STATE MEDICAID DUR BOARD MEETING

**THURSDAY, December 10, 2009**
**7:00 a.m. to 8:30 a.m.**
**Cannon Health Building**
**Room 125**

# MINUTES

**Board Members Present:**

**Neal Catalano, R.Ph.**
**Tony Dalpiaz, PharmD.**
**Peter Knudson, D.D.S.**
**Joseph Miner, M.D.**
**Kathy Goodfellow, R.Ph.**
**Brad Hare, M.D.**
**Wilhelm Lehmann, M.D.**
**Joseph Yau, M.D.**

**Board Members Excused:**

**Mark Balk, PharmD.**
**Bradley Pace, PA-C**
**Dominic DeRose, R.Ph.**
**Cris Cowley, M.D.**

**Dept. of Health/Div. of Health Care Financing Staff Present:**

**Lisa Hulbert, R.Ph.**
**Jennifer Zeleny, CPhT, MPH**
**Connie Keuffel, R.N.**
**Merelynn Berrett, R.N.**
**Rick Sorenson, R.N.**
**Tim Morley, R.Ph.**
**Amber Kelly, R.N.**
**Marisha Kissel, R.N.**

**Other Individuals Present:**

Mary Shefchyk, NNI
Elizabeth Howell, M.D., U of U
Morrie Olson, Rickitt Benckiser
Lynnette Wingert, DEA
Lori Howarth, Bayer
Michael Measom, M.D.
Vicki Winkel, M.D., U of U
Pat Wiseman, Medimmune
Stephen Farmer, Amgen
Robert Belaski, Alkermos
Robert Miller, M.D., UDOH
Lisa Gilliam, Reckitt Benckiser
Joshua Sonkiss, M.D., U of U

**Meeting conducted by:** Wilhelm Lehmann, M.D.

1 Review and Approval of Minutes: There were no minutes to review this month.

2 Suboxone: Lisa Hulbert addressed the Board. The DUR Board approved putting Suboxone and Subutex on PA during the June 2009 meeting. Since that time, a number of providers have provided input. The Board chose the put Suboxone on PA based on the information provided in that meeting. Based on claims data, it looked like many patients were being put on Suboxone and left on it, rather than tapered. It also looked like many patients were receiving opioids concomitantly with Suboxone. The scope of services of Utah Medicaid includes diagnostic and rehabilitative services for substance abuse, limited to those designed to eliminate substance abuse. The Board was provided with the current PA criteria, the Substance Abuse treatment manual, and a survey of other states on how they are handling Suboxone and Subutex. The

Board members were also provided with letters from Suboxone providers in the community.

Dr. Gary Oderda addressed the Board and presented information on Suboxone, and an analysis of Medicaid claims data. Board members also received this information in writing.

Lynette Wingert, group supervisor for the DEA in the diversion unit, addressed the Board. She described the types of investigations that her office handles. They handle on-site investigations of data-waived prescribers with X-DEA numbers, and will visit over 40 prescribers in Utah. The X-DEA numbers can only be used for the purposes of prescribing buprenorphine products for the treatment of addiction. The use of buprenorphine products for pain relief requires the prescriber to use their regular DEA number. The prescribers that the DEA chooses to visit are chosen using various factors. It may be based on scheduling, on complaints from the community, etc. The DEA looks at all buprenorphine clients, not just Medicaid, when doing a site visit or inspection. The DEA conducts investigations in a manner that is sensitive to the legal privacy rights of patients, so there should be no privacy concerns in reporting concerns to the DEA. She offered to answer any questions about the DEA's processes.

Tim Morley asked if there is a limit on the number of buprenorphine clients that an X-DEA physician can see, and how strictly it is enforced. Ms. Wingert answered that there is a very strict limit – data waived practitioners can only see 30 clients in their first year and can apply for up to 100 clients in subsequent years. That is the limit. However, there are data waived practitioners in group practices that cover for each other. In those cases, each primary care doctor may only have 100 clients and the patients they see when they are covering for other providers in the practice do not count against the limit. The DEA does look at this very carefully. The DEA has a lot of resources to validate how many patients the doctors claim to have. If they find a doctor that is seeing more than the specific number that they are supposed to see, this is a quite serious administrative action that the DEA will take. If they are prescribing for addiction purposes and the DEA sees other drugs being prescribed to this patient either by that doctor or other doctors, this also warrants serious administrative actions. Each case is handled differently, depending on the facts of the case.

Kathy Goodfellow asked if any prescriber can become data waived, or if only physicians can become data waived. Only MD's and DO's can be data waived.

Dr. Joshua Sonkiss, Resident from the University Of Utah Department Of Psychiatry, addressed the Board. He had no conflicts to disclose. He came to represent four concerns of many physicians in the University of Utah Recovery Clinic. His first concern was that the minutes of the June meeting did not look like the length of time for an 8 week taper for a PA was specified. His second concern was that much of the discussion of the minutes in the meeting centered around the training required for physicians to obtain an X-DEA number. Physicians do receive training about how to maintain opioid dependant patients over the long term. Third, there was some mention in the minutes over the controversy whether or not addiction is a chronic medical condition or something that can be cured over the short term. This is a controversy in some criminal legal circles and in the political arena, but this is not controversial at all in medical literature. Addictions are regarded non-controversially as chronic illnesses in medical circles. Requiring an addict to taper off Suboxone over 8 weeks is analogous to requiring an HIV positive patient to taper off anti-virals over a period of time. It can be done, but the disease will

not go away. The fourth issue is regarding the different approaches by the state for Suboxone use. The information presented today shows that there are a wide variety of approaches that can be taken for Suboxone use. Utah leads the nation in opioid addiction, so it is important to consider how to handle policy in this regard. It is an opportunity to ignore the problem or treat it in a way that will not help the problem get better, on the one hand, or to take on a leadership role in policy development to lead the nation in helping the problem to get better.

Elizabeth Howell, M.D., from the University of Utah Department Of Psychiatry addressed the Board. She provided the Board with her CV. She shares Dr. Sonkiss' concerns. She disclosed past research that she did on buprenorphine and training she has taught for buprenorphine treatment. She has been prescribing buprenorphine since 2005, and is a DEA-waived practitioner who could have up to 100 clients. Her main concern is that Medicaid is looking at addiction as an acute illness rather than a chronic disease. There is little evidence for detox as an effective strategy, and she will provide a study to Lisa that reflects this. There is a big harm reduction component in providing either methadone or buprenorphine as maintenance therapy. Medicaid does pay for maintenance therapy with methadone, and this is the same therapeutic model as methadone treatment. This is the only office-based treatment that can be provided for patients with opioid dependence. Utah is always in the top 5 for overdose deaths, mostly from opioids. Having more than just one option besides methadone is highly desirable in this State. This is anecdotal, but since she has moved here, there were quite a few more overdose deaths in the hospitals from methadone. Since buprenorphine has been used more consistently, it has decreased dramatically. She asked Lisa to provide the studies that she will forward to the DUR Board members. Dr. Tom McLelland who is now the U.S. Drug Czar wrote an article for JAMA about 12 years ago discussing drug dependence as a chronic illness. This is now an accepted concept. There is treatment available, and it would be a tragedy to think that everyone can detox. It is a dangerous assumption. Some people can, but some people cannot. She has some patients who have been on Suboxone for 3-4 years, and their function is improving even at the 3-4 year mark. We don't tell people once their blood sugar is stabilized to come off their insulin. This is the same type of condition. There are neurobiological changes, some of which cannot be reversed, which need ongoing treatment. This is the consensus in the field. She was recently at the American Academy of Addiction Psychiatry meeting, and she brought up that the Utah Medicaid DUR Board recently decided that patients would only be approved for an eight-week taper. There was quite an uproar about that. The clinicians who deal with this on a daily basis felt that it was highly inappropriate. It may be appropriate for some patients, but it is not appropriate clinically for all patients. She included a letter from one of her patients who received a letter from Medicaid stating that she would have to taper off. She has bipolar disorder, and panicked when she received the letter stating that she would need to taper off. She provided the letter to the DUR Board.

Lisa Hulbert stated, by way of clarification, that the minutes are not transcriptions of the meeting. There are recordings of the meeting. Medicaid did ask for the DUR Board to specify an amount of time for the taper schedule that was being recommended, and the eight week time period did come from the Board. There is absolutely nothing that shows that Medicaid shows that Medicaid is trying to somehow call or define Suboxone therapy as an acute therapy; however, there are limitations on what Medicaid can provide payment for. It is a benefit definition, rather than how long a doctor feels is an appropriate therapy. Methadone has a labeled indication for pain, whereas Suboxone has a labeled indication only for addiction. Medicaid limits other addiction

therapies as well, including smoking cessation products, Chantix, and Vivitrol. Medicaid policy is closely tied to federal regulations. The Board was provided with examples of how other states limit Suboxone therapy. Again, those limitations are strictly related to what Medicaid pays for rather than what physicians can prescribe.

Dr. Howell replied that in the Medicaid population, if Medicaid does not pay they will not be able to obtain the medication, whatever it is. She did not think that there is a limitation on methadone treatment, and feels that Suboxone should be treated the same way.

Dr. Morrie Olson from Reckitt Benckiser Pharmaceuticals addressed the Board. He understands that there is the opportunity to extend the course of therapy beyond eight weeks if patients are able to stay within certain guidelines, and he appreciates that. He wanted to bring to the Board's attention that for the purposes of good quality care, especially in opioid dependence, when you are titrating, what is significant is that the dose be individualized. As the individual is inducted onto therapy, there is a point that is unique for each individual where cravings and withdrawals cease. With an eight-week limit, there will come a time at any point on that curve where the patient will again begin to experience cravings and withdrawals, and the effectiveness of the treatment is lost. With the opportunity through Utah Medicaid to add additional weeks, he wanted to appeal, for the sake of those patients, to at least consider it as a two-month treatment program so that the individualized needs of the patient can be met and the effectiveness of therapy is not lost. He agreed with the Prior Authorization. Buprenorphine, being a partial agonist, has a greater degree of safety than most opioids. However, early on because of the original product information where there were seven deaths that needed to be reported to the FDA because of events in France where people illegally injected buprenorphine with benzodiazepines, it has become a misnomer that there is a contraindication. There is actually no contraindication and it is actually safer. Bear in mind that all other opioids except fentanyl are ineffective with buprenorphine. Buprenorphine was originally developed and marketed as a potent analgesic throughout the world. The indication for Suboxone is not for analgesia, but it is highly effective.

Dr. Robert Miller of the Utah Department of Health addressed the Board. He works half time for the Health Clinics of Utah. He has been prescribing Suboxone for a number of years. Much of what he wanted to say has already been said. Buprenorphine is a partial opioid agonist. As such, it only partially stimulates the neural fibers, and that is where its use came from in terms of tapering patients off narcotics. Since his primary experience with prescribing Suboxone is through the Health Clinics of Utah, his experience relates to what he learned to get his certification, what he has read since, and his experience with patients. The major use for buprenorphine is for detoxification that is medically supervised. The reason that Medicaid became interested has to do with the pain program. Many people in the pain program had already been on fairly significant doses of opiates that were, in some cases, life-threatening. The hope was that buprenorphine would provide a means to reduce the dosage of that. He has had four people die, all of whom were on opioids before they got Suboxone. The second use for Suboxone that is not authorized is for pain relief. There is an important exception to that, since a lot of his patients who get Suboxone for opiate withdrawal initially received opioids for legitimate physiological pain. About 40% of those patients, through the Suboxone withdrawal, are pain-free. He had wanted to stay away from the addiction side of Suboxone. Statements have been made repeatedly that addiction is not just a matter of cognitive therapy. The

implication has been that addiction is similar to AIDS or diabetes, or ADD, and that addictions can be ended by given a certain medication. There are addictions all over the place that are not affected by medications. He can pick pain as an example. The absolute best medication for pain is diacetyl-morphine, which is also known as Heroin. That is illegal in this country. He cited several studies indicating that remission rates as high as 76% using Heroin for addiction treatment. This is probably because they get high when they come to receive their addiction therapy. Remission rates from Morphine from the Cochrane study are around 64% for people who are free from other opiates after twelve months. With buprenorphine, the rates are down to around 45%. Buprenorphine is good, but it is not perfect and it is not the answer for addiction. He wanted to also give examples of smoking and alcoholism, which are the prototypes for addiction treatment. In a very large study of smokers, about 37% stopped smoking with no medication whatsoever. It is a psychological problem, where a person, if properly motivated, can say no to cigarettes. In alcoholism treatment, Alcoholics Anonymous remains the number one treatment modality, and is much better then chemical therapy. Remission rates for people who stay in Alcoholics Anonymous are around 100%, and rates for people who drop out are quite a bit lower. The point is, addiction should not be compared to diseases like diabetes, because it is not. It has to do with habits, motivation, and how your brain processes these particular disorders. In that regard, he does not consider buprenorphine to be a miracle drug.

Dr. Howell wanted to make some additional comment. She objected to many comments that were just made. Dr. Lehmann wanted to move on for the sake of time. He stated that he would forward written comments to Board members.

Dr. Hare stated that he is involved in chronic pain treatment. It seems like many people in addiction medicine feel that addiction in patients with chronic pain is the primary problem, and that if the addiction is treated it will take care of the chronic pain. There is definitely an overlap, and he sees patients where addiction is an issue. Those patients are sent to physicians like Dr. Howell, to keep a clear line between addiction treatment and pain treatment. If pain continues to be a problem after addiction is addressed, he will see the patient back in his clinic and address it as is appropriate. He agreed with the comments made by his colleagues from the University of Utah, and felt that it is appropriate to keep patients on it for long term treatment in some cases. He felt that the DUR Board should reconsider the length of time allowed for Suboxone therapy for that reason. As far as the use of Suboxone for chronic pain, he feels that the use of opioids for chronic pain is, in general, overdone. Most of the patients do not get any measurable benefit from opioids. He sees people doing much better off opioids than on opioids. Many of his chronic pain patients are not addicts, but are mis-taking medications because believe that they will feel worse if they do not take them, or they are taking them to treat anxiety disorders. There are a small patients of chronic pain patients who do well on chronic opioids, but Suboxone is not appropriate for chronic pain.

Dr. Miner stated that he agrees with Dr. Hare and felt that it should be covered for chronic maintenance for opioid dependant patients. Medicaid could impose some restrictions to ensure that they are enrolled in an appropriate addiction treatment program. Dr. Yau agreed.

The Board members felt that Medicaid should consider rejecting claims for concomitant opioids with Suboxone therapy, as other states are doing.

Dr. Lehmann summarized the discussion to indicate that length of the PA is an issue that the Board wants to address. The other consideration is how to rule out concomitant use of opioids, whether or not to rule out concomitant use of benzodiazepines, whether to require enrollment in an addiction treatment program.

Lisa Hulbert stated that Vivitrol, for example, requires the physician to disclose the type of psychosocial support the patient will be receiving with the medication, and requires urine screens.

Tim Morley stated that one of the things that has been noticeably absent from many of the requests that have been submitted to Medicaid is a lack of a treatment plan. There is no plan on how to manage the patients, how long the therapy is planned, and no mention of the psychosocial component of the therapy. Requiring that these things be present takes the needs of the patient into consideration, and ensures that the physicians are not just giving them Suboxone to keep them happy.

Dr. Miner stated that methadone treatment can go on for years. They do have a plan and are receiving therapy during that time, and it is reasonable to require this for Suboxone. But it should not be limited to eight or sixteen weeks if there is a treatment plan.

Rick Sorenson stated that the providers do not always give much documentation to ensure that they are doing urine tests or DOPL pulls. He wanted to know how strictly the nurses should enforce that.

Dr. Miner stated that methadone treatment programs do this all the time. The other PA nurses stated that they get requests all the time where the documentation is lacking or where form letters are used with a statement that the patient is not on other opioids. Often, the statements in the form letter can be refuted with Medicaid claims data. These claims are denied, but are time consuming for the PA nurses to research.

The Board stated that better wording for how to rule out concomitant opioids would be considered for the updated PA. The Board feels that it is inappropriate and wastes time and money to give opioids to pay for prescriptions when a patient is on Suboxone.

Jennifer Zeleny stated that it would probably be feasible to do a hard computer edit to prevent opioids from being prescribed within 30 days of Suboxone. Such an edit could be overridden by the pharmacy team, if the Suboxone prescriber were to call or write to indicate that acute pain relief was required and the Suboxone taper protocol was being followed. She also stated that the Board could consider approving an initial PA for a short induction on Suboxone, and require a urine screen before renewing the PA on a maintenance basis.

Dr. Knudson suggested that Medicaid put together a suggested modification to the Prior Authorization for the Board to consider at a future meeting. Dr. Miner seconded the motion. The motion passed unanimously with votes by Dr. Knudson, Kathy Goodfellow, Dr. Hare, Dr. Yau, Dr. Lehmann, Neal Catalano, Tony Dalpiaz, and Dr. Miner.

Tim Morley suggested that the documents could be circulated via email prior to the next Board

meeting.  The Board members did want to do that.

Next meeting set for January 14, 2010
Meeting adjourned.

The DUR Board Prior Approval Subcommittee to considered 6 petitions this month.

Minutes prepared by Jennifer Zeleny