

Finally, the economic support for outpatient practices to join the EHR of neighboring hospitals, and hospitals to work with outpatient facilities to incorporate them.

So my central message is that hurdles to care delay and prevent it. Clinical decision making should reign over arbitrary deadlines. Patients should be able to be seen the first time by telehealth. Audio only must remain a viable option without hurdles, otherwise you perpetuate racial and ethnic disparities in mental health care. And any registration should not be burdensome to health care providers and should as much as possible look at the systems that are already in place and try to

incorporate. And finally, additional documentation should be at a minimum. All additional paperwork is an obstacle to provider/patient interaction time.

I am happy to be of any help and am excited for this time. Thank you.

MS. MILGRAM: Thanks so much. Just a couple of followup questions.

You talk about supporting internal auditing and reporting. What kind of information -- expand on that a little bit of what that kind of internal audit could look like.

DR. ARMAH: For instance, we have a behavioral health, what we call our behavioral health dashboard. So on it we're looking at things like okay, are we looking at whether or not people have done urine toxicology screens. So we're checking to make sure that people aren't taking other medications at the same time that could make it more dangerous for them to be on a particular controlled medication. We're looking at all of the information down the line. Looking at how often have they been seen? Have they been seen by anybody in person? Where are some of the qualified health centers, so at least we do have our primary care providers. It's possible they may have been seen by them. Oftentimes they haven't as well

unless it's absolutely necessary.

The other thing is, just looking at them as a whole person. So they have a lot of other medications that they may be one that are, their medical map, and also just looking at laboratories. So what are some of the labs that might lead us to be a little bit worried. Notice something like there are certain labs you can look at and see oh, there might be a problem with alcohol here. Let me be careful. Let me check beyond what maybe the usual urine toxicology screens would look for.

MS. MILGRAM: I was going to ask you how you handle the drug tox screens in the virtual setting? In the pure virtual setting.

DR. ARMAH: We have a couple of things. We do have some patients who are able to go to one of the Quest centers, so that's one of the laboratories that exists here in Connecticut. And they can go and get their labs done there. Right next door to their house, right next door to their job. Even if we're two hours away from them, they're still able to access that pretty easily. So that's one thing that we do.

Sometimes we will have patients come in between their visits. So maybe they can't come in and see us. There are for instance we had a patient who

can never come in on any day but a Thursday and a Friday, which are the only two days that I'm not clinically there. So they can come and see somebody else. They didn't want to, but they come in and they see our RN, who has a visit with them, talks with them. It's a delegated order, so I tell them all the things that I want them to find out. They collect the urine toxicology screen as well and do some other things that will get triggered based on algorithms.

MS. MILGRAM: My last question. You talked a little bit about audio only, and I just want to clarify. Were you suggesting audio only for initiation and continued care? Or one telehealth visit or something. How is that working?

DR. ARMAH: Right, exactly. I think that again, just employing the piece on clinical judgment. So it's really hard to say in just 30 days we're going to be able to get to the bottom of something or to really help someone and eliminate some of the obstacles. So I really think that really should be that clinical judgment piece. Not an extended long period of time, a year is going to be too long for never having seen someone even by video. But you could have, you know, partnered with someone who is seeing them in person as well, who's local to that

person.

Additionally, I think it would be helpful if you were given the opportunity to sort of explain why you feel like, you know what, in this case I do want to continue this. And then if we can have some additional safeguards to just make sure that it's actually that person. I know there are safeguards at the level of the pharmacy to say okay, this prescription is for this person and they are seeing someone in person and they won't hand those medications out if it's not the person.

So I think there are some additional safeguards down the road that can make sure that it is the person that you were speaking to on the phone.

MR. PREVOZNIK: That's actually what I want to ask you. What safeguards are you thinking down the road?

DR. ARMAH: I could get some technical person to help as well, but I think being able to -- just the one thing is, obviously I'm asking all of the information about the patient, but if there could be some additional systems in place for patients to be able to identify themselves. I know there were some pretty cool programs that got suggested to me in the past. Sign up for this, all of your information will

go to all of your doctors.

Right now we have something called All Of Us that we are participating in where all of our biometric information is stored in a particular place, because the purpose is to make sure that research is more inclusive. So they're gathering a lot of information and integrating that and looking at the electronic health records and seeing how people fare over the course of time.

So we're sort of putting myself, my information out there so that I can help research in the future. But it will also help me potentially if they find something. But they collect everything, you know, they're swabbing me, everything under the sun. Not that everybody feels comfortable with something like that.

MR. STRAIT: Okay. Thank you very much, Dr. Armah for your comments.

My production crew tells me we have four more virtual presenters for the afternoon. I did want to just acknowledge that our two additional in-person presenters from this morning will follow directly after.

So with that, let me now transition to Virtual Presenter No. 11.

DR. LUSINS: Good afternoon, my name is Dr. John Lusins. I'm a psychiatrist -- and it's L-U-S-I-N-S -- in private practice in Corpus Christi, Texas. Thank you for inviting me. I was very surprised, and I was honored to be selected to present today.

When I saw this come across the notification, the DEA email, I was first hesitant and said, you know, as a person that owns a small private practice in a third or fourth-ranked kind of city in terms of size and who we are in the states, would they want to hear the opinion of somebody like myself? And so I thank you for this.

So I started out here about 10 years ago and all in-person. I was doing in-patient in the morning and out-patient in the afternoon. Over that time my practice currently has three MDs and six nurse practitioners in two different locations, including San Antonio.

When the pandemic came we, of course, switched as fast as we could over to virtual. I had training in West Virginia University and ran rural clinics down into the rural areas where there was such a need that they couldn't get up to Morgantown.

And when we had a nurse on site, at that

point of time that's how we ran them, in clinics where they had to come in and visit, we saw much increased, higher utilization, and in great success rates, and so I believe in telemedicine, I believe in telepsychiatry. I think that the whole idea of optimizing care without compromising the patient's safety and increasing outcomes, increasing accessibility is truly the whole goal.

When this proposal came up to then cut off the ability to do controlled substances, I thought there would only be one certain aspect of it that I am in agreement with in terms of how. What we've seen and what bothered me to actually put my name into this was the rise of many psychiatrists, and also nurse practitioners, working together to create just virtual companies where we've seen solely prescribing perhaps some SSRIs, but truly just marketing towards prescribing ADHD medications and stimulants only.

I'm not talking about things such as Atomoxetine and Clonidine for kids. This is marketing primarily for ADHD. Just five minute visits. I know if you look on Instagram, if you look on the web, that you will see these. It's not a hidden fact.

I think that my prior presenter, she had amazing points. I agree with her about racial

disparities, I agree with what she was saying that there needs to be greater access for all of us; however, when you now see a market where a psychiatrist in Texas can supervise six, seven nurse practitioners and get paid anywhere from $1,000 to $1,200 per nurse practitioner and never truly have a face to face supervision, and then those nurse practitioners, through -- will sign these controlled substances and that psychiatrist then can go on and send them in, this is not what the system was set up to provide. This is not how medicine should be practiced in that aspect of it.

Are we checking the national databases? Are we checking the DEA databases? Yes. Are they integrated into emergency -- I'm sorry -- into external electronic medical records? Yes, they are. These things. I think that there are circumstances that my office has now gone back to truly providing a hybrid, where we ask if ultimately 100 percent possible we can get you into the office to see you for the first visit and then for the three month follow up.

And if the provider has questions, then we try to pull you in. We try to have people come in and do random drug screens, sending people to Quest that

they can randomly choose their own times, and they can have a wash out time if there's other substances in there and say that they got busy. We found that that just doesn't work. We ask people to come in and see them. We ask detailed medical history.

My child psychiatrist, I was talking to him about this, but he was saying that truly observing a child -- and this is what they're trained to do during their fellowship -- and watching them throughout their interaction, when you have just a camera, yes, we have gotten so much better at that, but there is nothing like that true visit at some point in time that you're going to have them come into the office and see the interaction between the parents and the child and watch the children, hyperactivity or inattention, and get a true history without the influence perhaps of the parents at that point.

Now, certain situations, like the college student that's here for the summer and then we have to just continue to prescribe while they're away and we see them back at Thanksgiving, or the teacher, telemedicine, that we -- and telepsychiatry for police and firefighters that have such great difficulty in coming in, this has been fantastic, and we work with people as much as possible; however, we've just seen a

dangerous rise in diversion, we've seen a dangerous rise in inability for pharmacies to continue to stock these medications, and people truly calling again and again.

In talking with my colleagues, I haven't seen true research on this but I think it would be a fantastic topic, to really look and see -- I've had several -- I'm looking in physician forums about Board complaints now about physicians, where they have been reported because they didn't send in the script within two or three days. That never happened with somebody's Prozac. That never happened with somebody's -- those are just as important, but with the controlled substances you have a different type of environment that it really, truly needs a face to face visit to have a relationship and understand the need. Why do they need these?

Methamphetamine is a huge problem down here in south Texas. I'm not saying that the link is any one, but between truly treating ADHD and then also methamphetamines, but what we see is diversion. When I'm talking with my patients in the hospital that -- when they can't get methamphetamines, which are very available, then they're also taking these medications from their brothers and sisters or they're sharing

them amongst each other.

Lastly, I think that, and since talking about other controlled substances, we haven't seen -- which I predicted we'd have seen more difficulties with benzodiazepines, but what my major concern truly is is the monetization of the ADHD diagnosis and the too easy access now of local clinics, MDs, charging in between visits cash for people to come and pick up their ADHD script.

Because of the laxity that the rules have provided, it's turned into an environment where I think we all try to do our best and follow kind of guidelines, but I think that at least should be seriously looked at and tightened up, primarily for stimulants, and stop these loopholes that are allowing companies to take advantage of these aspects while continuing to provide access and great care, because I think that's the majority, but the minority argues in these rules. Thank you.

MR. STRAIT: Thank you, Dr. Lusins.

Do we have any comments?

(No response.)

MR. STRAIT: I do not see any so I will say thank you, and I will call upon Virtual Presenter No. 12.

MR. CHESTER: Hello, my name is Dr. Jeffrey Chester, J-E-F-F-R-E-Y, C-H-E-S-T-E-R. I represent those prescribing practitioners who treat patients with chronic pain disorders, and with substance use disorders, and with both conditions. I am an outpatient solo practitioner full-time for nearly two and a half decades on the island of Maui in the state of Hawaii. In addition to my private practice, I've owned, operated, and medically directed multiple levels of outpatient programs for addiction treatment.

I maintain a total of three medical board certifications, one by the American Board of Physical Medicine and Rehabilitation, one by the American Board of Addiction Medicine, and one in the subspecialty of addiction medicine by the American Board of Preventive Medicine.

As I prepared for this presentation today, I wrote several versions, and as I've been listening to the people that have come before me, I'm going to scrap most of what I was going to say and talk about this differently. I think part of the problem is we're attempting to take chronic pain, addiction, and various psychiatric diagnoses, like ADHD, and because there's an overlap between the schedule of the medication treatments that may be used, try to have

one rule to govern how those medications are prescribed and dispensed.

What I believe will not be helpful will be to have a legal requirement for an in-person evaluation either prior to, or within 30 days of, an initial prescription of a C2 or C3 controlled medication, and the reason for that is sometimes an adequate physical examination was performed by the referring doctor, by a physical therapist, fairly recent to the initiation or subsequent prescription of a controlled substance.

And the timing of a physical examination can be crucial in determining what medications should, or should not, be prescribed, but the timing has to do with clinical changes that occur with the patient. In other words, if there's a change in status, one might gain a lot from a physical examination. If there's no change in status, a physical examination, an in-person visit, will not necessarily change a pain medication treatment decision.

It is more likely that we're going to rely more and more on laboratory testing, either blood or urine, and different x-ray examinations such as ultrasounds, x-rays, MRIs, CT scans, when looking for precautions or adverse outcomes from our treatments.

An example would be if one prescribed Naltrexone. Naltrexone is a non-controlled substance that is often used for opioid use disorder treatment, alcohol use disorder treatment, and sometimes in other conditions such as chronic pain. When prescribing this non-controlled substance we look for liver damage and that liver damage is more likely to be monitored on blood laboratory testing or an ultrasound of someone's liver than with a physical, in-person examination to see if a liver is enlarged or not.

Bringing someone in to perform pill counts is not necessarily helpful to detect diversion as it was once thought to be. It is easy to fake those pill counts with counterfeit pills. In order to help reduce diversion, taking time to listen to the patient during a medical encounter and hearing what wording they use and how they are asking for the start of a medication or continuation of a medication can be quite helpful. That could be done through telemedicine just as easily, if not more easily, than with an in-person encounter.

Checking the state prescription drug monitoring program is essential, but there are a few limitations. One is our local methadone clinic here does not need to be included in that prescription drug

monitoring program, so someone coming to see me, for instance, and receiving any type of controlled substance for any type of reason might also be going to the methadone clinic and therefore getting two different prescriptions essentially.

So the prescription drug monitoring program should include in the future methadone clinics, as well as mentioned before, a federal registry would be excellent because, as we know now, people travel from state to state quite easily.

We, in this practice, have always checked public legal websites. We check the Circuit Court system and the Hawaii Criminal Justice Data System prior to accepting a patient into our practice. If there were more collaborations between law enforcement and the medical community, then I believe prescribers would be better able to detect if a potential patient or one of their existing patients might be diverting their medications.

We don't have that kind of access on an ongoing basis, we rely on these public websites, but if we had some sort of more input from law enforcement, I think we'd better be able to identify who might be drug dealing or otherwise illicitly doing things with their medications prescribed.

I do find it very helpful to take the time to speak with our local pharmacists and often stop in and actually show my face, and so they know who I am. Most of us here on this small island of Maui can identify each other by the sounds of our voices on the phone, certainly by face, and that's been very helpful, to have that sort of intimate relationship with the pharmacists and with the patients.

We also utilize urine drug screens quite often, sometimes through local laboratories -- that has pros and cons -- and sometimes through our office -- that also has pros and cons -- and we find that the urine testing to be quite helpful to look for what we call aberrant results or unexpected results, and that would inform our future directions of prescribing.

However, we don't often test for certain substances that are not Schedule II or Schedule III, and some of those medications do have significant implications, such as gabapentin, where misuse and diversion is quite common. And in certain states there is mandatory reporting to the prescription drug monitoring programs, but not in all states.

Also, there are medicines, such as Xanax, and Soma, Valium, Ativan, Ambien, that also are often a source of diversion and addiction and we don't

necessarily treat those with as much respect as we should when it comes to the C2 or the C3 medicines.

In-person evaluations come with some disadvantages, including it's more costly for patients. They necessarily will have to find childcare or miss work. So there are definitely times when telemedicine is better for the patient. Also better for us, as practitioners. It can utilize fewer resources for us. In Hawaii there are different islands and sometimes people move from island to island and I can still treat them even though they are, necessarily, a plane ride away.

In summary, I don't think that mandating a specific timing of an in-person evaluation will be helpful in decreasing diversion. I do believe that more communication with law enforcement and expanding prescription monitoring programs to be federal and include methadone clinics will be quite helpful.

So I want to thank you for inviting me. It's been my pleasure. And if there are any questions or comments for me, I'll be happy to field those out.

MR. STRAIT: Thank you, Dr. Chester.

Let me turn to the group. We're good?

(No response.)

MR. STRAIT: Okay. Well, let's see. It's

six hours behind so you're still in morning time so hopefully you can get to patient care.

We will move on now to Virtual Presenter No. 13.

MR. COHAN: Good afternoon, everyone, my name is Jerome Cohan, J-E-R-O-M-E, C-O-H-A-N. I am the facility director and nurse practitioner at Catalyst Health Solutions which operates in northeast Tennessee and southwest Virginia out of four locations. In Virginia, we are considered an OBAT, which is office-based addiction treatment, in Tennessee, an OBOT, which is office-based opioid treatment. The clinic's been open for 10 years fully.

I represent five physicians who are all board-certified in addiction. Two are addiction psychiatrists. We have six nurse practitioners in total and 11 Master level social workers, or counselors.

In northeast Tennessee and southwest Virginia -- before I read what I've wrote, after listening to a lot of the presenters, it kind of fills me with a little bit of positivity because all I've witnessed for the last eight years here in these mountains has been a nightmare: a nightmare of methamphetamine, a nightmare of benzodiazepines, and a

nightmare of dysfunctional homes, families being broken up, and the Department of Children's Services going crazy with methamphetamine.

And so it's really comforting to hear that other people are having a better experience with telemedicine. My experience has been nothing short of pretty much a nightmare in regards to what we're trying to deal with or tackle here, in our community.

So I'm not saying that to be argumentative or try to start a conflict with other people who are in support of telemedicine, I just want to make sure that, at least from where I'm from and what we're dealing with, without controls and regulations on people who are only interested in making money, our community will continue to suffer because of polysubstance abuse.

So, with that said, I'm going to go ahead and read what I wrote here. In the addiction field, we've experienced a nightmare with the proliferation of telehealth services in northeast Tennessee and southwest Virginia. A hallmark of addiction is dysfunction in the structure and accountability of a person's life.

In the wake of COVID, online buprenorphine prescribers started popping up pretty much everywhere

and providing all addiction services over the internet, including the prescribing of controlled substances. From our clinical experience, polysubstance abuse has not been addressed with this approach, especially when it pertains to methamphetamine abuse, addiction, trafficking, et cetera, et cetera.

From the onset of the telehealth explosion, the providers at our clinics, NPs, MDs, and social workers, immediately realized the negative implications of this if not put in check and kept in control. We put in place internally on our own protocols to resist the use of telemedicine services for most of our patients suffering from meth, benzos, alcohol addiction. Most were still at greater risk of overdose. Some of them actually did overdose under telehealth from polysubstance issues related to worsening polysubstance abuse being missed with inadequate accountability online.

Many of our patients tried online services because of the convenience, only to return to face to face visits often related to substance -- other substances of abuse other than OUD, opioid use disorder, suboxone, suboxone, suboxone.

Behaviors we are concerned about, we,

Catalyst, and all the providers, include behaviors such as altering urine drug screens, which often we see are -- devices hidden on or inside someone's body with another person's urine in it to try to falsify a test. And, of course, we're not law enforcement so we use that as an opportunity to provide compassionate care, to let them know that's how sick their brain has gotten, that they're going to hide somebody else's urine inside their body to give fake information to us.

Simply put, trauma-informed witness urine drug screens save people's lives. One study in the VA found that by implementing witness urine drug screens, by implementing -- there's drug screens were positive, it basically increased from 25 percent to 41 percent. Now, the clinical implications of that are -- is now that you can catch things, or at least observe things -- I don't want to use the word catch, but at least clinically observe things, that now you can talk to a patient about to give them accurate information. We advise the use of telehealth services for only well-established patients, use sparingly, and regular face to face visits.

The final thought from me, and some of the other providers mentioned it on this call, is that the

importance of physical exams -- and maybe it's just the nurse in me, maybe it's just for 20 years I've just been touching people, caring for people -- that the idea of not doing a physical exam for somebody who has polysubstance abuse is madness to me.

So part of that is looking for track marks. Often these track marks are infected. We've sent people to get things lanced, we use antibiotics to treat infections that are up and down people's arms, often in their necks, in their groin, in their feet. And so the other thing is I commonly do is assess people's nasal cavities for cavernous type activity there, septum erosion from snorting of all kinds of substances. Not just suboxone, but methamphetamine, benzos, you name it.

Part of the face to face thing for me is that I read once in passing that the opposite of addiction is relationships. My contention is it's very hard to have a meaningful relationship through a computer screen with somebody who's suffering from polysubstance abuse problems or addictions.

So I came here today, which I truly am grateful for you all listening to this, to urge any policy makers or people of influence to consider the negative effects of telehealth activities in the

context of our realities. I can only speak to northeast Tennessee and southwest Virginia. Our reality is that we are in a polysubstance abuse epidemic. It's polysubstance. It's not just OUD, it's just people want to escape from -- somehow.

And the majority of what we're seeing, 70 percent of the patients that show up for new intake admissions are positive for methamphetamine, positive for benzos, positive for ETG, which is a metabolite for alcohol.

It's very, very, very, very, very rare for us to see an opioid use disorder problem by itself. I can't recall the last time I saw a new patient, or neither can any of the other providers, where somebody came in with a pure opioid use disorder problem that buprenorphine is wonderful at taking care of. But if that were the case, then buprenorphine for everybody, but unfortunately, quite often, buprenorphine can make things worse for folks that are suffering from polysubstance abuse.

So some of the suggestions that I have, again, is just -- I'm not really sure about regulations and how to prevent it. I do think that personal when it comes to addiction treatment, polysubstance abuse, personal, face to face visits are

vital to care for the entire person. I think telemedicine gives people a free pass to ignore problems that potentially can kill whole families called methamphetamine. And even if people are still breathing, the families are still destroyed. Talk to any DCS worker and they'll tell you about it.

So, again, not trying to sound self-righteous. I'm a little passionate about it because it can get out of control very, very quickly. The telemedicine products that we see pop up, in my opinion, have questionable intentions and motives. I just want to put a little plug in for Dr. Kevin Duane, as well as Ms. Jodi Sullivan, for the DEA folks. In my opinion, as a provider who sees patients and have been doing this a long time, those two people spoke some very deep truths and reality of what's going on at the point of service care for polysubstance abuse which we are engaged in every day.

So that's pretty much all I have to say, and I really appreciate the opportunity to speak my mind here from east Tennessee on our behalf.

MS. MILGRAM: Thanks so much for joining us. Can I ask a couple of follow up questions?

MR. COHAN: Sure.

MS. MILGRAM: I mean, I don't know if you

have this information, but just to try to clarify, what percentage of the folks that you see are polysubstance right now? Do you know?

MR. COHAN: Eighty, 85. Honestly, I cannot remember. And I even queried before this talk some of my nurse practitioner buddies and the physician I work with. It's just very rare to find somebody who's just purely opioid use disorder. That's why I just, like, am, like, surprised when the president of ASAM was talking about opioid use disorder, opioid use disorder. I mean, wow, that would be nice, to just talk about that, but we can't. We cannot go a day without taking care of meth, benzos, alcohol.

And you can't really assess that without seeing somebody in person and getting a trauma-informed urine drug screen. I apologize. Go ahead.

MS. MILGRAM: No, not at all. Just to follow up on it, you said that BU can make it worse. I just want to clarify. You said something like BU can make it worse for someone who's polysubstance. Can you just elaborate a little?

MR. COHAN: Yes, ma'am. One, whenever buprenorphine contributes to somebody's death it's almost always mixed with something else: benzos,

alcohol, et cetera. The other thing is that it's a cultural phenomenon. There's a great paper I'll share with you guys. We had some anthropologists embedded in our clinic for a while to study the culture in southwest Virginia out of the University of Virginia the culture of suboxone, diversion, use, or as a currency somewhat.

And the point is if you have methamphetamine involved -- and I'm convinced of this not only from my own family members and friends who are in recovery, but patient, after patient, after patient -- that if methamphetamine is involved, you can pretty much be assured the diversion of buprenorphine is involved. At least in our area, it just goes hand in hand.

The other thing is that buprenorphine, in my professional opinion, and my partner, Dr. Smyth's professional opinion, buprenorphine is a very potent partial opioid, right, but it has side effects associated with it, including depression, anxiety, insomnia.

If you look at buprenorphine products that are measured in the micrograms for the treatment of chronic severe pain, such as Belbuca, those side effects aren't on the medication probile (phonetic) at lower doses, so keeping somebody at high doses of

buprenorphine for extended and ridiculous periods of time, in our opinion, sometimes is not the best approach. People often feel better once their lives get cleaned up and they start obtaining life goals on lower doses of buprenorphine to avoid the unpleasant side effects associated with such a potent medication.

So there's a cultural nuance to it, but, again, addiction is defined as a psycho social phenomenon, right? So when you start mixing other controlled substances in there, including buprenorphine, it can often make life situations, as well as physical situations, worse. So I hope that answered your question, boss.

MS. MILGRAM: Yes. Thank you so much.

MR. STRAIT: Yeah, thank you Administrator Milgram.

And thank you, Mr. Cohan. Appreciate your comments and your candor.

I will now turn to our last virtual presenter, Virtual Presenter No. 14, and, like I said, we'll then transition over to our last in-person presenters before we wrap up.

MR. PRATT: Good afternoon. My name is Tony Pratt, T-O-N-Y, P-R-A-T-T. I'm with Piedmont Access to Health Services, a Federally Qualified Health

Center in south central Virginia.

And while I encourage steps to improve access to care, particularly valuable health and substance abuse treatment, as a practicing pharmacist, I'm concerned about the impact that this rule could have on pharmacies. At present, pharmacists are held to what seems to be an almost arbitrary and nearly impossible standard of ensuring a valid patient provide a relationship exists before a prescription can be dispensed, and this standard became of particular concern and note as the opioid crisis was unfolding.

While pharmacists are typically comfortable with the practices of our own local providers, it has become increasingly difficult to maintain this standard with the growth of out-of-town referrals to specialists and even more so with telehealth. It is not physically nor fiscally possible for a pharmacy to verify every prescription that comes to them, and if we are now responsible for policing whether a patient has also had the required in-person visit in a timely fashion, it will increase the already excessive burdens on a noble work profession.

The need for telehealth clearly exists. However, prior to instituting regulations, no matter

how well intentioned, due consideration must be given to those regulations' impact on every facet of the healthcare industry.

Pharmacies have historically been the de facto enforcers of many DEA regulations. However, our industry is at a breaking point. Independent pharmacies are going out of business daily because of unfair reimbursements often tied to unobtainable clinical measures. Chain pharmacies survive by demanding more productivity from their pharmacists than is reasonable or safely conceivable. And pharmacy errors are occurring at alarming frequency because of these external pressures, putting our patients at risk.

Adding yet another level of recordkeeping and policing the activities of patients and providers runs the risk of further exacerbating an already critical problem.

Again, I encourage improved access, but I implore those responsible for formalizing the rules to carefully consider the potential burdens that the regulations may create in a pharmacy and strive to minimize that impact lest a greater impact limits the pharmacy access to the many patients who are already at risk of losing access.

And I would like to add to that that the question was raised earlier about what you would like to see in a federal PMP. The one thing that I would like to add to that presenter's comments would be that it would be an actual live-in-time issue where we can send a claim to an insurance company and get a response back in three minutes as to whether or not that prescription is valid to be filled. We need to be able to see that on the pharmacy side too. It would be extremely beneficial to us to know that a patient just walked down the street 15 minutes ago as opposed to having a one or two or sometimes even three days or, in some places, at some point, it used to be as much as a week delay in what was actually submitted to the PMPs.

And much like Mr. Cohan, I applaud the frankness of those who have spoken out that are actually in day-to-day practice. While the group presenters gave some very valid points, really, I think the DEA needs to be talking to the people that are in day-to-day practice to really see how the rules are going to impact the practices and the individual patients. There will be some benefits to every situation, but there are also going to be some very concerning limitations at times, and we need to be

coherent and -- or cognizant of those concerns.

And with that, I'll end, and I'm happy to answer any questions that you may have.

MR. STRAIT: No? Okay. Thank you very much, Mr. Pratt. No further questions or comments.

So I will now call up to the stage our in-person Commenter No. 14.

DR. KAFTARIAN: Thank you very much. My name is Dr. Edward Kaftarian. My first name is spelled E-D-W-A-R-D, last name, K-A-F-T-A-R-I-A-N. And I'm with Orbit Health Telepsychiatry.

Good afternoon, ladies and gentlemen. I'm Dr. Edward Kaftarian, a triple Board-certified psychiatrist with specializations in general psychiatry, forensic psychiatry, and addiction medicine.

I've had the privilege of serving as the former Vice Chair of Mental Health for the American Telemedicine Association and am an active longstanding member of the Telepsychiatry Committee for the American Psychiatric Association. I've written books, book chapters, and articles on the subject of telepsychiatry and speak extensively around the nation on the rules and regulations of telepsychiatry.

I'm a physician leader at Psych Congress,

and I've also developed the largest correctional telepsychiatry program in the nation overseeing 30 California prisons. And I'm Johns Hopkins trained.

Today, I also represent Orbit Health, a national telepsychiatry organization committed to delivering high-quality mental healthcare through innovative technology. Our mission is to make mental health services accessible and effective, and we do so by partnering with a wide array of healthcare facilities ranging from hospitals and outpatient clinics to youth homes and correctional institutions.

Our team comprises highly qualified psychiatrists, psychiatric nurse practitioners, psychologists, social workers, and licensed marriage and family therapists. Together, we strive to offer comprehensive mental health solutions to both public and private sectors.

As we navigate the complexities of mental health in today's world, the role of telepsychiatry becomes increasingly vital. The primary focus of Orbit Health is on quality. We only partner with high-quality institutions and work with high-quality clinicians and providers, and our reputation has grown and we're considered by many as the telepsychiatry company with the highest degree of quality,

reliability, and ethics.

I'd like to first discuss the critical role of telehealth in enhancing access to mental healthcare. Telehealth has emerged as an invaluable resource for treating various mental health conditions that often require controlled substances for effective management. Specifically, conditions like opioid use disorders, ADHD, and certain severe anxiety cases have shown significant improvement with telehealth interventions. The technology is especially beneficial for populations that face barriers to traditional healthcare access, such as those in rural or low-income areas.

Envision this. A life hanging in the balance ensnared by the unforgiving clutches of opioid addiction. The individual is isolated not just by societal stigma but also by the insurmountable distance from a treatment center.

In my own practice, I've seen firsthand how telehealth acts as a revolutionary lifeline, shattering those barriers as if they are mere illusions.

The evidence is compelling, almost shouting from the rooftops that telehealth exponentially amplifies access to life-saving medication for opioid

use disorders. This is not a mere coincidence and it's not a mere convenience. It's a seismic shift that annihilates the dual barriers of distance and societal judgment. Telehealth doesn't just offer a treatment pathway. It offers a road to redemption. This is not just an alternative, it's a life-saving revolution.

Now let's shift our gaze to the transformative power of telehealth in the realm of ADHD. I've personally treated countless children, and the results are nothing short of miraculous. Telehealth is not merely opening doors, it's obliterating barriers. When children are precisely diagnosed and judiciously treated with stimulant medication, the metamorphosis is awe-inspiring. We're talking about a seismic shift that elevates academic performance, refines behavior, and creates a ripple effect of focus and discipline that uplifts not just the individual but the entire classroom.

And the benefits don't end in the classroom. These children, when treated appropriately, are far less likely to descend into the abyss of substance abuse later in life. The societal impact is monumental, reducing the crippling costs associated with academic failure and juvenile delinquency. This

isn't just healthcare. This is a societal renaissance.

Appropriate treatment of opioid use disorders, ADHD, and anxiety with controlled substances can sometimes mean the difference between life and death, and qualified practitioners should be able to prescribe these medications without having to overcome overly restrictive or cumbersome regulations, whether it's in person or via telehealth. Mental healthcare save lives, regardless of whether it's in person or via telehealth.

In regulating controlled substances, the DEA should focus on two main issues. First, verifying patient identity is essential to prevent illegal access to medication. While advanced technologies exist, simple identification should suffice. We leave it up to the DEA to specify acceptable forms of identification.

The second issue for DEA to focus would be ensuring qualified practitioners evaluate patients before dispensing controlled substances. We see no difference -- we see no need to differentiate between telehealth and in-person visits. Both should require proper evaluation for a valid medical condition. Adding extra hurdles for telehealth lacks a public

safety rationale.

For years, I personally have immersed myself in the complexities of the Ryan Haight Act, a law conceived from a heart-wrenching tragedy. Ryan Haight lost his life because he secured controlled substances online without ever seeing a physician or a provider. This Act, the Ryan Haight Act, was designed with a laser-focused aim, to mandate that patients must see a provider before receiving such potent medications. But let's contextualize this. Back in 2008, telehealth was barely a blip on the radar. At that time, seeing a doctor meant an in-person visit in most cases.

Fast-forward to today and the landscape has dramatically changed. If Ryan Haight was alive today and obtained pills, the focus would be whether he saw a qualified physician or provider either in person or via telehealth to ensure legitimate medical use. If no consultation occurred, those supplying the medications should be held accountable. But consultation methods should be treated equally in legislation.

Let's shift the narrative here. Instead of launching an assault on telehealth, a modality that is rapidly filling gaps in clinical care, why not zero in

on the real culprit, those ill-intentioned providers who exploit the system for their own personal gain, whether they lurk in the corridors of brick-and-mortar clinics or behind the screens of telehealth platforms. They are the ones that should be held accountable.

Let's not tarnish an entire medical revolution because of a few bad apples. It's time to focus our regulatory cross-hairs on those who truly deserve scrutiny, irrespective of the medium they use to practice. This isn't just a call to action. It's a clarion call for justice in healthcare.

I foresee that within the next decade, as telehealth becomes an integral part of our healthcare system, the government will come to realize that imposing arbitrary restrictions on telehealth is not only counterproductive but inexplicable.

We in the medical community struggle to understand the DEA's rationale for singling out telemedicine when it comes to prescribing controlled substances. Telehealth is not merely an extension of traditional healthcare. It is on track to become indistinguishable from healthcare itself. I firmly believe that the government will eventually recognize that stifling the growth of telehealth doesn't prevent abuse. Rather, it deprives communities of essential,

sometimes life-saving treatments.

My aspiration is that a single DEA number will suffice to prescribe controlled substances via telemedicine or in person, thereby streamlining the process and broadening access to healthcare.

If our request seems too ambitious or progressive and the DEA opts for stricter telemedicine regulation, we urge the establishment of a streamlined special registration process based on evidence. This should be nationwide to maximize telemedicine's benefit and avoid healthcare fragmentation. Dual state registration for practitioners is unnecessary and only adds red tape. Special registration should be open to all medical specialties competent in prescribing controlled substances.

I propose that regardless of what regulations are put in place the DEA should allow at minimum a 90-day period for the practitioner to prescribe the medication. This would enable a safe tapering process, reducing the risk of withdrawal symptoms and ensuring a smoother transition in the treatment plan. I ask that you include this as an exception to any other mandate that would prevent the provider from being able to safely manage such a patient.

Moreover, irrespective of the final regulatory landscape, I implore the DEA on behalf of the entire psychiatric community to maintain the confidentiality of practitioners' home office addresses. This isn't merely a formality, it's a critical safety measure. Exposing us and our families to the potential risks posed by dissatisfied or unstable patients who might seek to confront us in our residences is just not unfair only, but it's also a breach of our personal security and peace of mind.

In closing, I want to remind you that the opioid crisis was ignited not by telehealth but by in-person mills, pill mills. So what was our response? Did we outlaw face-to-face medical consultations? Of course not. The issue was addressed through education, awareness, and holding the culpable parties accountable, not by banning an entire mode of healthcare delivery.

Let's not forget that the DEA's mandate is not to micromanage the intricacies of medical practice. That's the purview of the state medical boards. When a qualified licensed provider determines that a telehealth consultation provides sufficient grounds for prescribing controlled substances, that decision should be respected as their professional

judgment.

We do recognize and deeply respect the DEA's indispensable role in thwarting the illicit spread of controlled substances. However, if the sword of regulation must fall upon telehealth, let it be surgically precise, targeting only two critical issues, the verification of patient identity and the evaluation by qualified providers for legitimate medical needs.

To venture beyond these boundaries is not merely an over-extension of regulatory power, it's a betrayal of healthcare's very soul, a jeopardizing of patient lives, and a barricade to essential care. This is not a mere request. It's an impassioned plea echoing from the core of medical ethics, a clarion call for the sanctity and integrity of a practice that holds lives in its hands.

Thank you.

(Applause.)

MR. STRAIT: Thank you so much. Let me just ask if there's any questions.

Do we have any questions?

(No response.)

MR. STRAIT: Okay, thank you.

DR. KAFTARIAN: Thank you very much.

MR. STRAIT: Okay. And I will follow up with our commenter, in-person Commenter No. 15 and our last for the day.

DR. ROTELLA: Well, good afternoon. You made it to your last presenter of the day, and I personally thank you for finding space for me after my morning flight was canceled. It would have broken my heart not to have this chance to talk to you today, so thank you so much.

My name is Dr. Joe Rotella, J-O-E, R-O-T-E-L-L-A. And I am the Chief Medical Officer of the American Academy of Hospice and Palliative Medicine. AAHPM is the national professional organization for physicians who specialize in hospice and palliative medicine. Our membership also includes nurses, social workers, spiritual care providers, researchers, and other health professionals deeply committed to improving quality of life for the expanding and diverse population of patients of all ages living with serious illness, as well as their families and caregivers. Together, we strive to ensure that patients across all communities and geographies have access to high-quality, safe, and equitable palliative care at any stage of a serious illness and hospice care for those nearing the end of

life.

The timely and effective management of pain and other distressing symptoms is central to providing high-quality palliative care to patients with serious illness. and opioid analgesics and other controlled substances are critical tools in alleviating their suffering.

AAHPM appreciates the intention of the proposed rules to advance public safety and urges taking a balanced approach that also prioritizes access to care and relief of suffering.

Therefore, we believe it is imperative for DEA and the Department of Health & Human Services to account for the unique needs of seriously ill patients, including those near the end of life, when finalizing policies related to the prescribing of controlled substances via telemedicine.

In particular, my comments today focus on three main areas: the need to clarify that in-person requirements for prescribing of Schedule II through V controlled substances do not apply to patients enrolled in hospice.

Secondly, the need to establish a special telemedicine registration to allow that qualifying practitioners may prescribe Schedule II through V

controlled substances without conducting an in-person medical evaluation to enable ready access to controlled medications for patients with serious illness who are not all in hospice care.

And, third, the need to extend telemedicine prescribing flexibilities for controlled substances that have been in place in response to the public health emergency for COVID-19 through at least calendar year 2024 to provide for a reasonable transition period while a special telemedicine registration process is implemented.

DEA asks if there are any circumstances in which telemedicine prescribing of Schedule II medications should be permitted and, if so, what safeguards stakeholders would recommend. AAHPM asserts that telemedicine prescribing of Schedule II medications should be permitted in cases where patients have elected to enroll in hospice.

Likewise, telemedicine prescribing should be permitted in cases where patients outside of hospice are truly identified as having a serious illness and uncontrolled symptoms, with the added safeguard that the prescriber has demonstrated training and expertise in pain management or palliative care and met any qualifications for a special registration.

We understand that in-person evaluation requirements are intended to ensure that an established patient/physician relationship is in place prior to the prescribing of controlled substances via the internet.

The Academy takes the position that a proper physician/patient relationship can be created and that sufficient safeguards are in place to support telemedicine prescribing without an in-person evaluation when a patient is certified as having a terminal illness and enrolled in a hospice program. Under the Medicare hospice benefit, hospice patients must be certified to be terminally ill by two physicians who each attest the patient has an estimated life expectancy of six months or less.

Once enrolled, the hospice model of care creates the equivalent of a physician/patient relationship in the form of care provided by an interdisciplinary hospice team under the supervision of a hospice physician. This team includes advanced practice registered nurses, physician assistants, nurses, social workers, chaplains, and others based on need, and they conduct comprehensive skilled admission assessments and are in regular face-to-face contact with patients, including through frequent home visits,

extensive education and supervision, and 24/7 availability, making them better equipped to detect and address drug diversion and safety concerns than a physician in a typical outpatient clinic. They're there. They're there with the patient on many, many occasions.

In addition to these guardrails, inherent to the structure and processes of hospice care that protect against diversion or misuse, we know that hospice patients have a particularly urgent need for ready access to opioids and other pain medications. As they contend with terminal illness, they often develop pain or symptom crises which represent a true medical emergency. Hospice programs must be able to prescribe and administer medications for pain and other severe symptoms quickly, including Schedule II controlled substances when indicated.

Requiring hospice patients to obtain an in-person evaluation with a prescriber could delay treatment by hours or days, prolong suffering, and drive many to go to the emergency department or hospital even when their primary goal for their care is to remain comfortable at home.

So, given the wrap-around hospice care management structure as defined by the Medicare

hospice benefit conditions of participation, as well as the high clinical need for urgent management of pain and symptoms in a home setting, it's clear that the benefits of telemedicine prescribing of controlled substances outweigh the risks for patients enrolled in hospice. We therefore respectfully request that DEA provide clarification that specifies that in-person evaluation requirements for telemedicine prescribing does not apply to hospice patients.

AAHPM also believes that other non-hospice patients with serious illness should likewise not have to face unnecessary barriers in accessing medications to address their pain, including Schedule II controlled substances.

Patients with serious illness often experience significant challenges in accessing in-person care, including mobility, cognitive issues, pain, frailty, medical instability, and they disproportionately have to rely on caregivers to assist in their transportation. These challenges and burdens underscore the need to allow telemedicine prescribing of controlled substances without in-person evaluation for this high-need population.

For example, imagine an 86-year-old homebound woman with moderate dementia and a flare-up

of bone pain due to metastatic breast cancer who receives oral chemotherapy and accesses all of her cancer and palliative care from her home via telehealth. It's highly unlikely that a physician home visit would be available to her on an emergency basis. Transporting her to an emergency department or outpatient clinic for an in-person evaluation just to prescribe pain medication would be extremely challenging for her and her caregivers and would only add to her distress.

Timely access to a palliative care specialist to manage distressing symptoms is an even bigger challenge for pediatric patients with serious illness. It's not unusual for a child suffering from a life-limiting rare childhood disease to receive their specialty care from a tertiary care hospital many hours away by car. Local medical resources are often unavailable, unwilling, or incapable of prescribing controlled substances for such complex patients. It would be inhumane to subject that child and family to a long car or ambulance transport to the specialized medical center simply to access a prescription for a controlled substance that could otherwise be managed safely and effectively at home.

To provide safeguards while supporting

access to urgent symptom management for people with serious illness, AAHPM recommends that DEA implement a telemedicine special registration process enabling qualified practitioners to prescribe Schedule II through V controlled substances via telemedicine without a prior in-person medical evaluation.

We support robust requirements for special registration, for example, demonstration of specialized training in palliative care or pain management, and would be happy to work with DEA on identifying appropriate qualifications specifically for those caring for people with serious illness.

Finally, we appreciate that Congress extended Medicare telehealth flexibilities through calendar year 2024. AAHPM urges DEA to likewise extend the telemedicine prescribing flexibilities for controlled substances through at least the end of 2024 while it implements a telemedicine special registration process.

While we appreciate that DEA extended flexibilities for six months after the Public Health Emergency for COVID-19 and for an additional year thereafter for relationships established between the start of the PHE and November 11, 2024, we believe that the flexibilities should be extended more

broadly, including for all telemedicine encounters for new and established patients, including for hospice patients if they are not clarified to be exempt, through the end of 2024.

Thank you so much for considering our comments in support of patients with serious illness and their families and caregivers.

(Applause.)

MR. STRAIT: Any questions?

(No response.)

MR. STRAIT: Okay. Thank you.

DR. ROTELLA: Thank you.

MR. STRAIT: Thank you so much.

Well, this does conclude our session. I would first like to just say a couple thanks to Administrator Milgram and Assistant Administrator Prevoznik for making your time. I know you have a hard stop at 4:00, so I would welcome you -- thank you.

For those of you that are still here, either watching us in person or virtually, I do want to say a hearty thanks on behalf of all of us at DEA for making time out of your busy schedules to be here, to be present, and in many cases to be heard. I think the comments we heard today were absolutely wonderful and

really give us some really great perspective as we move forward with our important regulation-drafting in this effort.

I do want to just say that -- I want to give a special shout-out to our production company, which is Real Impact. They made this effort look completely seamless, I hope, for the virtual presenters who got a chance to watch this. All understanding that I had was that this thing went really well today from a production standpoint, and there's no way we could have done it without Real Impact, so I do want to extend hy hearty thanks to you all.

I also know that we have stenography services being provided by Heritage Reporting Corporation, which again will become part of the administrative record for our rulemaking in this space, so I want to give a hearty thanks to our stenographer for being here, and I'm sure they have their work cut out for them trying to interpret everything and all the technical words that were said during today's discussion.

With that in mind, we will close our session for today. We're going to begin tomorrow at 9 a.m. We're going to flip the script, so we'll have our virtual presenters in our morning session, and then

we'll close our afternoon session with in-person presenters. I welcome you all to come back, and, again, thank you for being here.

(Whereupon, at 4:00 p.m., the listening session in the above-entitled matter adjourned, to reconvene at 9 a.m. the following day, Wednesday, September 13, 2023.)

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REPORTER'S CERTIFICATE

DOCKET NO.: --

CASE TITLE: DEA Telemedicine Listening Session

HEARING DATE: September 12, 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 13, 2023

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