



**MEDI-CAL DRUG USE REVIEW BOARD  
MEETING MINUTES**

**Tuesday, November 12, 2013  
10:30 a.m. – 12:30 p.m.**

**Location: Department of Health Care Services  
1500 Capitol Avenue  
Training Rooms B+C  
Sacramento, CA 95814**

Topic	Discussion
<p><b>1) WELCOME/ INTRODUCTION</b></p>	<ul style="list-style-type: none"> <li>• The meeting was called to order by the Chair of the Board, Dr. Marilyn Stebbins</li> <li>• Board members present: Drs. Marilyn Stebbins, Timothy Albertson, Patrick Finley, Janeen McBride, Robert Mowers and Andrew Wong</li> <li>• Board members absent: Dr. Stephen Stahl</li> <li>• Board members and attendees introduced themselves.</li> <li>• Pauline Chan, R.Ph. introduced new pharmacist staff present from the division: Dorothy Uzoh, Pharm.D., Jeanette Kao, Pharm.D., Anh Le, Pharm.D., and Diane Tran, Pharm.D.</li> <li>• Patrick Robinson, R.Ph. (Xerox) announced that the DUR Board meetings are being recorded and reminded everyone to sign in.</li> </ul>
<p><b>2) CALL TO ORDER/ REVIEW AND APPROVAL OF SEPTEMBER, 2013 MINUTES</b></p>	<p>The Medi-Cal Drug Use Review Board (the "Board") reviewed the September 10, 2013 minutes. Dr. Wong had several minor changes and motioned that the minutes be approved with these changes. There was no discussion. The Board voted unanimously to approve the minutes with these changes.</p> <p><b>ACTION ITEM:</b> Incorporate Dr. Wong's edits into the minutes and post to the DUR website.</p>
<p><b>3) OLD BUSINESS</b></p>	<p>a. Review of Action Items from Previous Board Meeting:</p> <p>i. Pauline Chan conducted a survey of state Medicaid programs to determine how they report drug cost information to DUR Boards, including cost comparisons and the inclusion of rebates. California was included in the survey. Ms. Chan reported the results of the survey as follows:</p> <p>The survey questions were:</p> <ol style="list-style-type: none"> <li>1. How is cost reported to the DUR board in your state?</li> <li>2. Does your state use therapeutic class cost comparisons, such as \$, \$\$, \$\$\$ or does it use an index?</li> <li>3. If using comparisons, does the cost include rebates?</li> </ol> <p>A total of 24 states responded to the survey; Ms. Chan reported the preliminary results as follows:</p> <ol style="list-style-type: none"> <li>1. How is cost reported to the DUR Board in your state? The survey's preliminary findings showed that cost is reported using the following five methods:           <ul style="list-style-type: none"> <li>• Reimbursement to pharmacies (16 states)</li> <li>• Full cost disclosure (2 states)</li> <li>• Report drug cost by therapeutic class, no rebates, no individual drug cost (2 states)</li> </ul> </li> </ol>

- Report drug cost by individual drug, no rebates (1 state)
  - Do not discuss any cost (3 states). Reasons for not discussing cost were listed as: prohibit by statute (1 state), board discussion is only clinical (1 state), and no specific reason given (1 state).
2. Does your state use therapeutic class cost comparisons, such as \$, \$\$, \$\$\$ or does it use an index?
    - 4 states use \$, \$\$, \$\$\$ to report therapeutic class cost comparisons
    - 1 state uses cost index
    - 19 states do not use any comparisons
  3. If using the comparisons, does the cost include rebates?
    - The preliminary survey results reported that no state participating in the survey includes rebates in any cost comparisons.

Two pie charts were presented:

    - California is one of the 16 states using reimbursement to pharmacies at cost (66.7%).
    - California is one of the 4 states to report \$, \$\$, \$\$\$ as therapeutic class cost comparisons (17%).
    - The Board noted this was very good information and appreciated the efforts made in conducting this survey. Dr. Mowers asked if the survey separated out fee-for-service (FFS) and managed care (MC) Medicaid plans. Ms. Chan responded that the survey did not make this distinction. She also noted that the survey questions were specific in how states report cost to their DUR boards. The states surveyed offered five specific methods of how cost is reported. A motion was made – and seconded – with no further discussion, and carried unanimously to try and get follow-up information, specifically on the surveyed state by identifying whether these were FFS or MC.

**ACTION ITEM:** Follow-up on the survey of state Medicaid programs specifically on information on states by FFS and MC.

- ii. Dr. Stebbins reported that the Board had a follow-up call with Department of Health Care Services (DHCS), at the request of the Director's office to discuss two proposed agenda items with Pharmacy Benefits Division. The DUR board proposed agenda items are as follows:
  1. Discuss analytical support for the Board
  2. Discuss therapeutic class relative cost comparisons. A mock-up of relative cost comparisons for the therapeutic class arthritis treatment will be discussed in new business.
- iii. Ms. Chan presented proposed changes to Section 10, DUR: Introduction of the Medi-Cal DUR manual. The proposed changes included replacing the word "recommends" with "advises," adding the title sections of the CMS annual DUR survey, and replacing the Education for Providers section with an excerpt from the Social Security Act that governs DUR: 1927(g) 42 CFR Title k 42 vol. 4 part 456 subpart K.
  - Dr. Wong questioned why "recommends" was replaced. Ms. Chan responded that the DUR bylaws state the DUR board is an advisory board, and the proposed change is to reconcile between the DUR bylaws and the DUR manual for consistency with the DUR bylaws.
  - Dr. Stebbins noted that the Board understands the addition of "advises" but believes the word "recommends" captures the intent.
  - Dr. Wong suggested DHCS add "recommends and advises" into Section 10.
  - Dr. Mowers asked if the federal government changes the law or regulation, is there a

process in place to bring the changes back to the board in a timely manner. Ms. Chan indicated that DHCS would bring any law or regulation changes back to the Board.

- A motion was made – and seconded – to add “recommends and advises” to Section 10 of the DUR manual. There was no further discussion. The motion was carried.

**ACTION ITEM:** A revised version of Section 10 of the DUR manual, which includes the DUR Board suggestion to keep the verbiage regarding recommendations, will be submitted to both DHCS and the Board for comment. If there are no comments or suggested edits by either party within one week, then the revised Section 10 of the DUR manual should be submitted to publications.

- iv. Mr. Robinson presented proposed changes to Sections 20 and 35 of the Medi-Cal DUR manual to reflect the inactive status of the excessive duration (MX) alert. Dr. Albertson motioned to accept the changes. There was no further discussion. The motion was carried.

**ACTION ITEM:** Submit revised Sections 20 and 35 of the Medi-Cal DUR manual to reflect the inactive status of the excessive duration (MX) alert to publications.

- v. Mr. Robinson reported that the updated DUR target drug list and formulary file alert table for drug class: antipsychotics is under review with DHCS.
- vi. Mr. Robinson noted that a formal prospective DUR review regarding the test-run of the additive toxicity (AT) alert for acetaminophen is being presented today. The Board advised DHCS to turn on the AT alert for acetaminophen products in test mode at the September meeting. Currently, this is under review with DHCS.
- vii. Mr. Robinson informed the Board that the DUR educational article on medication management of asthma is in preparation for publication in the December pharmacy provider bulletin.

**4) NEW BUSINESS**

**a. Board Activities:**

- Dr. Finley reported that his paper examining a significant drug interaction between certain beta-blockers (propranolol and metoprolol) with CYP2D6 inhibitors was approved on November 5, 2013. The requested was submitted in May. Dr. Finley wondered why the process takes so long and suggested an understanding of the process is in order.

**b. DUR Board Elections:**

- The DUR Board Vice-Chair election was duly conducted in accordance with the DUR bylaws. Dr. Mowers was elected chair elect/vice-chair by a vote of 4-2.

**c. Pharmacy Update:**

- Ms. Chan presented information from the First National Conference on Academic Detailing (AD), which was sponsored by the Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women’s Hospital and Harvard Medical School and the National Resource Center for Academic Detailing (NaRCAD). The conference series was supported by a grant from the Agency for Healthcare Research and Quality (AHRQ). The two-day conference included topics of the history of AD (30 years), the past, present and future; the psychology of conflict of interest with a public policy perspective; AD on the front line, how to connect with the doctors and develop effective messages; managing an AD program in training, supervising a workforce, financing and sustainability of program; policy in AD outcome evaluation and integrating AD in quality improvement initiatives. Conference speakers came as far as from Australia. There were also three presentations from California: Veterans Hospital Administration from San Diego, Kaiser Permanente in Southern California and LA Net Primary Care.
- Dr. Stebbins asked where DHCS wanted to go with AD. Currently, DUR uses the educational articles to provide evidenced-based guidelines to providers.
- Dr. Stebbins wondered if it would be the intent of DHCS to conduct face-to-face detailing, noting that cost is a huge factor in face-to-face academic detailing. Ms. Chan noted she learned from this conference that some AD occurs via face-to-face interaction and some AD

is conducted remotely with the use of technology. Both have merit and could be applied. Ms. Chan also clarified her attendance at this conference was self-supported and not supported by DHCS.

- Dr. Albertson noted that if Medi-Cal opted to pursue AD, both high-impact and high-cost drug categories would be worth pursuing.
- Dr. Finley suggested that Medi-Cal could do more of the expert/educational training like what Dr. Stahl has done in the past.
- Dr. Lee Worth from DHCS Audits & Investigations explained that they send letters to prescribers outlining their prescription writing habits compared to their peers in the pediatric treatment area. The letters draw no conclusions or make any judgments. Dr. Worth noted that by communicating this information, they have seen success with this approach.
- Ms. Chan reviewed the California Department of Social Services (CDSS)/DHCS Foster Care Quality Improvement Project. The goal of this project is to improve the oversight and monitoring of psychotropic medication use for children and youth within the foster care system. This is a three-year project, from July 1, 2012 to June 30, 2015, with over 50 stakeholder organizations participating.
  - Year one activities included a kick-off stakeholders meeting, conducting three workgroups: clinical, data and family/education. The workgroup recommendations have been summarized in a draft action plan that was released in June 2013 for comments.
  - Activities planned for year two include: data exchange, conducting pilots, and developing improvement measures with continuous tracking and trending of data.
- Ms. Chan presented the follow-up of the discussion with the board on reporting therapeutic class cost comparisons on behalf of Dr. Mike Wofford, Chief of Pharmacy Policy Branch, who sent his regrets for not able to attend this meeting due to urgent matters.
- The original cost comparisons were presented to the board in a narrative form. The board was interested in a graphic presentation of the cost comparisons and the document was sent to Xerox/UCSF to prepare in a prototype dashboard format.
- The prototype dashboard displays relative drug costs for arthritis treatment drugs, which consists of several classes of drugs: a) non-steroidal anti-inflammatory drugs (NSAIDs), b) corticosteroids, c) non-biologic disease modifying anti-rheumatic drugs, and d) biologic response modifiers.
  - Dr. Mowers was not sure why celecoxib (NSAID) was listed as on the contract drug list (CDL) because it has some restrictions.
  - Amanda Fingado explained that this document was put together on very short notice and did not include restrictions. The only requirement for drugs to be listed in green was if they were listed on the CDL.
  - Mr. Robinson explained that this document was very preliminary and was not peer-reviewed, so the document should be viewed as a starting point for further work.
  - Dr. Stebbins asked why rituximab was on the CDL. Ms. Fingado replied that it is on the CDL for cancer treatment only.
  - Dr. Wong was wondering if there is a preferred drug of all drugs listed in the red (\$\$\$) section. For example, etanercept was preferred over other medications listed in the red (\$\$\$) section.
  - Dr. Wong also suggested a tiered approach instead of the stop light system may be better understood.
- Dr. Stebbins motioned that a committee of Board members, including Dr. Wong, review the relative cost dashboard and recommend improvement. The motion was seconded with no further discussion and was carried by the Board unanimously.

**ACTION ITEM:** The dashboard of relative drug costs for arthritis treatment drugs will be reviewed and improved as a special project and will be reported back to the full Board.

- d. Presentation: "CURES: California's Prescription Drug Monitoring Program" by Mike Small
- California has the longest running Prescription Drug Monitoring Program in the country. CURES is a database that stores dispensing reports from direct dispensers and prescribers; please note that it is not necessarily factual information. CURES allows registered providers to inquire on patients in their program and their medications.
  - The CURES application can be completed online but must be printed and submitted as a hard copy. Due to CURES minimal staff, processing of applications can take a few months. Mr. Small described a special registration offer where he will collect the CURES applications himself and waive the notary requirement for any organization that has 20 or more dispensers or prescribers complete the CURES application.
  - Of note, CURES was defunded in 2011, and is currently being supported by two individuals. Funding will be restored to CURES on January 1, 2015.
- e. Quarterly Report – 3Q2013 (July – September 2013)
- Amanda Fingado (UCSF) presented the DUR quarterly report for the 3<sup>rd</sup> quarter of 2013. She pointed out that the 3<sup>rd</sup> quarter report will always contain two additional tables than what is found in the other quarterly reports: 1) the annual utilization summary of drugs by sourcing status for the federal fiscal year 2013 (FFY), which will appear in the annual report to CMS, and 2) the top 10 drugs within each source code category, by total utilizing beneficiaries. There were decreases in the total numbers of paid claims across all three source codes, ranging from a decrease of 13.9% for single-source drugs to a decrease of 18.3% for innovator multi-source drugs. Ms. Fingado noted these decreases are consistent with the overall decrease in total paid claims from FFY 2012 to FFY 2013.
- f. Prospective DUR presented by Amanda Fingado
- i. Review of DUR Alert: Overutilization/Early Refill (ER)
- Both Sections 20 and 35 of the DUR manual do not include language to show that the ER alert is active for all drugs. Section 20 also mentions that insulin drugs are excluded from the ER alert, which is not consistent with the current policy.
  - A motion was made – and seconded – to update both Sections 20 and 35 of the DUR manual to include ER alert is active for all drugs. There was no further discussion. The motion was carried.
- ACTION ITEM:** A summary of the DUR Board recommendations for updating Sections 20 and 35 of the DUR manual to clarify the ER alert applies to all drugs on the Medi-Cal formulary file will be submitted to DHCS for review.
- ii. Review of DUR Alert: Drug-Drug Interaction (DD)
- A review of the DUR manual in both Sections 20 and 35 does not include language to show that the DD alert is active for all drugs and Section 35 of the manual does not include the DD alert in the table of DUR alert definitions. Finally, Appendix C of Section 20 contains an outdated list of interacting drug pairs that will generate the DD alert.
  - A motion was made – and seconded – to update various sections of the DUR manual:
    - Section 20 to include DD alert is active for all drugs
    - Section 35 to include the DD alert in the table of DUR alert definitions
    - Delete Appendix C of Section 20, which lists interacting drug pairs that generate the DD alert.
  - There was no further discussion, and the motion was carried.
- ACTION ITEM:** A summary of the DUR Board recommendations for updating Sections 20 and 35 of the DUR manual will be submitted to DHCS for review. The recommendations will include: 1) specifying the DD alert applies to all drugs on the Medi-Cal formulary file, and 2) describing how the DD alert is generated by screening for drug combinations based on the First Databank classification system of Severity

Level 1 drug-drug interactions.

iii. Review of Prospective DUR Criteria: Acetaminophen

- An initial review of the claims data showed that during 2012, a total of 571,836 paid claims for acetaminophen-containing products were processed for Medi-Cal fee-for-service beneficiaries. Of those, it appeared that 2.4% of paid claims were for prescriptions that averaged greater than 4 grams per day of acetaminophen. The Board expressed concern at this high number, but it was clarified that the calculations used the "Claim Days Supply Num" field, which, it was suggested, could be inaccurate because of "take as needed" directions, in which the pharmacist may place a small days supply in this field. Regardless of any potential data issues, the Board expressed concern about overuse of acetaminophen in the Medi-Cal FFS population. Ms. Fingado clarified that as part of their services provided to the online Medi-Cal prospective DUR system, First Databank now has the ability to issue additive toxicity (AT) alerts for claims that would lead to beneficiaries taking amounts of acetaminophen greater than 4 grams per day (across all acetaminophen-containing products). The Board agreed this alert might help with acetaminophen overuse.
- A motion was made – and seconded – to recommend initiating a test of the AT alert for acetaminophen-containing products. There was no discussion. The motion was carried.

**ACTION ITEM:** The DUR Board recommendations for initiating a test of the AT alert for acetaminophen-containing products will be submitted to DHCS for review.

g. Review of DUR Publications presented by Dr. Shalini Lynch (UCSF):

i. DUR Educational Alert (October, 2013): Immunization Update: The 2013-2014 Influenza Season

- While there have not been changes to the federal Advisory Committee on Immunization Practices (ACIP) recommendations, this alert summarized the new influenza vaccine products available for the 2013-14 season including quadrivalent vaccines containing an additional influenza B strain and two new formulations for adults with a history of egg allergy. The Immunization Branch of the California Department of Public Health reviewed this alert prior to publication.

ii. DUR Educational Alert (November, 2013): Immunization Update: Tdap with Every Pregnancy

- The Immunization Branch of the California Department of Public Health recommended the DUR program publish this alert to help publicize the new ACIP recommendations for use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) in pregnant women. As of February 2013, the ACIP recommends Tdap vaccine with every pregnancy due to early evidence that suggests Tdap vaccination in the third trimester may help prevent pertussis in young infants through maternal antibodies transferred through the placenta. The optimal timing for administration is between 27 and 36 weeks gestation.

h. Retrospective DUR presented by Dr. Shalini Lynch (UCSF):

i. Review of Retrospective DUR Criteria: Promethazine with Codeine

- An increase in reports of promethazine abuse in combination with opioids has been observed in recent years. In the current Medi-Cal fee-for-service program, there are age restrictions in place for codeine and promethazine cough syrup, with use restricted to individuals 2 years of age and older. The current maximum quantity limit for codeine and promethazine cough syrup is 9,999 ml, the maximum days supply is 100, and maximum dispensing limits have not been established. A review of paid claims for codeine and promethazine cough syrup over a one-year period was presented. Of note, a total of 377 beneficiaries (0.56%) had paid claims for promethazine with codeine cough syrup in amounts greater than 5,760 ml (5,760 ml = one 480 ml bottle every month for 12 months). In addition, 51 beneficiaries averaged more than 30 ml/day (the recommended maximum dosage in a 24-hour period) every day, for an entire year.
- Dr. Worth reported on efforts by Audits & Investigations to curb the abuse of codeine and

	<p>promethazine cough syrup, including a campaign where letters were sent out to the top prescribers. He suggested restricting the maximum quantity per dispensing to 240ml, as the 480ml bottles are more in-demand for drug diversion. The Board agreed with these recommendations.</p> <ul style="list-style-type: none"> <li>• A motion was made – and seconded – to limit the maximum quantity per dispensing to 240mL and the maximum days’ supply to 30 days. There was no further discussion. The motion was carried.</li> </ul> <p><b>ACTION ITEM:</b> The DUR Board recommendations for changing the maximum quantity of promethazine with codeine to 240mL with a maximum days’ supply of 30 days will be submitted to DHCS for review.</p> <p>ii. Review of Retrospective DUR Criteria: GLP-1 and DPP-4</p> <ul style="list-style-type: none"> <li>• In recent months, concerns of an association with pancreatic changes have been raised related to the use of incretin based therapies (dipeptidyl peptidase-4 inhibitors and glucagon-like peptide-1 receptor agonists) in patients with diabetes. The American Diabetes Association, the European Association for the Study of Diabetes, and the International Diabetes Federation have issued recommendations for clinicians and people with diabetes concerning the use of incretin therapy and pancreatic disease. A review of claims data showed minimal use of GLP-1 agonists in the Medi-Cal FFS population. The Board recommended a brief educational alert to providers summarizing the recent clinical recommendations for incretin therapy.</li> <li>• A motion was made – and seconded – to publish an alert summarizing the recent clinical recommendations for incretin therapy. There was no further discussion. The motion was carried.</li> </ul> <p><b>ACTION ITEM:</b> Publish a brief education alert summarizing the recent clinical recommendations for incretin therapy.</p> <p>iii. Discussion/Recommendations for Future Educational Bulletins:</p> <ul style="list-style-type: none"> <li>• The Board made a motion for a review of the use of cough suppressants in general, as these agents have questionable efficacy and as the use in the Medi-Cal fee-for-service population seems high.</li> <li>• A motion was made – and seconded – to review use of cough suppressants in general. There was no further discussion. The motion was carried.</li> </ul> <p><b>ACTION ITEM:</b> Draft a DUR educational article on the entire class of cough suppressants in the Medi-Cal fee-for-service population, including clinical recommendations for their use.</p>
<b>i. PUBLIC COMMENTS</b>	None.
<b>j. CONSENT AGENDA</b>	<ul style="list-style-type: none"> <li>• The next Board meeting will be held on February 18, 2014, in Training Rooms B+C at 1500 Capitol Avenue, Sacramento, CA 95814.</li> </ul>
<b>k. ADJOURNMENT</b>	<ul style="list-style-type: none"> <li>• The meeting was adjourned at 12:34 p.m.</li> </ul>

Action Items	Ownership
Incorporate Dr. Wong’s edits into the minutes and post to the DUR website.	Patrick
Follow-up on the survey of state Medicaid programs specifically on information on states by FFS and MC.	Pauline
A revised version of Section 10 of the DUR manual, which includes the DUR Board suggestion to keep the verbiage regarding recommendations, will be submitted to both DHCS and the Board for comment. If there are no comments	Patrick/Pauline

or suggested edits by either party within one week, then the revised Section 10 of the DUR manual should be submitted to publications.	
Submit revised Sections 20 and 35 of the Medi-Cal DUR manual to reflect the inactive status of the excessive duration (MX) alert to publications.	Patrick
The dashboard of relative drug costs for arthritis treatment drugs will be reviewed and improved as a special project and will be reported back to the full Board.	ALL
A summary of the DUR Board recommendations for updating Sections 20 and 35 of the DUR manual to clarify the ER alert applies to all drugs on the Medi-Cal formulary file will be submitted to DHCS for review.	Patrick
A summary of the DUR Board recommendations for updating Sections 20 and 35 of the DUR manual will be submitted to DHCS for review. The recommendations will include: 1) specifying the DD alert applies to all drugs on the Medi-Cal formulary file, and 2) describing how the DD alert is generated by screening for drug combinations based on the First Databank classification system of Severity Level 1 drug-drug interactions.	Patrick
The DUR Board recommendations for initiating a test of the AT alert for acetaminophen-containing products will be submitted to DHCS for review.	DHCS/Xerox
The DUR Board recommendations for changing the maximum quantity of promethazine with codeine to 240mL with a maximum days' supply of 30 days will be submitted to DHCS for review.	DHCS
Publish a brief education alert summarizing the recent clinical recommendations for incretin therapy.	Amanda/Shalini
Draft a DUR educational article on the entire class of cough suppressants in the Medi-Cal fee-for-service population, including clinical recommendations for their use.	Amanda/Shalini