STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
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Nevada Medicaid
Drug Use Review (DUR) Board
Draft Meeting Minutes

The Division of Health Care Financing and Policy (DHCFP) Drug Use Review (DUR) Board conducted a public meeting on April 23, 2015 beginning at 5:30 pm at the following location:

Best Western Plus Airport Plaza Hotel
1981 Terminal Way
Reno, NV 89502
Phone: (775) 348-6370

Board Members Present:
Paul Oesterman, Pharm.D., Chairman; Dave England, Pharm.D.; James Marx, M.D; Chris Shea, Pharm.D., Michael Owens, MD

Others Present:
DHCFP:
Coleen Lawrence, Chief, Program Services; Mary Griffith, RN, Pharmacy Services Specialist; Darrell Faircloth, Senior Deputy Attorney General;

HPES:
Beth Slamowitz, Pharm.D.

Catamaran:
Carl Jeffery, Pharm.D. Account Manager

Others Present:
Philip Malinas, MD; Gerado Rodriguez, MD; Jeanette Belz, NV Psychiatric Assn.; Larry Nussbaum, MD; Joe Haas, PhD; Ryan Ley, MD; Perry Olshan, Ademes; Jon Bloomfield, Jazz Pharm; Chris Holtzer, Abbvie; Lovell Robinson, Abbvie; Amy Khan, McKesson/HCGP; Rama Karina, Abbvie; Pauline Whelan, Alkermes; Ann Nelson, Vertex; Gregg Gittus, Alkermes; Matt Larsen, UNSOM; Shane Hall, Purdue; Sal Fofaso, Horizon; Karen Nishihara, Alkermes; Brandon Snaffe, Celgene; Melissa Walsh, Novartis; Tom O'Connor, Novartis; Kathrine Thomas, UNSOM; Erika Ryst, MD, UNSOM; Natalie Jaymes, Child Neurology; Jen Stanton, Zogenix; Errol Gould, Zogenix; Jill Gardner, Jazz; Robin Wat, Zogenix

1. Call to Order and Roll Call

Carl Jeffery, Catamaran
James Marx
Dave England
Paul Oesterman
Darryl Faircloth, Deputy Attorney General
Chris Shea
Mary Griffith, DHCFP
Coleen Lawrence, DHCFP

2. **Review / Approval of Meeting Minutes:**
   One change requested of prior meeting minutes. There is a statement that forensic pathologists perform 1,000 forensic autopsies a year in Las Vegas. The correction is that EACH pathologist performs 1,000 forensic autopsies a year. That winds up closer to 8,000 – 9,000 for Las Vegas for the year. The reasoning behind that statement is that the National Academy of Forensic Pathologists recommends that no more than 250 forensic autopsies be done a year per pathologist and in Las Vegas they are doing 1,000. This was on page 4, halfway down. The upshot of doing so many forensic autopsies a year is that the pathologist really doesn't have enough time to do a thorough forensic examination because they are doing four times as many autopsies as they should be. As a result, some of the deaths that are written off as opioid overdoses may be something else. No other changes.
   JM - Move for Approval
   DE - Seconded.
   Voted Ayes Across the Board
   Motion Approved

3. **Public Comment on Any Matter on the Agenda**
   None

4. **Administrative**
   a. Status Update by DHCFP – Coleen Lawrence, Chief, Program Services - Specifically spoke about the legislative session. From our last meeting, we have two bills that are specific to Pharmacy. SB422 - Pharmacy and Therapeutic committee with our PDL. It doesn't really impact the DUR Board. Changes have been made to the original writing of the bill, a friendly amendment was added. The sunset language has been amended that we will now have an extension of the sunset language for an additional two years. Now the sunset language will be extended until 2017. What that means is that we will continue to operate our PDL as we do today for an additional two years.

      For SB14, a Division bill, recommends and requests that the membership of the Pharmacy and Therapeutic Committee be modified. For the Pharmacy and Therapeutic Committee to meet the law, the way that the membership was written, we were having difficulty filling the Pharmacy and Therapeutic Committee because we had to be at 50% and at less than at 50% we had a requirement of having so many members and not to exceed an amount of membership. If you do the mathematical equation, we were really having a hard time meeting the recruitment requirements. There was a point in time when were not able to hold two Pharmacy and Therapeutic Committees back to back and that was because we were having a

hard time filling some membership slots. With this bill, the minimum and maximum membership requirements were changed and the 50% rule will keep the same intent of the makeup of the pharmacists vs. physicians, it just doesn't put us into the mathematical equation that makes it nearly impossible for us to recruit pharmacists vs. physicians. Literally it made it near impossible for recruitment for the Governor's office.

Both bills have passed their first house. We are pretty positive that they will pass their second house.

5. Presentation and Discussion of Nevada's Health Care Guidance Program

a. Dr. Amy Khan, MD, MPH, Medical Director, Nevada Health Care Guidance Program, McKesson Care Management - Nevada Health Care Guidance Program is relatively new. Pharmacists are a key part of our team when it comes to the health care team. The spirit of the Health Care Guidance Program is really about collaboration and supporting integrative care in the service of our patients. I'm an internist by training, also an addiction medicine physician with a background in public health and preventive medicine.

I want to talk about goals, who is eligible for the program, and then opportunities to drive better health outcomes, quality of care, and clinical effectiveness for those who are benefiting from these services.

This is a program that launched in June of 2014. It's supported through a CMS grant waiver program, a research and demonstration project. I work for McKesson and we subcontract with Value Options. We provide the services for this program. It's a Care Management Organization, also known as a CMO and not to be confused with an MCO or Managed Care Organization. We serve the FFS Medicaid population among those who are qualified.

Our goals for the program are simple: We are going to improve the quality of care for the members who are participating in the program through letting providers know about care gaps, care improvement opportunities, driving good quality care through the adoption and provision of clinical quality services. We do track numerous quality measures as well as assure others provide good quality care for those being served and ultimately to drive better health outcomes. Most, not all, of those in our program have a chronic condition. The exception being pregnancy. We want to assure that mom is healthy throughout that pregnancy and all those who have those chronic illnesses, we're driving their optimal health outcomes, which isn't always the case in health care. We want to do that through assuring "Right Place, Right Time, Right Dose" if you will and I use that term broadly along with "Right Location, Right Provider" and ultimately improve the patient experience in the process so that these individuals are not only aware of what their issues are, but feel confident in being able to adopt practices, lifestyle changes, adhere to medication compliance, or other types of treatments that drive better health outcomes. Ultimately this is about recognizing we have a finite amount of resources. We need to not only use them preciously, judiciously if you will, but ultimately this is about optimizing the value of what we spend in health care.

We are absolutely committed to, at the very least, cost neutrality by providing this additional level of benefit. We're certainly not going to spend any more money, but through the addition

of care coordination, redirecting people away from places like emergency departments for their primary care, or avoiding ambulatory sensitive hospitalizations, we're going to be able to improve costs as well.

Who is eligible to participate? It's important to, and I know you probably have been tracking this, is the landscape today within Medicaid. We have roughly 600K recipients in Medicaid in Nevada. The majority are enrolled in Managed Care, or that MCO because our geographic distribution is such that you either live in urban Clark, or urban Washoe. 30% of Medicaid is in the FFS product. Our program serves those medically complex, chronically ill individuals who have one or more selected conditions that are permitted within the waiver. That really boils down to roughly one out of four of that 30% of Medicaid are enrolled in this program. The figures that I've provided and the slide (presented during the meeting) are based on March data. There has been a bump in the enrollment due to redeterminations. It's still roughly a 70/30 split. Our program can enroll up to 41,500 qualifying individuals, but we are excluded from enrolling those who are receiving other types of aid.

(Page 3 of handout presenting during meeting) I've listed for you those chronic conditions. These are the usual suspects. Listed is diabetes, heart disease, COPD, asthma, obesity, as well as chronic HIV/AIDS, as well as oncology conditions, chronic kidney disease, end stage renal disease, and a host of issues including musculoskeletal disorders, as well as many behavioral health issues - substance abuse disorders, primary psychiatric diagnosis, and a number of other conditions. Again, we enroll those eligible and qualifying FFS Medicaid recipients, including children and adults. We are precluded from enrolling those in certain categories which you see in the shaded box - The dual eligible, those who are the Medicare/Medicaid folks are not eligible for our program, nor are those who are receiving services in other programs, like those who are recipients in other waiver programs, those who are receiving targeted case management services from selective providers for certain behavioral health issues, or active in the Juvenile Justice System, active in the foster care system, etc.

Questions about who we enroll in this program?

Question: Why is there a 41,500 limit?

Answer: That is the cap that CMS put on the research and demonstration waiver. Essentially we are going to demonstrate that compared to the before, after we've made a difference in this. Depending upon how the growth of Medicaid proceeds, we may find that there may be a waiting list.

Question: So this is for a proof of concept?

Answer: Yes. What's important is that we all think about what's working in our health care delivery system today and what's not. And this demonstrates a real need that we know is the bridge between that patient and the provider, so we can essentially extend the care of that provider, so that it's much more clinically effective for the person for whom it's intended. That's what is important when we think about our opportunities to improve care models, via team based models, and also work in terms of continuation and coordination of care.

Our program supports clinical effectiveness in a number of ways. First, our administrative office is conveniently located right next to the Business Lines Unit in Carson City, right next to the Division of Healthcare and Financing and Policy. We have a local leadership team, all from Nevada, the majority does reside in northern Nevada, although our Clinical Operations Lead is in southern Nevada. Our staff is geographically distributed across the state in the communities where the majority of our recipients who are enrolled in the program live, work, and get their care. The staff is diverse with clinical registered nurses with various certifications and experience with disease management, risk case management, maternity management, oncology management, as well as licensed clinical social workers and other counselors who are licensed. We have a few non-licensed staff, community health workers, as well as peer specialists. As you can imagine, the subset of the individuals we serve are very mobile. They do not have a steady domicile. Folks do not necessarily map to an address, or a phone number. Our team will actually go out on the streets and look for people in all sorts of places with the intent to develop a relationship, develop a connection, and to really bring people into the fold. It's really quite broad in terms of the dimensions that we serve, or provide support to these individuals.

If you look at the top of page 4 (hand out provided in meeting) this is the delivery model. None of this is unique in and of itself. Everybody is standing on a platform. In the center is the patient. The most important entity next to the patient is their family member, their neighbor, their partner, those who are most familiar with the patient who may be providing housing, who might be providing food security, who might be offering support to take people to appointments, or in terms of just social connections and social support. Surrounding that individual would be that primary provider, whether that's a behavioral health provider, primary care provider, etc. On the right of this picture is that primary care nurse / community based primary nurse. That's really what I would say our care management staff would be. That could be a social worker, a community health worker, but behind is all the folks involved in the care of the individual and it's really important that people are connected to each other, that the right and left arm know what's happening because ultimately this is to serve the patient. What we have today and historically is that we don't always have the ability to work together. Essentially what I see in the back with the social workers, the community health educators, maybe folks within a hospital system, or extended care system, Pharmacists, are others who are meeting the needs, or helping to address that care plan that the patient understands, can embrace, can deploy, has the confidence to follow through with, and we'll support the individual.

We work very hard with the provider and the recipient to make sure there is transparency with what the provider has intended and what the patient who is going to be deploying that treatment plan is actually doing. There are 3 kinds of areas / primary components of the program that are listed on the bottom of page 4. Those are the services that enrollees get. We review the eligible population on a monthly basis, assess them based on claims, demographics, and other data including utilization management data from our partners at HP. Basically we look at and assess a different level of risk. Identifying those who are most impactable and deploying resources as appropriate in terms of the intensity of the Care Management services. We focus on care coordination, transitions of care coming from one side of service to another

(from a hospital, to a skilled facility, to a rehab facility, to a home health situation, to home, or living with a neighbor or a family member)

We also work with the myriad of providers who might be local, or not. We know that many of constituents live in rural Nevada and they are not getting their specialty services there. So how do they get to their appointment in Las Vegas, or maybe they are being referred to the University of Utah. How are we working with them to insure that they are getting to their appointments? We work with individuals around education, skills training, assess their ability and their competency, and assess literacy and take a broad, 360, holistic approach to assessing those dimensions. Working directly with providers, we will identify care gaps, opportunities for improvement. When we do talk with individuals and confirm a care plan, we share that information with the primary treating provider, so that if there needs to be adjustments, or additional considerations, we will note that and review that with the individual. Providers are encouraged, as are other stakeholders who serve this population, to refer patients to us to bring up new issues in a timely manner, or to provide referrals for those who aren't in our program who would be eligible to join. We have a 24/7 nurse advice line that our recipients are eligible to use. We promote that use for those particularly who may not know where to go for care with an emphasis of redirecting people to the appropriate place of service. For many folks, their primary home for care was the emergency department, so we really do understand how important it is for folks to have the right information given that kind of feedback based on their symptoms, based on their condition. This is an informed nurse advice line. This isn't a call where we didn't know anything about the patient.

I want to share with you some of the outcomes of the findings since our launch in June. At the top of page 5, what you'll see here is a bar chart looking at the distribution by age group and noting male vs. female. About half of our recipients are under the age of twenty.

There are slightly more males than females. As you look in the over 20 age group, we see that the distribution is a little bit different. There are more representations of women. It drops down when you get into that 60+ age group because as you know and heard earlier, the Medicare/Medicaid folks are not eligible for this patient program. We looked at those who are enrolled based on one or more of the qualifying conditions and then looked at what was the most prevalent diagnosis that we got on claims of those enrollees. The bar chart on the bottom of that page shows that roughly half of the diagnoses were behavioral health (psychiatric diagnosis, substance abuse diagnosis) The other half were chronic medical conditions. I think it's important to talk about the opportunity to serve this group and all Nevadans when it comes to addressing behavioral health needs.

We assessed among the enrolled population, those top 10 gaps in care. When you look at the top 10, 3/10 relate to individuals getting the recommended preventative screening for cancer. That would be mammography, pap smears, and colorectal cancer screening for those that are recommended. For example, colorectal cancer screening is now recommended for those aged 50 years and older. Those came up as the three of the top 10. The next 3 have to do with the management of chronic disease, in this case, diabetes and heart disease. This would be the use of aspirin in those with no contra indication for diabetes and those with cardiac artery disease. And then 4 out of the 10 relate to pinning this access and availability to behavioral health

services and the ability of primary care to manage behavioral health conditions and in this example, what came up was bipolar and depression. What we saw was medication compliance for both antidepressant therapy and patient treatment for bipolar disorder were among the top 10.

What I've included to share with you tonight were some selected quality measures. These are certainly similar to HEDIS, but these were just a spot measure. We weren't able to do the precise HEDIS measure for this particular presentation, but basically I'm sharing with you the proportion of those enrolled recipients that would meet that particular recommendation. In this case, 75% of those who had asthma, had access to their medication. Another case, beta blocker use after acute MI. 41% of recipients in the program had achieved that particular measure.

Question: On the identified conditions, the second identified condition is hypertension and then in the slide you show that the second lowest proportion made meeting ideal is hypertension, yet it's not in your 10 identified gaps.

Answer: The gaps in care were those top identified gaps. The people had hypertension, but it wasn't a gap in care necessarily. It didn't make the top ten gaps in care.

Question: How do you define a gap in care?

Answer: A gap in care would be, for example, it's recommended that you have colorectal cancer screening because you're over 50, but you didn't get it. You haven't had it within the period of time it would be appropriate. So if you were hypertensive, the gap in care that would have made the top 10, would be if you weren't on antihypertensives, or you hadn't been looking at the gap, you hadn't gotten a refill.

Question: How could hypertension only be 38% met and yet it wasn't one of your gaps? I don't understand that.

Answer: This particular measure was multidrug therapy, including a thiazide diuretic. 38% of people with hypertension, in this particular group, had been on multidrug therapy including a thiazide diuretic. 38% of that particular group. It wasn't among the top 10 gaps across all of the population.

Moving on to the top of slide seven, there is a highlighted need in Nevada for behavioral health care. There is a need for access and availability for psychiatric care. For these particular measures the slide shows that we are having a tough time with timely follow ups after hospitalization, or mental health conditions. 0.2% of those who are discharged with a mental health disorder where seen within 7 days. 0.6% within 30 days. What relates to that is are we able to make sure that those individuals get on the proper medications and are monitored on the medications and have their medications refilled in a timely manner, or are taking them as appropriate? We absolutely support these individuals. Many times our psychiatric nurses or social workers, their relationship is really therapeutic with these folks, but we're not the provider. Getting that person to a provider is something we are working hard to do.

Stakeholder involvement, provider involvement is really key to the success of this program. We want to work closely with the treating community. We really have to think about a team based approach. The pharmacist provides education, nurses, MAs, community health workers, all sorts of people helping to support the individual, but we've got to do it in a coordinated, collaborative way.

We're interested in ideas and thoughts to help us achieve our goals.

Top of page 8 - A screen shot of the eligibility verification system/method to readily identify those who have been identified for enrollment in this program. It would be listed as first, FFS Medicaid, and then the very next line would be CMO Care Management. The moniker we use is the Health Care Guidance Program. Seeing the CMO Care Management label, it might be an opportunity for the pharmacist to reinforce to that patient the tools available to them as part of the program.

Our real-time referral form is available on the DHCFP website under the CMO Care Management Organization tab.

Question/Statement: I think one way that the Board could possibly partner with the Health Care Guidance Program is that the Board is always looking for opportunities to look with the retro profile letters and with the medication compliance. I think that would probably be a really good opportunity. We could talk with Dr. Khan offline further about looking at the compliance letters and we could look at how we could feed that information over and that might be a good referral opportunity.

Statement: Just like how we identify Lock-Ins.

Statement: Exactly. Except it would be medication compliance.

Question: Out of the 41,500 that you can enroll in this program, how many do you currently have enrolled?

Answer: We saw about 39,500 in the fall of last year, however, with the redeterminations process, we've had some flux that peaked and then came down in the new year. In the past month we've seen an additional lowering due to pulling deactive case management folks. We're at roughly 35,800 now. Hoping to expand this because we believe there is real value in helping people, particularly in this category of Medicaid recipients who are FFS and have chronic conditions. There's a long list of conditions in which you're eligible to participate. For many of these folks it's numerous conditions that they are managing.

Question: This is funded by CMS for 5 years. What happens in 5 years and CMS dries up?

Answer: We need to demonstrate things that work. This will show value. What we have to learn from it is how is this going to become part of the new paradigm of health care? We're in the midst of a new statewide innovation planning model, we have opportunities for reform. Recent changes in congress related to fixing SGR, so it's catalyzing some opportunities to be

more accountable around outcomes and collaboration and integration of services. I can't tell you exactly what is going to happen at the end of 5 years, but I will tell you this is a great opportunity to demonstrate innovation and collaboration to drive true clinical effectiveness.

Question: How is the program publicized to providers because I wasn't aware of it at all and I think it's a great program? Unfortunately if you really promoted it now, you only have a very small window of opportunity for maybe 5,000 patients. There could be a deluge if you really start promoting it.

Answer: We've been very actively promoting it. All participating Medicaid providers were mailed a Provider handbook. We've mailed them every six months. In addition to that we link the patient back to the physician. We start with the high volume practices and move down.

Statement: You might be better to send postcards, pamphlets, flyers, because doctors aren't going to read handbooks.

Answer: Noted. We are going to start a quarterly newsletter that will be faxed. We have many advertisements in many primary care educational conferences, Nevada health conferences, Medicaid conferences, blurbs in newsletters in other organizations.

Statement: I believe one of the challenges has been having the FFS plans and then the MCO plans. Honestly the FFS doesn't have a marketing budget. We depend on the vendor who comes in and a lot of associations vs. having the value added with the Managed Care plans is they literally have departments around marketing. That is one of the issues.

Question: What does this program do in regards to specialist care? As a physician, I can't get patients in to see specialists. Is there anything in this program that would help me identify providers who might be enrolled?

Answer: We have limited access and availability. Some areas are harder than others. What we will do is work with you, your patient, identify who would accept the Medicaid patient into the practice. We assure that patient gets to that appointment. If the patient gets appointed with a specialist, one way we know we can help particularly with the next patient you have, is make sure that patient keeps their appointments. If they have a specialty appointment that takes 2 months to get in and they don't show, the appetite for that specialist to book a Medicaid patient is not very good. We work very hard to make sure people get to their appointment. We look across the field where we can find a specialist and it's a challenge. We together are going to have to talk about what our opportunities are with specialty care.

There are many communities doing all sorts of creative things about that including econsultations, to prioritize a consult, this way the sickest patients will have some priority to get in and be seen so that they are not harmed by waiting. A less complicated patient that might be able to be managed with less collaboration could then get into that next available slot. These are ways, if we work together, between the patient, provider, the specialist, the hospital, or the other services that the patient needs, but this is where we'll all have to come to the table and work together.

Question: Sitting on various medical staff across rural Nevada, psychiatry is one of the number one issues that those physicians struggle with. They have a patient that is comes in and it's either fly them out to Reno from Hawthorne, and 9 times out of 10, the patient comes in and they have absolutely no support, so I guess, I'm assuming you have reached out to those providers because they are out there trying to provide primary care in a clinic for a sore throat and then they run across the hallway to try to deal with an ER patient, walk down the hallway to deal with a long term care patient, and they have absolutely no support. It's getting better with econsults, but there's really nothing for psychiatry.

Answer: We know behavioral health is a big challenge. A good portion of our staff is behavioral health trained. To a certain extent that relationship can be therapeutic. We work very hard with the psychiatrists in the state. There are not many of them who will accept Medicaid patients. We are educating primary care to feel more comfortable in managing some of the non-complicated, basic psychiatric diagnoses. Many folks who trained in primary care didn't have formal psychiatric training. How to screen and treat substance related disorders, or other types of psychiatric disorders. That may or may not have been part of training. So to the extent that we can partner, we work with them at health centers, other Federally Qualified Health Clinics. We're on the docket with the project Echo group to get didactic education, some case examples. We arming the physicians out in the rural fields who have to be primary care and the specialist with the education that they need to be able to treat some of the simpler cases. Excited about the efforts around telemedicine. There continues to be some debate in the legislative session right now. It's a Medicaid covered service but we don't have a lot of people taking advantage of it right now. Also, to what extent are we helping our future doctors to be able to address the needs that we have here in Nevada and how do we work with the educators and trainers to really help develop the kinds of expertise that we need, not just for physicians, but for mid-level providers or nurse practitioners, PAs, etc.

Question: Do you have the ability to provide this educational support?

Answer: We do. Dr. Ley has a multi-level educational program looking at common psychiatric conditions, management of substance abuse issues, recognition and treatment of delirium and psychotic disorders and has offered that up to clinics. That is why, with project Echo, we can be more efficient with getting out to many more providers. I've been in contact with Dr. Class, who is over project Echo, as recent as a couple of days ago to confirm that the Health Care Guidance Program is involved. There has been one class on diabetes and what the role of care management is. Many physicians don't know what care management is.

We know there is an area for education on what is care management, what is care coordination, what's case management, what's utilization management. We want people to know about the 24 hour nurse line so that they are not running to the emergency department inappropriately, or accessing a service when they could have called a few days before. When to call to doctor, for example. Arming these individuals with a kind of confidence, knowledge, and ability to utilize the health care system appropriately.

Statement: I think the practitioners at Hawthorne would really like to hear about your

program.

Response: We have been down to the medical facility a couple of times and would love the opportunity to meet with the clinicians as well.

Dr. Ley - Value Options Medical Director, Psychiatrist: Anytime, I can come out to Hawthorne to present, if you wanted to talk about depression and how to manage it, or what to do if someone comes in who is cutting, or self-harm, dually hospitalized, anything like that.

Response: I'll bring it up with medical staff next week and make sure that they are aware.

Comment: We don't have any problems with referral of worker's comp patients. The bottom line is, if you have adequate reimbursement you'll find that there are plenty of providers available. We really have this system where we have very good reimbursement and readily available consultations and we have a very parsimonious system where we have a hard time actually coercing providers to even serve in that system, so I think that somewhere in between you have to be able to bring that reimbursement level up. There has been a recent survey of healthiest states and if you look at the healthiest states, those states all have the highest instance of physician reimbursement. We really have to get these objectives in alignment because you can't have both.

Response: There are efforts in the budget to request increasing reimbursement, but I would submit that in addition to the reimbursement issue is collaborative care. Even with reimbursement adjusted we have to have people working together for the individual. How do we work together to serve our neighbors, our community? We're talking about nearly one out of 4 or one out of 5 people are covered under Medicaid.

6. Clinical Presentations

a. **For Possible Action:** Discussion on Psychotropics for Children and Adolescents prior authorization process and policy.
   i. Public comment on the prior authorization process and policy.
   Dr. Matt Larson - Child Psychiatry Fellowship Program - Concerning the new PA policy.
   I assume it was implemented to decrease the polypharmacy and to decrease the overuse of psychotropics in children. I spoke last week to about 100 doctors telling them to watch out for bias and off label use and spoke about the subject myself. At the same time, I fear that the patient harm greatly outweighs the patient benefit, as I've already seen in my own patients in the last three weeks.

   First, I have a 12-year-old with impulse control disorder that I can't put on Depakote because I can't get it approved with a citation of why it should be approved for him. It's been rejected and I'm telling his mother he will either have to be in juvenile detention, or residential treatment because he's going to be kicked out of school and beat people up and that is where he's headed.

Next, I have a 3-year-old who was born on heroin and was in the NICU for 2 months and never developed because he couldn't sleep. We went through melatonin and other medications. Now we're up to Trazodone and I think, how would I ever, with the new policy, get a 3-year-old on Trazodone? No one is going to approve that. There is no evidence for it. There's no peer review literature because there isn't much for heroin addicted children who can't sleep and don't develop because of it.

The patient this week is a 15-year-old autistic hemophiliac who is severely aggressive, who has been stabilized with risperidone, but has gained 4 pounds a month and has been for the last 7 months. He's now getting gynecomastia. I'm worried about diabetes, metabolic syndrome. I tried to change him over to Geodon, however Geodon is not approved for aggression related to autism. I cited literature from the American Academy of Child and Adolescent Psychiatrists, their practice parameters. It was rejected and now I'm forced to tell the family, "You can either pay cash (about $160 per month), we can keep him on risperidone and fight diabetes, or we can take him off and you can have an aggressive child." And that is kind of where I'm stuck.

As Dr. Khan pointed out, there is severe shortage of Medicaid providers for child psychiatry in the state. My fear is that this further limits our time to see patients. When I saw the letter of medical necessity, I asked myself "What is a prescription from a child psychiatrist, if not a letter of medical necessity?" I don't do cosmetic psychiatry. I prescribe anything that I don't see as medically necessary. When I write prescriptions, it is medically necessary for that child. Then I get the PA back already from the previous policy, where I state Yes I've seen them, yes I've seen them regularly, yes they need this, I'm not doing polypharmacy, it's for its own indication, trying to detail exactly why it's medically necessary and now there's an additional letter required. All I can see is that we are trying to decrease access to care for our patients. If the current policy stands, my question would be, I've received two letters so far asking that my medications have been denied and I'm asked to attend hearings. Do you want me spending my time writing letters and attending hearings, to get my patients the best evidence based medicine, or do you want me seeing more patients, but I'm not able to use the best medicine available because my hands are tied because it won't be paid for? That is my concern and that is my worry with the new policy as I've already seen it in the last 3 weeks affect multiple patients. This is someone in child psychiatry. I don't know what's happening with neurology, family practice, pediatrics, across the state. Thank you.

Carl Jeffery Catamaran: You must have some sort of training that says using Trazodone in a 3-year-old is safe and effective.

Larson: Yes.

Jeffery: Is that something you can share with the call center? I'm just wondering where that came from.

Larson: There is no peer reviewed literature using Trazodone in infants and toddlers that I could find. The only one I found was a study of 8 kids who had severe neurological disorder and it worked to help them sleep and in my note before this came out, I cited that because I'm already scared. I'm using Trazodone in a 3-year-old. I want a little bit of evidence so that in case someone goes back and looks in my charts to see that I looked this up and tried to find what I could. My concern is if I can't even get Depakote for an impulse control disorder teenager, how would I ever get this approved with the new policy. So I have a lot of training, but as far as peer reviewed literature that's required and a letter of medical necessity even citing it, I'm afraid it will be denied.

Coleen Lawrence: I want to clarify. This is not a new policy. It has always been in Chapter 1200 of the Medicaid Services Manual. The policy states that Nevada Medicaid is not allowed to pay for off label medication unless it's peer reviewed or found in the compendia. That's why Carl is trying to find, do you have any literature to support it?

Larson: Yes.

Lawrence: So it's not new policy that we implemented. All we were asking for now is on the form, because if you were to call in and you were to have that peer discussion with the call center, they should be asking you "What was your source for this prescription, for your background to write this prescription?" This was not a change in policy. The change in the process was that letter of medical necessity for the 0-5-year-olds. Yes that absolutely was a change. We did not create it. We did not envision this as a brand new one, we did steal it from a couple of states. The actual policy has been in Chapter 1200 for all drugs. It's not just for psychotropic medications for children. So that's why Dr. Jeffery was asking "Do you have any of the background information for this?" I'm pretty sure that people who have been in this room with me plenty of times have heard our DUR Board talk about this.

Larson: It must be new application of the policy because until 3 weeks ago, everything was approved when I made those phone calls and I'm told on the phone, "We can't do this as a phone call. This cannot be approved over the phone. You must send in the documentation." I send it in with the practice parameters stating that I can use the medications and it's still denied. So if it's not new policy, then it's being applied in new ways.

Lawrence: You did cite the information then?

Larson: Yes. I wrote the citation.

Lawrence: That's one thing we need to look at. If you wrote the citation, absolutely because that's one thing we want to do. We are not trying to make this a punitive measure by any means. But we are trying to make it an appropriate application of these medications and so one thing that we've talked about is putting on our website

the FDA indications for one. That was in the web announcement. We will collect all of the citations together and we will put them out there as other states have done because, I'm sure you're an absolutely outstanding prescriber, but I always have a bad apple out there. And we want to educate that bad apple and we want to make sure that they are appropriately using appropriate prescribing patterns. We want to use this as an education opportunity and I want to make sure that my clinical call center is on the same page that you are.

Larson: I assumed that was the purpose, but my fear is ultimate consequences. That this is extended much, much further than you expected and it is harming far more than it is benefiting. But there will be a benefit because you will stop the bad apples and you will stop a slew of good. That's my fear. It's already happening.

DE: Evidence based and peer reviewed literature and what's on the net are pretty open. The discussions that we had through the first round of all of this. Our main concern was, going by the book, or going by what the FDA says are two different things. Because what the FDA approves is what the manufacture wants approved and that's what makes the most money. If there are studies going on out there that shows what a drug has been used for and there are peer reviews on that, that is one of the reasons we put a lot of the information into the process because knowing the FDA guidelines isn't enough to treat everything. There's always other things out there that are good but they just haven't had the emphasis put on them by the manufacturer. And that is why we specifically went after looking at peer reviewed journals to give you options. Even though you may have a small case study, but at the same time, if there is something out there, whether it is from Australia, Asia, Africa, wherever that shows that this might help, let's give it a try. But at the same time, we can't fund experimental therapies, but at the same time, maybe with some of these patients you might want to contact some of the pharmaceutical industries and say "We might meet an issue here." and you could go after orphan drug status, if they are that unique.

But we specifically put a lot of options into the process so that you could have access to things rather than just restricting it to what the FDA says.

Larson: I don't believe the policy is being implemented the way you intended it. I'm already using these peer reviewed articles. I'm already doing those things and they're still being rejected. I'm not given a chance to resubmit. They say come to a hearing.

Board: Then we have some process issues we need to take a look at.

Response Larson: That is my concern. There are severe process issues and I want it addressed.

JM: From a prescriber's standpoint, I would be a little uncomfortable proposing a dose that I know is neither safe, efficacious, nor possibly even therapeutic or maybe

toxic, based upon a study of 8 patients. The other hat I wear is as a malpractice insurer and I would be on very, very thin ice defending a doctor who proposed something like that on the basis of that sort of information. I think that if you're not even a little bit uncomfortable prescribing something like that, I would wonder why. I prescribe off label all of the time, but I feel that I have better foundation, better ground for doing what I do. Obviously you deal with some very challenging situations and we all appreciate that, but we have policies in place that are directed toward the middle of the road and not the outliers. I would be very uncomfortable proposing therapy like you are on the basis of such thinly investigated dosing. Especially in a 3-year-old. The dosing regimen can be very, very different due to a lot of brain issues, but I would be very uncomfortable in your situation.

Larson: And I would hope everyone is. Isn't that the purpose of a subspecialist? To identify mechanisms and medicines for these kids? Because I don't see the kids that go to family practice and pediatrics.

JM: You're dealing with people. I think you have to be really aware of what you are doing.

Larson: Right. That's why I have attending physicians checking to make sure they agree.

JM: If they're willing to go to court for you, that would be good because that's the world we live in. I have to defend doctors all of the time for doing very, very appropriate things.

Larson: And I hope the same. If patients are being harmed everyone is willing to go to court for them. For those who are not getting the medications they need.

JM: You're probably on safer grounds not doing something that's recognized than doing something that is sort of out there.

Larson: There's no harm, but I'm afraid we're doing the opposite.

JM: Exactly. I appreciate that.

Geraldo Rodriguez: Pediatric Neurologist - I second what Dr. Larson just said. He's referring to patients who are covered under the guidelines of what we are discussing. So children under 5 being treated with medications that are being used off label. Pediatric psychiatry and pediatric neurology are off label. We have essentially no FDA approved medications. That's just the way it is. Using Seroquel in a 3-year-old, we do it. We have little printed data, but there is plenty for anecdotal and training data, and sometime we cannot convey that in a complete scenario. I want to share with you the plight of the patients with epilepsy. Many patients with epilepsy are treated with emergency first aid seizure medications that are to be used for an emergency at the discretion of the family and myself. This is to

avoid having to call the ambulance and go to the emergency room. One of the medications that are accepted nationwide as standard of care is , or Ativan. It is in the textbooks, but it is not an FDA approved use to use for epilepsy, but in emergency rooms, in intensive care units, across the country on our patients, it is used widely and successfully. It saves lives and it saves resources. Since three weeks ago, with the new implementation of the old policy, we have had numerous patients have their not filled. The message they get from the pharmacy, or what I hear from the parents is, the pharmacies said the medication was not approved for insurance, or the pharmacy didn't fill my medication, or you (me) must have done something wrong because my prescription wasn't ready. But most of those patients will not purchase the agent. They will just go without and then we hear about it when they land in the emergency room. So some of our patients have had seizures and have had to use the emergency medical services. I want to give you an example of a couple of kids who have been on for over a year. One is a near drowning victim. He is on a home respirator, a home feeding tube, has epilepsy, is on various other agents, and he has been receiving for over a year. Whatever implementation with the pharmacy that was taking place allowed him to have this medication and allowed me to prescribe it. Now it was denied. Between patients, in my lunch hour, I got on the phone after it was denied, and I spoke with a very nice young man who happens to be in Massachusetts. I was trying to explain to him what was going on. I asked him what was his degree. He said he had no degree, he was a pharmacy tech. So I asked him what he does. He said he gathers information to approve or deny these requests. After a little bit, he offered for me to talk to the pharmacist. Sometime later I was able to talk to the pharmacist, explained the issue. He understood and agreed completely, but he said "You're in the state of Nevada and the state of Nevada needs a letter of medical necessity." I asked him what it should say and he offered some ideas. He said we need peer review literature. We did provide that and the medication was approved sometime later, the next couple of days. But that took some time. The other patient, on the same day, another baby with epilepsy. This one has hydrocephalus, a shunt, hemorrhage at birth, an intensive care nursery survivor, cerebral palsy, a very sick little baby. His , which had been prescribed and filled for over a year, was denied. So we have the same situation, but now I'm catching on to this. I updated the documentation with the help of a prior authorization specialist. We also received approval for that medication. But we have heard of several patients where we were not notified or the parents did not advocate. They fell through the cracks. The medication was not filled and they went without it. Most of my patients with epilepsy have a prescription for lorazepam. Since I learned to use it, I minimized their morbility and utilization. I'm not going to do this for every patient. I don't have time. The guy in Massachusetts said, "Why don't you put him on diazepam?" Diazepam has an FDA indication. And it kind of does and it doesn't quite work as well, so I may use diazepam and they may have to dose up a little more frequently. It may work, but it won't work as well. This is one example of a medication that is not esoteric. It is used nationwide. It is the standard of care, but we're hitting roadblocks. Not every family and every patient can negotiate these roadblocks. I hear from other providers who don't have the will, or the time or the assistance, or don't have someone like a prior

authorization specialist to help. So they just tell the parents "Sorry, your insurance doesn't cover this medication." And in pediatric neurology, in the Medicaid population, that means this kid is not going to get his medication because those families are unlikely to pay for this medication out of pocket.

PO: Coleen, just a quick question. Part of this PA process, was it to include anti-epileptic drugs?

Lawrence: We were just reading the policy. We found a hole in our existing policy because neurology actually bypasses this entire process.

Jeffery: There's a contradiction in the policy. I was emailed about your specific case. On one side we've got Chapter 1200 that says if you're a pediatric neurologist and you're writing for anticonvulsants for a seizure disorder, then you are exempt from the policy. But in another part of the chapter it says we can only approve it for FDA approved indications, or somewhere it's listed as common compendia. We're going to have to get that clarified.

Rodriguez: I appreciate the language, but in pediatric neurology, many of the agents that we use are not approved under 18, or under 12, or under 5, or under 4. By the time you're under 3, you pretty much have access to only herbal medications.

Lawrence: Let me answer your question in 2 different parts. For the treatment for seizure disorders, we do have the piece of the policy that reads that the following diagnosis begins with and we talk about epilepsy. We had it for anticonvulsants and for the provider specialty code, for neurology / pediatric neurology. If you wrote those diagnoses on the claim, we bypassed that. That's been in our policy for years. That's why we were trying to read over here to see why you were even hitting the system for that drug to be an appropriate utilization in the system. If it had the proper indication.

Jeffery: Let me clarify that one. The benzodiazepines in our system, there are two classes listed in there twice, so they're under anticonvulsants in one area and as sedative-hypnotics in another area. So the Ativan falls under a sedative-hypnotic and under a psychotropic. Whereas diazepam, it falls under the anticonvulsants.

Lawrence: The intent is for epilepsy, for pediatric neurologists, we were trying to get you through with the diagnosis. We have to figure out the system piece of it. The bigger picture: The DUR Board has a regulation that we are not allowed to reimburse for drugs that are off label unless there is peer reviewed literature or they have supporting compendia. All Medicaids have that across the nation. That is how we are different than commercial payers. It's in the Social Security Act. The first piece of this is if it has an indication and you're clear on that indication, and you're a pediatric neurologist, the goal when our policy was written, is to bypass this entire process. Just like our ADD/ADHD drugs are in a different policy and we have a different policy that handles this in a different bucket. If it is off label use and it's

not supported through an FDA indication, or peer review or compendia, it's a whole other obstacle that we unfortunately have to tackle.

PO: There is enough literature about the .

Lawrence: Yes and that's why it was eventually reimbursed, but it did hit a snag and the process brought it to our attention.

PO: Thank you for bringing it to our attention.

JM: Don't we also have a policy for providing a 3 day fill on denials?

Lawrence: We have a 96-hour.

JM: 96-hour. So you're talking about 4 days. People need to be aware of that in the call center.

Jeffery: The call center is aware of that too. The other thing we are doing at the call center is that if we do receive a renewal PA for somebody who has been stabilized on a medication for a long period of time, they will authorize a 90-day override with the intent that the prescriber will taper that patient off. We understand that it's very bad to just cut someone off their psychotropic medication.

Dr. Edward Lynam - Child Psychiatrist, practiced in Ohio for 12 years after doing training in Pennsylvania and has been in NV for 9 years. I've been dealing with the policy now for years. Delays in treatment, interrupted treatment, hassles for my staff. One of my staff spends 3/4 of her time dealing with parents, pharmacies, doctors, and other people just trying to get this whole process to work for our patients. The amount of time it takes me is extraordinary. I've looked at other states that border Nevada and other states that were mentioned to me by people for Medicaid. I looked at my old states of Pennsylvania and Ohio. As far as I can tell, I've not seen any state that requires even half as many PARs by child psychiatrists. In fact, if I move to another state, I believe I would get about 25% or less, even the most stringent state of all. I believe your policy is way out of line with other states. I don't understand why, but I am done. I'm going to leave the state. I have had it. I'm not going to see any more new patients. I'm phasing out my practice. I believe you will have a hard time retaining child psychiatrists if you retain the policy. Thank you.

Dr. Philip Malinas - Child Psychiatrist to both private practice here in Reno, taking Medicaid patients. I also work in the state of Nevada rural clinic in Carson City seeing Medicaid patients and I've been doing that for 8 years. Prior to that I was in California for 20 years where I treated MediCal. I've always treated this population and plan to continue. To summarize what is going on here from my perspective, since April 1st, we have a new form that has to be faxed. We are not allowed to call in on children anymore. That takes more time than the old system. We now have to

present these citations for off label meds. That takes a lot of time, as you've heard, time that we don't have. The turnaround time on these PA requests is much slower. That's causing interruptions in treatment for our patients. This letter of medical necessity for young children - I haven't had to do one, so I don't know what it is. It's not defined, so I don't know how that's going to work. As Dr. Lynam alluded to, none of this is required by the Medicaid carve-out plans in Nevada, by private plans, or other state Medicaid programs. There must be another way to satisfy regulation 1200, Chapter 1200. My sense is the way you satisfy this is, without requiring each of us to go through this process on each patient, every time (we're talking about so much duplication of effort and time taken away from patients) I assume this could be satisfied by having a (unintelligible). That is if, for example, Welbutrin is used by a child psychiatrists for ADHD, and there is documentation for it, which I've submitted but haven't heard back yet if it got approved, once one of us shows that, or if there's a subcommittee that would put together a formulary, then we could have it put on the formulary, then we know that we can prescribe Welbutrin for ADHD for children. Medicaid can legally reimburse for that because there is peer reviewed literature for that and we're done. And each of us doesn't have to submit that citation to a pharmacy tech in Massachusetts every time. I assume that is how every other state and insurance plan, and Medicaid plan is getting by this and I think that would be the solution.

PO: I appreciate the fact that you're coming to us with a possible solution.

Lawrence: I have to acknowledge Dr. Malinas. He has been very helpful behind the scenes. He gave us several solutions within the first 2 days and that is why the form has been modified multiple times behind the scenes. We applied 5 different suggestions by his comments behind the scenes. We actually have been talking about that. When we talked about the citation list that we sent back to you, what we are trying to figure out is if they have a citation list and it's on one citation list, then we know that that is the approved citation list. What can we do to utilize that as the source document? I want to be careful that we are not confusing that with the preferred drug list, the formulary. Because that's a little bit different. We are not more aggressive than other states. They are doing this similar to other states. What you do see on other states is that they've combined their preferred drug list and have put the FDA indications right on their PDL. That might get a little bit messy. We are trying to quickly look at how we can do one source document. That's going to be a lot of partnership, putting that list together, but we are doing that. There are still going to be drugs that are prescribed that do not have peer review literature and are going to be completely off label, which we are going to still deny. I do have a question about the call-in.

Jeffery: From the call center prospective, they need to have all of that documentation documented. That's why it needs to be in a faxed form rather than called in. Potentially in the future, maybe we can get to the point where you can say "I'm prescribing this based on this article, this is my justification for using it." Maybe we'll get to that point down the road.

DE: Along the same lines, another question too. I've had to do this at another facility where I was working at one time where you're trying to get your information across and all they wanted was emails. My MO is if I can say it in once sentence, I'll text it to you. If I can give it to you in a paragraph, I'll email it to you, but if I have more than 2 questions, I'm going to talk to you. That is the problem that I have with these places that want a fax, or you email all day. You email back and forth, your question, 2 or 3 hours before you hear back and then you have forgotten what your question was in the first place. Does the Call Center have the option to use different methods of communication so a fax for certain things, a call for certain things, and email for others. Put some criteria in there so that it can be done without a whole lot of hassle at times. Personally I would rather do a lot of things electronically. Once I've found an article, if they want an article, I scan it, keep it pdf, save it and then shoot it out to whoever wants that email, or that citation. Can we set something up like that? Because everything we've heard tonight is that we've got a process problem. It's not that the system is broken, but the flow is broken down somewhere.

Lawrence: I appreciate the call, that piece of it. We can definitely look at that piece of it.

DE: The idea of the citation list, would this be something that if one of the practitioners or prescribers wanted to know something, could they go online, or access this somehow and see the literature that's being supported right now that is current, as opposed to going to do a search or their own process?

Lawrence: Yes. That is kind of what I had envisioned. We're starting to put it together. Then it will be a one source document to look at and we could add to it that way we all agree that this is a viable list to use. You could add additional sources if you found one but it would be a good running list at that point in time.

DE: Most the literature out there, when you go to look at something, there are certain stages that are the paragon of how it's going to be done. If you have that, there is no reason to reinvent the wheel.

BS: I just wanted to share something because I've heard it a few times now that our policy is so restrictive and other states don't do what we do. I went through and did a lot of research. I went to each one of the state's Medicaid sites, pulled down their PA forms and their PA policies and I wanted to mention a few of them just so that you can see that we're on par with some of the other states and what they are doing. For Florida, their Medicaid, they do require PA for children aged 6 and under who are prescribed antipsychotic medications, over age 7 who receive multiple prescriptions. Georgia requires a PA for all atypical antipsychotics and then they have what they call Peach Care for kids and they require PA for any children who are younger than FDA approved ages and they also require monitoring plan for safety and effectiveness which is required for each prescription that is prescribed. Illinois requires for children aged 6 and under who receive medication for ADHD

and also under age 8 for any atypical antipsychotic. Maryland is for all children under age 18. They also have a peer review program for mental health medications. So not only do you have so submit the PA, but then it goes to a peer review committee that also has to review and approve. Massachusetts also has a PA for concurrent use of antipsychotic medications and prescriptions in excess of established quantity limits developed by the mental health and pharmacy program. Minnesota, New York, the FFS program requires PA for atypical antipsychotics prescribed to children according to the FDA minimum age and diagnosis criteria. They also have, through Magellan Health, they manage PA for the children statewide. North Carolina has a pretty extensive program. Also they require safety monitoring documentation. Any antipsychotic prescribed without a clinical diagnosis code corresponding to an FDA indication, all ages up through age 17. So you can see we're not the only ones. Pennsylvania, I heard that one mentioned, all antipsychotics for children under age 18, all stimulants and related agents for children under age 4, and all benzos for children and adolescents under age 21. So you can see there are policies not as restrictive as maybe some of us may have thought.

Malinas: Your research is for mostly all antipsychotics. Your policy is all psychotropics, everybody under 18. It looks like other states have targeted antipsychotics which are very expensive and have a lot of side effects. Maybe they have more reasons for scrutiny.

BS: It also depends to if you go to some of these websites, they break it down, so they will have. I'm just sharing the data, just like you did.

Malinas: Just keep in mind, as you work on this, hopefully improving the system, this process problem, as you so well put it, that if it continues to be that every time I prescribe, I've got to make a call, or I've got to fax a form, and then follow up with a call to a pharmacists sometimes, and we all have to do that every time, you're going to clog the system terribly. I don't have time. I see a lot of Medicaid patients and I want to continue, but I don't have the time if it clogs up, I'll just go with other insurances that are easier.

BS: I can appreciate that as well and as another note to share, I'm a licensed foster parent for Washoe County, so I have had these children in my home. They have slept in my home, they have been there for months, so I can appreciate the treatment of these children and what they need, and yes a lot of it can be off label, because sometimes you just run out of options. But like Coleen said, you also want to take into consideration those bad apples. There's a lot out there. So we're just trying to do the best for the greatest good.

Lawrence: So what we want to do is, for psychotropics in general, we want to keep the policy intact. I think that is something the Board has stayed strong and didn't change the policy, but the process. And I think if we continue to work through this specific policy bumps, procedure bumps, like the one you had brought forward,

brought up several to work through, whether it's new patient, continual patient, again it's the PA once a year that we are looking at. A call vs. a fax...those are the kinds of things we want to see what is going on with these. As I've stated before, it's a national trend that we're trying to protect a venerable population. You're all valuable prescribers with us. We want to work through this process. I want to understand the process issues so that we can make this the most seamless process for you to continue it. We can work through the citation list, so we can educate, and make this an opportunity to improve the education on appropriate prescribing.

DE: I think when we went through these initial processes to put together, several years ago, Nevada was the top 5 of providing psychotropics to pediatrics and younger. And we thought, What are we doing wrong, or what aren't we doing in our process. That's when these processes came up and we've never had the outpouring of concern or problems with them until now, so that's what leads me to believe that we went down the right path, but how it's being implemented is where our problem is and we need to take a look at that. Like Paul said too that we appreciate that this has come to our attention that our process is broken, but we feel that the process we put in there to protect the vulnerability of some of these people and maybe we need to go back and look at the process again and see what we need to shake around so that it's easier to work with.

Lawrence: I would definitely share the data. This Board is very strong on data and we just posted our new numbers. They're out on the website for everybody. Our data is still not the most favorable data out there for the number of prescriptions in our 0-4 population. It's still concerning out there for what we have.

Malinas: Concerned with just a number?

Lawrence: Number of prescriptions we have.

Malinas: Is the assumption that that is harming young children, as opposed to treating?

Lawrence: It's the number of prescriptions per child. We have a lot of poly pharmacy occurring still.

Malinas: But you're assuming that the polypharmacy is bad. We don't know that, or do we know that? Or are they cases like Dr.Rodriguez's, or Dr. Larson's, or mine, or Dr. Lynam's?

Lawrence: It's per case.

(Group talking over each other)

Malinas: Thus being at the top is bad. Maybe it's just that we have child psychiatrists who are treating tough cases, prescribing a lot of meds, yes, but are the outcomes bad? Are there emergency room visits? Are there problems?

Lawrence: These are retail pharmacies only. There's no physician administered claims and there are no emergency room claims. These are only retail pharmacy claims.

Malinas: So there's a large number that looks bad for Nevada, but we don't know that it's bad for the patients.

DE: I think, in one to the studies, one of the things we wanted to look into at that time, when we first saw that numbers was ok, do we in Nevada have a higher incidence of these types of disorders that need to be treated, as opposed to other states, and if so, why is that? Maybe we have an issue with more people having these conditions here, we have a public health issue going on here that we need to take a look at, not just that we're over prescribing the drugs. Therefore, we have a lot of issues going on out there. That's what is driving this. It's coming down to the fact that, true, maybe our numbers show that we're treating it appropriately, but we don't have anything nationally or federally to show that that is happening. All we have is the stats that show we have a higher proportion of numbers of those drugs and people with those conditions in those age groups. We may need to have a look at a public health issue as opposed to just prescribing. That is what our concern was, why we were having these numbers when there isn't a national brouhaha going on as to why Nevada has more mental health issues in their youth, as opposed to other states. And that's what pushed the emphasis for this.

PO: One of the things we were looking at was the concurrent use of behavioral therapy. That seems to be very poorly documented from what I've seen so far. We want to make sure we're doing the best for these kids. We're all on the same page.

Joe Haas - I'm a psychologist administrator with Washoe County Department of Mental Services and Social Services. I come at this from a little different angle and that's the kids that my agency serves. It seems we have a real dilemma. The rates of prescribing are up in these kids, but also the rates of child welfare in juvenile justice population are astronomically higher in the general population as well. My hope is that the Board can take this and work with Coleen and take a look at an issue that would deal with quality, but put as little burden on the prescribers as possible. To give an example, we, as a juvenile justice system employ two full time workers to link families with services. Sometimes that involves getting them Medicaid, sometimes that involves linking them with a doctor. It took one of my workers who is a Master's degree in counseling who has worked in our system for years, 4 hours to find a child physiatrist on a private insurance plan for a family. Most of the families that I'm advocating for don't have the attention span. They are stressed in multiple areas and they don't have the ability to sustain that kind of an effort or the knowledge base to do that. This worker is also incredibly determined, so it was very

important. It seems to me that some solutions that I've heard that are important is that this quality assurance measure was imposed in part on a system that had challenges already. Potentially looking at how the burden could be shifted to Medicaid, in terms of compiling a list of medicines so that the doctors don't have to, for every case, present the same peer reviewed literature establishing some institutional memory would be important. The other would be to see how your issue with bad apples could be dealt with very strongly from a quality assurance prospective and identifying the prescribing patterns of individual doctors and finding outliers from the data you have, as much as if not more from a PA. The other is to make sure your system doesn't "throw the babies out with the bathwater" because there is a risk of implying that all child psychiatrists are suspect, so you have to do this PA. If you get together with the ones in our community in the north, I think there can be some solutions leveed to really not put the burden back on them. From a buying and selling prospective, it's really hard to find a child physiatrist in our community. If you put more burdens on them, they will go elsewhere and one already has. I'm not sure what we are going to do to fill that gap in our system. It really seems important to keep the good ones happy, as happy as you can. Where you're ready to build a system of quality assurance, you'll build it and no one will come because people will drop off, or they may not see as many Medicaid patients, so that worries me. The other thing that has been helpful in my dealings with Medicaid as we worked to find our kids placement, is the deal with the process issue, by identifying a single point of contact the psychiatrist can call after any smell of a problem, where they can call and say "This is happening." and then that person acts as a guide through the program to solve that problem quickly. I think you'll get docs to stay if they establish good working relationships with someone they can call. We're working with that in our consortium Mental Health of Washoe County. Medicaid takes a beating amongst family members and providers, but nobody really deals with that at an individual level and we're working to set up a form in a way where instead of repeating complaints at meetings that we work with a single point of contact. I've found Medicaid to be responsive in their approvals for residential treatment. We're able to access someone to talk to help us solve a placement issue for kids in need. Those are the kind of things I suggest. I come at this as a psychologist. I don't prescribe. I support behavioral therapies. There's a lot of support nationwide. There was a big report in the LA times recently to show over prescribing at least from that reporter's prospective for child welfare and juvenile justice populations, but I can tell you having worked for 15 years in the public mental health sector, in children's mental health as well as in the juvenile justice, the kids that we see in juvenile justice and child welfare, the ones that have problems, have very severe problems and often times defy a lot of very good treatments, including psychosocial treatments and the innovative approaches that are still based in evidence and not so far an outlier that kids get hurt. The other thing you should know is in social services already legislation has been put into place and a lot of the FFS kids are social services kids where there are dedicated workers that approve medications for social services kids all the persons legally responsible. Those are also peer reviewed by a clinical staff and looked at by physicians both north and south. You should also have a comfort level that some of this is already being done

for at least part of your population. I'd be happy to answer questions, but it really worries me that the kids I see, who need services, whose very placement in the community depend on a medication, are going to go without because it's really hard to find docs right now. If this makes them unhappy, and I'm not hearing a lot of happiness right now, it's going to hurt the kids I see, so that will be my perspective. And I think if you look at some of these and even if it's possible to postpone some of the regulations and go back to see how to easily resolve process issues, make it so docs don't have to repeat. My understanding is now, if you want to prescribe Prozac for someone younger, you have to justify that with peer review potentially over and over again.

Larry Nussbaum - Chief of the Child Division of the University of the Nevada School of Medicine. I've been involved in the public sector, on various Boards, the utilization Board. I want to thank Carl and Coleen because they have been incredibly helpful, not only in this process, but over the last several years. About your question about what we can do about giving the other people a list of the information. The University has set up a list and actually I'm working with Coleen a bit on that. I've got a list of practice parameters for child and adolescent psychiatry that the American Academy of Child and Adolescent Psychiatry has and talks about utilizing meds off label. I hear what's going on and I understand that it's been a very stressful kind of situation for all the people that are both on the Board, as well as people that are on Medicaid. And I guess one of the things that is a real concern is that it sounds like, as a child psychiatrist, that there is a perception that we don't police ourselves very well. That you guys have to take the responsibility of policing us and that we don't identify the bad apples. And I really want to discuss that because I think there is a concern and I think it is that way in all medicine. I think it's that way everywhere and there's not a really good way of determining, in many ways, who is a really good practitioner and who is not. Right now I'm involved with the child welfare program. for the kids in Las Vegas, I do the second level peer reviews on those and some of the bad apples that Coleen has talked about, I've done peer reviews on those and they're really concerning to me as well. The issue is, even though I do peer reviews, if there is not a bad outcome for those kids, even though they are being given poly pharmacy, or huge amounts of medications, or 3-year-olds on 2 different antipsychotics. There's a very difficult way of policing those kinds of people unless something bad happens. So we're really trying to work on that piece of it and to let you know that I don't think that should be your responsibility for determining who's a good physician whether it's a psychiatrist or whatever. One of the things that really needs to be done is us working better in order to help keep kids and adults safer and not to screw them up with medication. Especially kids who are in the midst of developmental crises all the time. That's part of the reason there are not many FDA approvals. Because kids develop and it's hard to do studies for kids when they're changing their neurological stuff every day. So there's a huge placebo effect. There's millions of reasons why pharmaceutical companies don't pay a lot of money for studies. The issue that I see, is not so much from the child psychiatrist because we have access to a lot of this information. We have lists of this stuff and we have it available for child psychiatrists across the state. From the mental health

standpoint and the public health standpoint is that out in the rural areas and even here, and in Vegas, many of these children are being treated with these medications, not by psychiatrists, but by pediatricians, by nurse practitioners, by PAs, by family medicine people. If those people aren't able to prescribe medications for the kids, then it's going to be a disaster and those are the ones I'm really worried about because they are going to say "I can't do this. I don't have this information. It's going to take me forever. I'm seeing kids every five minutes, every seven minutes, every nine minutes. It's a crazy situation, so I'm going to refer those people to a child psychiatrist." There's like 38 of us in the state. I'm really concerned that this is leading, from a public health standpoint, to a disaster. Kids aren't going to get services out in the community, that only will you have problems like Dr. Lyman that's leaving, but there's going to be waiting lists forever and these kids are not going to get services and that's really my worry. How we're going to address that. I don't know the answer. I think the concern about making things difficult for those people and those people not giving treatment to kids is the real disaster, especially with the affordable healthcare plan and how many new Medicaid people under ACA now. It's a public disaster. I'm clearly working with Coleen in some type of way of addressing the system of whether it's poly pharmacy, or how we make the right kinds of medications for kids, but throwing this out in the middle of March and not letting anybody know about it, it kind of took everybody by surprise and it's really created a big crisis and it's kind of where things are at. I want to continue to work on this situation, but we've got to figure out something to do now because it really feels like a mental health crisis.

Coleen: To address the...it's not trying to police I will say that. We're not trying to police the psychiatrists by any means, it is looking at the medical necessity of a psychotropic medication and that's why when we started talking about the list, obviously FDA indications are easier to come up with. Most states have those up on their website. We put it in our web announcement. The psychiatry profession has more readily access to those types of lists that we can come up with and the peer reviewed literature, but coming up with that list together and then putting it back up on a website where it's more accessible for all prescribers, that was the goal.

LN: What happens if Dr. X of Las Vegas, who is a terrible prescriber, and she does all kinds of horrible things and she has access to that list and says "This is a list and this is a study where somebody got Seroquel and Abilify and Trazodone and all of that", what is to stop Dr. X from saying "I'm going to cite those types of things and I'm going to give the medication"?

Coleen: When it comes to the ethics and the scope of the practice, those are left to the Board. We're trying to do the medical necessity in making sure there is proper documentation that support the use of the medication. That's within our scope and what is required to do based upon the act. That is all we're trying to do.

LN: But they go together.

Coleen: They do, but there's only so much that we can come down to. We have literally Congress coming down on us over the last several years, coming down on Medicaid about these types of issues, so we have to make sure that we're using our due diligence that we're having the proper policies around psychotropic medications. The Board has been focusing on this for 8 years. It's definitely not aiming at the practice of just psychiatry on that piece of it. The other thing is about polypharmacy. We're one of the states that actually allows for multiple medications within a class where some states do not. We allow the diagnosis and the other drug if it's treating a separate condition. We're still trying to allow the different...

LN: But there's documentation for that.

Coleen: There's absolute documentation, so we're still trying to allow some of that piece as long as there is documentation. As far as ethics and scope of practice, you're right. That comes down to the Board. We just have to make sure that we're doing our due diligence and I appreciate that piece of "Where is that line?" We take that line as we do with all of our other policies.

DE: One comment I want to make too on that, and again, in part of our discussion, one of the other concerns we had is - I remember a show called "Friday is a long time ago" they had a pharmacist skit on there and his punch line in the comedy was "Got a problem, take a pill." And I think that was what we were concerned about when we're seeing these multiple pharmacies. One time during our discussion, we specifically wanted to have a part in there, especially with psychotropics and antipsychotics, that there was psychotherapy along with it, because the drugs in and of themselves are not going to solve the problem. In some cases, some of these people are in circumstances that we probably couldn't give enough pills. The only thing we could do is give them something to put them out so they're not worried about the environment that is causing the problems they're having. So that's why we came up with some the discussions that we had and we wanted to require a psychotherapy component and then we found out we couldn't do that because it was out of our purview. But that was one of the concerns when we went into some of these things and came up with these PARS. We felt that yes this is a DUR Board, but drugs are not going to solve all the problems. Sometimes the drugs are the problem and that's where we have to find that happy medium. Maybe we are too tight now and maybe we need to lighten up a little in our process, but at the same time we don't want to just allow medication to be prescribed just because it can be, but we want medication to be prescribed with some rationale.

LN: One of the things you'll see in practice parameters is the practice parameters almost always talk about psychotherapy as the first type of choice of treatment for the kids. I agree with that. I probably prescribe less than anybody in the state and take many more kids off of medicines than I wind up putting them on. The practice parameters, being a good child psychiatrist is to attempt to do the least disruptive, the least toxic, the least frightening kind of thing and to do the best kinds of things from the front end and for me that's therapy. Sometimes you have to give

medication to help the therapy go along. Sometimes therapy doesn't work. Sometimes kids are in such a condition that they can't benefit from therapy, so you need to find medication. But that's the standard of practice and that's what the child academy supports and I have no problem with doing that. I think the concern is what is standard of practice and how do you really define that kind of stuff. It's a really complicated kind of issue.

DE: I think the thing that complicates it even more, especially in psychiatry, there's the art of medicine and the science of medicine. I think psychiatry leans more to the art. There's some science to it, but the art of how to tweak this because you can't get samples through spinal fluid like oh, your norepinephrine is up, or your epinephrine is not up, it's just not easy like it is with other medicines.

LN: I think all medicine is art. Even if we don't have CFS levels or whatever, it's the relationship with patients. It doesn't matter if one patient has a physiological issue and another person has the same one, the relationship and what they deal with shows a completely different pattern.

Jeffery: Dr. Nussbaum, I gave you a bunch of my cards. Please, in all honesty, call me. If it's a process issue, please call me or, email me. Our call center does the best they can with the tools they have. They are following orders. If there is a process we can improve, absolutely.

LN: Darryl used the term "Throwing the baby out with the bath water" and I really worry that we're close to that kind of situation.

Dr. Ryan Ley - Child and Adolescent psychiatrist - West Hills Hospital: Just to highlight a couple of processes that have been sort of difficult as it has been implemented. The form went from one page to two pages which, you know, whatever. The call piece - I was told specifically on the phone "We will not accept PAs over the phone." What was maddening about that is that I have a colleague who was in the hospital. He got it for somebody on the phone and what they told him was "Well we can do it for you if you are primary care, or if you were calling from a clinic." And I'm thinking, I'm in a psych hospital. This is emergency stuff. I'm cheap and easy and that is the way I approach medicine in terms of the medication I use and probably a lot of people in the room would attest to the fact, if anything, I under medicate. It's been really difficult with the way the process has been unfurled. Kids aren't getting their meds. Two little clinical vignettes. There was a kid who came into the hospital and he was stable on Topamax and things were good. He ran out and the doc that was prescribing the med tried to get it approved. He sent the form, sent the peer reviewed literature, and followed up with a call, and this was over a period of a couple of days, came back denied. The kid had been stable on the meds, but because he couldn't get it filled, and this is a med that isn't expensive, he came back into the hospital. Now we've got another kid that was suicidal, unstable, went to juvenile detention, we didn't change the meds. I didn't change the dose, I didn't change anything. She went to the pharmacy to get the meds and they said "You've

got to do a PA for every single one of these." Now she's in jail, banging her head and she's in a gown. It's a mess. To go back to your point of "Is this a matter of over prescribing", or is it something that reflects the ills of the state? In Nevada, we're terrible, for mental health. We're the worst. We really are. There was a time for a few years when we were the #1 for unemployment, foreclosures, meth, teen pregnancy, I mean you name it. You have all of these social dynamic issues and I think on some level, we just don't have enough in the way of therapy, infrastructure, and support. I don't want to go on ad nauseam, but it has been really difficult, the process. What was interesting about the change is that I used to always call because it's easier for me. I'm in the hospital, it's hard to send a fax, it's hard to send all of this stuff. Never once was I asked on the phone what the diagnosis was. Not a single time. I wasn't one time asked for the ICD-9 code. I haven't had a denial ever, in the last 3-5 years. That's frustrating because if it wasn't on the form when I faxed it, that would be an automatic denial. When we are looking at are processes, it's important to think of what matters. What are we trying to get out of the whole thing? What we are trying to get out of it is if the medication is indicated. I don't have a problem saying why I'm using something. I do have a problem jumping through 10 hoops to get that done. Medicine is already a terrible mistress and this is making it way more needy.

Coleen: So Dr. Ley, we did change the institutional. There should be an institutional transition upon discharge from an institution. We're definitely working on the call in piece of it. That was one of the changes instituted right away, afterwards. It should have been that when a child is discharged from an institution, they are automatically transitioned to the 90 days to allow for that transition, which is concurrent with what we do on all of our other behavioral health drugs so that shouldn't happen any longer for you. That was one of the immediate changes.

CS: I have a question for Coleen about that. I don't work in the retail pharmacy side of things, but how would a patient, if he were to come in a see Dr. Ley on a Friday night, and you make an adjustment, or he does something. And then on a Monday, or whatever day they are released, they go to a pharmacy, how is that pharmacy going to know that? So when they get that rejection at Wal-greens at 10:00 at night downtown for a med, how does that happen?

Jeffery: The pharmacy should be calling. If it's denied for PA and they need to get a PA through, they should dispense a 96-hour override until they can get the override over to-

CS: So who's calling?

Jeffery: The pharmacy should be calling.

Coleen: All of our PAs have an institutional box that they've been discharged from an institution.

CS: Maybe there is a piece of education that needs to go out to these retail pharmacies and these docs because a lot of times, I don't know, I've never done it. I'm a clinical pharmacist that works with docs and I do all of the PAs and I have frustrations that I've been emailing over the same thing that I can't call anymore. I used be able to call and say "This is what I need." and they would say "But it doesn't fall in this category." and I say "The drug isn't in that category." and they say "I don't care." which is what you get. My point is, I'm wondering if part of the processing is also linked to the electronic communication from maybe Wal-greens to Medicaid. And then that pharmacist gets a rejection and just says "Rejected". So now they're left sitting there saying "I can't give out Wal-greens' drugs, or I'll get fired." So I'm just wondering maybe there's some education on that side because I'm hearing that there's a processing problem, maybe at the call center, there's changes that definitely need to be made. Being able to make these simple calls saying this is the difference. This is why I'm looking at this. And we used to be able to do that all of the time. I've done 100s for doctors.

LN: I think part of the issue is that it was rolled out really, really quickly. I didn't hear about it until March 17 or something that it was going to go into effect on April 1. I think just the rolling out piece of it and not letting providers or pharmacies know that this was going to happen, I think that was a mistake. I think that piece of it has really caused a lot of some of the difficulty. We can always tweak things and make them better, but I think when things are done quickly, it kind of brings on a lot of sense of crisis and I think that's part of what this is about.

CS: Is it normal, Carl, for the pharmacist to get a rejection at the point of sale, to pick of the phone and call to say, how would they know to do that?

Jeffery: Well I think they know to do that, but they get that rejection, they look out there and see 10 people who are waiting for their medications and then they don't do it.

CS: Case in point.

Jeffery: It's easier to tell that patient "It's not covered." and send them out the door than to spend even a couple minutes calling to get that override.

CS: But that's what I'm saying. I think there's a lot of pieces here that are out of process and I don't think there are lots of parts here that are trying to deny the use of any one of your folks' drug. Starting at the pharmacy - It rejects to that pharmacist who doesn't know that they can say hey, we know that, at the rehab level. We have pharmacies call all of the time and say you can't refill that. The drug was just filled 5 days ago. It was filled 5 days ago in a long-term care facility and that patient is now a community patient. There's a communication breakdown. These pharmacists don't know that they can pick up the phone and call and say this patient just got out of the hospital.

Dr. Ley - It's a good point about how it could lead to more lag time too because if someone goes to their pharmacy after being discharged from the hospital and they get there at 8:00 at night, they may not call in the first place, but if they do call, they might send a fax to me and half the time they have the wrong fax. I may not get it until a day later and then start that process. Now if I know that they are Medicaid and that's going to be an issue, I'll do it beforehand, but sometimes I don't know and then I'll only know it when they go to the pharmacy.

Coleen: We can do a quick outreach to our pharmacies on the 96-hour fill. We can do institutional discharge. We can do a couple drugs.

ML: With so many issues with inpatient, to outpatient, to neurology that supposed to be exempt, to psychiatry, is there any reason the policy can't be applied the way it was four weeks ago until a certain date? While this didn't go well, so September 1st, we'll go back to this.

????: We did it for 3 years.

ML: Let's get the list ready and let's get all of these issues covered as best that we can so that we can avoid this crisis, address as many issues that we know about and then implement.

PO: That is something that the Board can address. I think we've received very good input from all of you and I do appreciate it, even if you are leaving the state, sorry to see you go, but I value the input that everybody has shared. We obviously recognize that there is an issue with the process and so I think it is up to the Board now to try to decide what we are going to do now to resolve this problem. Whether we go back and say this didn't work, but we've got ideas of rolling out a list that can be utilized by specialist, or the Family Practice people who want to use that list if a patient has been seen one time by a specialist. We should all work together to resolve this.

JM: I'm really puzzled. Was there in fact some sort of process change that prompted this?

Coleen: That back fill process change would be the letter of medical necessity for the 0-5 year-olds. That was an additional form. And the requesting of a citation for off label medication for peer reviewed literature or compendia. The rest of the PA forms is the actual policy put into checkboxes onto the actual PA form.

JM: But there was some sort of internal change.

????: Do you want to see the two forms? I have the two forms right here if you want to see them.

PO: We've got them.

DE: One more thing. This being the age of electronic medical records. I know there are still some issues with them out there. I just saw an article about them in one of the journals, where they are finding out a lot of the medical records aren't talking to each other like they are supposed to be doing. Can't all this information be sent to the call center electronically from the patients' profiles?

Coleen: Yeah, but the Call Center would have to take the phone call.

DE: I've worked in some situations in inpatients and outpatients where, when we had electronic medical records, I could go look at that patient's profile and you could read the reports on the person, read the progress notes, I could find out what was going on and I could answer some of these questions, whereas if we are not taking advantage of some of the electronic stuff, maybe we need to have some of the electronic reports to transfer as opposed to paper.

Coleen: If you wanted to redo what was occurring, you could implement the old PA form. That would be going back to what was occurring. The policy hasn't changed so you could implement the old PA form.

JM: Why could we do that because that really seems to be the root of the problem?

Coleen: You are more than welcome to do whatever the Board chooses to do. You could do the old PA form if you wanted to.

Jeffery: You talked about electronic records. What the call center sees in the claims data, isn't always, and frequently doesn't match what is on the PA form, so the doctor may say they have been on Risperdal and Zyprexa. And they pull it up and they've been on Geodon and Abilify. So something is not matching up and the call center doesn't know what to do with it. Do they send it back to the provider and ask "Did you prescribe these? Are they seeing another doctor who is writing these?" They're seeing all of this information.

Coleen: That is why we're trying to get better information. That is the issue we brought to the Board last time for better PA forms.

DE: Along the same lines. This was medication reconciliation taking place all along. Isn't the medication reconciliation records somewhere crossing the line that someone, a pharmacist, or a doctor, if someone has looked at this medication reconciliation, and that should solve the problem? Yes we've seen all of these, yes we are not using this one because it failed, or something like that because I see a lot of medication reconciliations. By looking at that medication reconciliation, you can figure out what the problem is. Look at all of these medications this person is on, or maybe some of these things should be gone.

Coleen: You mean in claims that we have behind the scenes, or that is on the form?

DE: My question was aren't these medication reconciliations going to the call center, or aren't the physicians' offices having these medication reconciliations to review?

Coleen: That was the biggest feedback received on the new form, was not wanting to put the medications on the form. That was the biggest feedback on the PA form.

DE: How can you evaluate the therapy if you can't evaluate the medications?

Coleen: That was the largest feedback I received, not wanting to write down the medication profiles.

Dr. Ley: Most of the time the patient has no idea. I mean if their taking Oxycodone, they know exactly how much, how many milligrams....

DE: This has been an actual safety goal since 2004, 2005. And there's emphasis on these in the hospital situation where patients are being discharged. You can't discharge a patient without their medication reconciliation. What's happening to that medication reconciliation, is it being done?

Dr. Ley: I think because all of that info comes to us just for the patient, then we write on the form, then the call center gets the form and they say "They were never on this." all we have is what the patient said they were on.

Jeffery: When you see patients and you say "Let's stop the Abilify. We're going to switch you over to Zyprexa, the patient may not understand they need to stop the first one before taking the new one, so that's what the call center is seeing. It really throws them a curve.

Coleen: That's why the new form. The Board came back last time with the new form to ask for the new information and that's what the second page has, the medication profile list.

CS: I'm not sure how it might work for younger patients, but a lot of time what will happen is they will say they are on the medication for 45 days and we will have no proof of that and they will say they were in the hospital. So they're not paying for the drugs like they are when they go to Walgreens. They've been on the drug and stable on the drug for 45 days. They've been in the hospital, now they are going to rehab where they are maybe under medicated, now we're getting a rejection because we haven't tried drug one, two, or three when in fact, it has all gone on in the hospital and they won't see that data. Then when we try to call, they won't see that and they say no, you have to try one, two, and three.

JM: I'd like to move that we temporarily go back to the old PA form, study it until the next meeting and then have everybody come back here. In the meantime, we need all of you guys to collaborate with us and really work out something that

works for you. It seems like the old form was working, at least as well as it was working. We can at least get back to that point and then see if we can come up with something. The motion will be that we go back to the old PA form until such time that it has been investigated and we come with some other criteria that we can propose in time for public notice, prior to the July meeting.

PO: We have a motion.

Seconded.

DF: For the record, Darrell Faircloth, I wanted to ask what you meant by that, just to clarify there were three items mentioned that were part of the policy changes that were implemented April 1st. I don't know if you intended for those to be reversed in their entirety pending additional development. Was it your intent that only the letter of medical necessity be reversed, or the other changes involved?

JM: All of the implemented changes as of April 1st, whatever they were, stay those changes pending investigation and reformulation of those forms.

Voted ayes across the Board.
Motion Carries.

Laurie Squartsoff - I think this conversation has been particularly helpful and it's really important for us as policies are being designed, that we have the conversations to look at and we have the processes in place with public workshops where we can get input from all of the providers, from the experts on the DUR Board, from all of those who are interested in this particular issue because the last thing is that we need to have a community public health issue related to children with mental health issues. Perhaps that is an alternative that we, as the agency, can work with you so that we can have a public forum where people can share their ideas, share their concerns, and can come up and with consensus on how we can continue to move this conversation forward because it's obviously one that's really important for us as a State and one that frankly we have been working on this State for probably longer than 8 years, but one that we need to continue to move the conversation forward, so I offer that form as an opportunity to help everyone who has the best interest of the children at heart, so that we can come up with a policy that we can incrementally work toward.

JM: I would like to bring a point of information up to the pediatric psychiatrists. This is not a closed Board and we are really looking for more participation on it.

Coleen: This was on the agenda last time. The form came up in the agenda last time. That's how it came around because we were discussing this.

JM: So if you guys are here and at the table, it's actually going to help us a lot and you'll feel like you're more a part of the process, which we really welcome also.

Call for 10 minute break.

b. **For Possible Action:** Discussion and possible adoption of policy and delivery model for Vivitrol® (naltrexone)
   i. Public comment - Public Comment – Dr. Perry Olshan, Clinical Psychologist with Ademes as the Medical Science Director. I'm going to cover Vivitrol as quick and as articulate as possible so as not to waste anyone's time. Vivitrol has two indications. One is for alcohol dependence for patients able to abstain from alcohol in outpatient settings. The second is for opioid dependence. It is really indicated for prevention of relapse following opioid detoxification. Treatment with Vivitrol should be part of a comprehensive management program that includes psychosocial support. Opioid dependent patients including those being treated for alcohol dependency should be opioid free for 7 to 10 days prior to Vivitrol administration. Vivitrol is a 280 mg, once monthly extended release formulation of naltrexone administered by intramuscular gluteal injection by a healthcare professional. Naltrexone is an opioid antagonist, which is a blocker, which is the active ingredient in Vivitrol. Unlike buprenorphine or methadone, Vivitrol is not an opioid replacement therapy. It does not maintain physiological opioid dependence. Vivitrol does require opioid detoxification prior to use. In patients physically dependent on opioids, Vivitrol will precipitate acute withdrawal when administered. Vivitrol is also not a controlled substance, unlike methadone which is a control 2 and buprenorphine which is a control 3. It's also not associated with the development of tolerance or dependence. There's no potential for abuse or diversion issues. Unlike methadone buprenorphine. Vivitrol is also not aversive therapy and does not cause a disulferam like reaction either as a result of opioid use or alcohol ingestion. There's no withdrawal syndrome associated with discontinuation of Vivitrol. I'm going to jump into the efficacy for both alcohol and opioids. Vivitrol for alcohol was evaluated in a 24 week, placebo controlled, multicenter, double blind, randomized trial with 624 alcohol dependent outpatients receiving psychosocial support. Subjects treated with Vivitrol demonstrated a greater reduction in days of heavy drinking than those treated with placebo. Efficacy for Vivitrol was evident in the first month and maintained over the entire treatment period. In reference to opioid dependence, Vivitrol was evaluated in 24 week, placebo controlled, multicenter, double blind, randomized trial with 250 detoxified opioid dependent outpatients receiving psychosocial support. The percentage of subjects achieving opioid free weeks was significantly greater in the Vivitrol group compared to the placebo group. Complete abstinence was obtained by 23% of subjects in the placebo group compared with 36% of subjects in the Vivitrol group from week 5 to week 24. I'm going to jump into the pharmacoeconomic data. I'll start with alcohol dependence. Published claims database analysis looked at healthcare utilization and cost associated with treatment of alcohol dependence. In patients treated with oral naltrexone, dysulforam, or Acamprosate and Vivitrol. Results show that patients treated with Vivitrol were associated with fewer inpatient detoxification days compared to all other groups. Fewer alcoholism related inpatient days compared to patients receiving dysulforam or Acamprosate and an increase in an outpatient

substance abuse visits compared to all groups. An economic analysis has been completed assessing the retrospective cost for alcohol dependent, commercially insured patients treated with Vivitrol or naltrexone, Acamprosate, or disulfiram. This was from 2006 to 2009. Vivitrol was significantly more cost effective than all 3 oral medications across patient hospital cost parameters. Underpinning this cost effectiveness was longer persistence with therapy among Vivitrol treated patients as compared to other groups and a corresponding pattern of lower rates of admission to inpatient services. I'll touch on the opioid dependence pharmaeconomic data. A 6 month retrospective study of insurance claims assessing total healthcare costs in patients treated with Vivitrol, naltrexone, buprenorphine, and methadone. The results show the total costs per patient was significantly lower in those using Vivitrol compared to methadone and no more expensive than buprenorphine or oral naltrexone due in large part to the fact that patients treated with Vivitrol had fewer inpatient admissions compared to all other groups. Adverse events include: more than 1,100 patients received Vivitrol in preapproved trials. Approximately 700 patients for 6 months, 400 patients for less than one year. The most common adverse events for alcohol dependence included nausea, vomiting, injection site reactions, muscle cramps, dizziness, fatigue, anorexia. In controlled trials, less than 6 months, 9% of patients discontinued Vivitrol due to adverse events compared to 7% with placebo. Jumping to safety information, after opioid detoxification, patients are likely to have reduced tolerance to opioids. Use of opioids after Vivitrol is discontinued, at the end of a dose interval, or missing a dose could result in life threatening opioid detoxification. Attempts to overcome the opioid blockade while on Vivitrol may result in a fatal overdose. Some people on Vivitrol treatment have had severe reactions at the site of injection which I touched on earlier including tissue death. Some of these injection site reactions require surgery.

Coleen: Did you cover the temperature issue?

Olshan: The temperature issue on label indicates the ideal is 46-77 degrees, refrigerated, however it can be outside the refrigerator for 7 days as long as it's not going over the 77 degree heat. Basically the technology is in the microsphere is if it gets hot, it expands, it's already going to.

PO: My question is that you said there was a significant difference in the opioid patients, however, it looks like only 36% of patients remained opioid free. That's a very low number.

JM: Actually if you compare it to buprenorphine therapy where only 6% remained opioid free, it's pretty good.

Olshan: 23% in the placebo group compared to 36% from week 5 to week 24. There’s a study that goes farther out that would show that difference continues. Obviously people who are on Vivitrol are staying on it longer than 3 months.

No other public comment.

Coleen: The Division has asked that this be brought forward to the DUR Board because there is a lot of legislation this year regarding controlled substances and actually this was one of the topics -antagonists - What has happened is because there is so much attention, we already have requests coming in as far as coverage. For us it wasn't a matter of whether we are covering the drug, or whether we are not covering the drug, what the reimbursement was, or anything like that, but when we started receiving the calls, we didn't have policy on it. We didn't have policy as far as how we would cover the drug, what the delivery model was, would it be in an outpatient hospital setting, would it be in a retail pharmacy, would it be in a specialty pharmacy? We didn't have anywhere to point for policy on this. The manufactures were very helpful. We started reaching out and trying to figure out what was going on and what was most safe and effective for the product. That's how I knew the temperature issue. Mary did some research also. Obviously population could be an issue for us, and so we brought it forward to you guys because we need a policy to point to because there is a lot of attention already. It's not a matter for us on whether we are going to cover it or not. We know we want to cover it. We just needed to know. There are some ideas some states are doing through specialty pharmacy. We weren't looking at mandating a buy-in bill. We're not worried about what we call a buy-in bill in our state because everybody comes through an NDC program in billing. So we don't have to worry about duplicate billing in our state. There may be some issues. We don't know that we want to turn it over to a patient to have a patient walking around with it. So do we want to from the pharmacy to the prescriber? Then we have the idea of having the clinics within the pharmacy, or right next door to the pharmacy and how that works. It could be one of those issues where we have to know if they have a specific diagnosis and to let it go through on the claim on that diagnosis. Those types of issues. We just bring it over to you guys because we need a policy to point to because it's already starting to come into our offices.

DE: So basically we are going to follow the guidelines on the attached buprenorphine?

Jeffery: I just included those in there for reference for the buprenorphine. I think what Coleen talked about was maybe limiting it to either specialty pharmacies because right now I've got the utilization date in there. These are all outpatient pharmacies. Not a single one of these claims is billed through a doctor's office.

Coleen: I'm up for suggestions. I just need a policy right now to point to honestly. We had to do research for a patient as to where to find it. It's already coming in through some of the drug ports in our state. They're being referred and we had to do some research as to where. It will be prescribed in a physician's office, or in an outpatient hospital. We have utilization that Carl did run. Carl did you find the utilization?

Jeffery: Yeah. It's in there. We have between 1 and 7 claims per month. It's not a huge utilization yet, but I think it may pick up.

JM: I think the real critical issue on this is not so much the physical properties, but you're dealing with a patient population that is not terribly reliable, and there's opportunity for diversion, so a patient could actually pick up a prescription, give it to somebody else who wants to get clean, not take it, continue with their old ways, and there are ways of verifying compliance with that. It can be tested for in the urine. I think it would be a bad idea to have a retail pharmacy sort of environment. I think this needs to be specialty pharmacy 2 prescriber/injector. That would be the only way I would be comfortable with the criteria for this. There might be some rare exclusion, but to have a patient carry this out with them is just a bad policy. And certainly in Las Vegas, the physical considerations, half the year it's never 77 degrees for 6 months of the year, so it would be subject to outside its normal storage range anyway. This is a valuable product and it should be available. We may also want to include some sort of verification, so that there be some sort of periodic urine testing so that we can verify that the patient is actually using it and actually getting it.

PO: I looked at some of the other states and what they are doing and they are utilizing specialty pharmacy and maybe we could consider maybe the patient has failed on oral Naltraxone, 30 day trial, to see if they are really planning on getting clean. If they have failed that, there is an injection product that can be sent from the specialty pharmacy to the practitioner, who would administer it in an IM injection (they're usually not going to be doing that on their own at home, hopefully) and how often are they using it?

Olshan: Once a month.

PO: Right but is it continuous. Or is it after 3 month course?

Olshan: I think that would be a decision they would make with their healthcare provider.

JM: Is there any PI indication, for example, on some of the buprenorphine products, there's a 6 month recommended and no recommendation to taper.

Olshan: We've got PIs that we've done 3 and 6 months, but our company isn't recommending, again that's with utilization and psychosocial treatment and a healthcare provider. I think that's a discussion you have going into it. It is an injection. It's going to be in your system for a month. You want to have that conversation on the front end.

Coleen: What if you have a physician that is willing to carry that product vs. willing to have a specialty pharmacy ship to them.

DE: How do you monitor that now?

Coleen: We allow for it because we don't have to worry about duplicate billing because they're both billing through the same...I just don't know that we want to mandate it coming through a specialty pharmacy because of access.

Jeffery: I think our intent was to make sure it is administered at the correct place, by the correct person, and the storage is appropriate, so I think either a physician's office, if they're going to buy it and administer and bill for it, that would be fine. Or if there is some way to coordinate the delivery from the pharmacy, keeping it temperature controlled, directly to the prescriber who is going to keep it temperature controlled.

Olshan: I want to address, if you move to a fail first policy, I think you'll be dealing with a population who that in itself, that policy with addicts in general, is a really slippery slope, where if you're looking at the antipsychotics and those types of things, it's a little different. There's a neurophysiology prospective that we're looking at that's already been hijacked. They're coming into the office, their executive functioning is all over the place and just to put that demand on top of them, when they are seeking help, you're going to wind up with a lot more people failing on Vivitrol, rather than just starting there and getting on with their lives and working on what they need to.

Coleen: The one thing we do have is according to SB-459, the Good Samaritan act.

Audience: It's related to naloxone.

Olshan: Not naltrexone.

MO: You have to be withdrawn from...you have to have the opioid.

Olshan: 7-10 days opioid free. There's definitely a washout date in there. You can give a challenge - .25 of oral and you'll know if someone has been using or not. It's going to precipitate withdrawal, but you'll see it in your office which no one really wants to see, but at least you'll know if the patient has been using. Safety is the key here. That's what we're shooting for. You could do a urine test, but if you've got the patient right in front of you, you could do the naloxone challenge.

BS: So if you allow this to be in a physician's office, would you limit the type of physician? Because I know, especially with suboxone and things like that, you have a lot of physicians who are taking advantage and having a suboxone type clinic.

Olshan: You don't have to have any special training to write this script.

BS: That's what I'm saying. Are you going to be able to have any doctor be allowed to administer it? It doesn't matter?

JZ: Does it come in a single dose?

Olshan: Yes. 380mg. Theoretically you could use half of it.
MO: Where do you get the challenge? That's part of the dose? You're just going to give them a little sublingual?

Olshan: You can give an oral challenge, cut it in half, or quarter?

MO: And that's an immediate response?

Olshan: I wouldn't say immediate. I would say in 45 to 60 minutes. You could always do an oral lead in. Someone takes it home. If a patient walks into your office and you have a good history of what they are doing, there's a relationship there. There are definitely precautions you can take before giving the injections. Being conservative is always on the safe side, especially this.

DE: Considering all of the other concerns about how it's difficult for practitioners to get the patients med list, let alone how long they've been off of it, especially if this person has been on opioids. So you're saying that this person has to be off of it for 7-10 days and who are you going to believe that they are telling you that?

Olshan: That's why you give a challenge, a naloxone challenge, or you could do a urine test.

DE: With a urine test, if they've been off of it for 7-10 days, they could still have a positive for opioids, so that wouldn't do it. So basically you're saying you would have to see an opioid withdrawal reaction in the office to know that they still haven't been off the opioids for long enough and tell them to come back in 7-10 days and we'll give them an injection.

Olshan: Right.

DE: So in 7-10 days are you going to go out and get more opioids probably in the meantime. So we really have to have a motivated patient to be able to use this.

Olshan: Or a good support system.

DE: Which is probably what they don't have and why they are using the drugs anyway.

Olshan: There's all kinds of variables you could look at. If someone is coming out of a treatment facility and are maybe detoxed.

JM: There is also a Clinical Opioid Withdrawal Scale (COWS) you could actually use which will give you some indication. Obviously if they are seven days out, I'm

not sure how positive your COWS is going to be, but generally dealing with a lot of these opioid addicted patients, they're pretty savvy and pretty honest, particularly my patients because they are all paying me cash, so they are all very motivated to get clean. You don't have the same motivation in a Medicaid patient. He may be there because of a court order. It's a totally different environment.

Olshan: I think in those individuals, some of the criminal justice populations are getting the injections prior to discharge/release. And then they are being referred to a provider with the Vivitrol already on board.

PO: Do we want to put this under a Prior Authorization criteria that the indication is that it meets the FDA indications, can be obtained from specialty pharmacy to a provider, or a provider can get it directly from a prescriber.

JM: It's also used off label for some other addictions like gambling and things like that.

PO: Do you have any proposed criteria?

Jeffery: I don't have anything documented to propose, but I think the criteria I would propose would be an FDA approved indication. It is dispensed by a pharmacy that is capable of delivering it to the prescriber's office in a temperature controlled means.

PO: Administered by a prescriber.

Jeffery: Or a practitioner.

Coleen: It's a direct delivery to the prescriber.

MG: So it's a physician administered drug, basically.

Jeffery: Yes and then then physician is going to give that and the physician would also be able to bill that. The prescriber's office would also be able to bill, but me personally, I don't think I would put restrictions on it beyond that because when you are looking at rural Nevada, I don't think you have the access to the specialists that are going to need this on a routine basis.

DE: Also thinking along that same lines, in Nevada, pharmacists can administer medications if it's within scope of practice and their training. In a rural area, you might want that patient to come in, if it's a once a month dose, it can be administered at that pharmacy if the pharmacy has the capability of either doing the administration, since they can administer vaccines and other things. They can go through some training to learn how to do this IM, or witness the patient giving themselves the IM injection before they go.

Olshan: I don't see a patient giving themselves the injection.

JM: It has to be given properly. You can't treat it like you're taking some insulin or something.

DE: Maybe we wouldn't necessarily want it to come out of a specialty pharmacy, but it could be dispensed out of a pharmacy, but the pharmacy individuals have to be able to do the administration.

Jeffery: If the pharmacy has to deliver to the point of administration, it's going to be from a practitioner. I think that leaves it open. So if a pharmacist does have that collaborative practice agreement.

DE: There are exceptions in rural areas. There might be some...

BS: I think there is huge opportunity, but I don't think....

Jeffery: If we leave the door open, we don't have to come back in 6 months...

Coleen: If we write it to where a healthcare practitioner has to deliver the medication - As long as we write it so that it's not being delivered to a patient.

JM: I don't see a pharmacist doing a naloxone challenge.

Jeffery: Once they are established and they are coming back for their follow up shots...

Coleen: So I think that is the question. Is that step being requested, to do the challenge?

Olshan: That is our on label.

Coleen: That's on label.

JM: That's on label, yeah.

Coleen: So then the diagnosis is on label also.

MG: If a pharmacist does it, how does the pharmacist know...?

Jeffery: That would be on the prescriber who is writing the prescription for the Vivitrol. They would be the ones who would identify that this patient is opioid free for 7-10 days.

JM: And is a candidate for it. Ok.

PO: So what do we have proposed? Meets FDA guidelines. They've been challenged and that it's administered by the prescriber. If we leave it at that, we're good.

JM: So we're not specifying how it gets delivered to the prescriber, so the patient could potentially pick it up and deliver it to the prescriber? Is that what you're saying?

PO: No. We need to add that. We need a motion.

Audience: Can I take a moment to speak about the drug being administered by the prescriber?

Board: Sure.

????: My name is (inaudible) and I work with Ademes with the Policy and Government Affairs team. We have been doing some work in the state which might be why you've heard about the drug court issues and the like. But also why you see so few prescriptions. This is medication that nobody will be rushing and knocking down doors to get, I can assure you. There won't be people running out and saying "Please let me have your Vivitrol! I want to get clean!" It's usually the other way, as you've mentioned. Looking at what's happening nationwide, we're seeing PAs being removed, not added. Why? Because of the opioid epidemic. In fact, the opioid epidemic has caused SAMHSA to release a grant which they released at the end of March and they listed 18 states that had a huge increase in their opioid epidemic and Nevada was on that list. In fact they are encouraging Nevada to apply for that grant to increase the availability of all medications to treat addiction. There aren't many. There are maybe 7 or 8 at the most. Adding a PA to a medication that has little use that is hard to get a patient to a willing stage and to get them prepared to be opioid free, often that is happening behind the walls of the jails and prisons. We've been talking to the Director of Corrections. We've been talking to the jail in Las Vegas. We're having these discussions because they are dealing with these patients. The other part is, most states, and I've done a lot of work in California, the provider often isn't the person who gives the injection. A medical assistant, a nurse, maybe a PA, it's very hard to find to physicians who actually have a specialty in addiction medicine. It's very hard to find treatment centers that have physicians. Treatment is often the behavioral health level and it's at the cognitive treatment level. There isn't a lot of medication in treatment. There isn't a lot of medication associated with it. Just like we had with our other issue recently. We don't have a lot of doctors with that specialty. We may be adding another layer of complexity by insisting that the physician be the one to administer the injection.

PO: Maybe we can phrase it "The physician's office", that was not my intent. To your comment about not having a Prior Authorization and that being a blockage, I tend to disagree with you there. I think it gives us a little bit of control, the same as we have PA for other meds that are used for addictive behaviors.

????: This is not an addictive medication, however, and many of those other medications, methadone and suboxone, do have and addictive quality. This is the opposite. They're agonist, or partial agonist, and this is an antagonist.

PO: I understand what you're saying, but don't push your envelope too hard. Anybody have any questions? So we need a motion.

JM: I vote that we adopt the PA for Vivitrol based upon the patient meeting the criteria of FDA indicated indications that the product be delivered to the prescriber's office and that the FDA indicated Naloxone challenge be given prior to the injection of the Vivitrol.

Coleen: So for verification, really what we are doing, the PA would be based upon, is the challenge being successful.

JM: I think you want to follow up the challenge right away, so you can specify that the challenge be given prior to the time of the injection.

Coleen: I'm trying to see what the actual clinical criteria would be for the prior authorization. It would be that there was a challenge and that the diagnosis are appropriate.

Jeffery: And now it's going to be enforced because once the PA is approved and in there, any pharmacy will be able to afford it. Enforcing it is going to be a challenge. It's going to be the word of the prescriber, and we can assign it to one pharmacy if we need to.

Coleen: We'll figure it out. I just want to make sure we have the clinical criteria, what the authorization was for, for the challenge.

JM: Do we need a second on that?

PO: I've got a question before we do that. On your amendment, do we want to indicate how long the PA will be good for? How many months?

JM: I would say 6 month prior authorization.

PO: Do we have a second.

DE: Second.

PO: We have a motion and a second for the approval of the prior authorization for naltrexone with the 5 criteria being used for FDA indicated indication, the challenge will be given, delivered directly to the prescriber's office, to be used once per month, and the PA is good for 6 months. Any further discussion?

Voted: Ayes Across the Board.

Motion Carries.

c. **For Possible Action:** Discussion and proposed adoption of prior of clinical prior authorization criteria for Ombitasvir/paritaprevir/ritonavir and dasabuvir (Viekira Pak®).
   i. Public comment on proposed clinical prior authorization criteria.
   Chris Ultzer - Pharmacist - Medical Affairs with AbbVie - Viekira Pak, with or without ribavirin is approved with dosing recommendations for treatment of patients with genotype 1 chronic hepatitis C infection, including those with compensated cirrhosis, HCD HIV co-infection, and liver transplant recipients. Viekira Pak is not recommended for use in patients with decompensated liver disease. Viekira Pak does not require adjustments in patients with mild, moderate, or severe renal impairment. For patients that require ribavirin, further ribavirin prescribing information is available for your information regarding the use for patients with renal impairment. Additionally Viekira Pak can be administered with proton pump inhibiters, such as Omeprazole without directly affecting the direct acting antiviral. In patients with compensated cirrhosis, Viekira Pak is administered with ribavirin. SVR rates were between 92 and 100% in genotype 1A and 1B respectively. Genotype 1B cirrhotic patients required treatment duration of 12 weeks with ribavirin. The dosing duration for genotype 1A cirrhotic patients is 24 weeks, however, 12 weeks may be considered for some patients based on prior treatment history. In patients with HIV co-infection, the recommended treatment duration follows the genotype 1 mono-infected patients. SVR rates were 91 -100% for genotype 1A and 1B patients respectively. Viekira Pak is contraindicated with efavirenz, but not with tenofovir. Any HCV/HIV 1 co-infected patients treated with Viekira Pak should also be on suppressive antiviral drug regimens to reduce the risk of HIV 1 pro use inhibitor drug resistance as a result of the paritaprevir component of Viekira Pak. All direct acting antivirals have drug interactions and these should be assessed before starting therapy per the AASLD guidelines. In open label clinical trials, 99%, or 526 out of 571 of those who achieved an SVR 12 maintained the response for 48 weeks post treatment, or an SVR 48 demonstrating durability of response. In clinical trials, less than 1% of subjects treated with ribavirin had hemoglobin levels decrease to less than 8 grams per deciliter, which is a grade 3. Seven per cent, 101 out of 1,551 patients, of subjects across the phase 3 program underwent ribavirin dose reduction due to decreases in hemoglobin. But of these, 98% achieved an SVR 12. Additionally, a low viralogic failure rate at 2% was observed in clinical trials and the Viekira Pak discontinuation rate due to adverse events was less than 1%. In subjects receiving Viekira Pak with ribavirin, the most commonly reported adverse events, greater than 10% of subjects, were fatigue, nausea, pruritus, insomnia, asthenia, and other skin reactions. In subjects receiving Viekira Pak without ribavirin, the most commonly reported adverse reactions greater than 5% of subjects, were nausea, pruritus, and insomnia. Comprehensive safety and efficacy data for Viekira Pak can be found at rxabbvie.com. If Viekira

Pak is administered with ribavirin, the warnings and cautions for ribavirin do apply. In summary, I am requesting the Board to take this information under consideration as you decide on the PA criteria for Viekira Pak with further consideration of the following points. High SVR rates in genotype 1, naive in treating inexperienced patients, flexibility and duration in treatment of cirrhotic patients, approved dosing in HIV co-infected patients, flexibility in treating patients with mild, moderate, or severe renal impairment, approved dosing of liver transplant patients, and lastly the ability to use concomitantly with patients on Omeprazole, up to 40mg.

Jeffery: Chris, did you get a chance to look at our proposed criteria?

Ultzer: I did actually looked for them, but I did not see them.

Jeffery: Ok.

DE: I was wondering this too, because I was wondering if you had any, because as you were going through your presentation, I think we've covered all the bases on this.

Ultzer: What this testimony, and it's a very scripted testimony, if you haven't figured it out, what it emphasized is really the areas of differentiation. If the previous topic was complex and initiated a lot of debate, this one is obviously very complex and initiates a lot of debate, so we tried to narrow it down to just areas of differentiation.

Jeffery: I think it follows the AASLD guidelines.

PO: We've got in front of us, a proposed PA criteria and Chris, I think you're looking at it right now. In the meantime, does anybody have any questions on this proposal?

Jeffery: It's just a high level overview - It's just another very effective hep-C treatment. I think we wanted to make sure it was getting to the right patient is the point here. So far we've had two claims for it. Right now it's still stopping for PA because it's non-preferred, but the P&T voted to make it preferred at the last meeting. The next time the PDL is updated, it will be preferred.

DE: I'll move to accept the PA criteria.

JM: Second.

PO: Ok, we have a motion and a second to accept the proposed PA criteria for Viekira Pak, any further discussion? Seeing none.

Voted: Ayes across the Board.

Motion carries.

d. **For Possible Action:** Discussion and proposed adoption of prior authorization criteria for Sodium oxybate (Xyrem®)
   i. Public Comment on proposed clinical prior authorization criteria.
   Jill Gardner - Jazz Pharmaceuticals- Medical Scientist and Internist by training - I'm going to take few minutes to go over the indications, warnings, mechanisms of sodium oxybate, as you've already said, known as Xyrem. Sodium oxybate is the sodium salt of GHB and we'll talk about that later. It is indicated for the treatment of narcolepsy for the symptom of cataplexy. Cataplexy is the spontaneous loss of muscle tone. It can be lasting a few seconds to several minutes. The patient is conscious, usually has shallow breathing, but is paralyzed and cannot move. I did say it can be complete, so they could fall to the ground, or partial it could be just the nod of the head. That's the most debilitating aspect of this disorder and then there is the excessive daytime sleepiness, or EDS. This is sleepiness to the extent that is so profound that it's throughout the day and yes there is the possibility of taking naps that could be partially restorative, but within minutes, you have this profound sleepiness again. Sodium oxybate is considered a standard of care by the American Academy of Sleep Medicine. It is the only FDA approved drug for cataplexy in narcolepsy. There are currently 12,000 patients on sodium oxybate in the US. That is in comparison to the 50,000 that are diagnosed with the disorder and another 150,000 that are undiagnosed. It is an orphaned disease because of its prevalence is 0.05. The efficacy study shows that 69% reduction was found in cataplexy over 4 weeks and excessive daytime sleepiness reduction occurred over 8 weeks. A person with narcolepsy is characterized with sleepy/wake instability they're sleepy during the day and paradoxically they have the inability to sleep at night. We call that disruptive nighttime sleep, or DNS. The evidence suggests that there is an autoimmune destruction of certain neurological cells of the brain and that is what causes this inability to maintain wakefulness in the daytime and difficulty sleeping at night. Sodium oxybate, as you are aware, is a schedule 3 drug, so it has moderate to low abuse potential. The FDA recommendation, but it was a requirement too, that it be distributed through a central pharmacy, so there is only one pharmacy and that allows us to control its distribution, its misuse, abuse, and aversion. Historical rates of diversion have been very low, less than 0.001%. There are reports of illicit use of GHB, the illicit form of GHB. These were mostly reports back in the 80's and 90's. Those reports were doses between 18 grams and 250 grams. The maximum therapeutic dose of sodium oxybate is 9 grams. Before a healthcare practitioner can prescribe, they must be educated on the compound, indications, contraindications, side effects, dose administration. They must also check a box and attest to the fact that they have also counseled the patient. We are currently providing a 24-hour on call pharmacist at the central pharmacy and we are working on a new platform. It's a nurse case manager model in which we want a single point of contact for patients where we can do the monitoring, looking at compliance, or adherence, looking at dose changes and things like that. sodium oxybate is a CNS depressant. It has rapid sedation. It can cause clinically significant respiratory depression. It is associated with CNS adverse reactions, such as seizure, coma, and death. The most common side effects, however, are nausea and dizziness. It is contraindicated in combination

with other sedative hypnotics. It is contraindicated with alcohol. A recent study also suggests a 20% dose reduction with Depakote. We found out that it increased levels with sodium oxybate. The dose increments are at 1.5 grams, starting at 3 grams, going to 4.5, 6, 7.5, and 9 grams is the maximum therapy dose. We have patients at all the dose ranges. They are not necessarily at 9, or 6. The dose is split nightly, so you take half when you go to bed, in bed, and then you would wake up 2.5 to 4 hours and then they would take the second dose also in bed. Lastly, I wanted to talk about the mechanism of action, which is hypothetical. We have some evidence, but because it's not complete, I must say it's hypothetical. We believe that the therapeutic effects that we see the benefits for, resolving the cataplexy and reducing the excessive daytime sleepiness, is through the actions of dopamine, which by helping the patient to sleep and sedating the patient, they reduce their release of dopamine. That allows them to have higher levels of dopamine during the day and dopamine is the primary alerting nerve transmitter during the day. When you look at how stimulants, which are alerting agents, they help individuals with excessive sleepiness, they work on the dopamine transporter where they inhibit the reuptake and that keeps circling levels of dopamine to help the patient stay alert during the day. We often see sodium oxybate patients on that agent along with stimulants. It is a common therapy combination. However, stimulants are not indicated for treatment of cataplexy, but sodium oxybate is.

Jeffery: Do you see it prescribed by anybody other than a sleep specialist, or a neurologist?

Gardner: No. But I need to clarify, a sleep specialist because of the way Board certifications go can be in the specialty of neurology, pulmonology, psychiatry.

JM: I noticed that you didn't mention anything about an MSLT to verify the condition. Is that part of your PI, or anything?

Gardner: Yes. That's a whole other discussion, the diagnostic criteria. That has been propagated by the sleep medicine academy and those are very clear and you can refer to those - The ICSD3.

JM: Should we require that they have an MSLT to verify the diagnosis?

Coleen: Is that in your indication?

Gardner: The criteria gives you several ways to diagnose. You can diagnose by a spinal tap and getting CSF fluid to measure the low cells. That's really only done in research by Stanford and other centers of excellence. The other is a clinical diagnosis of the signs and symptoms, but the recommendations is like to have one objective measure and that objective measure could be a PSG, where you see a short REM latency within the first 15 minutes, or you could go ahead and do an MSLT. Usually you do a PSG and an MSLT. MSLTs are expensive and so the academy is

going away towards one objective test as opposed to two. There's evidence of where you could require both, but some only require the PSG.

PO: The other narcolepsy agents are not indicated for cataplexy, correct?

Gardner: Right. This is the only agent so far.

PO: Is Xyrem indicated for narcolepsy also?

Gardner: Yes. Specific to those two symptoms. Cataplexy and EDS. There are three other symptoms, but I don't believe there are other agents that are indicated for the, there are 5 symptoms it's a pentad. It's certain dreams that are very violent in thought and it causes you to be awakened and frightened, sleep paralysis, and disruptive nighttime sleep. We know it's associated, but there are no drugs that are specifically indicated for that.

JM: This certainly doesn't seem like it would be a first time drug for EDS for excessive daytime sleepiness, so I think that should be some sort of criteria in there as...

Gardner: What we see in practice is that it is definitely a drug of choice for cataplexy. Cataplexy is so profound. Cataplexy is triggered by emotions and it is often humor. So these patients end up living with a very flat affect because if they laugh, they could go into cataplexy.

JM: It seems to me that the dopamine receptor is screwed up and that's where the CMT fits into that.

Gardner: And we think that is the key and we are researching that.

Jonathan Willfield - Jazz Pharmaceuticals - The only thing I would say about the MSLT is that typically when a patient goes in for a PSG and then they go through and they have some sort of diagnosis, if they suspect after that PSG that possibly the patient has narcolepsy, then the sleep specialist would want to see an MSLT after. Which then you would have to go in for a PSG again and then an MSLT and that is very exhaustive and very challenging for a schedule and it's expensive.

DE: Have either of you see the prior auth criteria?

Willfield: I have not.

DE: What do we have so far, Carl?

Jeffery: Right now coverage and limitations say, and we also include the Provigil and Nuvigil in here for the treatment. It says authorization will be given for following criteria: Used for an FDA approved indication and the request for sodium

oxybate one of the following: 1. The request is submitted by a neurologist or sleep specialist, or there's documentation that the recipient has had consultation with a neurologist or a sleep specialist. Then it would be approved for one year. If they are treating for narcolepsy, maybe we should have some kind of step through Provigil, or Nuvigil before moving on to this one. Because this certainly isn't first line for general narcolepsy.

DE: This doesn't make any mention of cataplexy.

Jeffery: It would be an approved indication.

PO: So what you're proposing is the coverage and limitations would indicate that the use would be for cataplexy or narcolepsy if failed either armodafinil, or modafinil.

Jeffery: Correct.

MG: Clarification: You have here the agents for narcolepsy are the Provigil and the Nuvigil and then down below it says authorization will be given if the criteria are met requests for sodium on one of the following. Does that mean there is criteria for one of them and not all of them, or are they all...

Jeffery: If the request was for Provigil, they would only need the FDA approved indication.

MG: So should we even take them out, because that is true for every drug.

Jeffery: So why don't we document or submit that indication to the call center or on the claim form.

DE: As I read this and understand this, if we're treating for narcolepsy, we can use any of these. So is Nuvigil or Provigil to be used before we use Xyrem, or would Xyrem be used with all of these whenever we are treating narcolepsy.

PO: For narcolepsy, you have to fail the first two.

Gardner: I failed to mention that 70% of narcoleptics have varying degrees of cataplexy. The stimulants help to treat excessive sleepiness, but they don't treat the cataplexy.

DE: That's what I gathered from your presentation. If they have narcolepsy, we can use these first two products. Your product is more selective in the fact that if they have narcolepsy and cataplexy, this is the one to go with. Even if it's in conjunction with the other one. We wouldn't want to put Nuvigil and Provigil on someone with narcolepsy and cataplexy, but we could have Nuvigil, Provigil, and Xyrem if they have cataplexy and/or if the narcolepsy is not effectively with the awakening agent.

Gardner: Yes. The stimulants help to keep the person awake, the Xyrem helps to resolve the cataplexy which is absolutely essential to restoring a normal life. Some patients, 30%, are able to be on Xyrem alone because it does treat the EDS and, but in 80% of our studies most of them are on a combination.

MO: Quick question, in the cataplexy in narcolepsy, when you say that in this trial where they were withdrawn from the sodium oxybate and they experienced significant increase in cataplexy attacks, that's back to their baseline, right.

Gardner: Yes. That's to show the rebound that in fact the treatment was durable. So we withdrew it to prove that symptoms would return.

MO: And they just went back to base.

Gardner: Yes. They didn't increase.

PO: Can we get a motion to approve the prior authorization for these agents?

Willworth: Xyrem does have an indication for use with narcolepsy type 2 without cataplexy for excessive daytime sleepiness, with or without induction with an awakening agent.

CS: I think we're trying to use Nuvigil or Provigil for narcolepsy alone. If they fail that, they can have Xyrem, or if they have narcolepsy with cataplexy, then they can have Xyrem regardless. That's my motion.

JM: Seconded.

PO: We have the motion and the second. Further discussion? None. All those in favor of the revised proposed prior authorization criteria for narcolepsy agents, say Aye.

Voted Ayes across the Board.

Motion carries.

e. **For Possible Action:** Discussion and proposed adoption of updated clinical prior authorization criteria for Omalizumab (Xolair®).
   i. Public comment on proposed clinical prior authorization criteria. – None.

Jeffery: One of the reasons we brought this back to the Board is to include the allergists and the immunologists and we had some people upset with us because we left them out. I think we wanted to include some other ones into that. Add the allergists and the immunologists because I think we only had pulmonologist for the asthma and we had dermatologists and rheumatologists for the chronic uticaria. We

wanted to add the allergists and immunologists too. Also we added the dosage chart that follows the FDA indications.

PO: Any discussion? Can I get a motion to approve the proposed updated prior authorization criteria for Xolair?

DE: So moved.

PO: Second?

DE: Seconded.
PO: We've got a motion and a second. Any further discussion?

PO: Call for the vote. All those in favor say Aye.

Ayes across the Board.

Motion Carries.

f. **For Possible Action:** Discussion and proposed adoption of prior authorization criteria for Naproxen/esomeprazole magnesium (Vimovo®)
   i. Public Comment on proposed clinical prior authorization criteria. Sal Fofaso: I represent the company, but have no comment. Just need to know the PA criteria for the Vimovo and Rayos. I represent both companies.

   Jeffery: Vimovo specifically is a combination naproxen and esmeprazole and as you know both products are available separately. We proposed the criteria similar to the Duexis a couple of meetings ago. We proposed the criteria that it's for an FDA approved indication, have tried both agents independently before moving to the combination agent. The proposed criteria in here, we also include arthrotec as well. We've updated those.

   JM: Why are we including Arthrotec in here?

   Jeffery: It's just another combination. To treat everything fairly, there is another combination. But we can strike that if you don't see it as appropriate.

   JM: Well it's in a totally different class drug as a secondary agent.

   PO: The misoprostol cannot get over the counter. The others are all over the counter.

   Jeffery: We can certainly strike that, if that is how you feel.

   PO: Anybody wish to make a motion?

DE: So moved.

PO: We have a motion to approve the prior authorization criteria as presented with the removal of the Arthrotec products and their quantity limitations also. We have that motion.

PO: We have a second?

JM: Second.

PO: Any further discussion?

JM: I think there is a solution in search of a problem. I don't see this at as all being any real...you're taking two ten dollar drugs and making them $1,000s. I don't understand why we have to have these in the formulary. I mean we have to have them in the formulary, but why do we have to approve it?

CS: But you're saying we're approving this if they have failed the individual agents. How does that happen? If they fail them, how are they going to do with them together? Are they just not purchasing them? Both of these drugs are available generically, over the counter. It's an FDA approved product.

Lawrence: As long as the manufacturer is participating in the drug rebate program, and is an FDA approved drug and is not part of our excluded categories such as weight loss, cosmetic, those types of things, we do have to make them available. Now, you do have choices, so if there appropriate clinical step therapy, not based upon cost, but if there are step therapy items that you would like to do, clinically, you could do something to that effect.

JM: If they failed either one of the components, then they probably are not appropriate to take the combination. It defies logic.

PO: We do have a motion and a second.

PO: So one way or another, this drug has to be on there.

Lawrence: We can research what some other states are doing on that too, from a criteria prospective.

PO: Next time we'll look at that in the meantime, we have a motion and a second. All those in favor in passing this as it is presented with the deletion of one element, say Aye.

Ayes: 4

Nays: 2

Motion Passes.

g. **For Possible Action:** Discussion and proposed adoption of updated clinical prior authorization criteria for Hydrocodone extended release (Zohydro ER®).

Public comment on proposed clinical prior authorization criteria. Dr. Harold Gould - Director of Medical Affairs at Zogenix which manufactures and markets Zohydro ER, hydrocodone bitartrate, extended release capsules. We propose to remove the 5 dose per month quantity limit for Zohydro ER and propose that the non-preferred formulary status quantity limit for Zohydro ER be 60 capsules for 10, 15, 20, 30, 40, and 50 mg with a step through the preferred extended release analgesics, or immediate release hydrocodone for patients with a diagnosis of chronic pain taking hydrocodone for at least 90 days. Like all other extended release, long acting opioids, Zohydro ER is a schedule 2 opioid indicated for the management of pain severe enough to require daily, around the clock, long term opioid treatment for which alternative treatment options are inadequate. Zohydro ER is the first single entity hydrocodone containing product which was intended to fill an unmet medical need for the estimated 2.4 million Americans currently taking hydrocodone combination products such as Vicodin chronically to manage their chronic pain. Because these products contain acetaminophen, patients who are taking them chronically are at risk of developing acetaminophen induced liver injury, which often times results in death, or a need for a liver transplant. Approximately 2/3 of all unintentional, non-suicide acetaminophen overdoses in the US occurred in patients taking immediate release hydrocodone combination products. Further these products require patients to take doses 4-6 times per day, resulting in multiple peaks and troughs in blood levels of medication resulting in suboptimal pain control and the need to wake up in the middle of the night to take their medication. Zohydro ER is an extended release formulation that is dosed every 12 hours resulting in less peaks and troughs throughout the entire day and night. On January 30th of this year, the new formulation for Zohydro ER was approved. Zohydro ER with BeadTek. The capsules now contain both beads of polyethylene oxide, a well-known pharmaceutical excipient and beads of hydrocodone. The beads are indistinguishable from one another and a viscos immediately forms when the contents of the capsules are crushed or dissolved in liquids or solids. The new formulation should retain the same efficacy and pharmacokinetic profile as the original and the clinical experience is expected to be similar to the original formulation, allowing providers to continue to prescribe the same way. The clinical significance of BeadTek on abuse and misuse has not been established. As detailed in the Zohydro ER prescribing information, Zohydro has the same abuse liability as all other extended release, long acting opioids. Much misinformation in the media exists with regard to the potency of Zohydro ER relative to both immediate release hydrocodone combination products and other extended release opioids. The fact is that hydrocodone and Zohydro ER has the exact same potency as any other hydrocodone containing products. Hydrocodone is actually a less potent opioid than other marketed opioids such as oxymorphone, hydromorphone, or fentanyl. Our company takes prescription opioid abuse, misuse, and aversion very seriously and

we were the first company to have implemented from the launch of the product, safe use initiatives that go above and beyond the mandated US Food and Drug Administration risk evaluation and mitigation strategies. We believe strongly that abuse deterrents requires a systems approach and not just a formulation. This system approach incorporates the FDA REMS for extended release opioids regulation under schedule 2 prescribing requirements, industry leading responsible commercialization practices, and implementation of a comprehensive approach to surveillance, ensuring that the appropriate use of Zohydro ER by the right prescriber, for the right patient, is a priority for Zogenix. As abuse is often laid to the availability of the product, our current DA quota for hydrocodone is less than 1/100 that of immediate release hydrocodone containing products. We provide educational materials to healthcare professionals and to patients. For prescribers this education consists of helping to assess which patient is the right patient for opioid therapy, as well as assessing the development of abhorrent behaviors and ongoing monitoring to ensure our patients are continuing to get the benefits of both pain relief and functional improvement. For patients, we provide education on taking their medication appropriately and on their responsibility that medication is being stored properly to reduce the risk of diversion. To that end, we provide locking caps, free of charge, as well as home medication safes at a reduced cost to patients. To conclude, Zohydro ER with BeadTek is designed to be a better alternative to those patients taking hydrocodone / acetaminophen combination for greater than 90 days, for severe, chronic pain by reducing the risk of acetaminophen induced liver toxicity, provides less frequent every 12 hour dosing. Zohydro ER provides a consistent pharmacokinetic profile, minimizing peaks and troughs. Lastly, the patient should not notice any change in efficacy or tolerability with Zohydro ER with BeadTek from the original formulation.

Jeffery: The FDA has 5 levels of abuse deterrent technology. Have you been evaluated through that program? What's your status?

Gould: We currently have our abuse liability studies that are ongoing. They should be complete shortly with the intent to have a label change by the end of the year.

PO: We have proposed criteria here in front of us. When we talked on the phone, there was a typo in here.

Jeffery: I don't think it's a typo. The more I looked at it, I think it identifies the drug product.

JM: How did we arrive at the limitations? Number per day for example.

Jeffery: That's from the typical package, or typical dose.

JM: Except for the oxymorphone, they are all about 100mg morphine equivalent a day limit which is maybe politically correct, but I'm not sure it's clinically adequate

in all cases. For example the Hysingla is 120 mg once a day, but we're limiting Zohydro to 100mg a day.

Jeffery: It's just based on units available.

JM: But there are some lower dosage units available besides 50.

Jeffery: It's a maximum quantity, so if they wanted more, they would have to step up to the higher dose.

JM: But they can't get more than 100mg, 2 tablets a day.

Jeffery: Not with this quantity. They would need another PA.

JM: Can they get a Prior Auth to exceed the quantity limit?

Jeffery: Yes. They would need to provide the justification for why they need the higher dose.

Lawrence: Does this one allow Prior Authorization to exceed quantity limitations?

Jeffery: We don't have any criteria that would state...

Lawrence: This was not a hard block, right?

Jeffery: There's no criteria that we have documented here of why they would exceed the criteria.

JM: There's no step therapy required either.

Jeffery: It would be a clinical judgment on the pharmacist.

PO: What is our current quantity limitation?

Jeffery: Right now for the Zohydro, it's that 5 per 30 days. It's really low.

JM: So just a temporary.

Jeffery: Yes. The other ones are similar to this. It's in chapter 1200.

MG: So are these drugs on the bottom, Avinza and Kadian, are they subject to this criteria also?

Jeffery: Yes.

JZ: Basically all of them are subject to the same criteria. But Zohydro is significantly lower quantity limits. So all of the Zohydro ER products coming out right now, does it all have abuse deterrent technology in it now?

Gould: As of two weeks from now, May 4th, it will be available with the BeadTek in it. So right now we've bled out all of the original formulation out of the supply chain. So as soon as the new, the manufacturer releases it, it will go right into the supply chain. There should be very little of the original formulation left.

JM: There's kind of a disparity here. We allow up to 400 mg of Kadian a day, which is obviously 4 times the morphine equivalent of the hydrocodone. Why are we arbitrarily cutting these limits?

Jeffery: It's based on how frequently it's dosed. Kadian is typically every 12 hours, Avinza is once a day.

JM: But still, to take total accounts, that is what they are getting a day, is 400 mg.

Jeffery: If you want to add some quantity limits on total morphine equivalent doses, we can do those too.

Lawrence: When it first came out, you guys wanted to see what the utilization was. That's why you didn't utilize that number from the very beginning. And that is why it was reagendized. When it first came out, that was your plan, to relook at the quantity limitations. That's why you have taken that first number from the very beginning.

Jennifer Stanton: On your proposed criteria, it says severe pain that requires daily, around the clock, long term, opioid therapy and documentation that alternative therapy…an example is immediate release opioids is ineffective.

Jeffery: Ineffective, not tolerated, it goes on.

Stanton: But there's no step through like a generic.

Jeffery: Not in here. We still have the preferred drug list. This is something for the preferred drug list.

MO: So a patient who has been on 90 days + of immediate release hydrocodone combination, but they are doing fine, but they are pushing the mg limit for acetaminophen, they still would be doing fine. They wouldn't meet that criteria, because based on that, they wouldn't be doing poorly. It wouldn't be ineffective, it's just that they are at risk for other problems, so would they be allowed to be switched?

Jeffery: I think that would fall into the not tolerated. If they are not achieving control, then they can certainly move to something else.

JM: I guess I'm just concerned about the disparity between the totally mg daily limits. If we can go up to 400 mg of morphine, I think we should be able to go up 400mg Zohydro. Although that's certainly not within package or PI, or whatever. I think as a clinician, you have to use what is clinically indicated, or even in the case of Avinza, it's 320mg of that. I think these numbers tend to be artificial in terms of that.

Jeffery: I think these are just based on the number of times they're given and we can certainly talk about it. Kadian, 2 per day at a max of 100.

JM: I wouldn't limit it. I have a lot of patients on 200-300mg. I've got patients on 600mg of morphine, or even more than that. It just depends on what is clinically indicated. Obviously a PA override could be done.

Jeffery: This is a starting dose. This is for your average.

JM: The problem we see is what happens when these patients go to the pharmacy, just like Chris was saying, the pharmacist says it's denied. Be that as it may, the pharmacist is supposed to notify us by state law, that the prescription was denied, but they don't and they just tell a patient that it was denied and the patient walks off and two weeks later they finally call and they've used up all the stash that they've hoarded and now they are desperate and we ask what happened and they say it wasn't approved. Then we ask why didn't they call? They say the pharmacist said it wasn't going to be approved, so they gave up. The problem is that you create these artificial boundaries at the retail level. They tend to be a big barrier to dispensing. Obviously it's not Zohydro's problem, but it's the patient's problem. I would like to address that because it really is becoming a major problem we're seeing all the time.

CS: That's my concern. They come in to see you and they are your last patient on Friday. They don't have any and because it's schedule 2, obviously it makes it more difficult. You go home and they have no drug and the pharmacy...now you want them to have 150 mg, however you prescribe it. Now they can't even say "I can give you 100." It puts everybody in a weird spot. Then you end up with the other issue of pharmacists not wanting to carry these schedule 2 drugs.

JM: And they probably won't for this one either. They'll order it and get it in the next day or two days.

CS: Is there a dose that would be reasonable?

JM: I think the 2 per day is reasonable for Zohydro, but I think it's an artificially low number. I would go for 3 a day to give you a little more latitude. You're a little bit more than the Avinza, or Kadian dose, so.

Gould: In our clinical trial, the pivotal phase 3 trial, they are allowed to go up to a dose of 200mg a day. But they were capped. If they needed more than that, they weren't even allowed to continue in the clinical trial. We had capped it internally at 200mg a day.

JM: But there were people who could have used more than that.

Gould: There were a few patients that didn't qualify for the study because they couldn't stabilize their dose.

JM: The FDA would probably look very askew at that and say that you guys are promoting drug use and drug abuse and overuse.

CS: My question, if we put a maximum, at what point would you like to move somebody from Zohydro? If they got to 200mg and weren't achieving the level of pain management that they needed, would you want to move that up, or would you decide to move them on to something else?

JM: It would depend on a lot of things. It would depend on what they could get coverage for, on an override on a quantity limit. If they don't respond to 200mg, could you go to Fentanyl, and give you 200 mics an hour of Fentanyl. I actually have people on 400 mics an hour.

PO: I think one of the main concerns is with the quantity limit of 5. Whether we shouldn't maybe consider revisiting that quantity limit right now and for next, or future meeting to look at the whole thing.

JM: I could propose the motion to increase the quantity limit to 90 or 60 a month and then we can clean it up and have some sort of logical way of dealing with this. There's a lot more going on here.

JM: We're talking about removing the quantity limit of 5 on the Zohydro and bumping that up to 60, or 90 and then allow quantity limit overrides as necessary as a motion.

Jeffery: Which one? 60, or 90?

PO: 60, for now.

PO: We have a motion to remove the 5 quantity limit and raise it to 60 for Zohydro. We will bring this back to the next meeting to discuss the entire class.

Voted: Ayes Across the Board.

Motion Carries.

h. **For Possible Action:** Discussion and proposed adoption of updated clinical prior authorization criteria for Prednisone delayed-release (Rayos®).
   i. Public comment on proposed clinical prior authorization criteria. None.
   ii. Presentation of utilization and clinical information.
   Jeffery: No utilization on this one yet. 1, 2, and 3mg extended release prednisone tablet. It may have some benefits to it. I think there may be some more step to it products that may be more appropriate, like immediate release prednisone.

   JM: Is it the idea that it reduces GI complications?

   Jeffery: I don't think it does that. You can take regular prednisone once a day, so I honestly don't know what the point is.

   JM: I will make a motion to make failure of immediate release prednisone a criteria for prescribing the extended release.

   Board: Second.

   PO: All those in favor of accepting the criteria exactly as proposed say aye.

   Ayes across the Board.

   Motion Carries.

7. Public Comment on any DUR Board Requested Report

8. DUR Board Requested Reports

a. Report on diabetic patient compliance for blood glucose monitoring receiving insulin
   Jeffery: Skipping to more interesting reports. I pulled the number of patients on insulin without getting test strips. There were several patients, almost 4,000 recipients on Medicaid are getting some form of insulin, but not having any claim for any test strips in the past year. This is a little concerning. I separate it out by product, so you can see the Lantus, almost 1,000 claims but none of these patients have gotten test strips. Potentially, if they are Medicare B also, they could only be getting them through Medicare B, so there's a possibility, but that would be relatively small.

   PO: This one would be a good one to drill down into to see the ages.

   Jeffery: Yes to see if they are all Medicare B.

   MO: Is this at point of pick up, or that has at least been ordered to the pharmacy?

Jeffery: I took all the patients who had a claim for insulin and then I took all of those patients and I matched them to every claim that had test strips, so these are the people fell out, who didn't have a claim for test strips who were on insulin. I didn't account for Medicare B, so I'll go back and look at that.

Lawrence: That is something we can turn over to the healthcare guidance program.

b. Report on Guaifenesin with Codeine Utilization.
Jeffery: Skipping down again to the Guaifenesin - Average claim per quantity here is averaging about 180 mls, per claim. It wasn't as high, so I don't know if we want to put similar quantity limits. But we don't have any quantity limits on this one yet.

8. Public Comment on any Standard DUR Report - None

9. Standard DUR Reports

10. Closing Discussion

a. Public comments on any subject.
b. Date and location of the next meeting.
   i. July 23rd maybe. TBD. Evening meeting is working well. Thursday is still best.

c. Adjournment.