MEDI-CAL DRUG USE REVIEW BOARD
MEETING MINUTES
Tuesday, February 8, 2011
11:00am – 1:00pm

Location: **Department of Health Care Services**
1500 Capitol Avenue, Training Room A
Sacramento, CA 95814

Topic	Discussion
1) CALL TO ORDER	• The meeting was called to order by Dr. Stephen Stahl • Board members present: Drs. Stephen Stahl, Janeen McBride, Andrew Wong, Ross Miller, Patrick Finley, Robert Mowers, and Marilyn Stebbins • Board members absent: Drs. Paul Perry, Timothy Albertson, and Kenneth Schell
2) APPROVAL OF LAST DUR BOARD MINUTES	• The minutes from the May 11, 2010 meeting were reviewed. • Dr. Wong made several edits to the minutes. • The minutes were approved as amended.
3) REVIEW OF ACTION ITEMS	**a. DUR 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.** • Dr. Stahl expressed concern regarding the obstacles preventing the Board from being proactive and asked if that was going to change. • Pauline Chan, RPh stated that DHCS has prepared a process, as requested, for data requests and will be presenting that in today's meeting. • Dr. McBride stated that due to the transition to a new vendor, this may be a good opportunity to go back and start from scratch on prospective DUR. • Dr. McBride asked if there was a way to review what is currently set up in the system prior to the next meeting so that the Board can come up with ideas on how to proactively change the DUR alerts and retroactively focus on certain categories of drugs such as antipsychotics and narcotic analgesics. • Dr. McBride suggested starting over with the DUR system, and re-program it with a focus on cost and new industry standards so that unnecessary alerts are not generated. • Dr. McBride stated that in order to do so, the Board would need to review what is in the system today, such as all the alerts and edits, the restrictions on quantity, day supply, and fill frequency. • Dr. Stahl asked if there were documents the Board would need in order to do so, or do they base it on what is known historically. • **Action Item: Dr. Ann Nguyen stated that she could supply the Board with information pertaining to the current edits in the system. As long as it is okay with DHCS, she can send the board the prospective DUR alerts table.** • The board asked to see the edits on all drugs rather than just the ones on the target drug list. • Dr. Stahl asked if there was a way to obtain aggregate cost of drugs in order for the Board to more effectively perform their function. Cost effectiveness cannot be performed without knowing cost. • **Action item: Pauline will bring this back to the division to determine what type of cost information can be shared without breaking any confidentiality agreements.** • Dr. McBride indicated that the bylaws states that the Board can recommend intensified

specific provider intervention. In some of these situations, that is what needs to be done.

- Dr. Stahl stated that granular information such as diagnosis is needed.
- Dr. Nguyen stated that she doesn't know how the new system from the new vendor will be. With the current system, diagnosis can be pulled and a temporal relationship can be made, however, the direct relationship between the diagnosis and the drug cannot be determined.
- Dr. Finley asked if the system allows for the determination of the provider and their specialty. Dr. Nguyen replied that it can.
- Dr. Wong stated that it would be helpful to have representatives from the new contract to let us know what they can or cannot do.
- Dr. Stahl stated that it may be worthwhile to have a separate after lunch session that is informal and open to the public. The board expressed that such a session would be great.
- Dr. Stahl asked if doing that at the next Board meeting would be possible, or if it would be too early.
- Pauline stated that the contract start date is still yet to be determined.
- Dr. Nguyen stated that the official date is currently June 30th.
- Dr. Stahl asked if September would be okay.
- Pauline stated that it would depend on the logistics and how fast the agenda can be prepared.
- Dr. Stahl would like it to be during the first reasonable opportunity.
- Dr. McBride expressed that for the time being, having access to the necessary information would allow the Board to start thinking about it ahead of time and discuss it on a broader level at the next meeting, then in more detail once the after lunch session is established.
- Dr. Lisa Ashton stated that the RFP response from ACS is available to the public and how they responded to the requirements can be determined.
- Pauline clarified that the Board would like HP to prepare documentation on the state of the current system so that the Board can go through the red lining process.
- Dr. Miller expressed that ACS is welcomed the opportunity and expected to present at the first DUR Board meeting once they are on board to let the Board know more about them.
- Dr. Miller asked in prior meetings if someone from the Board can be involved or be a representative in the formal committee that reviews data requests.
- Pauline stated that this will be part of the new business discussion.

b. DHCS to provide an update on the process for which data requests for the Board are considered.

- This item will be addressed during the meeting.

c. Dr. Marco Gonzales to look at benzodiazepine exposure for recipients >65 years of age, in connection with the question regarding Beers criteria and appropriate prescribing in adults over the age of 65

- At the last meeting, several drug interactions were looked into but no immediate risk to the senior population was found.
- The action item was to look at recipients who were greater than 65 years old, determine the number who were on benzodiazepines and compare that to the general population.
- It was found that about 15% of the adult population (19 years or older) had taken a benzodiazepine in the last year.
- Of the adult population, 44% were adults 65 years and older.
- 2.5% of sample beneficiaries were 65 or older, and had 6 or more claims for benzodiazepines.
- This data was over a 1 year period.
- Beneficiaries 65 or older were more likely to get a benzodiazepine if they had Medicare Part D.
- Of those ages 65+, surprisingly, there were fewer instances of fracture for those who had a claim for benzodiazepines. Marco believed this may be an anomaly of the data.
- This was a 5% sample. Only FFS beneficiaries who were 19 years of age and older and were continuously eligible for the entire 2009-2010 fiscal year, were included. This 5% sample population had about 62K beneficiaries.

- Medicare beneficiaries were represented in this sample since benzodiazepines are an excluded category from Medicare Part D and Medi-Cal receives those claims.
- Medicare cross over claims also come to Medi-Cal, and includes diagnosis codes.
- Take home message: Looks like the risk of fractures are coupled with other things. There are many confounding variables that may cause hip fractures rather than it just being due to benzodiazepines alone.
- Dr. Stahl stated that one of the confounders may be the first dose effect rather than chronic use.
- Dr. Gonzales stated that benzodiazepines do not appear to be a problem within the Medi-cal elderly population. There doesn't appear to be a link between benzodiazepines and fracture with this population either.
- The Board agreed that it would not be worthwhile to pursue this further.

d. Dr. Ann Nguyen to check the 2009 DUR Biennial Report to see if the COPD educational article was included in the report.

- Originally Dr. Miller had proposed a project on COPD using the 2008 HEDIS measure, at which point it was expressed that HP had already written an educational article on COPD using the same HEDIS measures.
- Dr. Miller proceeded to suggest a remeasure of the original data pull.
- At the last meeting, Dr. Nguyen stated that a biennial review had recently been submitted to DHCS and may have included the COPD article. If it does, then a remeasure would have already been done as part of the biennial review.
- It turns out the COPD article did make the cutoff for the last biennial review. This review was presented.
- There were four outcomes that were measured. The first three outcomes measured had slight improvements. These outcomes were:
  - Patients who filled a prescription for bronchodilators within 30 days of episode date.
  - Patients who filled a prescription for corticosteroids within 14 days of episode date.
  - Patients who did not fill prescription for corticosteroids.
- The downside was the fourth outcome measured, which showed a 15% increase in patients admitted to a hospital stay for COPD within 7 days of the original episode date and didn't fill prescription for corticosteroid prior to admission to facility.
- Dr. Miller asked if there is still the impression that there is inappropriate treatment of COPD patients from a quality perspective that has cost consequences from a medical side.
- Dr. Mowers expressed that if something needs to be done, it might be an educational component to the prescriber or practitioners to do a good job at getting patients to pick up their medication and be compliant.
- Dr. Miller asked if this was something that the Board should perform additional follow up on and if there is a way to target certain providers as a follow up to the educational article and this data analysis. Who do we target and how do we do it?
- Dr. Stebbins suggested drilling down on the prescribers and asked if that data is still available.
- Dr. Stahl stated that due to the likelihood of high turnover over the three years since the article was written, it is likely this data is obsolete.
- Dr. Mowers stated that a discussion in September with ACS will give the Board an idea on what sort of data they can expect to get and what is the turnaround time.
- Dr. Stebbins doesn't believe there is much that can be done at this time with regards to this data presented for COPD. She also express that this should wait because the state is in the middle of a transition.
- Dr. Miller stated that there needs to be an initial discussion and the bridging of that relationship can start now regardless of the data vendor transition.
- **Action item: This topic will be put down for follow up in the future. In the meantime, the Board would like to find out how the process of stimulating interchange between pharmacy and medical works. That way, when they are ready to embrace and work with the new vendor, it wouldn't take more than six months.**

	• Dr. Wong stated that COPD can be used as a sample case to the new vendor.
4) DHCS UPDATES	• Pauline gave a presentation discussing the role of the DUR Board, the mission statement, the operational guidelines and the 2011 goals. **a. Mission Statement** • The mission statement of the DUR Board, along with the purpose and goals, were presented. b. Bylaws • The bylaws in draft form were included in the agenda packet. c. **Operational Guidelines** • The Operational Guidelines included the DUR bylaws, proposal, and Annual report. i. **DUR Proposal Submission Evaluation and Approval** • DHCS has a new form, followed by instruction for completion of the form. • A flow diagram depicting the process for submitting a proposal to the pharmacy policy branch was presented. • If a proposal is approved by pharmacy policy, it will be presented at the DUR Board for discussion. • If a proposal is denied, it will either be returned for revision and resubmittance, or moved forward as an independent study. • The form will need to be submitted at least 6 weeks prior to the DUR Board meeting. Any supplemental information should be attached and submitted as one package. • DHCS's commitment to the Board is to facilitate and move the proposal through as sufficiently as possible. • The proposal is preferred to be submitted via electronic mail. • Pauline went over the 19 sections of the form that are to be completed by the requestor. • Dr. Miller asked if only DUR Board members can submit a proposal. • Pauline confirmed that only DHCS staff and DUR Board members can make this submission. • Dr. Finley asked if the proposal goes to the Board first, then DRC, then IRB. • Pauline stated that the proposal goes to pharmacy policy first, and will take three weeks to evaluate. The policy chief will either approve or deny the request. If it is approved, it would go to the Board. • Dr. Finley asked if it will go to the DRC once it is approved by the DUR Board. • Pauline indicated that once the study is approved by pharmacy policy, the collection of the data will be pharmacy policy's responsibility to follow through. • It is not pharmacy policy's responsibility to follow through with the data collection if it is an independent study. • The proposal may also be faxed or mailed. The form should be made to the attention of the DUR pharmacist, which would be Pauline. • Upon receipt of the proposal, Pauline would issue a control number and record the submission date. • Pauline also went over the evaluation criteria for the proposal: program impact/relevance, methodology, intervention plan, program workload impact. • Dr. Miller asked if the evaluation committee will include a member of the DUR Board. • Lori Bradley, RPh indicated that it had to be an internal committee. • Dr. Stahl suggested using the Board meetings to informally bring up ideas prior to formal submission to DHCS, to allow the Board to prioritize the ideas. • Pauline stated that multiple Board members can work together to submit the same proposal. **ii. Annual Report** • DHCS will use the new format from CMS for the 2010 report and will present it to the Board in May.

	• The report will include a description of the nature and scope of the prospective and retrospective DUR program, summary of interventions used in retrospective DUR, assessment of the educational programs, board activities, and assessment of the program's impact on quality of care, as well as any cost savings generated by the program. • The report will be used as a guide for future activities and guidance for the board to move forward. **iii. 2011 Goals** • Pauline reviewed the goals for the DUR program and encouraged the Board to come up with additional goals. • Pauline asked the Board to approve the bylaws, which will then be signed by the chair. • Dr. McBride asked if the mission statement should mention something about cost savings since the DUR program is part of the Budget Act. • The Board added the word "cost" in front of "effective" and the term "pharmaceutical care" was changed to "healthcare". • Dr. Finley asked about the program description which only referenced physicians and pharmacists, and does not include other healthcare providers. • The Board decided to changed "physicians and pharmacists" to "healthcare providers". • The word "HP", depicted in the flow chart included in the Proposal Submission, Evaluation and Approval Process Handout, was changed to "Fiscal Intermediary". • The Board voted to approve the mission statement, bylaws, operational guidelines, and 2011 goals as amended.
5) HP UPDATES	**a. Quarterly Utilization Reports** • Reports for the 1st, 2nd, and 3rd quarter of 2010 were presented. • Dr. Nguyen explained that the format of the reports have been changed since the last time the Board reviewed them. • Much of the text analyses of the tables are now excluded since they weren't describing anything that couldn't easily be seen by looking at the tables themselves. • The tables that use to be in a separate attachment are now incorporated into one single document. • Dr. Finley asked about the key for the conflict codes from Table 2. • Dr. Nguyen stated that ER = Early Refill, TD = Therapeutic Duplication, ID = Ingredient Duplication, and LR = Late Refill. • The Board asked that the key be included in future reports. • **Action Item: Dr. Nguyen to include the key in future reports.** • Dr. Miller asked if there were any summary or high level trends observed. • Dr. Nguyen explained that HP's Program Integrity Organization (PIO) is looking into the drugs on the ER report to see if there are any trends that may be questionable. The same drugs continue to show up on the list month after month. • Other than that, there was really nothing out of the ordinary. • Dr. Miller expressed that one of the values of the data vendor is to translate data into actionable information, which may help the board address that in projects. • Ann stated that aside from changes associated with seasonal changes, we continue to see the same drugs in the top ten lists. • Dr. McBride asked if this data includes Medicare Part D. It was indicated that the data included seniors that are not in Medicare.
6) DISCUSSION OF BOARD MEMBER PROJECTS	**a. Ongoing Projects** **i) Rheumatoid Arthritis (RA) Study** • Dr. Wong updated the board on his study looking at RA medication use during the period of 1995-2006. • 1999-2000 was a pivotal year in which TNF-α inhibitors were added to the Medi-Cal

formulary.

- Two abstracts have been submitted this year.
- The first abstract is titled *Patterns of Medication Use in California Medicaid Population For Rheumatoid Arthritis: Twelve-Year Period 1995-2006*
    - This abstract was sent to EULAR (European League Against Rheumatism). Will find out in March if it will be accepted.
    - Dr. Wong distributed the abstract to the Board for review and a graph depicting patterns of medication use.
    - The graph showed that prior to the availability of the biologic agents in 1999, up to 80% of the patients were placed on traditional DMARDs.
    - After the introduction of biologic agents, the use of traditional DMARDs only decreased slightly to about 72-75%. The difference was made up by those patients being placed on biologic agents.
    - Overall, about ¾ of the patients were on traditional DMARDs.
    - Starting in1999, there was increased utilization of TNF-α inhibitors from only a few percentages to about 23% in 2006.
    - Utilization in managed care organizations usually runs at about 20 – 30%.
    - In the private sector, usage is 20-40%.
- At the last ACR meeting, a head to head comparison study looking at triple combination of traditional DMARDs (methotrexate, sulfasalazine, and plaquenil), compared to a biologic agent along with methotrexate, was presented.
    - Symptomatically both groups performed similarly at the one to two year mark. However, radiographic outcomes were delayed in patients who were on biologics compared to those who were only on traditional DMARDs.
    - Over time, we expect to see an increasing trend in utilization of TNF-alpha inhibitors along with traditional DMARDs as appropriate and standard of care.
    - Prior to the availability of biologic agents, which revolutionized the treatment of RA, glucocorticoids were overutilized in about 65% of the patient population. This trend has decreased down to about 45%, which is the trend we'd like to see for these drugs.
    - The COX-2 inhibitors were utilized in about 55% of the patient population starting in the year 2000, but decreased significantly in 2004 **after** the first COX-2 was taken off the market down to about 19% utilization.
- The second abstract submitted is titled *Racial Disparities in Utilization of Biologic and Disease-Modifying Anti-Rheumatic Drugs in a California Medicaid Population with Rheumatoid Arthritis.*
    - The biologic agents were seen to be utilized more in the white population and disproportionately in some of the ethnic populations, especially in the black population, which is statistically lower.
    - The study also looked at predictors of biologic agents.
- Dr. Wong read the conclusions from each abstract
    - First abstract conclusion: While Biologic-TNF usage has gradually increased since 1999, traditional DMARD utilization in this indigent Medi-Cal population was appropriately substantial and remained stable in recent years. The overall use of glucocorticoids and NSAIDs decreased (but COX-2 inhibitors decreased to 19%) over this study period. Longer RA disease duration, younger age, race, access to rheumatologist, and dual Medi-Cal/Medicare eligibility were significant predictors of annual utilization for Biologic –TNF and DMARD use.
    - Second abstract conclusion: Biologic-TNF and DMARDs were used disproportionately in Blacks and Hispanics across 1999 to 2006. In addition to race, clinical/treatment factors, comorbidity, and Medicare eligibility have a significant impact on utilization of biologic-TNF.
- Dr. Wong hopes to see additional data in the future. There are now 5 TNF-α inhibitors available, along with other new biologic treatment.

ii) Antidepressants and Pregnancy

- Dr. Finley gave an update on the study.
- The study was just approved.
- The study will be looking at detection rates for depression and treatment patterns for depression during pregnancy and postpartum.
- Most of the evidence appears to suggest that women are at higher risk for depression during pregnancy and postpartum.
- What we don't know are treatment patterns.
- New studies done in this area actually used the women as their own control, which was a huge selection bias and not an ideal way to study this.
- Using the Medi-cal database, the study will isolate women who gave birth and compare them to women who are now pregnant and are age and sex matched. The study will be looking at detection rates and how they are treated.
- This study will be looking at a pretty pristine population who does not have any history of depression or antidepressant use. Getting only new onset depression.
- The study has been approved by the DRC, CPHS, Board of Pharmacy, and UCSF.
- Will get the encrypted data sometime next week.
- Marco did a preliminary analysis which fully supports the hypothesis that depression largely goes undetected in pregnancy and is undertreated.
- Women who gave birth, compared to the non-pregnant age matched control, the control was 3 times more likely to receive an antidepressant and 2 times more likely to be diagnosed with depression.
- Pregnant and postpartum healthcare delivery appears to be suboptimal.
- There is a real problem with continuity of care for depression. Depression is often detected and treated at the well baby visit, which is 6 weeks postpartum. After that, the OB/GYN no longer sees them. Care goes back to the primary care doctor or maybe the OB/GYN again a year later.

b. Others

i) Marketed Unapproved Drugs

- Dr. Miller presented this topic.
- Turns out there are many FDA unapproved drugs available on the market, along with many prescribers prescribing them, lots of patients taking them, and lots of dollars being paid out of Medi-Cal for these drugs.
- There has been some lay press, drugs pulled off the market, and warnings about the dangers of using cough and cold medications with certain ingredients or combination of ingredients. The main issue is that these drugs may be unsafe, and secondly, they are unapproved. For example, oral colchicine has been on the market for over 30 years, but was never FDA approved until recently.
- Dr. Miller had a phone conference with Pauline discussing this as an opportunity to address safety, quality of care, and potentially cost savings.
- Pauline stated that they discussed the adverse drug events that were included in the handout.
- Carbonoxamine was pulled off the market in 2006, so recent data was not available.
- The second drug was colchicine, which was approved in 2009, however, that approval made the drug very expensive.
- The third drug was quinine and had only about 127 claims during the entire year.
- Also addressed were the cough and cold medications, many of which were approved by the FDA back in 1976.
- Because these cough and cold medications have been used safely in the adult population and there were no studies conducted in children and adolescents, the FDA determined the children and adolescent dose by adopting a formula based on extrapolation of the adult dose: Children ages 6-11 are to use half the adult dose, while those ages 2-5 should use ¼ of the adult dose.
- In 1976, the FDA stated that these products should not be used in children less than 2 years old, however the FTC which governed consumer advertising allowed the package

	labeling to say "consult with your doctor." • In 2007, a group of pediatricians voiced their concerns to the FDA, after poison control centers around the country reported and identified more than 1,500 emergency room visits were related to children under the age of two who were given cough and cold preparations. • In 2008, the FDA issued another warning to advise against the use of these cough and cold preparations in children less than 2 years old. • Manufacturers voluntarily removed the wording "consult with your doctor" from the packaging. • In November 2009 the FDA's published recommendation was to follow the package direction and use the included measuring devices. • A study looked at 200 products on the market and found variation in the measuring devices. • The inaccuracies in the measuring device had affected the dose. • The package label should not have been allowed to say "consult with your doctor" but instead state "do not use", which had a strong implication that it was unsafe. • Pauline expressed that the cough and cold preparations may be worthwhile to have more educational awareness on. • Dr. Miller asked if it would have to go through the new process or can the legacy be used. • Pauline stated that as an educational bulletin, additional data would not be needed. But will make sure that they run the content by the Board. Dr. Stebbins asked if Medi-cal is removing all Tylenol – containing narcotic products that exceed 325mg. She has been getting lots of inquiries from doctors who stated that they received letters from Medi-Cal. • Lori said that they were only taking off OTC Tylenol products for ages 21 or older. • Dr. Stebbins stated that the letter did not state OTC products; it included vicodin, and other combination narcotic drugs that contained more than 325mg of Tylenol. Lori stated that DHCS did not send them. • Dr. Ron Sanui asked that Dr. Stebbins bring the letter in the next time for him and Mike to look at.
7) PUBLIC AND DUR BOARD COMMENTS	• Dr. Sanui stated that pharmacy medical managed care is now officially under the pharmacy benefits division; however the majority of his work is still in managed care.
8) CLOSING REMARKS AND ADJOURNMENT	• The meeting was adjourned at 1:05.