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DRUG USE REVIEW BOARD

Meeting Minutes

Date of Meeting: **Thursday, April 26, 2018 at 5:15 PM**

Name of Organization: **The State of Nevada, Department of Health and Human Services, Division of Health Care Financing and Policy (DHCFP), Drug Use Review Board (DUR).**

Place of Meeting: **Hyatt Place Reno-Tahoe Airport**
1790 E. Plumb Ln
Reno, NV 89502
Phone: (775) 826-2500

ATTENDEES

Board Members Present
Paul Oesterman, Pharm.D.
James Marx, MD
Michael Owens, MD
David England, Pharm.D
Yvette Kaunismaki, MD
Netochi Adeolokun, Pharm.D.

Board Member Absent
Marta Bunuel, MD
Jennifer Wheeler, Pharm.D.

DHCFP
Holly Long, Social Services Program Specialist
Linda Anderson, Senior Deputy Attorney General
Cody Phinney
Jack Zenteno

DXC
Beth Slamowitz, Pharm.D.

OptumRx
Carl Jeffery, Pharm.D.

Managed Care Organizations
Thomas Beranek – Silver Summit Health Plan
Ryan Bitton – Health Plan of Nevada
Jeannine Murray – Anthem

Public
Khanh Pham, NV Pharmacy Association
Laura Hill, Abbvie
Tom McCoy, ALS CAN
Ann Nelson, Vertex
James Kotusky, Gilead
Tracey Meeks, Vertex
Mark Schwartz, GSK
Laura Benthale, AMAG
Tom Horton, AMAG
Christy Lemons, Orexo
Patrick Moty, Horizon
Jennifer Zins, Nevada Partnership Access Treatment
Paige Barnes, Crowley and Farrato
Jenny Reese, Carrara NV/PhRMA
Lea Cartwright, NPA
Krystal Joy, Otsuka

Public Online
Stacey Frisk
Melisa McEwen, Otsuka
Betty Chan, Gilead

AGENDA

1. Call to Order and Roll Call

Chairman Paul Oesterman, Pharm.D, called the meeting to order on April 26, 2018, at 5:15 p.m. A quorum was established. Ground rules for the meeting was established.

2. Public Comment on Any Matter on the Agenda

Dr. Oesterman called for public comment.

Tom McCoy, ALS, CAN: I work for government relations for the American Cancer Society. ACS CAN working with that organization is a nonprofit, nonpartisan, advocacy of the American Cancer Society. They support Veteran's base policies, legislative solutions that designed to eliminating cancer (indiscernible). ACS CAN is concerned that the proposed Prior Authorization Policy being considered by the Drug Use Review Board is so blatantly based on price as opposed to the best treatment practices, political guidelines. We encourage the state to deduct a robust surveillance and engage in careful monitoring to this policy moving forward to ensure that enrolling and access of care is protected and that there are no unintended consequences either in near or short-term policy application. ACS CAN would be supportive with final decision on when to do prior authorizations if they are done within 24 hours.

Jim Marx: Speaking as a private citizen, I guess I would like to give an on-the-record summary of how we handle prior authorization situations when patients move from one managed care or fee for service organization to another and how do we implement that. Is there some process we need to implement or define?

Holly Long: Let me just be clear. So, you're asking what the process is when Medicaid recipient transfers from one MCO to another?

Jim Marx: Right, because what we see for time to time is that a patient has prior authorization grant under managed care organization. Two months later for some reason or another, they switch to another organization and go through the entire process exists, which sometimes can be several hours, so it's really a labor-intensive situation.

Holly Long: There is a Transition of Care Form that was established, and I'm not sure how exactly that was distributed as far as education to providers. Maybe one of the MCOs might have the information but I know that those Transition of Care Forms should be providing all of the information that would be consistent to be able to make that process as easy as possible. Are you familiar with those at all?

Jim Marx: Never heard of them.

Holly Long: Okay. Well I can definitely forward you a copy of one and we can get more information about how that whole process works to you. I know that it includes a lock-in program information; that's my side of it.

Jim Marx: Yeah, lock-in's a different issue.

Holly Long: But, it doesn't, actually I've seen the form and I know about it.

Jim Marx: Right, so I think that we need to do a better job informing all providers, not just me and Michael, so, I think that we really need to get that out there because I think that the inefficiencies that are imposed on the system really discourage good care.

Holly Long: Thank you. Yeah, I will definitely get more information to you and if you…

Jeannine Murray: Part 2 of with the 07/01/2017 contract was a change of the Transition of Care period and what that allows for is continuity of care of drugs. The way that I understand maybe have it implemented was that for any drug it's at least 30 days so if they had a P.A. on one and they came over, they should be able to at least get one fill but then if it is a maintenance drug, it's allowed for 60 days and if it's a behavioral health drug, and there was a list I believe that it classes, it's allowed for 90 days. So, there should be at least a minimum of a 30-day transition period before P.A. would be asked for. There's not a PA sharing process between anybody.

Jim Marx: That could be sort of opposing on some occasions, especially with different formularies so when you have situations where there's prior authorization on one formulary, it may not be yours or (indiscernible) formulary, but it does create a lot of problems and I think maybe what we should be looking for is maybe sort of a unified sort of formulary not necessarily preferred drugs but I think that at least having a common formulary might be something that you want to get addressed at some point.

3. Administrative

a. **For Possible Action:** Review and Approve Meeting Minutes from January 25, 2018.

There was a motion to accept the minutes as submitted and a motion seconding the approval. The minutes from January 25, 2018, were approved.

b. Status Update by DHCFP

Holly Long: These are a couple of things. Our hearings unit has updated language for consistency with the federal policy language specifying the circumstances under which a provider for requested expedited fair hearing for a recipient, that falls within Chapter 3100 of the Medicaid Services Manual. There are a couple of approvals that went through for the State Plan Amendment on February 22, 2018. Those include revisions for each of the alternative benefits plan. These include the prepaid ambulatory health plan delivery model. The service plan would provide authority for DHCFP to implement dental benefits administrator for DBA for managed care recipients. The DBA will serve urban Clark and Washoe County recipients for dental services. The DBA is intended to strengthen access to dental care providers for urban Nevada Medicaid recipients. Also, the ABP expanded coverages of the podiatry services by adding to allow for all Medicaid eligible recipients. The ABP also expanded coverage to include genital reconstruction procedures based on medical necessity for Medicaid recipients with the diagnosis of gender dysphoria and last, preventative enrollment services and chronic disease management now allow for coverage of medical nutrition therapy by registered dieticians for recipients with nutritionally-related chronic diseases. Also, I'm going to add that we have added the prescription drug take-back information with a link to DHCFP Pharmacy and Nevada Medicaid websites. The link is to the U.S. Department of Justice with resources listed that include information on the upcoming national prescription drug tack-back day

which is on April 28, this Sunday. Collection sites and other drug disposal information are listed and it also includes collection results from previous take-back days, and I have the website if anyone is interested. I also want to add that we are currently recruiting for the P&T or Pharmacy and Therapeutics Committee for a physician position if anybody would like to nominate a member for that, I'd be happy to share my contacts for those.

Paul Oesterman, Chair: Just one clarification. On the DEA take-back, it's Saturday.

Holly Long: Oh, I'm sorry, it's Saturday, thank you.

Paul Oesterman, Chair: This is something that I'm actually very passionate about. It's something that I actually started with the metro police in Las Vegas many years ago and it has now expanded nationally. I'm pleased to have all you people safely discard any unwanted or unused or expired medications; there are multiple drop-off sites throughout the country.

4. Clinical Presentations

a. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for hydroxyprogesterone caproate (Makena®)

Laura Benthale: I'm a senior medical science liaison with AMAG Pharmaceuticals and they are the makers of Makena. Makena is a progestin that is indicated for reduce the risk of preterm birth in women with a single-term pregnancy who have had a history of single-term pregnancy and preterm birth. The rate of preterm birth in Nevada in 2016 was 10.4%, increased from 9.9% in previous years. The March of Dimes has set a goal of 8.1% for all states by the year 2020. Makena is a sterile solution of hydroxyprogesterone caproate, or HPC, in castor oil for injection manufactured in both 1 ml single dose and 5 ml multidose vials. Additionally, a single-use prefilled disposable autoinjector was approved by the FDA as of February 14, 2018, via a supplemental new drug application referencing the safety and efficacy data of Makena intramuscular. As a result of this recent approval, Makena's prescribing information includes additional information regarding dosing, administration, pharmacogenetics, and adverse effects. Makena is administered either intramuscularly into the buttocks or by subcutaneous autoinjector into the fat of the upper arm once weekly by a healthcare provider beginning treatment between 16 weeks 0 days of gestation or 20 weeks 6 days gestation and continuing administration once weekly until 36 weeks 6 days gestation or delivery, whichever occurs first. Compared to control, Makena treatment reduced the portion of women delivering preterm at less than 37 weeks and similar reductions were found at earlier gestational ages, as well. The most common adverse reaction was injection site pain by the treatment groups. The Society for Maternal and Fetal Medicine clinical guidelines for use of progestogen in preterm birth prevention originally published in 2012 and reaffirmed in 2014 and 2017 recommended the use of hydroxyprogesterone caproate injection consistent with the Makena indication. Despite the ASMF guidelines, the utilization of this intervention has remained suboptimal as described in several published retrospective reviewed of HPC in various settings. Additionally, a 2016 publication by Stringer, et al. roughly identified barriers of potential solutions to prevent recurrent preterm birth. One recognized barrier included preauthorization processes that may influence provider willingness or ability to prescribe and offer HPC for the patient and potentially delay the initiation of this time sensitive therapy. Makena is the only FDA approved

pharmaceutical intervention to reduce the risk of recurrent preterm birth in certain women at risk. I would like to request the removal of prior authorization requirement for the Makena prescription provided on Medicaid.

Carl Jeffery: I have our proposed PA criteria or the removal of the PA criteria. Makena has come a long way from I think it was introduced in 2011. It has since progressed and Makena has proven itself effective. There used to be an option for some pharmacies to get this available compound in for a fraction of the cost but these are becoming harder and harder to come by to find any pharmacies that will make this in a sterile environment, and then there's supposed to be a generic coming out here shortly of this, too, so eventually that may be an option, as well. So, we just felt it was the right time to remove the criteria in here because we're really not seeing any PA denials for it and just to make sure that it's available to the people who need it.

Paul Oesterman, Chair: So we have a proposal to remove the current prior authorization restriction on the hydroxyprogesterone caproate.

Carl Jeffery: I don't know, it's kind of a new world for us, too, but now we have the MCOs here. I don't know if you guys want to opine about your agreement or disagreement to remove criteria modifying. Probably now is the time I would think to offer your opinion.
MCO representatives offer their approval of removing the criteria.

Paul Oesterman, Chair: I think it's fairly interesting having the 3 here for MCOs and the different formularies so hopefully Dr. Marx has said, we could consolidate a formulary and make life much easier for everybody; we'll see how that progresses. We need a motion to remove the existing prior authorization criteria for hydroxyprogesterone caproate. We have a motion and do we have a second; we have a motion and a second. Any further discussion on this topic?

Jim Marx: Carl, I think years ago when this issue came up, I don't exactly know what the action was, but I think we were just allowing the compounded alternative; I don't recall the action of the state reviewed; there was something on the books that I think they wanted us to deal with, it may still be there.

Carl Jeffery: Okay, we'll take a look. I think everything is in there. Chapter 1200 is in here. I don't think it highlights anything that has anything of the compounded products. I know that was being used as an alternative sometime.
(indiscernible speaker)

Carl Jeffery: I don't think it's really being compounded much anymore.

Holly Long: I have the existing criteria in front of me but I don't see compound language in here.

Paul Oesterman, Chair: I've got it also and I don't see…

Carl Jeffery: Yeah, it's all in the binder or two.

Jim Marx: As I recall, the action is the same (indiscernible).

Paul Oesterman, Chair: I have a motion and a second. Any further discussion? Hearing none and seeing none and call for the question, all those in favor of the motion to remove a prior authorization restriction for hydroxyprogesterone caproate please indicate so by saying aye. All opposed say nay. The motion carries unanimously.

b. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for the monoclonal antibody agent class.

Paul Oesterman, Chair: Is there anybody in the audience who wishes to address the Board? Okay, hearing none and seeing none, we'll go ahead and talk about the brand-name Fasenra, benralizumab is the generic name. Carl, do you want to go ahead.

Carl Jeffery: Yeah and this one is a pretty simple one, too. We already have 3 drugs in this category that have similar criteria, all the similar indications for the eosinophilic asthma. Criteria is in there with the Optum logo on it. It kind of look's similar to what's in chapter 1200 already so we'll just incorporate those in there. But Fasenra is another effective product for reducing the effects of eosinophilic asthma and approved under the age of 12. There was one change. Holly did a really nice job of all the comparisons of what the different plans have for the proposed criteria. The recent change with the blood eosinophilic level, so I just wanted to make sure it is 150 and not the 300; I think some of them are 300 but there is some data that should be done at 150.

Paul Oesterman, Chair: Are any of these 3 different agents preferred through P&T?

Carl Jeffery: These have not been discussed at P&T. We tried but we didn't have a quorum last time so they will be discussed at the June P&T meeting.

Paul Oesterman, Chair: From our managed care organizations, any input?

Ryan Bitton: I think the criteria proposed is compared with all 4 of the criteria which is about the same, at 150. We don't prefer one from the medical benefit.

Holly Long: Was there any reason for the initial authorization, looking over Summit and it looks like in HPN, and an initial authorization for 6 months compared to the 12 months that's proposed.

Ryan Bitton: I think it is just to be consistent, there is no clinical rationale.

Paul Oesterman, Chair: So we have the proposed criteria for some coverage consistent with the addition of the Fasenra products. We have all 3 products requiring prior authorization, 12-month initial authorization. Do we have a motion to approve the addition of the Fasenra products? We have a motion. Do we have a second? I have a motion and I have a second. Is there any additional discussion? Hearing none and seeing none, we will call for the question. All those in favor please indicate so by saying aye for the addition of the third products into this class. All those opposed say nay. Motion carries.

c. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for GnRH Analogs

Paul Oesterman, Chair: Is there anybody in the audience who wishes to address the Board? Hearing none and seeing none, we will go ahead and start our discussions on the GnRH Analogs.

Carl Jeffery: So if you remember, maybe 2 years ago we had this discussion about covering the hormone therapies for gender transitions. This is kind of in that same line where we're covering Lupron. I think what it is being used for most frequently is to delay puberty for youth that are questioning and so it's kind of the gender identity disorder. We've had a lot of requests for it and we just don't know what to do with them because we don't have any established guidelines and there's not an FDA-approved indication but it is approved in the common compendia and it's something that is frequently used so we put some criteria together and took a stab at what I think is appropriate in the binder. Basically it's to delay the onset of puberty until maybe the youth has some time to get some counseling and find out which road they want to go down.

Jim Marx: Carl, number 2, who needs to demonstrate knowledge, prescribers, pharmacists, the patient?

Carl Jeffery: That would be the prescriber. So this will be just added because we already have some criteria for the Lupron and the GnRH Analogs in Chapter 1200, this would be in addition to what is already listed, the other criteria would not change.

Holly Long: I believe it is correct that each of the managed care organizations have this diagnosis listed. Is that right?

Ryan Bitton: Yes

Jeannine Murray: We have it as a "Not", so we would have to flip it to allow.

Ryan Bitton: Carl, there is no age limit or hormone limit in the proposed criteria.

Carl Jeffery: I did think about that, but my thought was to leave it up to the prescriber as to what is appropriate as every child is different when they start puberty. It would be hard to document that in a role like that.

Beth Slamowitz: There's no way to verify lab values, so if anything, we're asking for certain values, they would just be in an attestation from the prescribers and yes we did allow within these limits, but nothing we could verify.

Paul Oesterman, Chair: The only product that we're looking at right now for this gender dysphoria is the Goserelin?

Carl Jeffery: I think there's some utilization for the Zoladex but I don't think it's being used for this indication. I don't see Zoladex as really or any other ones out there, and I don't see

anything here; it's mostly for the prostate cancer. I did break the utilization down. I was interested in seeing it. The utilization starts on page 129 of the counts and which ones are being used and then the age of the recipient. So on page 130, it's kind of a confusing graph, let me see if I can pull it up for a second. So here we have just the fee for service Medicaid utilization on the next page. Over here, the numbers on the left are the identifier of the prescriber so we only have 7 different prescribers that actually use this for youth. Up at the top is the age of the recipient so we've got any ages from anywhere from 7 up to 17 and one 30 year old which I'm guessing it's probably for Oncology or some other indication. But, the specialty is here so you can see that most of these are coming out of the Endocrinology department, the nurse practitioners, pediatrics, and then a couple unknown but it's mostly where we're seeing these come out of anyway.

Jim Marx: Are any of the nurse practitioners practicing under endocrinology department or pediatrics department?

Carl Jeffery: They didn't show up as being under that site, I don't know. Our specialty database is kind of questionable most of the time so we have to kind of take it with a grain of salt.

Jim Marx: There's a little bit of concern, I guess. The nurse practitioner has almost the majority of the patients under the age 12.

Carl Jeffery: And they may be endocrinologists or it's hard to say; I'm not sure what kind of practice they're in. Anthem is also broken down by age, down to age 10, but again we've got the identifier is the 3, 4, 5 over here and then the age of the recipient from the prescribing. I don't know if those are the, you have to break down the specialties, for that.

Jim Marx: I guess I'd like to see a little bit better breakdown of what those nurse practitioners with regard to practicing maybe totally appropriate and maybe just they work with an endocrinologist. Is there any way of drilling down into that database? Sounds like a whole lot of …

Carl Jeffery: Usually there are just two providers and usually what I end up doing is just getting their names and find out where they practice.

Jim Marx: Yeah, that, I can't imagine it would take a long time, but I think it is relevant.

Beth Slamowitz: There are two nurse practitioners?

Carl Jeffery: Right.

Paul Oesterman, Chair: Would you be willing to approve the criteria and have it brought back next month or next time with a look at the nurse practitioner information?

Carl Jeffery: Could we also say we do look up the nurse practitioners and find out there is endocrinology, then you're okay and…And then we can leave it?

Paul Oesterman, Chair: Part of the issue is that it's an off-label. So, are we going to end up with 2 sets of criteria or with 1 being the off-label indication and then the other?

Carl Jeffery: Well, we just we'll put in there. I mean, it is supported in common compendia, so we got it allowed. So it'll be included in the chapter 1200 under a separate header for coverage.

Paul Oesterman, Chair: As Dr. Owens pointed out, the existing criteria says the medication is prescribed by or in consultation with the pediatric endocrinologist. How many pediatric endocrinologists to we have in the state?

Carl Jeffery: At least one. I'm aware there's one in Reno; I'm sure there's a couple more.

Paul Oesterman, Chair: Okay, so we have the criteria for coverage for Lupron products for gender identity disorders. Do we have a motion to approve this with the understanding that the nurse practitioners will then examine and brought to the committee next time unless it's determined that they are working in association with pediatric endocrinology? We have a motion and second. Any further discussion? Hearing none, I'll call for the question. All those in favor please indicate so by saying aye. Motion carries.

d. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for Hepatitis C Direct-Acting Antiviral agents.

Paul Oesterman, Chair: Our next possible action in the clinical realm is the discussion and possible adoption of updated prior authorization criteria and/or quantity limits for Hepatitis C Direct-Acting Antiviral drugs, and I believe this is left over from last meeting that we were trying to simplify the criteria. Do we have anybody in the audience who wishes to address the Board, either on the phone or in person? Hearing none….

Betty Chan: Hi, yes, this is Betty Chan from Gilead Sciences. I just wanted to get some clarification on the simplification of that the criteria. From reading the binder, it looks like that first page or what you're showing on the screen, can it be more of the simplification, basically those criteria have to be met, and then what the choices between which agent to choose. There is no preference for the fee for service population. I just want to get some clarification and some confirmation.

Carl Jeffery: Whatever decision is made here tonight is independent of what has been the preferred choice, so we would still have our preferred medications in the category and I believe the MCOs would as well.

Betty Chan: Okay, so the simplification is really kind of what you have on the screen is what you're, what is that?

Carl Jeffery: That's the proposed clinical guidelines for these. If they were to get a nonpreferred at least for fee for service, I believe it is similar for the MCOs, but if they wanted to get a nonpreferred product, they would have to either try a preferred product first or have some good reason why they couldn't use the preferred product before they get nonpreferred, and that's the decision from our P&T committee.

Jim Marx: What's the, how do we designate an HIV specialist? Is there some sort of recognized board or?

Carl Jeffery: It's pretty much all of these specialties that are self-proclaimed.

Jim Marx: Self-proclaimed.

Carl Jeffery: Yeah, anybody can hang a shingle; most of the time they've got some kind of training, but we don't ask for board certification. A lot of these are board certified specialists but we don't ask for any of that so they can proclaim themselves to be that way.

Jeannine Murray: Can I ask a question? On simplification and I don't know, it's sometimes what I hear, so I'm certainly not an expert in the area, but is there thought to be given around how when the diagnosis was first made and how long they've had it, because isn't it true that some people with hepatitis C will just revert and cure on their own? I mean, is there a thought around that maybe they have had the virus for 6 months, I mean, I'm just wondering if there's some type of timeline like that that might need to be considered before treatment, or else I'm afraid you would treat people that maybe would have just cured on their own.

Carl Jeffery: Yeah, I think you've got a point and I don't remember all the exact numbers. Betty can probably run them off the top of her head, but I know there's a population that is infected with hepatitis C, only a small percentage, whatever it is, breaks down, carries the virus, and you're right, some of them resolve on their own.

Betty Chan: About 15% spontaneously get through the virus on their own and acute infection within the first 6 months so the criteria is consistent for someone that has had it maybe 6 months versus a person who has had it chronically.

Carl Jeffery: Right it would be chronic hepatitis C I think would be the word.

Jeannine Murray: You should add that to the diagnosis of chronic and then define chronic.

Carl Jeffery: Yeah, that would be a good way to do it.

Paul Oesterman, Chair: So I'm hearing that we want to modify bullet point number 1 to the diagnosis of chronic hepatitis C and now let's determine what defines chronic.

Jim Marx: Are we specifying that they meet or exceed that 6-month interval, are we going to allow that 6-month interval, could have an SVR in that period of time spontaneously.

Carl Jeffery: Yeah, I'm not sure how the diagnosis is stated with the chronic hepatitis C.

Paul Oesterman, Chair: Betty do you have any input on that?

Betty Chan: From the criteria, I have from other plans. I would recommend to say the diagnosis of chronic hepatitis C, acute infections actually resolve usually were up to 2 to 3 to 6 months so I think anything over 6 months is appropriate, but I do know that in literature, it does say that most of the acute infections that do respond or resolve spontaneously happen within 3 to 6 months. After 6 months, I think would be fair.

Carl Jeffery: So say a sustained viral load of greater than 6 months from…

Betty Chan: However, though, I do caution against when you get your first viral load and you know that's chronic or when they got their infection, that is kind of tricky, so a person may not know when they got infected.

Carl Jeffery: I think when I initially put this criteria together, I put that responsibility on the prescriber, too, so it's up to them to identify and I think this is what the simplified criteria really embodies is that we are going to really put this back on the prescriber to make sure that the appropriate patients are getting the treatment.

Beth Slamowitz: You could still state Chronic but just not have to describe it.

Ryan Bitton: I think by just putting the chronic in there is kind of in lines with this department and having prior authorization to cross our company. You don't say six months, three months, say just call it chronic and for most part, the provider is not treating acute hepatitis with this stuff. We don't see an issue with that.

Paul Oesterman, Chair: Okay so we have the proposed initial authorization for 24 weeks with all of this criteria with 5 points being that point number 1 would be a diagnosis of chronic hepatitis C, point 2 the genotype has been confirmed, point 3 the liver disease has been assessed, point 4 the prescriber certifies the shortest duration of treatment will be used based on the indication of the requested drug, and bullet point 5 is prescribed by or in consultation with one of the following specialists. I think this criteria is quite simpler than what we had previously and it's nice for us to be able to once in a while make life a little bit easier and simpler for people.

Ryan Bitton: I'll give my 2 cents. I speak for HPN, but conversations with Jeannine and Tom probably similar. I think we agree with simplification and I think that it's scary to get a look at a prior authorization document that is 20-25 pages, but I think that what that document did was give instructions for use, and 12 weeks, 8 weeks, and 24 weeks, this is how you use Vosevi, this is how you use Harvoni, and I think the simplified criteria embodies all the restrictions that we've kind of had in place but now it's 24 week. But some of these agents should be used for 8 weeks or 12 weeks. Some them aren't indicated for all genotypes, and so the concern I have is that we simplified it and maybe it's a better way to take so many pages down to 4 but rather taking 20 pages down to half page, I'm cautious and it's a real concern. If we're paying for 24 weeks of 15 to 30,000 a month therapies that aren't supported by the IDSA guidelines that oversee hepatitis treatment, I think all of our guidelines with prior authorizations were built off, to document it, and those guidelines continue to change and thus our protocols continue to be updated. We have aligned with the CMS's mandates around hepatitis-C, and so I know it's good to simplify but it might be losing a little bit of the guidance and steer us to the appropriate duration of treatment and oversimplify.

Beth Slamowitz: Could we possibly for the window but up to 24 weeks based on FDA and patient guidance?

Jeannine Murray: Or even could we ensure a chart that would list the drugs and the length of time because you're right, it does appear 12 to 16 weeks, they're all the different, that we give the guidance on the specific drugs what genotype, I just feel like you could have a chart where you have the drugs, the genotypes that are approved for…

Carl Jeffery: And those are all listed in the indications, so I think we could have under the approval criteria that it will be approved for the duration of therapy of which genotype and so they would leave it up to the call center to define to get together that inform and they would go down and say yeah, we're judging on type 1, you know, all the way down there and say, yes according to the FDA indications, it's for 12 weeks.

Beth Slamowitz: I think the idea of a chart is good for clarification but I think the reason for the simplification was so that with each new product that comes out, there wasn't a need for an additional update, an additional criteria added, to simplify it so that a little bit of the responsibility on the provider to prescribe appropriately but that it was still within the FDA guidelines of the class of drugs so like Carl said, whether you put the approval length up to 24 weeks or if you put as indicated for prescribing medication, however, you want to define that or word that so it locks it into a specific drug but with the chart maybe just kind of constantly updating.

Jeannine Murray: How is that going to work for denial language if we don't have a specific policy?

Ryan Bitton: If it's clearly stated that it's based on the duration, based on FDA approval for the specific product combination and as on IDSA guidelines, treatment for hepatitis C on exam, that covers what it's appropriate, but what is happening is reviewing pharmacists, or people that are not experts in hepatitis C, they'll need guidance and so what's going to happen is we'll have to simplify criteria but then in order to guide people who are reviewing to make sure they are doing what is appropriate, they'll be another piece of information, and I'm sure Optum Rx will have cases similar.

Jeannine Murray: Well won't it take longer to approve it?

Ryan Bitton: Well, we're also looking for similar alternatives, so they…

Beth Slamowitz: Don't they still have to do that, though, I mean I guess this is going to need your process, so I mean if they call in for Harvoni and the individual whether it be a technician or pharmacist on the other end of the phone that takes the request for the prior authorization, do they not have a protocol that they have to follow where they look up the drug and it has the requirements and exactly what needs to be improved for this diagnosis or whatever.

Ryan Bitton: It's a 25-page policy and guide to them, these are the 5 questions to ask that appropriate use. So, we have been on a path of having 2 documents and tried to transparent and all the followed criteria that we have out there so there's only been (indiscernible). I just think that; president is the wrong word so I think simplification is compressive and we need to understand the process. This has 25 pages. I mean, you can go to page 8 where it talks about how to use Vosevi and there was a guidance on what other criteria listed for Vosevi. This is a lot of repetition because we're repeating these 5 or 6 things 10 times for each drug and it looks scary, and I could understand but I think, there wasn't anything hidden in the MCO and I didn't get those long policies; that it goes against what we've got up here. There's a nuance here how the process works and how to support people who are actually in the clinic to assist us when they get the phone call with the fax of the electronic prior authorization.

Beth Slamowitz: So you're saying you'd have to take that 25-page policy and that would chop it up into multiple worksheets from this checklist and say, okay for this drug, all we get from that criteria, all these things were met.

Jeannine Murray: That would have to be appropriate that we could still use that criteria in that way. I think taking it down, making it simple; I agree with everything that Ryan said. I just feel like for us, I know the policy is there so that if a denial should occur and you have to have a policy to fall back on and if the policy is just those 5 bullets and we don't have any direction on drugs, I think it would be difficult to say, well but our policy on Zepatier is this because we're not talking about a Zepatier policy here and I think it's just going to have to be an understanding then that are you saying that the MCOs cannot have our own drug?

Paul Oesterman, Chair: What if the criteria from the approval like something to the effect of up to 24 weeks based upon the specific agent's indication per manufacturer?

Beth Slamowitz: Well, the number four actually states that it the prescriber certifies the shortest duration of treatment so it kind of already sets that precedent that the prescriber should use the shortest duration based on the drug that's being requested.

Netochi Adeolokun: What about the situations where patients have decompensated cirrhosis and they have to use like ribavirin plus whatever. Would a different prior authorization be required for those agents?

Carl Jeffery: We don't have P.A. restrictions for ribavirin, so they could be able to get whatever the primary antiviral is plus the ribavirin.

Jeannine Murray: Using it like retreatment and stuff, isn't that a different policy? It makes me think about other things that we're not talking about.

Carl Jeffery: Specifically it doesn't address retreatment management or kind of co-infections or anything.

Paul Oesterman, Chair: Dave, you've been pretty quiet. What are your thoughts? Well at this point, we have in front of us the proposed criteria for the change of number 1 to include the word chronic or the diagnosis of chronic hepatitis C. Do we have a motion to approve this criteria? In the absence of approving this criteria we would retain the existing criteria.

Jim Marx: I would suggest since the MCO has some issues with this, let's get your heads together and come up with something that you think is sort of succinct, cohesive, usable, and put this on the bench until the next meeting and see if you guys can come up with something that maybe suits you better and works better, that you feel more comfortable with, so again, I think the issue is really we want to be consistent and we don't want to have any sort of strife and enmity between the MCO and fee for service and all that and I think if we can control something more mutually acceptable then I see there is a lot of reluctance on your part.

Beth Slamowitz: I think the other thing you keep in mind, too, is to kind of discuss the other is there is a lag time before this actually becomes policy, before it actually goes on the books so there is some time for internal processes and align and get in place because we

have the same issues that we have to address. I don't know if that's helpful or not but just throw that out there that if there are some concerns for it, not necessarily with the policy but more with internal processes, how to execute the policy, that it's not going into something that is going to have to start tomorrow.

Holly Long: If we push it out it will have been the second time that we have pushed it to another meeting.

Ryan Bitton: And, I think my problem was, I appreciate your sentiment and I think the historic policies, I think you were pretty much in alignment from the consistency of how we approve drugs, and I think there's implication if I remember the meeting last time correctly what that time before, trying to simplify it, so the documents were long but the criteria is repeated for every drug to be sure we would have the appropriate guidelines. So, not that anyone is going to be guided by clinical rationale criteria on a website, they already know, but that's just how we do things, so there hasn't been any enmity with fee for service criteria or on our end. This is one arena, but for the most part, the criteria is pretty well consolidated, but it just looks different because it's all divided down on papers, but it was long.

Carl Jeffery: And I think our issue that we didn't have any criteria for the Mavyret or Vosevi and that's what was going on there. We don't have any specific criteria for those medications.

Ryan Bitton: I think there's always going to be new drugs, and I think that if we simplify the processes to update criteria, I get worried because there is always going to be drugs and simplify things with the new drug of the criteria. I get the concept.

Holly Long: Bringing in a little bit from what's going on in other states. Other states are looking at simplifying their criteria, as well, and in reaching out to other Medicaid states. They're all kind of like, well what are you doing, do we want to do the same thing but nobody can really organize their thoughts as to whether that's the way to do that. A lot of the states are still looking at fibrosis scores and they make their decisions off of that. I think looking at other states, Nevada's really doesn't look that bad. It's a lot more condensed than the other states that I looked at. And, there was a State of Medicaid Access Report Card that came out within the last year (in 2017) and the state of Nevada received an A- on the hepatitis C prior authorization criteria and compared to the other states, we're doing really well. So, I don't know where that would put us by simplifying it, They like it because we increased the access, but there is the safety aspect they take into consideration too.

Ryan Bitton: They are all long, trying to make things very comprehensive and criteria from a safety perspective and from a cost perspective too.

Paul Oesterman, Chair: At this point, we have the proposed revised criteria down to at least 5 points in front of us. I have not heard a motion to approve it so at this point, the existing criteria will remain in place until such time as our MCOs can get together and present to us their version of a revised criteria.

Paul Oesterman, Chair: So this agenda item will be deferred to the next meeting.

Holly Long: I would like to add to it, we're going to still work on the simplified criteria and make a decision around whether we're going to choose a different simplified criteria than what we have that we also consider adding the PA criteria for Mavyret and Vosevi that we never addressed initially.

Paul Oesterman, Chair: We cannot do that at this meeting because it was…

Holly Long: No, no, I meant next time. Sorry, yeah.

Paul Oesterman, Chair: We'll put that on the agenda for next time.

Carl Jeffery: Going back to the old days where we had hep-C on every agenda.

e. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria for High Dollar Claims.

Paul Oesterman, Chair: Just as a reminder for our guests online, on the phone, or in the audience, one of the purviews of this committee is not to focus on specific drug costs. We can look at, and this was discussed with the approval of our Deputy Attorney General on the phone the other day, the over-arching high-dollar claims not specific drugs, per se. With that being said, do we have anybody in the audience who wishes to address, please step forward, state your name, for your 5 minutes of fame.

Khanh Pham: On behalf of the Nevada Pharmacy Association, my name is Khanh Pham. I am a practicing pharmacist. Also, a CDE. I see patients with diabetes and hepatitis, too, and my concern is the high-dollar claims. How do you define that? Because all that's left with hep-C is expensive. One out of three baby boomers have it, too. How do you put the price on a patient's life? I commend you for taking such good care of patient you debate. How would you come up with the right criteria to save lives? I appreciate that. Also, the patients that I see, that would be really active to care and I see a lot of things you don't see, I see them every day. I also work in endocrinologist center. I see a lot of things you don't. I ask, I urge you to remove the criteria for high dollar and please remove it.

Paul Oesterman, Chair: For clarification for the audience. Right now there are a couple of different dollar figures and these are for single claims that would require prior authorization. It is not to say that these drugs should not be available, but they would require prior authorization and Anthem has a 5000 dollar limit, HPN has a 10,000 dollar limit, Optum is 10,000, and Silver Summit doesn't have any…

Carl Jeffery: But, that's what's proposed for Optum. We don't have a current limit now but I think Anthem is the only one that does currently, right?

Jeannine Murray: We have a limit, and I was going to say to address her question, there are drugs that are excluded from the high-dollar limit like the obvious hep-c and certain specialty drugs because they just are always above that. The cost limits that we had in place, and one that comes to mind for me, is Vivitrol. It's in place because sometimes what happens is the pharmacist will put in 4, as in 4 ml instead of 1 vile, and so that's where the high cost limit comes from is more maybe the data entry issue, so I just wanted to put that out there because I see that with Vivitrol. I guess I don't really look at everything else; but

I do see that one. Yes, we have a limit. We also have a limit on compounds to a different dollar amount.

Ryan Bitton: You have other groups that more than operational like preventing fraud or miscoding because it's been approved by the FDA, we allow coverage and trying to go through the prior authorization perspective. It's above 10,000 and for some reasons we don't already have the prior authorization, all hepatitis C drugs would have prior authorization, would these be non-formulary to protect. It could be Vivitrol, or miscoded then it would be approved if it goes above that 10,000 dollar amount. So we don't see a lot of these types of requests because we already have a 10,000 dollar limit in there because most claims are not 10,000 dollars. Vivitrol doesn't cost 10,000 on a regular month.

Jeannine Murray: No, it shouldn't cost 5000.

Carl Jeffery: So, and maybe we should go back and cover some history for the public and the new members of the board. So at the last meeting, we had a discussion about specifically the orphan drugs. There's a lot of new drugs for orphan indications coming out. These are extremely rare diseases that we may not even have anybody in Nevada that has these, but we want to get our hands around them not to have open access to these to make sure that these appropriate patients get them. So in lieu of bringing every new medication that comes to market with an orphan disease indication to have criteria placed on this, this was kind of our thought is that well we can just add this and we'll have an FDA-approved indication related to all of them. Some of the more complex therapies will certainly like that. We've had a lot of muscular dystrophy drugs. We've talked about those. They're very complex medications and have some very specific guidelines. We will still bring those to the board for specific guidelines but this is to capture those, like the Luxturnas of the world that we may not ever see a claim for it but we want to be prepared and make sure that the correct person is getting the correct medications.

Holly Long: We didn't want to pick on orphan drugs and we didn't want to miss the FDA fast track that we're having now.

Paul Oesterman, Chair: I think we also need to remember as you brought up today, that this is a CMS mandate, that these products have to be either FDA approved or the existing literature and peer reviews indicating the possible safety and efficacy for these products.

Holly Long: And, there are a lot of other states that are doing the same thing and a lot of other states have a much lower flag as low as 2000 dollars where it starts flagging.

Carl Jeffery: And, that's where we did break it down so we did look at those numbers so starting at the utilization numbers. There's 214 the breakdown of the products. Page 218 is a summary and that gives a breakdown of starting about 1000 dollars in 500-dollar increments of about how many claims per month we're seeing of those medications. So, why we picked 10,000 was it would seem to capture, just a number; it's a good starting point I think is our point there and we'll assess how that goes, and then our process would be that any of these would require prior authorization at the point where they would deny at the point sale, they would have to call in for a prior authorization, meet the guidelines where it's an FDA-approved indication or it's in a common compendia that's used, and appropriate indications. And, it'll be approved for a year so they wouldn't have to do this

every single claim; it would be just making sure that we're not using something way off label that some providers maybe makes a mistake or maybe doesn't understand the indication. We just want to make sure that everybody's doing their due diligence and I think this is a good safeguard in place.

Jim Marx: Do we have any access to their utilization as obviously we get a lot more power with these analysis if we had more numbers and raise the n, I don't know if it's any more proficient to get the MCO utilization and that will give us more impact on how these policies will be really effective.

Carl Jeffery: There is some utilization, and starting on page 221, there's some utilization there for the Health Plan of Nevada.

Jim Marx: Okay so we've got HPN in it.

Ryan Bitton: The request for utilization, it was kind of broad because Carl was trying and Holly were trying to determine the dollar amount? And, so it's broad so we just chose our specialty list and brought it to the specialty program. Most of the utilization seen from our submission is much less than 10,000 dollars, but I think that we can just look at that amount. You have a similar report that has to do with properly diagnosing.

Carl Jeffery: And, I think I did get some from Anthem but it was just in a format that wasn't conducive to putting in a binder.

Jeannine Murray: We could maybe, if this is what you're asking, not so much to look at a list of drugs but would it be appropriate maybe to look at what drugs hit that kind of reject, is that possible? I'm trying to think like how it rejects in the system to see if it's possible but maybe that would be something to look at.

Carl Jeffery: It was easy for us because we don't require prior authorization yet on any of this so we just basically report any single claim that's over 10,000 dollars. And certainly we can exclude some medications, certainly some classes that maybe not included here like hemophilia medications. I don't know if they want to exclude the antineoplastics. And, I think the question then, too, becomes if you want to apply this to only pharmacy point of sale claims or for apply this rule to physicians administering drug claims. There's really not very many physician-administered drug claims at this level. A few of them are going to be this antineoplastic.

Holly Long: I do want to comment, too, that DHCFP in general, we were really happy to see that Optum came up with more options rather than just this is the limit and FDA approval. Even if it's not FDA approved there's some other options, especially with the specialty drugs that work with drugs to be able to get that access to the patient. The one thing that we did want to see is the exception list to be able to add that to the list to see those that would be excluded in the criteria.

Paul Oesterman, Chair: We don't have the exception list at this point.

Holly Long: Jeannine do you have your exceptions to this?

Jeannine Murray: I don't. I don't know that I would have given it to you.

Holly Long: Oh, okay.

Jeannine Murray: I just know that, like I know hep-C is one of those drug classes that is an exception. I know a lot of our specialty drugs are exceptions because for the most part, they're all over on that.

Carl Jeffery: Yeah, and I think I had that on criteria, too. Let me pull it up real quick. I know the criteria that any, it's hard to see in here, but if there's any product that already has the PA criteria established, that would take precedence over this criteria.

Paul Oesterman, Chair: We had a couple of people state that they are concerned about access to these products and I feel that access is not being prevented, it's just that the prior authorization criteria will be in place.

Carl Jeffery: It assures that the state is in compliance with CMS regulations saying that they, because CMS has gone back to states in scenarios and saying you're not using this per label, we're going to take our money back because we get federal match, so it does happen.

Paul Oesterman, Chair: We've got the proposed criteria here for single point of sales claim that exceeds 10,000 dollars would require prior authorization. If other prior authorization criteria exists, it would supersede this criteria. Prior authorization for these point of sale claims over 10,000 dollars would be good for 12 months and the medications would have to have an FDA approved medication or peer reviewed articles, two of them that support the use of the off-label use.

(indiscernible speakers)

Carl Jeffery: I did recently; it's not included in your binder, so Beth was asking me about PAD claims, as well. I ran a report a couple days ago looking up PAD claims that exceed 10,000 dollars and there's really not that many so most of them aren't going to exceed that. We're going to address that at a future meeting with the PAD claims that we want to.

Paul Oesterman, Chair: So, at this point, I'll ask, do we have a motion to approve this criteria for single point of sale claims that exceed 10,000 dollars? We have a motion, do we have a second? Okay, we have a second. Any additional discussions?

Yvette Kaunismaki: Did we talk about exceptions to the criteria?

Paul Oesterman, Chair: Most of those that would have an exception would already have a prior authorization so they wouldn't even fall under this.

Carl Jeffery: The only one that wouldn't, and maybe I would ask the board to consider, is the hemophilia drugs. Those, of course, frequently exceed that. The antineoplastic is up for debate but for me, I would think I would stick with having that criteria in there, as well.

Paul Oesterman, Chair: Okay, so we have a motion and a second.

Jim Marx: Is there any provision for like an override process for immediate dosing and an urgent PA process to handle it. Is there some means that would provide for an override?

Carl Jeffery: We have an emergency override for 96 hours while the PA is being processed.

Jim Marx: And that would apply to this category?

Carl Jeffery: Yeah, and then we turn around all PA's within 24 hours and that is CMS mandate. Our average is about 6 or 8 hours.

Paul Oesterman, Chair: The hemophilia drugs do not require prior authorization.

Carl Jeffery: They don't currently.

Paul Oesterman, Chair: So, we have a second and a motion to approve this. Can we get a modification amendment to exclude hemophilia drugs? Is any motion and second to agree to that?

Netochi Adeolokun: Yes.

Paul Oesterman, Chair: Okay, so we have an amendment to the motion to approve the single point of sale claims that exceed 10,000 dollars where other prior authorization criteria, if they exist, would replace this criteria and hemophilia drugs would be excluded from this. Any further discussion.

Beth Slamowitz: Can I add a caveat to that?

David England: Go ahead.

Beth Slamowitz: Sorry, it's a quick one. But, just like Jeannine and Ryan were talking about as far as what I would call fat finger mistakes with data entry, we see that a lot usually with drugs as far as quantities because they are such large units and quantities a lot of the times, so just a consideration, I know you don't necessarily exclude it, but this will definitely catch that if they were included; a lot of those fat finger mistakes that Carl and I actually do manually every month so I guess (indiscernible).

Paul Oesterman, Chair: My gut feeling is that the expenditure is totally excluded in the pharmacies that make those fat finger mistakes, they have a price for their failure to type in the right number.

Carl Jeffery: I think, you know, hemophilia has been something, getting off the side topic, it's something that I've kind of wanted to address at some point anyway so maybe we'll come up with something next visit and maybe we can address some of that.

Beth Slamowitz: Some of the data that Carl researched and we looked at and coming up with this policy, again, the majority of the expenditure is from the hemophilia patients and so that maybe something that needs to be addressed at some point.

Paul Oesterman, Chair: Right now at this point we have the motion that includes the exclusion of hemophilia patients so I'll call for the question. All those in favor of the proposal with the single point of sales claims exceeding 10,000 dollars requiring prior authorization, if prior authorization criteria already exists for the product, we can supersede this criteria and hemophilia products currently excluded. All those in favor please indicate

so by saying aye. All opposed say nay. The motion carries. And, we'll add to the agenda for next time's discussion on hemophilia products.

5. Public Comment on any DUR Board Requested Report

Paul Oesterman, Chair: At this point, I'll ask if there's any public comment on any additional topics and issues that need discussed? Hearing none and seeing none, we'll go ahead and continue on with the Drug Utilization Review Board Requested Reports.

6. DUR Board Requested Reports

a. Acetaminophen Utilization

Carl Jeffery: So this was quite a challenging report to put together as I needed to have some paper. The MCO was running copies for it. So, it's starting on page 228. On the fee for service side, we only have 2 patients exceeding 4 grams per day, so the member ID is 19 or 181. I've got the details on the following pages so I took those 2 patients and broke down what exactly they're getting. So page 231, you can see member 19, they just get a lot of Tylenol with codeine and butalbital/codeine with caffeine with codeine every 5 days and that's a lot. There's 30 tablets of each every 5 days on those.

Jim Marx: It seems like, I guess I haven't seen it recently, we occasionally see a lot of typos with the (indiscernible).

Carl Jeffery: I am, too. What I think our…

Jim Marx: I wonder if some of these amounts (indiscernible).

Carl Jeffery: Well, and we don't know…

Jim Marx: And a lot of it's over-the-counter, too.

Carl Jeffery: Right, and that's what I was going to say. If they're using it over-the-counter, we won't know that they're taking it with their regular acetaminophen prescription products. But this one, I would like to find that prescriber and the pharmacist and slap their hand. I don't know what pharmacist would let this go out the door. You see the breakdown. It includes the other members, too. How I did it was I had to break it down by month and the fills they received per month, so there could be a few false positives in there where somebody filled 30 tablets, they were getting a high dose for 3 days at the beginning of the month and high dose for 3 days at the end of the month and it's going to show up on these, so there's going to be some false positives. It's just hard to track down the number of patients with the acetaminophen dose totals. But overall, I think our limit is working pretty good so I don't see any problems with these. We do have the other ones on page 235 is the report we have received from Silver Summit including the utilizations of acetaminophen per day. Theirs is all very midline or how you want to give anymore details on that report. And, then there's 2 pages that were passed out earlier.

Jeannine Murray: Quick shout out and thanks to Holly for telling me that I had just calculated the Tylenol amount in the liquid. I sent over something that 7 people were getting like 75 and 50 grams of Tylenol a day.

Paul Oesterman, Chair: Well, it's good to see that the minimal got over the 4 gram per day.

Carl Jeffery: I think it's something that's provider education is working, as well, I think it's something that every pharmacist will accept but at least 2 pharmacists that I can see in this report that are acutely aware of the acetaminophen dosing as that is pretty easily identifiable.

Jim Marx: I guess I have to shine new light on it. I still feel like the 4 grams is excessive.

Carl Jeffery: Well, our limit is 2.8 grams, so our system, we're not able to set up limits across products.

Jeannine Murray: I was going to ask you that question. So, is it accumulative or is it 2.8 grams per fill.

Carl Jeffery: Ours is set up per product, per fill.

Jeannine Murray: Per fill, okay.

Carl Jeffery: I wish we could set it up so it would cross products.

Jeannine Murray: Well, I was talking to them and they said, oh I think they'd have to go to an accumulator and I don't think you can do that so I wanted to ask.

Holly Long: Seeing how there's only 2 providers that stick out like this, is this one of those situations where you might feel the right to reach out to them like you have in the past and send them a letter, you know, we're recommending this because we see this utilization or, because there's only 2 of them not do anything.

Jim Marx: I think they should have the pharmacy board do that.

Holly Long: Pharmacy board?

Jim Marx: They have to pay more attention to the pharmacy.

Paul Oesterman, Chair: There's 2 members, do we know if they're getting all of these at the same pharmacy or?

Carl Jeffery: I've got the data. I don't have it included in here, so we can look at that.

Paul Oesterman, Chair: I definitely agree that there should be some kind of follow-up on these 2 members. Any other discussion on our acetaminophen utilization?

b. Opioid utilization – Members under age 18 years

Carl Jeffery: So, it's kind of a similar report that we looked at last time. We looked at more MCO data on these. You can see that the product on page 241, it's actually broken down by age for the fee for service here, so you can see what the different ages are, which products are more popular for the different ages. I think you probably want this as an action item at the next meeting to add some limitations on this and I think you eluded to the cough syrups, as well. So, we'll come back at the next meeting with some proposed criteria for all the opioid children and include the opioid cough syrups.

Paul Oesterman, Chair: The current recommendation is all opiate-containing cough syrups not be prescribed for patients under the age of 18. We'll be bringing criteria to that effect for the next meeting.

Jim Marx: I'm a little concerned about the methadone and spiking in the 0 to 5.

Carl Jeffery: I bet those are detox babies.

Jim Marx: Oh, detox babies.

Carl Jeffery: I'm concerned about them too, but they shouldn't be getting it. It's too bad they are even in there but.

Holly Long: Looking at national numbers, too, the age group that is having the most trouble nationwide is 12 to 17. They have high utilization across the board.

Carl Jeffery: You've got kids in high school sports that hurt themselves and go in for a knee operation or something and then get that or dental.

Jim Marx: If you have this narrowed down to a diagnosis, that would be nice.

Carl Jeffery: Yeah, diagnosis is a really difficult thing to get.

Paul Oesterman, Chair: I've heard this before.

Carl Jeffery: Yeah, we tried, I think we got a report for the diagnosis of diabetes in there, terrific report it's just 200 pages long. And in this one, you've got all the MCOs. I don't know if the MCOs want to speak to any of their data.

Ryan Bitton: We are in the process of doing a cough syrup criteria as well. We'll come back to that.

Carl Jeffery: No, the 4 or more is to cross out all. Yeah, 243, it's in our next item there.

Paul Oesterman, Chair: It says 4 or more opioids in what time?

Carl Jeffery: Concomitantly, so usually it ended up being per month.

Jim Marx: Do you consider a dosage form of other opioids or others, oxycodone 15 or oxycodone 5, would that be 2 opioids versus 1?

Carl Jeffery: That's why I included the strength on there so you can see like encrypted ID #1 here, they've got several different strengths of morphine sulfate.

Jim Marx: But see, that wouldn't really be; I'd be concerned if he really was getting 4 of the oxycodone and methadone, morphine, and say fentanyl or something like that.

Carl Jeffery: The way my query was built, it was a whole dose members in there and look for the 2 different opioids, but that's why I included the specifics on their use across.

Paul Oesterman, Chair: Encrypted ID #6, this data is for 1-year period, but you have 393 days of hydromorphone tablets. Are of any of these, you probably don't have the data either, but are any of these patients our lock-in patients? We haven't talked lock-in for a while.

Carl Jeffery: Good question. I don't know. I could take the IDs and cross reference the IDs. With that one that got 393 days, it's possible they filled it April 2st and then March 31st they got another one, so it actually would be 13 months of a medication.

Paul Oesterman, Chair: I would recommend you take a look at these 62 patients and look to see about possible lock in or just if we could get diagnosis information.

Carl Jeffery: Well this is four within a year so there's a potential they switched products.

Ryan Bitton: The report that HPN ran a report for Q4. We identified 8 members, the population is going to be different but back, there's not a lot of patients, that was a year, over 3 months, and it was for the unique what we call GPIs dosage, dosage forms and strengths. That's what we did. So, we're not seeing a lot in ours, 280,000 members.

Jeannine Murray: In Amerigroup population really quick looking at what our report was and it looked like 24 people for the year that we had for 8 months.

Paul Oesterman, Chair: I think one of the really exciting things for me is on page 251 and I know I'm getting ahead, but it looks like our usage is steadily declining. Unlike Facebook, our member counts seems to be dropping, too.

Paul Oesterman, Chair: Those patients are declined and finding street drugs and overdosing, that's why they're (indiscernible).

Carl Jeffery: Those are the numbers that are effective. Those are the numbers I've seen, too. I think there's some unintended consequences of the opioid crackdown. The opioid deaths associated with the fentanyl in particular on the street.

Jim Marx: We have doctors telling us; they're not prescribing fentanyl any more.

Carl Jeffery: It's not the same thing.

c. Opioid Utilization – Top prescriber and member, including more than four concurrent opioids

Paul Oesterman, Chair: We have the opioid utilization, top prescriber and member, top 10 prescribers. Refresh my memory because I know it was a nurse practitioner that was

in Carson, in Las Vegas. That we reached out to and their supervising physician wrote back.

Holly Long: I think we read that letter last time.

Carl Jeffery: That reports on 250 you're looking for. We looked at the period before so I think we wanted to re-review that. So, the encrypted IDs on the prescribers so you can see our nurse practitioner in Vegas, he's still there, number 1. Has decreased member counts and decreased claim counts so it is something to be said for that.

Jim Marx: How would a physician in Greenfield, Wisconsin be number 3, on page 256.

Carl Jeffery: Some of the…

Jim Marx: That is a little suspicious.

Carl Jeffery: Some of those I think are and you can probably speak to them, but I know in our database, sometimes we get addressed of their billing office and so this could be their billing office.

Jeannine Murray: I would have to go in and look specifically.

Jim Marx: I think somehow we should capture their practice address. I think that's a real problem.

Jeannine Murray: I think it's what's tied to their NPI is the problem.

Jim Marx: No, the NPI is the practice location so it wouldn't be reflected in their billing address.

Jeannine Murray: Sometimes the addresses that they have listed on there, but I mean I can look at that.

Jim Marx: It's a mailing address, so.

Jeannine Murray: It's the same thing when we talk about like specialty and whatever their first specialty is, that's listed on their NPI but I can look at the Wisconsin person for sure, and you guys were talking about the nurse practitioner in Vegas and made me wonder if that's the number 1.

Carl Jeffery: So, I did a comparison across the different plans here so on page 263, I couldn't use yours because you didn't send me NPIs so they were already encrypted IDs. I couldn't include yours because I didn't know them but the other ones, so you have fee for service, Silver Summit, Health Plan of Nevada. So our number one prescriber that we would see is prescriber X. He doesn't show up in any of the other plans, or at least in my data. I could share that data. I just didn't want to publicly announce this. We don't want to call the providers out to publicly shame them, or maybe we do. The red highlighted ones are the ones that show up in multiple plans.

Jim Marx: Which pages?

Carl Jeffery: 263. I guess yours doesn't have color in here so.

Paul Oesterman, Chair: They're shaded.

Carl Jeffery: Yeah.

Paul Oesterman, Chair: While we're looking at this, I mentioned lock-in patients and it might be nice to be able to take a look at lock-in patients and see if there is some that we can unlock at this point now to balance out the workload.

Carl Jeffery: We've talked about how to unlock patients before. You know, once they're locked in, there's really no maintenance associated with them. I mean, we don't really do anything.

Holly Long: Actually I think some of the MCOs do move them out after a period of time and I've talked to them about not doing that because it is a burden if you only lock them in for a year and then you have to reevaluate it and go through the process again and realistically once the person is locked in, what would that be like to unlock them and then have to put them back in lock-in, which it sounded like it was more realistic. I can't remember who it was, was it you, Ryan?

Ryan Bitton: Yeah, we have criteria, but we're not going to lock in someone who's no longer meeting the criteria for the lock-in program.

Holly Long: So do you reevaluate it after, over time?

Ryan Bitton: Yes, I can't remember the specifics but it's a year lock in and then I can't remember if it's 18 months and then every month thereafter. There are a few people who have been in for a long period of time. If they don't meet criteria, then we pull them out. It's really not a lot of effort on our part. We put them on and off, there is a letter sent. Most people don't fall off. I think when you put them in a lock-in, we've stated that is the kind of policy.

Jeannine Murray: We reevaluate, as well, at 12 months but we don't remove a lock until they've been evaluated. For the lock statement, they get reevaluated.

Ryan Bitton: Yeah, we don't take it off until they don't meet criteria any more.

Jim Marx: The real problem we see where the rubber meets the road and with lock-in is that we've seen supply issues and a lot of the pharmacies don't understand lock-in and our programs are for alternative pharmacies where there is a supply issue, and a lot of them are not really well informed so I think that is something you guys can do a better job on, informing those pharmacists how to handle those rare situations but there is still a very problematic education scope, very belligerent when that happens.

Ryan Bitton: I know they escalate; people hear about those and you're right, though, there's confusion with that, saying look, you can't get it with that pharmacy then still with the process that will allow you to work around that.

Carl Jeffery: So on page 262, we also looked at the source. We had a great report coming out of the HHS system. Again, there's a ton of data that was kind of hard to distill down into something that I could present here, so I will continue to work with support and see if there's some other good information to share with you, but I thought

it was interesting to find that opioid overdose services on page 262, I've got it up on the screen, too, it shows…

Jim Marx: How do you define that? What's the filter for that?

Carl Jeffery: It's actually a diagnosis of.. So, these are people who have gone to the ER or had been admitted to the hospital with an overdose.

Jim Marx: So, this is a mode of admission.

Carl Jeffery: This is the place of service where they're admitted to so I do see the… The most predominant place is the hospital emergency room where we had 200…

Jim Marx: There are some people admitted to an ambulance?

Carl Jeffery: Ambulance has the service where they transported somebody with the opioid overdose

Holly Long: I think when I asked for it, I asked for primary or secondary or tertiary diagnoses are going to fall into this to be evaluated for.

Carl Jeffery: And what Holly asked me to do, I didn't get a chance to do it, she wanted me to look at the dates service and find out how the services they think they're declining, so again, I didn't get a chance to put that in the other…

Holly Long: Paul you had asked for deaths due to overdose, which I ran into a little bit of any obstacle using toxicology reports and when those are available so the report that I would have would be very, very limited and I was trying to compare it before the quantity limit criteria implementations and after, so I believe in talking to the team that develops that report, if we do it at the next meeting that that will give me a good 6 months before and 6 months after that we can look at, so we chose to go this route instead but yeah, would be nice to be able to see like Carl was saying, if there's some differences between before and after implementation.

Paul Oesterman, Chair: We'll try on that for next meeting.

Jim Marx: It's interesting how many more ambulance situations there are with MCOs in the fee for service.

Carl Jeffery: Well, keep in mind that that's just the population. We have about a third or even a quarter of the population, they've got 75% of it.

Jim Marx: Yes, so you're looking at all count.

d. Diabetic patients with hospital admissions

Paul Oesterman, Chair: We have our top 10 drugs and reports. It doesn't look like there's any significant changes in quarter to quarter.

Carl Jeffery: I've got one little quick chart on 264. This is what I eluded to earlier. This was the diabetes 200-page report. So yeah, 264 was how many patients with diabetes-related diagnosis with going to the emergency room. So, this one was really hard to distill down so there's a lot of data on here. So you can see in 2017 versus 2018, the primary diagnosis about 2700 in 2017, 2300 patients in 2018.

Jim Marx: Weren't we looking at lapses in compliance, too, because I remember we talked about that at some point.

Carl Jeffery: Well, I think what I remember we looked at was if they were monitoring and doing some blood monitoring on insulin, but it would be interesting to see compliance, too. The medication possession ratio has kind of fallen out of favor but I think there are some new measures that they can use talking about how compliant patients are.

Jim Marx: There's probably not a lot of money in the overall scheme of things.

Carl Jeffery: Now, and it's hard to say, secondary diagnoses aren't very accurate because they go to the hospital for a sprained ankle and they also have diabetes so it gets coded in there.

7. Public Comment on any Standard DUR Report

Paul Oesterman, Chair: Anybody in the audience have anything they wish to add at this point?

8. Standard DUR Reports

Paul Oesterman, Chair: These are the DUR Reports. For our new members of the Board, these are reports that we get each meeting and we are using this as a guide for specific topics that we want, additional information on for the next meeting. So, if you see anything in your area of expertise which you'd like us to drill down on, Carl would be more than happy to do it.

Carl Jeffery: It is interesting to see the decreased amount, so look at the top 10 group, sorted by paid amount. The antivirals were number 2 in second quarter 2017 before and now moved down the list and number three, a pretty significant amount. So, I think that's the trend and I think it would be good to continue looking at those antivirals and we'll be talking about hep-C at the next meeting again but it's interesting to see how that decline goes. With antivirals, it just occurred to me, too, it is also probably including HIV.

Jim Marx: Is that a liposomal lidocaine or something?

Carl Jeffery: Which page is it?

Jim Marx: On 269 at the bottom.

Paul Oesterman, Chair: Topical patches?

Jim Marx: But those are generic

Carl Jeffery: There's still crazy expenditures.

Paul Oesterman, Chair: We have taken those off our formulary and are using the menthol/lidocaine patches.

Carl Jeffery: Are you using more than just topical use or anything?

Paul Oesterman, Chair: Same topical.

Carl Jeffery: I see that sometimes they prescribe for arthritis and we argue about it's not effective for arthritis.

Jim Marx: I've had patients responding pretty effectively actually who started it, so I could testify. We're pretty positive about the patches.

Netochi Adeolokun: Also, on page 269, right above pregabalin the glucose blood, is that like testing supplies or…

Carl Jeffery: Right, those are testing supplies. I'm going to have to look at the lidocaine ones. There shouldn't be that many, I mean claims, we have prior authorization code so I'm wondering how those are.

Paul Oesterman, Chair: Especially with the shortage of lidocaine there has been.

Carl Jeffery: Oh really?

Jim Marx: Yeah, we can't get it .

Carl Jeffery: It's all going to the Medicaid population.

Paul Oesterman, Chair: Have you redone the last report for activity.

Carl Jeffery: I did.

Paul Oesterman, Chair: It looks different.

Carl Jeffery: I did, so this is my first stab at it, so I did just a raw output of DUR things. I could format it however I want so. I put it together here as just kind of a first stab at it to see what you guys like to see? Let me know if there's something more or less you don't want to see on there. But, I know we talked about like the different severity levels. That wasn't showing on the previous report; how many claims. So, this actually shows the number of claims that were originally denied that were then later paid versus the ones who were initially paid and I would like to think that they go the message and then reverse it.

Jim Marx: Morphine and gabapentin; it's like everybody on board is getting that.

Paul Oesterman, Chair: I'm still a little confused on the total count, original paid versus original rejected and then rejected to paid.

Carl Jeffery: Right, so page 275, you go across the columns. So we've got some have total alert count, that's the total number of alerts whether it be, sometimes the pharmacy can see the message, sometimes it's denies with a message, so this is going to include all of those. So, the final paid count, so those are how many you've actually got paid until they ask for an override or it's an alert and they pass it and then it would be sort of the final reverse and for whatever reason, it created an alert and then the pharmacy reversed it. We don't know if it's because of the DUR, it could be just because it sat on the shelf or even the case member came to get it. So, the final rejected, so that's how many rejected and they could never get an override code in there just to get it approved and then sum of the original paid claim accounts, essentially it's how many messages they received or eventually got them paid on there. And, then on the paid to reverse counts, it's how many paid and then they either saw the methods and then reversed them and then rejected the paid so it rejected initially and then paid, and then rejected or rejected the entry into the override. There's a some overlap between these columns and…

Paul Oesterman, Chair: So are there any particular topics that you would like to have data presented at the next meeting that would be of interest? We have a new psychiatrist on our board. Is there anything in the psychotropic realm, because I know pediatric psych has been addressed fairly extensively in the past. Is there anything else?

Yvette Kaunismaki: Not at this time, I do notice there is a lot of utilization.

Carl Jeffery: It's something we struggled with. I don't know if you're involved with some of the policy making from about 3 ago years now. It's been kind of a while since we've updated that, but we had a lot of input from that.
Paul Oesterman, Chair: That's an understatement.

Carl Jeffery: From the psychiatrists in the community about half the policy that we eventually ended up with, you know the one medication from each class is allowed to four different classes than anything more then requires prior authorization. I don't know if you…

Yvette Kaunismaki: I wasn't around for that.

Carl Jeffery: Yeah, and if you ever speak to the colleagues that are maybe wanting a refresh, we can open that can of worms again.

Holly Long: I have a couple of topics I would like to propose for the agenda next time. Along with the high cost criteria and the research that I did for that and Jeannine is familiar with this, we saw that a lot of other states are doing criteria around compounds and so I also talked to Carl about putting it on the agenda for the next time, proposing some criteria around compounds. A lot of states have proposed a dollar amount and a lot of them said 500 dollars and they are working their way down because of the abuse that they see. So, I would like to bring some information around that next time. I was surprised. I wouldn't really think of it. I would like to see access open for things like that where it's difficult for recipients to be able to

get a drug that they need and they have to mix things to make that work for them, but unfortunately there is a lot of abuse around it. Once we started researching it, it was very easy to find a lot of information around it. The second topic for that I would like to bring to the agenda is Botox. When we were looking for something else, unfortunately we came across over-utilization and problems around Botox. We need to look at specifically what the diagnoses are getting for that and then also like to talk about that next time.

Paul Oesterman, Chair: Does it require a prior auth?

Holly Long: No, does it? .

Carl Jeffery: I thought we had some criteria for the Botox.

Holly Long: I believe it's in policy that it's not supposed to be prescribed for cosmetic reasons but I don't know exactly what the edit is so…

Carl Jeffery: I don't think we have any criteria on it now. I know we discussed this in the past and we've decided to not put any criteria on it.

Jim Marx: How would Botox be a pharmacy benefit? Usually Botox is given as a buy and bill type situation.

Carl Jeffery: We still see a lot of claims that the pharmacy fills for it which gets into the doctor's office.

Holly Long: Most of what I saw so far, and I just started diving into this, was around migraines and incontinence is used. There is criteria around it in another chapter so part of what I would do is look at what they had in the chapter that exists around Medicaid and try to outline with pharmacy so that it can be consistent across the board.
Paul Oesterman, Chair: We have cough syrups…

Holly Long: And, under 18.

Carl Jeffery: I have all our notes.

Paul Oesterman, Chair: With that being said, anybody have any last-minute public comment? Hearing none, we are scheduled for our next meeting when?

Carl Jeffery: July 26.

Paul Oesterman, Chair: July 26, same time, same place.

Carl Jeffery: Yeah.

Ryan Bitton: I would just like to say thank you to everybody for having us at the table. I felt it was collaborative and I really appreciated the graciousness of it.

Paul Oesterman, Chair: We appreciate your input. It's a good marriage.

Ryan Bitton: Yes.

a. Adjournment.

Paul Oesterman, Chair: With that being said, we will adjourn the meeting. I thank everybody, especially those in the audience who chose to be here.

Meeting adjourned at 7:30 PM