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DRUG UTILIZATION REVIEW BOARD

Agency for Health Care Administration

Tampa Hilton Airport/Westshore

Saturday, September 24, 2016

8 a.m. - 10:45 a.m.

REPORTED BY: Sharon L. Boyd
Integra Reporting Group
Court Reporter
Notary Public
State of Florida

Pl. Trial Ex. 248

APPEARANCES:

BOARD MEMBERS

Anna Hayden, D.O. (Chair) - Absent
Jeffrey Martorana, M.D. (Vice-Chair) (acting chair)
Moses Allen, Pharm.D.
Diane Fagan, R.Ph.
Larry Field, D.O. - Absent
Venessa Goodnow, Pharm.D.
Kevin Olson, Pharm.D.
Alfred Romay, Pharm.D.
Luis Seanz, D.O. - Absent
Amy Zitiello, D.O.

AHCA STAFF

Kevin Dewar, Assistant General Counsel
Vern Hamilton, AHCA Liaison
Arlene Elliott, R.Ph., Pharmacy Policy Administrator
Susan Williams, R.Ph., C.Ph., Senior Pharmacist
Shevaun Harris, Bureau Chief, Medicaid Policy
Beth Kidder, Assistant Deputy Secretary, Medicaid Policy & Quality

MAGELLAN MEDICAID ADMINISTRATION

Elboni Moore, Pharm.D.
Rebecca Borgert, 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: Good morning. I officially have 8:02. Use the gavel? Good morning. I'm Dr. Jeff Martorana. And I think I would like to open up the Saturday, September 24 edition of the Drug Utilization Review Board. And we've got several new people here.

Actually, I'd first like to thank Dr. Borgert and all of her contributions to the committee over the years. I understand this is her last official meeting with us. She is moving on to a new role within Magellan. Thank you for all of your contributions to the committee.

And with that, she's brought some new learned team members that will be taking over, Drs. Stephanie McGriff and Selika Sampson.

And I think, kind of in that vein, if we would go around, since this is some new faces to them, and if we can all introduce ourselves, and who you are and what you do, that would be wonderful.

DR. ZITIELLO: I'm Dr. Amy Zitiello. And I actually have changed positions. I'm a pediatrician by trade, but I am now with Avalon Health Care Solutions as their vice-president and medical director, which is a lab benefits management company. I'm getting a crash course in targeted therapies, cancer.

DR. ROMAY: Good morning, everyone. My name is

Alfred Romay. I am director of pharmacy at Molina Health Care.

DR. OLSON: Kevin Olson, pharmacy manager, Johns Hopkins, All Children's.

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

DR. FAGAN: Diane Fagan, director of pharmacy, Wellcare, here in Tampa.

DR. ALLEN: Moses Allen, director of pharmacy, Magellan Complete Care.

THE CHAIRPERSON: And Jeff Martorana. I'm a family physician, chief medical officer for Sunshine Health. Okay. Actually, before we start, we're going to have a little quiz this morning. I'm going to put our learned counsel on the spot. What happened today in 1789?

MR. DEWAR: I don't know. Failed.

THE CHAIRPERSON: It was the establishment of the Judiciary Act, establishing the Supreme Court. You'd better read the paper in the morning. Okay. I believe the first order on the agenda is Ms. Harris.

MS. HARRIS: Good morning, everyone. I'm not a morning person, so if I talk a little slower -- I'm just joking. Okay. All right. So thank you all for coming in this morning.

I want to give you a little bit of an overview over

a process that we have within the agency, because I think that it will help you all in review of a set of criteria that we're going to put in front of you in today's meeting.

So as you all know, under the Florida Medicaid Program, we cover any service that's medically necessary for a recipient under the age of 21, even if the service isn't listed on our fee schedule or listed in our policy. We have a special process that we go through to approve those types of services on an exceptions, or one-off basis, to determine if it's medically necessary.

We do all of that under the federal regulations called Early Periodic Screening and Diagnosis and Testing. EPSDT. And so -- but the service has to be medically necessary. And we have a formal definition and criteria that we use to determine if something is medically necessary.

As a part of our medical necessity definition, a service must be -- must not be experimental or investigational and must be generally accepted -- must be generally accepted professional medical standards.

And so there are times when a prescriber or a treating practitioner might order a service, a drug, a treatment, et cetera, and we have to go through the rigor of determining -- making sure that it meets that third prong of medical necessity, that it is a generally accepted professional medical standard.

And so, the agency was presented with a situation where we had to review the use of puberty suppression treatment for children and adolescents who are contending with gender dysphoria.

We went through a rigorous process of reviewing the literature out there to determine if it -- if use of that treatment is a generally accepted professional medical standard, because in -- the drugs that are used to suppress puberty, based on the FDA indications and the authorizing compendia, don't list gender dysphoria as a diagnosis for which these drugs can be used.

So we had to go look at the supporting literature, evidence-based literature, to determine if there's any indication that it would be appropriate to be used in those situations or for this diagnosis. And what we determined is that there may be instances where authorization of this treatment, or use of this treatment, outweighs some of the risks.

The evidence is not that strong that it is a generally accepted professional medical standard. There are -- so -- and so, we have to see where the literature evolves, where the research evolves on this. Not sure that we'll ever get there, quite honestly. It's a very small population of children and adolescents who are diagnosed with this condition.

So I'm not sure that you'll ever get to a place with the research trials where you'll be able to wholly say that it's not experimental or investigational or a generally accepted professional medical standard.

That being said, the literature was pretty clear that in this population, children experience great distress and undergo a great amount of psychotherapy and treatment to deal with the symptoms and feelings, et cetera. And so there are times when the feelings of distress are so great that we see instances of self-mutilitation, suicidal ideation, et cetera.

So what the agency determined is that while we will not cover it and add it to our PDL or fee schedule, et cetera, cover puberty suppression treatment for -- specifically to treat gender dysphoria, through what we call our exceptions process, which I just talked about a minute ago, we can review a one-off request on a very individualized basis to determine if that course of treatment is appropriate for that child, and poses as the best alternative, based on, you know, the child's current situation.

So, in the event that we get a request, we wanted to be prepared. We are going to be providing you with a copy of draft criteria that the agency prepared. It's really just to make sure that the clinicians who will be reviewing this have, at that first level review, something to go off of,

because there are no criteria.

And again, the FDA and compendia has not authorized use of this drug, or these drugs, for this condition. So we wanted to be prepared, and we thought it would be good if we had the DUR board review what the agency has developed, to give us any feedback. It would only be used in a special circumstance or an exceptions request that's presented to the agency, or one of the health plans. So we'll share that with you.

My team can chime in at any point. But I wanted to give you that backdrop, or history, so that you understand why you're being presented with the criteria, and also to make it clear, we're not wholesale covering this treatment.

THE CHAIRPERSON: And we're talking about the GnRH analogs?

MS. HARRIS: Yes.

DR. ZITIELLO: May I ask a question? The Tanner Stage requirement and the age requirement, what particular documentation or evidence-based literature did that come from?

MS. HARRIS: So that's actually a part of the -- oh. So the references are listed at the bottom of the second page. But the Tanner Stage II, III comes from the Endocrine Society Guidelines for use of the analogs and treatment of gender dysphoria.

THE CHAIRPERSON: I would also ask, because I don't see it in here, would there be any length of time that they have been in counseling prior to even consideration of going on drugs? So, you know, the first time that it's diagnosed and then, you know, to immediately go to a drug solution, I would like to see something to that sort, like at least six months of therapy.

DR. ZITIELLO: It says six months.

THE CHAIRPERSON: Okay. I must have missed that.

MS. HARRIS: It's the fourth bullet down.

THE CHAIRPERSON: Got it. Sorry.

MS. HARRIS: Let us know if you feel that time frame is not sufficient.

THE CHAIRPERSON: And then duration of therapy, obviously it says consent until 18. But then, when someone turns 21, and would no longer fall under the EPSDT, where do we go from there?

MS. HARRIS: So --

THE CHAIRPERSON: You pay me big money to ask the hard questions.

MS. HARRIS: So, as you know, there's a series of -- going down this path, the use of analogs is just the first step. At the age of, or beginning at the age of 16, it's recommended that if you are interested in sex reassignment surgery that you begin taking the cross-sex hormones,

ultimately leading up to the full surgical procedure.

It's a step-wise process that we'll have to look at as requests come up. We haven't had any of those requests yet. And then, at the age of 21, we wouldn't be governed by the EPSDT, so we wouldn't have to cover.

DR. ALLEN: So, just for clarity, are we making a decision on it now? Or do we have the opportunity to take it back and review and present recommendations?

MS. HARRIS: We'd like you to review it now. Only because we meet again in a quarter.

DR. ALLEN: Sure, sure.

THE CHAIRPERSON: Well, to that point, if you'd like to make a motion, but I would suggest that if we do act on this now, that we would bring it back the new quarter for review, so if -- you know, we all have our own experts. And not that you haven't done an exhaustive review, but if we kind of want to tweak it a little bit, that we not wait a full year to bring it back.

MS. HARRIS: Absolutely.

DR. ALLEN: Exactly, because I guess from my perspective, I mean, half of something is better than nothing, which is what we have now. So basically, that fact alone, I would be in favor of accepting the recommendation that's presented, but just have an opportunity to bring back additional suggestions, once we have an opportunity to review

it with our clinical staff.

MS. HARRIS: Absolutely. I think that's fair. And we would welcome that.

DR. ALLEN: Did I hear a second?

THE CHAIRPERSON: No. I didn't move.

DR. ALLEN: I'm sorry. I'd like to make a motion that we accept the recommended -- the recommendations for the policy that was presented to us.

THE CHAIRPERSON: With review next --

DR. ALLEN: With review next quarter.

DR. ZITIELLO: Second.

THE CHAIRPERSON: We've got a motion and a second Any further discussion? Questions? All in favor signify by saying aye.

THE COMMITTEE: Aye.

THE CHAIRPERSON: All opposed? The ayes have it. Okay.

MS. HARRIS: Thank you all.

THE CHAIRPERSON: Okay. The next order of business before us is the voting for chair and vice-chair of the committee. There were two nominations that were submitted. One was for Dr. Hayden and the other was for myself. And before I call for a vote, I will open it up to the floor for any floor nominations.

DR. ALLEN: Moses Allen. I'd like to nominate

Dr. Martorana.

THE CHAIRPERSON: Okay. So, with that, should I recuse myself and leave? Or we just open it up for a vote?

MS. ELLIOTT: I read the Robert's Rules and you do not have to leave.

THE CHAIRPERSON: I do not have to leave? Okay. All in favor for Dr. Hayden, please raise their hand. And all who would like to vote for myself, please raise their hand. I guess I am the newly-elected chair. Thank you.

Okay. Next is for vice-chair. There was only one nomination and that was for Dr. Moses Allen. So once again, I will open up the floor for any nominations. And you can nominate yourself if you'd like. Hearing none, all in favor for Dr. Allen? Okay. Congratulations.

Okay. All right. Next order of business is the approval of the minutes from the June 18 meeting.

DR. ALLEN: I'd like to make a motion to accept the minutes from the prior meeting.

THE CHAIRPERSON: Okay. I have a motion. Do I have a second? We're voting on to accept the minutes.

DR. FAGAN: Second.

THE CHAIRPERSON: Any opposition? Any discussion? Hearing none, minutes accepted.

MR. HAMILTON: Thank you very much. No corrections anybody found? I appreciate that.

THE CHAIRPERSON: Okay. And the next is the review of the P&T minutes from the June 17 meeting.

DR. ZITIELLO: Motion to accept.

DR. ALLEN: Second.

THE CHAIRPERSON: Any discussion? Any correctionS? Any opposition? Oh. We don't vote on this? Just a review? All right. Sorry. I'm going to be impeached. All right. Next up is the quarterly DUR reports.

DR. MOORE: Good morning. Before we get started, I would like to introduce our team. So we have Dr. Selika Sampson. As Dr. M said, this is Becky's last meeting with us. She has accepted a position within the company, so she'll still be a part of the family, but just not working on the Florida POS account.

Dr. Sampson comes from our clinical call center. She's been with the company since 2011, so she's not new to Magellan, but she's new to this role. She has a lot of experience. She's worked in the industry. She's worked in long-term care facilities. She's worked in the community. And she's a leader of our local community. So we're very excited to welcome her in to the clinical services side of Magellan.

Dr. Stephanie McGriff has also been with the company for a very long time. Actually, longer than me. She's been there for almost nine years. She's our clinical account

manager. She worked very closely with me when I was in that role, so she knows just about everything that I know, as far as how Magellan works on the POS side.

And I am -- I've moved over to the director of the account role. So that's kind of how we all play a part for the Florida POS team. And Becky's last time.

DR. BORGERT: Thanks, Elboni. Okay. Good morning, everyone. We will start with some follow-up items from things that we have pending, or questions that came up, or data that we have back now regarding topics that have come before the DUR board in the past.

The first item for follow-up is, if you will recall, as part of one of our P&T reviews, where we look at P&T classes that are -- the classes that are upcoming for the P&T to review, at one point, Pulmozyme was one of the drugs in one of those classes.

And at that time, the DUR board did vote to place an auto PA for diagnosis on Pulmozyme, since the only FDA-approved indication for that drug is for mucolytic therapy for cystic fibrosis patients. And so that edit on the fee for service side went into effect, I believe, in April -- April of 2016.

So the numbers are on the screen there, broken down by fee for service and MCO, and in the bottom are the totals. So if you look at the totals at the bottom, and you look to

the far right-hand column, under total pay, that is comparing the January through March of 2016, then looking at three months post implementation of the edit. And so, you can see, there was about a $500,000 cost savings.

So, if you annualize that over a year, that's about a two million dollar cost savings by attaching a diagnosis to Pulmozyme. So I think that was a successful edit, in terms of keeping that drug to its FDA-approved population. Questions about that? Okay.

The next topic is a topic that came out of -- I think it was one of our January quarterly activities, where we looked at top therapeutic classes for Florida Medicaid recipients and anticonvulsants. To no one's surprise, anticonvulsants were one of those top therapeutic classes.

And so, for the last couple of meetings, we've been sort of doing a deeper dive into anticonvulsants and -- I have some feedback, here, Vern. I don't know if it's bothering anybody else. But we've been doing a little bit of a deeper dive into anticonvulsant utilization.

So this is a slide that was presented at the last DUR meeting. So you can see here, broken down by most frequent, in terms of claims. Gabapentin, Levetiracetam, Topiramate, Lamotrigine, Divalproex, et cetera, et cetera, on and on. So that's kind of the breakdown of what our anticonvulsant mix looks like.

And then we also looked the last time at how many anticonvulsants were a particular recipient receiving. So -- and we also broke it down at the request of one of the DUR board members by pediatric patients, patients under the age of 18, and then adult patients that were 18 and over.

So this represents the number of recipients that received just one anticonvulsant in the first quarter of 2016, two anticonvulsants, and then three, four, five and six anticonvulsants. Because if you'll recall, we had some patients that were getting six and seven anticonvulsants within a ninety-day window.

So the most common scenario was for a recipient to receive two anticonvulsants, which I think seems probably understandable. And then, the thing that's new this time is, what we did last time is, we looked at -- we took those patients who were getting the most anticonvulsants.

Like, I think we took the recipients who were getting seven or eight -- that had received seven or eight anticonvulsants within that ninety-day period, and just kind of looked at them, just by age, and listed the drugs. And there were two recipients from that list that the DUR board asked for a little bit of further information on.

They asked for diagnoses, how many prescribers were prescribing those anticonvulsants. And then, there was also a question that came up about whether or not there was a

second clinical review being performed by the USF behavior health team for these patients.

So these were the two patients. The first patient was an eleven-year-old. And you can see there, they had seven different anticonvulsants that were filled over a ninety-day period. So when we looked at the diagnoses on file for these patients, it was pretty understandable.

Some of the pertinent diagnoses, probably, were cerebral palsy, obviously generalized idiopathic epilepsy that was intractable, congenital quadriplegia and dysphagia with a gastrostomy tube.

And this particular patient with the seven different anticonvulsants did only have -- had two different prescribers; however, those prescribers had the same -- were at the same facility, with the same address. So it didn't really look like it was, you know, seeing multiple providers.

And very much the same story with the fourteen-year-old. Again, seven different anticonvulsants. But diagnoses -- anoxic brain damage, non-fatal drowning, convulsions and also a gastrostomy tube.

So I think both of those patients, when you look at their diagnoses, kind of give you a picture of, those are the type of patients you maybe are not surprised are on multiple anticonvulsants. And again, there were three prescribers for those seven different anticonvulsants, but all three of those

prescribers had the same physical address. So they were probably within the same practice.

So I think it was good that it -- oh, and then, the question about behavioral, was USF looking at those patients? The answer is no, because the USF second medical review is strictly for behavioral health types of medications. So antipsychotics, stimulants, that sort of thing.

And neither of those two patients, A, had behavioral health diagnoses -- specific behavioral health diagnoses, or were on any other behavioral health medications. So USF was not involved with the care of those two patients.

So that's the follow-up information on those two patients that were receiving the highest number of anticonvulsants. Questions about that? Okay. I thought it looked pretty medically sound when we looked at it.

Okay. The next topic has to do with P&T classes that we looked at for the upcoming January P&T meeting. And one of the things that the committee talked about was possible inappropriate duplication therapy with GLP-1 receptor agonist and DPP-4 inhibitors.

So let me just try to walk through the pharmacology on this. I'm not a diabetes expert. So for type 2 diabetes, multiple classes of drugs. If you look there in step 2, most of those classes of drugs are listed -- Metformin, sulfonylureas, TZDs, DPP-4 inhibitors, SGL2 inhibitors, GLP-1

agonists and insulin. So that's kind of the armamentarium of pharmacologic classes available for management of type 2 diabetes patients.

And the way -- GLP-1 is what's called an incretin mimetic. So it's a hormone that's released from the gut. And what GLP-1 receptor agonists do is, they activate that receptor. So when GLP-1 is released, it causes insulin secretion from pancreatic beta cells. It decreases inappropriate glucagon suppression and it also slows gastric emptying.

So that's what GLP-1 does in normal physiologic state, in response to a carbohydrate or fat load. So that's the normal physiologic process.

So what a GLP-1 receptor agonist does is, it activates that receptor and causes GLP-1 to be released. Where the DPP-4 comes in is, DPP-4 is an enzyme that actually inactivates GLP-1.

So if you have a GLP-1 receptor agonist and a DPP-4 inhibitor, they're basically doing the same thing. They're both basically increasing the amount of GLP that's available systemically, because the agonist will obviously cause the release of GLP and -- which is glucagon-like peptide, by the way, and the DPP-4 would normally inactivate that.

But if you give somebody a DPP-4 inhibitor, to inhibit that enzyme, then you're keeping that GLP-1 around

longer than it would normally be. Everybody follow that? Okay. I just figured we'd kind of go through that, to understand this.

Okay. So when you look at the American Diabetes Association Guidelines for Standards of Medical Care in Diabetes, step one for most all patients, if there's no contraindication, is Metformin. And then if the hemoglobin A1C target is not met after three months, the recommendation is to move on to basically adding a drug from a different class. And then, at that point, if the A1C target is still not met after three months, the recommendation is to add a third drug.

And so, like, for instance, look at the very first box there. If, in step one, they were on Metformin, and then, in step two a sulfonylurea was added, then step three would be to add a TZD or a DPP-4 inhibitor or a SGLT2 or a GLP-1 agonist or insulin.

So I'm not going to go through every one of these, but I think the important thing to note is that if you have somebody that was put on a DPP-4 as step two, then you're not supposed to put them on a GLP-1 at step three, because those -- for the reasons we just talked about.

And likewise, if they were put on a GLP-1 in step two, DPP-4 as step three is not recommended. So the bottom line is basically we shouldn't be using those two drugs from

those two classes together for the treatment of diabetes.

So, having said all that to set the stage, the DUR board wanted to look at what kind of -- what we were seeing in the claims. So this is what we saw: We had about 8,600 patients for claims with DPP-4. Again, this is fee for service and MCO combined.

Only 62 had more than one DPP-4. This was in the second quarter of 2016, so a ninety-day period. We had 1800-ish claims for a GLP-1 agonist and we had nine patients who had claims for more than one GLP-1 receptor agonist.

Where there might be a problem is that -- so, if you got a DPP-4 or a GLP-1 -- so if you look at 86 plus 1800, that adds to 10,530. So those are all the patients that got one or the other. And of those 10,000 patients, we did have 356 patients who were getting both. So potentially something that the DUR board might want to talk about. I'll stop talking now.

DR. GOODNOW: Just a quick question. So how -- just so I'm reading the columns right, the 62 and the 9, and then, how does it jump to the 356? So 356 would be the combination of both, or --

DR. BORGERT: Combination. That means they got a DPP-4 and a GLP-1. So the first -- they got two DPP -- 62 patients got two DPP-4s. Nine patients got two GLP-1s. And 356 got a GLP-1 and a DPP-4.

DR. ALLEN: Would a remedy to this scenario be to implement a duplication of therapy edit?

DR. BORGERT: That's a possibility.

DR. ALLEN: I'd like to make that recommendation, or open it up to further discussion.

THE CHAIRPERSON: I do that.

DR. ALLEN: Sorry, Chair.

THE CHAIRPERSON: I have a motion for the -- for an edit, duplication of therapy edit. Do I have a second to that motion?

DR. ROMAY: Second.

THE CHAIRPERSON: Now, is there any further discussion? Is there any opposition? Hearing no opposition, we'd like to go ahead and institute a duplication of therapy edit.

DR. BORGERT: I guess the only question I would ask, just to think about -- and maybe Magellan could come up with a standard, but what would we want the look-back period to be? Because it could be that at some point, they'll change therapy. So what do you guys think about, in terms of when you look back, to see if they've had that previous therapy? What kind of window are you thinking about?

DR. ROMAY: I would say somewhere around a three-month period, and allow that washout, you know.

DR. BORGERT: So, look back 90 days, and if they've

had a claim for the other one within 90 days, the claim would deny for further review?

DR. ROMAY: Right.

DR. GOODNOW: I have a question. So if they -- let's say that they -- it will look like a duplication of therapy, but it's actually just they're switching from one to another. So you won't see it on the edit, but then we'll just -- when they go to file the second agent, that's when their clarification would occur?

DR. MOORE: Yes. That's what I was kind of thinking as Dr. Romay was talking. So I think that we should allow it maybe for one time. And then if there's a second time that we notice it, then deny it. Because there could be a chance that the patient filled one, they got switched, and filled the other within that 90 days.

DR. BORGERT: All right. Thank you. Did you vote on it? I know we made a motion.

THE CHAIRPERSON: Yes, we did.

DR. BORGERT: Okay. Thank you. Okay. The next topic also came out of reviewing upcoming P&T classes, and that was looking at Zolpidem, particularly in female recipients.

And if you'll recall, back in 2013, the FDA mandated labeling changes for Zolpidem products, due to basically increased adverse effects that were being documented and

reported, in terms of patients being impaired the following morning. And particularly they made the notation that women, in particular, seemed to be more affected by this, and that the starting dose for women should be five milligrams for the immediate-release product and should be no more than 6.25 for the extended-release product.

So one of the things we talked about at the last meeting was, it looked like most of our female patients were getting 10 milligrams. So when we looked at it, what we found was that there were about 15,000 female patients -- these are female patients only -- about 15,000 patients who were getting -- excuse me -- 15,000 claims for 7,000 recipients.

And if you looked at all the Zolpidem -- and again, just females -- you know, 20,000-ish claims, 9,000-ish recipients. So 75 percent of the recipients, female recipients, were getting ten milligrams or more of Zolpidem. So what we want with -- so the new part of this information is, the committee said, well, let's look back and see, have they previously been on five milligrams and the dose has been increased.

So when we looked in this history for a prior prescription for five milligrams in the previous six months, we only found 423 of those 7,000 recipients who had a prescription for five milligrams in the previous five months.

So not very many. Comments for the board?

THE CHAIRPERSON: So I guess that would be maybe an opportunity for a step through edit to say before you can get to ten, you've got to at least go through five.

DR. ZITIELLO: Would you add the extended-release as well, the 6.25, even though --

DR. BORGERT: Right. Yes.

THE CHAIRPERSON: So you would --

DR. BORGERT: And this was actually greater than or equal to ten milligrams. So we lumped the extended-release in with this.

DR. GOODNOW: Should there also be a term limit for the fives, like maybe three months? Or a certain duration, instead of just the single fill? Or do we want to also have, like a -- how long they need to be on the five before increasing?

THE CHAIRPERSON: Is there anything in the literature to suggest that --

DR. BORGERT: You know the FDA labeling doesn't give a length of therapy. It just says, you know, to begin with five milligrams. And you know, it doesn't. So I think -- no. I don't know. I'm not aware of a duration of which you have to try that and fail it before you are eligible to move on.

THE CHAIRPERSON: Because, you know, to

Dr. Goodnow's point, I'm sure there's a lot of people that would just give you one month, and then jack it up.

DR. GOODNOW: That would be my concern. But I don't think, clinically, there is a duration that is --

DR. BORGERT: I supposed theoretically they shouldn't even be on this long term. But that's a whole different discussion.

DR. OLSON: So you're looking for a motion?

THE CHAIRPERSON: Yes. And I would say on that motion, do we want to go ahead and impose a 30 or 60 or ninety-day piece to it?

DR. OLSON: I say 30 -- recommend 30 days.

THE CHAIRPERSON: Thirty days? Okay. So a motion to have a step edit for the 5 or 6.25 ER with a thirty-day trial. Do I have a second?

DR. ROMAY: Second.

THE CHAIRPERSON: Any further discussion? Any opposition? Hearing no opposition we'll go ahead with a step edit of 5 and 6.25 for 30 days prior to the 10 and 12.5.

DR. BORGERT: Okay. Thank you. Okay. This was a quarterly activity from the second quarter of 2016. We looked at the overall utilization of compounded medications. And as part of that data, when we were looking at that -- when the DUR board was looking at that, you guys kind of really focused in on compounds that involved bulk powders.

And there was some question as to why we had so many claims that were involving bulk powders. And so, we broke that information out specifically and it did appear that a very large number of our compounds contain a bulk powder as a covered ingredient.

Because, you know, when they submit the claims, we didn't even look at the ones that weren't included as covered in the compounds. We looked at the ones that were included as covered in the compounds. And we had 766 claims, 366 recipients. And a good deal of the money involved in those compound claims were tied up with these claims that used -- that involved bulk powders.

So when we looked at that, the request from the DUR board was to look for patterns, to look for certain prescribers, to look for certain pharmacies, to look for certain, you know, compounds that were being dispensed regularly. And when we looked at it, in fact, there was a pattern.

There was a particular compound, and this compound contains these ingredients: diclofenac -- I think they must be using a tablet, because that wasn't a bulk powder. Diclofenac, gabapentin powder, bupivacaine powder, cyclobenzaprine -- tablet, I guess -- clonidine powder and then a cream base. And so, that compound seemed to show up over and over and over again when we looked at the data in

the first quarter of 2016.

And there was only one prescriber who was prescribing that. And it involved 124 claims for 67 recipients at a total of $555,761 for the quarter. And it was mostly the same pharmacy. There were a couple of different pharmacies, but by and large, it was a pharmacy.

DR. ALLEN: So -- if I may --

DR. BORGERT: I think the appropriate place for this is probably the agency.

MS. ELLIOTT: I just wanted to make a comment that from one of our quarterly meetings with the plans, a recommendation was that to put a cap dollar amount on these compound prescriptions, and we did. We accepted that recommendation that the max is $300. For a compound that cost more than that, they would have to send prior auth and it would be reviewed for appropriateness.

DR. BORGERT: And perhaps this one particular provider would be information that we might pass along to NPI. I don't know how the agency feels about that. That would obviously be an agency decision. But that might be something -- an appropriate place for this information to go.

THE CHAIRPERSON: I would second that recommendation very highly. We could all go in a little mini bus and have a discussion, I'm sure.

DR. ALLEN: So just for clarity, our plan had the

same findings. I probably could name the physician and the pharmacy. We had the exact same statistics here. But I guess that from a clarity standpoint, Arlene's point with the implementation of the max cost edit on the compounds of $300, I think this will probably flush out a lot of the issues anyway.

But of a secondary concern, the bulk powders, by FDA definition, they're not considered an FDA-approved drug. So would the agency also -- well, I guess, just for clarity, are we -- does the agency currently cover them?

I guess I'm not completely understanding how they were approved in the compound anyway. And would they -- could a patient potentially get a compound with a bulk powder today if it's under $300?

DR. BORGERT: I don't know the answer to that.

DR. MOORE: The agency does not reimburse -- generally speaking, they don't reimburse for bulk powders. There are a few bulk powders that the agency will reimburse for, such as, like, the progesterone, estrogen, because those things are compounded. But generally speaking, we do take a look at this.

Will it be caught by the edit? So that's kind of a tricky question, because it depends on how the pharmacy is submitting the compound. So if the pharmacy submits the compound with a the indicator on there that says, hey, I'm a

compound, we do look at each and every ingredient in there to see if it is payable, or if it is reimbursable.

But if the pharmacy decides to put a submission clarification code of 8 that says, you know, regardless of what's in here, as long as I have at least one payable ingredient in here, the claim will adjudicate. The pharmacy will not be reimbursed for the products that are not reimbursed through Florida Medicaid, but as long as the system sees one payable agent, the compound will pay. It will adjudicate.

The agency isn't paying for products that they do not reimburse for in that compound. So the pharmacy's at risk for losing, in that instance.

MS. ELLIOTT: But in that case, we will stop at the 300. It will deny.

DR. MOORE: Right. But he said if it's under 300.

DR. GOODNOW: And just to clarify that amount, if there are some compounds where the actual active ingredient is more than $300, how would that be taken into consideration?

DR. MOORE: So that would require prior authorization, and it would go to our clinical call center for review -- the regular PA process.

MS. ELLIOTT: And if I also -- if I could add, for your information, that there is a lot of compounds that don't

have powders or ointments, or whatever. So, you know, it's like for kids that cannot swallow tablets. So we are focusing on compounds like this. And this is not a $300 compound. This is a thousand-plus compound.

DR. OLSON: So that limit is going to apply to bulk powder compounds, not other commercial product compounds -- tablets and other? Or is it applying to all compounds?

MS. ELLIOTT: It's more like topical compounds are the ones that seem to be the highest price.

DR. OLSON: But is there a $300 limit only on topicals, or does it apply to all orals and topicals?

MS. ELLIOTT: Not the orals. We have -- at the beginning, we -- it included everything that came in as a compound. And it was problematic, because of the kids.

THE CHAIRPERSON: I don't think we need a motion or action on that.

DR. BORGERT: I don't know that we need to do anything. It's just kind of more informational, information for the committee.

THE CHAIRPERSON: Would it also be prudent for this prescriber -- and I don't know if it's out of protocol or not -- to send a letter from this committee, saying that we reviewed your practices and we find them highly irregular?

DR. BORGERT: I think probably the place is for Medicaid Program Integrity. But I'll let the agency speak to

that.

MS. HARRIS: Yes. We will be following up, if we haven't already.

DR. BORGERT: And the next question that came out of our review of compounds was about the Revatio suspensions that we were seeing on the list of compounded medications.

So a little bit of further information about that. It turns out that the commercially available products have been available since September of 2014. I don't -- none of us could remember exactly when it -- but when you look at FDB, it actually became -- the first date that it actually became available, September of 2014.

The commercial product is a powder for reconstitution that results in a ten milligram per ML suspension. It's 120 MLs at a wholesale acquisition cost of about $6,500.

There are directions in compendia for extemporaneous compounding of Revatio suspension, and I think this probably dates back to prior to there being a commercial product, when children needed this product.

So clinical pharmacology, other compendia have directions for extemporaneous compounding. And the directions for that extemporaneous compounding results in a 2.5 milligram per ML suspension, per the directions. We did have many claims for extemporaneously compounded Revatio

suspensions.

The reimbursement ranged anywhere from $3.91 that the pharmacy got paid, and that was a 270 ML prescription -- claim, all the way up to 27.56 for a 648 ML product that was dispensed.

And then, I just have there, for your reference, the dosing. It is a milligram per kilogram every eight hours for neonates and infants; 10 milligrams Q 8 for children under 20 kilos; and 20 milligrams every Q 8 for children 20 kilos and above. As you can see there, most of the utilization is actually in fee for service, as opposed to the MCOs.

DR. GOODNOW: I just have a quick question for the variation in reimbursement. It there any reason for that?

DR. BORGERT: I think it has maybe to do with what Elboni was just saying, in terms of the way that the pharmacy submits the -- what code they utilize. Any other questions about the Revatio?

DR. ROMAY: I was under the impression since there was a commercially available product on the market that it couldn't be extemporaneously made. Is that -- am I correct with that? Or is that something that we're kind of veering off from?

DR. BORGERT: I don't know the answer to that.

MS. ELLIOTT: That is a federal rule from CMS. Yes. So I don't know if we want to find out -- since most of them

are fee for service, would we -- we can find out who is the one that is still compounding it and contact them.

DR. ROMAY: The Revatio suspension is a lot pricier. On the cost basis, it probably would be a better angle. But, you know, we can look at it and see what we decide on it.

DR. BORGERT: Thank you. Okay. The next item for follow-up has to do with -- if you'll recall, one of the quarterly activities we did is, we looked at high-utilizing members. And so, we kind of picked an arbitrary definition of a high-utilizing member.

And the original definition that we picked was any patient who received nine or more different -- excuse me -- 15 or more -- let me get the numbers right, here. Yes. Nine or more different medications within a sixty-day window. So that was the cut-off that we used.

So we wanted -- what we brought back, when we looked at that quarterly activity is, how many members did we have that were getting nine distinct -- so, not different strengths of the same medication, but nine different medications within a sixty-day window.

And we had an astounding number. We had 47,533 recipients that accounted for one and a half million claims, when we used that as a definition -- how many people got nine or more prescriptions within 60 days.

So that was kind of an unmanageable number, and so

we decided to kind of just look at the worst of the worst, or whatever -- the highest of the highest, is maybe a better way to phrase that.

So we -- because we, literally, had patients who were getting 30 medications within that sixty-day window. So we used nine as the cut-off, but it went all the way up to some patients were receiving 30 different meds within that sixty-day window. So we kind of decided to start there and focus on that, since it was such a huge number of patients.

And so, what we did is, we cut it down to a thirty-day window. And so, we said, anybody who had 15 drugs or more -- 15 or more different drugs within a thirty-day window. And we had -- Magellan has compiled all of those medication profiles and broken them down by the different plans.

And that information will be passed along to the agency, because that was one of the requests, was that, you know, you guys maybe would bring this up in a call, or you know, that we could provide the agency with that information, and then they could follow up as they felt was appropriate.

So we have all that information for the members. You've got 15 or more medications within a thirty-day period. And we have the entire medication profile for each recipient, broken down by plan. And that information will be passed along to the agency.

DR. ALLEN: Could I ask a question, just about that data?

DR. BORGERT: Yes.

DR. ALLEN: Just to make sure there weren't any false positives. I guess where I'm going with this is, depending on what the refill-too-soon tolerance is, I guess a patient could theoretically get 10 on the first of the month, but he's eligible for a refill on the 24th of the month, or the 25th, right?

And if he's taking nine medications during that month's profile, it would essentially look like he's taking 18 medications, if that makes any sense. I just wanted to know if that was taken into consideration.

DR. BORGERT: Well, we looked at -- I'm not sure I understand your question, but we looked at distinct HSNs. So if they would have refilled it, it wouldn't have counted against them. Do you see what I'm saying? These were distinct HSNs. So the HSN is basically the drug, not strength specific.

So whatever -- if you were on gabapentin, there's multiple different strengths. But at the HSN level, it's gabapentin. So you only get counted for gabapentin once, no matter how many times you got that, or got the different strength within the thirty-day window. Okay. So that's part one of this topic.

Part two of this topic that came out of the board's discussion regarding this topic was people -- the board was concerned about members with HIV who were perhaps not getting complete regimens. So I can't remember exactly how the conversation went, but what came out as a follow-up of the high utilizing recipients was a desire to look at patients who are on HIV regimens, and were they getting complete regimens for their -- for the treatment of HIV.

So what we did to try to look at that was, we tried to look at patients who received only one HIV medication. Now, we excluded Atripla, Genvoya, Stribild -- you know, Complera -- all the ones that -- where it is appropriate to just have -- because they have multiple chemical entities within the same tablet, so, that's -- they're designed to be single drug regimens. So we excluded those.

And so -- but then, with the other HIV medications, we looked at within -- and we started to look at a thirty-day window, and we had a really large number. So what we did is, we expanded it to a ninety-day window. We said, okay, you know, maybe something happened with the refill. Maybe you didn't get it exactly on time. So we were going to limit it to a thirty-day window. We looked at 90 days.

And we said, how many patients only got one HIV med, excluding those, in a ninety-day window. And we had 1,029 recipients who only received one HIV medication, excluding

those, within a ninety-day window.

Now, some of those are probably explainable. Within that 1,029, there were 54 recipients with an age of zero who got one-time fills for zidovudine, 50 milligrams for five. So that's probably postnatal exposure. So those are probably appropriate.

We had 267 patients out of 1,029 who received Truvada. So that likely could have been pre-exposure prophylaxis therapy. So that likely could have been appropriate, as well.

If you want a specific breakdown of what these drugs were that they were only getting one of, this is the breakdown by pharmacologic class of drugs, in terms of -- so you can see, the highest one there, in terms of number of recipients, was the Truvada.

So that -- you know -- and again, if we say, okay, that's probably pre-exposure prophylaxis therapy. But there were, you know, several patients who were receiving only one of these types of classes. And I know Dr. Saenz was the one who kind of brought this topic up, and he's not here today, but that's the information, and I'm bringing it back to the committee for any comments, or to ask questions.

THE CHAIRPERSON: Comments? Questions?

DR. ALLEN: Great information.

THE CHAIRPERSON: Go ahead.

DR. ALLEN: No questions. Great information.

THE CHAIRPERSON: Now, these were fee for service findings that we were looking at?

DR. BORGERT: No. We're looking at both, fee for service and MCO. So a thousand, and if you take away roughly 300 or so of those, you're left with about 6- or 700 patients who are only getting one. I think Dr. Saenz, some of his concerns were that patients didn't understand.

You know, maybe they went to the pharmacy and the pharmacy didn't have one of the medications, or something, and they said, "We're going to fill this one. Come back and get the other one," and then they never did. Or I think he was concerned about maybe people selling their medications.

THE CHAIRPERSON: Yes. I know that was one concern. I guess the only potential follow-up I could see is if those unique members could be identified to the MCOs.

DR. BORGERT: Okay.

THE CHAIRPERSON: I'm sure our case managers, whatever, would be more than happy to do outreach to see if it is truly a misunderstanding, or see that they're on the appropriate regimens. Relatively small number, that spreadsheet, they could probably handle.

DR. BORGERT: Okay.

DR. GOODNOW: I think definitely, now that we're aware of the information, I think it's good, if there is a

potential for an intervention of a patient.

DR. BORGERT: I'm sorry. I couldn't hear you. What did you say?

DR. GOODNOW: Just saying, now that we know the information, that if this is an opportunity for an actual intervention to assist the patient, if it is maybe an outreach issue, either for the provider or the patient, I think it's definitely significant enough to reach out to them.

DR. BORGERT: I will compile those -- the list of recipients with their medication profile and I'll pass it on to the agency to pass it on to the MCOs, or however the agency wants to handle it.

MS. ELLIOTT: So you're running the same report for them, to also bring it over also for the next meeting, so we can see if the numbers for those recipients stay the same or change?

THE CHAIRPERSON: No. The ones that she's already run the report on is to give us --

DR. BORGERT: I think the request was for those 6- or 700 patients that were impacted who only had one HIV medication, which is probably an inappropriate regimen for them, that we provide that recipient information and those claims information to the particular plans and have those recipients too, that they do internal follow-ups to see, you

know, why is that happening.

MS. ELLIOTT: I got that. I was just saying if we bring the results, or kind of similar results for all of them -- because we can only give them the specific patients for the specific plans.

DR. BORGERT: Sure.

MS. ELLIOTT: So we would have, like, the summer for the next meeting or the -- because we're running the reporting for the same patients, right? Or we're getting those numbers for the specific patients, but what I'm saying is, if we see a pattern still in the next --

DR. BORGERT: So basically repeat the analysis?

MS. ELLIOTT: That's my suggestion.

DR. BORGERT: Okay. Sure. Right. Absolutely. So, you know, we disseminate that information. We give the plans time to, you know, intervene, or do whatever they -- you know, do their due diligence and find out if there's interventions that need to happen with the provider or the member. And then we basically re-assess and see if the situation has improved.

MS. ELLIOTT: That's what I --

DR. BORGERT: Yes. We'll have to think about what that time frame will look like, because obviously we need to get the data to the MCOs to give you guys time to, you know, research it and figure out what, if anything, that needs to

happen. And then we can remeasure again. Maybe -- I'm guessing maybe in the spring, or something, would be a good time to remeasure that -- the indicator.

All right. We are on to -- that ends the follow-up section of the presentation. We are on to new business. Vern, I'll let you -- okay. So the first item of new business is a request that came from the P&T committee at the June P&T committee meeting.

They specifically requested that the DUR board take a look at drugs that go into what we refer to at Magellan -- we have a market basket that we call Cytokine Antagonists. And basically these are medications for things like rheumatoid arthritis, Crohn's Disease, psoriasis and psoriatic arthritis, et cetera.

So when you look pharmacologically at the drugs that we're talking about here, they kind of fall into one of three buckets. We have the biologic TNFs, or tumor necrosis factor -- they're actually tumor necrosis factor inhibitors. And these are biologic products. And so, the list is there -- Humira, Enbrel, Remicade, Cimzia, Simponi. So those are our biologic TNF inhibitors.

And then, we also have other biologic drugs that they don't work by the same exact mechanism. They are biologics, but they don't work by the same exact mechanism. So they're not TNF inhibitors. A lot of these are

interleukin inhibitors -- IL-6, IL-17, IL-23. So that's the list of the other biologics that are not TNF-inhibitor based mechanism of action.

And then we have two drugs that are non-biologics. These are oral medications. And those are Otezla and Xeljanz. So those are the three buckets of drugs that we're thinking about when we're going to look at this polypharmacy issue. So we're going to look at guidelines. We're going to look at what's happening. And again, this was a request of the P&T committee.

So, again, it's a little bit of a diverse bag of diseases that we use these drugs in. So we need to look at, maybe, several guidelines. RA is probably the number one overall utilization.

So when you look at the guidelines from -- the 2015 guidelines from the American College of Rheumatology -- I don't want to read all this to you, but the bottom line is -- and I'm going to just skip to -- cut to the chase, and then I'll go back. There are no recommendations in any of those three guidelines to either use two TNF inhibitors together, to use a TNF and a nonTNF biologic, and -- or a TNF or nonbiologic with a nonbiologic.

So, I know it's a little bit confusing, but basically the point is, don't use two -- don't -- in the biologic TNFs, don't use two of those together. Don't use

one from a biologic and a nonbiologic. Don't use that together. And then, if you're using one of these oral ones, it shouldn't be combined with either of those classes, either.

So I'll go through the guidelines, just to kind of help everybody understand. So, in RA, basically, your bottom line is, if you're going to use combination therapy, it's Methotrexate or a conventional DMARD -- sulfasalazine, leflunomide, with a TNF inhibitor or a nonTNF biologic, or a nonbiologic. So Methotrexate or a conventional DMARD in combination with any of those three. But not those three combined together.

And then, for psoriasis and psoriatic arthritis, the American Academy of Dermatology says monotherapy with either a TNF inhibitor or another type of biologic is acceptable as first-line therapy after failure of topical or phototherapy.

And in patients who have moderate to severe psoriatic arthritis, use one of those drugs or a combination of Methotrexate plus one of those drugs.

So, again -- and then, lastly when we look for the management of Crohn's or ulcerative colitis with these drugs, same type of thing -- antiTNFs in combination with thiopurines. That would be something like mercaptopurine. And then, other drugs in the maintenance setting.

Bottom line is, and I think what the P&T committee was

trying to get at is, we don't use those three buckets of drugs in combination, per the guidelines, for any of those. And so when we looked at it, what we found is that we had 16 recipients who were getting two different TNF inhibitors within a quarter. We had five recipients who were getting a TNF and a nonTNF biologic. And we had six recipients who were getting either a TNF inhibitor or a nonbiologic plus the nonbiologic.

So -- however, it's maybe not as bad as it looks, because -- and here's exactly what that looked like, in terms of the drugs. So you can see, 13 of them -- so we had 27 recipients. And so half of them, almost, were getting Enbrel and Humira. But when I looked at that, when I looked at the service dates on the claims, it looked like probably at least ten of those patients were switching therapy. Not concomitant therapy.

However, there were three patients who most definitely got both drugs filled on the same day every month. So there were a few big outliers.

And the same is true kind of with the rest of these. There were a few that looked like maybe they were switching therapy. But there were also at least four or five patients who were getting those two -- both drugs filled, particularly, like, the Otezla and the Enbrel. They were getting both filled on the same day every single month.

So, it wasn't a huge problem, but we did have some issues. So that was information that the P&T specifically asked to come to DUR. So that's the information for the DUR board.

THE CHAIRPERSON: So, much like our previous discussion, I think a thirty-day overlap is probably something that would be -- like you said, someone that's changing from one agent to another. But we could certainly put an edit, or look to put an edit for not duplication of these three classes.

MS. ELLIOTT: I have a question.

DR. BORGERT: Yes.

MS. ELLIOTT: Did you look at the physicians? Are they different --

DR. BORGERT: Yes. I did look at the physicians. And a lot of times, it was the same physician. As a matter of fact, I would say the majority of the time, it was the same physician who was prescribing both drugs.

Whether it was the -- it looked like a switch, or whether it was they got the same two drugs on the same day, by and large, it was the same -- not obviously across the board, but for each individual recipient was -- it tended to be the same provider.

DR. ROMAY: I think it's very important to capture that and put a hard stop, so we can at least have the

opportunity to reach out, if we see that duplication. And especially if it's two different providers, we can kind of, you know, get and see which one -- maybe they're not talking to each other, which happens a lot, and we don't get that opportunity to have an intervention.

DR. BORGERT: I know there were at least a couple of instances where it was a different providers. But the majority were the same. One thing I thought, you know, just having looked at the data, I don't know if a thirty-day window might be enough, because, you know, a lot of times they got -- you know, let's just say -- okay. So we're in September.

So they got, you know, Enbrel in September and then they were switched to Humira in October, but it might not have been exactly 30 days. I mean, it might have been six weeks, or something like that. So I'm not sure that 30 days is going to be a big enough window. So maybe 60 days.

DR. ROMAY: And I think we also have to look at the fact that, you know, we have to give these biologicals a chance to work. A lot of these providers are just getting -- you know, there's a lot of discussions that come around when patients have been on these medications. I mean, I get it from when I speak to the providers. They say, "These patients are xenophobic," or, "They can't come in because they're not complying with their medications."

So I get it. But there's a lot of leakage, you know, between those therapies that really should give a chance, at least a six-month period, to get that medication, to really see if it's working or not.

DR. ALLEN: Trying to find the best way to frame my question. This is second quarter data, correct?

DR. BORGERT: Second quarter. Correct.

DR. ALLEN: So my time line might be off.

DR. BORGERT: No. You're right. I know where you're going.

DR. ALLEN: So Enbrel and Humira during that time were both on the PDL.

DR. BORGERT: There was probably some overlap in terms of the PDL changing with that. Exactly.

DR. ALLEN: So, in theory, Enbrel and Humira would have just -- there wouldn't have been a dupe therapy edit to prevent that from happening previously?

DR. BORGERT: No.

DR. MOORE: There is a dupe edit, but it doesn't stop the claim. It posts at the pharmacy.

DR. ALLEN: So, just for clarity, would that just be the messaging, or does the pharmacist have to go in and put in a code?

DR. MOORE: It was soft. No code necessary.

THE CHAIRPERSON: Dr. Romay, would you like to

propose a hard edit?

DR. ROMAY: Definitely. I propose that.

DR. ALLEN: Second.

CHAIR: With a sixty-day?

DR. ROMAY: Yes.

THE CHAIRPERSON: Any -- so I've got a motion by Dr. Allen and a second by Dr. Romay --

DR. ALLEN: Reverse.

THE CHAIRPERSON: -- with the hard edit, 60 days. Any further discussion? Questions? Any opposition? Hearing no opposition, the motion carries.

DR. BORGERT: Thank you. Okay. So what we'll do is, once the edit is implemented, we'll give a period of time and then we'll do a follow-up analysis to see the impact of the edit. And we'll also take that information back to P&T, since it was a request directly from P&T. But that's the action the DUR board took, based on review of the information.

And what Elboni said just reminded me of something I forgot to mention. When we were looking at the high utilizing recipients -- remember when we were talking about these patients who were getting 15 meds in 30 days? One of the other things that had come out of the discussion in June was, what about the Produr edits that are -- what Elboni just said made me thing about it -- that are therapeutic dupe and

ingredient dupe.

Why are those not stopping them? Or, are those stopping them? And so, we tried to pull that information. We tried to look at, okay, were any of these Produr edits that were overridden by the -- hard edits that were overridden by the pharmacy, by using the service -- professional service codes.

We tried to look at that to see if maybe we could pinpoint, you know, some bad actors that were just blowing through the Produr edits. And unfortunately what I found out was that when we get the encounter data, the Produr information is not part of that encounter data. Or it's certainly not consistently part of that.

So there's really no way for us to capture that information on a large scale basis for the MCO. So rather than bring back bad data, we just decided to scrap that, and trying to look at that, because we just didn't have the information.

We didn't have the Produr information in the encounter data that would enable us to really look at that in a systematic way. I just thought of that. I just remembered that. And I wanted to bring that to the board.

DR. ROMAY: I know we're looking at, specifically those Produrs, and things like that, that can be overridden at the pharmacy. Can we maybe perhaps look at those edits

that we currently have that are overridable at the POS? Maybe look at them more closely, to see if maybe there's opportunities to kind of turn those off?

I know we're trying to provide access to the members, and not have them walk out without something, but I think we need to do something a little bit more streamlined, so we can at least look at what's being overridden at the POS level.

DR. BORGERT: So, I just want to make sure I understand your question, or your request. So what you're requesting is that in terms of Produr edits that we have -- maybe, say, for therapeutic duplication or ingredient duplication, where it's just like a -- messaging to the pharmacy, it doesn't stop the claim, you'd like to have information about what those are to review, to see if -- maybe convert those to a hard stop? Is that even something we can do, Elboni?

DR. MOORE: The ones that we do have activated, we do provide to the plans on a weekly basis. It's on that comprehensive drug file that you all have. So you all have possession of which Produr edits that fee for service has activated. If you want us to try to pull it up today, if you want to discuss it today, we can try to do that. So, it's up to the board.

DR. ROMAY: That wouldn't include the therapeutic

ingredients that we were talking about earlier?

DR. MOORE: We do have the therapeutic duplication edit activated. It does deny for particular situations, but not everything. So some are soft, some are hard. But most are soft.

DR. ROMAY: Yes. I mean, that's probably what I would want to look at, to see what those are, so we can at least -- because I know, a lot of times there are players out there that will override that just to get the claim to pay. And to really look at patient safety, you know, make sure that they have the right recommendation.

DR. MOORE: So what I'll do is, I'll let Becky continue. I'll pull it up. I'll send it over to her and she can pull it up at the end, and we can come back to it and discuss it.

DR. BORGERT: Thank you, Elboni. Okay. We're on to the new business section about upcoming P&T classes. If you look in your packet that came to you, there was an Excel spreadsheet. I will pull up the Excel spreadsheet here so that it's on the screen. I'm sorry I can't make it much bigger than this, for some reason.

But basically, there were three classes that we pulled out this time to look at. So the first one to look at is the topical immunomodulators. And obviously the product here is Imiquimod. I think that's how you pronounce this.

And so, this is the utilization of Imiquimod in our population between April and June -- April 1 and June 30.

And so, one of the things that I found a little bit interesting is, it's not FDA approved in children under the age of 12. And so, of that utilization that we just looked at, we did have 55 recipients and 59 claims with this amount of money for Imiquimod.

As I looked at it, it looked like probably molluscum contagiosum, and I wanted to get everybody's opinion on that. And you know, I will definitely need the board expertise here, you know. In the literature, it says, you know, self-limiting condition, you shouldn't treat it, blah, blah, blah. But, you know, I'll defer to the board and get their input on what they think about that.

DR. ZITIELLO: I suppose you would like me to speak up on this. Since leaving Amerigroup, I can tell you that the vast majority that we got for this age group were for viral warts, molluscum contagiosum. I don't have a real strong feeling on -- this is a self-limiting illness, just like warts.

I can say personally that I did a lot of denials for these. I'm surprised there is any that are coming through. Yes, cosmetically it's a little stressful. My own daughter has had it and she did not go on Imiquimod. Again, it's self-limited, so I don't really see the reason for that.

DR. BORGERT: My understanding is, it's a preferred agent.

DR. ZITIELLO: The denials were really based on diagnosis. Obviously there are indications for this.

DR. BORGERT: Sure. Absolutely. And I have the indications listed here -- actinic keratosis, basal cell carcinoma, HPV. Those are the indications. But typically, obviously, not conditions that you normally see in children under the age of 12. So from what I'm hearing you saying is that when you reviewed them, in your medical opinion, you mostly tended to deny them.

DR. ZITIELLO: Almost 100 percent.

THE CHAIRPERSON: So if we put an age edit --

DR. BORGERT: Actually, we do have a minimum age of 12. So, you know, I don't know that -- and a quantity limit. But I don't know -- you know, still, it looks like some plans were still approving it. I don't know. Just an FYI, more than anything really to the board to think about, in terms of is it therapy that makes sense to continue to do.

Other P&T classes to maybe think about, I just wanted to bring this to the board, just to make sure the board was aware of this, that in May of 2016, the FDA did put out further warnings regarding fluoroquinolones, advising that the serious side effects associated with fluoroquinolones generally outweigh the benefits for patients

who had acute sinusitis, acute bronchitis and uncomplicated UTIs who have other treatment options.

So the FDA now says that for these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options. So I just wanted to make sure the board was aware of that recommendation by the FDA. We typically bring that type of stuff to the board.

And then to just provide you with a list of -- you know, there, in the left-hand column, is our preferred and nonpreferred, fluoroquinolones. And you can take a look there at the utilization, both by fee for service and MCO, and just see if the board had any comments or anything that they wanted to do with fluoroquinolones based on that FDA information.

DR. GOODNOW: I apologize. This is a very, very silly question. But on fee for service, amount paid, there are a couple of choices at the bottom -- a couple of agents just with a zero amount paid. Is that just because the fee for service they were in, maybe the portion to -- like, there wasn't --

DR. BORGERT: My guess would probably be that they had coordination of benefits. Like, they had another plan, maybe, that picked it up. And then, so Medicaid's portion of the prescription was zero, that whatever other insurance paid for it -- covered the entire amount.

THE CHAIRPERSON: So, other than a step through --

DR. BORGERT: And you know, antibiotics are tough, because, you know, they're acute therapy. You don't want to stop them at the pharmacy, and yet you've got the FDA, you know, saying don't use it for acute sinusitis, bronchitis or UTIs, and they are very obviously -- you can run the utilization numbers and see, you know, we have, you know, 40,000 claims in a quarter for Cipro. They're obviously highly utilized medications. But it's really, really tough.

DR. ROMAY: Can we maybe suggest putting, like, a banner message, just as an educational standpoint, saying, you know -- you know, I know there's a lot of overprescribing antibiotics out in the community, including Zithromax.

I mean, everybody gets a Z-Pak every time they walk through the door, or they call a physician and get it. So I think we've seen that a lot, even though it's inexpensive, but we're creating a lot of resistance out in the community. So I think maybe a banner message could circumvent that.

THE CHAIRPERSON: And we do have a hard age edit on this? Isn't there evidence of bone marrow suppression for use under the age of 12? Or -- not bone marrow --

DR. BORGERT: Or cystic fibrosis.

DR. ZITIELLO: I was going to say on that banner message, perhaps add some of the information about bronchitis.

DR. BORGERT: And I suppose as we're coming into cold and flu season, too, it's probably timely to think about that.

DR. MOORE: We've done a similar initiative in the past through DUR. We did a letter campaign to provide to the community, talking about, you know, antibiotic resistance, and when it should be used, and perhaps when it shouldn't be for viral instances. So, like Becky just said, coming into the cough and cold season, it wouldn't hurt to do it again.

DR. BORGERT: And provide them at the same time this information from the FDA about, hey remember that the FDA is saying that the risks of these drugs outweigh the benefits, in these types of infections. Even if you do need an antibiotic, this it probably not the best choice.

DR. OLSON: Just a question to the IV solution claims that are coming through there. Where is that coming from? It's small dollars, but there's --

DR. BORGERT: Yes. I mean, sometimes those are billed through point of sale. So, like, maybe if it's a home infusion pharmacy, or something like that, that was billed through point of sale, that's what that is.

Okay. So a banner message will be drafted and that will be brought back to the board at the January meeting.

And then, there is -- the other class that we pulled out to look at was the tricyclic antidepressants. I know one

of the things that we've done as a board, sometimes, is looked at an overall class and see if there is any streamlining or anything you wanted to do with it. You can see that we had a lot of preferred TCs.

So, you know, nothing in terms of financial, but just, you know, they can also be difficult drugs to manage. So, just looking over the list of tricyclic antidepressants, and is there anything that the board would be interested in streamlining? Or do we think it's okay, and we just want to leave it as it is, I think, is the question there.

THE CHAIRPERSON: I mean, jumping off the page are the amoxapine, desipramine -- relatively low utilization, and obvious alternatives. I would recommend paring those down as nonpreferred.

DR. BORGERT: Sure. We can take that back to the P&T committee, if the DUR board wants to recommend that.

DR. ALLEN: If that's a motion, I second.

THE CHAIRPERSON: No. I'll ask you for the motion. With a new chair, I tend to not make motions. I don't like motions. I've got to move things along.

DR. ALLEN: So I'd like to make a motion that we recommend doxepin to the P&T for suggesting the generic -- was it for the generic, or to remove --

THE CHAIRPERSON: Just removal to nonpreferred.

DR. ALLEN: Okay. Move to nonpreferred, the doxepin

brand.

DR. BORGERT: Just to clarify, I think Dr. M said amoxapine, as well. But you just want to make it doxepin?

THE CHAIRPERSON: No.

DR. BORGERT: Or did I not hear you right?

THE CHAIRPERSON: No. Desipramine.

DR. ALLEN: I'd like to rescind that motion, and I'd like to make a motion that we make a recommendation to the P&T to remove desipramine from the PDL, or move to nonpreferred status.

CHAIR: I've got a motion. Do I have a second?

DR. GOODNOW: Second.

THE CHAIRPERSON: Okay. Any further discussion? Any opposition? Hearing no opposition, the motion carries.

DR. BORGERT: Thank you. Okay. We are to the quarterly activities section of the report.

MR. HAMILTON: Mr. Chair, at the risk of Dr. Borgert's ire, may I recommend a brief break?

THE CHAIRPERSON: Well, I was going to say, how long do you think we need to do this? Do we want to just power through it?

DR. BORGERT: All depends on how much the board wants to talk about it, so I can't really predict it. So, I mean, I will say this: I will say that the P&T committee yesterday had a great interest in these topics that the DUR

board is going to review today regarding the CDC opioid guidelines. So I think there might be a fair amount of discussion.

MR. HAMILTON: Ten minutes? Twelve minutes?

THE CHAIRPERSON: Well, I say, it's 9:27. How about an eight-minute break?

(Recess)

THE CHAIRPERSON: By my clock, it is 9:36. That's nine minutes past. All right. I'd like to reconvene. So, the quarterly activities is where we are starting.

DR. BORGERT: We'll move on to quarterly activities. For this quarter, the DUR board decided to look at -- focus on the CDC recommendations regarding opioid prescribing guidelines.

I'm sure everyone is aware, but just to reiterate, in March of this year, the CDC published guidelines. They were said to be recommendations for primary care clinicians who prescribe opioid for chronic pain. So not necessarily acute pain, but chronic pain, outside of active cancer treatment, palliative care or end-of-life care.

So we're talking about non-malignant chronic pain here. The CDC broke these guidelines down into three sections. Those sections were -- the first one, Determining When to Initiate or Continue Opioid for Chronic Pain. The second one was Opioid Selection, Dosage, Duration, Follow-up

and Discontinuation. And the third category was Assessing Risk and Addressing Harms of Opioid Use.

And within those three categories, there were 12 specific recommendations regarding the prescribing of opioid for that defined population. So the ones in red here are the ones that we are going to focus on. So we didn't pick any from the Determining When to Initiate or Continue Opioid for Chronic Pain. Doesn't mean we can't do that at some other point, but for this quarter, we didn't pick any from that category.

We did, however, pick two from the second category that -- those -- that was, when starting therapy, prescribed immediate-release opioids, instead of extended-release opioids. And the second one is, when starting, prescribe the lowest effective dose. Carefully re-assess evidence of individual benefits and risks when increasing to greater than 50 morphine milligram equivalents per day, and avoid increasing the dose to greater than or equal to 90 morphine milligram equivalents per day.

And then, the third topic that we picked came from the Addressing Risk and Addressing Harms of Opioid Use. And one we picked there was, avoid prescribing opioid pain medication and benzodiazepine concurrently whenever possible.

So those are the three items from the 12 CDC recommendations that we're going to take a look at today.

So, the first is, use immediate-release opioid prior to extended-release opioid.

And I have good news here, and that is that, so we looked, in the first quarter of 2016, at how many claims we had for long-acting opioid. And we had 9,175 claims for long-acting opioid. And what we found was, so, we looked back to see if there was a prior claim for an immediate-release opioid. And there were only 1,446 of those. But, you know, we don't know when those people started.

So we had to basically allow -- say, well, okay. If you got the long-acting within the same period of time, within that ninety-day window, then you're basically going to be -- we have to bucket you as okay, because we don't know when you started these.

So all patients, every single patient, either had a prior claim for an immediate-release opioid or had a claim for the same, long-acting opioid within the period of time. So, it was good. I mean, it looked like, you know, the people who were on long-acting opioid -- and we did exclude patients with a diagnosis of cancer, by the way, when we looked at these numbers.

So it did appear that everybody that was getting an extended-release opioid had either been on that, or had received an immediate-release prior to that. So, in this

way, it was good, but, you know, the flip side of that is, we really have no way of knowing, you know, did they start? What did they start with? Because we're not looking at new starts there. We're looking at a snapshot in time.

So, I don't know what the DUR board wants to think about or talk about in relation to this recommendation of the CDC about using immediate-release opioid prior to moving to the extended-release opioid in the chronic pain population -- chronic non-malignant pain population.

THE CHAIRPERSON: I don't see anyone rushing to their microphone.

DR. BORGERT: I mean, to me, it does seem like it's something that would lend itself to an edit. You could certainly look back -- when you get a prescription for a long-acting, you could look back and see if they even had that, or if they've had an immediate-release within whatever period of time, you know, the board thought was appropriate.

DR. ZITIELLO: Do you have a recommendation for a period of time?

DR. BORGERT: I guess I would say 60 days. Because, I mean, if you're on a long-acting opioid, the whole point is to try to have a steady blood level, et cetera, et cetera. So it's not like you should be taking it PRN, or anything like that. So I think 60 days is probably a reasonable window of time.

THE CHAIRPERSON: And what about -- because I know a lot of times in joint replacement surgeries, they'll prescribe both, from discharge from the hospital.

DR. BORGERT: We could probably -- that would be built into the edit, because it was -- you know, would be basically concurrent. I guess if they literally physically filled the ER before they filled the IR, it might cause an issue, but if they had both --

THE CHAIRPERSON: So that would be a hard edit for ER without a -- with a sixty-day look-back for an IR?

DR. BORGERT: I think that would address the CDC recommendations. But clearly it's up to the board, what they think is best to do.

MS. ELLIOTT: Did we address the ones that are already?

DR. BORGERT: Well, that's what I'm saying. Look-back even for itself, or any other long-acting opioid. So basically the only people who would fall out of that edit would be somebody who didn't have a claim for a long-acting opioid or a short-acting opioid with the previous -- and they were getting a long-acting opioid.

So, you come to the pharmacy, you have a prescription for Embeda, and you look back 60 days and you've had no immediate-release opioid or long-acting. So you're opioid naive, as far as the claims history goes, and you've

presented with a prescription for a long-acting opioid.

DR. GOODNOW: Is there any -- I know that abuse potential is lower with the long-acting, versus the IR. So, like, how -- I wonder what the look-back history of the patient would be, to see if it was, like, postadmission or maybe a chronic disease state. I'm just trying to see, to make sure -- I know the intent of the request for the IR, but also just to tread lightly on, like, from a safety aspect. But the concomitant would be okay, if they did --

DR. BORGERT: Yes.

THE CHAIRPERSON: And that is aggregate data from both fee for service and --

DR. BORGERT: Correct.

THE CHAIRPERSON: Discussion? Any recommendations? Dr. Romay?

DR. ROMAY: I think that's a good step to take, the look-back.

THE CHAIRPERSON: Would you like to phrase that in the form of a motion?

DR. ROMAY: Motion to approve.

DR. ALLEN: Second.

DR. BORGERT: I'm sorry. What are we approving? You're going to have to state that a little bit better.

DR. ALLEN: So my interpretation -- and I'm not trying to speak for you, but I think you actually presented a

recommendation to the board.

DR. BORGERT: Well, I'm not a member of the board, so I can't make a motion. I'm just here to facilitate conversation.

DR. ALLEN: Right. Well --

THE CHAIRPERSON: Go ahead.

DR. ROMAY: I agree to have that sixty-day period to check back, to look back for an IR.

THE CHAIRPERSON: So a hard edit with a sixty-day look-back for an IR previously.

DR. BORGERT: Or an ER.

THE CHAIRPERSON: Or an ER.

DR. ALLEN: In line with the CDC's recommendations.

DR. ROMAY: Correct.

DR. ALLEN: And I'll second that.

THE CHAIRPERSON: Any further discussion or comments?

DR. OLSON: Just one comment about the compliance. If you're looking back 60 days, is there anything to look at whether they are consistently taking their long-acting? Because, yes, they might be abusing it, but some people already are probably getting it and doing other things with it. But can you look at that with the combination of the sixty-day, or no? Duration between fills? I don't know if that makes sense.

DR. BORGERT: I don't know if there's any way we can edit that. We can certainly look at it. I don't know if there's any way to --

DR. MOORE: Yes. We can do that. We can look for a particular medication with a particular day supply on there. You know, we can't ensure that the patient's actually taking it, but at least we're looking for -- we're matching the drug with a day supply each month.

THE CHAIRPERSON: So, I have a motion and a second. Any opposition? Hearing no opposition, the motion carries for the hard edit for 60 days.

DR. BORGERT: Okay. Thank you. All right. The next topic from the CDC guidelines were the concomitant use of opioid and benzodiazepines. There was quite a bit of discussion about this in P&T yesterday. And just in addition to the recommendations from the CDC last March, at the end of August -- so just less than a month ago, the FDA actually announced that they were requiring labeling changes to opioid and benzodiazepines to increase the visibility of the risk.

And so, this was a public statement by the FDA that after an extensive review, they were requiring class-wide changes to drug labeling, to help inform healthcare providers and patients of the serious risks associated with combined use of opioid and benzodiazepines.

And they are requiring boxed warnings to go on all

prescription opioid analgesics, opioid-containing cough products and benzodiazepines, a total of about 400 products, with information about the serious risks associated with using these medications at the same time.

So this is coming from the FDA to, you know, again, sort of add even more weight to the CDC recommendations about concomitant use of opioid and benzos. And unlike the IR before ER, I think this is an area where we do have an issue.

So this is what the data looks like from the first quarter of 2016. We had 66,000 benzodiazepine recipients, 56,000 opioid recipients, and 23,779 who overlapped, who received -- within a day's supply range, they were receiving both an opioid and a benzodiazepine. 23,779 recipients.

DR. ZITIELLO: Can we break that down by diagnosis, age, anything like that?

DR. BORGERT: I can only -- I mean, I can go back and do that. I can only tell you that, again, cancer patients were excluded from the diagnoses, from the pool that we pulled from. But that's all we did, is exclude those patients. And no, I don't have a particular list of diagnoses, but I could certainly go back and pull that in aggregate type of information.

THE CHAIRPERSON: I was just thinking, who wants to take those phone calls. Discussion?

DR. ALLEN: Yes. I guess maybe we'll ask for a

lifeline from Dr. Borgert. Do you have any recommendations?

DR. BORGERT: Yes. I think it's a tough problem, but I think that it's really become -- you know, increasing pressure to address it from a federal level. And, like I said yesterday, the P&T committee was very interested in having the DUR board address it.

You know, one of the things that I wrote down here -- let's see here. One of the things the CDC said was that because the risk of benzodiazepine withdrawal is greater than the risk of opioid withdrawal overall, and just tapering opioid can cause anxiety for patients, that, you know, kind of their thought process was that when a patient's on both a benzo and an opioid that needs to be tapered, it might be safer and more practical to taper the opioid first.

They say clinicians could then gradually taper benzodiazepines. And they recommend that a reasonable tapering schedule would be a reduction of the benzodiazepine dose by 25 percent every one to two weeks. So that's what the CDC had to say about how to approach it from a global standpoint.

I think the problem for us, how do we approach it from a recipient, patient-specific type of standpoint. You know, I think there's two trains of thought. I mean, I think we can look at it from, let's tackle the problem from here forward, or let's try to tackle the problem that exists

today.

And I don't know, you know, if the board -- it obviously would probably be easier to tackle it from here forward, than to try to go back and do those. I mean, there's probably educational campaigning that might be able to occur. So, those are my general thoughts, Dr. Allen.

DR. ALLEN: From my thoughts, I mean it's a difficult point to address operationally -- in operational eyes. Certainly I welcome feedback from the board on this one, but I was thinking more so of a banner message, or something, just so do some education.

I mean, you have to do something, if it's serious enough for the CDC to address it. But at the -- I guess from a plan standpoint, I am just not 100 percent sure how you operationalize it.

DR. BORGERT: I think it might -- I think it becomes a medical legal issue maybe for prescribers. So I think, you know, in some ways we would be helping prescribers by saying, hey, there's really a lot more attention to this, and if you have patients who have adverse consequences and you're acting outside the standards of best practice, that's probably not a good thing for you, as a provider.

THE CHAIRPERSON: So, a couple of things. One, with new starts, certainly you would want, in the discussion I'm hearing, that we want to put a hard block on new starts for

both -- for the combo meds.

The other would be if -- and I'm just kind of throwing it out -- is to have, say, a ninety-day limitation on the duplicate therapy, so that, you know, one, you're blocking any new combo starts, and then, the other would be if you put a ninety-day and you give opportunity for that prescriber to taper either/or or both over that ninety-day time frame.

I'm trying to get creative here. From a pharmacological standpoint, where -- am I skating on thin ice, or --

DR. GOODNOW: Do we think a query of the same agent, same provider? I don't know if that's a good place to start. And I know same practice might be along the same lines. But then they are consciously -- you would have a -- it's very hard to target this, because we all know the patients that we're talking about, because there are some patients that -- especially the more complicated -- like pediatric cases, or -- you know, there are scenarios where it's appropriate.

So it's hard to clean this data up, to really target. But maybe the two agents by the same providers, for the same patient? Then the provider is then aware that they are prescribing them at the same time, and then you're sort of hitting that target. But there -- it still might be justifiable, but at least you are informing. I think that

the message is, we're informing them of their practice.

DR. BORGERT: So, the request for some follow-up information regarding how many of these patients involve the same provider or practice, and how many of them are separate providers.

DR. GOODNOW: Because then you're -- I think you're doing a single phone call, instead of two phone calls. You're doing one phone call to that practice to say, "Just to clarify, there is a concern with this prescribing pattern," as opposed to trying to get two providers to work together.

THE CHAIRPERSON: And you could very well -- I go back to my joint replacement earlier. You can have someone that might be on a benzodiazepine for just general anxiety. They go in for a procedure and that orthopod is not aware that they are on a benzo and prescribes an opioid.

DR. FAGAN: Would it be possible to do a soft messaging edit when these two come up in the POS system? And then also an educational -- some sort of an announcement for the physicians as an update? And then when we get more material and more information, we can go back and revisit this?

DR. MOORE: Yes. We certainly can do that. We can start with a banner -- you know, two-prong approach, banner, soft message. So we'll have, you know, a table that says, you know, for these particular drugs, soft message this to

the pharmacy. We'll turn it on, then revisit maybe six months later, see if the behavior has changed, based on these interventions. And if there hasn't been a change, then we move further.

THE CHAIRPERSON: Okay. I think that's a nice halfway point.

DR. ROMAY: I'm not sure if we've done a banner message before regarding benzodiazepine use. I don't know if we did that prior. I think I recall we did something like that.

DR. MOORE: Not most recently, but we have in the past. But it was more focused towards the elderly population. Not opioid plus benzos, just the safety concerns with, you know, chronic use of benzos.

THE CHAIRPERSON: In greater than 65.

DR. MOORE: Yes.

DR. ALLEN: Just a quick question. I know it may be silly, but would this protect a guy who's taking an opioid and also using clonazepam for a seizure? Like, wouldn't he kind of be triggered in this bucket, as well? And would his therapy be potentially adversely impacted?

DR. BORGERT: That's a good point. You know, PRN. I mean, we certainly do, like, you know, Diastat. We can throw that out of the edit. But clonazepam, you know -- yes. I don't know. That's a good thought. We can screen for --

DR. ALLEN: For, like, diagnosis or something. That's kind of like what I was thinking. And I think that's kind of what has me a little uneasy. So I write globally opioid, BZPs. I got it. But, like, for the clonazepam, he could potentially be adversely affected.

THE CHAIRPERSON: But right now we're just talking about messaging. Let's see if we get any behavior change, and then we'll see.

DR. OLSON: Do we have the ability, or do we have any data on e-prescribing with -- obviously with the opioid, it's low. With the benzos? Is that possibly an avenue of communicating this information with physicians? Because a lot of it is focused at the POS end.

What else could we do at the provider end, to do the alert ahead of time, not at the point of dispensing? I don't know if e-prescribing is the methodology to do that.

DR. BORGERT: I don't know the answer to that.

DR. MOORE: Well, we do get the data from the e-prescribing, but we don't have the ability to send out any messaging from Surescripts. That's who the vendor is. So we get their information, based on, you know, how many claims went through that process, or how many prescriptions were e-prescribed. But we do not -- we don't have the ability to send things to pharmacies up front.

DR. OLSON: That would be interesting, because it

might be worth pursuing -- partnering with e-script, or something. Can we get the e-prescribing data on the percentage of --

DR. MOORE: Absolutely.

THE CHAIRPERSON: So, we need a motion for that messaging, or --

DR. BORGERT: For the soft messaging that we talked about earlier?

DR. MOORE: It's two, right? So we're going to do a banner message, as well as a soft message to the pharmacies indicating the use of a benzo plus an opioid.

DR. FAGAN: Is there any way to get a banner message out to the physicians, as a physician alert?

DR. MOORE: The banner messages are posted on AHCA'S website where anybody -- any provider in the community can go out there and click on it. They can even get the alert sent to an e-mail address. So it's readily available. With a revisit in -- do y'all want to do a year, or half a year?

THE CHAIRPERSON: Let's go six months and take a look. Can I get a motion to that effect?

DR. FAGAN: I have to repeat the whole thing? Or can I do a motion to that effect?

THE CHAIRPERSON: I think a motion to that effect, to the banner and the soft message.

DR. FAGAN: And then a six-month revisit.

THE CHAIRPERSON: Second?

DR. ROMAY: Second.

THE CHAIRPERSON: Any further discussion? Any opposition? Hearing no opposition, the motion carries. Are you clear with that? Okay. Great.

MS. ELLIOTT: Just an FYI, I looked at the alerts, and the last one that we sent was in 2011. So I think it's appropriate.

THE CHAIRPERSON: Okay. Great. Thank you.

DR. BORGERT: Okay. And the last topic from the CDC guidelines that we wanted to look at were morphine equivalent daily doses. And what the CDC has to say about this is, they say that the clinical evidence finds that higher opioid doses are associated with increased risk for motor vehicle injury, opioid use disorder and overdose.

According to the CDC guidelines, the clinical and contextual evidence reviews found that opioid overdose risk increases in a dose-response manner, and that doses of 50 to 100 morphine milligram equivalents per day have been found to increase the risk of opioid overdose by a factor of 1.9 to 4.6.

So two to five times higher risk of overdose in patients who are receiving 50 to 100 milligram morphine equivalents per day, when you compare that to patients who are receiving lower doses of opioid.

So, in our population, this is what it looks like. The majority are receiving less than 50 milligrams of morphine equivalent daily dose. However, we did have 17,000 patients who were receiving between 50 and 90, and we had over 10,000 patients who were receiving over 90.

And again, remember, we excluded cancer patients from this diagnosis -- from this data set. So, you know, we have a lot of patients out there who are using high doses of opioid. I will say, I did find that this is -- I want to show you guys these. I thought they were interesting.

These are tools on the FDA website. So these were some tools that, you know, I don't know if the board has any interest in utilizing, in terms of helping to educate, but, you know, these are just, like, some little infographics that talk about why it's important to calculate the total daily dose, and then, you know, kind of talks about how much is that, in terms of, what are some of the common medications.

And then, on the second page of that, that PDF, they actually go through exactly how you calculate morphine on a daily equivalence, and they give you the chart that the CDC recommends that you use, so how you figure out -- and I -- you know, I thought this might be worthwhile information, because I think people throw that around a lot, morphine equivalent daily dose, or morphine milligram equivalents.

But, you know, I don't think -- I don't know if everybody -- all the providers really have the nuts and bolts of the tools at their hands, and how do I figure out what that is for my patient, based on what drug that I'm prescribing for them. So I thought that these tools were kind of interesting.

And then, there were actually several tools, not just that one. But this -- this is the CDC website. And so they have several of these. Pocket Guide, Tapering Opioid for Chronic Pain, Guidelines for Prescribing Opioid for Chronic Pain, a checklist when prescribing.

So there's some tools on the CDC website that -- you know, I don't know if this is something that, you know, the DUR board thinks would be beneficial for helping to educate our Florida Medicaid prescribers.

I just thought I would throw those out to you, especially if we were talking about the morphine equivalent daily dose. I thought that that was a handy little two-pager that kind of goes through, you know, how exactly do you figure that out. So, I'll just throw that out there.

THE CHAIRPERSON: I think referencing these in either the PDL and/or the prior auth areas of the AHCA website are an excellent idea.

DR. ALLEN: Agreed.

THE CHAIRPERSON: I would make that motion.

DR. ALLEN: Second.

THE CHAIRPERSON: Discussion? Opposition? Okay.

DR. BORGERT: Okay. I mean, we'll pass that along to the agency and they will have to determine what they want to do with that.

THE CHAIRPERSON: Sorry I gave you some homework.

DR. BORGERT: All right. So, you know, I think the take-home message here is just that, you know, this is really snowballing, you know. This is really becoming -- you know, more governmental agencies are getting involved. More resources are being put towards addressing the opioid epidemic.

And I think, you know, as a DUR board who looks at prescribing patterns and medication utilization, I just think that, you know -- keep that in mind and figure out what our role is, in terms of how we can help our -- protect our providers and our recipients, in terms of opioid usage.

DR. GOODNOW: Is there any way to do a little bit deeper dive on the 10,000 patients getting the nine or greater diagnosis-wise, prescriber-wise?

DR. BORGERT: Sure, sure. So that 10,383 patients, take a little bit closer look at what are their diagnoses mix, who are the prescribers? Is it -- you know, we don't really have a way to look at the specialty of the providers, unfortunately. But, yes. We can try to do that, bring that

back as a follow-up for the committee.

THE CHAIRPERSON: Our quantity limits are not rigid to the point that we're adhering to those, or --

DR. BORGERT: Well, you know, we -- you know, obviously, we have the four controlled substance limit, but that doesn't do anything about dose. We do have quantity limits. Stephanie is our quantity limit expert, so let me ask her, what are our opioid limit situation, exactly?

(Conferring)

Okay. So, what she's telling me is that we have some quantity limits surrounding Oxycontin, but we don't necessarily have quantity limits surrounding morphine, at this point. I know that there are states that are looking into doing those type of calculations at point of sale and messaging based on that, or building edits based on that.

(Conferring) Okay. So, the long-acting morphines, we do have some quantity limits on. Just not the short-acting.

THE CHAIRPERSON: So maybe, for next time, maybe we could get -- if you would be so kind as to work up some of those, as what we could potentially use on some edits for -- around the max dosing guidelines.

DR. ROMAY: I think once we agree on, you know, the reporting that you bring back to us, maybe we could look at -- perhaps if we see that alarming circumstance, maybe we can look toward maybe a cumulative edit at point of sale, or

we can look like we did with Tylenol, across all the formulations and, you know, capture it, what the maximum dose would be and then hard stop it at that point.

DR. BORGERT: I think that makes sense. Any other final comments about the opioid activities? All right. So we are up to proposed topics for the fourth quarter of 2016.

DR. MOORE: All right. So, we have this spreadsheet that's going to talk about the Produr edits that we currently have in place, as promised. Okay. So, looking at the spreadsheet here, column A identifies if we actually had this edit turned on for fee for service.

So, perform edit, yes or no. Yes means that we do edit on it; no means, no we don't. Column B tells the action that we do with that particular Produr edit. So, for drug-to-drug interaction, for severity level one, which is identified through First Data Bank, we don't necessarily set the severity levels. We just message. Level 2, we message. And level 3, it's pretty much nothing. We don't do anything with level 3.

And then, column C says what type of Produr edit it is. So, drug-to-drug, early refill, late refill, so on and so forth. Column D says what type of intervention we allow. Provider level means that the pharmacy can override the edit.

And Column E identifies if Magellan performs that edit. So does that edit come over to us in the call center

for a review? If Column D says yes, then Column E will say no, and the reverse. So, if Column E says yes, then Column D will say no. That means that we don't allow the pharmacy; we have to do it. Or we don't do it; we allow the pharmacy to do it.

So based on Column A, what we currently edit upon -- so we do drug-to-drug interactions, where we allow the pharmacy to override the drug-to-drug interaction. However, we do have specific lists for the HIV combos. I believe we spoke about it the last meeting. We looked at the therapies that are not necessarily recommended, where we put particular edits on those. We did that back in 2013 or 2012.

We'll scroll to the bottom in just a little bit to let you see those -- that list. For early refill, we do perform that edit. We deny it. We do not allow the pharmacy to override it. It has to come to our call center for review. Late refill, we just message only on those. And there are particular classes. So we looked at this through DUR years ago, as well, and that's when we activated this edit. We look at chronic conditions, where patients do need to take their medications on a consistent basis.

So we would like to let the pharmacy know, hey, you know, this patient is little late. Can you talk to them as they're getting their medication? So there's a particular list of products that we have that edit apply to.

Next, for therapeutic duplications -- earlier I said it was a messaging, but it's actually stopped at the pharmacy for the DUE Service Intervention Outcome Codes to be implemented at the pharmacy level. But there are products that we do not stop. So that list is at the bottom of this spreadsheet, too. And as we scroll, you'll see those.

So some, we don't stop at all. But most, we do. We allow the pharmacy to override. Ingredient dupe, we do edit for that, too. We also deny that particular exclusionary list, as below, as well. We do not edit on duration of therapy limits, pregnancy precautionary limits, drug to lactation.

For maximum daily dose or high dose, we do stop those claims. It has to be approved through our call center. FDB sets limits for us. And most of those limits are exactly as the prescribing information. So anything above that, we want to take a look at it.

Low dose, we don't have that edit activated at this time. Drug to gender, we do allow the pharmacy to override, if that does deny at the pharmacy level. Pediatric precautionary limit -- it's only a messaging. Drug to disease, we don't. Drug to inferred disease, we don't. Allergy adverse reactions, we don't. Prereq drug therapy, we don't. And acute maintenance, we do not.

So this list below are duplicate ingredients that we

screen for, for the HIV drug class. And then, the HIV combos not recommended, we look particularly for those combos. If found, we deny those claims. And the same for ingredient dupe. We look for the particular ingredients that are within the combination, HIV products, and we want to stop those, because we do not want to pay those claims, as well. They require review.

And then, finally, the list -- the therapeutic bypass list. These are drugs that -- or products that we really don't need to take a look at. TPN solution being mixed. And they're pulling from those pick threes, those specific therapeutic classes. We bypass those therapeutic duplications. Pharmacies don't need to receive a rejection for those.

So that's the list of products that we do not edit on their therapeutic bypass. Those actually -- I mean, therapeutic duplications. We bypass those products.

THE CHAIRPERSON: So, Dr. Moore, I'm sorry, but I'm totally lost as to what we're looking at.

DR. MOORE: These are Produr edits. And Dr. Romay wanted to take a look at what we currently do for the Produr edits in our system, in hopes that either we, you know, add more, make them more restrictive. Just taking a look at what we currently do. Sorry.

THE CHAIRPERSON: So it's Alfred's fault.

DR. MOORE: It is.

DR. BORGERT: So, in terms of things that we do a hard denial on, it looks like really just mostly the HIV meds, in terms of therapeutic dupe, ingredient dupe. By and large, that's the main class that we have a hard stop on. The rest are message and -- post and pay, we call it.

DR. ROMAY: So the HIV ones are hard stopped at the pharmacy. They would have -- they can't be overridden?

DR. BORGERT: That's correct, because they're not recommended combinations or, you know, you're getting the combo tablet that has that same ingredient in it, plus you're getting a script for the single agent.

DR. ROMAY: That was my concern, in terms of having that, especially if they're going to different pharmacies, that systems don't talk to each other. They may be getting inappropriate regimens.

DR. BORGERT: Right. All right. We are on to quarterly activities. So I will open up the floor for the board to suggest activities for the next quarter. Dr. Allen?

DR. ALLEN: Ladies first.

DR. ROMAY: I had something that I wanted --

DR. BORGERT: Okay. Sorry. He was over there grinning, so I just called on him.

DR. ROMAY: Oncology topics. I have come across a lot of scenarios where prescribers are requesting

inappropriate regimens, even though some of the drugs are -- so, for instance, they get an Ibrance request through the oral pharmacy, you know, claim, and then they're requesting another drug through the utilization management process, another department, for a drug that's currently on formulary.

So, for instance, they're using -- I forgot the name of the drug now -- so they're requesting it in combination with Ibrance. And nowhere in the literature does it support that regimen. So we find ourselves, you know, in a hard place, where a drug is on the formulary.

So it happens with the oral aromatase inhibitors, where you know, they're requesting another drug which is not appropriate in combination.

DR. BORGERT: So you're talking about looking at the medical claims and the POS claims, as it relates to oncology, and looking at -- for inappropriate regimens?

DR. ROMAY: Right. And it happens as well, in the realm where you have either, you know, a breast cancer drug and you want to add Letrozole, but it's not indicated. So that's when we kind of find a problem with a little bit of loophole, in terms of getting access to that, even though writing them together is not an appropriate regimen.

DR. BORGERT: Right. Sure. We can take a look at that.

DR. ALLEN: Just two things. I was just going to

ask if we could take a look at Hepatitis C. I know it's a hot topic and I'm not trying to -- certainly not trying to go there. But when I was reviewing the data that was on the website, I actually saw that there is actually more claims for Sovaldi, and the Harvoni and Viekira Pak had the same number of claims. Both had 11 for the quarter.

So obviously Viekira is a preferred medication. Just wanted to see if we could have some type of reason of why Sovaldi utilization is still higher at this point. Is it contraindication? Or what was going on? The numbers that I'm looking at for Sovaldi uses for the quarter is 18 claims. Harvoni and Viekira are 11, respectively.

And secondly, I just wanted to bring up -- Embeda, obviously, is a hot topic. I know we addressed it in yesterday's meeting regarding the grandfathering. But another thing that I think will be pretty interesting for us to take a look at is, it's the only abuse deterrent medication on the PDL right now.

So, in the event that a member, you know, fails Embeda, or if they can't take it for whatever reason, are we redirecting them back to a non abuse deterrent product? Which, in theory, wouldn't make a lot of sense. Or what they -- or I guess, what's the next step?

I mean, obviously Embeda was placed on the PDL because of its abuse deterrent properties. And I think this

issue came up in P&T yesterday, but I just want to make sure that we're doing the right thing for the patient, truly, to deter them away from opioid. It doesn't make sense to deny for fentanyl, or whatever else is on the formulary.

MS. ELLIOTT: So, to clarify, do you want us to -- are you recommending that we do, like, a criteria for fall-out -- fall-off Embeda for another --

DR. ALLEN: Well, I think it's a slippery slope right now, because, in theory, there really is nothing on the PDL for us to redirect them to, right? So, I was going to say, if there was a second abuse deterrent, if they failed Embeda, they could go to that second one.

But as it stands right now, if they fail Embeda, or they don't want to take it, or whatever the reason, they have to go back to fentanyl or whatever else -- whatever other narcotic is on the formulary that is not abuse deterrent.

MS. ELLIOTT: So, to your point, you're recommending we can work on that criteria?

DR. ALLEN: Yes.

DR. BORGERT: Yes. And you know, to that point, I think, you know, one of the things we looked at when we looked at this data was, we still have an enormous amount of generic MSER utilization that doesn't seem to have moved over to Embeda.

DR. ALLEN: I can only speak for my plan. I would

probably imagine it's the same with similar plans, that the response that we received from -- we had a lot of provider upraising when that information came out.

Obviously, we had a number of patients, or providers that had their members on morphine ER for years. I mean, it's been out forever. So obviously, they were reluctant to change, which led to the discussions about the grandfathering of those medications, that occurred yesterday.

DR. BORGERT: What do you see with new starts? Are new starts going on the abuse deterrent products, or are they going on --

DR. ALLEN: Well, I think with new starts, I think it's an easier story to sell. "Hey look, this is the preferred medication. We'll use it in new starts."

But it's primarily -- most of the conversations from the providers -- well, most of the anger from the providers, to be quite honest with you, has been, hey, look, I've had this patient established on this medication for years. What are you guys doing here?

DR. ROMAY: I think at one point the Embeda had some kind of stock issues at pharmacies. A lot of pharmacies weren't able to get it. So I think that caused another kind of barrier for those members when they were trying to access the formulary. But I think that's resolved, from what I hear.

THE CHAIRPERSON: And, then, going back to the Hep C, I know this probably is another topic, but can we at least get some utilization data on the retreatments that we've been seeing coming through? I know that's a further discussion, as far as where we go from here. At least just have a birds-eye view of where we are.

DR. ROMAY: I think along with the retreatment, we need to look at the level of support from the national guidelines. A lot of them have stronger recommendations. So we need to look at those, as well, to see what would be the true optimal regimen for these members. Of course we want to prevent, you know, reinfection or, you know, try to prevent any kind of risky behaviors.

THE CHAIRPERSON: That's a different topic. I was staying away from that one.

DR. GOODNOW: Same lines. I think getting some utilization of duration of therapy, those type of things. And if there's any information on, like, time to cure, or anything, just to make sure it's consistent with labeling and what we're anticipating. So that might be nice to see, based on the product -- the duration of the product and not just the product alone.

So I think that might give us some more information, too, of a product we might have a preference to, based on what duration of therapy was actually needed.

DR. BORGERT: So, you're talking about looking to see if patients completed therapy? Is that what you're saying?

DR. GOODNOW: Actually, more to the -- you know, like, with some of the agents you may repeat a course, or -- depending on the duration of the therapy. So it might be interesting like, say, per product, what was the total course needed to cure. What do you anticipate the duration to be, versus what is the actual course duration? And I know compliance might affect that, too.

DR. MOORE: We can provide that information from a fee for service perspective, but knowing the actual PA information as to the physician's claim for that patient from an MCO perspective, we don't have that information.

So Dr. M, in regards to the utilization on retreatment, from a data perspective, the way we can probably handle that is, I think that yesterday we talked about, you know, patients moving from plan to plan and starting therapy in this plan, and then switching to plan B, and information not following that patient.

So we'll be able to pull plan assignment, the claims, the therapy that they received, and when they switched plans, plan assignment and the therapies that they received. So maybe we can infer it through the data that way. But that's all that we have.

MS. HARRIS: I have a quick question for the board. Is there any interest in perhaps convening an ad hoc or special meeting in between this meeting and the next one, since the P&T will be looking at the Hepatitis C class in January, and if there are any recommendations or information you would like presented to the committee, we can do that.

Obviously you guys meet after P&T, so it's a little late, you know, if you get all this information afterwards. I don't know that it would inform P&T anyway, because we're talking more about clinical criteria, but they are reviewing that class in January. If you're interested in that, we can -- it would be a phone call, a conference call.

THE CHAIRPERSON: We can do that on a weekday? Not a weekend?

MS. HARRIS: Yes. We'll pick a weekday.

DR. ALLEN: And actually, I guess, while we're on that --

THE CHAIRPERSON: Well, let's -- any other activities that we'd like to --

DR. BORGERT: So, just to reiterate, the three that were mentioned, oncology, in terms of looking at the pharmacy claims and the medical claims, and looking at regimens that are being used there.

The Hepatitis C topic that we've just been talking about. And then, the third topic was abuse deterrent opioid

and what's going on with patients who fail or need a different therapy -- they're intolerant to Embeda. Are there guidelines around what we should be doing with those patients, given the fact that we don't have a second abuse deterrent formulation on the formulary.

What does that look like? What are we seeing with that, and what steps do we need to take? So those are kind of the three topics that I have listed from the board so far.

THE CHAIRPERSON: I think so. Anything else? All right.

MS. HARRIS: Can I make clarification if you would like a conference call in between?

THE CHAIRPERSON: I think we said yes.

MS. HARRIS: Okay.

DR. ROMAY: Could I add another item, in terms of the isotretinoin products for cystic acne? There's -- currently, those drugs are at limited distribution, which means that the pharmacy has to submit. I was wondering if we would consider adding an age limit.

I know the age limit, usually it should be 12 and over. Currently that's -- there's no age limit on that, and I think that's important to have that in place. I don't know if that's something that we discussed before.

DR. BORGERT: I thought we added age limits to all the acne products few months back, actually.

DR. ROMAY: I was looking on the list here, and I don't see it on the formulary.

DR. BORGERT: Let me double-check.

DR. ROMAY: There isn't an age limit on it.

DR. BORGERT: Okay. We will take that back.

DR. ROMAY: Thank you.

MS. ELLIOTT: If I can clarify --

DR. BORGERT: We only did it on the topical-acting products.

DR. ROMAY: Not really topical. It's more oral.

DR. BORGERT: Right. That's what I'm saying. The age limits that we put in place were topical products. So that's where that fell out of the edit.

MS. ELLIOT: We had a recommendation from one of the plans to add an age limit of 18. We did not put the age of 18, because we were thinking that some of those products are used for other than acne. And we had an adult that told us that she gets acne every month. So we can look to see, maybe run a query, to see how many patients over the age of 18 are using it.

DR. ROMAY: That's fine. I agree with you. I mean, there are certain instances where an adult is going to have to take that. But we just want to make sure that the right population is getting it in the beginning.

MS. ELLIOTT: Okay.

DR. BORGERT: Okay. So that is basically going back and looking at those isotretinoin products and what are the ages of the patients that are getting that, and seeing if there is any appropriate limits that we need to put in place.

Okay. Got it. So that's four topics. I think for Selika, being her first meeting, that's probably enough. So if you guys want to vote on those four topics for the next quarter?

DR. ROMAY: Motion.

DR. ALLEN: Second.

THE CHAIRPERSON: I've got a motion and a second. Any further discussion? Any further topics? Any opposition? Hearing no opposition, the motion carries. Okay. Dr. Allen, you had a --

DR. ALLEN: You know, it's hard to imagine. I was just going through my DUR CDs this morning and it's hard to imagine that I think this is actually our year anniversary here.

THE CHAIRPERSON: Yes, it is.

DR. ALLEN: So congratulations to the board for making it through one year. Certainly a lot of changes have occurred in that time.

I just wanted to see if this would be an appropriate time to readdress one of the questions that was presented at the first board. Maybe Ms. Harris remembers verbatim what

that was, but it actually was a request to see if there was an opportunity to reschedule the meetings to perhaps a week day, versus the current Saturday format.

MS. HARRIS: Okay. So I think now actually is a good time for us to have some discussion on that. We did take the request back and talk about it and we played around with some different options.

Since we're dealing with the P&T committee and the DUR board, we were -- we started thinking about shaking the whole thing up, all right? And we'd have to take votes in both, or present options and take votes in both. And we couldn't guarantee that we would have it aligned perfectly.

So just trying to figure out -- just trying to coordinate travel schedules, et cetera. So if you guys have suggestions that you'd like for us to consider, I think that we can talk about that here. We try to time P&T and DUR together.

So we did look at potentially having DUR in the morning, Friday morning, but that makes for a very tight day and schedule. We looked at having DUR the day before, in the afternoon. We thought about having P&T first, like on Thursday, and then DUR Friday. But if we can just isolate moving the DUR board meeting, what are the recommendations or requests of the board members?

THE CHAIRPERSON: I think either the Thursday

evening before, like you said, in more deference to the staff at Magellan that has -- it's a lot of prep, although it's no more prep than doing it Friday and Saturday, but it does make for a very long day.

I think historically DUR is a shorter meeting, so if we were to do them on the same day, I would maybe suggest doing the DUR in the afternoon, with P&T in the morning, so you're maybe be more energized. Not to say that we don't need the energy here at the DUR. And I'll open it up for my colleagues. I'm not adverse to a Thursday afternoon or evening meeting. Any takers?

DR. ROMAY: I think that's fine. I think it's reasonable to do it on a Thursday afternoon, and then it kind of leads into the P&T the next day and kind of -- if there's any topics that maybe we want P&T to look at, we can kind of, you know, have it segue in there, into that meeting.

THE CHAIRPERSON: I mean, it's certainly -- keeping the two of them in close proximity, the two contiguous days, is definitely, from everyone's standpoint, from travel, is definitely where we would stay.

MS. HARRIS: Okay. I do think it presents some opportunities for us to be better able in real time to present information from the board to the committee, as opposed to how we've been doing it.

THE CHAIRPERSON: We're a quarter lag. This way it

would only be a day.

MS. HARRIS: Yes. Doesn't give -- well, the Magellan team a whole lot of time to work on any information, but I'm sure they'll respond and react accordingly. Out of respect for Dr. Hayden, I do want to point out that she presented -- that she requested that we take into consideration -- did she give us a statement that she wants read?

MS. ELLIOTT: Okay. She asked that if there was a conversation about moving the meeting that -- she says, "If there is discussion about changing the date of the next -- of the meeting to a work day, please consider the impact that the Medicaid system, for these patients may go -- these patients may go to the ER for access to care, which then may fiscally impact another aspect of the Medicaid budget. Respectfully submitted, Dr. Hayden."

MS. HARRIS: So she isn't here, but I think where she's coming from is, she's a practicing physician. So if she had to miss half a day or a day to participate in the meeting, her concern was the impact it could have on her patients and her practice.

I just wanted to put that out there. Again, she's not here and able to speak for herself. If you guys want to put forward a motion and vote on it today, to change the date, or the day of the week in which the board meets, you

are more than welcome to do so.

MR. HAMILTON: And I might add, if I could, here, this is an opportunity to say that I -- if you'll notice on the agenda, we do not have a definitive location or date down yet. And I am in the process of negotiating. And so, this comes at an opportune time. And so, you would not be impacting me. In fact, you would be helping me, as I plan the dates and location for 2017. Thank you.

DR. ALLEN: What a coincidence.

THE CHAIRPERSON: Can you phrase that in a -- Alex Trebek, please phrase that in a motion.

DR. ALLEN: Well, so I think -- quick question, here. Certainly I appreciate the agency and Magellan asking the board members, you know, what our preference was. But, I guess, what's an ideal, I guess, situation for you guys? I mean, maybe we can kind of work backwards from there.

MS. HARRIS: Okay. So I think our most ideal was having it Thursday, later in the day. And we would travel that morning, and have P&T on the Friday.

DR. ROMAY: I approve that.

THE CHAIRPERSON: No. You need a motion.

DR. ROMAY: I have a motion to approve the request to change the meeting to a Thursday afternoon.

THE CHAIRPERSON: Do I have a second?

DR. FAGAN: Second.

THE CHAIRPERSON: All right. Any further discussion?

DR. ZITIELLO: I'm a little concerned about practicing physicians' input into the board. I think that's a valid concern of Dr. Hayden's. I am not practicing, except at a free clinic once a month. It will not impact me in any way. But I think there is value there. And I want it to be taken into consideration.

DR. ALLEN: I agree. I think it's a valid concern, as well.

MS. HARRIS: Just in response, we could look at holding the meeting later in the day. I mean, we don't have to start at one o'clock. Maybe do a three to -- because this meeting goes a little bit shorter, we could maybe do a three o'clock to six o'clock meeting, if the board is amenable, so it reduces the impact to the patients.

DR. ZITIELLO: I think that would be a nice compromise.

DR. ALLEN: I agree.

DR. ZITIELLO: Meet everybody's needs.

THE CHAIRPERSON: And just -- also, in deference, there are physicians -- practicing physicians on the P&T meeting that do attend and have regularly attended, even though it is during the work part of the day. So, you know, I would just throw that out there. Okay. I have a motion

and a second. Yes.

DR. FAGAN: And I understand the consideration, but it is only four days per year.

THE CHAIRPERSON: And it would only be half a day. Okay. I've got a motion and a second. Any further discussion? This one, I will call the question: All in favor, please signify by saying aye.

THE BOARD: Aye.

THE CHAIRPERSON: Those opposed? Any abstain? The motion carries.

MS. HARRIS: Is the time three?

THE CHAIRPERSON: Well, I think we'll leave that open to -- you know, we would be moving into Thursday, and what might suffice.

MS. HARRIS: We'll have to go back, as Vern works on conference room scheduling, et cetera, and the hotel plans. We'll get back to you.

MR. HAMILTON: I take it, since you did not bring it up, that travel was not an issue? That has often played into our scheduling, too. Flying in, out. Some people have mentioned to me in the past that this is becoming more difficult, to get into Tampa. But if that's not an issue, that's great, for those of you traveling the farthest distance. I just wanted to make sure.

Very good. Thank you. I appreciate that. I'll

work with that. We'll all work together and we'll get back to you as soon as we can. I would hope that, you know, in the near future -- not waiting until like Thanksgiving, or anything like that. We'll have information back to you long before then.

MS. HARRIS: Thank you, Vern. So we do still have one more item on the agenda, Mr. Chair, vice-chair -- chair? Are you official today in your new role?

THE CHAIRPERSON: Well, I don't know. I'm interim chair.

MS. HARRIS: We still have to review the Vivitrol.

THE CHAIRPERSON: Okay. All right. This was an add-on agenda item, Vivitrol.

MS. ELLIOTT: Yes. And I just wanted to point out, because we were talking about the opioid dependence and opioid abuse, Vivitrol, at the agency we only have it available to the medical side. But Dr. Allen, in one of the previous DUR meetings, he had requested that we review and consider having Vivitrol available to the pharmacy also, pharmacy benefit.

And this is a criteria that we wanted for you all to review and mainly what -- you know, we have other states' criteria and also we looked at the criteria from the Florida Alcohol and Drug Abuse Association. So this is very similar. I just wanted to see if you can take a look at it and give us

some feedback.

DR. ALLEN: Yes. I'll take the lead on this one. So this was just more so an access issue. To Arlene's point, it wasn't under the pharmacy benefit. So I would just like to make a recommendation to the board that we take the same approach that we did with the hormone agents. We previously didn't have any guidance under the pharmacy benefit. We do have it now. So maybe we just accept these with the opportunity to come back and make additional recommendations.

MS. ELLIOTT: I second the motion.

THE CHAIRPERSON: Are we voting on these, or we're going to look at these and bring them back?

DR. ALLEN: Correct. That's my motion. So my motion is to accept the current policy for Vivitrol with the opportunity to come back with recommendations, if necessary.

THE CHAIRPERSON: Okay. Second?

DR. ZITIELLO: Second.

THE CHAIRPERSON: Any further discussion? Any opposition? Clarity?

MS. HARRIS: Just a quick question. So would you like to re-review it at the next DUR board meeting, or give it more time? Do you have a preference?

DR. ALLEN: Yes. Next DUR is fine. Anybody have any opposition to that?

MS. HARRIS: Just to be clear, to distinguish this

from the earlier one, this actually is a covered drug, under the Florida Medicaid program, whereas the other, we are not recommending coverage. The criteria is just in the event we get a request through our exceptions process that the agency and the plans maintain. I just want to clarify that.

DR. ROMAY: So the Vivitrol would essentially -- are we still tabling it to the next meeting to make it a pharmacy benefit, or are we actually adopting that? I just want to clarify.

MS. HARRIS: Yes. You can adopt it to use this criteria for requests that come through in the pharmacy setting.

DR. ROMAY: Okay. All right. I just didn't understand what we were tabling it for.

DR. ALLEN: So, as of now, at least my interpretation -- please correct me if I am wrong -- is we have open access to allow Vivitrol to adjudicate under the pharmacy benefit. We now need criteria. We don't have criteria. So this is what's being presented.

We're accepting this today, but since it's on the spot, and people are kind of hungry, we're just -- you know, we're going to accept this today with the opportunity to come back and make recommendations.

MS. HARRIS: That's correct.

DR. ROMAY: I just wanted to make sure we were

accepting --

THE CHAIRPERSON: Accepting this today. Yes.

MS. HARRIS: Yes. Sorry if I've made it all confusing.

THE CHAIRPERSON: I'm glad you did. I was a little bit hinky myself. So, just for clarity, we are accepting these as presented today, with the caveat that we would -- if we may have any recommendations, to bring it back to the next committee for some updates, if so desired.

DR. ROMAY: Yes.

THE CHAIRPERSON: Okay. So with that, I have a motion and a second. Any further discussion? Any opposition? Hearing none, we'll go ahead and approve.

I just want to go on record to say that while the Judiciary Act that happened in 1789 -- I read that in the paper. I was not there for it. Do we have any other business before the committee?

DR. GOODNOW: Just a thank-you to Rebecca. I know we've worked with her for a very, very, long time. So thank you for everything you've done.

MS. HARRIS: On behalf of the agency, we'd like to do the same. You've done a phenomenal job. And good luck.

THE CHAIRPERSON: Big shoes to fill.

MS. HARRIS: I know they will do a very good job.

THE CHAIRPERSON: With that, do we open to the

public? Does anyone from the audience care to speak? Seeing none, with that, I'll entertain a motion for adjournment.

DR. ROMAY: Meeting adjourned motion.

DR. ALLEN: Second the motion.

THE CHAIRPERSON: Motion approved.

CERTIFICATE OF REPORTER

I, Sharon L. Boyd, Court Reporter, Notary Public for the State of Florida at large, do hereby certify I stenographically reported the proceedings at the time and place so indicated and that my notes were hereinafter reduced to a computer-generated transcript.

I further certify that I am not an employee or relative of any of the parties and am not an employee or relative of either counsel, and further certify that I am not financially interested in the outcome of this litigation.

I hereby affix my signature this 13th day of October, 2016, in Hillsborough County, Florida.

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Sharon L. Boyd
Court Reporter

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