Jane Doe

vs.

Joseph Ladapo

June 23, 2023

LEXITAS™

Doe Pls' Trial Ex.
39

JANE DOE,

Plaintiff,

vs.

JOSEPH LADAPO,

Defendant.

_____

CASE NO. 423CV114RHMAF

TRANSCRIPTION OF AUDIO RECORDING

FLORIDA BOARD OF MEDICINE AND OSTEOPATHIC MEDICINE

JOINT RULES/LEGISLATIVE COMMITTEE MEETING

JUNE 23, 2023

TRANSCRIBED AUDIO RECORDING BY:

Julie Thompson, CET

Job No.: 323393

Thereupon,

The following proceeding was transcribed from an audio recording:

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CHAIRMAN ROMANELLO: This Florida Boards of Medicine and Osteopathic Medicine Joint Rules and Legislative Committee meeting to open.

Ms. Strickland, can we have a roll call.

MS. STRICKLAND: Yes. Mr. Romanello is present.

Dr. Ackerman.

DR. ACKERMAN: Present.

MS. STRICKLAND: Dr. Benson.

DR. BENSON: Present.

MS. STRICKLAND: Dr. Derick.

DR. DERICK: Present.

MS. STRICKLAND: Dr. Di Pietro.

DR. DI PIETRO: Present.

MS. STRICKLAND: Dr. Kirsh.

DR. KIRSH: Present.

MS. STRICKLAND: Dr. Mortensen.

DR. MORTENSEN: Present.

MS. STRICKLAND: And Dr. Diamond, Dr. Zachariah, Ms. Garcia, and Dr. Hunter have been excused. Also present are Paul Vazquez, Executive

Director of Board of Medicine; Danielle Terrell, Executive Director Board of Osteopathic Medicine; Christopher Dierlam, board counsel; Donna McNulty, board counsel, Cassandra Fullove, senior legal assistant, Cherise Strickland, program operations administrator, and Brad Dalton, public information officer.

Chair, you have a quorum.

CHAIRMAN ROMANELLO: Thank you.

Mr. Vazquez, Ms. Terrell, do we have any comments from either of the executive directors?

EXECUTIVE DIRECTOR VAZQUEZ: Yes. Good afternoon. It's Friday, June 23, 2023. The time is 1:02 p.m. My name is Paul Vazquez; I'm the executive director of the Florida Board of Medicine. This is a duly noticed Joint Rules/Legislative Committee meeting of the Boards of Medicine and Osteopathic Medicine.

This is a public meeting and it's being recorded. The audio will be available on the boards' websites next week. I will now go over some instructions, so this meeting will be successful, and the committee members will be able to take care of the matters that are before them today.

There is a court reporter in the meeting.

If you speak to the committee, it's important that you state your name for the record. When appropriate, the Chair will ask for public comments. Therefore, please refrain from speaking during the meeting until the appointed time. Please remember, this is a public meeting and is being recorded. Any side conversations may be recorded and become part of the public record. At this time, please silence all electronic devices.

The Boards of Medicine and Osteopathic Medicine are apolitical bodies that have the primary mission of protecting the people of the state of Florida. As with any issue before the boards, the board members will look to the available science and appropriate standard of care while putting aside any personal feelings they may have on the issues before them today.

I want to take this opportunity to thank the joint committee for its continued efforts to address the requirements of Senate Bill 254 titled Treatments for Sex Reassignment. The governor signed SB 254 into law on May 17, 2023, and it became effective upon signing. The law, as enacted, requires the Boards of Medicine and Osteopathic Medicine to do the following:

Adopt emergency rules within 60 days pertaining to standards of practice under which a patient younger than 18 years of age my continue to be treated with a prescription if such treatment for sex reassignment was commenced before and is still active on the effective date of the law.

In developing rules under this paragraph, the boards must consider requirements for physicians to obtain informed consent from such patient's parent or legal guardian. For such prescriptions and treatments, the boards must consider the provision of professional counseling services for patients by a board-certified psychiatrist licensed under chapter 458 or chapter 459, or a psychologist licensed under chapter 490, in conjunction with any prescription treatment.

The law also requires the boards to adopt emergency rules regarding informed consent forms to inform patients 18 years of age or older of the nature and risks of sex reassignment prescriptions or procedures in order for the patient to make a prudent decision.

At a joint rules legislative committee meeting held on June 1, 2023, the following occurred:

An emergency rule was developed to attempt to provide a way for patients receiving sex reassignment prescriptions to continue to receive such prescriptions while the boards worked to implement the provisions of section 456.52(1), (2), and (6), Florida statutes.

Pursuant to section 456.52 Florida statutes, the committee began the process of and made provision for the development of a standard of practice and informed consents for minors continuing to receive sex reassignment prescriptions, and informed consents for adults who will receive sex reassignment prescriptions and procedures.

An interim meeting was scheduled for June 23, 2023, at 1:00 p.m., with the intention of completing the emergency rulemaking mandated by section 456.52 Florida statutes.

The Boards of Medicine and Osteopathic Medicine approved a modified version of the committee's emergency rule on June 2nd and June 20th respectively. The primary goals of today's joint committee meeting are to final practice standards for minors that were receiving treatment prior to the effective date of the law to continue to receive that treatment; finalize any necessary informed

consent forms for minors; and finalize informed consent forms for adults.

A subsequent joint virtual meeting of the Boards of Medicine and Osteopathic Medicine has been scheduled for June 30, 2023, at 1:00 p.m. to consider any actions the committee takes today.

In terms of how this meeting will be conducted, it is the committee's expectation that we will have a civil discourse while discussing the issues on today's agenda. We require that everyone refrain from making any disruptive comments or taking any disruptive actions during the duration of the meeting. The boards reserve the right to remove any individual who chooses to disrupt the progress of the meeting. Please conduct yourselves accordingly.

Public comment will be allowed today as time permits. Appearance cards are located at the table outside of the meeting room. Please return completed speaker cards to board staff at the table in the back of the room. The following guidelines will apply to public comments:

Interested parties will be limited to three minutes to provide comment, which may only be extended by the Chair if time permits based on the

number of proposed speakers. If an interested party is part of a larger group of persons, you are requested to identify one individual who will speak on behalf of the group if possible. Interested parties may use pseudonyms if they do not wish to identify themselves on the record.

The public comment process will be randomized and will be as equitable as possible. However, it's possible that not everyone who wishes to speak will be able to speak given the nature and time constraints of the meeting.

If there are any publicly elected officials with us today, please make yourself known to the Chair during public comment to ensure that you have an opportunity to speak. Thank you.

CHAIRMAN ROMANELLO: Ms. Terrell, anything? No. Okay.

So before we start the discussion, I'd like to provide an overview of the agenda for this afternoon's meeting. The Boards of Medicine and Osteopathic Medicine have been assigned the task of developing an emergency rule pertaining to the establishment of a standard of care for the treatment of gender dysphoria in minors, which includes language to be used in informed consent

forms. And two, an emergency rule outlining informed consent procedures for the treatment of gender dysphoria in adults.

I'll remind the committee and the members of the public who are here today that these two issues have been thoroughly discussed in a number of public meetings beginning back in August of last year in Dania Beach; in October of '22 in Tampa; again in October in Orlando; in November of last year in Orlando; earlier this year, February, up in Tallahassee; and earlier this month in Tampa.

Moreover, the department and the board has received an impressive number of letters and public comments by folks wishing to express their opinion on the rule and which the committees have taken into consideration in forming the emergency rules today.

As advised by Mr. Vazquez, we're conducting this emergency rulemaking process in accordance with a statutory framework that requires the adoption of the emergency rule. After today's hearing, we will convene a virtual joint board meeting on June 30th to consider whatever action the committee takes up this afternoon.

On behalf of the joint committee and the Department of Health staff that are here, I want to

extend a warm welcome to the members of the public that are here today, including any elected office holders who may be here. And I want to give you all an indication of how we're going to proceed this afternoon.

So the committee has under and for its consideration six different informed consent forms, and those consent forms are intended for different patient demographics and presentations. And although these forms are somewhat different, there's a lot of overlap among those consent forms. The committee is going to take up a discussion of those consent forms first.

Following the discussion on the consent forms, we'll take a short break and then we'll come back, and we will take up a discussion on the two emergency rules that are before us today. At the conclusion of our discussion on the rules, we'll open the meeting for public comment, and we'll take public comment up through 4:30 this afternoon, at which time we'll discontinue public comment, and the committees will vote on whatever proposals are before us. And we'll adjourn today's meeting at 5 o'clock.

Finally, grateful for the members of the

public who are here today, especially those who have come to multiple meetings. Understand that this issue holds significant importance for many people. We appreciate the public comment and the interaction with you, and we'll take your public comments into consideration in the rulemaking process.

With that, do any other committee members wish to make comments?

DR. ACKERMAN: Mr. Romanello, I would

CHAIRMAN ROMANELLO: Yeah. Dr. Ackerman.

DR. ACKERMAN: Thank you, Mr. Romanello. And I also want to address the committee and also the public.

For those of you who don't know who I am, my name is Scott Ackerman; I'm the chairman of the Florida Board of Medicine. And it's nice to see the public here again today. I took a little walk before the meeting. I went over to Starbucks, and I wanted the lobby and I saw a lot of familiar faces, and you know, welcomed the public who are here today. I'm glad you guys are all here today. It's good. We really do appreciate your input.

That being said, we have a lot of work to do. We're mandated to put forth -- as you heard from Mr. Romanello -- put forth consent forms and to

debate and to discuss amongst ourselves the nuances of these consent forms. And we really will appreciate your comments at the appropriate time. What we're not going to appreciate is cheering and jeering and that sort of stuff that's not very -- it's just disruptive to the meeting. And I'm going to instruct law enforcement, as you can see who is here today, to have anyone removed who participates in those sort of activities.

We really want your constructive input, we -- you know, having cheering and jeering and snapping of fingers and those sort of things aren't helpful to us. It just makes the meeting go longer and it makes it so we can't do our job that we need to get done. And we -- again, I want, and I think the whole committee wants, is good, construction comments as to what we can do.

Comments such as do away with everything aren't very constructive because we're mandated to do this process. We're mandated to put forth consent forms. So comments saying that we should not have a rule and we shouldn't have consent forms, that's great, bring it up with the legislature, not with us. We're mandated to do this and so please don't take it out on us. We really want to be

helpful. We want to put forth a consent form that is reasonable that is able to be enacted by physicians throughout the state, and that's our job today.

So again, thank you again for being here, and please -- I want to thank you in advance for participating with us in a meaningful, productive way.

Thank you, Mr. Romanello.

CHAIRMAN ROMANELLO: Dr. Ackerman, thank you.

Any other members of the committee?

Okay. So at the last meeting in Tampa earlier this month, we delegated and asked Doctors Mortensen and Benson to help develop one or more informed consent forms. Dr. Mortensen did a lot of the heavy lifting there and aided by Dr. Benson. And I would look to them, as we want to discuss the informed consents first, which one would logically be the best place to start off with?

UNIDENTIFIED SPEAKER: Which one would be the best place to start?

DR. ACKERMAN: I think we should start with puberty -- we should start with the adolescents, with the minors, and let's go in order. Let's do

puberty blockers, then do feminizing, then do masculinizing.

CHAIRMAN ROMANELLO: Yep.

DR. BENSON: Yeah. I think that makes sense to just follow the order.

DR. MORTENSEN: I agree.

DR. BENSON: Bates 264 is the first one.

CHAIRMAN ROMANELLO: But Doctors Benson or Mortensen, do you want to introduce the concepts here around the informed consents, or do we want to open it up for questions from the fellow committee members?

DR. MORTENSEN: So I took a good deal of time, as we have over the last year of all the information that's been provided to us and I've also recently attended the Endocrine Society meeting in Chicago to kind of take all that stuff and see if anything else needed to be updated but I feel this gives a very good representation of what the concerns would be in regards to using puberty suppression agents, or the continuation of them.

So more than happy to open it up for discussion if anyone had any questions or concerns about the verbiage or the side effects.

CHAIRMAN ROMANELLO: And so again, for

members of the committee, this is in the portal under tab one. As Dr. Benson said, at Bates 264. This is the consent for the use of puberty blockers.

DR. ACKERMAN: So I can make sure I understand what this is. So Dr. Benson -- so the public understands, as well -- Dr. Benson and Dr. Mortensen each submitted a consent form that they independently put together regarding puberty blockers. In fact, for all of these different things.

CHAIRMAN ROMANELLO: Right.

DR. ACKERMAN: Then staff took those consent forms and kind of merged them into one. I guess they both probably had a similar theme to them and similar points in them, but then merged them into one form that had -- so we can have one form that we use rather by both the osteopathic physicians as well as the allopathic physicians.

CHAIRMAN ROMANELLO: Yep.

DR. ACKERMAN: So that's what we have before us. And I can tell you that I've thoroughly looked through these forms over the last week and a half --

EXECUTIVE DIRECTOR VAZQUEZ: I'd add one other thing. So yes, DOH staff merged those two,

but also, the AG's office merged those two but also, the AG's Office review them, as well.

DR. ACKERMAN: Attorney General's Office.

UNIDENTIFIED SPEAKER: Mr. Chairman?

DR. ACKERMAN: But that was all merged and that's what we have in front of us today is this merged entity that was done by Benson and Mortensen independently and the staff put together.

CHAIRMAN ROMANELLO: Yes.

DR. ACKERMAN: And I can say that I've looked through regarding the puberty blockers. I think it's very -- you guys did a yeoman's work. It's very, very thorough. It goes through -- you know, for me, it reminds me of a lot of the consent forms that I use in my practice when I have patients that are involved in cancer treatment, especially ones that are involved with getting multiple different drugs and radiation. In that it's not just a general consent form where you're signing away -- you're signing not waiver. You're signing saying, "I accept puberty blockers." But it's going through each of the benefits, and risks of those puberty blockers, and what one could accept over time.

And I use the same sort of things in my

practice in those patients that are being put on -- we have a lot of patients in clinical trials. As you guys know, I use proton radiation and it's very complex stuff, I think. For me it's complex too. And so with our patients, we go through all those sort of things.

So I think that -- at first, I looked at it and said, woah, this is a bit thorough, but after I digested it a bit, I said, no, it's not. It's really very similar to what I do in my cancer practice. So I like this.

Turn on your mic.

DR. KIRSH: I echo that very much. I just have a question. There's some holes in, or blanks in it. Is that something for us to deal with or is that what you're going to point out because there's an inconsistency?

ATTORNEY MCNULTY: I think there's one on page 1 of 8, regarding options. Is that the one you're referring to, Dr. Kirsh?

DR. KIRSH: As an example, yes.

ATTORNEY MCNULTY: Yeah. I think that's the only one in this form, and that's the same one -- it flows through a number of forms. So to the extent you -- and this would be true for any of the

changes that flow through all the forms. If you change one thing, just make clear that you want it changed on all the forms, so that way you don't necessarily need to repeat it, and we'll flow through those changes. And that's an option if the minor does not want to continue treatment or the adult doesn't want to continue treatment with said medicine.

DR. ACKERMAN: So is that blank meant to be filled in by the physician?

ATTORNEY MCNULTY: No, no. It's --

DR. ACKERMAN: Oh, okay. I read it as to be filled in by the physician.

CHAIRMAN ROMANELLO: To answer your question, you're right. That needs to be addressed by the committee today and those blanks would need to be filled in by the committee in the discussion today.

DR. ACKERMAN: But that's the only blank that's on each form. It's the same blank as on that page --

ATTORNEY MCNULTY: Correct.

DR. ACKERMAN: -- of each form.

ATTORNEY MCNULTY: Correct.

CHAIRMAN ROMANELLO: Dr. Derick.

DR. DERICK: So in addition to this form, it doesn't preclude a physician from providing additional informed consent that they would --

ATTORNEY MCNULTY: Absolutely.

DR. DERICK: Because if there was something that a physician would like to convey to a patient, whether it be benefit or a risk, that could be a supplemental consent form. So this is required as the minimum.

ATTORNEY MCNULTY This is the mandatory, that's correct. That's a good point. Nothing prohibits a physician from having a supplemental --

DR. ACKERMAN: And that's consistent with what physicians do. When I have patients in clinical trials, we have a separate consent form for the clinical trial, and we still use our regular consent form.

DR. DERICK: The second thing I have a question is related to the requirements to receive the treatment. You know, the word prescribing physician is used. "Undergoes an evaluation by the prescribing physician at least every three months." From a practical perspective, what happens if that physician was on maternity leave or something else? Is it not able to delegated to someone who is

covering for that physician or how is that going to be contemplated?

ATTORNEY MCNULTY: But wouldn't that person covering for them be a prescribing physician?

DR. DERICK: They wouldn't be -- that's a good point, actually, Donna. If they prescribed the medication, does that make them the prescribing physician or it's the person who gave informed consent discussion with that patient and originally prescribed the medication?

ATTORNEY MCNULTY: I think in terms of who is signing the form has to be the prescribing physician, and the continuation of treatment is a different issue, right. But if they're prescribing, they have to be a physician, per statute.

DR. DERICK: So a patient comes in and sees Dr. Jones in person, informed consent is signed. And then three months later, Dr. Jones is on maternity leave and needs to evaluate the patient, but Dr. Smith then is the prescribing physician who will write the prescription and then evaluates the patient. Is that the understanding?

DR. ACKERMAN: Could you tell us where you see this? What Bates page?

DR. DI PIETRO: It's on 265, and I think

she's referring to number --

DR. BENSON: Eight.

DR. DI PIETRO: Seven.

DR. BENSON: Or sorry, seven, yeah.

DR. DI PIETRO: I think Dr. Derick's point is the way it's read, and I understand that can be read two ways, but the way it reads now is the original prescribing physician is the physician that has to evaluate the patient at least every three months. And to her point, if the original prescribing physician is on maternity leave or on vacation, how do you rectify that that prescribing physician originally cannot see that patient? So do we change "the" to "a" or --

DR. ACKERMAN: "Their."

DR. DI PIETRO: -- "their." "Their prescribing physicians," maybe.

ATTORNEY MCNULTY: Does it have to be a prescribing -- who do you want to -- could it be "a physician"?

UNIDENTIFIED SPEAKER: I mean, it's true it is sort of redundant. A physician is able to prescribe as part of their job, so if it -- the way that I read it, it sounded like the original person for whom they did the consent form with.

DR. DI PIETRO: That's the way I read it, too.

DR. BENSON: That's the way it's written.

UNIDENTIFIED SPEAKER: That is the way it's written, so --

DR. ACKERMAN: You don't want to tie it to just that physician because there's multi-physician groups.

UNIDENTIFIED SPEAKER: Right.

UNIDENTIFIED SPEAKER: So Dr. Derick, would you --

DR. DI PIETRO: I would say, I think, if I'm reading it, if I read "a" or if I read -- I think "a" could be kind of any physician. I would write "their prescribing physicians," then you incorporate anyone that could be in their practice.

CHAIRMAN ROMANELLO: I'm seeing nods from "covering physicians."

DR. ACKERMAN: I don't like covering physicians --

CHAIRMAN ROMANELLO: No, no. I'm not saying the term, I'm asking the question. What about covering physicians? So if they're not in the same practice, and they cover your practice.

DR. DI PIETRO: But then that would still

be -- I mean, that patient is still under your care, so it would still be part of "their physicians." Right. If you write a prescription, legally, they're under your care.

DR. ACKERMAN: Correct.

UNIDENTIFIED SPEAKER: If a patient decided to switch doctors though, if we wrote it that way then they couldn't continue with their new physician because they're not part of that group.

DR. DI PIETRO: Okay. I mean, "a" --

DR. ACKERMAN: Couldn't you say something like -- what type of physician is this? Is this a physician who is treating gender dysphoria, right? So could you say that in there? Because you don't want them to just call some other random physician and get some other random physician, an orthopedic physician, you know. But you want a physician who is actually treating their gender dysphoria, whether it's their original one or their designate.

When I go on vacation, my partner does it. Or maybe I'm a solo practice and I got some guy across town that covers for me. But that guy covering for me is still, I'm going to have someone who, like me, treats gender -- if I was treating gender dysphoria, I would have one of my buds who

treats gender dysphoria across town, you know, cover for me.

DR. DI PIETRO: I think that's a very good point, Dr. Ackerman. It really should be someone who is experienced within gender dysphoria, not someone's primary care physician.

DR. ACKERMAN: Right.

DR. DI PIETRO: I think that's the essence of --

DR. ACKERMAN: So maybe saying, "Undergoes evaluation by a gender dysphoria physician at least every three months." A gender dysphoria physician. A physician who specializes in gender dysphoria.

UNIDENTIFIED SPEAKER: That could be very difficult because, you know --

DR. KIRSH: There's no --

DR. DI PIETRO: There's no board for that.

DR. KIRSH: -- there's no board for that. How do you rectify that?

DR. ACKERMAN: I know.

DR. KIRSH: So I mean, it's what your experience is and what you feel comfortable as, so that's certainly limiting, you know, a population from being taken care of. Maybe there's another term that we can use.

DR. DI PIETRO: Could you just say, "a physician who regularly treats gender dysphoria patients"?

DR. ACKERMAN: Yeah.

UNIDENTIFIED SPEAKER: You know, that's --

DR. ACKERMAN: You wouldn't want someone covering for you who doesn't do that because if the drugs need to be tweaked, he's an orthopedic surgeon, you know. As an absurd example.

DR. DI PIETRO: I just think the essence of what it's trying to get at is the person -- and I understand why we're having the discussion from the beginning with -- you know, from what Dr. Derick is saying. But the essence of what it's supposed to be is the person who is prescribing it is supposed to be following up with the patient, unless there's something that happens, in which case, they can't.

I just hesitate to change it to where it's like, "Well, they could go see this doctor this month because they're a gender dysphoria doctor, or this doctor this month because they're dysphoria doctor." I want to keep the essence of it that really, unless something happens, that it should be the physician who is prescribing it on a regular basis. Do you see what I'm saying?

DR. DERICK: Yeah. Continuity --

DR. DI PIETRO: It's just hard to make it work.

DR. DERICK: Yeah. Continuity of care is very important, I just get concerned with the logistics of appointments and making sure that the patients can fall within the window in order to get the medication.

DR. DI PIETRO: Or, you know, maybe someone's insurance changes and they can't see that physician anymore, they have to see a different physician. So we've just got to figure out a way to make it work where it reads that it's the current treating physician.

DR. ACKERMAN: Right. And you may be current for just a week because someone is on vacation, but you're still the treating physician. And you're covering for someone, and you write a prescription, you have full responsibility. That's if you're the primary physician. You know, and so --

DR. DI PIETRO: Well, how about "prescribing physician or their designated coverage"?

CHAIRMAN ROMANELLO: I like that.

DR. DI PIETRO: "Every three months."
DR. ACKERMAN: I'm good with that.
ATTORNEY MCNULTY: Or "their designated coverage physician"?
DR. DI PIETRO: Yes. "Designated covering physician." Covering. Because when you go away, right, you designate someone to cover you, right? I mean, I do.
DR. ACKERMAN: You have to.
DR. DI PIETRO: It's not some fly by night thing, right. So --
DR. ACKERMAN: But generally when they -- if they're going to -- in my area, if they're going to be prescribing radiation treatment when I'm not there, they don't just do what I wrote down on the piece of paper. They actually do an evaluation and make sure that a lot of the work is already done, but they see the patient.
CHAIRMAN ROMANELLO: Absolutely.
DR. ACKERMAN: Because otherwise, I could have made a mistake and they could be treating the wrong side, the wrong breast, the wrong --
DR. DI PIETRO: Then that would cover it though, right? Because it's saying that they have to undergo an evaluation. So "undergoes an

evaluation by the prescribing physician or their designated coverage -- or the designated covering physician every three months."

DR. ACKERMAN: Yeah. I like that.

UNIDENTIFIED SPEAKER: I go for that.

DR. ACKERMAN: So someone just doesn't call it in, they have to actually see the patient.

UNIDENTIFIED SPEAKER: Right.

DR. DERICK: Well, that's the question I had is define evaluation. Is that something that could be done over -- the first one for sure in statute has to be in person, but these follow up visits, is it permissible or desirable to have all of those be in person or is it permissible to have the evaluation done via telemedicine?

DR. ACKERMAN: Well, that number seven doesn't say in person, it just says evaluation.

CHAIRMAN ROMANELLO: Right.

UNIDENTIFIED SPEAKER: Every three months. So just every three months.

CHAIRMAN ROMANELLO: And the statute does address certain elements that have to be in person prior to a new prescription being issued but as you pointed out, the every three month, the statute doesn't address, so it would not --

DR. DI PIETRO: So then my opinion on that -- and thank you, Dr. Derick for bringing that up too -- would be a sub under seven or after that semicolon "with at least one in person visit annually." So it can't just be telehealth in perpetuity. I mean, we do that in primary care. I require my primary care patients to come in and see me once a year, so -- so "undergoes an evaluation by the prescribing physician or a dedicated covering physician."

UNIDENTIFIED SPEAKER: "Designated."

DR. DI PIETRO: Sorry. "Designated covering physician at least every three months, with one in person visit annually, in minimum." Or something along those lines.

ATTORNEY MCNULTY: I thought you had, "with at least one in person visit annually."

DR. DI PIETRO: Yes.

DR. BENSON: Well, I think though, part of this is being -- if you read like the 2017 Endocrine Society Guidelines, they specify certain things that are supposed to happen at three months, such -- every three to six months, like anthropometry, height, weight, sitting height, blood pressure, tanner staging. So some of these things --

DR. ACKERMAN: Well, that would be in person with the physician.

DR. BENSON: Yeah. But you can't practically do that very easily virtually, you know, most of these are done -- these kind of exams in endocrinology are done in person.

DR. ACKERMAN: By the physician or by the --

DR. BENSON: By the physician.

CHAIRMAN ROMANELLO: I don't think you're taking away from it. I mean, I don't think you're taking away from that, it's just giving the option. You may practice differently than somebody else. You know, I'm just wondering if that would, you know, kind of limit --

DR. BENSON: Yeah.

CHAIRMAN ROMANELLO: You've got to worry about access.

DR. BENSON: Well, I think maybe then a simpler way to get around this would be say "every three to six months." Give some flexibility there. So if there's -- you know, if that's adhering with the Endocrine Society Guidelines as far as what evaluations are supposed to be done, and having a range I think makes a lot more sense than just every

three months.

ATTORNEY MCNULTY: If you mean six months, then say six months. Because remember, this is a rule and it's -- if you have a range --

DR. BENSON: Well, the rule would be every three to six months.

ATTORNEY MCNULTY: But then say, "at least every six months."

EXECUTIVE DIRECTOR VAZQUEZ: Right. Because from a prosecutorial standpoint, that's the same as saying every six months, because saying three to -- it could be every month, that still would qualify as every six months. So we make get a (indiscernible) letter if you include the "three to six months." That's all.

UNIDENTIFIED SPEAKER: I just think it's a little different for the adult population than the pediatric population. I think for the adult population doing the telemedicine visits are appropriate, but for pediatrics, we do need height measurements that tells you whether they're breaking through therapy or what their final outcome is going to be. And physical exams for pubital staging cannot be done via telemedicine, and that's vital in these assessments. So I think I'd rather stick to

what Dr. Benson is saying the "at least six months."

ATTORNEY MCNULTY: Right now you have three months. So --

DR. DI PIETRO: Oh, I think they wanted to change it to "in person at least every six months."

UNIDENTIFIED SPEAKER: Yeah. That makes sense.

DR. ACKERMAN: Versus annually.

UNIDENTIFIED SPEAKER: Versus annually, yes.

DR. ACKERMAN: The same language, (indiscernible).

CHAIRMAN ROMANELLO: And that's for pediatric patients, not for adults.

ATTORNEY MCNULTY: One in person visit every six months?

DR. DERICK: At least every six months. Because then if the doctor decided at three months it was required to come in, then they could make that decision.

DR. DI PIETRO: So it would be "undergoes an in-person evaluation by the prescribing physician or" -- what did we say -- "designated covering physician at least every six months."

UNIDENTIFIED SPEAKER: Sorry to harp on

this just a little bit but if the patient switches doctors, then to me, they would not be able to -- that's not the prescribing physician or the covering physician.

DR. ACKERMAN: No, it's a new prescribing physician.

DR. DI PIETRO: So then it would meet the criteria.

ATTORNEY MCNULTY: So there's no need to see the patient then for an evaluation in under six months. Is that what I'm hearing? Because now you want it --

DR. BENSON: Yes. Every six months.

ATTORNEY MCNULTY: So "undergo an evaluation by the prescribing" --

DR. BENSON: "In person evaluation by the prescribing physician or their designated covering physician" -- is that the right --

UNIDENTIFIED SPEAKER: Yes.

DR. BENSON: -- "at least every six months."

CHAIRMAN ROMANELLO: Getting nods.

DR. ACKERMAN: Endochronologists like that?

DR. DI PIETRO: Yes.

CHAIRMAN ROMANELLO: And just to clarify,

that's for minors, right?

UNIDENTIFIED SPEAKER: Yeah.

CHAIRMAN ROMANELLO: Okay. Thank you.

Dr. Derik, have we --

DR. DERIK: Yeah. I think it's -- we've decided in person, the frequency seems reasonable. If somebody wanted to do it more frequently, they could. But it gives them flexibility to schedule out.

DR. ACKERMAN: Someone else can cover.

DR. DERIK: Someone else can cover. It seems more flexible and will allow --

CHAIRMAN ROMANELLO: Got it. Hey, let's go --

ATTORNEY MCNULTY: And before you leave this, do you want that to flow through all of the forms for the minors?

UNIDENTIFIED SPEAKER: For the minors, yes.

DR. ACKERMAN: For the minors, yeah.

DR. BENSON: Not adults but minors.

DR. ACKERMAN: Do we need a motion for that amendment? We don't have a motion for this. So why don't we do this, why don't we move to accept this. We're not going to vote until the very end.

UNIDENTIFIED SPEAKER: Right, right.

CHAIRMAN ROMANELLO: But we have to first have a motion with a second, then we can make amendment -- vote on the amendments, then eventually have the last motion which would be the amended original motion. Is that by Robert's Rules of Order?

ATTORNEY MCNULTY: Well, we don't do Robert's Rules, but yes. You can do that.

DR. ACKERMAN: Whatever rules of order, the state rules of order.

DR. BENSON: Well, we can come back at the end and talk about the consents as amended.

ATTORNEY MCNULTY: Yes.

DR. BENSON: You don't have to go through every --

DR. ACKERMAN: Oh, that's fine. So I would like to make the motion to amend it.

ATTORNEY MCNULTY: Or how about you just vote on each of these changes that you flow through as you go.

DR. ACKERMAN: Right.

ATTORNEY MCNULTY: And that way it's clear --

DR. ACKERMAN: So I'm making a motion to amend this with that change that we just said.

CHAIRMAN ROMANELLO: Is there a second?
UNIDENTIFIED SPEAKER: Second.
CHAIRMAN ROMANELLO: All in favor?
(Unanimous ayes)
Opposed?
It carries.
ATTORNEY MCNULTY: And just to clarify your question, that covers all of this language in all of the minor forms, correct?
CHAIRMAN ROMANELLO: Correct.
So if we can go back to Bates 264, there is a blank that needs to be filled in in terms of options.
DR. ACKERMAN: I like it when we have multiple choice. Dr. Benson, can you give us some multiple choices of words as to how you would fill in that blank? I think I like true false better than multiple choice.
DR. MORTENSEN: I didn't really see any other options but left it open if anyone else had any other insight.
DR. ACKERMAN: That's true false. False.
DR. BENSON: I mean, unfortunately, we don't have studies to say -- there's no controlled studies that say --

CHAIRMAN ROMANELLO: Dr. Mortensen, could we just strike that? Another option is blank and strike that language?

DR. MORTENSEN: Then you would probably have to take out the word "one" at the beginning of the paragraph.

DR. KIRSH: Yes.

DR. BENSON: I think it's implying that --

DR. ACKERMAN: I would change it -- there may be other options you could discuss with your physician.

DR. BENSON: -- no medical treatment is an option for some people, and then some people do choose that.

DR. ACKERMAN: Choose what?

DR. BENSON: Don't go through with hormonal treatment always.

DR. ACKERMAN: Well, could you just say there, instead of "another option is," say, you know, "Other options can be discussed with your physician"?

DR. BENSON: Yeah. I think that would be fine.

DR. ACKERMAN: One option is "psychological therapy" -- "other options can be discussed with

your physician." I don't know what other options there are but maybe some practitioner has some other options. Diet, I don't know.

CHAIRMAN ROMANELLO: So the proposed modification is to strike "another option is," and substitute in --

DR. ACKERMAN: "Other options may be discussed with your physician."

CHAIRMAN ROMANELLO: Is there a motion for that?

DR. ACKERMAN: So moved.

CHAIRMAN ROMANELLO: Dr. Ackerman.

DR. KIRSH: Second.

CHAIRMAN ROMANELLO: Second by Dr. Kirsh.

DR. ACKERMAN: And I move that that goes through --

CHAIRMAN ROMANELLO: All through the -- yep.

ATTORNEY MCNULTY: And that would be all the -- and the adults? This one?

DR. ACKERMAN: That one all -- both adults and minors.

ATTORNEY MCNULTY: Correct.

CHAIRMAN ROMANELLO: All in favor?

(Unanimous ayes)

Opposed?

Motion carries.

DR. BENSON: So Bates 266 --

ATTORNEY MCNULTY: Before --

DR. BENSON: A question?

CHAIRMAN ROMANELLO: Dr. Benson?

DR. BENSON: So this phrase is kind of used throughout the consent forms. I would say it's similar in all the consent forms. It's not identical in the youth and adult consent forms. But it talks about that they're not FDA approved for this treatment. And I think there should be some language in there that, you know, we don't have a lot of long-term perspective trials.

Most of the trials within interventions are only going out 18 months, 2 years, and some have reported very serious adverse events that have happened in the population of kids, such as in the Trans Youth Care study that just got published earlier this year where they had 2 completed suicides and 11 with, you know, suicidal ideation and some other adverse outcomes.

But I think we need to maybe just include a few paragraphs or a few sentences in this section just to make it very clear that these therapies are

somewhat outcome indeterminate and there's a, you know, high risk of potential side effects that we just don't have a lot of research to support.

CHAIRMAN ROMANELLO: So two things. Dr. Benson, if you can get closer to your mic, please.

DR. BENSON: Oh, sorry.

CHAIRMAN ROMANELLO: That's good.

DR. BENSON: Yeah. Just something that basically illustrates that these -- you know, it's based on limited data. That we've seen some improvement in psychological functioning in short-term studies, but we have, you know, other things that in longer term where people have reports of, you know, adverse outcomes. And that I think it's important that people understand the profound uncertainty regarding the benefits and risks of these medical therapies is -- there's somewhere we just say that very clearly that we just don't -- you know, this is speculative data that these therapies are based on.

ATTORNEY MCNULTY: Maybe we can add that further on the next one where it says, "Risks, the adverse effects, and safety of puberty blockers used for the treatment of gender dysphoria in minors is

not well known."

DR. BENSON: Yeah.

ATTORNEY MCNULTY: And then maybe add on, "There's been limited data."

DR. BENSON: Yeah. That would be a good place. I did provide some wording to the staff earlier that maybe would be potential wording that could be used.

ATTORNEY MCNULTY: I would suggest if it's in this section where you are signing something off, it would be like one sentence, something succinct. Otherwise, I think a more appropriate place -- and you would have to provide the exact wording -- would be on page 1 of that form, second paragraph where they talk about the off-label use from the FDA in the beginning of the document.

DR. ACKERMAN: You mean 264?

ATTORNEY MCNULTY: Yes.

DR. BENSON: Are you talking about under the second question?

ATTORNEY MCNULTY: Yes.

DR. BENSON: So yeah, so you know, I think we just need to put in there --

ATTORNEY MCNULTY: Put in which section?

DR. BENSON: Put something in there that

just makes it very clear that these practices are -- we don't have extensive long-term data. We definitely don't have controlled studies. So you could use something like, you know, "Medical treatment of children and adults with gender incongruence is based on very limited data with only subtle improvements seen in some patients' psychological functioning, in some, but not all research study. This practice is speculative, you know." And then you could say --

CHAIRMAN ROMANELLO: Dr. Benson, where are you reading from?

DR. BENSON: Sometime I wrote.

CHAIRMAN ROMANELLO: Okay. So we're going to attempt to incorporate or consider what you're reading but you've got to go a little slower.

DR. BENSON: Oh, I'm sorry.

CHAIRMAN ROMANELLO: Because you've got to lawyers here and you've got the staff sprinkled all over the place, right.

DR. ACKERMAN: I want to understand. We're putting this into the preamble, if you will.

DR. BENSON: Yes.

ATTORNEY MCNULTY: But on page 264, that's where you're talking about, Dr. Benson; is that

correct? On the middle of the page where the paragraph that begins, "Pediatric endocrinologists"?

DR. BENSON: Yeah.

ATTORNEY MCNULTY: At the bottom of that paragraph?

DR. BENSON: I mean, I think it could go right at the top under "Patient information, informed parental consent, and assent for minors." You could put a paragraph there or you could put it under the second one. I just think it needs to be clear from the onset.

ATTORNEY MCNULTY: I think it -- you are the doctors, but it seems like it would go where you're talking about, the off-label use.

DR. DI PIETRO: I see it going as a second box under that.

DR. ACKERMAN: No, no. We're in the preamp, page 264.

ATTORNEY MCNULTY: No, not in the box. In the explanation second.

DR. DI PIETRO: Well, I think it should go in the boxes.

CHAIRMAN ROMANELLO: Let me ask, Matt. The concept that you're introducing is that the off-label use is not the product of --

DR. BENSON: I don't know that most people understand what that really means --

CHAIRMAN ROMANELLO: Right.

DR. BENSON: -- who are not physicians, scientists, et cetera. I just think we need to be explicit about what we know and what we don't know.

CHAIRMAN ROMANELLO: So you want to highlight the fact that the off-label use is not predicated upon robust research and data. Is that --

DR. BENSON: Yeah. It's not based on the best kinds of quality data that typically would underpin therapies that have significant risks associated with them.

CHAIRMAN ROMANELLO: All right. So before we decide where it goes, can we talk about the language that you are proposing, and then maybe we can figure out where it might best go into the form. So again, for the lawyers who are going to scribble this down, not me, can you walk us through that proposed language?

DR. BENSON: I mean, you know, I wrote about eight sentences here. I don't know if you want me to read through it all?

CHAIRMAN ROMANELLO: So did you provide

that --

DR. BENSON: I did. They have a Word document with it in there. Yes.

DR. ACKERMAN: Can you put it in one simple sentence? Because the thing is, we're saying this is off-label use. Now, I know that people pooh-pooh off-label use because we prescribe medications all the time for off-label use. So people do pooh-pooh that. And I think that what you're saying is we need something stronger in there that, although this off-label use, this isn't just off-label use, you're saying. This isn't just off-label use, but this is off-label use that is not completely studied and that, in fact, the studies that are out there are mixed, and many of those studies have shown adverse outcomes.

DR. BENSON: Okay. Let me give you this. This would be a few sentences, okay.

DR. ACKERMAN: Okay.

DR. BENSON: "Medical treatment of children and adults with gender incongruence is based on very" --

CHAIRMAN ROMANELLO: Slow it down.

DR. BENSON: Oh, sorry. "Medical treatment of children and adults with gender" -- I guess we

should stick with gender dysphoria because that's what we've been consistent with -- "is based on very limited, poor-quality research with only subtle improvement seen in some patients' psychological functioning, and some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments, and in many cases, the need for lifelong medical treatments." Something like that.

DR. DI PIETRO: How many sentences was that?

DR. BENSON: It's three. I mean, you know --

CHAIRMAN ROMANELLO: So first, I would look to the committee to see if there's consensus that it makes sense to include that language or add that language to the consent.

DR. BENSON: And the way I intentionally am writing this is it's something that could apply to both. It would be the same form for all adult and pediatric.

CHAIRMAN ROMANELLO: And to keep them on their toes, I'm going to ask Donna or Paul to read it back to us. No, I'm not. But do we have

consensus that type of disclaimer or addition to the informed consent is appropriate?

DR. DI PIETRO: I don't have a problem with it, I just feel like if we look at, on Bates 264, what we should all be looking at, "What are different medications that are used to suppress puberty," second paragraph, halfway through. "None of the medications have been approved by the FDA to be used in minors with gender dysphoria, due to lack of X, Y, Z." "Due to lack of randomized control" -- however you want to -- but you can -- I think you can simply all of that into about 10 words.

DR. BENSON: All I'm saying is I think it should be a few lines that are very explicit in the beginning. If you've ever gone over consent forms with people, you need to give them enough time to go through it. There's a lot in this to digest. And people get tired after reading very long consent forms, especially when they have long lists of side effects that are nonspecific. I try to avoid that. So I think just having something explicit in the beginning would be helpful.

DR. ACKERMAN: Well, I agree. I really agree with Dr. Di Pietro. I think that putting it in that spot that she just identified, in 8 words or

less, or 10 words or less would be fine. Because later on in the document, it goes through all those specific things. And I don't want to get too crazy now with all this stuff in the beginning saying that there's poor studies and there's all sorts of crazy outcomes and that sort of stuff. Because we have in here a few pages later, "itchy eyes, ringing in the ears, pain in the eyes, nausea," all that sort of stuff is all there. All that stuff is there.

I think it's over -- a little bit overreaching or a little bit overkill to put too much of that in the beginning. But I agree with Dr. Di Pietro in that second paragraph, the one that begins with, "Pediatric endocrinologists." Putting it in there would be very appropriate, just make it shorter.

ATTORNEY MCNULTY: And while you are thinking of what to fill in that space, in the actual signature blocks where the parental consent, under number two it says, "I know there may be other unknown short-term and long-term effects or risks."

DR. ACKERMAN: I'm sorry, where are you?

ATTORNEY MCNULTY: I'm on the last -- on page 6 of 8 where the parent --

DR. ACKERMAN: Give me the Bates number,

please.

UNIDENTIFIED SPEAKER: 269.

DR. ACKERMAN: Thank you. I'm sorry because we have a different format. I know you have it printed out.

ATTORNEY MCNULTY: I know, I just printed it out.

DR. ACKERMAN: I know. 269. Go ahead.

ATTORNEY MCNULTY: On number two it says -- as part of the last sentence, it says, "The information provided to me in the form and by the prescribing includes the known effects and risks of treatment with puberty blockers. I know that there may be other unknown short-term and long-term effects or risks." Just so you all know that that's -- that they're signing to that, as well, while you're thinking about how to fix that other paragraph, if that's what you want to do.

DR. BENSON: I think it's important, too, you understand a lot of these could be 8, 9, 10 year old children who are undergoing this treatment, and I just think for kids, I was on the IRB in my role, I mean, you have to make things simple and clear. Because these are for young kids, and especially the ones --

DR. ACKERMAN: So do we want to put this language in the beginning in the preamble? And I think what Donna is saying is that we also have that here. But I think Dr. Benson has a good point and I think we should put some more stronger language in the preamble. And again, I'll say what I said before, I think Dr. Di Pietro's idea of putting it in the middle of that paragraph is --

ATTORNEY MCNULTY: I need to know what to -- what do you want -- I mean, what are the words?

DR. DI PIETRO: Well, I mean, I was just -- I just feel like it goes well there because it's kind of like why it's not FDA approved, right. So it's "None of these medications have been approved the FDA to be used in minors and gender dysphoria due to" -- and then you can say something about "lack of long-term randomized controlled trials, lack of, you know, long term outcomes -- data -- long-term outcome data."

DR. KIRSH: So Dr. Di Pietro, would you mind considering one other thing? Is that don't link it to that specific sentence. Go ahead and start another sentence. Because the reason why there's off-label use, and reason why the off-label use is done is economics. It's the fact that the

drug companies don't go through those trials for the purposes of that. And so 26 percent of our medications are used off-label today. So the issue is it's not because it's off-label is the reason. You know, if we just leave that, I think that's good. Just add another sentence.

CHAIRMAN ROMANELLO: So Dr. Benson, I'm looking at the language that you proposed and I'm looking at it on counsel's screen. What you read, "Medical treatment of children and adults with gender incongruence is based on very limited, poor-quality research," that doesn't necessarily go to FDA off-label use. That's a different issue, right?

DR. BENSON: A different issue, yeah.

CHAIRMAN ROMANELLO: It's not -- the conversation I'm concerning myself about is getting into the rationale as to why FDA has approved or not approved a certain medical therapy. So again, Doctor, can you read what you propose to include somewhere in the consent form, and then I might have an idea of where we could place it.

DR. BENSON: Okay. "Medical treatment of children and adults with gender dysphoria is based on very limited, poor-quality research with only

subtle improvements seen in some patients' psychological functioning, and some, but not all research study. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments, and in many cases, the need for life long medical treatments."

CHAIRMAN ROMANELLO: Got it. So that doesn't go to FDA off-label use, that goes to any kind of therapy or intervention for gender dysphoria. So I think, and I'll defer to the group, that's either a preamble up at the top or on page -- the signature page for the parents or the guardian at Bates 269. You could either add a number eight to that list, or you put it at the top of the consent form.

DR. ACKERMAN: I think you're right, Mr. Romanello.

CHAIRMAN ROMANELLO: Because it's not --

DR. ACKERMAN: I think I like the first page better than the last. Yeah. In the beginning, first or second paragraph. But a separate paragraph in and of itself.

DR. DI PIETRO: Right after the first paragraph of the first page.

CHAIRMAN ROMANELLO: Okay.

DR. DERICK: What I liked about the consent forms, in part, are that they're -- you know, they're facts. Like "here is the side effect from this medication," blah, blah, blah. This is more of a -- like a summation point that's being proposed as part of the consent form, like an overview, and so it kind of changes the nature of the consent form a little bit, I think. I just wanted to say that. I mean, I think that the way it's written now, it's more of, you know, "Here are the things that we see," and adding that really gives it like an element of -- I'd don't want to say judgement but it's like a --

DR. ACKERMAN: That's why on the first page, it's really not part of the consent form.

ATTORNEY MCNULTY: It is all part of the consent form.

DR. ACKERMAN: Well, I know. But it's not part of the --

CHAIRMAN ROMANELLO: The specific risks and --

DR. ACKERMAN: The specific side effects.

CHAIRMAN ROMANELLO: Yeah.

DR. ACKERMAN: In there in the beginning,

the first -- the preamble page is --

CHAIRMAN ROMANELLO: 264 is questioned --

DR. ACKERMAN: You either not have it in there at all, which I'm not sure if that's what you're saying or not, Dr. Derick -- but you could either not have this language, but if you do -- and I can go either way. But if you do have the language, I think the first page, you could say that there's limited data and that's why we have this consent form, is basically what you're saying.

DR. BENSON: Yeah. I think -- I mean, I understand what you're saying but I think, you know, I do a research study, I literally have to report everything that happens to a kid when they're in a research study getting drug XYZ. I have to report things that probably aren't related to the intervention. I report everything. But because we don't have long-term controlled studies where you typically would ascertain risks and benefits, a lot of this is just cobbled together from case reports and short-term studies that have been done.

So, you know, that's the nature of the data. I don't think we're being disingenuous at all as far as where we're at as far as what we know. Hence, the reason the -- you know, the Dutch that

started this and now huge parts of Europe are looking at this very acutely and making policy changes. So I think it's just something that we should make clear in there. That's all I'm saying.

DR. ACKERMAN: So in the interest of moving on, could we just put --

CHAIRMAN ROMANELLO: Yeah. I was going to say, is there a motion to add that language?

UNIDENTIFIED SPEAKER: Can I make a suggestion before we do a motion, if you don't mind? Just a couple of suggestions on the language. We use the term "minor" throughout, and I would suggest changing children to minor just to be consistent with -- before we make a motion. And the other thing I was going to ask, should we include adults in that statement? Because this form is specifically for minors. That was just my only other thought.

DR. BENSON: The only reason I included it is I was trying to somehow simplify it. I think something similar should appear in the adult forms but if you want to --

DR. ACKERMAN: Well, if we do language now that says, "Neither adult nor minor," then we can use it in all the forms, right. So if you repeat

the language back, I would make the motion we put it as a paragraph two on page 264.

DR. BENSON: All right. I can read that. Do you want me to read it?

DR. ACKERMAN: You understand where I want to put it. On the preamble page as a new second paragraph before the second -- before "What are other options?"

DR. BENSON: So "Medical treatment of" --

UNIDENTIFIED SPEAKER: "Minors."

DR. BENSON: -- "people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patients' psychological functioning, and some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments, and in many cases, the need for life-long medical treatment.

CHAIRMAN ROMANELLO: So there's a motion by Dr. Ackerman to add that language as paragraph two to Bates 264 at the top. Is there a second that motion?

DR. DI PIETRO: I'll second.

CHAIRMAN ROMANELLO: Who second?

DR. DI PIETRO: I'll second. Yeah.
CHAIRMAN ROMANELLO: Di Pietro.
All in favor?
(Unanimous ayes)
Opposed?
Motion carries.
UNIDENTIFIED SPEAKER: Any everybody voted?
CHAIRMAN ROMANELLO: They did.
UNIDENTIFIED SPEAKER: And that was for all forms?
CHAIRMAN ROMANELLO: That's for all forms.
ATTORNEY MCNULTY: And this is for all forms, correct?
CHAIRMAN ROMANELLO: It is.
UNIDENTIFIED SPEAKER: Correct.
CHAIRMAN ROMANELLO: Any other observations on this --
DR. ACKERMAN: Dr. Di Pietro shared with me an observation a second ago and that was on page -- on Bates 269.
Dr. Di Pietro, do you want to say what you just shared with me? I think it was --
DR. DI PIETRO: Yeah. I've got to remember which paragraph it was in. Oh, paragraph number two --

DR. ACKERMAN: Bullet two.

DR. DI PIETRO: -- bullet two. Somewhere I feel like we should add the word "potentially irreversible."

ATTORNEY MCNULTY: Do you mind repeating what page again? I am working on the Word version and I'm making changes as we strike through. Could you tell me what section header you're on? That would be helpful.

DR. DI PIETRO: Parental consent. It's the signature page.

DR. ACKERMAN: Number two.

DR. DI PIETRO: So "The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with puberty blockers. I know that there may be other known short term, and long term, and potentially irreversible effects or risks." Is that accurate?

DR. BENSON: You could just put "effects or risks which may be irreversible."

DR. DI PIETRO: "Which may be irreversible." That's fine.

UNIDENTIFIED SPEAKER: It says on Bates 266, "If a minor stops treatment with puberty

blockers, in a few months, their body may restart the changes of puberty at the developmental stage they were before starting medication. However, the effects of these medications could be permanent." So it's --

DR. DI PIETRO: Yeah. I just want a second -- I want to double down on it on the signature page.

DR. ACKERMAN: I think that's good because that signature page is kind of like a --

DR. DI PIETRO: It's like the "Here's the stuff you need to know one through seven."

DR. ACKERMAN: Right. It ties it all together. I second Dr. Di Pietro's motions.

CHAIRMAN ROMANELLO: So let's read it back.

DR. ACKERMAN: Modified by Dr. Benson.

DR. BENSON: Yeah, I agree with that. I mean, I think, too, in terms of puberty blockers, it's clear from the British research that about 95 percent of people who do puberty blockers do go on to cross-sex hormones. So it may be -- we don't know but it may be that that even affects the outcome in some sense. We don't know but that's an important observation.

DR. ACKERMAN: There's been a motion and

second. Can we move on?

CHAIRMAN ROMANELLO: Yeah. So the motion is to add "which may be irreversible" --

DR. DI PIETRO: "Which may be irreversible" at the end of the sentence.

CHAIRMAN ROMANELLO: Yeah.

UNIDENTIFIED SPEAKER: Is that for the adults and minors?

CHAIRMAN ROMANELLO: Yep.

All in favor of that motion?

(Unanimous ayes)

Opposed?

Motion carries. That will be for all consents.

DR. DERICK: I have a --

CHAIRMAN ROMANELLO: Dr. Derick.

DR. DERICK: Yeah. On Bates 266 it says, "(These medications will not change a minor's sex chromosomes and it will not change a minor's internal or external reproductive structures.)" Is that accurate?

UNIDENTIFIED SPEAKER: Where are you reading from, Dr. -- okay.

UNIDENTIFIED SPEAKER: Yes.

DR. ACKERMAN: I remember reading that.

It's on 266 where?

DR. DI PIETRO: 266.

DR. DERICK: I just was thinking like if you failed to develop breasts, for example, that is a change as related to this --

DR. ACKERMAN: Yeah. Doesn't it change their structures?

UNIDENTIFIED SPEAKER: Right.

DR. DERICK: I think the intent is to say that --

DR. ACKERMAN: Reproductive structures. It doesn't change your ovaries to testes.

DR. DERICK: You wouldn't have external genitalia that were --

DR. BENSON: Well, no. I mean, it doesn't -- no. It just keeps them from enlarging.

DR. DERICK: If it keeps it from enlarging, that seems to be a change.

UNIDENTIFIED SPEAKER: I think the key was "reproductive."

DR. ACKERMAN: Yeah. Reproductive. What's enlarging? You're not changing a testicle to an ovary.

DR. BENSON: No, no.

DR. ACKERMAN: You're not changing an ovary

to a testicle.

DR. BENSON: No.

DR. DERICK: I guess it all depends on if you consider your breasts reproductive organs.

DR. ACKERMAN: I don't.

DR. DERICK: Yeah, I know. But I understand what she's trying to say, you know. Ability to breast feed and --

DR. BENSON: Well, it is an organ, definitely.

DR. ACKERMAN: It's not reproductive.

DR. BENSON: Well, it's a sex organ.

UNIDENTIFIED SPEAKER: It's reproductive.

DR. BENSON: Yeah, I know. But it's an organ.

UNIDENTIFIED SPEAKER: But the language here say reproductive organ.

DR. BENSON: Right, right.

DR. DERICK: I mean, I'm okay with it written as is but I understand your point.

UNIDENTIFIED SPEAKER: I'm just trying to clarify.

DR. BENSON: I mean, the only other last thing that I think some people may want to add is just something that says, "We do believe that 95

percent of those children who start puberty blockers typically would go on to cross-sex hormones." That's been showed now in multiple studies, and so you might to state that but, you know. And that could be a point eight at the very bottom of the last page.

DR. ACKERMAN: Or the very first page.

DR. BENSON: Yeah.

DR. ACKERMAN: I wouldn't put a number in there, I would use the word "many."

DR. BENSON: Yeah. Or "most."

DR. ACKERMAN: Okay. Wordsmithing.

ATTORNEY MCNULTY: Where --

DR. ACKERMAN: So he's saying -- what Dr. Benson is saying is that he wants to give notice, you know, put like an alert, a package alert saying, "Package alert, you've used puberty blocking drugs that most patients go on to using cross-sex hormones."

ATTORNEY MCNULTY: Do you have a sentence?

DR. ACKERMAN: That's basically what he's saying.

ATTORNEY MCNULTY: Which is fine. I mean, where do you want to -- what is the sentence and where would you like it for discussion?

DR. DI PIETRO: May I just make a comment? Isn't that the point though? I mean, this is a progression of people that are going from each stage to the next. So I think that people would assume that they would be down the road doing cross-sex hormones if they're doing the puberty blocking in general. I mean, to me it would seem --

DR. BENSON: Well, initially it was argued that this was a way to pause an early puberty, so that you could affect the differences in the long-term and aesthetic outcomes. Because the early data from the Netherlands in adults showed that there was still a lot of bad outcomes long-term. So they thought, well, if we can intervene earlier with puberty blockers, then we could end up with an aesthetically better result and maybe that would help with psychological outcomes, et cetera.

So it was thought, well, it's a pause, too, to give you time to evaluate and see what's going on. But I think for a lot of people in the field, it was quite surprising to see how many, well over 90 percent, do go on to cross-sex hormones. The assumption was some people may decide not to do that, but it seems that most people actually do. The vast majority do.

DR. MORTENSEN: Right. But I would say that these are people who are continuing therapy, this isn't people who are starting therapy.

DR. BENSON: Right.

DR. MORTENSEN: So they may, or they may not. So I don't know how relevant it's going to be. Like how much are you encouraging that? Like, "Well, because you're on it, this is where you're going to go." You don't really know.

DR. BENSON: That's a good point.

DR. MORTENSEN: So I kind of feel that it's kind of irrelevant and doesn't need to be mentioned.

CHAIRMAN ROMANELLO: Any more observations on this form?

ATTORNEY MCNULTY: Thank you. On page 265, and that's page 2 of 8, number 4 says, "Has adequate psychological and social support during treatment."

DR. BENSON: Right.

ATTORNEY MCNULTY: Again, that's one of those --

DR. BENSON: Vague terms.

ATTORNEY MCNULTY: Yeah. So my suggestion is just to delete the word "adequate," so it reads, "Has psychological and social support during treatment," and to carry that through all forms and

the rule language.

DR. ACKERMAN: So moved.

CHAIRMAN ROMANELLO: So there's a motion by Dr. Ackerman.

DR. KIRSH: Second.

CHAIRMAN ROMANELLO: A second by Dr. Kirsh. All in favor?

(Unanimous ayes)

Opposed.

Motion carries.

ATTORNEY MCNULTY: Thank you. And then the second item on that same page is in number 11 where it requires the DEXA scan. But the other forms say annual. Is there a length of time you want that DEXA scan, like what period of time? Or just -- the other forms say like annual bone scan but I'm not sure --

DR. ACKERMAN: Other forms said a bone scan. It's a DEXA scan, not a bone scan.

ATTORNEY MCNULTY: It says, "Bone DEXA scan."

DR. ACKERMAN: No, no. It's a DEXA scan, it's not a bone scan.

DR. BENSON: It's a bone density scan.

ATTORNEY MCNULTY: So what should the right

--

DR. ACKERMAN: A bone scan is a nuclear study that looks at osteoblastic changes in the bones. A DEXA scan is basically a low dose x-ray of the bone to look at the bone density. So it should be -- it's a DEXA scan, it's not a bone scan.

DR. BENSON: You could put a bone density scan or something.

DR. ACKERMAN: Yeah. Bone density scan, yeah. Bone density scan. Don't use -- so I move that we change all of that terminology to say, "Bone density scan (DEXA)."

ATTORNEY DIERLAM: Do you want it to say annual across all --

DR. ACKERMAN: No, no. I didn't get there yet.

ATTORNEY DIERLAM: Okay.

DR. ACKERMAN: We'll go with that in a second. Let's clarify what it is. "Bone density scan (DEXA scan)."

UNIDENTIFIED SPEAKER: Yeah, yeah.

DR. ACKERMAN: Because I get this -- it happens to me all the time that a patient needs a DEXA scan, and they get a bone scan. No, no. Because -- all the time.

DR. BENSON: Or bone age. They even sometimes confuse bone age with a bone scan.

DR. ACKERMAN: Right. But that's a different one. Now, how often? It doesn't say how often on this Bates 265.

ATTORNEY MCNULTY: But all the other forms say annual, so I'm not sure -- and I think your rule language says annual, as well.

DR. ACKERMAN: So I think -- so I don't think -- I think for adolescents, or young adults, pediatric and young adults, annually, but at some point, I don't think you need it annually. I don't do it annually on my patients that I put on some of these hormones. I do it maybe every two or three years.

DR. BENSON: You're talking about for adults?

DR. ACKERMAN: Yeah. My 60-year-olds, my 70-year-olds that I have on these hormones for treating cancer, it can cause the same problem with bone density. I have women who I treat for breast cancer with the same drugs, and we do extra bone density studies on them but we don't do it annually. You know, once it stabilizes, we do it every couple three years. But at what point, I don't know.

That's you guys.

DR. MORTENSEN: I would say for pediatrics annually is typically what we do. For the --

DR. ACKERMAN: Then you can annually for the first five years, or -- you know, for adults you can say annually for the first five years and then --

DR. MORTENSEN: As needed.

DR. ACKERMAN: -- and then as needed.

DR. BENSON: Yeah. The adult guidelines did specify. Let me just find that table.

DR. ACKERMAN: Yeah. I saw that in the adult -- it said annually in the adults, and I thought that that was --

ATTORNEY MCNULTY: All of them say annual except for this one.

UNIDENTIFIED SPEAKER: So can I --

DR. ACKERMAN: I think for the kids, it should be annually. I think for the adults, it should be annually for the first five years and then as needed after that.

DR. BENSON: That's reasonable.

ATTORNEY MCNULTY: Yeah. That's what I was -- I was trying to clarify.

DR. ACKERMAN: Five years is very

arbitrary.

CHAIRMAN ROMANELLO: So Scotty, let's do two motions. Let's do one for the minors --

DR. ACKERMAN: You called me Scotty.

CHAIRMAN ROMANELLO: Dr. Ackerman.

DR. ACKERMAN: It's okay.

CHAIRMAN ROMANELLO: Let's do two motions.

DR. ACKERMAN: My first motion is --

CHAIRMAN ROMANELLO: For the minors.

DR. ACKERMAN: Well, my first motion I think we did, we changed the bone density --

CHAIRMAN ROMANELLO: Yes.

DR. ACKERMAN: Okay, good. So my first motion is, in the pediatric forms, change the language to say in that bullet number 11 that this should be done annually. That the bone density -- whatever it is should be done annually.

CHAIRMAN ROMANELLO: Is there a second to that motion?

DR. KIRSH: Second.

UNIDENTIFIED SPEAKER: Second.

CHAIRMAN ROMANELLO: All in favor?

(Unanimous ayes)

Opposed?

That motion carries. And that will be

limited to the pediatric forms.

And second motion for adults.

DR. ACKERMAN: Because now these adults could be starting the drugs whenever. They could start when they're 18, they could start when they're 30.

ATTORNEY MCNULTY: Wait, I can't hear what you're saying, Doctor. For the adults?

DR. ACKERMAN: Adults, they could be -- might be starting these drugs when they're 18, they could be starting these drugs when they 30 years old. Who knows whenever. So I would say for the adults, annually for the first 5 years --

DR. KIRSH: Do you think that's really necessary and is it --

DR. ACKERMAN: Annually?

DR. KIRSH: Right. And do you think that we should limit it to say like transgender female?

DR. ACKERMAN: I do it on my men that are on Lupron.

DR. BENSON: I mean, what the adult -- the 2017, they say for transgender males, if they stop testosterone treatment, they're more at risk for bone density issues. But otherwise, they're a lower risk group for that. The higher risk group is trans

females who they recommended baseline bone mineral density testing in individuals at low risk. Screening for osteoporosis is conducted around 60 years of age.

DR. ACKERMAN: Okay. So help me, Dr. Benson. I get a little confused. So the men that are transitioning to women are being put on estrogen therapy, so the bone density will go down, right. Do I have that right?

DR. BENSON: Yes.

DR. ACKERMAN: Okay. So those should have the bone density study done annually for the first five years and then --

DR. BENSON: That's reasonable. Yeah.

DR. ACKERMAN: And the women that are becoming men are getting testosterone -- they're not getting Lupron, they're getting testosterone, so they don't need it.

DR. BENSON: Generally, no.

DR. ACKERMAN: Okay. Good. So --

ATTORNEY MCNULTY: So for the non-doctors, do you mind repeating this? Thank you.

DR. DI PIETRO: That's in the adult forms. Do you want to hold off until we can get to the adult forms?

CHAIRMAN ROMANELLO: Yeah. Let's do that.

DR. ACKERMAN: Okay. But keep that on the side though, Donna. Don't let us forget.

CHAIRMAN ROMANELLO: So are we done with this first form?

DR. DI PIETRO: So for the -- just to clarify -- so for the minors we're saying "bone density scan (DEXA), which will allow monitoring of the minor's bone density, bone strength during treatment, as puberty blockers may decrease bone density" -- and you're putting the word annually in there?

CHAIRMAN ROMANELLO: Yes.

DR. DI PIETRO: Okay.

ATTORNEY MCNULTY: So annual --

DR. DI PIETRO: Write the word "annual" in the beginning.

CHAIRMAN ROMANELLO: Yep.

ATTORNEY MCNULTY: Yep. "Annual bone density scan," blah, blah, blah.

CHAIRMAN ROMANELLO: Anything else on this initial form?

DR. ACKERMAN: Huh?

CHAIRMAN ROMANELLO: Anything else on this initial form?

Okay. Let's go to the next form. At Bates 272, "Feminizing Medications for Patients with Gender Dysphoria." Now, some of the modifications that we made are going to carry through here. So separate and apart from those, are there any observations or proposed modifications to this form that are specific to this form? We don't need the bone density here.

DR. BENSON: I highlighted a couple things, give me one second.

CHAIRMAN ROMANELLO: Dr. Benson.

ATTORNEY MCNULTY: Dr. Benson, if you're going to talk, can you please speak into the mic, so people can hear.

DR. BENSON: Yeah. No, I'm just looking. I highlighted a couple things. I just want to make sure I'm addressing them.

CHAIRMAN ROMANELLO: As Dr. Benson is looking through his notes, do any other members of the committee have observations about this?

Dr. Di Pietro.

DR. DI PIETRO: So this is just a personal thing that drives me crazy when people write --

CHAIRMAN ROMANELLO: What's your Bates number?

DR. DI PIETRO: I'm sorry, Bates 274 is where I saw it, but it might in other places. And I should have thought about this in the last one, although I didn't see these words in the last one. The words male and female drive me crazy because it doesn't say a male or female what. There's male and female dogs, male and female zebras, male and female everything. It should be man, or (boy), or woman (girl).

DR. ACKERMAN: On page 274 --

DR. DI PIETRO: That's an adjective, that's not a noun.

DR. ACKERMAN: So in the very first block there on Bates 274, the very first one, and it may be elsewhere.

UNIDENTIFIED SPEAKER: "Makes less like a male and more like a female."

DR. DI PIETRO: Female what?

DR. ACKERMAN: Yeah. I think she's right.

DR. DI PIETRO: It drives me crazy. I see it in notes all the time. So I would put -- especially since a minor is signing off on this, right, I would put, "Appear less like a man (boy), and more like a woman (girl)." Across the board for everything.

DR. ACKERMAN: Just to toss this around, masculine or feminine?

UNIDENTIFIED SPEAKER: Yeah.

DR. ACKERMAN: That way you don't have to say man, boy, and all that, you know.

UNIDENTIFIED SPEAKER: Yeah. Masculine, feminine. But male and female are adjectives and shouldn't be used.

DR. ACKERMAN: So "less masculine and more feminine."

DR. DI PIETRO: That's fine.

CHAIRMAN ROMANELLO: That's a motion by Dr. Di Pietro. Is there a second?

DR. KIRSH: Second.

CHAIRMAN ROMANELLO: Second by Dr. Kirsh.

All in favor?

(Unanimous ayes)

Opposed?

Motion carries, and that will cascade through all of the forms that have the words male and female in there.

UNIDENTIFIED SPEAKER: It will be masculine and feminine.

CHAIRMAN ROMANELLO: Masculine and feminine.

Dr. Benson.

DR. BENSON: Yeah. So this is something I think that's important for the adult forms as far as cross-sex hormones, and for the pediatric. I did -- you know, I did some reading with American Medical Association. There was a discussion regarding what is legally required in consent forms for physicians in general, just based on federal law, state law, et cetera.

There was a case in the federal courts in Washington, D.C., it was Canterbury versus Spence. But what -- a real quick summary, but what happened was a guy was going to get a laminectomy, it wasn't disclosed by the physician that there's a risk of paralysis with this procedure. The guy has the surgery, falls out of the bed, becomes paralyzed for the rest of his life. It ends up in court and they basically established sort of that we should be disclosing information if it's reasonable to do so. Previously, they used the community disclosure standard was sort of the standard for these consent documents.

But as part of that, there's really five elements that the federal court said should be part forms. And I think on these documents, we've hit

all of them partially. But on two, we've already addressed the one, and the first ones being the condition being treated; the nature and character of the proposed treatment or surgical procedure; anticipated results being the third; recognize possible alternative forms of treatment; and then five, recognize serious possible risks, complications, and anticipated benefits involved in the treatment or surgical procedure, as well as recognize possible alternative forms of treatment including nontreatment.

So those are the five elements. I think we did great. I think that overall, the consent documents are perfect. I think we addressed the nature and character already with the modification we just made. But in terms of anticipated results, desistance, persistence, and regret are mentioned nowhere in the consent documents at all. And I think while historically we've through desistence rates were very low, that was based on a lot of the older data. And in the last three to five years now, there's much more Pace publications, much more being published, and now we're seeing rates of 10 to 30 percent.

These are outcomes that if the 1 percent

was the standard in this case where the guy had a paralysis, I think we need to at least have a little bit of verbiage in these consent documents that talk about the possibility. "You could have desistance that's transient, and these are the reasons why, and we can see that from literature that's been published. You might be persistent in your desistance. You might decide to go back to your birth gender, for example, and these are the reasons why some people have done that."

And I think just stating that somewhere in there, we're covering that important outcome. I mean, the Dutch thought this was a very important outcome to consider. That's why the Dutch in their original protocol didn't do early social transition, because they knew for natal males who were initially the most common group to present with gender dysphoria, 85 to 90 percent of them, by the time adolescence, puberty came around, they didn't persist. Some of them became gay men as adults, some of them had other things going on. But it was very important to them not to influence those desistance rates and so they had very strict criteria.

But now we're starting to see older kids

coming with cross gender identification, some of them have other psychiatric comorbidities, and the rates of regret, desistance, are definitely now definitely now different than what they were originally reported.

CHAIRMAN ROMANELLO: So Dr. Benson, do you have proposed language to add?

DR. ACKERMAN: And where to add it. Should this be something in the very beginning in the preamble?

DR. BENSON: Yeah. But I mean, I don't think this is something that's amenable to like two words or three sentences. This is a little bit more complex. But I did send it, I did include that, as well, so you all should have a copy of that. I think it's basically two paragraphs, similar to the length of the previous. I fit all of this on one page.

UNIDENTIFIED SPEAKER: You're killing me.

DR. BENSON: But there's -- it just lists, you know -- but yeah, do you want me --

DR. KIRSH: Dr. Benson, can I make a suggestion? I take your comments well-founded, and I'm not sure though that today, in the context of an emergency rule, given the time that -- the time

constraints that we're under, that we can give your proposal adequate consideration. And I know that they don't like the word adequate. Can we --

DR. ACKERMAN: Thorough.

DR. KIRSH: Can we ask you to work on some proposed language which --

DR. BENSON: Well, I have the language already.

DR. KIRSH: So is it the language that you sent to the Attorney General's Office?

DR. BENSON: Yeah. Well, I sent it to I think Donna and Chris.

ATTORNEY DIERLAM: And just kind of I guess some clarification, is I do believe we did receive this language. However, I think it was sent over to us this morning. Is that correct?

UNIDENTIFIED SPEAKER: Very true.

ATTORNEY DIERLAM: So I don't think that we had -- I don't think the boards said they had an opportunity to get it in front of members.

CHAIRMAN ROMANELLO: Let me make a friendly suggestion, Dr. Benson, that you continue to work with the Attorney General's Office and Board staff to refine that language to make it more rule worthy and we will take it up under consideration in the

permanent rule.

DR. BENSON: Sounds good.

CHAIRMAN ROMANELLO: Yeah.

DR. BENSON: Makes sense.

DR. ACKERMAN: Yeah. I agree, I think it needs to be in there, some statement.

DR. BENSON: Yeah. Right.

DR. ACKERMAN: Not a whole page or eight paragraphs.

DR. BENSON: No, no. It's not. It's a half a page. I mean --

CHAIRMAN ROMANELLO: Yeah. And that's why, I mean, I'm looking at it --

DR. ACKERMAN: We should have adequate time to take a look at it.

DR. DI PIETRO: Mr. Chair, one other thing I forgot to mention earlier, if you don't mind, my preference would be for there to be initials at the bottom of every page. There's some non-signature pages, like the first page is a non-signature page, which is probably one of the most important pages in the entire document. And I'd like to have initials -- an initial line.

CHAIRMAN ROMANELLO: Makes sense. So the motion is to add initial --

DR. DI PIETRO: Yeah. The parent --
DR. ACKERMAN: On every page.
DR. DI PIETRO: Yeah. The parent, the minor, and then the optional second parent.
CHAIRMAN ROMANELLO: On every page of all the consent forms.
DR. DI PIETRO: Every page, yes.
UNIDENTIFIED SPEAKER: Well, adults wouldn't need the parent --
DR. ACKERMAN: Yes. Adults, as well.
CHAIRMAN ROMANELLO: That's a motion by Dr. Di Pietro and a second by Dr. Ackerman. All in favor?
(Unanimous ayes)
Opposed?
That motion carries and it will cascade through all of the consent forms.
DR. BENSON: And one other question I have: we're all comfortable with just one parent signing this document? What if another parent was opposed to it?
DR. ACKERMAN: That by the legislature.
ATTORNEY MCNULTY: That's by the statute.
ATTORNEY DIERLAM: Yeah. The statute specifically says, "A parent or legal guardian,"

singular.

DR. BENSON: Then we don't have to deal with that.

ATTORNEY MCNULTY: Correct.

DR. ACKERMAN: Makes it a lot easier.

CHAIRMAN ROMANELLO: Anything else on the consent that begins at Bates 298 which was "Feminizing Medications for Patients"?

DR. BENSON: You mean the minors, right?

DR. ACKERMAN: 272.

CHAIRMAN ROMANELLO: I'm sorry, 272.

DR. BENSON: I don't have anything else.

CHAIRMAN ROMANELLO: Then if not, we're going to move to the consent that starts at Bates 284, "Masculinizing Medications for Patients with Gender Dysphoria." Again, this is a minor form. We talked about some changes that are cascading through all of the forms. Those will impact this informed consent, as well. Are there any observations in addition to those which we have already made on the forms?

Dr. Ackerman.

DR. ACKERMAN: I have an observation and I just need some clarity from the endocrinologists in the room. In the adult form, in the adult consent

for masculinization, there's a whole discussion regarding the use of Finasteride that's not in the pediatric form. So you don't use it in kids?

DR. MORTENSEN: Correct. It's not approved. I haven't seen it --

DR. ACKERMAN: Nothing's approved. Nothing's approved.

DR. MORTENSEN: That's true.

DR. BENSON: I mean, I don't even -- I'd be interested to hear if many people are using Finasteride. It's not been shown to be all that beneficial in studies.

DR. ACKERMAN: Is it for adults or for minors?

DR. BENSON: For -- in treatment in this condition. It's --

DR. ACKERMAN: For adults or minors.

DR. BENSON: Yeah.

DR. ACKERMAN: Why is it -- is this being used for hair growth?

DR. BENSON: Because once you lower the -- you know, once you lower the testosterone levels, what benefit is there to blocking 5-alpha-reductase which can --

DR. ACKERMAN: No, no. But are you using

it for masculinization to promote hair growth?

DR. BENSON: They actually use it for -- some of the patients become bald, so they give it to them for that reason.

DR. ACKERMAN: Right. That's what I'm saying. It's to promote -- I'm trying to understand why it's being used. Again, as a non-endocrinologist, I use it to shrink prostates.

DR. MORTENSEN: Right. You do.

DR. ACKERMAN: Okay. So why is it being used here? I assume for hair growth?

DR. BENSON: Yes.

DR. ACKERMAN: Propecia, right? You spray it on or something.

DR. BENSON: That's the main reason.

DR. ACKERMAN: And so it would be used for women that want to become men --

UNIDENTIFIED SPEAKER: Correct.

DR. ACKERMAN: -- to give them more hair.

DR. BENSON: Yes.

UNIDENTIFIED SPEAKER: Correct.

DR. ACKERMAN: So would you not use it for girls that want to become boys? Because they already have hair. Is that why it's not in the minor section?

DR. MORTENSEN: I just don't think it's been used in the minor section. So the literature that I looked at, I didn't see it used as that. I don't see it in the World PATH recommendations either. The adult data is limited. I treat women with PCOS and adolescents with PCOS and elevated --

DR. ACKERMAN: PCOS?

DR. MORTENSEN: Polycystic Ovarian Syndrome.

DR. ACKERMAN: Uh-huh (affirmative).

DR. MORTENSEN: And elevated androgens can cause male pattern baldness, which is what this population can be experiencing. Not all of them, but a subset. So they were using it as an adjunct therapy to try to prevent the side effect of using high doses of testosterone. But they haven't really looked at it in children, so I haven't seen any literature that it was being used in anyone under the age of 18.

DR. ACKERMAN: Okay.

DR. MORTENSEN: Which is why I didn't include it.

DR. BENSON: Yeah. And I have a related question about it, too. Are you done with this point or are you still --

DR. ACKERMAN: Yeah. Well, I'd be interested in hearing from the public in a second if they have been using it --

DR. BENSON: I would, too.

DR. ACKERMAN: -- as a pediatric --

DR. BENSON: I have another question related to that. Cyproterone acetate has been mentioned. It is. It's in Bates -- what is it -- 298. But that's not even available in the United States. That drug is not --

CHAIRMAN ROMANELLO: Wait, that's the next form.

DR. BENSON: Yeah, I know. I'm just saying. But if we're going to ask the public for comment, I'd be curious to know.

CHAIRMAN ROMANELLO: Got it.

DR. BENSON: Are people getting it from Canada? Is this commonly being used?

DR. ACKERMAN: What drug is it?

DR. BENSON: Cyproterone acetate.

DR. ACKERMAN: Oh, it's the adult form of the --

DR. BENSON: It's not available in the United States. It's not available. At least it's not available through the routine channels.

DR. ACKERMAN: Canadadrugs.com.

CHAIRMAN ROMANELLO: So let me try and corral us back to the question at hand which is comments or proposed --

DR. BENSON: I do. I have a comment.

CHAIRMAN ROMANELLO: Dr. Benson.

DR. BENSON: So I think this consent form is based on a little bit older -- because oral testosterone now is FDA approved. We've got three different oral testosterones available. I don't know how commonly that's already being used but at the Endocrine Society just this last week, there was a lot of discussion about it. Earlier forms of testosterone had a lot of more liver toxicity. These newer versions, much, much safer. But we're talking about mostly transdermal, injectable, but we don't mention oral. But I think it's going to become increasingly more common --

CHAIRMAN ROMANELLO: So where would the proposed change for that be?

DR. BENSON: Well, it's Bates 284, "How is testosterone taken?"

I don't know. Monica, what do you think about that, Monica?

DR. MORTENSEN: Well, we're looking at the

minor forms, and that might be relevant for the adult forms but --

DR. BENSON: Or older adolescents.

DR. MORTENSEN: Right. But this is -- I mean, I went to Endocrine Society, but I didn't know everybody is using it for that. You could change some of the verbiage in there because it says it's typically not given in pill form, but you could just change it that it may be available in pill form.

DR. BENSON: Yeah. Something like that.

DR. MORTENSEN: And just change the verbiage that way.

DR. DI PIETRO: And just out of curiosity, you never use like -- like in adults we'll use gel and things like -- that's never used?

DR. BENSON: No. It's used sometimes in kids but it's difficult sometimes because I've had patients who were using AndroGel, get it on their hands or whatever, hug their mother, hug their sister, then you've got a sibling with a bone age of 12 and they're 6 years old.

DR. ACKERMAN: Well, I guess we should have all that covered in there. It should not just be the injection, it should be the gel and the pills.

DR. DI PIETRO: Or just various forms of

testosterone?

DR. MORTENSEN: You can add it. It's just it's not typically used in like the induction of male puberty for what pediatric endocrinologists usually do. Because you can't --

DR. BENSON: And there aren't doses appropriated for lower --

DR. MORTENSEN: -- dose is very specifically with the pump.

DR. ACKERMAN: And it does say here "Usually injected, typically" --

CHAIRMAN ROMANELLO: Yeah. I was going to say it's not that you could not administer oral testosterone, it just says it's typically not given in pill form.

DR. ACKERMAN: Or the gel.

CHAIRMAN ROMANELLO: Or the gel.

DR. BENSON: Yeah.

DR. DI PIETRO: Okay. Then I'm fine with it.

DR. BENSON: Just leave it then.

ATTORNEY MCNULTY: Just leave it?

DR. KIRSH: But maybe the bigger point we could give some further consideration to this in the permanent rule? Clean it up a little bit.

DR. BENSON: Yeah. I think that's reasonable. I mean, it does say, "Typically, it's not given," so it doesn't rule out the possibility that it could --

ATTORNEY MCNULTY: So, Dr. Benson, are you suggesting leave it as is for now?

DR. BENSON: Yeah. Just leave it as is.

DR. DERICK: I have another comment.

CHAIRMAN ROMANELLO: Dr. Derick.

DR. DERICK: Page Bates 286. This is a -- just to be consistent. "Summary of testosterone benefits and risks." One of the benefits is, "Appear more like a man." Just "appear more masculine."

UNIDENTIFIED SPEAKER: Yes.

DR. DERICK: "A masculine appearance."

ATTORNEY MCNULTY: And those changes will be made throughout the forms, Dr. Derick. I think you all -- that's what you all decided, right?

DR. BENSON: I mean, I like the wordage as it is. You know, I think for kids that are reading this, it's important for them to have simple words as much as possible.

DR. ACKERMAN: But it doesn't say male.

DR. DERICK: Yeah. I just don't like the

word male and female. Man, woman, masculine, feminine, fine. Male, female, no. So I'm okay with it saying, "appear more like a man." That's fine with me, just not "like a male."

DR. BENSON: Okay.

DR. DERICK: It's just a pet peeve.

DR. ACKERMAN: Although you could say in the risk the "male pattern baldness," that's actually -- we have that there.

EXECUTIVE DIRECTOR VAZQUEZ: Question. Is there a desire to be consistent throughout the documents because we have it two different ways now.

DR. BENSON: Paul, could you clarify that?

EXECUTIVE DIRECTOR VAZQUEZ: Well, we went to masculine and feminine in one place and now we're going to have man and --

DR. ACKERMAN: No. It says --

UNIDENTIFIED SPEAKER: Male and female to masculine and feminine.

EXECUTIVE DIRECTOR VAZQUEZ: We changed male and female to masculine and feminine and we're going to -- it's the same statement. That "Testosterone may be prescribed to make a minor look" -- we said, "less masculine and more feminine," in the other one.

DR. ACKERMAN: I know. But this doesn't say male.

CHAIRMAN ROMANELLO: This doesn't say male or female.

DR. ACKERMAN: We took the male and female.

EXECUTIVE DIRECTOR VAZQUEZ: So we're going to use masculine and feminine in one place and man and woman in another?

DR. ACKERMAN: Yes.

EXECUTIVE DIRECTOR VAZQUEZ: Okay. That's fine. Just clarifying.

DR. ACKERMAN: Just not use the word male or female, because that's not necessarily human.

EXECUTIVE DIRECTOR VAZQUEZ: Correct.

UNIDENTIFIED SPEAKER: You don't need to change it.

DR. ACKERMAN: Don't need to change it.

UNIDENTIFIED SPEAKER: Don't need a change.

DR. ACKERMAN: Nope.

CHAIRMAN ROMANELLO: Anything else?

DR. ACKERMAN: Now, I just want to point out, we are using the word male in the next column under "Risks," but that's a clinical diagnosis of male pattern baldness.

UNIDENTIFIED SPEAKER: Right.

DR. ACKERMAN: So that's allowed to be used there.

DR. DI PIETRO: It should be hyphenated.

DR. ACKERMAN: Not man pattern baldness.

CHAIRMAN ROMANELLO: Why did you look at me when you said that?

DR. ACKERMAN: Well --

CHAIRMAN ROMANELLO: Anything else on this form?

DR. ACKERMAN: I've got Kirsh -- Kirsh is in my eyes, too.

CHAIRMAN ROMANELLO: Dr. Benson.

DR. BENSON: So I don't remember which meeting it was at, but someone came forward and spoke about their personal experience with extreme vaginal dryness that led to painful like intercourse and they had like ulcers and abscesses in the pelvic related to that. Just saying vaginal dryness, if -- and I looked at actually some consents from some other studies that have been done.

It's Bates 287 under "The following changes could be permanent but may not improve if I stop taking testosterone." The last three are, "More muscle mass and strength, more sexual interests." But if people have typical penetrative sex, there's

a risk for very thin vagina --

DR. ACKERMAN: Right. Dyspareunia.

DR. BENSON: Yeah. For dyspareunia and tears and et cetera that can lead to infections and the like. I think we should just be a little more granular with that. I wasn't even aware of that, at the time, happening. And after that was said, I started reading about it and this has been reported a few times.

CHAIRMAN ROMANELLO: So do we have proposed language then? What would you add?

DR. ACKERMAN: He wants to add a few more bullets.

DR. BENSON: "Painful penetrative intercourse," or something like that.

CHAIRMAN ROMANELLO: Under the last dot point?

DR. BENSON: "Abscess infection."

ATTORNEY MCNULTY: Wait, you're going --

CHAIRMAN ROMANELLO: So on Bates 287.

ATTORNEY MCNULTY: Right.

CHAIRMAN ROMANELLO: The last dot point that is "vaginal dryness," we're going to add --

DR. BENSON: "Which could lead to painful penetrative intercourse, infections, et cetera," you

know.

CHAIRMAN ROMANELLO: Not et cetera.

ATTORNEY MCNULTY: "Which could lead to" --

UNIDENTIFIED SPEAKER: What about just saying "vaginal dryness which may lead to tearing -- which increases the risk of tearing"?

DR. BENSON: Well, what I think that they need to be aware of is that the vagina itself becomes thinner and they're more at risk for tears and infections if they have, you know --

DR. ACKERMAN: Yeah. "Vaginal dryness, vaginal tearing, vaginal pain, vaginal infections."

DR. BENSON: Painful intercourse.

DR. DI PIETRO: Painful intercourse. Yeah.

DR. ACKERMAN: Got all those?

ATTORNEY MCNULTY: Nope. You guys are going to need to tell us the exact language wish.

DR. ACKERMAN: Okay. It has vaginal dryness.

ATTORNEY MCNULTY: We've got that.

DR. ACKERMAN: So vaginal pain --

UNIDENTIFIED SPEAKER: "Vaginal dryness which may lead to" --

DR. ACKERMAN: No. You don't need to say, "may lead to," just additional bullets.

DR. BENSON: Yeah. Just bullets.
DR. ACKERMAN: "Vaginal pain, vaginal tearing, vaginal bleeding, painful intercourse, vaginal infection."
DR. BENSON: Yeah.
DR. ACKERMAN: I'll say it again, "Vaginal pain, vaginal tearing, vaginal infection, vaginal bleeding, painful intercourse."
CHAIRMAN ROMANELLO: That's a motion by Dr. Ackerman. Second by Dr. Benson. All in favor --
ATTORNEY MCNULTY: Wait, wait. We don't have --
DR. ACKERMAN: Pain.
ATTORNEY MCNULTY: We have pain.
DR. ACKERMAN: Tearing, bleeding.
ATTORNEY MCNULTY: Bleeding.
DR. ACKERMAN: Infection. Those all are vaginal whatever. And then finally, painful intercourse. Pain, bleeding, tearing, infection, and painful intercourse.
DR. BENSON: I think that's great. Yeah.
DR. ACKERMAN: Do our lawyers understand that?
ATTORNEY DIERLAM: Yes, we do.

CHAIRMAN ROMANELLO: Again, that's a motion by Dr. Ackerman, seconded by Benson. All in favor?

(Unanimous ayes)

Opposed?

Motion carries. Anything else on this form?

ATTORNEY MCNULTY: And would this be transferred to any similar -- wherever that is for any form, correct?

CHAIRMAN ROMANELLO: Yes.

DR. BENSON: I did want to -- I really actually like the wording at Bates 290. It's in the second big box, the bottom where it just discusses that "The prescribing physician is required to monitor the minor for any side effects during treatment." I think that's really, really good. "The undersigned parents are encouraged also to report." I think it's important that, you know, this is stated.

CHAIRMAN ROMANELLO: Yep. Any other proposed modifications or observations on this form?

Hearing none, we're going to move to the next consent form which is at Bates 298.

UNIDENTIFIED SPEAKER: (Indiscernible)

CHAIRMAN ROMANELLO: No. We're doing the

consents.

The next is the consent form found at page 298, which is titled "Feminizing Medications for Patients with Gender Dysphoria." This is the adult form. Again, recognizing that all the changes that we've previously made have cascaded through to these forms, are there any observations or proposed changes that are specific to this informed consent form?

DR. DERICK: So Bates 300, this is for adults. It says, "The specific requirements for you to receive and continue therapy include the following." You know, there are -- these are adults who are currently undergoing therapy, or possibly new people who would be starting it. But like evaluation every three months, or if we change it to six months, you know, in perpetuity, I think if someone is stable on these medications, it might be an overkill to be so prescriptive in the frequency of the visits that they need to have.

I mean, if someone starts it, maybe it could be for the first year or two and then the physician could decide after that. But to me, if someone has been stable on a medication for 10 years, to have to come every 3 months for an

evaluation seems --

CHAIRMAN ROMANELLO: This is on number nine, Dr. Derick?

DR. DERICK: Yeah. That's just an example. And you know, suicide risk assessment for someone who has been stable on these treatments for years --

DR. ACKERMAN: And remember, these are adults now. So the other ones were kids, and so --

DR. DERICK: Yeah. This is the adults.

DR. ACKERMAN: I think under the age of 18, I think they should be seen every 3 months. But I agree 100 percent with Dr. Derick. Every 3 months is a bit --

CHAIRMAN ROMANELLO: So is there a proposal to modify that language?

DR. DERICK: I feel like -- I feel like if someone has been in therapy and are continuing therapy at the time this consent form is signed, I don't think we should be prescriptive at all with the follow up. I think they should have the follow-up as they normally would do. I think if someone's newly placed as an adult on these medications then perhaps, we should consider modifying it to every six months for like a finite period of time. Because otherwise, you know, if it

seems -- you know, you obviously want to have follow up with these treatments but, you know, four times a year for the rest of life seems --

DR. ACKERMAN: Suicidal risk assessment every three months for the rest their life --

DR. DERICK: Yeah. I mean, it's --

DR. ACKERMAN: -- is ridiculous.

DR. BENSON: I mean, can I just read from the Endocrine Society Guidelines on this?

CHAIRMAN ROMANELLO: Sure.

DR. BENSON: They say, "Every three months the first year," this is for both male and female. And then "one to two times per year to monitor for appropriate signs of virilization or feminization, et cetera, and to monitor for adverse outcomes." So that's what they say is --

DR. ACKERMAN: For how long?

DR. BENSON: Every three months the first year of an adult starting this treatment and then one --

DR. ACKERMAN: Semiannually for how long?

DR. BENSON: -- to two times a year after that.

DR. ACKERMAN: One to two times a year after that.

DR. BENSON: Uh-huh (affirmative).
DR. ACKERMAN: Okay.
DR. DERICK: And this is for people who are newly on the medication, this isn't for a patient who has been on it for 10 years --
DR. ACKERMAN: I agree, 100 percent.
DR. DERICK: -- and then has to have a bunch of visits that seem unnecessary if they're stable.
DR. ACKERMAN: I'd make the motion that we change it to use Dr. Benson's language --
DR. BENSON: To be consistent with the --
DR. ACKERMAN: -- so that they undergo an evaluation by the prescribing physician or their -- whatever we said before -- at least every three months for the first year and --
DR. MORTENSEN: Returning induction. Because if you're switching providers --
CHAIRMAN ROMANELLO: Hold on. So we're talking about now Bates 300.
DR. ACKERMAN: Correct.
CHAIRMAN ROMANELLO: Number nine, "Undergoes an evaluation by a prescribing physician at least every three months."
ATTORNEY MCNULTY: I thought you were

talking about number 10, the suicide risk. Are you talking --

CHAIRMAN ROMANELLO: We're getting there, Donna.

DR. ACKERMAN: We'll get there, Donna.

CHAIRMAN ROMANELLO: So let's talk about number nine.

ATTORNEY MCNULTY: Okay. So number nine.

CHAIRMAN ROMANELLO: Thank you. Let's talk about number nine.

ATTORNEY MCNULTY: All right.

CHAIRMAN ROMANELLO: And the proposal is to modify number nine to Dr. Benson.

Want to read us the language?

DR. BENSON: "Evaluate patient every three months in the first year, and then one to two times per year to monitor for appropriate clinical changes," or something.

DR. ACKERMAN: Well, just say, "then once to twice a year thereafter."

CHAIRMAN ROMANELLO: Do our lawyers have that?

DR. ACKERMAN: Dr. Mortensen was just saying something. I caught her saying it, but I don't know what she was saying about induction. You

want to --

DR. MORTENSEN: Yeah. Because initially you had said -- the way you had worded it, but then Dr. Benson said initially.

DR. ACKERMAN: Okay.

DR. MORTENSEN: So when you're being induced through these medicines, you need in the first year to be seen more frequently, because your doses are going to have to be adjusted. But then if you change providers and you're already on stable treatment, you wouldn't need to be seen every three months because you're already on that medication. So it's just during induction that you would need that.

DR. ACKERMAN: If we're putting a rule --

DR. MORTENSEN: But the way that he -- the way that he --

DR. ACKERMAN: I think as a responsible provider, if you have a new patient that wasn't yours before, you would want to see that patient more often once a year. If you're inheriting somebody, even if they've been on the same medications for 10 years, if I'm inheriting someone, I see them more often for the first year because I don't know them.

DR. MORTENSEN: I would do.
DR. BENSON: Absolutely. I agree with you. In God I trust, everybody else, show me the data.
DR. ACKERMAN: Right. So as a rule, we don't have to say that. So Dr. Benson, initially, number nine, "Undergoes evaluation by a prescribing physician or their designate every three months for the initial year, and then at least annually thereafter."
CHAIRMAN ROMANELLO: There's the motion. Is there a second?
DR. KIRSH: Second.
CHAIRMAN ROMANELLO: Dr. Kirsh seconds. All in favor?
(Unanimous ayes)
Opposed?
Motion passes.
DR. ACKERMAN: And then I would use the same language for bullet 10.
CHAIRMAN ROMANELLO: Now for number 10, Dr. Benson, you want to read us from the --
DR. BENSON: As far as suicide risk?
CHAIRMAN ROMANELLO: Yeah.
DR. BENSON: They don't specifically say that. But I think, I mean, that's a major, major

risk. I think, you know, you want to definitely make sure that people are being monitored for that. And the long-term studies --

DR. ACKERMAN: Well, how often? We have every three months.

DR. BENSON: I think what we have here is -- maybe -- you know, like maybe you want to do a range, but I think -- I don't see anything specific in here in terms of that, but --

DR. ACKERMAN: Then why can't we just say the same thing? "Every three months, initially, and then at least annually thereafter."

CHAIRMAN ROMANELLO: Okay. Is that a motion?

DR. ACKERMAN: Yes, sir.

CHAIRMAN ROMANELLO: Is there a second?

DR. KIRSH: Second.

DR. DI PIETRO: Second.

CHAIRMAN ROMANELLO: Dr. Kirsh, Dr. Di Pietro.

All in favor?

(Unanimous ayes)

Opposed?

Motion carries. Anything else on this form?

DR. BENSON: Well, this is the form that has the Cyproterone acetate on Bates 298 and the Finasteride discussion. I don't know if --

DR. ACKERMAN: Where did staff get that from? Is it not available --

DR. BENSON: It's at the very bottom in the last two paragraphs.

DR. ACKERMAN: -- in the United States or is it illegal?

DR. DI PIETRO: It's not available.

DR. BENSON: It's not available. I don't think the FDA -- I don't think it's even approved. It's not an approved treatment. It's not available.

DR. ACKERMAN: So if it's not available, we shouldn't even have it in there.

DR. BENSON: I think it's available in Canada, but I don't know for sure.

DR. MORTENSEN: I left it on there only because when I was searching, you can buy these things from Canada, and you can buy certain things without prescriptions. So I just wanted to make sure that if they were looking at it, they were aware of the risks.

DR. DERICK: You know, the public has been so great with listening and allowing us to go

through these details and maybe they can speak to that when we're done with it if they are receiving those medications.

DR. ACKERMAN: But if it's something that can't be prescribed by a physician, I don't think it should be in this form.

CHAIRMAN ROMANELLO: Right.

DR. ACKERMAN: If it's something that a Florida licensed physician cannot prescribe, it shouldn't be in this form.

CHAIRMAN ROMANELLO: Agreed.

DR. MORTENSEN: Well, maybe you could just add, "This is not prescribed in the United States." Because maybe when they're doing their research they're saying, "How come you're not prescribing me this?" And you could say, "Well, because of the side effects and it's not available in the United States."

CHAIRMAN ROMANELLO: Dr. Mortensen, let's hold and wait until we hear if there are any public comments around this issue.

DR. ACKERMAN: Yeah. Keep track of the issues that we want, because I think I'd like to call on those people that maybe can speak to that first when we do public comments. This and there

was something else about youth using Finasteride and whatever else there was, I can't remember.

DR. MORTENSEN: We'll talk about the pill version of that.

DR. ACKERMAN: The pill version of testosterone. These are things that --

CHAIRMAN ROMANELLO: Anything else on this form?

DR. ACKERMAN: I saw also here that Casodex Bicalutamide is on here, wasn't on the kids form. Matt, do you want to --

DR. BENSON: Say it -- I'm sorry, I was reading something else.

DR. ACKERMAN: Bicalutamide --

DR. BENSON: Bicalutamide, yes.

DR. ACKERMAN: -- is on here. It was not on the kid's form. Is that correct or was it there, too?

DR. BENSON: Yeah. I mean, there's some -- there's some experience. I've prescribed Bicalutamide to kids with testotoxicosis.

DR. ACKERMAN: Was it on the kid's form?

DR. BENSON: No. It wasn't on the kid's form and it's one of those things that I don't think it's being routinely used.

DR. ACKERMAN: Do we need to put it on the kid's form? I don't want to make things more complicated if -- this is just the preamble, anyway, so it's not that --

DR. BENSON: I -- you know --

DR. MORTENSEN: Maybe we can see from public comment who's using it.

DR. BENSON: Yeah. I'd probably wait. Maybe we can hear from the public about Bicalutamide in children, and then Finasteride and Cyproterone acetate in the adults.

CHAIRMAN ROMANELLO: All right. So using that as a placeholder for further discussion, we're going to move on to the informed consent proposed form found at Bates 308. "Testosterone Treatment for Patients with Gender Dysphoria."

Again, recognizing that the changes that we previously made on the forms will kind of flow through to these forms, does anybody have any additional comments or proposed modifications to this form?

DR. DI PIETRO: My only question is -- and I guess for Dr. Benson and Dr. Mortensen, testosterone, since it's a controlled substance, usually the provider has them come in more than

annually. So I don't know if we need to change the verbiage based upon the sheer fact it's a controlled substance, or do we just leave it as is and then it's up to the physician to understand the rules of opiate -- you know, not opiate but controlled substance prescribing in the state?

EXECUTIVE DIRECTOR VAZQUEZ: Right. And I think to that point, it's important to point that out that all of the remaining standard of care elements --

DR. DI PIETRO: Fair.

EXECUTIVE DIRECTOR VAZQUEZ: -- all the other standards that relate to the practice of medicine, even if it's involving gender dysphoria, would still apply. This rule would not alleviate any of those obligations or requirements at any point.

DR. DI PIETRO: Then I'm okay with leaving it as is. Just I wanted to be on the record with saying it is a controlled substance, so normally it's at least every six months for controlled substances.

UNIDENTIFIED SPEAKER: Very good point.

CHAIRMAN ROMANELLO: Any other observations or proposed edits to this form?

DR. BENSON: We're talking about 308 and after, right?

CHAIRMAN ROMANELLO: Yes.

DR. BENSON: Let's look through. I highlighted a couple of things, but I don't think -- we have the vaginal dryness issue here, again. Might be good to use the same word verbiage that we used with the pediatric one.

CHAIRMAN ROMANELLO: Okay. So that's a motion by Dr. Benson.

DR. BENSON: It's on Bates 312.

CHAIRMAN ROMANELLO: Yep.

DR. DI PIETRO: I actually have one addition. On -- sorry -- on Bates 310.

CHAIRMAN ROMANELLO: Well, let me take up Dr. Benson's proposal on --

DR. DI PIETRO: Oh, I'm sorry.

CHAIRMAN ROMANELLO: -- Bates 312. Bates 312 at the top, we have vaginal dryness, and the motion is to include the previous language. Tears -- so that's a motion by Dr. Benson. A second by --

DR. MORTENSEN: Second.

CHAIRMAN ROMANELLO: -- Dr. Mortensen. All in favor?

(Unanimous ayes)

Opposed?

Motion passes.

Dr. Di Pietro.

DR. DI PIETRO: I've got to find my page again now, sorry. On Bates 310, "Who should not take," and then "It should be used with caution and only after full discussion of risks by anyone who" -- we need to add on there family history of -- actually, no, blood clot works. Never mind. I was going to say pulmonary embolism, but blood clot covers that. Scratch that.

CHAIRMAN ROMANELLO: Okay. Yep.

ATTORNEY MCNULTY: Mr. Romanello, there's one on page 312 when you have a chance.

CHAIRMAN ROMANELLO: Ms. McNulty, yes.

ATTORNEY MCNULTY: Thank you. I think this clarification needs -- the very last box on page 312 says, "Taking more testosterone than prescribed could/may/will increase/will not" -- I mean, that is awkward. I don't know what it should be. That's the way the form is reading.

CHAIRMAN ROMANELLO: "Taking testosterone more than prescribed" --

ATTORNEY MCNULTY: "Could or may."

CHAIRMAN ROMANELLO: -- "could" -- oh,

"could or may."

ATTORNEY MCNULTY: Maybe just both could and may?

UNIDENTIFIED SPEAKER: And get read of wills?

ATTORNEY MCNULTY: That way it just goes "will increase health" --

CHAIRMAN ROMANELLO: "May increase health risks, may not make changes happen more quickly."

DR. MORTENSEN: So I would just eliminate the words "could" and "may."

ATTORNEY MCNULTY: Yeah.

DR. MORTENSEN: So that way it's "taking more testosterone prescribed will increase health risks, will not make changes."

CHAIRMAN ROMANELLO: Motion by Dr. Mortensen.

DR. DI PIETRO: Second.

CHAIRMAN ROMANELLO: Second by Di Pietro. All in favor?

(Unanimous ayes)

Opposed?

Motion carries.

ATTORNEY MCNULTY: Thank you.

CHAIRMAN ROMANELLO: Thank you,

Ms. McNulty. Anything else on this form?

Hearing nothing more on this form, going to go to the form found at Bates 317. "Surgical Treatment for Adults with Gender Dysphoria." Again, we've made all the changes that are going to flow through tot his form. Any further proposed modifications, or observations, or proposed changes here?

DR. BENSON: I think --

CHAIRMAN ROMANELLO: Dr. Benson.

DR. BENSON: -- one of the things that we're starting to learn about vaginoplasty in people who are blocked in earlier puberty is that the penile tissue with which they use to surgically create a vagina can sometimes be too small. So they then go to other tissue sources now, like the colon, to create a vagina. And so this is just a, if you've been blocked from early on, you know, it can be a much more difficult procedure and more risks of major complications. So it may be good to have some verbiage in here regarding that. That if you were blocked from early on in puberty, your penile tissue may be --

DR. ACKERMAN: Inadequate.

DR. BENSON: -- inadequate for the surgical

procedure. And then I'm sure that, you know, that would be discussed by the surgeon and everything, but it's -- do you see where that is, Bates 317? It's under "Vaginoplasty."

ATTORNEY MCNULTY: Maybe not sufficient versus inadequate?

DR. BENSON: Insufficient.

ATTORNEY MCNULTY: Insufficient.

DR. BENSON: Yeah.

UNIDENTIFIED SPEAKER: "May not be sufficient."

DR. DERICK: Can you tell me one more time where you are on the document?

DR. BENSON: Bates 317 under "Vaginoplasty." There's bullets under "Genital or bottom surgery. Orchiectomy, vaginoplasty, phalloplasty."

ATTORNEY DIERLAM: And can you just one more time read in the proposed sentence? I guess you're talking about adding a sentence under the "Vaginoplasty"?

DR. BENSON: "For those of you who are treated with puberty blockers in childhood, an additional complication of this surgery could be related to inadequate penile tissue which may

necessitate the use of" -- sorry. I know, I do this on a daily -- well, not surgery, but -- "treatment with puberty blockers can lead to insufficient penile tissue that may necessitate the use of other" --

DR. ACKERMAN: Tissue sources.

DR. BENSON: -- "tissue sources, such as the colon to create a vagina." Or something like that.

ATTORNEY MCNULTY: Well, we need the precise language.

UNIDENTIFIED SPEAKER: They're not as good and fast as like Dragon or anything, so you got to get a little bit more deliberate.

ATTORNEY MCNULTY: So "can lead to insufficient penile tissue" --

DR. BENSON: "That would necessitate the use of other tissues such as the colon to create a vagina."

Monica, any suggestions there?

DR. MORTENSEN: I think that seems reasonable.

DR. BENSON: You know, I don't know if it would be -- if this is kosher, or if it could ever happen but is it possible that -- I'm not a

urologist, I'm not a surgeon. Is it possible that we could ever have a -- two or three people that do this for a living to actually, at some point, look at it and make sure that it's as robust as possible for the surgeons that --

CHAIRMAN ROMANELLO: We're going to come back and do a permanent rule. This is an emergency rule.

DR. BENSON: Okay.

CHAIRMAN ROMANELLO: And we will start this process all over again and have public comment again.

DR. DI PIETRO: When that happens, I have a contact in Miami, and this is her sole job --

CHAIRMAN ROMANELLO: We can invite those folks. Yeah.

DR. DI PIETRO: -- is gender dysphoria surgery, so I'm happy to invite her.

DR. ACKERMAN: We've invited some of these people in the past --

CHAIRMAN ROMANELLO: We have.

DR. ACKERMAN: -- and they've chosen not to participate.

CHAIRMAN ROMANELLO: So I want to -- Bates 317, the dot point "Vaginoplasty." Dr. Benson's

motion is to add language at the end of that dot point that reads --

Mr. Dierlam.

ATTORNEY DIERLAM: I believe that this may be -- I think I have it. Please correct me if I'm wrong, Mr. Benson. I believe it was, "Continued treatment with puberty blockers may result in insufficient penile tissue that could necessitate the use of other tissues to create a vagina."

DR. BENSON: What I would say, "For those of you who may have been treated with puberty blockers, or, you know, as a child, this is when it's an issue." It's not typically an issue if you started transition at 16 or 17. It's not an issue then. It's an issue if you started puberty blockers as a young child like 8, 9, 10.

CHAIRMAN ROMANELLO: Okay. So with that addition, we have a motion by Dr. Benson. Is there a second?

DR. MORTENSEN: Second.

CHAIRMAN ROMANELLO: Dr. Mortensen. All in favor?

(Unanimous ayes)

Opposed?

Motion carries.

Any other observations here?
DR. BENSON: What is -- I do have one more question. Bates 318, there's a question that says, "What are some potential complications of surgery?"
CHAIRMAN ROMANELLO: Yep.
DR. BENSON: There's a bullet list. "Changes in sexual sensation," et cetera. "Decrease in function." What are we referring to? Could we --
CHAIRMAN ROMANELLO: Wait, where are you?
DR. BENSON: Decrease in -- under "What are some potential complications of surgery?"
ATTORNEY MCNULTY: 319.
CHAIRMAN ROMANELLO: Decrease in function, right.
DR. BENSON: Because we talk about changes in sexual sensation --
CHAIRMAN ROMANELLO: Right.
DR. BENSON: -- infection, nerve damage. Decrease in function, do we know what we're specifically?
DR. ACKERMAN: I think we can strike that.
CHAIRMAN ROMANELLO: Dr. Mortensen?
DR. BENSON: It just seems redundant or something.

Do you know, Monica?

DR. MORTENSEN: I think it was related, also, to urinary complaints. But I'm okay with striking it.

DR. BENSON: Well -- yeah.

DR. ACKERMAN: Urinary function.

CHAIRMAN ROMANELLO: So motion by Dr. Mortensen to strike the dot point "decrease in function."

DR. ACKERMAN: Yeah. Function is just too ambiguous.

CHAIRMAN ROMANELLO: Second by Dr. Benson. All in favor?

(Unanimous ayes)

Opposed?

Motion carries.

ATTORNEY DIERLAM: And if I may, just on the next page --

DR. ACKERMAN: Although, I would -- you know, instead of "Trouble with bladder emptying," I would just say -- you know, maybe combine those, the function and that together. You know, "Diminishment of bladder function -- or urinary function."

DR. BENSON: Yeah.

DR. ACKERMAN: Because it's not just

bladder emptying, it's -- you know, it's flow rate, it's initiation of urination.

DR. BENSON: We did have people testify about blood clots in their urine with this treatment, so --

DR. ACKERMAN: Right. So instead of "Trouble with bladder emptying," just say "Diminishment of bladder function."

CHAIRMAN ROMANELLO: So the motion is to change the dot point on Bates 318 from "Trouble with bladder emptying" to --

DR. ACKERMAN: "Diminishment in bladder function."

CHAIRMAN ROMANELLO: That's a motion by Dr. Ackerman, a second by Benson. All in favor?

(Unanimous ayes)

Opposed?

Carries.

DR. ACKERMAN: Well --

DR. DI PIETRO: I have one more two.

DR. ACKERMAN: -- I just want to back pedal a little bit. Bladder function or urinary function?

DR. MORTENSEN: Well, they have some urinary complaints, as well.

DR. ACKERMAN: Right. So maybe just

"Diminishment in urinary function."

DR. MORTENSEN: Or urinary disfunction. Or problems urinating.

DR. ACKERMAN: Right. "Problems urinating."

CHAIRMAN ROMANELLO: So you want to add a second --

DR. ACKERMAN: Add another bullet "Problems with urination."

CHAIRMAN ROMANELLO: So motion by Dr. Ackerman --

DR. ACKERMAN: Ackerman to add another bullet saying, "Problems with urination."

CHAIRMAN ROMANELLO: Second by Dr. Di Pietro. All in favor?

(Unanimous ayes)

Opposed?

It's added.

DR. DI PIETRO: And --

CHAIRMAN ROMANELLO: Dr. Di Pietro.

DR. DI PIETRO: -- one more bullet point, sorry. Last bullet point where it says, "Side effects of anesthesia, including death," I think we should add, "Side effects of anesthesia and infection, including death" or -- infection is a big

part of this surgery. It's always a surgical --

UNIDENTIFIED SPEAKER: The same page.

DR. DI PIETRO: Where is it? Oh, infection. I'm sorry. Read right over it. Thank you.

DR. ACKERMAN: Never mind.

DR. DI PIETRO: Dr. Ackerman, never mind.

CHAIRMAN ROMANELLO: Okay. Anything else on this form? We're going to get to the AG and staff in a second, I promise you. No?

Donna? Chris?

ATTORNEY DIERLAM: Yeah. So my only comment, and it's on -- I believe it's the fifth box on Bates 319, it states, "I understand that if I my breast augmentation surgery." I think it should be, "I understand that if I have my breast augmentation surgery."

ATTORNEY MCNULTY: Not my. Just substitute have for my.

ATTORNEY DIERLAM: Right. "So if I have breast augmentation surgery."

ATTORNEY MCNULTY: Yes.

DR. ACKERMAN: Scribner's -- Scribner's error.

ATTORNEY DIERLAM: Yes.

CHAIRMAN ROMANELLO: Staff? Danielle?

EXECUTIVE DIRECTOR TERRELL: Yes, sir. If we can go back to -- and I apologize, I don't have the Bates numbers. This is the "Masculinizing for Adults Testosterone" form. On the third page when we talk about the specific criteria, it seems number two was repeated, and I just want to strike that.

CHAIRMAN ROMANELLO: Read what you're -- so I'm --

EXECUTIVE DIRECTOR TERRELL: Oh, I apologize. Minors -- "Masculinizing for Minors." I apologize.

CHAIRMAN ROMANELLO: "Masculinizing for Minors."

ATTORNEY MCNULTY: The third page?

EXECUTIVE DIRECTOR TERRELL: Yes, on the third page. If you'll read the second and third criteria are the same. There was just a repeat in there that I would like to --

DR. DI PIETRO: Under which --

EXECUTIVE DIRECTOR TERRELL: Under the specific requirements for minors to receive and continue hormone replacement therapy.

DR. DI PIETRO: Page 285.

EXECUTIVE DIRECTOR TERRELL: 285.

DR. DI PIETRO: Oh, okay. Yeah, that's duplicative.

EXECUTIVE DIRECTOR TERRELL: Yes. I just wanted to get a motion, so that we could correct that.

DR. DI PIETRO: I'll motion to strike number two, Bates 285.

CHAIRMAN ROMANELLO: Motion by Dr. Di Pietro.

DR. DERICK: Second.

CHAIRMAN ROMANELLO: Second by Dr. Derick. All in favor?

(Unanimous ayes)

Opposed?

Carries.

DR. ACKERMAN: I have one more.

CHAIRMAN ROMANELLO: You what?

DR. ACKERMAN: I have one more.

CHAIRMAN ROMANELLO: Yeah, please. Which one, Dr. Ackerman?

DR. ACKERMAN: Page 319, box 1, 2, 3, 4, 5, 6.

CHAIRMAN ROMANELLO: This is surgery.

DR. ACKERMAN: Right. On the surgery one.

CHAIRMAN ROMANELLO: Bates 319, yes.

DR. ACKERMAN: Box six, "I understand my surgery -- risk factors." Those are breast cancer, right, the breast cancer risk factors one?

CHAIRMAN ROMANELLO: Yes.

DR. ACKERMAN: So it says, "I.e." bracket one, bracket to. Technically, it should be "E.g."

CHAIRMAN ROMANELLO: Okay.

DR. ACKERMAN: For example, not that is. I.e. is that is, meaning those are the only two. E.g. is for example. There's more than just those two.

CHAIRMAN ROMANELLO: I appreciate the --

DR. ACKERMAN: Bates 319. Did you ask me where? Yeah, Bates 219.

ATTORNEY DIERLAM: We're on hard copies.

CHAIRMAN ROMANELLO: Hold on, hold on.

ATTORNEY MCNULTY: Page 3 of 6.

DR. ACKERMAN: Of the surgery. Page 3 of 6 of the surgery, that fifth box down where it talks about bracket one or bracket two.

ATTORNEY DIERLAM: I.e., e.g.

DR. ACKERMAN: It should be e.g. not i.e.

CHAIRMAN ROMANELLO: Nice catch.

DR. ACKERMAN: We're physicians here, we know Latin.

DR. DERICK: I know, between you and I, the two chairs are the grammar police.

CHAIRMAN ROMANELLO: Any other observations? Thank you for the catch.

DR. ACKERMAN: I would think the lawyers would know the Latin.

CHAIRMAN ROMANELLO: Ms. Terrell?

EXECUTIVE DIRECTOR TERRELL: Yes, sorry. One more. If you will go back to the form we were just one with the --

CHAIRMAN ROMANELLO: Which one was that?

EXECUTIVE DIRECTOR TERRELL: -- testosterone for minors, "Masculinizing Minors" is what it's called.

CHAIRMAN ROMANELLO: Yep.

EXECUTIVE DIRECTOR TERRELL: We need to add one and it has -- what happened was one got added and one got taken away, and it's the same as the other forms. "Has pubital changes resulting in an increase in gender dysphoria," which is what the other forms have, this one didn't have it.

DR. MORTENSEN: Oh, I copied it over.

DR. DI PIETRO: So I'll make a motion to accept that, to pull it over from the other form.

DR. ACKERMAN: Second.

CHAIRMAN ROMANELLO: That's a motion from Dr. Di Pietro, second by Dr. Ackerman. All in favor?

(Unanimous ayes)

Opposed?

Motion carries.

Any further comments or observations by the committee members with respect to any of the informed consent forms?

I want to thank you all for the thoughtful deliberation and the catches in Latin and grammar and syntax that we did. We landed the plane within two hours. Congratulations. We're going to take a 10-minute break and we're going to come back and we're going to do the rules.

DR. ACKERMAN: Can you review with us the agenda?

CHAIRMAN ROMANELLO: I'm sorry?

DR. ACKERMAN: Can you review the -- before we take the break, just for the benefit of the audience --

CHAIRMAN ROMANELLO: Right. We're going to come back and talk -- so we'll take a 10-minute break. We're going to come back and do rules, the two rules, and then we're going to take public

comment.

UNIDENTIFIED SPEAKER: Until 4:30?

CHAIRMAN ROMANELLO: Until 4:30, and then we'll take --

DR. ACKERMAN: And the rules shouldn't take too long.

CHAIRMAN ROMANELLO: No.

DR. ACKERMAN: Because the rules are very short.

CHAIRMAN ROMANELLO: Correct.

Ten-minute break.

(Recess taken)

CHAIRMAN ROMANELLO: I'm going to call the joint committee meeting back to order. Thank everybody for keeping it to 10 minutes. Appreciate that. Before we move on to the actual rules, staff had -- I think Mr. Vazquez had some questions about the titling or the naming of the informed consent form. So I'll turn it over to Mr. Vazquez with the questions.

EXECUTIVE DIRECTOR VAZQUEZ: Just one quick point. The titles seem to be consistent with the exception of the "Treatment with Testosterone for Adults," I believe it is. Is that correct that it should be "Testosterone Treatment for Patients with

Gender Dysphoria," or should it be "Masculinizing Medications for Patients with Gender Dysphoria"?

DR. ACKERMAN: I think it should be Masculinizing.

DR. DI PIETRO: Second.

CHAIRMAN ROMANELLO: All in favor?

(Unanimous ayes)

Opposed?

None. You've got a poll. Got it. Okay.

We're now going to turn to a consideration of the actual rules, and we'll start with Bates 294, which is the draft rule. "Sex Reassignment Standard of Practices in Minors." And I'm going to start with board counsel who had some technical observations, proposed changes, and then one that is going to flow through from the informed consent discussion earlier.

So Ms. McNulty.

ATTORNEY MCNULTY: Thank you, Mr. Romanello. On Bates page 295 --

DR. ACKERMAN: Donna, before you begin that, just again for our benefit -- pretend I don't know anything, but I do, but maybe for the audience's benefit, this rule is a rule that we put forth to allow minors to continue their medication

-- for those minors who are already in the program, who are already undergoing gender affirming care, to continue that care. That's what this emergency rule is for. Right?

ATTORNEY MCNULTY: Yes. And it adopts -- it does two things for the minors. It sets forth standards of practice and incorporates the informed consent forms you all just decided about.

DR. ACKERMAN: Right. And this is for those minors that were -- whose sex reassignment healthcare was commenced before and was still active as of May 17, 2023.

ATTORNEY MCNULTY: Correct.

DR. ACKERMAN: Okay. Just wanted to make sure that I understand that, and that's also for the benefit of the public that's here today.

ATTORNEY MCNULTY: And that is by statute.

DR. ACKERMAN: Right. Not our decision. This is by statute. Thank you. Ms. McNulty, I'm sorry.

ATTORNEY MCNULTY: No. Thank you for that big picture. It's helpful.

On Bates page 295 under subsection 4, "Standards of practice," the line before subsection 8, "Patient evaluations," there's a -- it just says,

"Clinical determinations," and I suggest that that be deleted, because that really is repeated in subsection B. So it says, "Clinical determinations." I think it's unnecessary and should be stricken.

DR. ACKERMAN: Move to strike.

CHAIRMAN ROMANELLO: Motion to strike by Ackerman, second by Derick. All in favor?

(Unanimous ayes)

Opposed?

Passes. Next.

ATTORNEY MCNULTY: Then also in number 4 on the following page, it says, "The patient will have adequate psychological and social support during treatment." Again, as you've done previously, to strike the word adequate.

DR. ACKERMAN: Move to strike adequate.

CHAIRMAN DERICK: Second.

CHAIRMAN ROMANELLO: All in favor?

(Unanimous ayes)

Opposed?

Passes. Next?

ATTORNEY MCNULTY: The next, as was discussed previously, subsection G says, "Bone DEXA scan." To clarify as you did before to have it read

"Bone density scan (DEXA scan) -- or DEXA -- DEXA scan."

DR. ACKERMAN: Just DEXA.

ATTORNEY MCNULTY: Just DEXA.

DR. ACKERMAN: Bone density scan or bone density study? What did we say before?

ATTORNEY MCNULTY: Scan.

DR. DI PIETRO: Motion.

CHAIRMAN ROMANELLO: Motion by Dr. Di Pietro, second by Dr. Kirsh. All in favor?

(Unanimous ayes)

Opposed?

Motion passes. Next?

ATTORNEY MCNULTY: And that's it.

UNIDENTIFIED SPEAKER: Do we have to adjust C?

DR. ACKERMAN: Yeah.

CHAIRMAN ROMANELLO: Yeah. We modified on Bates 296, sub (c). We had modified that language in the consent forms.

ATTORNEY MCNULTY: Well, did you do that for minors? This is just for minors, not adults.

UNIDENTIFIED SPEAKER: We did not.

ATTORNEY MCNULTY: You only did that for adults, is my understanding. Oh, for the covering

physician?

UNIDENTIFIED SPEAKER: Yeah. The physician, I think we decided on six months, not three.

DR. ACKERMAN: Can we just say, "a physician"?

UNIDENTIFIED SPEAKER: The covering physician.

CHAIRMAN ROMANELLO: C is patient visits and the quarterly evaluations.

DR. ACKERMAN: The physician or covering physician.

UNIDENTIFIED SPEAKER: Right.

DR. DERICK: Can we just carry over the language that we did --

CHAIRMAN ROMANELLO: So Dr. Derick is making a motion to carry over that language from the informed consent.

DR. ACKERMAN: Second.

CHAIRMAN ROMANELLO: Second by Dr. Ackerman. All in favor?

(Unanimous ayes)

Opposed?

Carries. Any other questions or proposed changes to the rule?

DR. BENSON: I do have a question on Bates 295. There's "A board approved informed consent form is not executed until" -- and then there's A, B, C, D. When we have like studies with children, we often have a parent permission form which is a consent form, and we actually are mandated a lot of times by the IRB to make a different ascent form that's usually one page or less that is in like very basic -- you know, very simple, basic language.

I'm just curious why do they have us do -- what does it mean when you say, "Assent to the informed consent form"? This isn't -- because we have the parents' permission to do it. It's just the kid signing their signature on the form, that's what you mean by that?

ATTORNEY MCNULTY: Yes. And that's what you just did in the forms.

DR. BENSON: Okay. Yeah. I understand that, I'm just -- it's not typical. It's not typically done that way.

DR. ACKERMAN: Well, what do you typically do?

DR. BENSON: We have like a separate assent form for a child under 12.

DR. ACKERMAN: Okay. They don't sign it.

But this is different. This is much more --

DR. BENSON: Yeah. This is different. And then the witness, is that a pretty standard thing, too?

ATTORNEY MCNULTY: Well, this is -- the medical boards have two other informed consent forms by rule, and each of those have a witness to it. It could be anybody, of course, and I didn't -- we thought we would just put it in there, just if you wanted to be consistent with what you have done in the past. Doesn't mean you have to do that. It's easier to take it out if you don't want it, but that's just been done for the other informed consent for the cataract surgery and medical marijuana forms.

DR. BENSON: I think it's good to be consistent. I mean, I don't have a problem with it.

DR. DI PIETRO: Yeah. I mean, every consent I've ever seen in the hospital has a witness, so --

CHAIRMAN ROMANELLO: Anything else?

We're going to move on to the adult rule.

DR. ACKERMAN: 323.

CHAIRMAN ROMANELLO: Thank you, Dr. Ackerman. At Bates 323. I'll ask board counsel

if they have any technical modifications that they want to propose?

ATTORNEY DIERLAM: We do not.

CHAIRMAN ROMANELLO: Thank you.

Committee members?

DR. ACKERMAN: And 30,000-foot view of this again, like I did before --

CHAIRMAN ROMANELLO: Yep.

DR. ACKERMAN: -- was for adults. They don't already have to be in the program. They can be an adult who wants to undergo sex reassignment healthcare can, by statute, and this is just saying that they -- in order to do that, you have to have appropriate informed consent.

UNIDENTIFIED SPEAKER: Required by statute.

DR. ACKERMAN: Or what's that?

UNIDENTIFIED SPEAKER: I said which is required by statute.

DR. ACKERMAN: Which is required by statute.

CHAIRMAN ROMANELLO: Any other observations or proposed modifications to rule --

DR. ACKERMAN: And what this effects is those adults who are already in the program that want to modify their drugs, need to make sure this

-- this form needs to be signed before the drugs or surgery can happen. So there's adults in Florida right now whose surgery has been canceled because this form does not exist. And so it's imperative that we get this form out, so those people can have the surgery as they want to.

CHAIRMAN ROMANELLO: Okay. If there is nothing else on the rule, we're going to start the public comment portion of the meeting. I want to start -- we're going to start by asking those members of the public who have specific observations or comments on those questions that the committee had during its conversation about the consent forms and the rules. So we talked about experiences with respect to oral testosterone, and we talked about other drugs who I'm going to botch the pronunciation of, but Dr. Ackerman has the --

DR. ACKERMAN: And during the break, I went out into the audience for a little bit --

CHAIRMAN ROMANELLO: Yep.

DR. ACKERMAN: -- and shared with them, because -- to kind of clarify with them the four issues that I remembered that had come up. There was a fifth one. What was the fifth one that someone said?

CHAIRMAN ROMANELLO: I had four.

DR. ACKERMAN: Right. And so I think some of them -- help me. Who was speaking to me? Someone wanted to -- you, come on up a second.

CHAIRMAN ROMANELLO: So as we start to do that, we're going to ask folks to come up to the microphone and state your name. You'll be granted the opportunity to comment up to three minutes.

DR. ACKERMAN: The four things we wanted to know about was --

CHAIRMAN ROMANELLO: Asking you to speak on the rule or on those issues that we've solicited comment on. Any comments that are outside the rule or outside those items will be considered out of order. And there may be a risk of forfeiting your time if you make a public comment that is out of order.

I've got to emphasize that folks who misuse their allocated time to disrupt the proceedings will be deemed out of order and risk being asked to leave. I appreciate the group's cooperation in helping us to maintain a respectful and constructive environment during the public comment section of the meeting.

So with that --

DR. ACKERMAN: Let me just say the four things again for them.

CHAIRMAN ROMANELLO: Please.

DR. ACKERMAN: So the first one is, is there widespread use or any use of testosterone in oral form?

The second question that we had -- and endocrinologists help me if I misstate any of this -- is there use of Bicalutamide, Casodex, in the pediatric population?

The fourth question is, is there use of Finasteride, also more commonly known as Proscar -- that's for hair loss -- in the male pattern baldness in the pediatric population.

CHAIRMAN ROMANELLO: Oh, that's right. Yeah.

DR. ACKERMAN: And the fifth -- the fourth thing was, there was a drug here -- and help me with the -- it was a masculinizing drug, right?

UNIDENTIFIED SPEAKER: Cyproterone acetate.

DR. ACKERMAN: That's a masculinizing drug?

DR. BENSON: Yeah. It -- no. It's a drug that it's very similar to 17-hydroxyprogesterone, which is one of the adrenal steroids that basically binds the androgen receptor in competition with

testosterone and dihydrotestosterone.

DR. ACKERMAN: Oh, it's used for feminizing.

DR. BENSON: Yes.

DR. ACKERMAN: I'm sorry. So it's Cyproterone acetate, and apparently, it's not available in the United States, so we're questioning is there use of this? Is it being prescribed by physicians, or is it just being recommended by physicians?

And was there another thing, Dr. Derick?

DR. BENSON: I think it was just four.

DR. ACKERMAN: Just those four. Okay.

CHAIRMAN ROMANELLO: All right. And so with that, you're recognized.

KATIE DANEHY-SAMITZ: Thank you. Thank you for your time. Katie Danehy-Samitz, vice president/founder of Women's Voices of Southwest Florida. I'm sorry, I'm a little confused. I'm not a doctor, I'm an activist. I know that, you know, we're the one that -- to, I guess, get you to come out from behind and answer those questions. But I have nothing to offer this part of the conversation and in lieu and consideration of the people behind me that have this experience may have answers. And

the fact that we turned out -- like we filled out forms for this, I'm just a little confused by like the proceedings. So for this question, should people be getting in line to speak?

CHAIRMAN ROMANELLO: Do you have a comment that you would like to make about the rule?

KATIE DANEHY-SAMITZ: No, no. I was confused about why I was called up.

CHAIRMAN ROMANELLO: Thank you.

Is there anybody who would like to make a comment on the rule? Come up to the microphone, please.

ANDRE MONTANEZ: My name is Andre Montanez (phonetic). I am part of -- coming from Orlando Heart Community Center. I am also part of the Women's Voices of South Florida, and Equality Florida. I was just a little confused when we had the cards. So I want to explain something about the rule, but you just asked question about the medicines. I can tell that by my own experience, but I'm not a doctor. But I was thinking here we have the right to speak like we do with common cards.

But anyway, you want to know about the Finasteride, you had mentioned that one. Yeah.

That medicine is given to us for -- it's prescribed. I was prescribed from the nurse practitioner I have that. I hope that they can keep doing the prescription because they really know about what they're doing. And I received Finasteride as a testosterone blocker.

They had another one, it's (indiscernible). I'm sorry. I don't know doctors, so I don't know the names. But because I suffer a little bit of blood pressure. They don't want to combine that because I've got my own -- my medicine for blood pressure. So they decide to give me Finasteride, and really my -- sorry, my testosterone came and really blocked that until I got my Estradiol. I just started with pills in estradiol. And they working really good for more than five years. Now I have to do an injection. I don't have anymore the Finasteride because I don't need it. My levels of testosterone are low.

I also did a surgery. (Indiscernible). How we surviving this because (indiscernible). And I got something that's like -- like the real -- you know, the medical name (indiscernible). And I did that and so my testosterone is coming totally down, so I need Estradiol to survive.

And yes, they check my blood test every three months because it's part of the -- every year they do every kind of exam. Like every single year (indiscernible). So I don't know -- I don't want to go why they -- this is complication with this (indiscernible).

I don't know, you cannot change the life right now, but we still need the nurse practitioner to do this because they really know what they do. I think you're doctors, and you -- my cardiologist that was before my transition, I was there, and normally the nurse practitioner doing everything to me. And another doctor trusting the nurse practitioner. So I don't you can get us opportunity in this emergency rule that we can use our prescription from nurse practitioner.

I was denied my prescription last week in Walgreens, like Walgreen pharmacy, because I don't follow your rules. Because you get the rules, it's still valid, and I had to fight with them to prove the Board of Medicine give the emergency whatever if it's signed before May 16th -- maybe I confused the date --

DR. ACKERMAN: May 17th.

ANDRE MONTANEZ: I can have my medicine.

So please do that because we need these not have more confusions everywhere. I really want to be alive and continuing my life as a human like everybody.

DR. ACKERMAN: So hold on, don't leave. The question --

CHAIRMAN ROMANELLO: Thank you for your comment. I appreciate it.

Dr. Ackerman, we're not going to go back and forth with questions.

DR. ACKERMAN: Can I ask him a question?

CHAIRMAN ROMANELLO: No, go ahead.

DR. ACKERMAN: Because this is about Finasteride.

ANDRE MONTANEZ: Yes, please.

DR. ACKERMAN: So did you receive Finasteride as a minor?

ANDRE MONTANEZ: No.

DR. ACKERMAN: Okay.

ANDRE MONTANEZ: Because you don't have me -- no. Because I started my transition older one in the 90s. In the 80s, when I was younger, unfortunately, we didn't have the opportunity that kids have to save the life. Unfortunately, they don't have in my time.

DR. ACKERMAN: I'm sorry, you started your transition as an adult or a minor?

ANDRE MONTANEZ: Yes, as an adult.

DR. ACKERMAN: Adult, okay. Thank you.

ANDRE MONTANEZ: Thank you.

DR. MORTENSEN: I have a question.

CHAIRMAN ROMANELLO: Yep.

DR. MORTENSEN: There was testimony last time that I think someone had quoted 80 percent of all the transgender care was being performed by nurse practitioners. So I know by statute, the initial visit has to be done by a physician. So I think that was the point that's being made. It would be interesting to know, in general, like how many people that are on these treatments have never seen a physician.

CHAIRMAN ROMANELLO: I agree. Yeah.

So I can I also call up to the microphone -- and forgive me if I don't get the names pronounced rightly -- is -- ma'am, you can stay -- Vanessa Galindo-Jackson, Dean Price, and Erica Imaoka.

Ma'am.

EMA ROY: Hi. I'm Ema Roy (phonetic). You asked people to come forward about Cyproterone

acetate, and I was prescribed Cyproterone acetate as a child. I was prescribed it as gender affirming therapy. I'm a cis female. I had polycystic ovarian disease that was chronic. I need eight abdominal surgeries to remove cysts even with the medication. So yes, I took Cyproterone acetate. It's an anti-androgen because I had so much male testosterone in my body.

I'm coming forward to say that because based on the consent today that 500 pages that my child read last night, I wouldn't have been able to get that therapy. And because of the side effects of polycystic ovarian disease, I would probably be dead from heart disease at the moment. I would not have had my two children. So not having access to that care would have been forced sterilization, and I'm delighted to have had two children.

I should have the same rights as a cis female, as transgender females. I don't know why my situation isn't in question here. I guess technically this would make me intersex. You know, you asked the audience to come forward about their experiences with these medications, and I did. But I don't know why you think that this is an appropriate forum and not at my doctor's office, or

with my gynecologist, or with my endocrinologist.

I still don't know why we're here. This is not the business of the state's governor appointed board. But yes, it helped me with polycystic ovarian disease. And by the way, I still have my other speaker card that me, like everybody else, filled out for the other parts of the 500 pages related to disability. How you want people with autism, et cetera, to be excluded. So I still want to be called for that part. Does anybody have any questions?

CHAIRMAN ROMANELLO: Thank you. I appreciate your comment and we'll call you back when we get back to your card. We'll certainly take your comments into consideration as we deliberate further this afternoon. Thank you.

EMA ROY: Thanks.

VANESSA GALINDO-JACKSON: Hello, I'm just confused. Am I allowed to speak on what I originally had intended, or can I not? Unless it --

CHAIRMAN ROMANELLO: Are you Vanessa?

VANESSA GALINDO-JACKSON: I am. Yes.

CHAIRMAN ROMANELLO: Welcome to the meeting. Appreciate it.

VANESSA GALINDO-JACKSON: I appreciate you

guys.

UNIDENTIFIED SPEAKER: The question -- just clarify, I think we're transitioning into normal comments now, right? We're not talking about the four questions.

CHAIRMAN ROMANELLO: Ma'am, you can speak about whatever you want.

VANESSA GALINDO-JACKSON: Okay. Well, first, hello. My name is Vanessa Galindo-Jackson. I'm an occupational therapy doctoral student and I take a Hippocratic oath, must like you do. So I hope as you consider your choices, that you reflect on the ethical standards that are sound and equitable decisions. Standards that I think of such as beneficence, which requires taking action to promote good, and then non-maleficence, which requires the avoidance of actions that would cause harm. Right. This is the crux of our standards, the whole do no harm.

But based on the previous board meeting and kind of some of the comments that were mentioned today about studies where individuals experience adverse effects, I feel it's important to remind you that we must work within the context of due care which states that the benefits of care outweighs and

justifies the risk in order to achieve the goal of their care. For example, we do know that chemotherapy is really hard on the body, and we know it can cause harm, but yet, it's a recommendation we make every day. And we allow our clients the freedom to choose that method. It's the power of autonomy, the freedom our clients have to choose.

Now, I understand that we are at the mercy of these atrocious bills that are already in place, but please remember that all clients we serve deserve the upmost respect and care. We take a Hippocratic oath for a reason, regardless of the laws and policies in place.

Moving forward, I challenge you, please stand up for your clients not just when it is presented to you in the face, but at all the conferences you attend, the board meetings you sit at, and so on. Please do not remain silent, as you are complicit to the pain and agony that these individuals experience. Afterall, these people are not -- you are not just making decisions for them as their patients that you serve, but they may very well be your family, your friends, and maybe, just maybe, your respected colleagues.

That's really all I have as far as this,

but I did want to bring up another point, since I have just a few more seconds. The previous speaker just mentioned about comorbidities. I was looking at your rules, and I don't know if they've been revised but it doesn't make sense to state "Does not suffer from psychological comorbidities that interfere with the diagnostic work." Why not instead maybe suggest something like, "Any psychological comorbidities might be managed or overseen by a qualified mental health practitioner," something of the sort.

CHAIRMAN ROMANELLO: Thank you. We appreciate your comments and certainly will take them into consideration as we deliberate.

So next up is Dean Price. We have Erica Imaoka. Again, apologies for the pronunciations. Calling up on deck, please, Paul Erins (phonetic), and Aaron James Clark.

DEAN PRICE: Hello. My name is Dean Price, and I was wondering if I can defer to my son? He has an appointment at 4:00 and we're going to have to leave, so in case we didn't both get called. Is that --

CHAIRMAN ROMANELLO: Sure.

DEAN PRICE: Thank you very much.

OCEAN PRICE: Hi. My name is Ocean Price (phonetic), and I am a transgender man. I am 21 years old, and I've been going -- I've been undergoing gender affirming hormone replacement therapy for two years at this point. And I have never once regretted my decision to undergo gender affirming care. I've never had any sort of major complications or side effects or anything like that. And being able to access that care was really life changing for me.

And at the beginning of the summer, I had spoken to a surgeon, and I was supposed to receive top surgery at the end of this month but unfortunately, due to the -- due to the new legislation requiring the consent forms, it ended up having to be canceled because we didn't have the consent form.

And that ended up being really disruptive to my life, and I'm sure that a lot of other people are going through similar things, as well. And so I just wanted to say that I really hope that the consent form gets done as soon as possible and that it's -- it doesn't require any -- a lot of unnecessary steps that are not medically supported before accessing treatment that we would have been

able to access anyway.

And I also did want to say -- I wanted to add a couple of other things, as well, that -- based on what you had mentioned. First of all that I'm on AndroGel. I know that had been mentioned. A big reason that's not prescribed as much is because it typically costs more.

And then I also wanted to state that I think something important to add to the consent form for testosterone, especially, is that it's not birth control. Even though it often stops menstruation it --

CHAIRMAN ROMANELLO: Ocean, in order to get everybody who wants to speak their time, we're going to have to hold everybody to three minutes, and you've exceeded that. I appreciate you coming before the committee and offering your comments. We'll certainly take them into consideration as we continue to consider the rules and the consent forms today. I appreciate your time. Thank you.

OCEAN PRICE: Okay. Thank you.

DR. ACKERMAN: Just to clarify, these consent forms should be all good to go in a week, right?

CHAIRMAN ROMANELLO: We're going to come

back next week, and we will consider --

DR. ACKERMAN: Assuming things go as planned.

CHAIRMAN ROMANELLO: Exactly.

ATTORNEY MCNULTY: And then after that meeting, we'll have to have time to actually file them. But with emergency rules, once they are filed with the Department of State, they are effective the day they're filed.

DR. ACKERMAN: Right. So for those of you that care, 10 days, 2 weeks from now, it should all be filed and good to go.

CHAIRMAN ROMANELLO: So we should have Erica, Paul, Aaron, and then calling up Seneca Bristol Manatee, I think -- and again, forgive me for the pronunciations.

Ma'am, you're recognized.

ERICA IMAOKA: Hi, I'm Erica Imaoka. Not too shabby on the name pronunciation. I'm an advance practice nurse here in Florida. I work for Folx Health providing telehealth gender affirming care. I don't prescribe oral testosterone. We don't at Folx, it's not part of our protocol.

But my question, I guess -- well, I know, actually, you can't go back and forth. But I guess

my comment would be then, A, I didn't get clarification, I don't think, on like the DEXA scans for adult, what time would require that. If it's immediately after starting hormone therapy or if that's going to be only post operatively, or what that recommendation or requirement would be.

And also, if the consent form -- and I'm sorry if it's in there, but I didn't get to read it -- includes the opportunity for advance practice nurses to continue care and only the prescribing portion outside of the informed consent is done by physicians. We didn't really have physicians doing care at Folx. We do now to meet the requirements of the statute.

But many of advance practice nurses want to continue to see our patients, so just wanting to get clarification if it will be in the informed consent that they can still receive care by advance practitioners and only particular parts are required by the physicians.

CHAIRMAN ROMANELLO: Yeah. So our rule is for physicians and physician's assistance. That's who we have jurisdiction over. It's the Board of Nursing that would have jurisdiction over nurses and --

ERICA IMAOKA: And so the consent form is specific only to getting the initial informed consent in person, not any other part of their care; is that correct?

DR. ACKERMAN: Right.

ATTORNEY MCNULTY: Or if they -- separate consent is required for any new prescription for a product that they haven't taken before.

CHAIRMAN ROMANELLO: Right.

ATTORNEY MCNULTY: So if they switch drugs. But like Mr. Romanello said, this is for -- you know, you've got the statutory requirement. If you have questions regarding the statutory interpretation you need to seek the advice of legal counsel.

ERICA IMAOKA: Okay. Thank you.

DR. ACKERMAN: And surgery needs its own form. So there's three consent forms, hormone blocking, masculinization versus feminization, and then surgery. They all have a consent form.

CHAIRMAN ROMANELLO: Thank you, Ms. Imaoka. I appreciate it.

ERICA IMAOKA: So was the DEXA scan requirement included in the adult form?

ATTORNEY MCNULTY: It's required -- it's in

all the forms.

ERICA IMAOKA: And that's for five years annually after starting therapy?

DR. ACKERMAN: Yes. Yes. Five years, annually, and then PRN -- as needed.

CHAIRMAN ROMANELLO: If Dr. Aaron is -- we have Aaron James Clark, Seneca Bristol Manatee, and then asking John Harris Maurer up to the microphone.

PAUL ERINS: Good afternoon, members of the board. My name is Paul Erins; I live in Tallahassee, and I'm a physician retired from the Florida Department of Health where I was the medical director for the HIV/AIDS program for 18 years. And also, from 2001 to 2005 I was chair of the Department of Health Institutional Review Board, the IRB. So I've evaluated a lot of consent forms. I've got five points I wish to make.

The form states, "I know enough to give informed consent to take, refuse, or postpone taking these medications." But there's no information if stopped about whether the medications need to be tapered, or what physical or mental changes are likely to occur. There needs to be added information about the pros and cons of de-transitioning and what is necessary for stopping

safely.

Secondly, the form states that the medication is off-label, not approved for this use by the FDA. I think it's only fair to add, "But it has been used effectively to treat gender dysphoria for decades by licensed, reputable clinicians who specialize in gender affirming care." Otherwise, this is not fully informed consent.

Third, for a patient whose primary language is not English, the interpreter certifies as the end that they are "fluid in English." In this setting, especially, fluid needs to be changed to fluent, f-l-u-e-n-t.

CHAIRMAN ROMANELLO: Good catch.

PAUL ERINS: Next, I realize these are emergency consents, but they are just not ready for prime time. I ask you please to workshop them further before publishing, with representative gender diverse individuals, with specialist docs. And I think your questions this afternoon have reflected the need for that. And in consultation with the Florida Bioethics Network whose MD/PhD cochairs are at the University of Miami and the University of Florida.

And finally, since the Florida statute and

Medical Board now officially recognize the validity of full spectrum gender dysphoria care for adults with informed consent and at least continuing medication treatment for minors with parental consent and assent, I urge you by formal resolution to add your voice to that of the courts in advocating for Medicaid reimbursement for such care for an estimated 9000 Floridians who are otherwise losing coverage. And I think you for the opportunity to testify.

CHAIRMAN ROMANELLO: Thank you for your comments. We'll take them into consideration as we deliberate these rules.

Aaron James Clark, Seneca Bristol, John Maurer, and Jessica Wilson (phonetic).

You're recognized.

AARON JAMES CLARK: Good afternoon, members of the board. My name is Aaron James Clark. I am the former treasurer of Rainbow Democrats. Recently, I resigned from my position because as a transgender man, I would like to transition, and I can no longer do that. I'm going to have to move in order to get the care that I need.

Also, on the topic of comorbidities, I have been chronically ill for my entire life. I was born

sick. And I really would urge you to consider to please have separate psychological and medical management for individual cases that are going under the gender dysphoria comorbidity umbrella. I also would like to -- if I am allowed to -- someone on the board had mentioned the Dutch study. I have the data in my hand. Am I allowed to present that in brief to you?

CHAIRMAN ROMANELLO: If you have -- if you want to make a public comment, this is the opportunity to do it.

AARON JAMES CLARK: Okay. I wanted to make sure that that was okay with all of you.

CHAIRMAN ROMANELLO: Sure.

AARON JAMES CLARK: So for the 2022 Dutch study, 820,063 transmen and women were referred to the Amsterdam VU University Medical Center during the period time of 1972 to 2017. And this study does not show increased suicide rates. And specifically, by 20 times that of their peers of 10 to 15 years after reassignment, which is what I typically hear from the study.

The data shows that over a period of 45 years, which is 1972 to 2017, the suicide deaths for transwomen were about 64 of 100,000, and the suicide

deaths of transmen were 29 for 100,000. I'm sure you all are very competent at math. But the suicide rates did not increase over that period of time.

During 2013 to 2017, there was actually a decline in suicide rates for the study participants. It reached 43 over 100,000 transwomen, to 34 over 100,000 transmen. And suicide rates were found to be 3 to 4 times higher than the average population.

CHAIRMAN ROMANELLO: Aaron, thank you for your comments. We've got to -- in order to get to as many people as we can --

AARON JAMES CLARK: No, you're fine. But that's basically what the gist is, so --

CHAIRMAN ROMANELLO: Thank you. Appreciate your comments.

SENECA BRISTOL: Hello. I'm Seneca Bristol. Manatee is my county. I'm the vice president of the U Chapter of Women's Voice of Southwest Florida. Let's get something right. Everything you're spreading is just misinformation. This isn't to protect children, this isn't to protect anybody. But you know what real information has shown? According to HCP, suicide risks reduce by 70 percent in transgender, nonbinary, et cetera, youth and young adults when gender affirming care is

accessible.

According to --

CHAIRMAN ROMANELLO: Ms. Bristol, do you have any comments related to the rules or the informed consents that we've been discussing all afternoon?

SENECA BRISTOL: Yes. I mean, I'm just trying to give you all information. I'm trying to, you know, help you all.

CHAIRMAN ROMANELLO: Do you have comments related to the informed consents or the rules that we've discussed this afternoon?

SENECA BRISTOL: Am I not doing that? Yes.

CHAIRMAN ROMANELLO: Could you make those comments then, please.

SENECA BRISTOL: Okay. Yeah. According to National Library of Medicine, it is shown that 82 percent of transgender folks have considered killing themselves, and 41 percent have attempted suicide. If you take this away, kids will kill themselves. Okay. You need to look at your guys' selves in the mirrors and realize the truth. And respectfully, but not really, you need to put your white hoods on and stop choking up lies and tell people the truth. You want the trans community to be wiped out like

the Nazis. The only difference is --

CHAIRMAN ROMANELLO: You're out of order, Ms. Bristol.

DR. ACKERMAN: I want to make sure I understand --

CHAIRMAN ROMANELLO: Mr. Maurer.

DR. ACKERMAN: -- we're putting forth the consent form --

CHAIRMAN ROMANELLO: No. Mr. Maurer is up. We're going to have Jessica Wilson followed by Chels Davis, I think is the name. Again, sorry for the pronunciations. Followed by Monica DePaul (phonetic).

JOHN HARRIS MAURER: Good afternoon, joint committee. My name is John Harris Maurer and I represent Equality Florida, the state's largest civil right organization dedicated to securing full LGBTQ equality. Respectfully, the proposed consent forms are rife with incorrect and misleading information and exceed the board's delegated rulemaking authority. Equality Florida appreciates that these forms must be finalized and adopted urgently because the state legislature has created a crisis of care for transgender Floridians, but this product is insufficient.

The proposed rule and forms include multiple substantive burdensome new requirements and stipulations that the legislature never adopted or approved. They impose undue and costly barriers to care that are not about individualized assessment and care.

With respect to adults' care in particular, this is not an informed consent form. This is an end run to create a new and unduly restrictive standard of care. The legislature only required these boards to adopt adult informed consent forms that "inform the patient of the nature and risks in order for a patient to make a prudent decision." Yet, here are multiple examples of new "specific requirements" for individuals to receive and continue HRT treatment that are not informational or on the nature and risks.

"The patient must be the criteria for gender dysphoria. Gender dysphoria must be marked and sustained. Patients may not suffer from certain psychological comorbidities. Patients must have adequate psychological and social support during treatment. Mandatory evaluation by the treating physician every three months. Mandatory suicide assessment by a licensed medical care professional

every three months. Mandatory lab testing every six months. Mandatory annual bone density scanning. Mandatory mental health assessment by a board certified, Florida licensed psychiatrist or psychologist. And mandatory continued counseling with a licensed mental health care professional." This exceeds the board's authority and is likely to lead to another lawsuit like the one recently rejecting board rules.

The forms and process for minors similarly suffer from misinformation and undue additional burdens like a prohibition on delegating responsibility for obtaining informed consent and requiring additional witness signature. These are about creating new burdens to care and not about patient well-being.

The forms require more input from experts with deep expertise in providing gender affirming care. There are simply too many inaccuracies or inconsistencies. Like meeting the requirement for gender dysphoria to continuing care, when alleving that gender dysphoria is the purpose of being and staying in care. Or referring to medication that's not even available in the United States as we've already talked about. Please revise these forms

with input from proper experts with the urgency required by these state-imposed circumstances.

I'll also add, please do check the records. I don't believe a motion was adopted on changing the DEXA scan frequency for adult testing, if that will be revisited. And also, the adult's regular evaluation risk assessment requirement should be based around induction and not just a change in physicians.

We have adults who have been thriving in care for years, potentially more than decades. The fact that they may have to change physicians because our providers are leaving the state because of the state legislature isn't a reason that those adults should have to subject to quarterly testing just because they're changing provider. Please revise the rules and take that into consideration.

CHAIRMAN ROMANELLO: Thank you for the observations. We'll follow up on those as we deliberate further this afternoon.

JESSICA WILSON: Hi, good afternoon. My name is Jessica Wilson, and I am here as a mom of a trans son. The legislators' only requirement -- I understand you're mandated to create these forms. The legislators' only requirement, however,

restricting trans adults from receiving care was that they see a doctor instead of a nurse practitioner, and that they sign informed consent forms while in that doctor's presence saying that they understand what the gender affirming care will do. There is nothing in the statute that requires blocking access to those with comorbidities or psychiatric conditions.

I shared in previous Board of Medicine meetings that my son has mental health diagnoses and tried to end his life at least once. At least once that I know of. And one of his many hospitalizations resulted in a gender dysphoria diagnosis at age 13. He has undergone years of therapy and started testosterone last year. Since beginning his medical transition, thoughts of suicide have greatly diminished. He's thriving, successfully employed, and a wonderful, attentive dad to my granddaughter. His mental health diagnoses have not gone away though.

If you proceed with blocking access to those with psychological comorbidities, you will be taking away life saving healthcare from adults who need HRT to live. This was supposed to be about protecting the kids but what you are proposing is

going to erase the trans population from Florida. Many of those who can leave, are leaving. Many already have. You at the board are overstepping the already egregious law by establishing additional barriers above and beyond what the statute requires. These forms are not informed consent forms. They are new requirements which are not outlined by the law. It's a massive overreach by the boards. Stop playing politics and do the job you're actually mandated to do.

CHAIRMAN ROMANELLO: Thank you. Appreciate the comment.

Calling up to the line Lucina Fenner (phonetic), Stephen Esocough (phonetic), and Felix Proia (phonetic). And thank you for spelling out, Mr. Proia, the pronunciation of your name.

CHELS DAVIS: Good afternoon, my name is Chels Davis. I'm a school counselor at the secondary level. So I specialize in caring for adolescents in the academic, career, and social emotional aspects of their lives. My job is to get my students graduated, help them explore career options, and to help them reach adulthood alive.

This last point has become more difficult this past year, and that's why I've come to speak

with you. I need your help to do my job well. School counselors and medical professionals both live, eat, and breath Maslow's Hierarch of Needs, so please hear me when I say transgender kids don't feel safe in Florida. There is a foundational need going unmet at a state level. This past year has left our most vulnerable Floridians shaken.

CHAIRMAN ROMANELLO: Ms. Davis, the purpose of today's hearing is to talk about informed consent forms that we've developed, and rules that we've been tasked to do. I'm certainly happy to hear those observations and comments with respect to the rules.

CHELS DAVIS: Yes, sir. I was just building up, sorry. Dr. Benson mentioned the risk of suicide in transgender minors. I am compelled to add clarification to that conversation specifically. With transgender people, adults and children alike, their level of suicidality is directly related to their level of perceived support, their sense of safety. This is from external forces, not internal. When they feel supported by their family, when they feel supported in their community, they don't want to die. When they don't feel supported, they are more likely to kill themselves. That's what we're

all trying to avoid here, and I think that's something we have in common.

A family's support for their transgender child is lifesaving and insulates the child from suicidality. A transgender person having a practical path to medical transition in their community is similarly lifesaving. We're talking about access. Please help me keep these kids safe, help me keep them alive.

We need straight-forward caring rules. Care in this state has had a major interruption, as we've noted, and that is dangerous. It would be wrong to implement rules which needlessly hinder access to lifesaving medical care. Unethical hinderances only endanger lives. WPATH, the World Professional Association for Transgender Health, standards have existed for decades. Those standards are a robust and valid reference, but I only heard them mentioned once in this conversation. Please consider the proposed rules carefully and to give our vulnerable populations the accessible care they need. Thank you very much.

CHAIRMAN ROMANELLO: Thank you.

MONICA DEPAUL: Hi. I'm Monica DePaul. I'm an English teacher; I also happen to be trans.

There's a lot of talk about studies over here. Let me tell you, it took me five minutes to look on Google and find a study showing that trans kids are happier after they transition. It wasn't hard. It was in the Journal of the American Medical Association. So I noticed that none of the studies that you all were talking about seemed to have any citations with them. So I'm just going to assume it came from some talking had on Fox News.

Now, I noticed that you included the language of "subtle improvements" as sort of like the only positive thing that would occur. That is, to put it lightly, BS. Mainly because, I mean, I have been on hormones for 10 years. When I meet new people, they don't even know I'm trans. Usually, I don't even have to mention it because why? The amount of improvements that I have experienced are far more than just subtle. Before I transitioned, I had this brain fog that is gone now. I can actually think. I can actually be myself. I don't have to pretend to be someone else. That is not a subtle improvement.

And now, here you are telling me that I have to change my doctor, I have to go through all of this, I have to sign an informed consent form

that has just lies on it. Lies. You all are lying. That I have to agree to that despite me having been doing this for 10 years. And only now is it suddenly a problem. Only now is this suddenly that I have to agree to all of this. We all know why. It's because one man wants to be President and none of you are willing to argue with him.

I knew I was a girl when I was nine, and this is back in the '90s. I knew who I was. Now, granted in the '90s, it would have been impossible for a kid to get gender affirming care, and my parents would never have taken me seriously.

On the matter of comorbidities, my ADHD has nothing to do with my transition, at all. Those are two very separate matters. And if you're going to prevent people from accessing gender affirming care because they have other like mental issues, honestly, that's pretty fucked up.

CHAIRMAN ROMANELLO: You're out of order. We're not going to accept that sort of language.

MONICA DEPAUL: You're all out of order.

CHAIRMAN ROMANELLO: Thank you. Next up is Lucina Fenner. Esocough on deck, Proia. And calling up Lola Smith.

ESOCOUGH: This is Esocough. I don't know

where Fenner is.

CHAIRMAN ROMANELLO: Okay.

ESOCOUGH: This is just my honest reaction hearing the restrictions or hurdles that have been inserted into this informed consent. It is government overreach. It is being perpetrated against one of the most targeted communities that we are in need of protecting. You aren't protecting anyone. What child whose parents and doctors are not already informed enough to do the work to make sure they're getting the care they need, what adult whose doctor in tandem with that adult are not able to decide what care they need? What additional safeguards are you putting in here that is genuinely protecting anyone who doesn't have a medical professional by their side?

You are limiting access and sensationalizing a lifesaving treatment that has been around for decades. It's been around since the '30s. There was a body of knowledge that was destroyed by a particular group that we would be referencing today if only that group had not been so adamantly anti-trans. Because of that kind of bigotry that has infected this state, and possibly even this body, Americans will be harmed. Do the

right thing. Thank you.

CHAIRMAN ROMANELLO: Felix Proia, Lola Smith, and Brandy Scappalis (phonetic).

FELIX PROIA: Good afternoon. Thank you for coming to South Georgia, aka Northeast Florida, and providing me the opportunity to provide comment. My name is Felix Proia, and my pronouns are they and them. I live and work in Duval County as a school psychologist and I receive gender affirming care.

I cried tears of joy when I booked my first appointment, feeling more empowered and cared for than other. I am livid that the new prescriptions and procedures are on hold until a consent form is approved by this board. And taking this moment to then put further rules is overreaching and harmful.

I am an adult living a life and this new consent form that is what I'm hearing today is overreaching from what the state had already put on adults. I will consent to my care with a physician, and I am an adult living a life that will be impacted by these proposed restrictions to my care. But what choice am I left with? I ask you to consider my freedom from government oversight for personal decisions.

This is my medication. It's medicine. The

discussion about my medical care should not be by a governor-appointed board, it should be between my doctor, and that's it. Being transgender is beautiful. There is nothing inherently dangerous about being transgender. I have gender euphoria, I do not have gender dysphoria. And maybe that's going to preclude me from getting care because of the consent form that is being proposed. I will consent to gender affirming care with a doctor. I believe these forms are just wrong, wrong, wrong. Thank you.

CHAIRMAN ROMANELLO: Thank you for your comment. We appreciate it.

Lola Smith, Brandy Scappalis, and Madison Natalya Hilt (phonetic).

LOLA SMITH: My name is Lola Smith. I'm 12 years old and I am nonbinary. And I am here today with Women's Voices of Southwest Florida. You've been speaking an awful lot lately about staying within the scope. Our comments don't count nor matter if they are not within the scope of what you deem the subject is at hand. Yet, the rules and steps you have laid out for the transgender adults seeking treatment also do not consider the scope.

These hurdles you have created for folks

seeking care are beyond the financial and personal scopes of many of the people required to fulfil them. People have jobs, families, and commitments. By demanding they commit so many hours and finances to these continuous and unnecessary reviews, you are ensuring many individuals will never receive the care they need.

In creating an impossible road to care, you are all participating in the active genocide of transpeople here in Florida. Stop trying to paint what you are doing as compassion or a compromise. You cannot put a flower in an asshole and call it a vase. Thank you.

CHAIRMAN ROMANELLO: Brandy Scappalis, Madison Natalya Hilt, and Julie Mench (phonetic).

BRANDY SCAPPALIS: I am Brandy Scappalis. I'm here today both as a social worker, PhD student who has spent the last two years researching this, reading all of the medical and mental health literature, as well as someone who has been receiving gender affirming care for over five years.

I wanted to comment on three main things. Number one, several of the things on here are new substantially burdensome requirements that are not part of standard practice in providing or assessing

gender affirming care needs. And that includes the x-rays, the bone density scan requirements, as well as some of the -- like the annual mental health assessments and suicide risk assessments. Those will impose substantial financial burdens on patients, and it will also impact insurance companies when they cover this.

My employer provided health insurance. The cost for a bone density scan, for just a copay would be $300. And that requirement for anyone is a substantial burden on finances if it's an annual requirement even for only five years. That's a substantial amount of money.

Additionally, I wanted to comment on item three on the informed consent form that gender dysphoria be marked and sustained. The purpose of gender affirming care is to alleve gender dysphoria. So someone who is being properly treated for gender dysphoria will no longer have marked and sustained gender dysphoria because of that treatment. Therefore, that is only valid for the initial assessment. After that, the goal is to see the reduction of gender dysphoria as a result of treatment.

And finally, I noticed that the forms

considered today don't include consent for surgery. These are hormone treatment forms. Many people have already been denied access to surgeries that were already planned prior to the passage of the bill, and we definitely need surgical informed consent forms as well. Thank you.

CHAIRMAN ROMANELLO: Thank you for your comment.

MADISON HILT: Hello, Board. Madison Hilt; I'm from Clay County, Florida. The real issues that I have with the proposed informed consent forms, really numbers 5 and 13 are my biggest issues. Number 5 stating that we can't have any mental health comorbidities. That's kind of like a cat chasing its own tail, right. When somebody has gender dysphoria, one of the biggest things that affects them is depression and increased suicidal ideation. We know this. It's been demonstrated in multiple studies, multiple peer reviewed studies. And as a matter of fact, it's listed in the Endocrine Society positional statement and their standards of care that was cited in this rulemaking session.

Removing that care from people with any kind of psychological comorbidity is going to just

increase their suicidality exponentially. I would -- I mean, I know it's pretty obvious I'm not a doctor, but I have been involved with medicine for quite a while. My father was chronically sick, I'm chronically sick, so on, Type I diabetes.

Anyway, that provision is going to just make people hurt themselves even more. I would highly suggest that you all follow the other guidelines that are in the Endocrine Society's, which are pretty conservative guidelines for the treatment of transpeople. It says that you all need to have a multi-module approach with a team of physicians. It does not say that you need to exclude people if they have a mental health issue. Because studies have shown that suicidality upticks, rather than goes down, if they lose that.

And number 13, a psychologist or a psychiatrist having to assess once a year. That's a bit burdensome when only 10 to 12 percent of the mental health practitioners in the state of Florida are psychologists or psychiatrists and your LMHCs and LCSWs are way better trained in a lot of cases at treating gender dysphoria because there's a lot of them that specialize in it.

Effectively, what this is going to be is if

you all pass this as it's stated right now is it's going to be a ban on care for trans adults. Because this is almost the same exact language that they used in Missouri. So you're going to see the courts strike it down. We're going to be back here doing this whole song and dance again. You all just follow the Endocrine Society standards. Just for one second think about the Hippocratic oath, care about your patients, and show the trans Floridians in this room that you want to help them, not make rules that are going to cause them to leave or hurt themselves. Thank you.

CHAIRMAN ROMANELLO: Hey, thank you for the comments. They were helpful and I appreciate them, really.

Julie Mench, Max Fenning (phonetic) -- who has exceptional penmanship -- and Bryce Hackmeyer (phonetic).

JULIE MENCH: Hello. Julie Mench. So one thing that has struck me this entire time listening, other than the willful misquoting of studies and seemingly apparent lack of knowledge of the topic that you were here to discuss, is your absolute, you know, dismissal of any positive outcome of gender affirming care.

Now, you can look behind me and I can show you a room full of people that will tell you that gender affirming care is lifechanging and a wonderful thing. Our lives have only been made better by gender affirming care, which has been, you know, regulated and a practice for -- like they said, since the '30s, with Christine Jorgensen being one of the first Americans to undergo transgender reassignment. And there was no reason for these bills, these laws. Medically, there weren't. Politically, well, we all know the answer to that.

So I really am just horrified to see that everything has just been a negative comment about gender affirming care from this board that is tasked with making ruling on gender affirming care.

And speaking on the comorbidities of mental health. Imagine going to a doctor, "Oh, hi. I'm sorry, You have a glioblastoma. It might be operable but it's fatal if we don't. But you seem to be really depressed about this, so let's give you six months of mental counseling to get rid of your depression before we can get rid of your tumor that is causing your depression."

You know, these things -- every tactic you're trying is just saying you're deliberately

trying to block gender affirming care. You know, it's not inapparent to us. We are very aware that, you know, nobody on this board seems to be pro gender affirming care despite the overwhelming evidence, the thousands and thousands of papers saying how effective it is. Millions of people telling you how effective it is. But yet, deaf ears.

So I mean, how is one really supposed to read that? You know, as someone receiving gender affirming care, how am I supposed to respect your opinion that is so anti my existence? I would really ask you to go and ask yourselves that.

And another thing I'm going to say is that I've known many transpeople. I'm a trans activist. And I have never heard them suicidal until State Bill 254. So you are willfully causing harm with your bills and your rulings, and I want you to look into that and hold up your Hippocratic oath. Thank you. I seed the rest of my time.

CHAIRMAN ROMANELLO: Thank you.

Max Fenning, Bryce Hackmeyer, and Kit M. (phonetic), followed by Omar Martinez (phonetic).

MAX FENNING: Hello and thank you for complimenting my impeccable handwriting. Hello, my

name is Max Fenning, and I am the president of Prism, a youth-led nonprofit that works to expand access to LGBT inclusive education and sexual health resources for young people in South Florida.

As someone who works closely with trans youth, I know the impact that gender affirming care can have. Trans healthcare including puberty blockers and hormone replacement therapy is safe, well-tested, and most importantly, lifesaving. Gender dysphoria can be debilitating. Transgender youth are twice as likely to attempt suicide as their cis gender peers, but suicidality drops sharply when gender affirming care is paired with an affirming and accepting environment. That's why almost every major medical association has formed a clear consensus that gender affirming care can lead to positive outcomes for trans youth.

And not only that, the proposed informed consent forms for both minors and adults is an egregious obstacle course of hurdles and fiery hoops to jump through. So while I appreciate the efforts today to temper some of those restrictions in discussion, this is still not reasonable informed consent. It's a process that represents a culmination of months of fear mongering and

dehumanization of transpeople of all ages and all backgrounds, and our state diluting transpeople's humanity to a political agenda of woke indoctrination.

But transness is not a political agenda. LGBTQ people do not want our lives, our bodies, and who we love politicized. It should be the decision between a child and their parents, or an adult patient and their doctor. Trans healthcare saves lives and it's why we've seen several injunctions against both your rulemaking as a board and several components of SB254, the legislation that necessitated this process today.

I urge you to reconsider some of the most cumbersome components of these informed consent forms, especially those that exclude folks with other mental health diagnoses, to ensure access to this care for all transpeople who need it in our state. Thank you for your time.

CHAIRMAN ROMANELLO: Thank you, Max.

BRYCE HACKMEYER: Sorry, I'm in heels. Hi, my name is Bryce Hackmeyer and I'm the health and technology director of Women's Voices of Southwest Florida and cofounder of the Justice Advocacy Network.

First of all, I'd like to remind the boards that the Florida State Legislature in its drafting of SB254 utilized arguments from both the Florida Boards of Medicine and Osteopathic Medicine as well as from the Florida Agency for Healthcare Administration, AHCA.

The claims made by the surgeon general and AHCA which triggered the board's rulemaking on gender affirming care in the first place back in August of 2021, had been debunked -- or 2022, excuse me -- have been debunked extensively in court. See Dekker v Weida, which I have already submitted to the public record, as politically motivated and discriminatory. I have many concerns regarding the requirements for continuing HRT but will only delve into a few for the interest of time.

First of all, what psychiatric comorbidities impede diagnosis and treatment of gender dysphoria? How expensive would it be to be evaluated by both a psychiatrist and/or a psychologist in order to continue HRT? Please elaborate on specific comorbidities and also research the expenses associated with such evaluations.

Second of all, I don't believe decreased

bone density is a significant side effect of testosterone HRT, but I could be wrong. There exists less costly and invasive methods to gauge bone mineral density than bone density scans, such as peripheral blood cell counts. Specifically, red blood cell, white blood cell, and platelet counts when controlled for confounding factors are positively associated with T scores, a measure of bone density.

A complete blood count differential including platelets, a routine blood test taken during physical checkups can provide this data at no extra cost to the patient. These relationships elucidate the close connection between hematopoiesis and bone formation. To those alarmed by the decreased bone formation -- or decreased bone density side effect of a particular form of HRT, I would say that calcium supplements go a long way.

All informed consent forms I've seen deliberated by these boards possess statements of bias and opinion. E.g. -- not i.e., low quality studies, purely speculative. Although you all are welcome to your personal opinions on these studies, I do not believe a consent form should contain biased statements such as these.

The Boards of Medicine are currently proposing additional restrictive and expensive hurdles on all transpeople who seek lifesaving care. These introduced requirements place undue burden, both temporarily and physically, on providers and their patients. I highly suggest that prior to the development of official and if possible, emergency consent forms members of the boards reevaluate all previous claims made regarding gender affirming care and conduct truthful scientific analysis of the vast body of research currently available, free of cherry picking, showing these patients the respect and basic human dignity they deserve. Otherwise, you will waste Floridian taxpayer money defending your baseless claims in court.

I encourage each board member to remember that these boards represent more than just board members and their research but the entirety of the practice of medicine in our beautiful state. Please take all necessary courses of action to debias yourselves to ensure Floridian gender affirming care patients may pursue and continue their care in peace. Thank you.

CHAIRMAN ROMANELLO: Thank you.

Kit M., followed by Omar Martinez, and

Katelyn Denehy-Samitz.

KIT M.: Hi, Kit. Yeah. So what's being pretty clearly communicated is that what is and isn't in the topic isn't entirely arbitrarily decided by you all on whether you like the comment or not. This is the most consistent way to determine whether or not you are going to interrupt randomly in the middle of a comment. For example, you lied about suicide in the informed consent forms but when corrected on suicide statistics, that is suddenly off topic because they were mean to you.

There is no reason to believe in your honesty. I mean, just look at your disgusted faces. The public book for this meeting, first off, was corrupted, which was very ironic (indiscernible) this whole situation.

CHAIRMAN ROMANELLO: Kit, do you have anything to offer on the rules or the informed consents?

KIT M.: The context in which the rules are made is necessarily relevant to the rules.

CHAIRMAN ROMANELLO: Do you have any comments on the rules or the informed consents?

KIT M.: Yes.

CHAIRMAN ROMANELLO: Can you offer those

comments, please.

KIT M.: Over a dozen studies with a sample size of -- with a sample size of 30,000 state the efficacy of these in improving mental health and decreasing suicidality, yet you lyingly state that treatment with gender affirming care will not prevent serious psychological events such as suicide. If you're going to claim that this is not on topic, this is directly from your consent form.

You are the most transparently corrupt governmental body, but you appeal to an imagined sense of decorum, again, with the relevancy of each and every single comment, which again seems to be entirely arbitrarily decided by whether or not people are polite to you.

You cite organizations that have disowned you repeatedly, such as the Endocrine Society, which published an article in November of 2020 entirely disowning the ruling as anti-science. Why require both a DEXA scan and an x-ray every year, which would cost approximately $700 combined, even for testosterone which increases bone density. The point, very clearly, is to block poor people from this which transpeople disproportionately are.

Why bar with -- and this is a direct quote

-- "any other active psychopathology"? This is not from the informed consent forms, this is later on in the public book, but it was relevant to be included in the public and therefore, it would be relevant to this meeting. This would include depression, anxiety, ADHD, autism, et cetera.

Why recite the limonite lies of a social contagion of rapid onset gender dysphoria? Why lie about desistance rates by citing a 1968 study calling the 12 patients "sissy boys and tomboyish girls"? Why desperately hide your unanimous DeSantis donations average $20,000 per year, per member, prior to being appointed by your whaler? Grow a damn spine and own up to what you are doing.

CHAIRMAN ROMANELLO: Omar Martinez.

OMAR MARTINEZ: Yes. Good afternoon. My name is Omar Martinez. I completed a dual degree in law and public health. I also have a master's in clinical research methods and completed a post-doctoral fellowship. I have dedicated my entire professional career to address health disparities and inequities impacting sexuality in minorities.

My work and the work of others have clearly documented the impact of systemic factors including

the larger social context, policies like the one passed in Florida, structural stigma, discrimination, and racism that I suspect disproportionately impact the transgender population. We have also developed programs and interventions that are resiliency based and really highlight the beauty, the magic of the resilience community.

Now, regarding the informed consent, in developing these consent forms, I should actually recommend considering the informed consent model, also known as the affirmation element, to help support the writing of this informed consent. The model has been adopted by many healthcare professionals. In particular, clinicians at the Callen-Lorde Community Health Center in New York City.

You have a duty to provide adequate and accurate information to enable a person to make an informed decision. The benefits have been clearly established and this board -- this is where this board has shown subjectivity, to my understanding, and impartiality.

The truth is that data from more a dozen of studies of more than 30,000 -- more than 30,000

transgender (indiscernible) and diverse youth consistently show that access to gender affirming care is associated with better mental health outcomes and the lack of access to such care is associated with higher suicidality, depression, and self-harming.

A recent study, last year, 2022, published by Tordoff and colleagues in JAMA with over 100 transgender youth found that mental health incomes increase significantly with the medication aspects of gender affirming care.

Another study published last year in pediatric, but also (indiscernible) colleagues, with over 300 -- 300 -- you want the data, you want the sample size? You have it there -- transgender youth found that the vast majority of those receiving gender affirming cares do not regret transitioning at all. Over 60, 60 high-quality, well-designed studies published in reportable journals have established the safety and efficacy of gender affirming care.

The new requirements that you -- just drafted are very problematic and not in line -- not in line with the standards of gender affirming care of data published in May of this year by JAMA, but

the World Professional Association of Transgender Health.

I'm particularly concerned with requirement number 10, requirement 13, requirement 5. I'm not going to go into details. These requirement deviate -- deviate from the standards of care. I'm actually very concerned about the potential breach of the standard of care and legal implications for this board and medical professions. You're deviating from well-established evidence and the standard of care by providers.

CHAIRMAN ROMANELLO: Mr. Martinez, thank you. Your time is expired. We appreciate your comments, and we'll certainly take them into consideration as we continue to discuss the rules.

Our final speaker of the afternoon is going to be Katelyn Danehy-Samitz. Did I get that halfway right?

KATELYN DENEHY-SAMITZ: Yeah. I feel like other people -- yes, you did actually get it right. But I think it's probably because of timing.

UNIDENTIFIED SPEAKER: Yeah.

KATELYN DENEHY-SAMITZ: Okay. Well, in the interest of time, if I can keep it under three minutes are we able to get another speaker since

it's 4:26 now.

CHAIRMAN ROMANELLO: You're going to be our last speaker of the day. Thank you. So if you have comments --

KATELYN DENEHY-SAMITZ: Regardless of the 4:30 cutoff?

CHAIRMAN ROMANELLO: You're going to be our last speaker of the day. Thank you.

KATELYN DENEHY-SAMITZ: Awesome.

UNIDENTIFIED SPEAKER: It's not 4:30 yet.

KATELYN DENEHY-SAMITZ: It's not, but that's fine.

Okay. Katelyn Denehy-Samitz, founder/vice president of Women's Voices of Southwest Florida. I would like to start off and apologize to you, sir, because apparently, I'm not sure what "masculinification" is but I don't think that hair makes the man.

Actually, as well, too, something I usually start off with and this is within the scope -- within the scope -- since I'm in a room full of doctors, if anybody can help me and figure out how to disjoint a human centipede, my email is on that form. Please keep it. Send me an email, admin@wvswfl.com.

So much to say and if I'm the last speaker, that's great. Let me check on my notes here; I might as well take my time.

Say that you're mandated to do this, and it's been reviewed several times the fact that you have been mandated to create the consent form. The hate that you are warranting and making this care that is lifesaving, which has been again shown over and over again despite the cherrypicked references -- oh, wow. I'm angry. I'm sorry. I'm not sorry. I'm trying very hard to be cordial.

You admitted to cherry picking the research that you choose to base these on. You are looking at a room full of people who drove hours to be here. I drove five hours here with my family, and we're allotted -- nope, this is within the scope -- we are allotted three minutes.

I would like to echo what Kit said and say that everything -- every one of these person's experiences is within the scope of what you are doing, and by refusing to listen to them, by putting your head in the sand for PR -- PR, putting your head -- continuing to put your head in the sand, you cannot allow Ron DeSantis to hide behind you and not expect to have shit thrown at you. That's it. Have

a wonderful day. Oh, God is disappointed.

CHAIRMAN ROMANELLO: Thank you. Your comments were incredibly helpful to the committee, and we'll take them into consideration. Appreciate it.

All right. We're now going to move towards actual now consideration and a vote on the informed consents and rules. And I'll ask Mr. Dierlam, just a process. We did the informed consents first and then the rules. Any --

DR. ACKERMAN: Do we have to act on the rule first?

CHAIRMAN ROMANELLO: That's what I'm asking. Right?

ATTORNEY DIERLAM: I don't think you have to act on the rule separately. I would advise that if the -- you know, first of all, the committee needs to determine if it wants to reconsider any of the prior discussions, make any changes to the consent forms based on public comments.

If the committee is comfortable with the consent forms as are, we would simply need a motion to adopt. I believe it would be appropriate to do the minor consent forms and rule language in one vote, and then allow me to ask the sunset questions.

Then move forward with the exact same process for the adults. You know, again --

DR. ACKERMAN: So Ms. McNulty, did you take any notes? There were some issues that came up. Should we --

ATTORNEY MCNULTY: Well, I mean, what in particular are you looking for?

DR. ACKERMAN: I just remember --

DR. MORTENSEN: There was one about fluid versus fluent.

DR. ACKERMAN: Yeah.

EXECUTIVE DIRECTOR VAZQUEZ: A technical change, I think we can take care of.

DR. ACKERMAN: Okay. I just wanted to make sure that we addressed that.

DR. DERICK: Okay. I have comments on the adult consent form.

ATTORNEY DIERLAM: So are we going to start with minor or --

CHAIRMAN ROMANELLO: Let's do minor first, if we can. So we have the minor consent form and then the minor rule. Any discussion that the committee wants to make with respect to the consent form or the rule that we discussed early, or any responses or comments to the public comments that we

heard this afternoon?

All right. So if there's no comment, we would entertain a motion to adopt the consent form as amended and the rule.

DR. ACKERMAN: Move to adopt the consent form as amended and the rule.

DR. DI PIETRO: Second.

CHAIRMAN ROMANELLO: Okay. There's a motion by Dr. Ackerman, a second by Dr. Di Pietro.

Do we need to do the conforming questions now or --

ATTORNEY DIERLAM: After we have a vote in favor of the ruling.

CHAIRMAN ROMANELLO: Got it. All right. All in favor of the motion?

(Unanimous ayes)

Opposed?

The motion passes.

ATTORNEY DIERLAM: So if you don't mind, board members, I'll go ahead and ask the requisite circ questions. The first question is: will the proposed rule amendments have an adverse impact on small business?

DR. DI PIETRO: I move that it will not.

DR. ACKERMAN: Second.

CHAIRMAN ROMANELLO: All in favor?
(Unanimous ayes)
Opposed?
Passes.
ATTORNEY DIERLAM: Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including the government, in excess of $200,000 within one year after implementation?
DR. ACKERMAN: Move that it won't.
DR. DI PIETRO: Second.
CHAIRMAN ROMANELLO: All in favor?
(Unanimous ayes)
Passes.
ATTORNEY DIERLAM: Will this rule amendment create an offense that would constitute a minor violation under the rule?
DR. ACKERMAN: Move that it won't.
DR. DI PIETRO: Second.
CHAIRMAN ROMANELLO: All in favor?
(Unanimous ayes)
Opposed?
Passes.
ATTORNEY DIERLAM: And then the final issue for consideration is a sunset provision and whether

or not the board wants to include one. I would point out that A, this rule is required by statute, and therefore, I don't know that a sunset provision would be required. And B, it's also an emergency rule, so --

DR. ACKERMAN: Move that there's no sunset provision.

DR. DI PIETRO: Second.

CHAIRMAN ROMANELLO: All in favor?

(Unanimous ayes)

Opposed?

Passes.

Moving to the adult, any comments by committee members? And I know that Dr. Derick had a comment.

DR. DERICK: So starting on Bates 309, I think that the audience actually had a lot of compelling comments and I kind of just wanted to walk through the issues related to the qualifications for adults to receive and continue HRT.

So I think if we go, number 1, meets the criteria for gender dysphoria. That seems like that's appropriate that they have gender dysphoria if they're being treated for it.

DR. ACKERMAN: We're on 309?

CHAIRMAN ROMANELLO: Bates 309.

DR. DERICK: You know, there was a recent knowledge that some people from a large transgender group were sort of rubberstamping after a 20-minute appointment with a provider. They were getting letters to their insurance companies, you know, saying that these people qualified, you know, for these very serious, like (indiscernible), for example, without really having a relationship with those people. So I do think that -- and it wasn't persistent, it had been like a month.

"Mental health and physical conditions that could negatively impact the outcome of the treatment have been assessed." So the comorbidity thing is interesting. It sounds like from number 2, if someone does have a mental health or physical condition, and it's discussed, risks and benefits are discussed, that that person could get the treatment.

DR. DI PIETRO: Correct.

DR. DERICK: Right. I mean, it doesn't preclude -- that one doesn't preclude it.

DR. DI PIETRO: Correct.

DR. DERICK: "3, gender dysphoria is marked

and sustained." I think the points that were made from the audience, if you are already being treated for gender dysphoria, you don't have sustained gender dysphoria, so maybe that one is redundant to the fact that you meet criteria for gender dysphoria in general.

DR. MORTENSEN: That kind of speaks though with hypertension, right. Like if you're taking your medication, you don't have hypertension.

DR. DERICK: Yeah.

DR. MORTENSEN: So if they are taking their medications, they still technically have gender dysphoria.

DR. KIRSH: It's a diagnosis.

DR. MORTENSEN: It's a diagnosis.

DR. DERICK: I think maybe it's nuanced with the way that it's written. But I mean, I think that, you know, you wouldn't -- if someone was stable and doing well, you wouldn't want to say that they were -- someone said gender euphoric, which is not gender dysphoria, so --

The next one, "Demonstrated capacity to consent." That seems fine.

Number 5, "Does not" -- this one -- "does not suffer from psychiatric comorbidity that

interferes with the diagnostic workup or treatment." So this is saying that if you're a new patient who is an adult and you have a psychiatric comorbidity that would interfere with the diagnosis of gender dysphoria then that would be taken into consideration. I do think it's compelling. People do have depression and other sorts of things that we wouldn't want to state that they couldn't get their treatments in adults, right. I mean, to me that seems inappropriate.

DR. ACKERMAN: I think it's a misunderstanding. I think that there could be a psychiatric comorbidity but the fact that it has to interfere --

CHAIRMAN ROMANELLO: Absolutely.

DR. ACKERMAN: -- with the diagnostic workup or treatment. I mean, everybody has multiple --

DR. DECKER: I mean, like if you have ADHD and have gender dysphoria, it seems like those things can be treated separately.

DR. ACKERMAN: Yeah. I agree.

DR. DECKER: If you have depression, gender dysphoria, if you're treated maybe the depression goes away or maybe it doesn't. Maybe it requires

additional treatment.

DR. ACKERMAN: I think it doesn't interfere with the diagnostic workup or treatment.

CHAIRMAN ROMANELLO: Right.

DR. DECKER: "Number 7, demonstrates knowledge and understandings of the risks." That seems normal, or fine.

"Number 8, understands the effect of gender affirming hormone treatment on reproduction." That's just informed consent again.

"Number 9, undergoes evaluation by the prescribing physician at least every three months." And then also number 10, which is the suicide risk assessment. You know, I sort of agree that, you know, once the consent is --

CHAIRMAN ROMANELLO: But Dr. Derick, we changed that, right.

DR. DERICK: No, I'm just reading the former -- the timing was changed. But to me it seems like in adults if they do informed consent in person with a physician that maybe this is too prescriptive in its language for adults.

Same with the bone scan and laboratory testing and the annual mental health assessments. You know, we were charged with creating a consent

form in adults to reeducate people on kind of the newest stuff that's going on in this field because it's -- you know, people here say we don't know the studies, but we've read probably 20,000 pages of studies. We've got 2 people up here who are specialists in pediatric endocrinology, which is like 4 years after college of medical school, and then like 3 years of pediatrics, and then 2 years of endocrine, or whatever it is. It's like a lot of time. So these people, I mean, this is what they do for a living. They see these patients and everything else.

So I mean, I don't want people to think we're not taking this seriously. We have very serious concerns about some of these treatments. But I do think that in adults in particular perhaps some of the prescriptive appointments and all of those things might be too much.

And I also think that would probably get rid of the issue with the nurse practitioners because then it would only be in the kids who were in that window of time where they needed to have -- they got grandfathered in or whatever else, they would need to be seen. But if we consider maybe removing some of these other requirements that maybe

the access to their doctor, they should be seeing their doctor regularly anyway.

So I don't know, I'm appreciative of the public here. I think that, you know, the intent always is to use all the knowledge that we have to do the best job that we can with the data that's presented and I think, unfortunately, there's just such a chasm right now of, you know, you either believe or don't believe and there's just so much uncertainty related to all of this. So I appreciate everyone's comments and I think that, you know, perhaps we should consider removing some of these requirements for adults.

CHAIRMAN ROMANELLO: Do you have any specifics?

DR. DERICK: Yeah. I think -- yes, I do. So if we go back through. I'm sorry to be so tedious with this. But I think the mental health comorbidity is -- if we're all on the same page where we agree with the lawyers that if you do have a mental health comorbidity it's just discussed as part of the evaluation, it's not that you can't get it if you have depression.

DR. ACKERMAN: Right. That's a misunderstanding.

CHAIRMAN ROMANELLO: Right.

DR. DERICK: Okay. Because I think that that's -- you know, that was a concern of a lot of people that we heard.

You know, obviously --

DR. ACKERMAN: So we're leaving that as is.

DR. DERICK: Yeah. Able to give consent and stuff like that, that should stay. I think maybe number 9, number 10.

DR. ACKERMAN: Well, let's go through one at a time. So number 9.

DR. DERICK: I'm saying that 1 seems normal. 2 is okay. 3 is redundant. 4 is fine. 5 we've clarified. 6 is fine. 7 is fine. 8 is fine. 9 is -- I would -- we had changed it when we were discussing it, before I heard public testimony on it, to 6 months or something like that.

DR. ACKERMAN: We said three months for the first year and annually thereafter.

DR. DERICK: Yeah. I feel like maybe that one should be stricken. I think that the patient probably as an adult will have a routine cadence of visits anyway that doesn't necessarily need to be mandated in this rule.

And the same thing with number 10, suicide

risk assessment. I did hear Dr. Benson, I'd like to hear his opinion about if he thinks that this should be a mandate, but I think that if it's good practice for physicians who are prescribing this in adults that it is an issue that hopefully they would do that on their own.

The laboratory testing, same thing, and the bone scan, same thing. I would consider not having those. And then 13, annual mental health assessment. And to be honest, I'm not saying these things aren't important. They are very important. I'm just not sure in the context of this task that we were given that this should be included.

"Number 14, continuing counseling with a licensed mental healthcare professional during treatment," I think that one probably should be taken out too. Not that that shouldn't happen, I just am not sure it should be as part of this.

DR. MORTENSEN: It says, "with the frequency recommended by the healthcare professional though," so it's not like we're mandating that they have to have it, we're just suggesting that if they are seeing somebody and that person says, "You really need to be seen more frequency," you do. And if they say, "No, come back in a year, or two years,

or if you have problems."

DR. DERICK: I mean, I think that that one is fine then if it's read that way. I mean, I think it's appropriate if you have an annual mental health assessment it can happen like maybe once, and if it's needed to be done -- if people are happy and they're not having problems with it and they're adults and they're on stable medications for a long period of time. I mean, I hear the access arguments, I hear the cost arguments, I hear, you know, a lot of those things and I feel that perhaps in adults that we are -- our duty is to inform them about the risks of the treatment, considering some of these have become newly -- we're becoming more aware.

You know, I know that the NHS in England recently came out with even more stringent guidelines related to not even promoting social transitioning of children. So I mean, we're looking at Europe, we're watching Europe. It's a constantly evolving discussion. And so I think that the refreshing of the informed consent -- and also, the people's doctors are going to give them their own informed consent, too. So they're going to get all the consents. But yeah, so I think that that that

might --

DR. MORTENSEN: I think it would be fair to strike some of it because as counsel had noted, the physicians are required to handle the standards of care and if you do look at the Endocrine Society Guidelines and the World PATH guidelines, they do recommend laboratory testing, bone mineral density, all those other things. So you could strike it from the consent because it falls on the physician to follow those standards of care.

DR. DERICK: Maybe it would be --

DR. MORTENSEN: But it would be fair to inform the patient to expect that these things are the standard of care and that their provider might be --

DR. DERICK: I like that idea. Instead of saying it's a requirement that it would be included in the informed consent that this is what you should expect, or your -- this is what's considered standard of care is to have these things done at this sort of cadence. But not make it a requirement where if someone doesn't have a bone scan they're out of compliance if it's been, you know, 370 days.

DR. ACKERMAN: Well, the first line here say above those numbers is "The specific

requirements for an individual," and then all these things are in there. So we're requiring these. So you want to loosen up on some of these requirements, like number 9 and 10?

DR. DERICK: Yeah. I feel like -- sorry, my computer shut like shut off. It's like --

DR. ACKERMAN: So number 9 says, "Undergo an evaluation by a prescribing physician" -- and I think we changed it -- "or their" --

DR. DERICK: Instead of making it a requirement make it "It is suggested that you" -- blah, you know.

DR. MORTENSEN: So why not leave the things that we need for specific requirements and then create a second subsection that says, "The following are recommendations" -- or the "The following may be recommended by your physician" and then list the other ones as recommendations?

DR. DERICK: I think that's a great compromise. I think that that's something that I think the audience would be supportive of.

DR. MORTENSEN: So we don't have to reinvent the wheel on the consent.

DR. DERICK: You know, and I think that it's --

DR. ACKERMAN: I think the economics of it is important -- is a concern, yeah.

DR. DERICK: It's good medicine to do these things, I just -- you know, if you require that they can't get prescriptions filled if these things A, B, and C haven't done, it's like a lot of burden to make sure that you're not out of compliance and it will make physicians nervous too to be prescribing these medications to make sure that they're able to comply.

DR. ACKERMAN: Right. But at the same time, we need to protect the public and have some requirements that -- I think there will be physicians out there that will take advantage of this and not see their patients and just -- you know, they'll be doing telemedicine and not doing these assessments in person. So I think we have to have some requirement in there of a frequency that they see a physician. So we said before every three months, and I think we said during the induction phase, or -- right? Help me with what we had said.

CHAIRMAN ROMANELLO: First year.

DR. ACKERMAN: The first year, every three months, and then annually thereafter. So you want

to strike that? You want to make it looser?

DR. KIRSH: Maybe the consideration might be is some of the things that would have a major impact financially, we put under recommendation by the physician and the patient. And then those that we believe are protective of the population we continue the standard similar to meeting with the physician on a regular basis at the beginning and loosen that up as we already have in the end for the adults. It's those things that may have the financial impact that we may say is a recommendation.

DR. DI PIETRO: But it shouldn't be about financial impact. It should be about health, safety, and welfare, right.

DR. KIRSH: Absolutely.

DR. DI PIETRO: And standards of care.

DR. KIRSH: Absolutely. But there is --

DR. DI PIETRO: So I mean, the standard of care is a cardiac catheterization and it's way more expensive than TPA. So I mean, it's -- although I recommend -- excuse me. Although I understand the financial aspects and even Dr. Ackerman and I were looking up the cash pay prices on DEXA scan sitting here. I mean, I get it. I deal with it every day.

I deal with uninsured patients in my hospital on a daily basis. But when we're coming up with standards and consents, it has to be standards of care and health, safety, and welfare.

I am completely fine with leaving certain requirements and then having a subtitle for things as they stand and putting, you know, "These should be expected as are recommended" if you want to put by the board by the state -- however you want to write it, I'm perfectly fine with that. But I don't think they should be exclusively removed because I think when things are in writing like this, it gives the patient the opportunity to read things that maybe their physician, if it's not a fantastic physician, failed to mention to them.

DR. KIRSH: No. I happen to agree with you but there are some things that, you know, is a decision made by a group that may not look at the full ramification, and so those things should be recommended, as you said, and those things that we believe is an absolute necessity, such as seeing the patient on a particular period, is something that we should keep that in the informed consent and fly it.

DR. ACKERMAN: Well, this is the standard of care part, so let's -- I'd like to -- it would be

good to get through this and just do one at a time.

DR. DI PIETRO: But the other option could be that the requirements apply to people who are new adults to the treatments, and the people who are currently under treatment, these are the recommendations.

DR. KIRSH: How do you define that? That's complicated. How would you define that from a --

CHAIRMAN ROMANELLO: Can I make a suggestion? I'm not hearing a consensus on where the committee wants to go on the issue. I'm hearing a couple of different competing ideas, all of which sound good. I think there is a general consensus to somehow modify those requirements for folks who receive hormone replacement therapy. I don't think that we've coalesced as a group on where those requirements or suggestions should reside.

As this is an emergency rule, this is not going to be the last stop on this journey. We're going to be back here for a permanent rule, and we've already talked about some other items that we've put kind of placeholders in this rule in that we're going to reconsider and have much more time to reconsider as we progress to the permanent rulemaking. Is this an area where we could -- we've

got notes and a record of the conversation, is this something that we can come back in the permanent rulemaking process to take up?

DR. DERICK: I just think there's going to be a gap between those two things and the physicians aren't going to know what to do during A and B.

CHAIRMAN ROMANELLO: Okay. Fair enough.

DR. DERICK: I see both sides and I think it's important to recognize that we can't lose our transgendered patients to lack of follow up. And I think that we're seeing a little bit of this rubberstamping sort of large sprawl of transgendered clinics where people have been on record saying that they don't have any gatekeeping philosophy because they believe everyone should be on these medications. And I think that's something that we really need to think hard about is that this is not for everyone, especially in the kids. It's not -- it's good for some that need it and it also should be considered that it might just take time to --

DR. BENSON: So I think the simple thing is with the DEXA scan, I think if you really look at the Endocrine Society Guidelines, they talk about a lot of what we talked about. When to monitor testosterone, when to get a hemoglobin and

hematocrit screening for osteoporosis. But for trans males, the fracture risk is probably low if they're staying on their testosterone. And for the trans females, you know, again, similar monitoring, checking testosterone, checking estrogen, shooting for the physiologic range. But BMD testing at baseline for that group, but the rest are low risk, so you're requiring a DEXA scan that would be something I think we could just eliminate for most adults.

CHAIRMAN ROMANELLO: So then is there an appetite? Because Dr. Derick has identified, and we've circled in on numbers 9 through 14. Would there be an appetite for the committee to consider a new section, as Dr. Di Pietro pointed out, after the specific requirements, another section that reads, "The following requirements may also be recommended by your physician," and we would take numbers 9 --

DR. ACKERMAN: Take out the word requirements. "The following may be" --

CHAIRMAN ROMANELLO: Right. "The following" --

DR. ACKERMAN: -- "may be also recommended by your physician."

CHAIRMAN ROMANELLO: Okay. "The following

may also be recommended by your physician," and we would take numbers 9 through 14 and put that in a subsection?

DR. ACKERMAN: Yeah. I could live with that. That would make it -- at least it's in there and it makes it so they're not obligated to do it. It's optional but, you know, if someone is not doing any of those on a regular basis they could have -- it could be looked "frownly" upon. So I'd make the motion to add an additional -- to after number 8, put a space --

CHAIRMAN ROMANELLO: "The following may also be recommended by your physician."

DR. ACKERMAN: "The following may also be recommended by your physician for individuals who receive and continue to receive HRT treatment."

DR. KIRSH: Second.

ATTORNEY DIERLAM: And that is for masculinizing and feminizing forms? Obviously wouldn't apply for the surgical forms but both for the adults?

DR. ACKERMAN: Right. Masculinizing and feminizing.

ATTORNEY DIERLAM: Thank you.

DR. ACKERMAN: "The following may be

required for individuals to receive or continue to receive HRT treatment."

CHAIRMAN ROMANELLO: "The following may also be recommended by your physician for an individual to receive and continue HRT treatment."

DR. ACKERMAN: I wouldn't say "your." "The following" -- you got to wordsmith it for me a little bit. "The following may be recommended by the physician." Because this isn't your, all this is in third person or whatever. Yeah "by the prescribing physician."

CHAIRMAN ROMANELLO: I have a motion by Dr. Ackerman.

DR. DERICK: Second.

CHAIRMAN ROMANELLO: A second by Dr. Derick. All in favor?

(Unanimous ayes)

Opposed?

It passes.

DR. ACKERMAN: Just fix the language there to make it so that it's the proper tense.

CHAIRMAN ROMANELLO: So then are we going to -- are there any other questions, or any other observations, or motions that we want to make about the informed consent --

DR. ACKERMAN: Yeah. Just regarding that, I can tell you that in people that don't have gender dysphoria that are treating with these drugs, I think it should be required. I require it, so I think it's a little -- you know, it's weird that we're not requiring bone density studies with people with estrogen blocking drugs, but that be as it may, I just wanted to go on record saying that. I think it's fine. They can do it ad-lib.

CHAIRMAN ROMANELLO: So with that, I would entertain a motion to adopt the emergency rules as amended, as well as the rule.

DR. ACKERMAN: Second. So moved.

DR. DI PIETRO: Second.

CHAIRMAN ROMANELLO: All in favor?

(Unanimous ayes)

Opposed.

If I said rule twice, I didn't mean to. I meant to say the consent forms along with the rules. So the consent forms as amended and the rule. A motion and a second, all in favor.

(Unanimous ayes)

Opposed?

It passes. Mr. Dierlam's got -- yeah.

ATTORNEY DIERLAM: Will the proposed rule

amendments have an adverse impact on small business?

DR. ACKERMAN: No.

DR. DI PIETRO: Second.

CHAIRMAN ROMANELLO: All in favor?

(Unanimous ayes)

Opposed?

ATTORNEY DIERLAM: Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity including the government in excess of $200,000 within one year after implementation?

DR. DI PIETRO: I move that it will not.

DR. MORTENSEN: Second.

CHAIRMAN ROMANELLO: All in favor?

(Unanimous ayes)

Opposed?

Carries.

ATTORNEY DIERLAM: Will this rule amendment create an offense that would constitute a minor violation under the rule?

DR. DI PIETRO: Move that it will not.

DR. ACKERMAN: Second.

CHAIRMAN ROMANELLO: All in favor?

(Unanimous ayes)

Opposed?

Carries.

ATTORNEY DIERLAM: And does the board committee want to impose a sunset provision for this rule or a rule amendment? All my prior comments for the last rule apply again.

DR. DI PIETRO: I move that there should not be a sunset.

DR. ACKERMAN: Second.

CHAIRMAN ROMANELLO: All in favor?

(Unanimous ayes)

Opposed?

Carries.

Again, I want to thank the committee for its time and its dedication to the issue. I also want to thank the members of the public who took the time to be here today. Particularly those who have come to multiple meetings and have commented on multiple occasions. We certainly appreciate it. And with that, we'll adjourn the meeting.

(END OF AUDIO RECORDING)

CERTIFICATE OF TRANSCRIPTIONIST

I certify that the foregoing is a true and accurate transcript of the digital recording provided to me in this matter.

I do further certify that I am neither a relative, nor employee, nor attorney of any of the parties to this action, and that I am not financially interested in the action.

Julie Thompson, CET-1036

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