

TRANSCRIPT OF PROCEEDINGS

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

Pages: 1 through 249
Place: Arlington, Virginia
Date: September 13, 2023

HERITAGE REPORTING CORPORATION

Official Reporters
1220 L Street, N.W., Suite 206
Washington, D.C. 20005-4018
(202) 628-4888
contracts@hrcourtreporters.com

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION

In the Matter of:)
TELEMEDICINE)
Listening Session)

700 Army Navy Drive
Arlington, Virginia

Wednesday,
September 13, 2023

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

PARTICIPANTS:

ANNE MILGRAM
Administrator, DEA

MATTHEW STRAIT
Deputy Administrator, DEA

THOMAS PREVOZNIK
Assistant Administrator,
Diversion Control Program

Virtual Presenters:

LAURA JANTOS
Healthcare Technology and Digital Healthcare
Management Consultant

FELICIA BAILEY
Family Nurse Practitioner, Avaesen Healthcare

BRUCE BASSI, M.D.
Telepsych Health

ALEX ARMITAGE, M.D.
Baylor Scott & White Health

Heritage Reporting Corporation
(202) 628-4888

PARTICIPANTS: (Cont'd)

Virtual Presenters:

ROXANNE TYROCH, M.D.
Intellimedicine PA

CONNIE GUILLE, M.D.
Medical University of South Carolina

CAITLIN GILLOOLEY
American Hospital Association

MARC BERGER, M.D.

JOHN HEAPHY
New York State Department of Health,
Office of Addiction Services
Department of Health Mental Health

PHILIP MOORE, M.D.
Gaudenzia

JESSE EHRENFELD, M.D.
American Medical Association

DELPHINE HUAN, M.D.
California Mental Health Service Authority

SARAH SPENCER, M.D.
Ninilchik Tribal Council
Alaska Tribal Health Consortium

Commenters:

DANIELLE VAETH
Qbtech

STEPHEN MARTIN, M.D.
Boulder Care

UJJWAL RAMTEKKAR, M.D.
Quartet Health

CHRISTA NATOLI
CTEL

JOHN WELLS
Louisiana State University Health Sciences Center

PARTICIPANTS: (Cont'd)

Commenters:

JUAN HINCAPIE-CASTILLO, PharmD
National Pain Advocacy Center

JAMES ULAGER, M.D.
Pursuecare

HALLEY CRISSMAN, M.D.
Planned Parenthood Federation of America

JESSICA RIGSBY
Ophella Health, Inc.

MARCELO FERNANDEZ-VINA
The Pew Charitable Trusts

DAN GOLDEN
East Coast Telepsychiatry

KEVIN SIMON, M.D.
Boston Children's Hospital Division of Addiction
Medicine

SHIRLEY REDDOCH, M.D.

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

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

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

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

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

1 Assistant Administrator to the Diversion Control
2 Division.

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

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

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

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

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

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

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

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

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

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

19 Once we have heard from all virtual
20 presenters, we will take a break, and this should take
21 us to sometime around lunchtime, around the noon hour.
22 We will take a recess and begin our afternoon session
23 at 12:40 p.m., where we will then hear from as many as
24 14 of our in-person presenters who are up in the first
25 two rows.

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

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

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

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

1 corner to the restrooms.

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

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

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

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

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

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

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

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

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

25 MS. JANTOS: Good morning. Thank you for

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

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

21 Methylphenidate oral was the medication for
22 pain management prescribed to me after a second TBI in
23 2018 and helped me establish a platform for cognitive
24 recovery, which has taken years to accomplish and has
25 allowed me to be able to work again enabling

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

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

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

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

1 if that's exactly what you're not supposed to do.

2 It's a difference between being able to work or not.

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

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

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

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

25 Having face-to-face encounters with

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

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

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

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

24 Thank you very much for your consideration.

25 MS. MILGRAM: Good morning. If I could ask

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

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

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

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

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

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

8 Thank you very much for your comments.

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

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

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

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

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

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

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

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

25 In that population, I would certainly

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

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

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

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

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

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

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

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

25 I would certainly say that laboratory tests

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

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

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

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

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

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

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

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

9 DR. BAILEY: Yes.

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

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

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

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

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

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

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

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

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

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

14 DR. BAILEY: Thank you.

15 MR. STRAIT: Dr. Bassi?

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

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

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

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

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

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

8 The vast majority of our patients do see us
9 for general psychiatric reasons, and I run a virtual
10 group therapy as well. During COVID, we wrote for
11 controlled substances for people with severe anxiety,
12 insomnia, and ADHD, and this comprised an additional
13 34 patients in 2022. In total, we sent in 15,000
14 different prescriptions that year, 406 of which were
15 for controlled substances, for an overall rate of 2.6
16 percent of prescriptions sent.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 the same practice.

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

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

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

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

7 MS. MILGRAM: Thank you so much.

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

12 DR. BASSI: Yeah, absolutely.

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

15 DR. BASSI: Like some --

16 MS. MILGRAM: -- what did you do?

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

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

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

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

17 MS. MILGRAM: And how did you identify that
18 7 percent?

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

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

25 You talked about an audit checking the state

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

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

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

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

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

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

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

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

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

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

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

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

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

22 MR. STRAIT: Okay. Thank you, Dr. Bassi.
23 I will now move on to Virtual Presenter No.
24 4.

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

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

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

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

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

1 likely to receive non-beneficial treatments.

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

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

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

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

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

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

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

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

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

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

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

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

3 Although we would not be surprised if any of
4 our supportive palliative patients were to die in the
5 coming year, annual mortality rates are in about the
6 50 percent range, clearly not hospice appropriate and,
7 like Sally, our patients wish to maintain disease
8 directed treatment. Thus, unlike the typically short
9 service time for hospice patients, in support of
10 palliative care, we serve patients for months to
11 years, most commonly in a hospital or clinic setting.

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

25 Hopefully, all can understand how

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

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

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

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

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

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

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

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

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

19 MR. STRAIT: Yes, it is.

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

1 Schedule II amphetamines.

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

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

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

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

1 Pharmaceuticals, a major supplier of Adderall
2 amphetamines.

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

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

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

25 The package inserts for stimulant drugs warn

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Just to highlight a few things that I think

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

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

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

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

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

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

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

25 We were given 180 days to transition all of

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

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

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

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

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

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

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

15 DR. GUILLE: In-person.

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

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

1 using audiovisual telehealth, synchronous encounters.

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

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

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

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

1 MR. PREVOZNIK: Okay. Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 That's all I've got.

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

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

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

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

7 MR. STRAIT: Yes, sir.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 Controlled III. It was unsatisfactory.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 MR. HEAPHY: Hi. Good morning, everyone.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Prescriptions should be issued in electronic

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

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

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

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

1 provide in-person services.

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

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

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

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

1 information and make it available at a cost.

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

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

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

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

25 However, if a telemedicine registration is

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

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

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

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

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

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

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

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

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

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

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

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

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

6 MR. PREVOZNIK: Okay. Thank you.

7 MR. HEAPHY: Thank you..

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

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

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

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

22 Our largest footprint and our corporate
23 office is in Pennsylvania. Last year, we served over
24 15,000 people, and our stance, Gaudenzia strongly
25 endorses the permanent integration of telehealth for

1 Schedule III to V drugs which was established during
2 COVID.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Removing this much-needed flexible tool

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

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

9 I really appreciate the opportunity to speak
10 today.

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

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

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

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

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

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

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

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

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

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

19 Does that answer your question?

20 MR. PREVOZNIK: Yes, thank you.

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

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

1 No. 11.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 MR. PREVOZNIK: Okay.

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

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

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

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

11 MR. PREVOZNIK: Okay. Thank you.

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

13 Ehrenfeld. And I do want to just make a point of
14 clarification and it bears emphasis because I know
15 that this, I think, is a fundamental assumption or
16 perhaps misunderstanding about our rule or the draft
17 rule that was published in March. And as Anne Milgram
18 mentioned on day one in her introductory remarks, the
19 Ryan Haight Act amended the CSA and required an
20 in-person visit be established and then created an
21 exception to that requirement when the practice of
22 telemedicine was occurring. All right? And then the
23 statute then listed seven or eight different
24 circumstances that constituted the practice of
25 telemedicine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 And I think we are now going to conclude our

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

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

12 //

13 //

14 //

15 //

16 //

17 //

18 //

19 //

20 //

21 //

22 //

23 //

24 //

25 //

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

2 (12:40 p.m.)

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

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

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

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

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

25 I stand here today in alliance with DEA,

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

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

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

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

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

25 Based on our experience with over 12,000

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

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

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

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

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

1 patients receive the care that they need.

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

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

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

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

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

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

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

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

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

1 which can be missed.

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

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

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

16 Our success extends globally. We have a
17 proven track record in countries that are already
18 prioritizing evidence-based objective data into their
19 pathways. Our testing system is now a standard of
20 care within the National Health Service in England
21 where 70 percent of NHS clinics are routinely using
22 Qbtech testing which after three years of study and
23 70,000 patients we received a nice appraisal this past
24 March.

25 We now serve over 4,000 clinicians in the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 You talked a little bit about, I think you

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

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

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

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

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

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

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

5 MR. PREVOZNIK: Okay, thank you.

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

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

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

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

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

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

1 UMass Chan Medical School.

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

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

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

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

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

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

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

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

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

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

1 7.5 million Americans with opioid use disorder end up
2 at the emergency department where even when they are
3 seen for an overdose they are prescribed Buprenorphine
4 less than ten percent of the time.

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

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

10 Since the suspension of an in-person visit
11 in March of 2020, our clinical team has conducted over
12 50,000 visits on secure video and engaged in 600,000
13 secure telecommunication touch points with several
14 thousand patients. Almost 90 percent of our patients
15 have Medicaid coverage -- the most underserved
16 population in substance use disorders and who have the
17 greatest needs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 Thank you for your time and consideration.

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

1 questions.

2 DR. MARTIN: Please. Thank you.

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

5 DR. MARTIN: Oh, certainly.

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

9 DR. MARTIN: Yes.

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

12 DR. MARTIN: Yes.

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

16 DR. MARTIN: Yes.

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

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

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

1 with opioid use disorder.

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

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

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

16 I hope that helps.

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

19 DR. MARTIN: Yes --

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

21 DR. MARTIN: Please --

22 MS. MILGRAM: -- available data --

23 DR. MARTIN: Yeah.

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

1 think should exist around telehealth providers.

2 DR. MARTIN: Oh, certainly.

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

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

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

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

21 DR. MARTIN: I apologize.

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

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

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

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

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

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

25 There is no data to show that video is any

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

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

10 I hope that helps.

11 MR. PREVOZNIK: It does.

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

16 DR. MARTIN: Certainly, certainly.

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

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

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

1 that at face value.

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

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

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

13 MR. STRAIT: Okay. Commenter No. 3.

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

25 I stand before you today as my role as the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 So, as the general framework, we would

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 So, from the number perspective, it would

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

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

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

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

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

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

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

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

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

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

18 MS. MILGRAM: PDMP --

19 DR. RAMTEKKAR: Correct.

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

24 DR. RAMTEKKAR: Correct. Correct.

25 MS. MILGRAM: Okay, thank you. Just wanted

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

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

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

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

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

1 use the facilities, if anyone needs to do so.

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

3 MS. NATOLI: My name is Christa Natoli.

4 C-H-R-I-S-T-A, N-A-T-O-L-I. I'm the Executive
5 Director of CTel, the Center for Telehealth and
6 E-Health Law. We're a 501-C3 non-profit telehealth
7 research institute focused on policies and regulations
8 that impact the delivery of virtual care. We are
9 bipartisan and not beholden to any particular
10 stakeholder.

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

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

25 In these remarks, we will present data that

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

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

14 As a health services researcher, I have over
15 25 years of experience, half of that with the Federal
16 Government Department of Health and Human Services.
17 As a researcher, I love data, so I always look at what
18 the evidence shows me before I endeavor into doing any
19 new research.

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

25 This is a really important finding. Even

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

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

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

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

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

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

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

1 professionals needed to ensure an adequate supply.

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

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

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

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

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

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

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

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

25 These include high rates of diversion of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 (Brief recess.)

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

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

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

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

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

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

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

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

1 of those patient populations in these FQs.

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

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

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

25 And this is not unique to telemedicine; it

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 stimulant across state lines sometimes can be very
2 problematic.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 colleagues in the Jaman Edwards Copeland 2023.

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

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

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

25 At a moment when the street supply is

1 especially dangerous, when the CDC is warning
2 especially about deaths from counterfeit pills, and
3 when overdose deaths continue to escalate, surpassing
4 107,000 in 2021, making policy decisions to roll-back
5 a proven avenue for care, and one that puts people in
6 harm's way, is reckless.

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

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

20 Alternatively, the DEA could allow
21 60-to-90-day initiation via telehealth by a new
22 provider, with appropriate documentation that accords
23 with relevant state medical board rules and
24 procedures. The DEA should also consider allowing a
25 60-day initiation via telehealth, even for new

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

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

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

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

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

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

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

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

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

1 that can be prescribed by telemedicine.

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

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

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

25 Finally, with regards to the additional

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

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

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

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

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

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

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

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

23 Buprenorphine is life saving medicine. The
24 meta analysis of half a million patients published in
25 2019 found people were eight times less likely to

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

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

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

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

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

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

18 The problem is buprenorphine is not
19 available. In December there was a publication that
20 13 percent of Americans with OUD get treatment, and
21 it's worse in rural areas. That makes it sound like
22 we're a developing country who doesn't have the
23 resources in place to take care of the chronic needs
24 of its patients, and the reason it sounds that way is
25 because that's true. We don't have the resources in

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 So what about the numbers? And the numbers

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

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

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

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

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

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

18 DR. ULAGER: Of course.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 lives.

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

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

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

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

1 obtained directly during a telemedicine visit.

2 Thankfully, healthcare providers are well-accustomed
3 with protocols for having patients obtain labs locally
4 and are not reliant on labs obtained concurrently with
5 an in-person visit.

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

16 An in-person evaluation for testosterone
17 requirement is medically unnecessary and burdens
18 patients that would be disproportionately impacting
19 individuals affected by systemic and institutional
20 forms of oppression.

21 Planned Parenthood centers, including those
22 I oversee, provide inclusionary care, but many members
23 of the LGBTQ+ communities, particularly trans and
24 nonbinary individuals, face discrimination and forms
25 of violence when seeking healthcare, including

1 misgendering, invasive, unnecessary questioning,
2 unwanted touching, and abusive language. A recent
3 survey found that approximately half of transgender
4 and nonbinary respondents reported having at least one
5 of these kinds of negative experiences with a doctor
6 or healthcare provider in the last year.

7 A particular vitriolic discourse now runs
8 rampant in some state governments and local
9 jurisdictions, compounding longstanding access issues.
10 Gender-affirming care is healthcare. It has clear
11 support from all major American medical professional
12 associations, including the American Medical
13 Association and American Pediatric Association, but
14 numerous states have severely restricted access to
15 gender-affirming care.

16 In 2022, state legislatures across the
17 country introduced more than 100 anti-trans bills. In
18 2023, there's been a dramatic expansion of anti-trans
19 legislation. Almost 500 anti-LGBTQ+ bills have been
20 introduced in state legislatures this year. Roughly
21 130 of these target trans healthcare. These bills are
22 extremely harmful. People of all gender identities
23 deserve civil and human rights -- I shouldn't have to
24 say that -- including the right to high quality,
25 affordable, and non-judgmental healthcare. These bans

1 actively impede access to care and stigmatize those
2 who seek it.

3 In this climate, telemedicine access for
4 testosterone is essential. An in-person evaluation,
5 or a referral for one, is, for many people, simply
6 unattainable. A return to in-person evaluation
7 requirements would interrupt patient care and, for
8 some, present insurmountable barriers to accessing
9 prescriptions for testosterone that they need,
10 particularly for patients who are young, live in rural
11 areas, are working to make ends meet, or live at the
12 intersection of multiple of these.

13 With respect to practitioner record keeping,
14 providers' record keeping obligations and practices
15 are already robust. For provider privacy and personal
16 security, and because records could be misused by
17 hostile lawmakers to target individuals who have
18 obtained gender-affirming hormone therapy, providers
19 should be required to document only their city and
20 state during a telemedicine appointment and maintain
21 any records at the registered location of their
22 dispensing registration.

23 Planned Parenthood's concern about the risk
24 of entities hostile to gender-affirming hormone
25 therapy misusing prescribing records to criminalize

1 patients and/or providers, like me, who receive and
2 provide this medically necessary care, extends to all
3 data keeping requirements, as well as to the DEA's
4 consideration of a special registration.

5 Planned Parenthood strongly urges the DEA to
6 exercise caution in deciding how to implement such a
7 registration. It is imperative that it be maximally
8 protective of patient and provider safety and privacy,
9 and does not burden access to care.

10 In sum, because testosterone prescriptions
11 made via telemedicine are safe and effective, because
12 an in-person evaluation requirement would severely
13 interrupt care for patients who need access to
14 testosterone, and because there are alternatives the
15 DEA could utilize to ensure a satisfactory
16 diversionary framework, Planned Parenthood strongly
17 advocates for the DEA to permit telemedicine
18 prescription of testosterone without burdening
19 patients with an in-person evaluation. Thank you for
20 the opportunity to testify.

21 MS. MILGRAM: So a question, and I'm going
22 to ask you a general question that a number of folks
23 raised the same issue yesterday around provider
24 privacy and not wanting to have the specific address.
25 You just mentioned, I think you mentioned, city and

1 state. What about zip code? If you could just sort
2 of expand a little bit about where you think that line
3 might be, that would be helpful.

4 DR. CRISSMAN: I don't know if I can comment
5 on a specific line in the sand without seeing
6 something written, and I know we would be happy to
7 submit written comments, but what I would say is if
8 the DEA thinks that a national registry is necessary,
9 or that collecting more details of location are
10 necessary, we urge adequate protections of this highly
11 sensitive medical information and urge cognizance, in
12 particular in relation to gender-affirming care, of
13 the hostility and real dangers that patients and
14 providers may face if this information is in hostile
15 hands, including of regulators who are anti-trans.
16 Thanks.

17 MR. STRAIT: And we now have Commenter No. 9
18 coming to the podium.

19 MS. RIGSBY: Good afternoon. My name is
20 Jessica Rigsby. That's J-E-S-S-I-C-A. Last name
21 Rigsby, R-I-G-S-B-Y. I am the head of legal
22 compliance at Ophelia Health. I'm a licensed attorney
23 as well as being certified in health care compliance.

24 I've been in the OUD treatment space for
25 many years. Initially with a typical brick and mortar

1 clinic organization and now in telemedicine. I can
2 say from experience the additional privacy and ease of
3 access in telemedicine helps patients get in and stay
4 in care well beyond what is standard in-person
5 treatment.

6 I'd like to start by thanking the DEA for
7 this opportunity to speak about the special
8 registration. I'm here today on behalf of Ophelia,
9 our clinicians and our patients.

10 Ophelia provides medical treatment via
11 telemedicine for opioid use disorder and mental health
12 care under a team-based medication and counseling
13 model. Our mission is to make health high quality,
14 evidence based MOUD care safe, affordable and
15 accessible to all.

16 I want to highlight that it's important to
17 understand that we believe telemedicine is a
18 complement to and not a total replacement for in-
19 person care. Telemedicine adds to the treatment
20 ecosystem improving access, outcomes, satisfaction and
21 reducing costs.

22 During the last three years, Ophelia has
23 navigated through state and federal level regulations
24 an PHE flexibilities and at the same time proven that
25 telemedicine MOUD care is safe and effective.

1 We've seen telemedicine decrease the
2 treatment gap which is one of the main drivers of the
3 epidemic of opioid overdose deaths. More than 80
4 percent of our patients had not received any type of
5 OUD treatment before coming to us, demonstrating how
6 clearly telemedicine creates access.

7 We've also spent time publishing studies to
8 demonstrate and share what we've learned, including a
9 study that showed high treatment retention rates,
10 irrespective of patient geography and race or
11 ethnicity. We've learned that 80 percent of patients
12 stay in care for at least six months if they can use
13 their in-network insurance benefits, but that some
14 insurance plans are skeptical of contracting with us
15 due to the uncertain future of telemedicine controlled
16 substance prescribing.

17 I won't spend my time today reiterating all
18 the wonderful points others have made at these
19 sessions about how much telemedicine increases access,
20 reaches populations otherwise unserved, et cetera, et
21 cetera. Ophelia submitted a lengthy comment in March
22 to the proposed rules which outlines all of that.

23 Instead I'm going to talk about some basic
24 best practices for telemedicine in general, follow up
25 with best practices specific to telemedicine MOUD,

1 discuss a few misconceptions about at-home urine drug
2 screens, and also some truth about Buprenorphine.

3 All telemedicine prescribers regardless of
4 the conditions that they treat should be adhering to
5 basic best practices and regulatory requirements.
6 This is a non-exhaustive list, but maintaining
7 clinical licensure and of course DEA registration in
8 good standing. Compliance with all state and federal
9 laws including state-level controlled substance
10 registrations and any collaborative or supervision
11 requirements for nurse practitioners and physician
12 assistants.

13 We should all be abiding by clinically
14 appropriate policies and procedures specific to the
15 care that we provide. And we should have established
16 processes for assessing patients for appropriateness
17 for telemedicine care and be prepared to refer
18 patients to in-person care either initially or at any
19 point during treatment when it becomes indicated
20 clinically or becomes patient preference.

21 We should have protocols for detecting and
22 managing emergencies and protecting confidentiality.
23 Telemedicine providers should be willing to
24 participate with major insurance plans including
25 public and private payers. And we should all be

1 addressing commonly occurring medical and psychiatric
2 comorbidities.

3 Clinicians prescribing Buprenorphine for OUD
4 via telemedicine should additionally be adhering to
5 requirements like using synchronous audiovisual
6 clinical visits as a standard. Diversion prevention
7 and detection protocols to include the use of all the
8 tools available to us. Things like PDMP checks before
9 every single prescription, real time UDS screen
10 protocols, film or pill counts when clinically
11 indicated, and advising patients on safe medication
12 storage.

13 Clinical leadership and supervision should
14 be done by qualified addiction medicine or psychiatry
15 specialists and should conduct internal clinical
16 oversight like clinical case reviews and clinical
17 support for monitoring controlled substance
18 prescribing.

19 Clinical models should include minimum
20 standards of care such as obtaining patient medical
21 and psychiatric history, collaborating with outside
22 providers like a patient's primary care physician or
23 other specialty care providers. Real time audiovisual
24 clinical evaluation starting with higher frequency and
25 decreasing as patients stabilize with a minimum of at

1 least one clinical visit per month per patient. A
2 treatment agreement with the patient and a documented
3 clinical treatment plan as well as periodic UDS and
4 maintaining comprehensive medical records of treatment
5 and medication accounting.

6 OUD telemedicine clinicians should build
7 referral and consultation relationships with treatment
8 programs in communities where their patients live.
9 These relationships should include primary care and
10 specialty care services as well as other in-person OUD
11 care options including OTPs and residential addiction
12 care. Often OUD care is a patient's first meaningful
13 connection with health care and we should be using
14 this opportunity to connect them to other crucial
15 preventative and comprehensive health care.

16 Before I move on, a few things about
17 diversion management.

18 We prevent diversion the same way in-person
19 care does, by establishing good relationships with
20 patients, assessing their progress, and maintaining
21 open communication. All that in partnership with
22 regular documented PDMP review and urine drug screens.

23 The topic of urine drug screens has come up
24 a number of times in these sessions. Anyone who has
25 been in health care for any time at all has heard a

1 wild story about a patient's attempt at faking a UDS.
2 Interestingly, though, a 2022 study found very low
3 rates of falsification of urine drug screens among
4 patients of OUD receiving treatment via telemedicine.

5 Our own study at Ophelia which included
6 close to 3400 patients which were monitored for at
7 least 180 days was recently published in JAMA. It
8 showed that it is feasible to conduct regular urine
9 drug screening in a remote setting with very low rates
10 of unexpected results such as being negative for
11 Buprenorphine or positive for other opioids.

12 At-home UDS kits are simple to use, screen
13 for multiple substances, include built-in tampering
14 prevention such as temperature readings and indicators
15 of adulteration. These results are easy for
16 clinicians to obtain and view during a clinical
17 audiovisual visit with the patient. Every Ophelia
18 patient has at least one if not more sealed UDS kits
19 on hand at all times. We can also refer patients to
20 local labs such as Quest if more sensitive or
21 comprehensive testing is indicated. We have detailed
22 UDS protocols and keep extensive records on the
23 collection and results of each UDS.

24 Now onto Buprenorphine.

25 We understand the DEA's concern about

1 diversion in telehealth in general, but Buprenorphine
2 is different from other controlled substances. It has
3 a much different risk-to-benefit ratio.

4 Buprenorphine isn't a recreational drug. It
5 blocks the opioid receptors in the brain, minimizing
6 cravings associated with OUD without producing a high
7 when used as prescribed.

8 Studies have repeatedly found that diverted
9 Buprenorphine is an attempt by individuals to initiate
10 OUD treatment they don't have access to on their own.
11 Studies also indicate that 70-90 plus percent of
12 people who use illicit Suboxone report using it to
13 prevent cravings and withdrawal.

14 A recent study by health authorities found
15 that despite increases in Buprenorphine prescribing
16 after the onset of COVID, there was not a correlating
17 association with the prevalence of Buprenorphine among
18 overdose victims. This study replicated findings from
19 an earlier study in New York City showing that
20 Buprenorphine was incredibly uncommon in the toxicology
21 reports for overdose victims, speaking to its risk
22 protective profile.

23 Our data speaks for itself. At Ophelia
24 we've treated over 10,000 patients during the past
25 three years with only 10 overdose related deaths

1 reported to us. That is one-tenth of one percent and
2 it's well below the incredibly high rate of mortality
3 otherwise observed among individuals with OUD which is
4 typically 1 to 2 percent annually, possibly higher at
5 this point with dangerous Fentanyl exposure.

6 Many individuals treated with Buprenorphine
7 are alive today because they were able to access this
8 treatment via telehealth. We firmly believe that
9 every patient in care is one less person seeking
10 diverted opioids. We reduce diversion not just among
11 our patients with our internal monitoring protocols,
12 but by reducing the number of customers in the market
13 for diverted opioids.

14 SAMSA's own publications show that patients
15 who discontinue OUD medication generally return to
16 illicit opioid use within just a few weeks or months.
17 Low barrier of access to quality Buprenorphine care
18 prevents diversion.

19 One final point. The opioid PHE is still in
20 effect and has been for six years. We would ask the
21 DEA to repeat the flexibilities and extend it to all
22 controlled substances during the COVID PHE to
23 Buprenorphine under the opioid PHE for as long as it
24 lasts.

25 In closing, we are directly addressing the

1 root cause of the opioid PHE one patient at a time.
2 We like to think we are your partners in the fight
3 against diversion and not the cause of it.

4 On behalf of our current patients and all
5 those still looking for an answer to their OUD, thank
6 you for taking the time to listen to our
7 recommendations. We appreciate your care and your
8 attention.

9 MR. STRAIT: Thank you.

10 I'm going to ask Commenter No. 10 to pause
11 before coming up. We're going to take just a five
12 minute leg stretch break. So we will come back at
13 2:55. Thank you.

14 (Brief recess.)

15 MR. STRAIT: Let's get started.

16 I am happy to call Commenter No. 10 to the
17 podium.

18 MR. FERNANDEZ-VINA: Marcelo Fernandez-Vina,
19 M-A-R-C-E-L-O F-E-R-N-A-N-D-E-Z hyphen
20 V-I-N-A. I'm with the Pew Charitable Trusts.

21 Good afternoon. I'm Marcelo H. Fernandez-
22 Vina appearing today on behalf of the Pew Charitable
23 Trust Substance Use, Prevention and Treatment
24 Initiative.

25 Pew works with state and at the federal

1 level to address the nation's opioid overdose crisis
2 by developing solutions that improve access to timely,
3 comprehensive evidence-based and sustainable treatment
4 for opioid use disorder.

5 The Pew Charitable Trust through its
6 Substance Use, Prevention and Treatment Initiatives
7 recommends that the pandemic flexibilities allowing
8 for Buprenorphine prescribing by all DEA registered
9 practitioners via telehealth without an in-person
10 requirement be kept in place permanently.

11 Overdose deaths have reached unprecedented
12 levels in recent years with over 100,000 overdose
13 deaths occurring in 2022, the majority of which
14 involved opioids.

15 In light of the public health crisis we
16 face, access to Buprenorphine should not be
17 restricted. Therefore, Pew urges the DEA to take
18 steps to maintain access to Buprenorphine in order to
19 curb the overdose epidemic. Allowing health care
20 providers to prescribe Buprenorphine remotely during
21 the pandemic helped more patients start and stay in
22 treatment without increasing overdose deaths.

23 The pandemic telehealth flexibilities helped
24 veterans, people experiencing homelessness,
25 individuals involved in the criminal justice system,

1 those living in rural areas, and racial and ethnic
2 minorities access Buprenorphine via telehealth with
3 audio-only visits helping many of these patients
4 access care.

5 Allowing Buprenorphine to be prescribed via
6 telehealth decreases challenges associated with the
7 transportation and geography and helps patients with
8 work and child care responsibilities. Telehealth
9 improved access to care for rural and hard to reach
10 populations, reduced wait times, and worked around
11 challenges with child care, work, transportation and
12 stigma.

13 Under DEA's pandemic flexibilities,
14 Buprenorphine was safely and effectively prescribed
15 via telemedicine and reached more people including
16 people that traditionally face challenges accessing
17 Buprenorphine by centering patient access, comfort and
18 empowerment and reducing barriers to treatment.

19 DEA's pandemic flexibilities improved access
20 to Buprenorphine by allowing patients to start
21 lifesaving medication via telehealth without having to
22 see a provider in person.

23 In multiple studies both patients and
24 prescribers report positive experiences with
25 telehealth for Buprenorphine prescribing, including a

1 greater sense of ease, flexibility and autonomy for
2 patients.

3 Earlier this year researchers at Harvard
4 Medical School found that providing OUD care via
5 telehealth may be comparable to in-person OUD care and
6 no evidence indicates that telehealth for OUD care is
7 unsafe or over-used.

8 A study published in JAMA Psychiatry found
9 that Medicare beneficiaries who received telehealth
10 services related to OUD were more likely to stay on
11 medication and less likely to experience an overdose.

12 Similarly Veterans Health Administration
13 patients using telehealth for Buprenorphine treatment
14 were more likely to stay in treatment than patients
15 being seen in person.

16 Based on this information additional
17 requirements for prescribing Buprenorphine via
18 telehealth including a special registration impose
19 arbitrary, non-evidence based barriers to lifesaving
20 treatment.

21 During the pandemic all prescribers were
22 able to utilize telehealth with no special
23 registration requirement. Given the administration's
24 and this agency's commitment to prioritizing
25 meaningful interventions that address substance use

1 disorders, DEA should carefully consider the effects
2 special registrations can have on restricting access
3 to Buprenorphine treatment.

4 Both DEA and the National Institute on Drug
5 Abuse agree that increased Buprenorphine prescribing
6 decreases diversion. DEA has previously stated that
7 it's actually lack of access to Buprenorphine that
8 drives Buprenorphine diversion, and that increasing
9 access to medication may be an effective way to
10 prevent diversion.

11 The National Institute on Drug Abuse has
12 also stated that as Buprenorphine access increases,
13 Buprenorphine diversion decreases.

14 An assessment of telehealth impact on
15 adverse outcomes found no data indicating evidence of
16 increased diversion for patients receiving care via
17 telehealth. Rather, Studies found that virtual
18 Buprenorphine access led to few adverse events.

19 There are existing robust safeguards in
20 place to prevent Buprenorphine misuse and diversion.
21 Prescribers of controlled substances are already
22 registered with the DEA and licensed through their
23 state boards, meaning they have to meet specific
24 standards of health care delivery to practice or they
25 risk losing their license.

1 In addition, most states require prescribers
2 to use their prescription drug monitoring programs or
3 PDMPs to track prescriptions for controlled substances
4 in Schedules II through V. Most PDMPs update their
5 data on a daily or weekly basis and participate in
6 interstate data sharing.

7 In our view, additional data collection by
8 DEA is unnecessary. Under DEA's pandemic flexibilities
9 Buprenorphine was safely and effectively prescribed
10 via audio-only and audio video telemedicine without
11 additional data collection measures, and prescribers
12 in the future should not be subject to additional
13 arbitrary requirements which can reduce access to
14 lifesaving medication.

15 I'd also like to note that CMS already
16 collects data on the use of telehealth by requiring
17 Medicare practitioners to use a modifier for
18 telehealth claims and Medicaid and other insurers
19 track telehealth claims.

20 Buprenorphine is extremely safe and the
21 overdose risk on Buprenorphine is extremely low as the
22 drug has a ceiling effect, meaning its effects will
23 plateau and not increase even with repeat dosing.

24 It's notable that as Buprenorphine
25 prescribing increased during COVID, overdose deaths

1 involving Buprenorphine did not increase.

2 The evidence is clear. Buprenorphine is
3 safe, effective and saves lives. Buprenorphine access
4 plays a vital role in reducing Buprenorphine diversion
5 and there are major benefits to public health and
6 safety that the pandemic flexibilities provided to
7 patients with OUD.

8 The Pew Charitable Trust strongly recommends
9 that the pandemic flexibilities allowing for
10 Buprenorphine prescribing by all DEA registered
11 practitioners via telehealth without an In-person
12 requirement be kept in place permanently.

13 Given the overwhelming evidence base in
14 support of our recommendations today, Pew urges the
15 DEA to finalize a rule for telehealth prescribing of
16 Buprenorphine without an in-person requirement as soon
17 as possible.

18 To avoid reductions in access to treatment
19 during the rulemaking process, we urge DEA to extend
20 the existing temporary rule or use the already
21 designated opioid public health emergency to keep the
22 pandemic flexibilities in place for Buprenorphine
23 prescribing via telehealth.

24 Thank you for the opportunity to offer
25 comment on behalf of the Pew Charitable Trust and for

1 your attention to these matters today.

2 I'm happy to respond to any questions you
3 may have.

4 MR. STRAIT: No questions. Thank you.

5 We re now calling Commenter No. 11.

6 MR. GOLDEN: He just told me not to worry
7 about the ten minute time limit, just do what I need
8 to do and go as long as I can.

9 (Laughter).

10 MR. GOLDEN: Everybody here's been extremely
11 courteous for the last two days, but it is the driest
12 event I've ever attended in my life. I mean honestly,
13 the people that's been here yesterday and today are
14 changing the world. It's an emotional thing and I
15 hope I can hold it together. All of my friends and
16 family are watching, but I'm passionate.

17 I've heard of doctors, lawyers, scientists,
18 professors from Yale, Harvard, Johns Hopkins
19 University, pharmaceutical representatives,
20 representatives from the government. And I'll tell
21 you who I am. I am rural America.

22 My name is Dan Golden, G-O-L-D-E-N. For
23 further clarification I'm Commenter No. 11 which so E-
24 L-E-V-E-N. See, we're smiling and having fun.

25 In all seriousness, I do represent rural

1 America. We have East Coast Telepsychiatry and our
2 provider is Amy Farr. She's a 29 year nurse
3 practitioner who is passionate about the care of her
4 patients.

5 When the telehealth thing went in chaos at
6 the end of March we panicked. Everything that we own,
7 we put into doing a telehealth business to provide
8 care for people, and people don't understand in rural
9 America the numbers are different.

10 Washington, D.C. and the DEA is not America.
11 America that I live in -- I live in Northumberland
12 County, Virginia. There are two stop lights in the
13 whole county. Twenty-three miles apart. And those
14 two stop lights are twice as many items that there are
15 providers. There are not two providers in the county.

16 The closest hospital does not accept
17 psychiatric patients because they have no psychiatric
18 doctor that works at VCU, Tapahanock Hospital in
19 Virginia. So obviously the statistics are there.
20 Rural America needs help. Rural America needs
21 telehealth, they don't need restrictions that punish
22 the patient.

23 Basic statistics that I'm going to try to
24 cover everything -- I want to talk like the micro-
25 machine guy from the commercials back in the '80s.

1 By 2034 the American Medical Colleges report
2 there will be a shortage of 124,000 providers in the
3 United States. Another statistic that I don't know
4 that people are aware of, telehealth visits increased
5 from 2019, from 840,000 to 52.7 million telehealth
6 visits in one year. From 2019 to 2020. According to
7 the United States Census Bureau, in the last four
8 weeks the survey was done in February, in the last
9 four weeks, 23 percent of all adult Americans had
10 attended a telehealth appointment.

11 Many hospitals have no psychiatric
12 providers. There are providers available but the
13 average wait time, according to a study from Virginia
14 Tech School of Medicine and Medstate (phonetic) in the
15 State of Virginia, only 18 percent of psychiatrists
16 were available to see new patients. The median wait
17 time was 67 days for in-person appointment, yet only
18 23 for Telepsychiatry. The crime factors, if the
19 patients don't get the medicine from providers, we
20 prescribe a lot of Adderall conserved to Ivans
21 (phonetic)

22 I can walk out probably on the corner of
23 this property and get that item from illegal drug
24 sellers, so we need to ensure that people are taken
25 care of by proper care.

1 In 2008 the White House mandated that the
2 DEA create special exemptions. Fifteen years later
3 we're sitting here trying to do so. One thing that I
4 want to make very clear. I think the DEA liked having
5 everyone here yesterday and today, getting this input,
6 and hopefully doing a lot of the work for them because
7 they can't think of all of the things that providers,
8 prescribers, doctors, pharmacists deal with on a day-
9 to-day basis.

10 I think one thing that is very important is
11 that the DEA needs to build a team of providers,
12 pharmacists and any other key parties to meet
13 virtually, maybe every 90 days or six months, because
14 the decisions that you make in the next few months are
15 going to be outdated in two years. Technology is
16 going faster than we can even fathom.

17 One thing that I do think is important
18 that's not been addressed, I do think a telehealth
19 visit should be done by a person, not an AI bot,
20 because that is going to be a factor probably within
21 nine months, sooner, or may already be happening. So
22 those are things that need to be looked at.

23 The PMP Awareness Program, everybody has
24 mentioned it and I'm going to strive that that thing
25 is crucial. We had a patient last fall, she scheduled

1 an appointment the first of November. She was
2 determined to have ADHD. She was prescribed Adderall.
3 She returned for a follow-up visit a month later. She
4 had obtained the exact same medication from four more
5 providers, all within a 30 day period.

6 The PMP system needs to be federal. If it's
7 state level, they're all going to have their own
8 quirks and additions. It needs to be one shot. So
9 when I click in and the guy just moved from San
10 Antonio, Texas to Lottsburg, Virginia, I can see what
11 he got over the last year, what medications he's been
12 on.

13 Talk about flagging providers and
14 pharmacists. The patients need flagged.

15 If I put in a prescription or our provider,
16 Amy Farr, puts in a prescription for a patient and
17 they pick up that medication, the problem is with PMP
18 that's not been mentioned by anybody, it is hugely
19 flawed. And if the government picks up on the PMP
20 today it will be an utter failure because pharmacists
21 put on the fill date of a medication. If I prescribe,
22 my buddy Pierre gets prescribed maybe Vyvanse, and we
23 send in the prescription electronically today and the
24 pharmacist has time to fill it this evening, he enters
25 into PMP that it's filled and he hangs it on the rack

1 in the little plastic bag for people to come and pick
2 up.

3 Well, Pierre may not pick his medicine up
4 until next Monday or Tuesday. So then when he comes
5 for his follow-up in 28 to 31 days, he's getting his
6 medication a week early. So now he's got extra
7 Adderall laying around where he can sell those seven
8 pills or he's not taking the medication properly.

9 Every patient that we see, and I do think
10 this should be something added on to providers, every
11 patient, every visit there should be a PMP check
12 pulled and stuck in their file for review. For the
13 simple fact that it prevents people from drug
14 shopping. It prevents pharmacists from giving out the
15 pills, even though somebody's gotten four different
16 prescriptions for Adderall 20mg in the last three
17 weeks. And something else the lady from Medicaid
18 yesterday mentioned there's fraud being done in the
19 EPCS. A federal PMP program would also eliminate that
20 because Amy Farr can say I didn't prescribe these
21 three medicines. So she can report, hey, somebody's
22 hacked my account or done whatever. You know, there's
23 multiple safeguards that can take place there.

24 This is a common sense thing to me. That's
25 why I'm glad I'm here and I don't have all those

1 degrees. I'm rural. I'm the country dude. I built
2 decks for 25 years. I have no medical background
3 until my wife decides we need to open a practice to
4 take care of people. She's been a nurse practitioner
5 for 29 years, and is passionate. And the rules that
6 are currently in place could devastate every penny
7 we've ever spent. And I know these rules are
8 changing. That's why we're here. It's just a matter
9 of lining up the dots and getting things done. So
10 we're thankful.

11 And this gentleman mentioned earlier, you
12 know, the grandfather thing. It's already in effect.
13 Don't worry about your current patients. The current
14 wording when you pull up on the DEA website is that
15 exemption was placed from March until this November,
16 but for previous existing patients it's active until
17 2024.

18 That needs to change immediately, and any
19 pre-existing patients and cases the wording needs to
20 say when somebody Googles it, they are grandfathered
21 forever. There's no reason that you have a patient
22 coming to us for the last 2.5 years and then November
23 2024, I have to say I'm sorry, I can no longer
24 prescribe your medication. I'm sorry about your
25 anxiety.

1 What's going to happen to a person with
2 anxiety if they can't find a provider within two
3 months? And they can't get to an office? It provides
4 undue stress.

5 So the people that we have, they don't need
6 to be limited to 2024. The patients we have now, we
7 have the right to keep those patients and they have a
8 right to choose and leave if they want to.

9 Drivers license, state ID or passport. In
10 my opinion if a person is getting a controlled
11 substance they have to produce that to the provider
12 and they have to produce it every time they pick up a
13 prescription. It's not Motrin, it's not some simple
14 cold remedy, it is a controlled substance.

15 Video visits versus telephone. A video
16 visit should be mandatory for at least the first
17 visit. Put eyes on the person so when the driver's
18 license comes in you at least know you're talking to
19 the same person. After that, go to a telephone.

20 The same care can be given on a telephone.
21 We don't like to do it. We require video visits. On
22 rare occasions we do the telephone. Just for the fact
23 you can lay eyes on the people. They may tell you
24 they're perfectly fine, but they may have tears coming
25 down their face. They may have physical problems.

1 They may have meth marks. You know, things that
2 people need to see.

3 So video's important. If it's done by
4 telephone only, that's okay, but the first visit I
5 think we need to establish yeah, this is John Doe
6 because that's what his driver's license says.

7 Let me see if I have anything else. I know
8 my time is ticking.

9 The DEA is worried about the future. The
10 future happened two years ago when the United States
11 was put into a pandemic, so it's too late.

12 You need to fix these rules now and you need
13 to ensure that you do things to continuously change
14 things as they need changed. Don't wait 20 years to
15 address this topic again because it's not happening.
16 You will be left behind in the technological dust.

17 So with that I'd like to thank everybody for
18 my time and putting up with my passion.

19 MR. STRAIT: No questions.

20 We are now welcoming Commenter No. 12 to the
21 stage.

22 DR. SIMON: Thank you to the Commenter No.
23 11, given the time that we're at.

24 My name is Dr. Kevin Simon. Kevin,
25 K-E-V-I-N. Simon, S-I-M-O-N. I am here from the City

1 of Boston. I appreciate the Pew acknowledging study
2 from our group with regards to opioid use and
3 telehealth.

4 I'm here today representing dual roles. I
5 serve as the first Chief Behavioral Health Officer for
6 the City of Boston. And professionally I am one of
7 these rare child and adolescent and adult
8 psychiatrists. I'm also board certified in addiction
9 medicine and operate or work through the Adolescent
10 substance Abuse and Addiction Program, also known as
11 ASAAP at Boston Children's Hospital.

12 I get to care for families, youth. A mother
13 emailed me today with regards to her son who is 14. I
14 met him when he was 12. He had to go to the ED in
15 part because he used to be in DYS, the Department of
16 Youth Services, the Juvenile Justice Service. Got
17 discharged on Friday and today is Wednesday or
18 Thursday. In school he was vomiting in part because
19 he's engaged in Percocet and other opioids.

20 So telehealth is critical. It is a
21 lifesaving measure that we've demonstrated through our
22 group. Particularly when we were thinking about
23 adolescents, and this hasn't yet been mentioned. I'm
24 going off the cuff and not really with my remarks
25 here.

1 In reference to -- for all the adult
2 patients that we're talking about, 90 percent began
3 their substance engagement before 18. So in terms of
4 who we really should be trying to target, it's those
5 who are adolescents. The reality is, adolescence has
6 prolonged itself over time because socially you get to
7 be on your parents' insurance until 26. The average
8 age of marriage, back when my parents got married it
9 might have been 21. That's not the case anymore.

10 So in terms of how do we ensure
11 appropriateness of care, we do it with our group. We
12 meet yes with the patient, but adolescents don't
13 really like to share information all that much, but
14 because they're under 21, or really under 18, we also
15 meet with their parents or their guardian. The
16 reality is, you have access to collateral information
17 to ensure the patient that you may not be able to see
18 visually, somebody else is able to see that person.

19 So I want to talk about two fictitious but
20 real patients. Anna, from rural America; and Jason
21 from urban America.

22 The reality is Anna, although she's not from
23 a city like D.C. or New York, she's not safeguarded by
24 having a condition like autism spectrum disorder which
25 50-60 percent of patients with autism have ADHD.

1 Patients that have ADHD, 20-30 percent of them have
2 autism. They're going to need medication.

3 If we're talking about Jason who lives in
4 let's say East Brunswick, it's really close to Jersey.
5 It's really close to New York City. But complicated
6 factors, neighborhood disorder, make it such that he's
7 experiencing life in a health condition, substance
8 abuse engagement, pre-addiction. The fact of the
9 matter is unless we're providing telehealth services,
10 we're going to miss a whole host of people and it's
11 actively happening now.

12 So of that 90 percent of adults that began
13 engagement with substances before 18, the truth of the
14 matter is less than 15 percent, the data here depends
15 on the source, but less than 15 percent actually
16 received evidence informed treatment. Now there's
17 treatment, but then there's evidence informed
18 treatment.

19 The fact of the matter is telehealth allows
20 clinicians to reach that population.

21 So I totally understand that the DEA is
22 required to do safeguards and practice and want to
23 ensure that there's no diversion. I practice
24 cautiously myself. But the truth is, as that
25 gentleman said, you probably should convene a group.

1 And I get that we have a two-day convening here, but I
2 know that there's -- I know that there's working
3 groups that are in the DEA in the health fraud
4 division that are trying to find bad actors, because
5 the reality is there are often bad actors. But just
6 trying to take away something that you've given to
7 many patients, the genie's out of the bottle. It's
8 hard to put the genie back in.

9 So in reference to proposed rules, the
10 registration, I know it's been on the books. It has
11 yet to actually be enacted. You have a whole host of
12 people who are prescribing actively to try to get them
13 to actively do eight hour training will be difficult.
14 We've seen removal of the X waiver has not shifted the
15 amount of people who actually should be prescribing
16 Buprenorphine. I prescribe it. But literally I have
17 colleagues in hospitals that say well, I'm not
18 comfortable. So I'm not really sure what adding an
19 additional layer of mandated requirements is going to
20 do. It's probably just going to stem people from
21 actually engaging.

22 So the reality is that as the person I think
23 Commenter 10, some research from our group identified
24 that those that have substance abuse problems, mental
25 health conditions, particularly that are adolescents,

1 actually do engage pretty well with regards to
2 telehealth services, and the key part about our study
3 was they were very willing to come in after being
4 established vis-a-vis telehealth. So I don't
5 necessarily think you need a mandate.

6 The reality is, if you're with a provider
7 that you trust and it's been three months or six
8 months and you make the suggestion to come in, it's
9 very likely that they will actually come in. And if
10 we're talking about those who are minors, if they
11 can't come in, some guardian can come in because
12 they're potentially not unhoused.

13 So when we're thinking about this idea of
14 the rural and the urban individual, the truth is you
15 have tools that are at your disposal. Yes, the PDMP.
16 You don't have current engagement with it. I'm sure
17 that would be very difficult to do for the fact that
18 it's technically I think 49 states. I'm not sure if
19 Missouri has added it yet.

20 So the truth is, this is a very complicated
21 issue. I greatly appreciate that you're attempting to
22 resolve some of the issues. I do think if we're going
23 to go back to the 2008 and try to do a special
24 registration there has to be some subset of criteria
25 in terms of who can prescribe. Again, there's less

1 than 8,000 child psychiatrists. I'm one of them. You
2 should take a photo of me because there's not many of
3 us. But we're not the only ones who can prescribe
4 stimulants, not the only ones who can prescribe
5 Buprenorphine. But again, even those that can,
6 aren't.

7 In terms of setting some kind of
8 standardization, just like every year for every state
9 that I'm licensed in, I have to get a renewal. So if
10 you're going to have a special registration there
11 needs to be a renewal process. And physicians and
12 prescribers are already used to a renewal process
13 because we already have to do that for the respective
14 states that we're in.

15 In terms of routine monitoring, I just don't
16 know what the jurisdiction is of the DEA in terms of
17 trying to set up some regular monitoring. The current
18 monitoring that I think is happening, there's somebody
19 who's a good whistleblower and says hey, something's
20 going on here. Then you guys go in and search. But I
21 don't know that you have the capacity to set up some
22 kind of monitoring system. That would be ideal.

23 Again, this tech integration doesn't yet
24 exist, but if it could that also would be ideal.

25 I know you've listened to many people and I

1 can see my time's winding down. The reality is the
2 special registration, that would be great. But the
3 problem that we're trying to figure out exceeds two
4 days of listening. And those of us at Boston
5 Children's, Children's Hospital Association, all of
6 the advocacy groups that you heard from will gladly
7 partner in trying to figure it out. But literally, as
8 I'm standing here there's a patient of mine that I'll
9 see vis-a-vis telehealth tomorrow because I'm here and
10 they're in Massachusetts. So it's going to be very
11 hard to curtail something that you've given to
12 millions of people over the last couple of years.

13 I'll stop there. Thank you for the
14 opportunity to be engaging here.

15 MR. STRAIT: Okay. We are going to be
16 bringing up our 13th commenter. I will say that we
17 had up to 14 today and I don't believe that Dr.
18 Kolodny is here yet if at all. So I will say that
19 assuming that we have no one after Commenter 13 we
20 will then go back to one in-virtual commenter who
21 could not join us in the morning and that will be our
22 last presentation for the day.

23 So, Commenter No. 13, welcome to the stage.

24 DR. REDDOCH: I have significant presbyopia,
25 so I can't work off of a small device. I bring up a

1 laptop.

2 MR. STRAIT: Absolutely.

3 DR. REDDOCH: And I use, like, 16 point,
4 and, hopefully --

5 MR. STRAIT: Wonderful.

6 DR. REDDOCH: -- I can capture this. Thank
7 you.

8 Good afternoon. I'm Dr. Shirley Reddoch,
9 S-H-I-R-L-E-Y, Reddoch, R-E-D-D-O-C-H, a Board-
10 certified pediatrician and pediatric hematologist/
11 oncologist with 40 years experience in direct patient
12 care and as a pediatric residency and pediatric
13 hematology and oncology fellowship program faculty.
14 Currently, at the latter part of my professional life,
15 I have a part-time faculty appointment in Pediatrics
16 at Johns Hopkins, a continuing appointment at Johns
17 Hopkins School of Medicine, where I serve as Clinical
18 Teaching Attending in the Children's Hospital.

19 Thank you for the opportunity to speak at
20 this DEA listening session centered on the subject of
21 telemedicine prescribing of controlled substances and
22 the role or necessity of in-person medical evaluations
23 by the prescriber.

24 Today, I speak to you as an individual
25 concerned physician and not representative of Johns

1 Hopkins or any other healthcare organization or
2 general medical or specialty associations, although,
3 like other presenters, I am a member of several
4 specialty organizations. To name some, the American
5 Academy of Pediatrics, the American Society of
6 Pediatric Hematology Oncology, and the American
7 Medical Association.

8 Before specific comments on the current
9 question, I'd like to give you a little bit more of my
10 background, experience, and observations over time in
11 medicine.

12 I started my residency training in
13 pediatrics in 1981, entering the Army on active duty
14 after completing medical school in the civilian
15 sector. Subsequently, I served as a general
16 pediatrician in an Army community hospital and clinic
17 before doing my pediatric hematology oncology
18 fellowship training at then Walter Reed Army Medical
19 Center.

20 Following fellowship, I served as Peds Heme
21 Onc and on pediatric residency faculty at two other
22 Army medical centers before transferring to this area,
23 Fort Meade, Maryland, in a healthcare admin role as
24 Deputy Commander for Clinical Services at Kimbrough.
25 I then returned to Walter Reed, first leading the

1 Department of Health Plan Management, then returning
2 to full-time Peds Heme Onc practice and on pediatric
3 residency and fellowship program faculty, with
4 clinical faculty appointment at Uniformed Services
5 University of Health Sciences. Those were my first 24
6 years of practice and were within the military
7 healthcare system, which I understood the beneficiary
8 population well as a member with a family in that
9 beneficiary community as well as a physician.

10 Given the size of our program and resource
11 allocations, we all practiced in the inpatient and ou-
12 patient setting, so knew our patients in both those
13 environments.

14 In those years prior to formal telehealth
15 programs, all care was considered in-person, though
16 telephonic communications were frequently made and
17 documented, with only occasional non-controlled
18 substance prescriptions associated with a telephonic
19 communication with a patient, again, already seen and
20 followed by a physician or service team of physicians.

21 It's important to know medical students,
22 residents, fellows in training at that time, at this
23 time, understood and were engaged in the continuity of
24 care between inpatient and outpatient settings and
25 direct communication between primary care and

1 specialty care.

2 Leaving practice in the military healthcare
3 system and affiliating with Johns Hopkins Pediatrics,
4 Pediatric Hematology, now 18 years ago -- I'm feeling
5 older by the minute as I read this -- I recognized the
6 challenges of much larger socioeconomically diverse
7 patient referral populations not only geographically
8 spread but often with primary care or other specialty
9 care outside of the Hopkins medical system.

10 As with any such system, there are those
11 patients who are well known to the service but many
12 others with only infrequent encounters within the
13 system and sometimes more in the emergency room or
14 inpatient setting than out. Various insurance
15 coverages and/or no coverage further separated
16 accessible or covered sites and sources of care and
17 services.

18 Establishment of a sophisticated electronic
19 records system with expanding capabilities helped
20 connect different electronic record sources via the
21 Health Information Exchange in the state, and PDMP
22 helped in monitoring certain controlled substance
23 prescriptions, but still the weaknesses interpreting
24 that information were often revealed when patients
25 were seen for their in-person visits.

1 Although I cannot speak to all areas of
2 Hopkins medicine, as I recall now, outpatient
3 telehealth visits were just being implemented by my
4 service colleagues at or around the time the COVID-19
5 pandemic hit. My activity was in patient care at that
6 time, but our service case management discussions
7 ensured awareness of in-person and telehealth
8 encounters and often covered opioid use and pain
9 management of conditions like sickle cell disease with
10 complications involving acute and chronic pain.

11 Formal video telehealth visits, video visits
12 with the ability to prescribe controlled medications
13 have greatly facilitated continuity of care of
14 established patients, but periodic in-person care,
15 advisedly outpatient but also evident with episodic
16 inpatient care managed by the same service team, is
17 still the practice.

18 We should also remember that during this
19 time, these last few years, there were severe
20 restrictions placed on outpatient in-person visits and
21 limitations set on who and how many members of the
22 care team and which members could even see patients on
23 the inpatient services directly and the level of PPE
24 required for a provider to wear to see patients in
25 either setting, medical trainees, students, residents,

1 fellows, were getting a very different learning
2 experience from those prior to the pandemic years and
3 immersed in such removed evaluations and care of
4 patients with their rapidly developing facility and
5 comfort with telehealth care.

6 It is my concern that this may heighten the
7 risk just in general for overuse of, overconfidence
8 in, or misapplication of telehealth, with emphasis or
9 preference for virtual care on the part of
10 practitioners as well as patients.

11 Following my further conversations with
12 physicians across the country, to include hospital-
13 centered and community-based hospice and palliative
14 care programs, psychiatry, and a chronic opioid use
15 pain management program, and listening to
16 presentations last day, my considered conclusion is
17 there still should be an inpatient evaluation that is
18 proximate in time and related to an initial telehealth
19 visit for prescribing controlled substances, and,
20 ideally, that visit should be with that prescriber. I
21 said ideally.

22 Ongoing telehealth prescribing of controlled
23 substances by that prescriber should be within
24 appropriate disease and condition management that
25 warrants such prescribing, with the telehealth

1 prescriber trained and appropriately certified in such
2 fields as substance use disorder or medical
3 specialties covering specific diseases, conditions
4 requiring frequent or chronic medications in the
5 schedules of controlled substance or hospice and
6 palliative care medicine.

7 The telehealth prescriber must be licensed
8 for telehealth in the state where the patient resides
9 and if by chance is so geographically removed from the
10 patient that the prescriber cannot see the patient in
11 person, there should be a primary referring
12 practitioner in room with the patient simultaneously
13 communicating on video platform, video visit platform,
14 with the consulting provider or specialist.
15 Documentation of such a visit must be adequately
16 reflected in both the primary provider and consulting
17 provider's records system.

18 If the disease condition management with
19 prescribing of controlled substances is continued by
20 the remote-only telehealth consultant specialist,
21 there should be a documented primary care or referring
22 provider relationship established to facilitate future
23 video, tandem video visits, in person as initially
24 established.

25 If the primary care provider with the

1 ability to do periodic in-person evaluations assumes
2 responsibility for prescribing of controlled
3 substances following the specialty consulting provider
4 care plan, there should be follow-up recommendations
5 with frequency and whether in-person or telehealth,
6 acceptable follow-up as stated and understood.

7 If the consultant specialist who is
8 accessible only via video visits assumes continuing
9 prescribing responsibility, it should be so
10 documented.

11 Exceptions to this process can be codified
12 outlined in policy established state by state with
13 involvement of the state practitioners' licensing
14 boards, with consideration of the healthcare needs of
15 the population, with attention to the underserved.

16 States should be cautious about permitting
17 any out-of-state practitioners organizations only
18 licensed for telehealth in the state to develop an
19 independent telehealth practice independent of any in-
20 person direct healthcare service or working with such
21 a direct healthcare service residing within the state
22 as this may directly compete with and undermine the
23 work of such similar services that may exist within
24 the state that I heard alluded to in visits in
25 presentations last day and with the in-state services

1 appropriately serving the state's populace.

2 Quality of care, adherence to care, outcome
3 measures should be tied to telehealth. Only exception
4 programs as well as those that offer in-person visit
5 capability. This again requires additional insights
6 as may be ascertained from state medical societies,
7 licencing board, health departments, nonprofit
8 healthcare organization, independent practices, and
9 FQHCs within the state.

10 Codification of policy at federal level for
11 exceptions to visits may also need to be reviewed
12 regarding programs that serve DoD and federal
13 institutions.

14 All controlled substances at high risk for
15 diversion, abuse, or overprescribing should be
16 reported on a standard PDMP platform that can
17 communicate across state lines essentially nationally,
18 as many others have recommended.

19 And with such tremendous input and some
20 concrete recommendations that have been presented by
21 in-the-trenches providers in these two days who have
22 identified specific risk mitigation measures to be
23 taken, including qualifications of providers
24 teleprescribing and particularly in psychiatric and
25 behavioral health only, telehealth-only practice would

1 suggest that DEA specifically look at those
2 recommendations made.

3 But I would also recommend reassessing
4 adequacy of education on controlled substance use and
5 prescribing for practitioners and pharmacists in
6 telehealth environments and a more robust standardized
7 education surrounding prescribing of controlled
8 substances in various settings, patient settings,
9 electronic prescribing, and telehealth platforms be
10 formally incorporated in and across all graduate
11 medical education before upcoming physician
12 transitions from care oversight within residency
13 programs to widely varying and increasingly narrower
14 focus of independent clinical practice settings.

15 This speaks to not just specializations in
16 care but sites of care, like ambulatory only, hospital
17 only, emergency medicine practices, where one can
18 easily narrow patient care focus to their environment
19 of care and can decrease attention to patients'
20 overall healthcare which requires access to other
21 settings of care.

22 And believe it or not, my final concern to
23 raise is actually the primary one that brought this
24 listening session to my attention. It is that of
25 legal lethal dose prescribing of single or combination

1 of medications prescription that can involve one or
2 more controlled substances or clearly off-label toxic
3 use of non-controlled medications. This type of
4 prescribing was legalized in several states via end-
5 of-life option or medical-aid-in-dying legislation and
6 offers the most protection of those prescribers, no
7 protection of patients or transparency to family and
8 other non-medical-aid-in-dying-involved providers.

9 There's likewise no real monitoring of
10 adherence to minimal documentation requirements,
11 thresholds for investigation, and no consistent way to
12 identify if and/or when the prescription is taken as
13 patients could have died of underlying qualifying
14 diagnoses before taking medication, delayed taking
15 prescription, gotten better, changed their minds.

16 There are no particular skills or training
17 required of a prescriber to prescribe a killing dose
18 of any medication. One would say this is not chronic
19 care or continuing medication risk, but telehealth
20 visits in lieu of in-person for this prescription
21 consultation promotes too-easily-obtained
22 prescriptions, no assurance of any care for the
23 patient by the prescriber who is not otherwise
24 involved in the patient's care if the patient chooses
25 not to take or delays taking medication.

1 Such telehealth providers must be licenced
2 in the state of the patient's residence and should not
3 be able to violate visit prescribing rules of that
4 legislation if not enacted in the patient's state.

5 There is ample opportunity to obscure
6 illegal prescribing as in illegal in certain states,
7 as in still the majority of states.

8 As I am not engaged in telehealth directly
9 with associated controlled substance prescribing, this
10 particular DEA request for input in listening sessions
11 did not actually get my attention or many of the other
12 people I consulted who practice good medicine in their
13 fields with good documentation of telehealth and
14 prescribing. But my antenna went up when I heard that
15 A Death With Dignity, that Death With Dignity sent out
16 alerts to their followers requesting and eliciting
17 approximately 10,000 comments by their count of your
18 38,000 comments to the DEA supporting telehealth-only
19 prescribing. I realized then that there's an
20 underappreciated risk that lay in this ongoing
21 expansion of telehealth, so I bring that to your
22 attention.

23 And, subsequently, I was sent a copy of a
24 letter that I think may have already been sent to you
25 from concerned organizations opposing assisted

1 suicide. So this is always on people's minds, and the
2 potential of this kind of use of telehealth actually
3 further undermines reliance and trust of those
4 providers involved in care of hospice and palliative
5 care.

6 And one final comment speaking to what a
7 prior speaker, a recent prior speaker just raised is
8 that the specter of AI as threat to integrity of
9 telehealth. I think that is very real, and with so
10 much imitation, you don't know sometimes will it get
11 so good that you won't even know if you've got a real
12 patient in front of you? Not just the provider but
13 the patient. So we need to move away from dependency
14 on this or any other singular encounter type as we may
15 need to pivot as we've had to so many times in
16 medicine.

17 Thank you very much.

18 MR. STRAIT: Any questions?

19 (No response.)

20 MR. STRAIT: Okay. Thank you so much.

21 Okay. And we will now, like I said earlier,
22 go to our Virtual Presenter No. 13. Thank you.

23 DR. SPENCER: Hello. My name is Dr. Sarah
24 Spencer, S-A-R-A-H, S-P-E-N-C-E-R, and I'm
25 representing myself today. I'm an employee of the

1 Ninilchik Tribal Council and the head addiction
2 medicine consultant for the Alaska Native Tribal
3 Health Consortium. I'm here today to speak on
4 telemedicine regulations of buprenorphine for the
5 treatment of opioid use disorder and to speak against
6 the requirement for an in-person visit.

7 I'm a Board-certified addiction medicine
8 physician, fellow of the American Society of Addiction
9 Medicine who has provided care for patients with
10 opioid use disorder in rural Alaska for 13 years, and
11 I've been offering telemedicine for OUD for years
12 prior to COVID.

13 To remind you of the vastness of Alaska, we
14 are, of course, more than twice the size of Texas, and
15 there are over 200 Alaska native villages spread over
16 660,000 square miles, most of them off the road
17 system.

18 I work in tribal health and I'm one of the
19 only addiction medicine specialists in the state that
20 provides treatment of OUD via telemedicine for any
21 Alaska native person regardless of tribal affiliation.

22 I work on the rural southern Kenai Peninsula
23 and I'm the only addiction medicine specialist in our
24 25,000-square-mile borough. The next nearest
25 addiction medicine specialist and the nearest

1 Methadone clinic are over 200 miles away in Anchorage.

2 In 2021, Alaska suffered the greatest
3 increase nationwide in our overdose death rates with
4 fentanyl-related deaths up 150 percent, and the
5 overdose rates in Alaska native people are triple that
6 of white Alaskans. In fact, indigenous Americans
7 nationwide are among the populations with the highest
8 overdose death rates.

9 Buprenorphine has been shown to reduce
10 mortality related to OUD by over 60 percent. However,
11 many remote areas in Alaska still have no local access
12 to this medication. Most of the 170 tribal village
13 clinics are off the road system, meaning patients can
14 only get in and out via boat or plane, and they are
15 staffed only by community health aid practitioners,
16 with licensed providers, such as doctors, NPs, or PAs,
17 visiting just a few times a month or sometimes less
18 than once a month, and there are huge tribal regions,
19 such as the 115,000-square-mile Arctic slope and
20 Norton Sound region, that have zero prescribers of
21 buprenorphine.

22 Historically, fear and stigma around
23 diversion or misuse of sublingual buprenorphine, as
24 well as the challenges in monitoring the use of this
25 medication in remote areas, have caused many rural

1 tribal clinics to shy away from offering this
2 medication altogether.

3 Monthly long-acting injectable buprenorphine
4 has less stigma surrounding its use and it could
5 potentially dramatically expand treatment
6 availability. But, unfortunately, due to DEA
7 restrictions, it cannot be shipped to a remote village
8 clinic staffed only by a community health aid
9 practitioner because it can only be shipped to clinics
10 that have a resident DEA licensed provider. So,
11 unfortunately, this medication is also not accessible
12 to patients living in remote native villages.

13 Most of the tribal organizations who do
14 offer MOUD offer medication options that can be
15 limited, and many only provide in-person care and they
16 require patients to travel from their remote home
17 villages to the hub clinic to attend in-person visits.

18 I am one of only two physicians in the State
19 of Alaska with the Indian Health Service Internet
20 Eligible Controlled Substance Provider exemption to
21 allow for buprenorphine prescribing without an in-
22 person visit.

23 However, that exemption requires that the
24 patient be present at the remote village clinic site
25 to receive services, and merely obtaining this

1 certification does not ensure the cooperation of the
2 distant tribal health organization. And I have
3 personally seen multiple incidences of patients
4 refused telemedicine access from their home tribal
5 clinic to access buprenorphine therapy.

6 Within these large tribal health
7 organizations exist many individual tribal clinics,
8 all with different tribal councils, different
9 administrations, and some have policies against
10 providing buprenorphine therapy, and they may refuse
11 to collaborate with an outside clinic offering the
12 service and refuse to host telemedicine specialty
13 consultation appointments originating at their clinic.
14 Patients may also be unable or unwilling to access
15 care through their local clinic due to very legitimate
16 privacy concerns in these very small villages.

17 Since the Internet Eligible Controlled
18 Substance Provider exemption does not apply to
19 patients being seen in their homes, I cannot provide
20 treatment to native beneficiaries living in these
21 underserved areas or to non-native patients living in
22 any remote native village if an in-person visit is
23 required.

24 The Alaska Native Medical Center in
25 Anchorage is the specialty care referral hub of the

1 state for native beneficiaries, but it does not have
2 an addiction medicine department and has no system in
3 place to offer buprenorphine therapy via telemedicine
4 for remote patients. So uninsured native
5 beneficiaries living in remote villages, lacking a
6 buprenorphine prescriber locally, essentially have no
7 access to this treatment.

8 When patients do need to travel for in-
9 person visits, the cost can be astronomical. The cost
10 for a patient to get from a remote village in
11 northwestern Alaska to my specialty clinic for an in-
12 person visit could easily exceed \$1500.

13 Even for non-natives who live on the Kenai
14 Peninsula, the majority live more than 20 miles from
15 my clinic, and the nearest pharmacy is 35 miles from
16 my clinic. Ninety percent of our patients have
17 Medicaid, and most either don't own an operational
18 vehicle or they don't have a valid driver's license,
19 and even if they do have those things, many may not be
20 able to afford the gas for the 70-plus-mile round
21 trip.

22 These patient costs were not adequately
23 accounted for in your cost impact analysis of this
24 regulation. Our clinic is the only one on the Kenai
25 Peninsula of Alaska offering low threshold

1 buprenorphine treatment. We offer telemedicine to all
2 patients for their intake appointment, and this has
3 dramatically reduced our no-show rates. It also
4 allows us to offer a more flexible open access
5 schedule so patients can get same-day telemedicine
6 appointments for urgent care.

7 To assist with medication monitoring,
8 patients who are not able to travel to the clinic may
9 choose to participate in drug testing through local
10 clinic labs or through mail-order oral fluid tests
11 with virtually observed collection. We utilize random
12 medication counts conducted by video when needed. And
13 the patients also have the option of demonstrating
14 medication compliance through video directly observed
15 therapy when appropriate for their care plan.

16 Most of our patients do a mix of
17 telemedicine and in-person care, and this flexibility
18 has greatly increased our ability to support our
19 patients' retention in treatment as well as improve
20 patient satisfaction.

21 Most of our patients self-refer for monthly
22 injectable buprenorphine. However, it's not unusual
23 for patients to have to take sublingual buprenorphine
24 for more than a month prior to being able to travel to
25 the office for their first injection. In fact, I've

1 had a patient that had to drive 250 miles one way to
2 get his first injection.

3 Also, there are many patients who struggle
4 and fall in and out of care in those first few weeks
5 and months, and they may need multiple follow-up
6 telemedicine appointments over several months to
7 motivate and enable them to attend that first in-
8 person visit.

9 Buprenorphine interruption such as would
10 occur if a patient had not attended their first in-
11 person visit by the end of 30 days is dangerous.
12 After buprenorphine discontinuation, 50 percent of
13 people return to use within a month, and one in 20
14 experience an overdose event the following year.

15 The Ryan Haight Act was intended to reduce
16 the inappropriate prescribing of medications such as
17 prescription opioids that increase the risk of
18 overdose. Buprenorphine, however, is a very safe
19 medication since it does not induce respiratory
20 depression and it dramatically reduces mortality risk
21 in patients with OUD. So it's not surprising that
22 overdoses involving buprenorphine did not increase
23 during the pandemic despite its increased availability
24 via telemedicine.

25 In August '22, a JAMA Psychiatry study

1 looking at 175,000 Medicare beneficiaries who received
2 telemedicine for buprenorphine therapy, the use of
3 telemedicine to access buprenorphine was associated
4 with a reduced overdose risk and improvement in
5 treatment retention.

6 Additionally, data that is gathered from in-
7 person visits such as urine drug testing has not been
8 shown to improve treatment outcomes or to reduce
9 diversion.

10 In summary, requiring an in-person visit to
11 prescribe more than 30 days of buprenorphine for OUD
12 treatment will only result in further exacerbating the
13 already disproportionately reduced access to treatment
14 suffered by our most vulnerable and most affected
15 populations, including Alaska natives and American
16 Indians, low-income patients, and those living in
17 rural areas.

18 The arbitrary decision to require an in-
19 person visit at 30 days has no basis in evidence to
20 improve patient outcomes, while we have strong
21 evidence that uninterrupted access to medication for
22 OUD is critical to reduce mortality.

23 I strongly believe that the requirement for
24 in-person visits for buprenorphine prescribing will do
25 more harm than good and recommend it to be removed

1 from the proposed telemedicine regulation.

2 Thank you for the opportunity to speak
3 today, and I welcome any questions.

4 MR. STRAIT: Okay. Thank you, Dr. Spencer.
5 My understanding is there are no follow-up questions,
6 so I want to thank you for participating and for being
7 our last presenter.

8 And I will say that by purposes of
9 concluding remarks, again, thank you for everyone who
10 took time out of your busy schedules to be here on
11 either one day or two days.

12 I want to give a special thanks to
13 Administrator Milgram and Assistant Administrator
14 Prevoznik for taking time out of their schedules to
15 also listen. I think and I hope it demonstrates to
16 you and the public and those that are watching us
17 virtually that we really do care about trying to get
18 this right.

19 So, with that, I will say again thank you.
20 Safe travels. And enjoy the rest of your week.

21 (Whereupon, at 3:55 p.m., the listening
22 session in the above-entitled matter adjourned.)

23 //

24 //

25 //

REPORTER'S CERTIFICATE

DOCKET NO.: --
CASE TITLE: DEA Telemedicine Listening Session
HEARING DATE: September 13, 2023
LOCATION: Arlington, Virginia

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Drug Enforcement Administration.

Date: September 14, 2023



Angela Brown
Official Reporter
Heritage Reporting Corporation
Suite 206
1220 L Street, N.W.
Washington, D.C. 20005-4018