



STATE MEDICAID DUR BOARD MEETING  
THURSDAY, February 14, 2008  
7:00 a.m. to 8:30 a.m.  
Cannon Health Building  
Room 114



## MINUTES

### Board Members Present

Mark Balk, PharmD, BCPS  
Derek Christensen, R.Ph.  
Tony Dalpiaz, Pharm.D.

Neal Catalano, R.Ph.  
Wilhelm Lehmann, M.D.

Bradford Hare, M.D.  
Joseph Yau, M.D.

### Board Members Excused:

Dominic DeRose, R.Ph.  
Bradley Pace, PA-C

Don Hawley, D.D.S.  
Colin VanOrman, M.D.

Joseph Miner, M.D.

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

Rae Dell Ashley, R.Ph.  
Tim Morley, R.Ph.

Lisa Hulbert, R.Ph.  
Nanette Waters

Duane Parke, R.Ph.

### Other Individuals Present:

Steve Farmer, Amgen  
Robert Springmeyer, Medimmune  
Lori Howart, Bayer  
Paul Pixton, Novartis  
James Gaustad  
Bill Kines  
Matt Johnson, Takeda  
Marty Daniels, Merck

Dana Pierce-Hedge, Gilead  
John Stocktin, Genentech  
Kevin Carson, Alparma  
Cap Ferry, LEC  
Roy Lindfield, Schering  
Devin Dufenhorst  
Linda Craig, AZ  
Kara Anderson, MHAU

Ton Holt, Schering-Plough  
Mei-Jen Ho, DRRC  
Barbara Boner, Novartis  
Dan Heincy, Merck  
Rich Heddens  
Trish McDaid-O'Neill  
Reed Murdoch, Wyeth

Meeting conducted by: Derek Christensen, R.Ph.

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1. The minutes for December 2007 were reviewed. Mark Balk made the motion to approve the minutes. Neal Catalano seconded the motion. The minutes were approved by unanimous votes from Mark Balk, Derek Christensen, Tony Talpiaz, Neal Catalano, Dr. Lehman, Dr. Hare, and Dr. Yau.
  2. Attorney General - Statutory Update on Prior Authorizations: Doug Springmeyer addressed the Board. He has represented the Department of Health as an Assistant Attorney General for 20 years. During the legislative session, representatives from the drug industry met with Dr. Sundwall to express concerns that, at their judgement, drugs

were being placed on Prior Authorization through the DUR Process without following the requisite statutory mandates set forth in Utah law. Dr. Sundwall persuaded them not to run a bill on the condition that the Department cooperates in attempting to make sure that if it had happened in the past, it would not continue in the future. Doug Springmeyer's purpose in coming before the Board is to review the relevant section of the Utah code, which sets forth the statutory requirements before a drug can be placed on Prior Approval in Utah; to try to answer any questions that there may be among members of the Board; and to encourage Board members to review any past decisions that may not have met these conditions; and to properly instruct staff to revisit those issues and make sure that Prior Approvals are done within statutory restraints that are given to the Board. Each Board member received a handout of the relevant statute.

In Utah Code Annotated Title 26, Chapter 18, Section 105, titled "Drug Prior Approval Program", any drug Prior Approval program approved or implemented by the Board shall meet the following conditions: 1. No drug may be placed on Prior Approval for other than medical reasons; 2. The Board shall hold a public hearing at least 90 days prior to placing a drug under Prior Approval. 3. The DUR Board must give 30 days notice prior to considering a drug for Prior Approval. The public hearing need not be anything more than the DUR Board meeting, provided that 30 days notice is given. The Division would then have to wait 90 days after the hearing at the Board meeting to actually place Prior Approval on a drug. 4. The Board shall consider both written and oral comments. Doug Springmeyer recommended that the oral and written comments are expressly in the meeting minutes that they were considered. Any comments made outside of the meeting should be provided to Board members, and noted in the minutes. 5. The Board shall provide evidence that placing a drug class under Prior Approval will: a) Not impede quality of recipient care. The duty is on the Board to consider that, and note in the minutes to show that the Board has decided that it will not impede the quality of recipient care; b) Show that the drug class is subject to clinical abuse and misuse. The Board should explicitly note these findings in the minutes. If the Board makes this determination, and meets the 120 day notice requirement for Prior Approval, then a second public hearing is held no later than 9 months afterward. Doug Springmeyer's recommendation was to schedule the second hearing 6 months later so as not to risk undoing the work that was done in placing the drug under Prior Approval in the first place. A Decision to review the criteria again in the future is at the Board's option. Points 7, 8, and 9 establish requirements of staff to accommodate providers once Prior Approval criteria are set up, so as not to interfere with patient care. Item 10 requires a majority vote of the Board before the Prior Authorization requirement can be placed.

Doug Springmeyer has provided Medicaid staff with a list of drugs that manufacturers are specifically concerned about, and made himself available for any questions that Board members may have.

Mark Balk asked how the DUR Board would know how a particular drug class is being used or misused based on the data that is provided to the Board members. Tim Morley stated that the Board is provided with utilization data that Medicaid has. If the Board

requests more information than what Medicaid has provided, Medicaid will gather and provide the requested information in a subsequent meeting.

Tim Morley stated that sections 1 and 2 of the statute discuss a “drug”, and later sections of the statute discuss a “drug class”. Tim asked if Medicaid and the Board are to distinguish between those. Doug stated that the statutory requirements are to review each drug. In the past, if there was a new entry into a class with PA requirement, the new drug was automatically placed under PA. It is Doug’s opinion that this may not meet the statutory requirement.

Derek asked if Medicaid has a schedule for reviewing the drugs under Prior Authorization for the nine-month requirement. Tim stated that this has not always been done in the past, but Medicaid does have a calendar and is scheduling drug classes for review at each meeting.

Dr. Hare asked who was threatening the legislation if the DUR Board didn’t “get their act together”. Doug stated that he did not feel that this was necessarily pertinent to the discussion of the Board. Dr. Hare stated that he hoped that it was a proponent of the public and not the pharmaceutical manufacturers pushing their agenda. Doug stated that the current bill would prohibit certain drugs for organ transplants under prior authorization.

3. P&T Committee Update: Duane Parke addressed the Board. The P&T Committee will be meeting the following day. Copies of the agenda were provided by the door. Last month, the Committee considered the ARBs and ACE Inhibitors for PDL consideration. The Committee did find that the drugs from this class are equally safe and efficacious. The Committee did say that Medicaid needed at least one product in each class that has a pediatric indication. Medicaid recommended that we cover 3 ARBs on the PDL: Irbesartan, Olmesartan, and Valsartan. On the ACE inhibitors, they expressly requested that the 2 branded ACEs be considered non-preferred. Medicaid thanked the industry for working together on the contracting process.
4. Opiate Analgesics - Review of Quantity Limits: Derek Christensen addressed the Board. The Board was provided with a handout of the existing guidelines.

Tim Morley addressed the Board. The P&T Committee recently took up the class of long-acting opioid analgesics. In conjunction with that, and in light of the fact that there was a recent study commissioned by the Department of Health through the Health Statistics Department where they studied drug-related deaths in the state of Utah, which found that 40% of deaths due to overdoses were due to medications for which the decedent had a valid prescription for opiate medications, Medicaid wanted to have a discussion to make sure that the quantity limits are adequate with this policy. Utah Medicaid likes to be fairly proactive in the quantity limits due to diversion factors. It seems that Medicaid still has a problem with this. Medicaid provided usage data for the last 2 fiscal years, and a summary of the quantity limits that are already in place in the

system. Tim had a brief conversation with Dr. Hare about these limits prior to the meeting. To summarize, Medicaid has two main groupings: short-acting, and long-acting. In the short-acting, there are two subgroups: combination products limited to 180 units in 30 days, and single-entity products limited to 180 units in 30 days. The lollipops and effervescent tablets are limited to 120 units in 30 days with a valid cancer diagnosis. A valid cancer diagnosis also waives the quantity limits for the single-agent products. The cancer diagnosis will waive any of the quantity limits for opioid products, since there is a significant problem with pain control for cancer diagnoses. In the long-acting products, there are long-acting special delivery systems such as Oxycontin and MS Contin, which are limited to 90 units in 30 days. Fentanyl patches are limited to 15 units in 30 days, up to 75mcg. The 100mcg Fentanyl patches are only available with a valid cancer diagnosis. Methadone, which is considered a long-acting due to its long half life, is limited to 150 units in 30 days for all strengths. This creates a new wrinkle, because the 40mg tablets, which do not have a valid indication for pain control but are indicated for the treatment and management of abuse or addiction clients, have been limited by federal action to addiction treatment centers only. Again, a cancer diagnosis waives the limits for the long-acting opiate analgesics. The P&T Committee action only considered long-acting agents. The P&T Committee found all long-acting opiate analgesics equally safe and efficacious. For preferred drug list consideration, morphine products were selected as the preferred long-acting agents. There was no recommendation from the P&T Committee to change any of the quantity limitations currently in place. The Board is invited to discuss the current quantity limits and make any recommendations about the limitations that are currently in place.

Dr. Hare stated that his recollection is that when these limits were initially considered, there were some clients receiving an extraordinary amount of pain medication. Based on his experience in treating chronic pain patients, it seemed like a reasonable thing to do would be to set a reasonable limit on the daily dose. The limits that were set were fairly liberal, and patients that needed more would need to justify that. The initial step was intended to skim off the clients that were getting extraordinary amounts of opioids and require justification to continue to get those doses. It looks like Medicaid lost some of that. For example, the 150 units of methadone was based on the upper limit of 50mg/day of methadone. It was never intended to allow 150 of the 40mg tablets per day. In fact, the 40mg tablets didn't even fit into that scheme. At this point, the Board should look at those limits again and consider if this is a reasonable thing to do. It may even be reasonable to tighten those limits even further. The 180 short acting units even seems excessive, and could be further reduced to 120. In chronic pain treatment, if a patient is taking 4 short-acting tablets a day, they would benefit from a longer-acting drug to provide more consistent pain relief. One of the other things that the Board was explicit about was that there should not be more than one short-acting drug and one long-acting drug prescribed. That did not seem to come through. People appear to be receiving combinations of percocet, lortab, oxycontin, and duragesic.

Tim Morley stated that the quantity limits apply to combinations - if a client receives multiple long or short-acting opiates, they can only receive up to those quantity limits.

Dr. Hare stated that the Board is willing to listen to cases where a patient is doing well on an unconventional treatment, since that does happen. In general, these ideas apply and make good sense and help minimize the inappropriate use of opioids.

Derek asked if Medicaid is dealing with the limitations of the tracking system. For example, if a patient is receiving a combination containing 650mg of acetaminophen, the daily limit of 4gm of acetaminophen is reached really quickly. At 6 per day of the 650mg tablets, the daily dose of acetaminophen is 3.9gm from that combination alone.

Mark pointed out that recent research is even suggesting that the 4gm daily limit of acetaminophen may even be too much, especially in the elderly where the limit should be closer to 2gm. From a safety standpoint, one could argue that 3gm would be a conservative limit shoot for.

Tim stated that the question needs to be asked if everything is being done outside of a medical remedy if the patient is really needing 180 tablets per month of a strong opioid.

Dr. Hare stated that pain medications are one small piece of chronic pain management. Primary care physicians may only have limited access to physical therapy and psychological consultations for these patients. Medications are of limited value, and these patients should be referred to be looked at in a broader sense and other therapies pursued. It is probably not appropriate care to have the patients receiving maximum quantities of pain medications without receiving any other therapies.

RaeDell stated that Medicaid does not find that physicians have any complaints about the existing quantity limits. The clients tend to forget that there are treatments other than pain medications.

Dr. Hare stated that he agrees with this. It seemed that physicians were relieved that Medicaid would not pay for excessive quantities, because they were likely being pushed to prescribe it. These limits were probably welcomed.

Tim asked if lower limits would provide additional relief for physicians and add ammunition to allow them to move patients into other treatment modalities that are essential for chronic pain management.

Dr. Hare stated that there are some things that could be done that would make clinical sense. Reducing the limits on short-acting opioids from 180 to 120 would be appropriate. One problem is that Medicaid does not pay for chronic pain management. Dr. Hare understands that this is federal. The University has not been able to treat chronic pain patients. His clinic saw 50 patients and never got paid for any of them. Ideally these patients should be receiving treatment modalities available from a chronic pain program, but it does not work due to the federal statutes.

Dr. Lehmann stated that it was a relief when Medicaid brought the limits down to 6 units

per day. This enabled the prescribers to tell patients that were requesting high quantities that Medicaid would not pay for them. From a primary care perspective, pain management models that are taught in medical school say to start at a certain level and then double the medication if it is inadequate. This is the classic cancer pain management model that gets applied to any pain management. It is easy to get outside of normal limits when treating pain in this manner. Dr. Lehmann worries somewhat about lowering the limit from 180 to 120. He would like to see how many people are receiving 180 a month to be able to know what kind of a burden a lower limit is going to place on a primary care doctor. The inability to send them to a pain management center could be problems for the prescriber.

Dr. Hare stated that a lower limit makes sense from a clinical perspective. When the limits were first set, there was a huge decrease in the number of opioid prescriptions. It was amazing how many people were in excess of the limits at the time. Within a few months, the Board was getting requests for exceptions, but those seemed to go away fairly quickly.

Dr. Yau said that this needed to be brought up from a safety perspective. The problem is that a patient may be receiving multiple agents, benzos included, that could suppress the respiratory system. He wondered if there could be something educational for patients receiving multiple agents effecting similar pathways, since that is where patients run into problems.

Derek stated that the report indicating 485 overdoses, 307 were attributed to non-illicit drugs. Of these, 56 were due to prescription narcotics, of which 30% were methadone.

Dr. Hare stated that this is an important and worrisome area. It is not unusual to see obituaries of young people who die unexpectedly. He knows for a fact that a number of those are people who, in one way or another, succumb to abuse or overuse of prescribed substances. It is not clear, so far, from some of those investigations if even if people who have been using prescriptions in the manner prescribed. From reviewing medical legal cases, it seems that most of the time they don't (e.g. people applying 7 fentanyl patches at once, misusing Oxycontin). It is not clear who has used appropriately and who has overused, but in his experience from reviewing cases, it seems that people have taken many times more than what was prescribed. The Board does not want to create problems for patients who need pain management, but also does not want to create a dangerous situation where it is easy for people to use it on the streets, etc.

Neal asked if any other treatment modalities are available for Medicaid patients. Tim stated that it does not fall under the purview of the pharmacy program. He is not aware of specific benefits that are available.

Dr. Hare stated that many patients who have comorbid pain and mood disorders, and it is not clear whether the patients are using their pain medications for treating pain or for attempting to treat their mood disorders. Valley Mental Health is strapped, and limited in

the number of patients that they can see.

Dr. Yau said that the sheer volume can be high, but Valley Mental Health is not necessarily limited. Very often, but not always, patients with mental issues can have substance abuse problems. Salt Lake County is the agency that provides funding for substance abuse. There is one agency handling it.

Mark Balk stated that the purpose of this agenda item is to look at quantity limits. He asked if there was agreement about what to do with the quantity limits. Looking at the grid, there are 4 out of 32 groupings of prescriptions that look like they exceed 180 doses per month on average. Those 4 are liquids.

Dr. Hare stated that buprenorphine is primarily used for substance abuse with not much of a following for pain. RaeDell said that Medicaid has found that it is sometimes used for pain.

Tim offered to reword the report based on who is getting above a certain quantity of short acting, or to get a better picture of utilization.

Derek asked if the proposed lowering of the limit would be for the short-acting combinations or single-entity. Dr. Hare said that it would be for both, but he would like to see who is taking between 120 to 180 units per month to see if anything would be accomplished by lowering the limit.

RaeDell questioned how many people are getting long acting in addition to short-acting. Dr. Hare agreed that this would be beneficial to see.

Tony asked if the system would allow for a titration during the initial dosing period. Tim stated that the limits in the system are hard limits. It creates some problems if patients start on partial prescriptions and they have to call for overrides.

Mark made a motion to review the data differently. The Board would like to see who is taking between 120-180 doses per month of the short acting, how many are on a short acting without a long acting, how many are on long acting alone, and how many are on long acting with a short acting.

Dr. Hare wanted to see how the daily milligram limits that the DUR Board has previously set to see if utilization is really in line with these limits that were set. For example, 90 of the 80mg Oxycontin per month would be double of what the DUR Board had originally set as a daily milligram limit.

Mark made a motion to table the discussion until the DUR Board had a chance to review the data based on daily milligram limits, who is between 120-180 doses, patients on who are on both short and long acting, patients who are on high quantity short-acting without a long-acting agent. Dr. Lehmann seconded the motion. The motion passed unanimously

with votes from Mark Balk, Derek Christensen, Tony Talpiaz, Neal Catalano, Dr. Lehman, Dr. Hare, and Dr. Yau.

Next meeting set for March 13, 2008

The DUR Board Prior Approval Sub-committee convened and considered 5 petitions. Drug histories were for 12 months unless otherwise noted.

Minutes prepared by Jennifer K. Zeleny