



**MEDI-CAL DRUG USE REVIEW BOARD  
MEETING MINUTES  
Tuesday, May 11, 2010  
11:00am – 1:00pm**

**Location: Department of Health Care Services  
1501 Capitol Avenue, Room 71.1203  
Sacramento, CA 95814**

Topic	Discussion
<b>1) CALL TO ORDER</b>	<ul style="list-style-type: none"> <li>• The meeting was called to order by Dr. Stephen Stahl</li> <li>• Board members present: Drs. Stephen Stahl, Janeen McBride, Andrew Wong, Ross Miller, Timothy Albertson, Kenneth Schell, Patrick Finley, and Robert Mowers</li> <li>• Board members absent: Drs. Paul Perry and Marilyn Stebbins</li> </ul>
<b>2) APPROVAL OF LAST DUR BOARD MINUTES</b>	<ul style="list-style-type: none"> <li>• The minutes from the February 10, 2009 and November 10, 2009 meetings were reviewed and approved</li> </ul>
<b>3) REVIEW OF ACTION ITEMS</b>	<ul style="list-style-type: none"> <li>• All action items were completed or will be addressed in today's meeting</li> </ul>
<b>4) DHCS UPDATES</b>	<p><b>1) Overview of DHCS Data Review Committee and the Health and Human Service (HHS) Committee for the Protection of Human Subjects (CPHS)</b></p> <ul style="list-style-type: none"> <li>• Dr. Larry Dickey, chair of the OSHPD Committee for the Protection of Human Subjects, the State's Institutional Review Board (IRB) and chair of the DHCS Data and Research Committee (DRC) gave an overview of the relevant policy and procedures when requesting access to DHCS data for research.</li> <li>• The California Information Practices Act specifies that data held by the State can only be released for research purposes to accredited universities (such as the University of California), or to other non-profit research institutions. The data must be the minimum necessary and have adequate security measures in place. In addition, all releases for research must be approved by the state IRB.</li> <li>• Requests should first go to the DHCS DRC, which uses five criteria to determine whether to grant a request. The most important criteria is that the data to be shared will directly benefit the administration of the Medi-Cal program. When applying, the applicant should clearly specify how the research will benefit the program, program recipients, and California in general.</li> <li>• The methodology used will be reviewed to determine if it will be able to answer the research question. Be prepared to justify the methodology used.</li> <li>• A risk assessment and determination of how much effort it will take the Department to fulfill the request, is then performed.</li> <li>• Applications may be downloaded from the DHCS website. The application is reviewed and then adjudicated by the Committee. A summary of recommendations is prepared for</li> </ul>

the chief deputy director, who makes the final determination. The researcher is contacted by DRC staff with the approval or denial. If approved, the researcher is put in touch with the data releaser to make arrangements for the data release.

- Although there is now a formal process put in place, budget cuts and limited resources could result in longer preparation periods to obtain data from the Department.
- Data elements that are Protected Health Information (e.g. social security numbers, names) will not customarily be released.
- The Department asks to be reimbursed \$125/hr for the processing of the data, but is exploring different models in lieu of the fee.
- Lori Bradley stated that DHCS is in the process of reviewing the protocol for obtaining data for the DUR Board and is also working with the IRB to see if separate policies and protocols can be set up to do so.
- Dr. Stahl requested that the Board be given priority and be waived of the fees. Lori replied that it would need to be discussed internally.
- Dr. Ross Miller stated that the outcome and potential benefits of the research may result in cost savings and quality improvement which will outweigh these costs.
- Dr. Teri Miller stated that DHCS is considering mechanisms to process requests from the Board and requests that the Board develop a consensus on issues that really do need to be addressed. DHCS is willing to develop a process to address high priority issues but it must be done in the realm of the resources available.
- Dr. Stephen Stahl stated that creating a consensus is not a problem; however, it would be a waste of time if the Board is not given priority, if they do not get services, if there isn't a budget for those services, or if there is a cost for those services.
- Dr. T. Miller stated that DHCS is in the process of coming up with proposals for how that process might work and that it is currently on the agenda in preparation for the next meeting.
- Dr. R. Miller requested that a representative from the DUR Board be on the committee and volunteered to be that representative.
- Dr. Dickey stated that DHCS committees are currently internal, but will present that recommendation to the leadership of the Department.
- Dr. R. Miller suggested that Lori and Teri include this recommendation in their proposal.
- Dr. Stahl stated that it would make sense to leverage the DUR Board, a committee with academic credibility, and use them as a tool to enrich and help the Department with their own agenda.
- Dr. T. Miller expressed that it will take some time to do so, due to the forthcoming MMIS system. DHCS is interested in a partnership regardless of how it was done in the past.
- This subject matter was bookmarked. The Board will revisit what their vision is with DHCS and will come up with a consensus process.
- **Action Item: The Board will consider what the most important issues are and how to create a consensus in the future.**
- Dr. Stahl asked if there is ability to quickly query something from the database without a full project, to determine if there is something worthwhile to have a formal project on. Lori replied that it would depend on the timing of the request and the workload of DHCS.
- Dr. Stahl suggested that maybe DHCS bring to the Board their utilization problems to see if the Board can help address them.
- Lori stated that Pharmacy Policy is looking at reevaluating the goals for DUR. The new system and improved technology will allow for more to be done. There are things done

in other states that Medi-Cal currently cannot do due to the limitations of the current system. Medi-Cal wants to do these things and is eager to do them because it saves money and it helps the beneficiaries. The Board is an excellent resource and the Department does want to utilize them.

- Dr. R. Miller asked if the process was the same for accessing medical data. Dr. Dickey replied that all requests come through the same committee; it's not just pharmacy data.
- **Action item: DHCS is to present an update at the next Board meeting on the process for which data requests from the Board are considered.**

**2) Enteral Products – Removal of Early Refill Alert**

- Lori informed the Board that policy has requested the early refill alerts be removed for enteral products, due to the low likelihood that anyone would be abusing these products.
- Dr. Ann Nguyen added that a recent change in the system now allows for the dispensing of different flavors of the same enteral products to be dispensed at the same time. It would be unnecessary for the system to set early refill alerts for dispensing of the different flavors.

**3) Addition of Quantity and Frequency of Billing Restrictions for Selected Controlled Substances**

- Lori gave an update on billing restrictions for selected controlled substances.
- The contracted drug list (CDL) was reviewed for controlled substances that did not have any quantity or frequency billing limitations (e.g. methadone, hydromorphone, meperidine, liquid morphine sulfate, oxycontin/APAP).
- The fill quantities on pharmacy claims were reviewed. Policy used the quantity for the top 75% of claims to set the billing limitations. For example, the quantity for hydromorphone 2mg was set for 90 tablets because 75% of patients were getting prescriptions for 90 tablets or less.
- In addition, a frequency limitation of 3 fills in 75 days was added.
- These restrictions will decrease work load for the TAR office without decreasing accessibility for patients.

**4) Government and Accounting Office (GAO) Report on Medicaid Drug Spending – Audits and Investigations Update**

- Dr. Lee Worth, senior pharmacist from the Audits and Investigations (A & I) branch gave an update on Medicaid spending and fraud, as it pertains to California.
- There were questions and concerns at the last board meeting regarding a GAO report dealing with fraud and abuse related to controlled substances paid for by Medicaid.
- One issue was on deceased beneficiaries having claims made in their names and under their confidential identification numbers (CINs).
- Dr. Worth explained that unfortunately, there tends to be a lag time between the time the death certificate is issued and when it gets into the system. Some of that money is recovered.
- Dr. R. Miller asked about deceased prescribers. Dr. Worth explained that deceased providers are a little more difficult to deal with. The A&I branch works with the California medical board to obtain a list of deceased and retired physicians. They also work with private insurance companies, whom may get a list of such physicians. Some databases are not available to the A&I branch directly.
- The biggest problem is with pharmacy providers inputting in the wrong national provider number when billing claims. For the most part it is due to error rather than fraud. If it is noticed that this is done frequently, A & I goes out and reviews and corrects the records.
- The last issue had to do with doctor shopping, particularly for controlled substances. Utilization controls such as quantity and frequency restrictions are very helpful in stopping these. Unfortunately, some patients pay cash and the system may not flag it.

	<p>Such prescriptions tend to be for schedule III – V drugs, not II. Vicodin and promethazine with codeine are popular with doctor shopping.</p> <ul style="list-style-type: none"> <li>• Some A &amp; I branches are staffed with law enforcement officers that handle beneficiary level doctor shopping and fraud. A &amp; I also works with the Department of Justice and other governmental agencies.</li> <li>• Dr. R. Miller asked if there was any follow up on doctors who were barred from participating in federal programs and the many claims that went through even though these prescribers were not allowed to be providing scripts to Medicaid beneficiaries.</li> <li>• Dr. Worth explained that this issue goes back to pharmacy providers using incorrect provider numbers on claims submitted at the pharmacy.</li> <li>• A &amp; I has the S &amp; I (suspended and ineligible) list for Medi-Cal, which is similar to a federal list of excluded individuals and entities that the federal government uses. When a provider is put on the S &amp; I list, their enrollment status changes. A hard edit is put in place for prescribers on the S &amp; I list. Claims that are submitted under their number will no longer pay. However, the issue is whether the number was put in correctly in the first place.</li> <li>• Dr. Kenneth Schell asked how often the S &amp; I list is updated and what happens if a claim went through for someone who is in the process of being put on the S &amp; I list but the list had not yet been posted.</li> <li>• Donna Grey – Bowersox replied that the mandatory exclusions are done through the office of legal services on a monthly basis. She also expressed that this was an issue of audits and education. In order to address this issue, it needed to be ensured that pharmacy providers are putting in the right information and checking at that same time. Consumers and physicians should also be educated about the requirements and cost of all this.</li> </ul>
<p><b>5) HP UPDATES</b></p>	<ol style="list-style-type: none"> <li><b>1) FFY 2009 Annual Report</b> <ul style="list-style-type: none"> <li>• There were no comments or edits on the report.</li> <li>• The report was approved.</li> </ul> </li> <li><b>2) Utilization Reports: Quarterly Report (October – December 2009)</b> <ul style="list-style-type: none"> <li>• Dr. Stahl expressed that the therapeutic duplication (TD) alert is perhaps not that useful because some of the combinations used is on purpose as part of medical practice. Most of the drugs on the list are psychotropic drugs, which are often used in combination. Trazodone is categorized as an antidepressant but is it typically not used as an antidepressant but rather as a hypnotic.</li> <li>• Dr. Stahl asked if this can be fixed without recategorizing the drugs.</li> <li>• Eric King stated that it has to do with the target drug list, which was set up some time ago. There are target drugs that have both TD and ingredient duplication (ID) alerts set. The list was set up some time ago and there was talk about updating it.</li> <li>• Lori stated that it may be a good idea to wait until the new system is in place before updating the target drug list.</li> <li>• Dr. Lisa Ashton stated that the drugs on the list were arbitrarily selected based on high cost.</li> <li>• It was suggested that the update of the target drug list be bookmarked and brought back when the new system is in place and when there is better understanding of the new system.</li> </ul> </li> <li><b>3) DUR Logo Update</b> <ul style="list-style-type: none"> <li>• There is a new DUR logo.</li> <li>• The new logo has been incorporated onto the DUR website and also appears in the agenda packet.</li> </ul> </li> </ol>

**6) DISCUSSION OF BOARD MEMBER PROJECTS**

**1) Ongoing Projects**

**a) Antidepressants in Children and Adolescents Study**

- Dr. Patrick Finley would like to delete this as an ongoing project but will provide updates if there are any in the future.

**b) Rheumatoid Arthritis (RA) Study**

- Dr. Andrew Wong provided an update on the study.
- A handout summarizing the utilization of different DMARDs and biologic agents was provided.
- The data came from a large database which collected about 10 years worth of data from 1995 – 2005.
- The pivotal year was 1999, when biologics and COX-II inhibitors became available and revolutionized the way RA was treated. Back in 1998 the only patients on biologics were those under experimental protocol.
- The availability of new medications over the years has made an impact on RA treatment. Patients are also treated much earlier in their disease. A lot of education has occurred over that time period.
- From 1998 to 2005, there was a 34% increase in usage of DMARDs.
- The use of methotrexate has increased every year with 57% of the population on it in 2005.
- Overall, about ½ of the population are put on traditional combinations of DMARDs.
- Many of the older agents (e.g. penicillamine, gold salts) are not being used anymore.
- The use of biologic agents is about 25%, which is not bad for a county population. In the private sector, the use of biologics has increased to about 20 – 40%. Usage in many county populations still ranges from 20 – 30%. This data is consistent with that.
- After 2006, the number of patients on biologics plateaued.
- Dr. Stahl asked about the cost per year of biologics. Dr. Wong replied that it was in the range of \$10K – \$20K, but it is possible that the state receives a considerable rebate.
- Dr. Schell asked if there were any reductions in utilization of other resources like hospital visits or emergency room visits, or productivity. Dr. Wong stated that such data requires patient consent to collect. In the future, if there is interest and funding available, it would be something of interest to look into. In the private sector, productivity was seen to increase but with the county system, it's more challenging to see.
- Dr. Marco Gonzales asked if the study looked at the type of providers and if they were rheumatologists. Dr. Wong replied that the study did not look at that, but the Medi-Cal educational bulletin did.

**2) Proposed New Projects**

**a) Antidepressants and Pregnancy**

- Dr. Finley stated that the study is still in its infancy. From a healthcare policy standpoint, this is a very hot topic.
- There was an Institute of Medicine commissioner report that came out a few months ago showing that there was a lot of ethnic disparity in treatment and massive under-treatment of depression in pregnancy and postpartum.
- There is little known about these conditions let alone the safety of these drugs.
- There has been discussion about what the most appealing research questions should be, given our database.
- We don't know much about treatment during pregnancy and even less about postpartum. At this point the sky is the limit.
- A lot of the available literature comes out of Tennessee, who has been successful at

publishing their data. We can maybe use them as a model.

- Dr. Finley will report on the study when there is further development.
- b) Beers Criteria and Appropriate Prescribing in Adults Over the Age of 65**
- Dr. Albertson has some preliminary data but also announced that the acetaminophen article using Medi-cal data was accepted.
- For the Beers Criteria, three different drug combinations were looked at for the date range of October 1, 2008 to December 30, 2009.
- For the warfarin and ibuprophen combination, the overlap was 0.35% for the general population. The same analysis conducted for patients >65 also showed a 0.35% overlap.
- For the clonidine and beta blocker combination, the overlap was 4.3% in the general population and 3.5% for those >65.
- As for the potassium sparing diuretic and ACEI combination, there was a 2.7% overlap for the general population and 1.7% for those >65.
- Overall, not seeing a huge trend suggesting that the general population or those over 65 were being exposed at a much higher rate or that the elderly was being put at a huge risk.
- It was requested that a report be written up for this.
- Dr. R. Miller asked how those specific drug combinations were selected.
- Dr. Ashton indicated that those particular combinations of drugs were selected based on data from Mercy Medical Group. These were the most prevalent combinations of drugs used. It was not feasible to have Dr. Gonzales run all 52 combinations but rather take the ones that were most prevalent.
- Dr. Wong asked if they would do it differently if they could. Dr. Ashton replied that it might be worthwhile to look into benzodiazepine exposure since these drugs are not carved out to Medicare Part D.
- Dr. Albertson expressed that it would be interesting to see but it would depend on Dr. Gonzales's time. Maybe look at exposure for the general population and then compare that to the over 65 population.
- **Action Item: Dr. Gonzales to look at benzodiazepine exposure for recipients >65.**
- Dr. R. Miller stated that the preliminary data looked at combinations of drugs as opposed to looking at the whole list of 35 drugs themselves that are potentially inappropriate. Would it be possible to run a separate query, or even a separate project to look at the 35 drugs themselves?
- Dr. Albertson stated that the key is looking at the population as a whole then focusing on those over 65 to see if the data reveals a need for additional data or an educational intervention.
- Dr. R. Miller asked if there has been an educational article on the Beers Criteria and stated that it may be a good thing if this could lead to an educational bulletin.
- Dr. Ashton suggested holding off on doing so because of an incentive program that will be starting January 2011. Part of the program uses the Beers Criteria to look at inappropriate medication use in the elderly. In the first year, the provider self reports, then in the next stages it would be recorded from their electronic medical records. It may be more interesting to compare that with claims data to see the accuracy of provider reporting.
- c) COPD Analysis**
- There was a Medi-Cal educational bulletin done in 2008 on COPD which included a one year analysis from 2006 – 2007 looking mostly at emergency room follow-up visits.
- Dr. R. Miller suggested morphing this project into a remeasure of the original study because the data was already ran and the intervention was done. By re-running the same query that was done previously, we can see if the educational intervention made a

	<p>change.</p> <ul style="list-style-type: none"> <li>• Dr. Ron Sanui from the Managed Care branch stated that there has been an ongoing quality improvement project in the area of COPD. The Department of Public Health is putting in a COPD link on their website.</li> <li>• Dr. Nguyen stated that HP had done a biennial report in 2009, in which data analysis from educational bulletins are re-ran using the same queries to determine the impact of the bulletins on drug utilization and prescribing trends. It is possible that the COPD article was included in this report.</li> <li>• <b>Action item:</b> Dr. Nguyen will check to see if the most recent biennial report included the COPD article.</li> </ul>
<b>7) PUBLIC AND DUR BOARD COMMENTS</b>	<ul style="list-style-type: none"> <li>• There were no public or DUR Board comments</li> </ul>
<b>8) CLOSING REMARKS AND ADJOURNMENT</b>	<ul style="list-style-type: none"> <li>• Lori announced that Eric King's last day is Friday and thanked him for all his help and contributions to DUR.</li> </ul>

<b>Action Items</b>	<b>Ownership</b>
The Board to bring back ideas on what the most important issues are and how to create a consensus to bring them forth to DHCS for consideration.	Board
DHCS to provide an update on the process for which data requests from the Board are considered.	DHCS
Dr. Gonzales to look at benzodiazepine exposure for recipients >65.	Dr. Gonzales
Dr. Nguyen to check the 2009 DUR Biennial report to see if the COPD educational article was included.	Dr. Nguyen