DRUG UTILIZATION REVIEW BOARD

Agency For Health Care Administration

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REPORTED BY:

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Anna Hayden, D.O.
Kevin Olson, Pharm.D.
Alfred Romay, Pharm.D.
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AHCA STAFF:

Shevaun Harris, Assistant Deputy Secretary
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Kevin Dewar, Esquire, Assistant General Counsel
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Medicaid Pharmacy Policy Administrator
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MAGELLAN MEDICAID ADMINISTRATION:

Elboni Moore, Pharm.D.
Selika Sampson, Pharm.D.
Stephanie McGriff, Pharm.D.

I N D E X

P R O C E E D I N G S

THE CHAIRPERSON: The time is now 2:02 and we'll be starting our First Quarter AHCA DUR Meeting. For those of you who are AHCA DUR geeks, this is actually the first quarter meeting, even though it's the second meeting of the year, because the fourth quarter meeting was held in January.

All right. Before we get started, we're going to have opening remarks from our deputy secretary, Shevaun Harris.

MS. HARRIS: Good afternoon, board members and audience members. Thank you for taking time out of your busy schedules to participate in this board meeting to assist the agency.

I have just two updates for you. We are in the process of working on the re-procurement of our statewide Medicaid Managed Care program. For those of you who follow what's going on in managed care, I wanted to let you know about that. We plan to issue our solicitation over the summer, so keep an eye out for that.

The agency has put out an invitation for any interested parties to let us know of their interest and we received quite a bit of

feedback. And if you're interested in the results of that, it's posted on our website. We can get that out to the board members if they're not quite sure where the link is on our website or what page it's posted on on our website.

The other thing, I think probably Arlene gave you updates at the last meeting. But if you're not aware, we have solidified our leadership team at the agency. Our secretary, Justin Senior, was appointed by the governor. He moved out of an interim role in January, I believe. And Beth Kidder, my supervisor, was named Medicaid director for the state of Florida. And I was recently promoted to assistant deputy secretary for Medicaid Policy & Quality.

So my position as bureau chief over Medicaid Policy is vacant. I'm working to fill that position and hope to still participate in these meetings as frequently as possible, but you probably won't see me as much as you have in the past.

We are in the middle of a legislative session. I will note that, too. The agency is

tracking quite a bit of activity that's happening. We've had several bills filed that, if enacted, would impact our Medicaid Managed Care program. Some activity around pharmacies and how our health plans contract with pharmacies as well. So the agency is just really tracking, at this point, how those bills are working their way through the committee process. And when we meet in June, we will be able to give you an update of any bills that passed that have any major impacts on the Medicaid program, in particular, our prescribed drugs benefit.

Any questions for me?

Thanks.

THE CHAIRPERSON: Outstanding. And congratulations on the promotion. I think at this time, since we know who you are, I'd like to go ahead and have introductions for the remainder of the committee, starting with Stephanie.

DR. MCGRIFF: Good afternoon, everyone. I'm Stephanie McGriff. And I'm clinical account manager for Magellan Health Services.

DR. SAMPSON: Good evening. I'm Selika

Sampson, and I serve as the DUR pharmacist for Magellan Healthcare.

DR. MOORE: Good afternoon. I'm Elboni Moore. I'm with Magellan and I'm the pharmacy account executive.

MS. ELLIOTT: Arlene Elliott with AHCA Pharmacy Policy.

DR. CRAIG: Good evening -- or good afternoon. I'm Sara Craig and I'm a senior pharmacist with the Agency of Healthcare Administration.

MR. HAMILTON: I'm Vern Hamilton with the agency. I serve as the liaison for these meetings.

MR. DEWAR: Kevin Dewar, Medicaid counsel, Agency for Healthcare Administration.

THE CHAIRPERSON: Moses Allen, director of pharmacy, Magellan Complete Care.

DR. FIELD: Larry Field, practicing physician.

DR. GOODNOW: Vanessa Goodnow, director of pharmacy services at Jackson Memorial Hospital in Miami, Florida.

DR. HAYDEN: My name is Anna Hayden. I'm a family practitioner in Ft. Lauderdale,

Florida.

DR. OLSON: Kevin Olson, pharmacist out of Tampa, Florida.

DR. ROMAY: Alfred Romay, director of pharmacy, Molina Healthcare of Florida.

DR. SAENZ: Luis Saenz, medical director of Molina.

DR. ZITIELLO: Amy Zitiello, pediatrician and medical director of Avalon Healthcare Solutions.

THE CHAIRPERSON: Great. Okay. We're going to go ahead and jump right into the agenda. As always, our stenographer does a great job of preparing the minutes. At this point, I'd like to ask the committee to review, and if it meets your approval, I'll need the motion to approve.

DR. HAYDEN: Motion to approve.

DR. FIELD: Second.

THE CHAIRPERSON: It's been properly moved and seconded. All those in favor, please say aye.

THE COMMITTEE: Aye.

THE CHAIRPERSON: All right. Moving on. Review of the P&T minutes, as we know,

this item is for information only, so we don't need an actual vote. So at this time, I just wanted to ask if there are any questions or concerns with those minutes.

Great. Hearing none. We're going to go ahead and move on to the Quarterly DUR Activity Reports. And at this point, we'll hand it over to Selika and Elboni.

DR. SAMPSON: Good afternoon. Without any further delay, we're going to move right into our review for this quarter.

Quick overview. Today we are going to follow up on our previous DUR items. In addition, to discuss the first quarter DUR activities and also decide on second quarter, 2017, DUR activities.

The first topic is Growth Hormone. This was a top therapeutic class review, previously reviewed at the January 2016 DUR meeting. The data at that time was fourth quarter 2015 data. And what we had to do here was follow up on that report due to the auto PA logic being -- the auto PA logic for preferred growth hormone products diagnosis verification was removed from the fee-for-service side, March 2014, 2016

and the post-implementation data was shared at the June 2016 meeting.

The post-implementation data, once that was removed, you have the clinical PAs that were reviewed for April 1st, 2016 through June 30, 2016, and, at that time, it revealed a fill of $3 million total amount paid over 817 claims for 354 users. So there you can see the decrease.

And on the MCO side, due to implementation for the MCOs, when that happened for them, their numbers remained steady. They got more recipients during this time as well.

Our next topic, Vesicare, Toviaz, minimum age limit of 18 years old. The purpose of this review was to address the misuse of long-acting agents in the pediatric population. The added details are as follows: Vesicare and Toviaz are not indicated in children. Recipients must be at least 18 years or older for either of those two products, and claims for Vesicare and Toviaz are directed to the preferred alternatives for children.

The fee-for-service and MCO utilization has significantly decreased 64 percent and 84

percent, respectively, 78 percent decrease collectively.

The prior authorization intervention for pediatric recipients under the age of 18 years is working. There were 54 claims at roughly $15,000 and also 58 claims for $16,000 on the MCO side.

Now, we'll take a look at the breakout for Toviaz. The pre-edit for children under 18 years of age for fee-for-service, it was a small population, but, again, the reason why the edit was done was because it's not indicated for children under 18.

And so, you can see there, again, that the intervention is working. Utilization has decreased overall. Relatively 60 percent for the fee-for-service and 76 percent for the MCO.

And when we take a look at Vesicare, that agent, again, you have a smaller population. Fee-for-service, overall utilization decreased relatively about 66 percent and MCO relatively about 83 percent.

Now, during the January 2017 P&T meeting, the PT committee recommended for the DUR board to review vasopressin receptor antagonists. At

that time, they asked for DUR to review it due to current utilization. And so, we took a deeper look into this particular class.

Vasopressin receptor antagonists are used to treat hypovolemic and euvolemic hyponatremia. So overall, it helps recipients with diseased states, such as hyponatremia as well as hypovolemia.

The population reviewed was a small population on the fee-for-service side. There was only one prior authorization done during the review period, January 2016 through June of -- I'm sorry, that should have been December. It was a whole year. There was only one PA on the fee-for-service side. And on the MCO side, for that entire, the claims total $239,861.

Currently, Florida Medicaid does have criteria for the oral product that is available.

Vaprisol is the other agent in this class that is available and it does not currently have criteria. The P&T committee, at that time, wanted the DUR board to review the class in its totality. So currently you have one

agent which is available and there is clinical criteria available. And then you have another agent in which we do not have any criteria at this time.

Our next topic that we're following up on, the opiate dependents treatments, agonists and antagonists. During the P&T committee for January 2017, the committee desired for the DUR board to determine how fee-for-service and MCO recipients were utilizing the medication Subutex, buprenorphine, the single agent medication. Did the recipients have a pregnancy diagnosis in addition to their need for the medication? The indication for buprenorphine with naloxone, the combination product, SUBOXONE, versus the single agent product, Subutex, preferred for maintenance therapy in medication assistance treatment patients.

The World Health Organization recommends buprenorphine mono therapy without naloxone for women who must receive an opioid agonist during pregnancy or while nursing.

So this came back to the DUR board due to the high utilization of the single agents

medication and they wanted to know, Well, do these recipients have a diagnosis of pregnancy, which would mean they should more likely get this particular medication versus the combination product? The utilization revealed only 14 percent of the fee-for-service claims have a diagnosis for pregnancy or nursing. And only 23 percent of the recipients reviewed -- of the MCO recipients have a diagnosis for pregnancy or nursing.

Now, we might add that each claim does not come with a diagnosis attached to it. So we have to do a two-year look-back from the study period. Both fee-for-service and MCO data was reviewed for October 1st through December 31st of 2016 within those respective populations.

THE CHAIRPERSON: I have a question.

So this is good information. Obviously, looking at this from a resolution standpoint, would it be possible to take a look at a gender edit for this? I think I would be curious to know if some of the non-pregnant members that received the Subutex, if they were men. If that were women -- at least the scenario that I picture in my mind is, a member comes on

board -- let's just say it's January and the member is pregnant January. I think if I recall, it's a six-month approval that you generally give this agent.

DR. SAMPSON: Roughly. It varied.

THE CHAIRPERSON: So the PA comes in for review again at Month 6. Then you approve it for another six months and they could, in theory, fall into this non-pregnancy category, which -- I mean, it is what it is. If they're a woman. But if they're a man, they shouldn't be on it at all. I mean, I can't think of a reason why a male would need to be on the Subutex.

DR. SAMPSON: Right. Other than them stating they have some type of reaction --

THE CHAIRPERSON: To Latoxin, right.

DR. SAMPSON: Right. And so, when we --

DR. HAYDEN: Selika?

DR. SAMPSON: Yes.

DR. HAYDEN: Isn't that another indication for induction, so that could --

DR. SAMPSON: Right. That could be it too. Correct. They have both of those there. And what I was going to say is Florida Medicaid

fee-for-service side, they do look at all aspects of that for the indication. And if it is a female, then she must also have any proof there, if she falls out of the other category, that she is either pregnant or nursing.

THE CHAIRPERSON: So just to make sure that I'm clear: On the actual PA, we're fine with this one, or are we taking recommendations?

DR. SAMPSON: At this point, when you look at the data, the fee-for-service side actually had lower utilization in that population. Whereby, the Subutex category, if the recipient was pregnant and/or nursing, the utilization there for total paid was only 765 for fee-for-service recipients. And that category had relatively -- the recipient numbers were low there. Whereby, when you look at it from the MCO side, their total utilization there was 54,000. And they had more recipients, whereby it was mixed, male and female.

So the recommendation was to go back and look at the prior authorization process because both medications do require a prior authorization. And there's lower utilization

on the fee-for-service side. So it would be back in the hands of the MCOs.

The next topic was the Narcan naloxone product. Again, another P&T activity. During the January 2017 meeting, the P&T committee asked for the DUR board to establish quantity limits and criteria for Narcan nasal spray. The indication for Narcan nasal spray. It is an emergency treatment of known or suspected opiate overdose as manifested by, of course, respiratory and/or central nervous system depression. The current quantity limit set is one pack, two nasal sprays every 365 days. That was established as the quantity limit. Subsequent treatment would require a prior authorization at this time.

We did take a look, in terms of utilization, during a year period and there was little to no utilization on both fee-for-service and MCO sides. So, as it stands, the quantity limit that's currently set is one pack, two nasal sprays, every 365 for Florida Medicaid recipients.

Our last follow-up prior to going into quarterly activity information is the gender

dysphoria. This was a third quarter add-on agenda item that the state presented.

And, at this time, I will turn it over to Ms. Elliott.

MS. ELLIOTT: So in the last meeting, we distributed the criteria and we were going to bring it back to this meeting to see if the DUR members had any recommendations. Remember that is a special service criteria. It's not a regular criteria. This is separate than the other criteria that have FDA limitations. So this was, like we call it, a special service.

So I'm going to open it for discussion, if I may.

DR. HAYDEN: I have a question on the logistics behind it.

So it's not a covered Florida Medicaid item. It goes under special services. Where does it come out of the, I guess, budgetary -- it's a separate item. And is it in our purview for Florida Medicaid to look at -- is it in our scope to look at this information because it's not a Florida Medicaid item?

MS. HARRIS: So there are federal regulations that require the agency and all

State Medicaid programs to cover services that are medically necessary for recipients under the age of 21. I generically call them "children" even though the 18-to-20 population are adults.

This is through the early and periodic screening diagnosis and treatment regulations that the federal government has established. We call it EPSDT. You might have heard us use that terminology before.

DR. HAYDEN: Right.

MS. HARRIS: Even if something is not covered under Florida Medicaid, we have to have a process in place to review and determine if the request is medically necessary if it's not listed on our fee schedule or on our PDL. For most of our drugs, if it's not on our PDL -- or for almost all drugs, if it's not on the PDL, we have prior auth criterion in place. And we look at whether or not the FDA has authorized it or it's authorized through one of the compendia.

When we brought this to the DUR board, it was because these drugs were being used off-label. We had requests for an off-label

use of the drug, not supported by the FDA, not authorized through the compendia.

So we needed to make sure the agency, in its plans, had criteria that they could use when such requests come in to ensure we were reviewing it under the EPSDT guidelines.

So it's not about what budget line it falls into or not. It's really about making sure we have solid criteria, so that we can remain in compliance with the federal regs that state that states need to have processes in place for these outlier types of requests and it doesn't happen that often with drugs. Actually, in my years with Medicaid, this is the first time.

DR. HAYDEN: What are the medications? I guess I'm not quite familiar with the -- I mean, I've heard of it. I've seen the name across -- from years of working, but, I guess -- and I understand we look at it, but is it in the -- logistically, is it in our scope?

MS. HARRIS: Yes, it is.

DR. ZITIELLO: We would just hope that health plans and other people making the decisions will have some sort of consistency in

their decision making. Because, truly, under the age of 21, you should not render a decision for not being a benefit. It really needs to be a medical necessity decision. So it's just -- it's the consistency factor, I think, you're looking for.

MS. HARRIS: You said it well. Thank you.

THE CHAIRPERSON: There wasn't any criteria previously, that this is being introduced to take care of scenarios where -- essentially for the transgender situation and maybe they may need hormone therapy.

And, essentially, you're looking for the committee to take a vote, really, on this initial criteria to address these issues.

DR. SAMPSON: Yes. So we brought it two quarters ago. If I'm not mistaken, the committee voted on the criteria that was established by the agency, but the committee had a request to have the agency bring the criteria back for re-review. I don't believe we've had any requests to actually use it, but still we're honoring that request.

DR. HAYDEN: So on the criteria itself, I looked at the information that was before us,

special services criteria. The only question I had was this language about a mental health provider. And I wasn't quite sure what that meant. If it was a licensed clinical social worker or a psychologist?

Because actually the prescription will be coming from the endocrinologist from what I understand, not the mental health provider. Psychologists don't prescribe. Social workers doesn't prescribe.

MS. HARRIS: Yes, because a part of the prior auth process, the plan for the agency would look to see that the individual or child has an established relationship with a mental health counselor, licensed clinician. It can be a LCSW or a licensed psychologist. Because, particularly with this diagnosis and condition, there are a number of comorbid mental health issues present, and we want to make sure that those are being treated.

DR. HAYDEN: I got that, yeah. But the guest of the prior auth is special services. It doesn't clearly delineate who is -- it doesn't say the endocrinologist is prescribing, I guess.

MS. HARRIS: So are you requesting that we add who is the prescriber?

DR. HAYDEN: Just a clarification. I understand there's a clinical team, that the patient is in care, and I understand that. But putting a mental health -- just putting those words in there gives them -- you know. Are we giving them prescribing authority here?

I mean, it's kind of confusing when I read the document. That's what I'm saying.

MS. HARRIS: Okay.

DR. HAYDEN: So it's just a further clarification. Because it's the endocrinologist who is ultimately responsible for the -- with the team approach, of course.

Those are the comments. Thank you.

MS. HARRIS: Thank you, Dr. Hayden.

DR. SAENZ: But you still need that psychologist or mental health standard because part of the guidelines that were established for gender dysphoria by this association, which is, like, WPATH, they state that before the trans -- because some of these kids may later want to become full -- you know, do the gender reassignment, so they still need to have this

before they get to that point. So it should be the same hormones. There's some counseling that needs to be involved. So I think --

DR. HAYDEN. That is fine. It's just that I was a little bit confused. I wasn't sure if the psychiatrist was writing the prescription or was the endo, when I read the document and I just wanted further clarity on that. That was it.

DR. ZITIELLO: Could we say something like "the appropriate prescribing provider as part of the disciplinary team treating the patient," and that would cover any appropriate provider?

MS. HARRIS: Yes.

DR. HAYDEN: Do we make a motion for approval then with the edits? I make a motion to approve the language with the language that Amy -- Dr. Zitiello --

THE CHAIRPERSON: Okay. Great. We have a motion on the floor from Dr. Hayden. Can I get a second?

DR. ROMAY: Second.

THE CHAIRPERSON: A motion has been made and properly seconded. All those in favor say aye.

THE COMMITTEE: Aye.

THE CHAIRPERSON: Motion passes.

DR. MOORE: I'd like to go back to the vasopressin receptor antagonist, if we can. There was some actionable items that the P&T actually requested. And so I think we kind of missed that as we were going through the review. So I'll have Selika flip back to SAMSCA.

There are two products in this class that the P&T committee reviewed back in January, and they asked for the DUR board to create some criteria around these products. And when we did further review, we realized that we had criteria for the oral product, but not the IV Vaprisol.

So it would mostly kind of be a class criteria at this point because there's more than one agent, and that's the IV product, but it's supposed to be given in the hospital. It's for a hospitalized patient.

So I think that if you-all want to move that over to, like, medical services, so it can be managed on that side of the business, I think that's the most logical approach. But I

needed to be sure that you-all were aware of that and so you-all can vote for that to occur.

DR. ROMAY: I think the current criteria for the SAMSCA, we would just want to maybe go back and look at it, see if it needs revisions.

DR. MOORE: Yes.

DR. ROMAY: I mean, not that I'm looking to add more criteria points to it, but it's a two-question criteria, so I think we might have to look back to see if there's other indications or anything --

DR. MOORE: Absolutely. We can do that now, or do you want to take that back and then review it and then let us know at the next meeting or -- it's up to you-all. What do you want to do? Your pleasure.

DR. FIELD: Is it also open for any physician around or specifically for a nephrologist?

DR. MOORE: It's open for any at this time. The SAMSCA?

DR. FIELD: Yeah.

DR. MOORE: Any.

DR. SAMPSON: This is the current criteria for the SAMSCA oral tablet, to the left, your

left. The recipient must be 18 years of age or older. They must have a confirmed diagnosis of hyponatremia, the serum sodium level should be below 125 milliequivalents per liter, or the serum sodium level must be greater than or equal to 125 with symptoms and resisted correction with fluid restriction noted in the clinical notes. That is the current criteria.

DR. FIELD: Do we have data on what physicians, meaning class of physicians -- who is actually writing that? Is it nephrologists already, or is it --

DR. SAMPSON: We do have that data. I can provide that for you. At this moment, I wouldn't want to readily say who they are, but we do have that data, yes.

DR. FIELD: I'd like to see it.

DR. GOODNOW: Those lab values are just single numbers? Do they require two consecutive -- I think when we were talking about more detailed, what we might want to elaborate on is -- and we can definitely share some criteria from different facilities, but they may require, maybe, like, two consecutive or that number being the last number that the

patient had, as opposed to ever having a number at that level.

So I do think some enhancement would be very effective.

DR. ROMAY: I agree with Dr. Goodnow. And that's what I was referring to. Like, for the second bullet point -- I mean, what's "resistive correction"? How much time frame does the member have to have that low sodium before it's considered, you know, chronic, where intervention is needed versus just other things to correct it?

DR. GOODNOW: I think that this might be a greater example of where the two teams can work together because if the patient is initiated on the inpatient side to make that process for the patient a little bit more smooth. So there might be a way for the medical side and the pharmacy side to work together so that the patient doesn't go without during that transition period, that it's a little smoother for all parties involved.

DR. FIELD: Do you also have the average time period the patients are given the medication? Are they on it for a week? Are

they on it for 30 days? Are they on it for six months?

DR. SAMPSON: It's a short prior authorization approval for the course of therapy written. So it's not an extended period.

DR. ROMAY: Yeah, the current criteria, it's 30 --

DR. SAMPSON: Up to --

DR. ROMAY: Date of service, per prescription, up to 30 days. But there are people who are on it longer.

DR. SAMPSON: And they have to do another prior authorization to reevaluate.

DR. GOODNOW: And I think there's also patients that sort of hang out with a lab -- like, they're just chronically at certain levels and it's not affecting them. I think that the specification is a good request because you don't want to hit one lab value and then do the prior auth based on one level.

THE CHAIRPERSON: So I think I'm going to try and summarize here. I think there's still two items we have to address.

I think the first was Dr. Moore is asking,

essentially, for a vote on the Vaprisol, if we want to keep it under the pharmacy benefit or move it under the medical benefit due to the use in the hospital.

So I'll ask the committee to take action on that item, if someone wants to make a motion.

DR. OLSON: Motion to move it to the medical side.

DR. ZITIELLO: Second.

THE CHAIRPERSON: So the motion has been properly moved and second to move Vaprisol from the pharmacy benefit over to the medical benefit. All those in favor of that motion please say aye.

THE COMMITTEE: Aye.

THE CHAIRPERSON: The motion has properly passed.

I think the next item here was essentially, at least from my interpretation, is to take the SAMSCA criteria back for review. There, obviously, were a number of suggestions, to take a look at the provider type, the time frame on the sodium. So maybe this is just me being ignorant to the fact, but what I

understood the next step in the process would be is for the committee to take those recommendations back and present it at the next committee meeting.

DR. MOORE: So we'll certainly look up the provider types for the PAs that we've received from the fee-for-service side because that's all that we have exposure to. And then, the date for the lab value is certainly a valid concern. And if you-all want to clearly state what you would like the criteria to be and take a vote upon it, we'll take it back to the agency for final approval and then institute it.

DR. ROMAY: I think that's what we want. We want to be able to have input into what the criteria would look like, and then we can bring it back to the agency for approval.

THE CHAIRPERSON: So essentially what we're saying is, we're going to take the SAMSCA criteria back for review, and we'll bring our suggestions back next quarter?

DR. ROMAY: Correct.

THE CHAIRPERSON: Okay.

DR. MOORE: Okay.

THE CHAIRPERSON: So we don't need to vote on that?

DR. MOORE: At this time, no. So thank you for that on Vaprisol.

MS. ELLIOTT: I want to clarify something. We will address the criteria on our side, bring it back next time and you vote on it?

DR. ROMAY: Well, we are, but we probably want to --

MS. ELLIOTT: Table the whole thing?

DR. ROMAY: Yeah. We'll bring our recommendations the next time, then we can vote on it.

DR. GOODNOW: Is it more efficient if we -- can we provide, like, recommendations in advance of the meeting or, like, we can maybe work on a draft during the time period until the next meeting and then vote it final at the meeting?

DR. MOORE: Yes. It can be filtered through Vern.

MS. ELLIOTT: What we'll do is we will email you the criteria that we have right now so you can see exactly what we have. It's easier to do it that way.

THE CHAIRPERSON: Just one point of clarity for Dr. Phil's request. He actually was requesting the provider type first.

DR. MOORE: Yes. We'll certainly bring that back for the next meeting. Absolutely.

DR. FIELD: Well, before we give you recommendations because that, perhaps, would filter into a recommendation.

DR. MOORE: Okay. So we'll submit it and Vern will pass it along to you. Is that good?

THE CHAIRPERSON: Okay. So I think that closes the discussion on those agents. I think we can move to quarterly activities.

DR. MOORE: Yes. I have something to say before we move right into the quarterly activity.

In the past, we had looked for some congruency between the DUR and the P&T committees. Probably like a few years ago, we started looking at how we can best utilize the two committees together. I think that we've come leaps and bounds from where we were. you-all are talking to each other very well now. But in the past, there was zero communication between the two committees.

Where we started was the P&T classes. So in the past, many drugs were open. It was almost like open access for most of the classes. And so, we said, Well, maybe we can start streamlining these classes with the recommendation from the DUR committee to the P&T committee to kind of tighten some of these classes up.

Each class is reviewed every year. So year after year, we're looking at the same classes over and over. And we've gotten to a point where our sister team that runs the P&T committee, they've done a really good job along with the agency in tightening down the availability of so mean products being available on a PDL that we've come to a point where it's probably time to just move on from that approach. That was a starting point to begin conversations between the two committees.

While we're happy to continue to look at specific classes that you-all would like to look at, we're happy to do that. But, in the past, we would bring the top five classes that we noticed that maybe there was some area where we could tighten up the criteria or maybe the

preferred drug list.

But like I said, the drug list is pretty well maintained at this point. And we'd be happy to entertain specific classes if you would like to look at them.

So what we're going to move into is something that we did used to do in the past, reporting the top 10 therapeutic classes from the MCO space and fee-for-service space -- because those are the classes where we spend most of our money -- and take a look to see if there are any edits or suggestions that you-all would like to do within those specific classes.

So that's what Selika has next on the docket for you to look at and I just wanted to explain why those P&T classes were listed in your report, but they're not in this presentation.

So any questions on that?

All right. Thank you.

DR. SAMPSON: Fee-for-service top therapeutic classes by total paid. The reporting period was for January 1, 2017 through March 1, 2017. So here you'll find the top 10.

You have your agents to treat hemophilia. They came in about 16 million. Antiretrovirals, 6 million. Anticonvulsants, 5.9 million. Antineoplastic, 3.9 million. Human Growth Hormone, 3.3 million. Insulin agents, 3 million. Antipsychotic agents, 3 million. Rheumatoid agents, 2.5. Cystic Fibrosis, 2.4 million. And Pulmozyme agents, 1.9 million.

So this is where they fall at this time.

THE CHAIRPERSON: Does the antiretrovirals, does that include the Hep C and HIV -- AIDS together?

DR. SAMPSON: That number does not.

THE CHAIRPERSON: So would it just be Hep C for that -- that's represented in that antiretroviral class?

DR. SAMPSON: One moment.

Yes. The hepatitis -- I'm sorry, I apologize. It does include the hepatitis agents, the Hep C agents.

DR. GOODNOW: It might be nice to have the number of patients and the number of scripts filled so that can give us an idea of how long a patient is staying in that category because I

think that might answer some questions.

DR. SAMPSON: Okay. Thank you. And I can pull that data for you.

DR. GOODNOW: For this side?

DR. SAMPSON: Right. Because the other side is just the same, whereby when we pulled the data, we pulled the therapeutic class in addition to the total amount paid.

So, yes, I will pull that up for you in a minute.

THE CHAIRPERSON: Just one more question, I guess, just for clarity.

DR. SAMPSON: Sure.

THE CHAIRPERSON: So on this slide it has antiretrovirals, which I guess I have to assume that would be HIV. But then, on the fourth column, it has HCV antiretrovirals, which --

DR. SAMPSON: That one is broken up for the MCOs.

THE CHAIRPERSON: Gotcha.

DR. SAMPSON: Two separate ones.

THE CHAIRPERSON: Okay.

DR. SAMPSON: That one is spelled out.

And we were discussing that sidebar. Yes, it's two separate numbers.

DR. GOODNOW: And the Anticonvulsants Miscellaneous, is that just called "anticonvulsants" or is it a specific -- are other anticonvulsants not included?

DR. SAMPSON: That number includes all. Hold on one second -- and this, it is grouped with all of them. And what was your specific question that you want to know so I can pull it for you?

DR. GOODNOW: I was just making sure that the category was all anticonvulsants and not just miscellaneous anticonvulsants.

DR. SAMPSON: No, all.

DR. GOODNOW: All? Okay.

DR. SAMPSON: And wrapping up the interventions that are coming out this quarter by the end of first quarter going into second quarter and the third quarter, previous topics that have been discussed with the DUR board: Overlapping use of benzodiazepines and opiates. Soft messaging to the pharmacies at the point of sale. That was previously voted on by the DUR board. This intervention would require the pharmacist to enter a code as of August 31, 2016. Of course, you know, the FDA issued a

black box warning on opiate products and benzodiazepine products discouraging use together.

The September 2016 DUR board review, the first quarter '16 data: At that time, 23,000 fee-for-service and MCO recipients had at least one overlapping claim for both products. And the end resolve was the soft messaging. So that particular intervention will deploy third quarter 2017; it's projected to go into production.

The second intervention is the Zolpidem intervention. It was discussed at the June 2016 and September 2016 DUR activity. Based on FDA Safety Communication published in 2013, the labeled dosing for Zolpidem products now states that the recommended initial dose of immediate-release Zolpidem product is 5 milligrams for women, while the recommended initial dose for extended release is 6.25 milligrams for women.

At the September meeting, the DUR board voted to implement a step therapy edit. In this particular step therapy edit, it will actually go across the board. There was much

discussion about that -- for male and female recipients, whereby, before they can get higher dosing, they must step through the lower therapy or at least a 24-day supply must be utilized before the recipient can have the higher agent. And that edit is set to deploy third quarter '17.

The next edit intervention that's coming up is the maximum daily dose of antidepressants for recipients greater than or equal to six years of age. The DUR board approved recommended maximum daily doses of antidepressants in recipients age 6 or older. That edit is set to deploy by second quarter '17.

The tumor necrosis factor edit was discussed at the September DUR meeting. This particular edit, it will prevent the use of more than one TNF inhibitor and/or the use of any other biologic agent that is not classified as a TNF inhibitor. It is set to deploy third quarter '17.

Last but certainly not least, the IR Before ER opiate step therapy edit. There's been much discussion on this particular topic

since the September DUR meeting. The IR Before ER intervention will deploy late March. That's the end of first quarter '17.

The IR Before ER edit has been merged into one intervention that also encompasses abuse-deterrent criteria, the narcotic automated prior authorization. The edit addresses the CDC's recommendation for recipients to receive an immediate-release product before an extended-release product. The abuse -- and this is all inside of your written packet. If you refer to pages 18 through 19, and it will take you through the steps for that automation.

While you're looking through that or thinking about that IR Before ER edit, in addition to that, we included the FDA-approved abuse-deterrent products and some of their release dates. Some of them are out there -- expected to be out there, but currently there aren't any NDCs for them, so the products are not available, but they're expected to be available in the near future.

We also included the abuse-deterrent formulations that are non-FDA approved just for

a point of information. They have claims for having abuse deterrents, but they do not meet the FDA standard for having all of the desired properties needed.

DR. MOORE: I wanted to know if you-all had a chance to look at the abuse-deterrent edit? The narcotic edit is what we're affectionately calling it. But if you have any questions about it, I'm happy to answer any questions that you may have. We can step through it if you would like to, specifically, because I know the plans will need to understand the edit. So it's completely up to you how you want to proceed.

DR. ROMAY: Did we ever revisit, instead of doing an automated PA setup, doing more of a criteria?

DR. MOORE: For the abuse deterrent?

DR. ROMAY: Yeah, instead of doing an automated. I know a lot of the MCO plans don't have those capabilities of adding multiple steps to have a PA logic work. So did we ever look and see if, maybe, we can just convert it into a criteria to make it easier to navigate through it?

DR. MOORE: Right. I think the agency is okay with a manual-based PA, if you do not have the capability to automate.

DR. ROMAY: Yeah, that's one of our challenges that we run into when we're programming these things with our PBMs. It's a lot of factors and there's system limitations.

So I don't know if the group feels the same, but I think it would work better if there's a document.

DR. MOORE: The criteria or the steps to the automation will be provided in your weekly file. And so if your PBM is unable to automate it, they can just follow the steps of the automation as a paper-based or manual-based PA.

DR. ROMAY: Okay.

DR. MOORE: If they want to use our criteria.

DR. ROMAY: So are you saying --

DR. MOORE: They don't have to use this --

DR. ROMAY: Well, are you saying that the agency is willing to just move towards, like, a just regular criteria base versus this? It's just a suggestion.

MS. ELLIOTT: Well, the initiative was to

do an auto PA to facilitate -- I mean, it prevents doctors having to send manual PAs every time. So we're fine if your plan can do the auto PA. You just use the same exact --

DR. ROMAY: Okay. So we can create our own criteria based on this and --

MS. ELLIOTT: Right.

DR. ROMAY: Okay.

MS. ELLIOTT: As long as it follows ours --

DR. ROMAY: Fine. Yeah.

MS. ELLIOTT: -- and it's not more --

DR. ROMAY: Absolutely. Yeah. Definitely.

THE CHAIRPERSON: Could I make a comment?

I remember this topic from the last meeting and, I guess, I have two concerns. Let's just say, for example, Dr. Field writes a prescription for morphine, right? He comes in. And even if he wants the morphine, it's going to reject him. He has to go to mData, right? That's pretty much -- right? And I get the rebates and everything.

But let's say, for example, he can't use the mData because, I don't know, he gets highs

or whatever. So now, I guess, based on the wording of the criteria, and since there's no other abuse-deterrent products, really, I guess, from my perspective, his only recourse is to go back to a non-abuse-deterrent agent, right?

I mean, if he -- I guess, based on the way the criteria is right now, if Dr. Field writes for another agent, he's going to be redirected to a beta, which he failed. So I don't know if there is another avenue to get to another abuse-deterrent agent.

I don't want my personal feelings about abuse-deterrent products to dictate what the group does. I personally don't agree with them. But, you know, since it's on the PDL, I get it; we have to do it. But I just think the way that the criteria is set up right now, it makes it very difficult for a provider who actually wants their patient to be on an abuse-deterrent agent. They essentially just have one choice.

DR. MOORE: And we did talk about this at the last meeting. I think it was No. 5 on our quarterly activities to do and it did not make

the cut for this meeting.

But Selika and I actually talked about this extensively this week. I think your concern was, well, what else are these patients taking? Because you have a valid concern that if you cannot take Embeda, then what? We were going to pull the claims for patients who may have had Embeda in their past and may not be on it today, just to see what they are taking. And that was No. 1 for our quarterly topics for next quarter. So you did make the cut for this coming quarter.

THE CHAIRPERSON: Moving on up.

DR. MOORE: Yes. And, absolutely, we'll address the criteria concerns at that time, what's next. And I think that's probably where we were headed with that conversation at the last meeting, so yes.

THE CHAIRPERSON: Thank you, Dr. Moore.

DR. SAMPSON: And this graph chart should look very familiar as we continue our discussion about morphine milligram equivalents, meaning continued since September and January and now. This chart was shared previously, whereby it is second quarter '16

data for Florida Medicaid recipients and -- approved fee-for-service and MCO recipients.

The data at that point revealed 10,383 fee-for-service and MCO recipients combined that were receiving a cumulative 90 morphine milligram equivalents per day or greater. This data did exclude recipients that had a diagnosis of cancer or sickle cell or were in hospice care. At that time, the DUR board voted to establish a maximum daily dose based on the CDC guidelines but, at the same time, they wanted to get a deeper dive into that 10,383 number and that's what we did.

So this is how the information comes back for those recipients in both categories. When you look at the cumulative number, the biostatistician was able to pull the data and give to us where the recipients were.

So starting from the top, you see you have a few recipients in that number that were receiving a greater than or equal to 500 MMEs within the review period and so on and so forth. And then the majority of the population was falling somewhere at that 150 number. So greater than or equal to 150 but less than 200

MMEs per day. You were looking at about 1,600 recipients on both sides.

The most common diagnoses associated with this number -- again, we cannot match claims to diagnoses, but we can go back and look at a two-year review period and use our knowledge there to see what the ailment may have been. The top five diagnoses during that period all were related to pain in some way, some fashion. Joint, limb pain, abdominal pain, chest pain, back pain, other long-term pain was associated with all of those claims that you see there over a two-year period.

So, where does that leave us? What we know for sure, we know that higher dosages yield higher risk. So patients who receive higher dosages of opiates have a higher risk of overdose and death. We also know that dosages above 50 MME per day increase the risk for overdose by at least two times. This is data that we know for sure.

So where do we go from here? The September 2016 DUR board voted to establish that maximum daily dose guideline based on the CDC's recommendation. An intervention edit

released over time to reach the 90 MMEs per day is what we see currently trending across the country. So no one is being cut off or anything of that nature. But it's making the providers aware of what the daily amount will be and then slowly releasing those edits over time.

MR. OLSON: Do you have number of claims for MME less than 90?

DR. SAMPSON: Yes, because those were the numbers that we previously discussed. I'm happy to pull that up for you. If we go back to -- this slide? This is answering your question?

MR. OLSON: Yeah, okay.

DR. SAMPSON: Okay. So what we have here, right, that number for the 50 MMEs -- greater than 50, that was a total on both sides, 72,000. And then if you look at the greater than or equal to 50, but less than 90, 17,000.

DR. GOODNOW: And these are not unique recipients? So they are not doubled up if they were fee-for-service and --

DR. SAMPSON: Okay, the statistician did address that. No, she can't confirm that

because sometime the patients do move.

Good question.

DR. FIELD: Do we have an idea whether those were coming out of certified pain clinics or whether they were done by, again -- since that dosage is quite high and normally you would expect somebody who specializes in pain to be writing that kind of stuff?

DR. SAMPSON: Right. We would have to go back in and look specifically at those numbers. But for the majority of the part, the physicians were all categories, all types. But if you want to look at the ones that are greater than or equal to 90 in terms of the providers?

DR. FIELD: Yeah, the 10,000 that may be --

DR. GOODNOW: And then given the top 10 providers of that 10,000, just to see if there's a trend for higher utilization, if there's a higher frequency provider in that higher -- the only thing is they're oncology now --

DR. FIELD: Oncology was included, correct? Cancer was excluded?

DR. MOORE: Yes.

DR. FIELD: So essentially we're talking about chronic nonmalignant pain?

DR. MOORE: Yes.

DR. FIELD: So we already know what physicians in the state have to be matched up and declare that you're going to prescribe like that. I don't know how many of us have that next to our license. But in that dosage, you would expect somebody to have a specialty. If it wasn't coming out of somebody with a specialty, that would be kind of surprising.

DR. SAMPSON: Yes, it would.

It was a cumulative edit, so we did it over time whereby each claim, we would go in and then add what would be their day because they were able to fill on the 1st, and then they were able to fill again on the 28th, and then they were able to fill again, maybe on the 20th. So we kept track of that and that's how the cumulative count went.

DR. MOORE: From a data perspective, we do not get a provider's specialty on the claim, so it's essentially impossible for us to determine the specialty of the physician.

Now, for the SAMSCA -- because that's similar, what you want -- you want us to do is to look up to see if it's a nephrologist. Because it's a paper-based PA, chances are I will be able to tell if this a primary or some type of specialty clinic, so that's why I know we can probably do that. But from products that do not require a PA or PDO and claims just pay, we won't be able to determine provider type because we don't get a provider's specialty.

DR. FIELD: I think we had this conversation before, but it goes back to an NPI, and the NPI has a toxomity related to it. There are ways, but it doesn't mean that we have the automated system to do it.

DR. MOORE: Well, we don't -- we don't gather that information from our vendor. I'm sorry.

THE CHAIRPERSON: So I just want to do a quick temperature check. The time is 3:05. It looks like we have two topics left, HIV and Transderm Scop. So I want to ask if anyone needed a quick break here, bladder relief, or do you want to push through?

THE COMMITTEE: Push through.

THE CHAIRPERSON: I agree.

DR. SAMPSON: HIV polypharmacy.

DR. MOORE: I want to restate the actionable items so that we're clear on what the request is because the homework from the last meeting was to bring back a stratification of the doses that were above 90 so that Magellan has a corporate solution that does evaluate any claims that had an MME of 90 and above. And we talked about perhaps setting that threshold a little higher, and so that's why we brought back the stratification. But I believe there's additional items that have come forth now.

DR. SAMPSON: The physician was one that we were unable to do.

DR. MOORE: And is that the only thing?

DR. ROMAY: So as I understand the threshold on the MME, is the approach going to be that we're going to do, like, a banner message sort of thing to start it out to educate the providers and then we're going implement the hard edit?

DR. MOORE: Sure. We can certainly take

that approach -- basic approach and first the educational campaign about what we're going to do and then move into -- honestly, because the coding takes a little while to get into place. So yes, I believe that's it.

DR. ROMAY: So I guess we'll bring this back -- we'll table this back for the next go-round.

DR. MOORE: Yes.

DR. SAMPSON: The P&T committee requested for the DUR board to look into HIV polypharmacy from a stance of, they wanted to evaluate recipients who are receiving multiple single-agent antiretroviral therapy medication versus some of the newer combination products where applicable.

So you have two additional -- here, we just created a cheat sheet that's already available -- readily available on the aidsinfo.org website. And so, here, at your desk, you have the FDA-approved HIV medications. And you have the class. Everything from the NRTs, NNRTs, PIs, so on and so forth.

And then, on the back of the document

there, you also have the combination products that are available, their generic name, the brand name and what the combination is comprised of.

In this particular look, as we already know, the gold standard for most patients, they may have two or more HIV medicines from one or more drug classes.

So what was done? The pharmacy claims were reviewed from October 1st to December 31st, 2016. Who was included? Recipients who received five or more HIV agents as single agents and/or via a combination therapy.

We'll go deeper into how that breaks out, how the data was pulled. What we have? We had recipients on the fee-for-service side, as well as the MCO side. Some of recipients received all single agents, so that means they didn't have any combination therapy, whatsoever. And you see the low numbers there for fee-for-service and MCO during that time period.

Then you have a population that may have had a two-agent combination, either with a two-agent combination medication and then so on

and so forth, whereby if the recipient had four agents, they could have had four by two combination, or a three combination plus one. That's how the statistician was able to pull the data back based on the drug class. And so it will make more sense when you take a look at the sample.

To your left you have all single-agent regimens. That was for the time period reviewed: October, November, December. And then, the way the data came back for October, November, December, you have a recipient there that had the four or more agents, but that four or more was comprised of therapy whereby it was a two-combination drug and then two additional or where you have one that is a four combination drug and then one additional.

So overall, when we took even a deeper dive into it, it could have been the course of therapy -- the start of therapy for these particular recipients, so we did not put up any latent red flags that there was an issue or problem.

Transderm Scop. This came up as a quarterly activity that the DUR board wanted to

look into. The first quarter data for 2017 was reviewed. The data review was October 1st through December 31st. There was a diagnosis check for the past two years for the FDA-approved indication for the Transderm Scop patches.

As you know, it is indicated for nausea and vomiting associated with motion sickness and postoperative nausea and vomiting. Each patch delivers 1 milligram of scopolamine over a three-day period. Only one patch should be worn at any particular time. One package equals four patches. Florida Medicaid will reimburse for 10 patches every rolling 327 days.

Based on the claims, we took a look at the diagnosis for a two-year period. And what we discovered was that there were at least 80 percent of the fee-for-service recipients and 27 percent of the MCO recipients, they did not have a valid diagnosis for Transderm Scop during that period. Again, we cannot match claims to diagnoses, but we can look back at a two-year period and figure, did they have the diagnosis during that said time.

DR. ZITIELLO: Was there a look at age there since it's not approved for under 18?

DR. SAMPSON: For under 18? Yes. We do have the ages. It wasn't pulled within this particular data, but we do have their age available.

DR. ZITIELLO: I think the concern was some use in nursing homes, some use like that. It's not my area, but is that correct?

MS. ELLIOTT: We brought up the drooling condition for nursing homes.

DR. MOORE: Right.

DR. SAMPSON: But when you take a look at did they have the FDA-approved diagnoses, no, the majority of the recipients did not. So the decision would be for you to discuss considering how you would like to proceed with the medication as currently preferred medication, but should a diagnosis check be added to the processing of the claim at the point of sale.

MR. OLSON: Do you have the information for what the diagnoses were? Because that would help determine --

DR. SAMPSON: Oh, well, again, we can't

match the diagnoses to the claim. We can take a look at all that they had and it was a gamut of everything that the recipients may have had. But to try to narrow it down in terms of they definitely had said diagnoses, off-label use --

DR. MOORE: So what we did was, the utilization came back. And then we also had the biostatistician pull any type of diagnosis that they had on file at the time of the date of service.

So there isn't a one-to-one comparison. We have to use deductive reasoning. So if there was a diagnosis of nausea and vomiting at the time of date of service, we said, Okay, check, you met the criteria because we don't require a diagnosis at this time.

So maybe that's the next step, is attach the FDA-approved diagnoses to this product so patients that are getting the product on that date of service actually have a diagnosis -- an approved diagnosis on file.

DR. ROMAY: I think we cite a diagnosis as other agents that the member would probably benefit from using prior to Transderm Scop. I mean, they're having nausea and vomiting, any

of the antiemetics that are currently on market -- you know, decadrone, things like that, or promethazine, things like that -- I think we need to kind of look at those to see if it's really, truly the only agent that's going to be suitable to control those symptoms.

So maybe a PA with criteria outlining some diagnoses that are preapproved, maybe an age and maybe something along the lines of preferred agents that should be used prior to -- depending on the diagnosis.

DR. MOORE: So then the next step would be -- this would be a recommendation to P&T. Because it is a preferred product, so it has to go through that process first. But it's good. Like I said, we've come leaps and bounds. We're making recommendations to the P&T committee, saying, we reviewed this class. It's a class coming up, I think, relatively soon, and the recommendation is to move it to a non-preferred status with this criteria. So that's the process.

If that's the route we want to go, we can certainly discuss that right now. I have to check the cycle. I think it might be up for

review in June, so we would need to discuss it.

DR. GOODNOW: The other potential is if they're also on another concomitant antiemetic. Sometimes they use, like, a multimodal approach. So that might meet criteria if they're already on an antiemetic and they need a stronger agent. I don't see it a lot, but theoretically perhaps some of the claim is just the multimodal approach to get them on multiple products.

DR. ROMAY: I think the majority of the use that is currently seen with that product is for vertigo. People taking a cruise or taking a long trip and doesn't want to be taking oral tablets. It's just a convenience factor a lot of times, so that's where I usually see it most. I mean, there may be some scenarios where either medically fragile kids who are either on benz or something that their secretions aren't controlled and they need to suppress it with more aggressive therapy.

DR. MOORE: So do you-all want to decide on the level of intervention you want to do? Do you want to do it as a diagnosis, attach a diagnosis -- because it is referred right

now -- so attach a diagnosis, or do you want to take a more stringent approach and say, Hey, we want make a recommendation to a non-preferred status and then establish some type of criteria?

DR. SAENZ: What is the utilization? There's a cost. How much is it really, like, driving the cost?

DR. ROMAY: We had that last time.

DR. SAENZ: We had that last time?

DR. ROMAY: Yeah.

DR. SAENZ: I forgot how much it was then. I guess it must have been a lot of --

DR. ROMAY: Yeah, there was a lot of funds associated with that drug. I remember.

DR. MOORE: Right. It's in the report, the report that you got.

DR. SAENZ: Okay. It looks like it was a lot of utilization. Otherwise, we wouldn't be --

DR. MOORE: Right. Yeah. It was a P&T class that we brought forth at the last meeting.

DR. SAENZ: I agree with his comments.

DR. ROMAY: So I motion to move that

forward to the P&T for non-PDL with criteria.

DR. HAYDEN: There was a lot of patients on this, but was the fiscal impact great to the Florida Medicaid program as well, or is it just the number of patients on it?

DR. MOORE: I'm going to see if I can resurrect that file that we talked about at the last meeting so we can give you a point of reference.

THE CHAIRPERSON: So at this point, we have a motion on the floor. We are going to table the motion until we get the information from Dr. Moore, and then, perhaps, a second of that motion, we'll deal with it and close out that issue.

DR. ZITIELLO: Can we also look at dual therapy with the antiemetics to Dr. Goodnow's point? Because I would hate to hold up therapy for somebody who is getting multimodal approach.

THE CHAIRPERSON: So I think just from Robert's Rules of Order, can I ask you to rescind your motion since we have some unreadiness here? Can you remove your motion from the floor because we have some

unreadiness?

DR. ROMAY: Sure. I remove my motion.

THE CHAIRPERSON: So you are looking up information for Dr. Goodnow.

DR. MOORE: Yeah, I just sent it to Salika.

DR. ROMAY: Wouldn't there be a DUR reject that's triggered if those two antiemetics are going to be delivered at the same time?

DR. MOORE: It would trigger. However, it will pay if it's the same physician and same pharmacy. So if there's a different physician or a different pharmacy, it will deny. But the pharmacy can override it with those service intervention codes, prescriber consulted MO, whatever those codes are.

DR. ROMAY: Well, I think we captured that intention if we do what we were going to do initially.

DR. MOORE. It would only stop if the doctor or pharmacy are different. Otherwise, the claim would continue to process.

DR. ROMAY: I just don't see that scenario coming up very often. It's very, very, very infrequently where the member requires two

antiemetics to control their condition. I mean, I just don't see that. At least in my clinical practice, I haven't encountered that.

DR. MOORE: Okay. So "N" means fee-for-service. "Y" means encounter, so plans. The data was from September 1st of '16 through November 30th of '16.

DR. SAMPSON: Fee-for-service and MCO.

DR. MOORE: Yeah. The other carrier amount, that's how much the plan paid.

DR. ROMAY: September? November?

DR. MOORE: September. So all of September, all of October and all of November.

Accounting for that, was the motion for moving Transderm Scop to the non-preferred status along with criteria creation, was that passed?

THE CHAIRPERSON: No. We rescinded the motion. I think we had some unreadiness. We had some questions on the floor. We have the data here. I think we need to make an informed decision.

Do you want to restate your motion?

DR. ROMAY: I would restate it, yes. So move forward to suggestion of moving it to

non-PDL with a criteria creation to supplement the edit.

THE CHAIRPERSON: All right. We have a motion on the floor.

DR. FIELD: Second.

THE CHAIRPERSON: Second by Dr. Field. Ready for the question. All those in favor say aye.

THE COMMITTEE: Aye.

THE CHAIRPERSON: Motion passes.

DR. MOORE: Thank you.

Would you like to discuss the criteria? Some items that you'd like to see in the criteria?

DR. ZITIELLO: Diagnosis.

DR. MOORE: First and foremost.

All right. So I heard diagnosis. I think I heard age somewhere.

DR. ZITIELLO: Yes, age.

DR. ROMAY: Formulate alternatives.

DR. MOORE: Okay.

DR. ROMAY: I think we can use the same concept as we did with the previous agent that we were reviewing that we were going to --

THE CHAIRPERSON: SAMSCA.

DR. MOORE: SAMSCA?

DR. ROMAY: The SAMSCA.

DR. MOORE: Okay.

DR. ROMAY: So we can kind of look -- I guess we can all get together and submit our recommendations.

DR. MOORE: Sure. Okay.

We'll review those at the next meeting. And I can certainly make the recommendation to our sister team that runs the P&T committee to move Transderm Scop to the non-preferred status. I can go ahead and make that recommendation.

Thank you.

THE CHAIRPERSON: Okay. I think that concludes our Quarterly DUR Activity Reports. If I'm not mistaken, we're going have an audible here to the agenda. We have open discussion next. But it's my understanding that we have some individuals in our audience that would like to -- some public comments.

I think we're going to just go ahead move right through it.

MS. ELLIOTT: Oh, I thought it was the report that we were going to -- okay.

MS. HARRIS: Just roll on.

THE CHAIRPERSON: The big boss has spoken. We open the floor for public comment. Does anyone want to step forward here for any items of discussion?

I think in the Moses imaginary rule book here, after 30 seconds, we close the floor.

MS. FUHR: Hello, everyone. We were given the opportunity to come here and speak. My name is Debbie Fuhr. I'm with Biogen. I'm the account manager that covers Florida.

I'd like to just give a very high overview on the new product that we just launched for spinal muscular atrophy. It's called SPINRAZA or nusinersen. I'd like to get into just a little bit of the dosing, the lab tests that are required, the distribution model, and then I'd like to bring up Biogen's rare disease reimbursement manager to come up and discuss a little bit about coding, site of care issues and that type of thing. We were told that we could have five minute, so we're going to fly through.

SPINRAZA (nusinersen) is a survival motor neuron 2, which is an SMN2. It's directed

antisense oligonucleotide and the first and only FDA-approved therapy indicated for the treatment of SMA in pediatric and adult patients.

The efficacy and safety of SPINRAZA was demonstrated in a double-blind double-sham, which went as a placebo. When it's an intrathecal injection, they would, for the sham-controlled, actually puncture the skin, so it's the placebo equivalent for an intrathecal injection, in controlled clinical trials for patients with infantile onset of SMA. And it was also supported by open-label clinical trials in presymptomatic and symptomatic patients.

Of the 82 patients that were eligible for this interim analysis, there was statistical significant differences in the percentages of patients that were able to achieve motor milestones and response where patients would normally not. So that includes kick, head control, rolling, sitting up, standing, walking; 40 percent for the SPINRAZA-treated patient versus zero in the sham-controlled.

And then, in addition, a greater percent

of the patients that were treated with SPINRAZA actually survived where untreated patients would not be expected to.

In the open-label uncontrolled trials, let me tell you that the FDA stopped our trials. They deemed that it would unethical to keep the patients that were on placebo because of the results that they showed. So then we have ongoing clinical trials go on.

Patients who were likely to develop SMA Type 1, 2 or 3, achieved milestones, such as the ability to walk or stand unassisted when they would otherwise not be expected to do so. Again, maintain motor milestones at the ages when they would not be expected to do so and survive to ages where they would not be expected to do so.

I'll quickly go through the dosing again. SPINRAZA is administered intrathecally by or under the direction of a healthcare professional experienced in performing lumbar punctures.

It comes in a 12 milligram vial and it is not weight based. So a newborn infant would get the same dose as child that would be 15.

The dosing includes four loading doses: Day zero, 14 days after that, so Day 14, Day 28. The final loading dose would be around Day 58. And then, thereafter, as a maintenance dose, it is once every four months.

The testing that needs to be done at baseline and prior to each dose would be a platelet count, a prothrombin time and quantitative spot urine protein test.

The distribution model, as with rare diseases, it's very common to have a limited distribution model. Accredo is the resource therapy, along with CuraScript, so that's the SP. And the reason they do that is to keep the handling, the storage, the distribution, and the transportation all very contained so it can be tracked.

At this time, I'd like to bring up Brenda for the other two minutes and let her tell you a little bit about the reimbursement and coding.

MS. WEAVER: Hi. My name is Brenda Weaver. I'm a rare disease reimbursement manager.

My qualifications include -- I'm a

clinical nurse. Practiced in ped ICU. I worked for Blue Cross Blue Shield in medical policy in Minnesota for eight years. And then I'm also a certified holder for physicians as well as for outpatient settings.

So some of the things that we are hearing from sites, at least on SPINRAZA, are they're very, very concerned. In the rare disease space, the products are very expensive. This is no exception to that rule. And these patients, they tend to congregate in MDA centers. So there's only so many MDA centers around the country. And so these institutions have actually quite large populations.

So when you have a drug in this expensive of a bracket, they simply can't afford to buy and bill the product. They just don't have the budget in their pharmacy whether it's -- well, these are mostly hospitals. A physician clinic certainly can't afford to buy and bill the product. So this is becoming kind of an issue with payors, especially in the Medicaid space, because Medicaid typically uses buy and bill as a methodology.

So I want to just see if we can open a

dialogue about whether or not this product could be allowed under the specialty pharmacy benefit as well or the pharmacy benefit versus medical. Accredo can dispense under the medical, but what we're finding out is a barrier is they need to have a letter of agreement in place with the payor. And typically inside the payor, those letters of agreement are single case agreements or contracting. That's going to go to a separate area in the payor, at least it did for us, a silo department.

They are non-clinical in nature and so they really don't understand the urgency behind getting these contracts done quickly. And they typically don't communicate with the medical side either. So that's kind of an issue that we're having.

I also can help you, if you need -- we can talk about this offline at some point. But we wrote our own edits. I wrote edits for our claim system at Blue Cross. And I've had some Medicaid plans that have said to me, we're a little bit concerned about using the SPB benefit or the pharmacy benefit because we

don't want to get the pharmacy claim adjudicated and then also have a medical claim externally billed to us, which that could happen in a mistake.

And so, we problem-solved and we talked about some ways to do reverse claim steps in the medical system -- in the medical payment system so that you can catch those claims. And I can take that offline, if you have questions like that.

Any questions that I can address?

MS. ELLIOTT: I just have a comment. This is a public information. I don't know if the members know how much the drug cost or are they interested?

DR. ZITIELLO: I'm interested.

MS. WEAVER: The price of SPINRAZA at the WAC price is $125,000 per vial. In the first year, treatment for a treatment-naive patient, that is going to be six doses in that first 12 months, $750,000 as a first-year treatment. Thereafter, SPINRAZA is dosed at every four months, three times a year, so that's $375,000.

Biogen participates in one discount program that would be the Medicaid rebate

program. So that's another thing to consider if you think about moving this over to your pharmacy benefit manager. If you produce this as a pharmacy benefit, Medicaid is going to get that rebate. It's very easy to adjudicate and control rebates on the pharmacy side versus on the medical side when have you the institution buying and billing.

I'm not saying that the best thing would necessarily be to block this drug to just a pharmacy benefit because, of course, when we did our research on this population, what we found, when the population is identified, they typically have a commercial insurer. Mom and dad might both be working.

But then, when this diagnosis hits, usually at least one parent ends up having to stop working to take care of the needs of the child. So what happens, in about six months time, these patients go onto a Medicaid -- either Medicaid as a primary payor or Medicaid as a secondary payor.

If you would block this only to a pharmacy benefit, then what could happen then is, if you have an instance where you have a commercial

payor as primary, Medicaid is the secondary, we would still want a buy-and-bill channel or at least a medical benefit channel. Because Accredo could provide the drug under the medical benefit as well. And then Medicaid would just have to pick up as a secondary payor, if that makes sense.

THE CHAIRPERSON: I have two questions. Thanks for great information.

Could you restate what the incidence is of this order? Forgive me if you stated that before.

MS. WEAVER: I did not. The incidence is approximately 3- to 400 life births per year in the United States. That doesn't mean that we -- I don't know exactly what the true population is, living population today. There's estimates between 8 and 10,000, I think, as far as live patients with SMA either Types 1, 2, 3 or 4.

DR. ZITIELLO: And there's very vast differences between the types in spinal muscular atrophy. The one that I was brought up in pediatrics understanding was type 1, where I think dispensing would have some

efficacy.

A little more concerned about the types 2 and 3 and this being implemented so soon after it's approved. There's also -- and I know this very well --

THE CHAIRPERSON: Would there be any dosing variations?

DR. ZITIELLO: Well, the studies that I have read, the dosing was very different for the types 2 and 3. There wasn't a real control on that. So that's why I'm concerned.

MS. FUHR: It's the same dosing.

And for the later onset for the SMA types 2 or 3, any functioning that they currently have, you would want to preserve. So if the older child has the ability to move the electric wheelchair, obviously, you would want to save that for mobility.

And I do have some literature I can leave. We just didn't know what the setup was here and what we could do. So I have some information for you.

MS. WEAVER: Type 3 is very variable as far as how it presents later in life. It can be very mild weakness also. When we're talking

wheelchairs, those would be more severe cases. The American College of Obstetrics & Gynecology just this month determined that all women who are pregnant and are wanting preconceptual care get SMA carrier so there's probably going to be recommendation of more of this disease coming out. So that's another way I see utilization will increase.

DR. ZITIELLO: Have you guys had an opportunity to comb through your claims data, by any chance, just to identify what you think your patient population is for your plan?

MS. WEAVER: We're the process of doing that.

DR. ZITIELLO: Okay. Sidebar. If you'd like, I can help identify and narrow down those diagnosis codes.

MS. WEAVER: We'll take that under advisement.

DR. HAYDEN: I just have a question. Logistically, if it goes to a pharmacy benefit and it's intrathecal infusion, do the parents pick it up at the pharmacy or what is the process?

MS. WEAVER: Good question. That's an

excellent question.

This product requires cold chain for chain of custody. So in the case of specialty pharmacy procurement, Accredo Specialty Pharmacy would ship from their pharmacy to the hospital pharmacy. This drug can't go in the hands of a family.

DR. HAYDEN: Or the infusion center.

MS. WEAVER: Right. It eventually gets to the infusion center. But typically how it works, it just goes into the inpatient pharmacy. The inpatient pharmacy does all their required storage and inventory and all that.

And then, at the time of the injection, then they hand it over, like, hand-walk it over to the suite where the injection is being done.

And to the physician over here, to the point of the variability, there's also a great degree of variability just from an injection standpoint. You have some patients that are extremely stable. They still have good respiratory support. They're okay to be put in the position for a lumbar puncture.

Then you have, on the end of the scale,

somebody that might already have scoliosis, growing rods, things like that, and they might actually need interventional radiology.

I've had a very few patients injected in the clinic setting because they were stable and safe. But the large majority of these are requiring actual hospital outpatient services for the injection.

And that's sort of what's coming back from some of the payors, with the hospital outpatient dates of service they've told me -- at least their CFOs have told me that their payment methodologies for buy and bill tend to be on a bundled rate, which is problematic if we don't have a carve-out or some way to carve out the price for the product if they have to buy and bill.

So there's two reasons, really, why they're really not able to buy and bill. Reimbursement, that's one of them. But then also just the strain to the budget, the impact to their overall pharmacy budget.

THE CHAIRPERSON: Very good. Thank you.

MS. HARRIS: I just wanted to make sure the board members are aware that we are

bringing forward the clinical criteria that would be utilized by the agency. And the health plan, if they so choose, they cannot be more restrictive than the criteria that the agency adopted. And so, if you had any additional questions for the speaker, as you contemplate the criteria that you have before you, I just wanted to make sure you are aware of that. The drugs that we're speaking of are not on our PDL and will be subject to prior auth.

THE CHAIRPERSON: Any additional public comments?

MS. HANSON: Hi. Jill Hanson. I just wanted to add a couple of comments.

First, just the importance of --

MS. ELLIOTT: Is it for the same drug?

MS. HANSON: My first comment is.

MS. ELLIOTT: Oh, okay.

MS. HANSON: I just wanted to first comment on SPINRAZA and just add one point for our health plan. We are in close communication for the LOAs SCA process for clinical and non-clinical. So I just wanted to mention that as far as covering it under medical. Some

plans are in very close communication with that process.

There's definitely a need for consistent criteria for not just this drug but other high-cost drugs that's on list, one, and the speed of getting those criteria out is important to us. So thank you for looking at this. We definitely appreciate the -- I guess, expediting it potentially.

My last comment, I just wanted to go back to the opiate dependence discussion and the buprenorphine. Since plans cannot be more restrictive than the criteria, I had hoped that the committee would look at the reapproval criteria for straight buprenorphine and revisit that because of the concern for overuse and misuse.

So that would be my suggestion, is to revisit that reapproval criteria.

Thank you.

MS. ELLIOTT: Before the next speaker comes up, I just want to make a comment.

I know you-all received the draft criteria for the two products that we're talking about. I just wanted to let you know that your chair,

Dr. Martarana, he had submitted some edits or recommendations for SPINRAZA. And I just wanted to let you know that I'll pass it around. Because it was so late, I didn't have time to send it.

Thank you.

MR. FERNANDEZ: I want to thank the committee for giving me a few minutes to speak about another drug. I didn't know that SPINRAZA was on the agenda and I would ask to say a few words about it.

My name is Ray Fernandez. I'm a pediatric neurologist in Tampa. I've been in private practice since forever -- since 1976, 40, 41 years. As mentioned, in private practice. I'm not an expert.

MS. HARRIS: Excuse me. Can I interrupt you really quickly? So for those in the audience, before you videotape or record this session, you must ask the permission of members of the audience. We already have a court reporter. And once that transcription is finalized, it will become a public record and you can request that from the agency. But if you are going to videotape, you need to request

permission from everyone in the audience.

THE CHAIRPERSON: And can I add one additional comment?

For most of the legacy DUR attendees, it's pretty atypical to have this many public comments as opposed to our sister committee. The P&T committee generally grants a two-minute time approval. So I do not want this to come across as a surprise to anyone, but I am keeping time here -- just for organizational purposes up here.

So if I cut you off, the intent is not to be rude but just to keep time.

MR. FERNANDEZ: How much time?

THE CHAIRPERSON: Four minutes and 40 seconds left.

MR. FERNANDEZ: I just want you to know, I've been in private practice in Tampa since 1976. I had the good fortune of having the Muscular Dystrophy Association contact me 35 years ago. They asked me to establish a clinic in Tampa for children with muscle disease. I said, sure. It was easy then because we did not know a whole lot about it.

What has happened over the past 35 years

is I have gained a whole lot of experience. I don't consider myself to be an expert, but experience is a very good teacher.

I've seen diseases over time from spinal muscular atrophy and Duchenne muscular dystrophy. Genetic advances began sometime in the '80s and they have skyrocketed since then. By mid 1980s to late 1980s, we were able to establish a diagnosis very specifically by DNA or gene analysis.

And then to subcategorize diseases, again, based on genetic analysis very specifically.

Spinal muscular atrophy, people have mentioned types 1 through type 4. The incidence of a disease, the frequency of a disease, is very tricky. When Biogen, I believe, began clinical trials for type 1 SMA, we had two babies born with it within a month: one in Tampa, one in St. Petersburg. Both were referred into the drug trials. I wasn't privy to what was happening so I do not know the outcome of these two early treated babies.

But I can tell you the treatment of the babies with type 1 with SPINRAZA, also called nusinersen, has made a huge difference. I

mean, these babies died by age two years.

It was a diagnosis that you could spot when you walked in the room. It was a baby that was hardly moving, struggling to breathe, at the age of a month or earlier. It progressed rapidly. Death within about two years. But I think treatment with SPINRAZA has made a huge difference.

The type 2 form is milder, but it's not really mild if you see it. The type 3 form was commented on. I have two children with type 2 spinal muscular atrophy. One just stopped walking at the age of 10 years. We're struggling now with whether we should fuse her spine now because she needs it. Her scoliosis is progressing rapidly. Or whether we should start treating her with nusinersen by spinal tap. Intrathecal is given by spinal tap. I have agreed to be the spinal tapper.

We have one child approved and we hope to be starting soon at St. Joseph's Hospital, the Day Hospital, the outpatient center.

The treatment of the type 1 babies has made a big difference. They're achieving milestones that they never would have achieved

untreated. There's no doubt it.

They're living beyond the age of two years. They're crawling, pulling up, standing with assistance, taking steps with assistance. That never happened.

So I would compel and urge you to consider this drug very closely. It's expensive, yes, but it makes -- it seems to make a big difference in the outcome, both in terms of quality of life and life span.

Do I go on to the next or does anybody have any questions?

THE CHAIRPERSON: You have one more minute, 60 seconds.

MR. FERNANDEZ: All right.

Well, as a treating doctor, I write prescriptions. And with these drugs, often there's denial and I follow it with a letter of appeal. Another denial. Another letter of appeal. And slowly, but surely, we are getting patients approved.

Again, the first one, the first approval for SPINRAZA, I was informed of while I was in Washington this past weekend at a muscle disease meeting. And this is a topic of

our discussion in Washington. It came up, the logistics and the difficulties involved with how to administer the drug, et cetera, and the cost of the drug. That's not part of my job description, but I recognize it is expensive and it creates a problem.

So, hopefully, we'll be able to move on with this because there are a number of patients -- these diseases -- I don't know what the numbers mean to you, 1 in 5,000 or 1 in 10,000, but we see them and they're not that --

THE CHAIRPERSON: Sir.

MR. FERNANDEZ: -- they're not uncommon.

THE CHAIRPERSON: Thank you very much.

MR. FERNANDEZ: Should I continue?

THE CHAIRPERSON: Does anyone have any questions.

DR. ZITIELLO: Any experience with SMA3 in treatment?

MR. FERNANDEZ: None have been treated that I know of. I'm not sure what's happening with the drug trials.

I have two patients with type 3 SMA that we're planning to treat. The indication for treatment is all four forms.

I understand from my adult colleagues that -- they call me when an adult calls them and asks them if the adult should be treated. I don't think we know. I'm not sure what the experiences are. I think most of the experience in clinical trials has been with the type 1 form.

But I think it is our intent to treat all patients with spinal muscular atrophy, no matter the type. And there will be exceptions. I think that we try to be reasonable about this. There's some patients in whom there will not be reasonable expectation of improvement. I don't think that any of us would push for treatment in that particular circumstance. These would be very far advanced people, very weak, virtually unable to do anything independently.

THE CHAIRPERSON: Very good. Thank you.

MR. FERNANDEZ: I was asked to say a few words about another drug. Do I get another five minutes for a second drug?

THE CHAIRPERSON: Unfortunately, no.

PUBLIC SPEAKER: So my name is Pratik Parikh. I'm the senior medical science liaison

with Sarepta Therapeutics. Duchenne muscular dystrophy is a progressive neuromuscular disease and Sarepta got accelerated at the approval on September 19, 2016 for Exondys 51.

I will actually, if it's okay with the committee, yield my time back to Dr. Fernandez, my five minutes, so he can speak on Duchenne. And if you have any questions, please feel free to ask me afterwards or during your discussion. If that's okay?

THE CHAIRPERSON: That is fine. We're at four minutes before yield.

MR. FERNANDEZ: All right. It's the same drug. I want to talk a little bit about another disease to talk about is Duchenne muscular dystrophy. Relatively common. I think I see new patients with Duchenne muscular dystrophy every year.

We just moved our clinic to Shriners Hospital. We have a multidisciplinary clinic where I am the director, and I have been for about 35 years. We have cardiologists, pulmonologists, physical therapists, everybody that we need to take care of these kids.

Duchenne muscular dsytrophy was brought

to attention every year by Jerry Lewis. It's probably, along with spinal muscular atrophy, it's about the most severe muscle disease you'll see.

The Duchenne form is the severe form. It's an x-linked disease carried by mothers, passed on to their boys.

There's a milder form called Becker that differs genetically in terms of mutation and the type of mutation. What we can do now with eteplirsen, which is Exondys 51, is more or less genetically, anyway, convert the severe Duchenne form to the milder Becker form.

And if there are questions about it, I will be glad to try to answer them. But, basically, that's what we do in terms of alteration of the mutation within the gene.

This drug is administered intravenously, so that's, somewhat, less complicated. It's administered weekly. The indications for treatment are very specific. Treatment will only be prescribed for boys that have a specific mutation that is amenable to exon 51 skipping. And that is accomplished by eteplirsen or Exondys 51.

That encompasses about 10 to 13 percent of boys with Duchenne -- 10 to 13 percent of the total of all boys with Duchenne muscular dystrophy. Only that relatively small fraction will be eligible for treatment.

The same problem arises as it does with spinal muscular atrophy. We have degeneration of older people that have never been treated. We feel if they qualify for treatment, based on their mutation type, that they should be treated. And these are older -- these are teenagers and young adults and, yes, some of them have severe weakness. Most of them are wheelchair-confined. They have not been able to walk since the age of about 10 or 12 years. We do not feel that should exclude them from treatment. And, again, we will be reasonable. We do have some treatment criteria or treatment indications that I'll send to the committee in written form.

And we also have come up with some exclusion criteria, so that not everyone who has a mutation that is amenable to exon 51 skipping will be recommended for treatment, depending on the degree of function of their

upper extremities mainly and depending on their ventilatory capacity. And those criteria have been drawn up. I have them. I'll get them to you in writing at the appropriate time.

We're starting to treat some boys with Duchenne muscular dystrophy. Two young adults have been approved for treatment.

We were planning to give the first few doses in the outpatient setting of the hospital. That became complicated. I made some phone calls around the country. Talked to real experts and they said, Why don't you just start treatment at home? That's being done.

I met the first boy we treated in Tampa. I made a home visit. The IV nurse was there. And the boy received his first dose without any untoward effect. In fact, it's really quite safe.

We know that boys that are treated are able to produce a protein that is called dystrophin, which they otherwise cannot make because of their Duchenne mutation. With treatment, these boys are able to make some dystrophin and it's incorporated within their muscle fibers.

THE CHAIRPERSON: Thank you for information. Unfortunately, your time is up.

I think I can pretty much speak on behalf of the board. I do not want to speak on behalf of the agency. But what I will say is this: Thank you for bringing that. I think it was very informative. I think the agency has shown their attentiveness to this matter by already beginning construction of PA criteria. Certainly, the plans will lean on it heavily. I'm sure we'll have more development on this issue to come.

MR. FERNANDEZ: If there are questions, I can be available at any time by telephone or whatever else it takes to move this along.

THE CHAIRPERSON: Perfect. Thank you.

MS. DUSSAULT: Hi. Good afternoon. My name Ginger Dussault. I'm a mother of a boy with Duchenne muscular dystrophy. I'd also like to speak to Exondys.

Duchenne is a rare progressive where boys lose their muscle function due to a missing protein call dystrophin. He is 21 years old. My son Dalton is patient of Sunshine Healthcare. He was diagnosed at the age of 17

months, meaning that he was born with a mutation on the dystrophin gene that keeps his body from producing the dystrophin and his muscles functioning properly. Dalton is here with his dog, Chulip (ph.), that helps him in his day-to-day life.

As you know, the FDA recently approved this drug, Exondys, and it treats Dalton's specific mutation; 48 through 50 are his missing exons. It skips 51 and puts together 47 and 52, and lets him express and make dystrophin.

Dalton is very lucky to have this specific treatable mutation. Like Dr. Fernandez just mentioned, only 13 percent of the entire Duchenne population is amenable to the skipping of exon 51 and eligible for this treatment.

Based off of my son's genetic report and Dr. Fernandez' years of experience in treating patients, such as my son, he has recommended my son for treatment. You've heard his testimony.

Since the FDA approval was granted four months ago, we've seen three separate denials in tireless efforts by myself, my doctor and this clinic. Sunshine Healthcare just finally

approved Dalton, his prior authorization, for last Thursday. Even though they only gave us a a three-month supply of that drug to start, Dalton will receive his first infusion next week. This is huge for our family.

I understand the purpose of today's meeting is to review the evidence surrounding Exondys 51 and to begin drafting a policy for the use and reimbursement of Exondys in Duchenne patients amenable.

Thank you for taking the time to hear from families and patients and for taking our perspectives into consideration. Given that Duchenne is such a rare and complex disease and that there has never been before an FDA-approved treatment for this disease, I urge you to also listen to the small number of medical experts who have dedicated their lives to treating children and young men with Duchenne. Dr. Fernandez is one. Dr. Byrne of the University of Florida Medical Center, Dr. Giordano, at Numerous Hospital, Dr. Finkel, and Dr. King, who is at Gainesville Medical Center are some of the Duchenne experts located in Florida who have provided written testimony

and are willing to provide guidance and recommendations to Florida's policy for Exondys 51.

While I encourage you to take time to hear from all of these experts and make thoughtful policy decisions based off their guidance, please do not take too much more time. The Duchenne community and the state of Florida cannot afford to wait any longer to access this drug.

During this period of information and evidence gathering, I also urge you to review a recent Medicaid policy that was established in California in collaboration with their Duchenne expert for Exondys-51-amenable residents who are on California state's Medicaid. Medi-Cal created this policy after robust engagement and communication with experts and patients and provided Medi-Cal with a better understanding of the natural history and -- anyway, the natural history of how it happens in Duchenne, the mechanism of action in exon 51 and how this therapy could affect patients in all stages of the disease progression.

Another example is that the Pennsylvania

Medicaid agency engaged the clinical experts to draft their state policy as well. Washington state and Louisiana have also done the same.

Typically, plans which have consulted with experts have resulted in policies reflective of FDA-approved and approving drugs for patients that will likely show a benefit.

I also want to remind you that your decisions today will affect whether or not Dalton is reauthorized by Sunshine Health Care to continue with treatment beyond the current three-month approval that we've been granted.

Dr. Fernandez, Dalton and I are all well aware that your decision here, today, on policy will have a direct impact on whether or not he gets to continue the drug past three months. The longer Dalton and other young men with Duchenne wait for Exondys 51, the more muscle function they lose. Their losses are irreversible. Once lost, the patients never gain skills that they once had, like, walking. Dalton lost his ability at age 10. He's now 21.

THE CHAIRPERSON: I'm sorry, I have to cut you off. Thank you so much for your time.

PUBLIC SPEAKER: I won't take up a lot of your time. I'm piggy-backing upon Dr. Fernandez and Ginger with Dalton.

My name is Joe Wilshire. I'm active duty military. I'm a single father. My son was diagnosed with Duchenne muscular dystrophy at the age of 7. He is currently on Exondys 51, eteplirsen. He's been in the trial for -- today was his 107th dose.

My son is 13 now. He's still able to get up from his chair and walk to the bathroom on his own. That's not typical. You can ask the lady right here how important that is. Just little things. He's able to open a bottle of water on his own, which is not typical.

These boys need this drug to maintain what they have. And in some instances, he may gain things. My son has fallen and hurt himself really bad and has recovered. That's not typical for Duchenne.

He's never going to run a marathon. He's never going to do any of those things. He's not going to be your typical kid, playing football or anything like that. But he can take care of himself at his house now.

The drug is expensive. I don't know the dollar amounts. That's all you-all's type thing. I'm more of a witness on what the drug does. I have nothing scripted for you. I can just go by my experience. I can talk to you guys after if that's what is needed as well.

It affects everybody differently. All drugs -- aspirins work for some people and don't work for others and what not, so there's going to be the variety of difference in it. But, I think, regardless of whether they're in a chair already permanently or not, it shouldn't exclude these boys from a chance.

My son's pulmonary functions have improved. Not typical. Cardiology functions, his heart, maintained. Not typical, not for his age.

So I don't waste any more of your time, please, really, really consider what these people are talking about. These are boys who deserve a chance and a dollar amount shouldn't affect that chance. If you guys have children, your children have a chance.

So that's what I've got to say.

THE CHAIRPERSON: Thank you. Thank you

for your comments and your time.

Any additional public comments?

Hearing none. We're going to transition back to Open Discussion topics for next quarter.

I'm sorry. Arlene?

MS. ELLIOTT: Yes. I just want, for the record, for everybody to know that the draft criteria that the members have received was a compilation of other state's Medicaid commercial plans. We received the one from California Medicaid yesterday, so the committee members haven't seen it yet.

So I don't know how you want to proceed, do an interim meeting or via email. But I have also Dr. Martarana's recommendations with your letter there.

THE CHAIRPERSON: I would make a motion to have an interim meeting.

DR. ZITIELLO: Second.

THE CHAIRPERSON: Okay. We'll move to our Open Discussion topics now.

Any topics?

MS. HARRIS: Mr. Vice Chair, you have to have a vote on your motion.

MS. HARRIS: I'm sorry. You're right.

I will rescind my motion. I don't think I can -- yeah, I'm going to rescind my motion. Basically someone else has to make it.

DR. ZITIELLO: I move to have an interim discussion on these policies.

DR. ROMAY: Second.

THE CHAIRPERSON: All right. The motion has been moved and properly second. All those in favor, please say aye.

THE COMMITTEE: Aye.

THE CHAIRPERSON: Now, we are at the Open Discussion.

DR. HAYDEN: So at the last P&T, I saw that one of the GLP-1 agents was removed from the Preferred Drug List. The Bydureon, I believe. It said, long acting.

MS. ELLIOTT: I'm sorry, I was --

DR. HAYDEN: At the last P&T, the formulary update revealed a Bydureon GLP-1 agent was removed from the Preferred Drug List.

MS. ELLIOTT: Was it both formulations? I can't remember.

DR. HAYDEN: And so we have no GLP-1 agents available currently on the Preferred

Drug List. So I have to do prior authorizations for all my patients. It's time consuming, but I'm doing them.

MS. ELLIOTT: Was it the pen versus the vial by any chance? Let me look it up.

DR. HAYDEN: Yeah, because right now, I think it was the pen. I think that was what was available before. And then it went to non-preferred. And so now, I'm completing prior auths.

DR. ROMAY: I believe the vial is preferred and the pen is non-preferred. It's the vials. It the formulation.

MS. ELLIOTT: Yeah, the P&T -- it was a financial decision by P&T.

DR. HAYDEN: So the vials are on there. So if she has the connect, she can inject.

The patients have to mix it themselves now? Because I didn't see that on the formulary. I just saw --

DR. ROMAY: Yeah, the 2 milligram vial is the one that's on the formulary. It's the vial, which is the same thing. It's just a different formulation. It's just the formulation.

DR. GOODNOW: We already mentioned it but I think the classes are very helpful, very interesting to take a look at. And I think looking at the number of patients and the number of scripts in addition -- will help us make some recommendations for that class.

THE CHAIRPERSON: I actually -- I'm sorry. Did you have any recommendations, Luis?

DR. SAENZ: No.

THE CHAIRPERSON: Alfred?

DR. ROMAY: I'd like to bring back Hepatitis C in terms of retreatment. And also, the current change in the criteria is to the black box warning on the reactivation of Hep B. I think the criteria -- and I think I reached out initially to make some recommendations on adding things to that criteria, but I think we need to bring that criteria back to the board and relook at it to see -- because there's a lot of things that need clarification in terms of products and certain retreatment and certain other scenarios that are not really evident on the criteria or spelled out.

THE CHAIRPERSON: Dr. Hayden?

DR. HAYDEN: I'm looking at the formulary guide.

THE CHAIRPERSON: Elboni, are we at our quota for --

DR. MOORE: I am the quota keeper.

So I've been taking my notes. I have the Embeda utilization. What are patients taking now? How do they get to the other agents? And criteria development for that. That's something that Magellen would handle as a quarterly topic.

And there's follow-up on the SAMSCA utilization to see what types of providers have been requesting these products.

There's homework for the committee to reviews vasopressin receptor antagonist criteria, specifically, Vaprisol and also Transderm Scop criteria.

And then, another follow-up item for Magellan regarding the top 10 classes are to bring in the recipients, the claims, the dollar amount, possibly the PDL status, which I think that would be helpful for you guys to see that for some of those products.

And also, Dr. Romay's Hep C development,

specifically around retreatment. He wants to look back at the criteria to see if there's a need to enhance the criteria. So that is not necessarily a quarterly topic. That's just follow-up. So you still have two more.

THE CHAIRPERSON: I just want to introduce one other thing. I think this was tabled from the last meeting, particularly since you weren't able to list the top 10 therapeutic classes.

I'm looking at antipsychotics and the fee-for-service as the top -- it's the second most expensive nonclass -- I suspect a large percentage of that are LAIs, so Abilify and Respidol and all of those are generic now.

I guess the question that I would like to propose to the state is, you know we're spending money on LAIs. I can tell you, in our plan, even though it requires a prior authorization, our approval rates are close to 96 -- 97 percent.

But I guess what I'm looking to know is, since we're paying for these agents, they are approximately $15- to $1800 per injection. Are the patients being compliant? How many of

those patients or still compliant on a dose post six months or something?

Because if we're essentially making the investment to make sure that they're compliant for that first 30 days, but they're not coming back in, it kind of defeats the purpose and perhaps plans may want to take a different approach, put them in case management, et cetera, et cetera.

DR. MOORE: Okay.

DR. ROMAY: Two more. I know we have room for two more.

THE CHAIRPERSON: We just have room for one more.

DR. ROMAY: Well, I can mention it and we can always, I guess, talk about it.

One item is, I know I previous -- a couple, couple, couple meetings before -- we had discussed, before Humera went preferred and Embril went non-preferred, we had talked about having -- I don't know if this -- I know we created auto PA criteria but I think we had once talked about creating specifically a criteria for rheumatoid arthritis diagnoses. And I think, right now, it's just the PA -- the

auto PA is just strictly if you have these diagnoses, it pays. But I think we had talked about the need for making sure that those members are adhering to just the gold standards, which are the DMARDS, you know, things like that.

I don't know if that was something that we just phased out because we moved to a different approach.

DR. MOORE. It boiled down to the specific contracting language and I can't get into that.

DR. ROMAY: Okay.

DR. MOORE: That was negotiated upon, so we had to move away from that approach and go with the method that we went with.

DR. ROMAY: Okay.

And then my second one was surrounding the bupropion products. So on the criteria, I think -- I don't know if I remember seeing this on here, but I think it was just updated where they added some film was where the preferred product was redirected to.

So I was wondering what led to that? It was just, you know, the pricing, or is it just a brand preferred. Because the bupropion

tablets are available in a generic form.

MS. ELLIOTT: Right. It was a financial decision.

DR. ROMAY: Okay. I just wanted to check. That's what I thought it was, but I wanted to verify that it was okay on that.

MS. ELLIOTT: But it's preferred with a clinical PA, just for the record.

DR. ROMAY: Right. Right. Right. Right. Right. Because I know before, that wasn't on there. So I know it was just recently done.

Okay. Thank you.

THE CHAIRPERSON: Okay. I think that pretty much wraps up the open discussion. Before we adjourn here, a couple of thank yous.

No. 1, thank you to the attendees for coming. Obviously, you could be somewhere else.

I want to thank those who came up for the public comments. I think those were very educational and certainly powerful.

I would like to thank AHCA, obviously, for assembling these meetings.

And thank the committee. As you know, our chair is unable to make it today, so we thank

you for having confidence in me to honerate (sic) this meeting.

With that being said, I need a motion to adjourn.

DR. HAYDEN: Motion to adjourn.

DR. ZITIELLO: Second.

THE CHAIRPERSON: Was that a third by Alfred?

Meeting adjourned. Thank you.

(Thereupon, the proceedings were adjourned at 4:18 p.m.)

CERTIFICATE OF REPORTER

STATE OF FLORIDA

COUNTY OF HILLSBOROUGH

I, JUANITA BUTLER, Court Reporter, certify that I was authorized to and did stenographically report the foregoing proceeding; and that the transcript is a true record of said proceeding.

I FURTHER CERTIFY that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of the parties' attorneys or counsel connected with the action, nor am I financially interested in the action.

Dated this 17th day of March, 2017.

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