



**MEDI-CAL DRUG USE REVIEW BOARD
MEETING MINUTES
Tuesday, February 18, 2014
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
1) WELCOME/ INTRODUCTION	<ul style="list-style-type: none"> • The meeting was called to order by the Chair of the Board, Dr. Andrew Wong • Board members present: Drs. Marilyn Stebbins, Timothy Albertson, Janeen McBride, Robert Mowers and Andrew Wong • Board members absent: Dr. Patrick Finley • Board members and attendees introduced themselves. • Ivana Thompson, PharmD, BCACP was introduced as the new Drug Use Review (DUR) Pharmacist at Xerox. • Pauline Chan, R.Ph. and Dorothy Uzoh, Pharm.D. were present from DHCS Pharmacy Benefits Division.
2) CALL TO ORDER/ REVIEW AND APPROVAL OF NOVEMBER, 2013 MINUTES	<p>The Medi-Cal Drug Use Review Board (the "Board") reviewed the November 12, 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>ACTION ITEM: Incorporate Dr. Wong's edits into the minutes and post to the Medi-Cal DUR website.</p>
3) OLD BUSINESS	<p>a. Review of Action Items from Previous Board Meeting. For informational purposes, a copy of Ms. Chan's presentation is included as Appendix A.</p> <ul style="list-style-type: none"> i. Follow-up to the survey of state Medicaid programs – Ms. Chan presented federal and state statutes that prohibit DUR Board access to managed care utilization data and drug cost data [42 U.S.C. 1396r-8; available at: http://www.gpo.gov/fdsys/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap7-subchapXIX-sec1396r-8.pdf] and [<i>California Welfare and Institutions Code</i>, Section 14087.48(b)(3); available at: http://www.leginfo.ca.gov/cgi-bin/displaycode?section=wic&group=14001-15000&file=14087.3-14087.48]. ii. DUR Manual revisions: Board activities (Section 10) – Ms. Chan reported the revisions have been submitted, approved, and published. iii. DUR Manual revisions: Maximum Duration (MX) alert (Sections 20 and 35) – Ms. Chan reported the revisions have been submitted, approved, and published. iv. DUR Manual revisions: Early Refill (ER) alert (Sections 20 and 35) – Ms. Chan reported the revisions have been submitted, approved, and published. v. DUR Manual revisions: Drug Interaction (DD) alert (Sections 20 and 35) – Ms. Chan reported the revisions have been submitted, approved, and published. vi. Revisions to dashboard of relative drug costs for arthritis treatment drugs – Ms Chan reported the work group had a meeting in January when it was discussed to include publicly available prices on the dashboard. The group will review the updated document off line. Dr.

	<p>Wong stated the group is trying to give a broad picture of publicly available cost data for different classes to demonstrate what options are available.</p> <ul style="list-style-type: none"> vii. Testing the AT alert for acetaminophen – Dr. Thompson reported Xerox is still working on the details for initiating the test. viii. Restrictions to promethazine with codeine – Ms. Chan reported DHCS agrees with the Board regarding adding restrictions; details about the potential restrictions are still being discussed. ix. Next DUR bulletin: cough suppressants – Amanda Fingado (UCSF) stated the bulletin is being submitted for publication today and will be presented in greater detail at the next DUR Board meeting in May.
<p>4) NEW BUSINESS</p>	<p>a. Board Activities:</p> <ul style="list-style-type: none"> i. Board Goals for 2014-2015: Dr. Wong presented the three DUR Board goals for 2014-2015. <ul style="list-style-type: none"> 1. Develop new strategies to identify relative cost comparisons that also comply with contractual requirements for cost confidentiality. 2. Conduct quarterly utilization review of Physician Administered Drugs (PADs). 3. Promote dialogue, collaboration and recommend best practices in pharmacy utilization management on drugs that are commonly used in both Medi-Cal Fee-for-Service (FFS) and Managed Care Organizations (MCOs). ii. Review Draft of the 2013 Annual Report to CMS – Request for Board Feedback: Ms. Chan provided a synopsis of the Comparison/Summary Report FFY 2012 for the Medicaid Drug Utilization Review Annual Report (available at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/2012DUR-Comparison-summary-report.pdf), which compiled the annual report surveys from all 50 states. Ms. Chan stated that her review of the report brought up a question for discussion about how to answer the 2013 Annual Report to CMS regarding prospective DUR messages being overridden. Ms. Chan proposed to add an explanation to the answer b for question 3 in the prospective DUR section, which would provide more information about California's Code 1 edits and TAR policy. Dr. Stebbins agreed that there should be an additional explanation added to our answer. Ms. Chan described the cost-savings estimate methodology noting it was the second year the methodology had been used to estimate cost-savings attributed to the DUR program. Ms. Fingado explained the methodology uses a multiplier to average cost-savings per claim that is either not adjudicated or cancelled, noting that California is using conservative estimates when comparing similar methods used in other states. As each state calculated their cost-savings using a different method, Ms. Fingado suggested the state-by-state comparison would not be valid. Dr. Wong suggested we contact CMS to request additional guidance to states on how to approach estimating cost savings. It was motioned and carried. <p>ACTION ITEM: The DUR Board recommends adding an explanation to the Prospective DUR section of the CMS Annual Report Survey (Question 3, Answer b).</p> <p>ACTION ITEM: The DUR Board recommends asking CMS for additional guidance to states for estimating cost savings.</p> <p>b. Pharmacy Update: Ms. Chan summarized DUR activities for 2012-2013, which included the following highlights:</p> <ul style="list-style-type: none"> 1. Published nine Medi-Cal DUR bulletins, exceeding the goal of four bulletins a year for the second consecutive year. 2. Developed and implemented a new and improved methodology to capture DUR program cost savings. 3. Implemented a systematic review and revision of the DUR manual, to ensure the web-based manual is up to date.

4. Conducted detailed review and analyses of the current prospective DUR alert system and its limitations, laying the groundwork for improvements in the new system.
5. Implemented a new process to develop retrospective DUR criteria.
6. Expanded data analytical support.
7. Improved the dissemination of DUR bulletins to providers through use of the Medi-Cal Subscription Service.
8. Improved the dissemination of DUR alerts to consumers through use of the DHCS Facebook page "Welltopia".
9. Began to develop strategies to align DHCS Quality Strategy (available at: http://www.dhcs.ca.gov/services/Documents/DHCS_Quality_Strategy_2013.pdf) to DUR.

Ms. Chan also provided the following three links related to the DHCS Data and Research Committee:

1. The primary portal for requesting protected data from DHCS for research and public health purposes: <http://www.dhcs.ca.gov/dataandstats/data/pages/accessingprotecteddata.aspx>
2. Data requests approved by the DHCS Data and Research Committee: <http://www.dhcs.ca.gov/dataandstats/data/Pages/ListofApprovedDRCProjects.aspx>
3. Publications that have resulted from research using DHCS data: <http://www.dhcs.ca.gov/dataandstats/data/Pages/ListofPublications.aspx>

c. Presentation: "Audits & Investigations" by Lee Worth, Pharm.D.

- Audits & Investigations (A&I) is responsible for preventing Medi-Cal fraud, waste and abuse. Dr. Worth presented to the DUR board the recent trend of abuse with promethazine-containing codeine cough syrup commonly called "purple drank."
- Codeine containing cough syrup was not previously investigated because it is a low-cost drug. Codeine containing cough syrup is not reported to CURES.
- A&I conducted a study of claims data for one year and, identifying the top 150 providers who prescribe the three most frequently prescribed narcotic cough syrups: promethazine with codeine, guaifenesin with codeine, and promethazine with both phenylephrine and codeine.
- The top prescribers were sent a letter from A&I with the intent to educate, review prescribing habits, reduce any unnecessary prescribing, and reduce the overall cost to the Medi-Cal program.
- The letter to the provider community produced a 24% reduction in cough syrup claims and a number of interesting responses from those providers who received the letter from A&I; examples of physicians who ended up losing their licensure due to improper prescribing were provided.

d. Quarterly Report – 4Q2013 (October – December 2013)

- Amanda Fingado (UCSF) presented the DUR quarterly report for the 4th quarter of 2013. She reported that one drug therapeutic category posted increases in total paid claims and percent of utilizing beneficiaries with a paid claim in comparison to both the prior quarter and the prior-year quarter: NON-NARC ANTITUSSIVE-1ST GEN ANTIHISTAMINE COMB. Similar increases for D-METHORPHAN HB/PROMETH HCL, a drug within this drug therapeutic category, were seen in the review of the top 20 drugs by total utilizing beneficiaries. In addition, PROMETHAZINE HCL/CODEINE, another antitussive, posted large increases in total paid claims (increased by 36%) and percent of utilizing beneficiaries with a paid claim (increased by 1%) in comparison to the prior quarter. Ms. Fingado also noted that HYDROCODONE/ACETAMINOPHEN posted decreases in total paid claims and percent of utilizing beneficiaries with a paid claim in comparison to both the prior quarter and prior-year quarter for the second consecutive quarter.

e. Prospective DUR presented by Amanda Fingado

i. Review of DUR Alerts for New GCNs

- Starting on November 11, 2013, new GCNs are reviewed and cross-referenced to the Medi-Cal target drug list for prospective DUR. If a GCN matches a drug on the Medi-Cal target drug list, the prospective DUR alert profile for the existing GCN is used to set the prospective DUR alert profile for the new GCN. GCNs are reviewed to make sure they are not for bulk formulations. At each DUR Board meeting a list of new GCN adds with prospective DUR alerts turned on other than ER and DD will be provided to the DUR Board for review. For this meeting, the DUR Board reviewed the alert profiles of these GCNs:
 - GCN #64429: CLOZAPINE, Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Drug-Age (PA), High Dose (HD), Low Dose (LD)
 - GCN #71688: LEVOFLOXACIN, Drug-Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), High Dose (HD), Low Dose (LD)
 - GCN #71690: LEVOFLOXACIN, Drug-Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), High Dose (HD), Low Dose (LD)
- A motion was made – and seconded – to accept these alert profile recommendations. There was no discussion. The motion was carried.

ii. Review of DUR Alerts: High Dose (HD) and Low Dose (LD)

- A review of the HD and LD alerts showed inconsistencies between drugs that appear on the Medi-Cal target drug list for prospective DUR and drugs that have HD and LD alerts turned on. Further, the DUR Manual lists only the incorrect dosage ranges for adults. Ms. Fingado reported that in total, 32 drugs with HD/LD alerts turned on (for the pediatric population only) are not listed as target drugs in the DUR Manual and an additional three drugs with HD and/or LD alerts turned on do not appear on the target drug list for either the HD or LD alerts (although these drugs do appear on the main list of target drugs in the DUR manual).
- Dr. Mowers expressed concern about the utility of the HD and LD alerts, given the low rate of cancellations for each alert. Ms. Fingado pointed out that the DUR quarterly report for the 4th quarter of 2013 shows 34.8% of the HD alerts were not adjudicated, so it is hard to infer the value of the alert based on the low rate of adjudication. The DUR Board expressed concern about turning off alerts without following clinical evidence-based guidelines.
- Dr. Thompson suggested reviewing the First Data Bank guidelines for each drug at the next meeting.
- A motion was made – and seconded – to table any decisions until there is more information provided to the DUR Board about each of the dosage limits and number of alerts generated for each of these drugs. There was no further discussion. The motion was carried.

ACTION ITEM: The DUR Board would like more information presented for each of the 35 drugs listed, including dosage ranges, total number of alerts generated, and total number of alerts adjudicated.

iii. Review of Prospective DUR Criteria: HIV Antiretroviral Medications and Ingredient Duplication (ID)

- As new combination antiretroviral therapies have come on the market for the treatment of the human immunodeficiency virus (HIV), the potential for antiretroviral active ingredient duplication increases. Evidence-based clinical guidelines for antiretroviral therapy (ART) include fixed-dosage recommendations. The risks of antiretroviral active ingredient duplication may include an increase in adverse events and/or a detrimental impact on

clinical outcomes.

- A motion was made – and seconded – to recommend turning on the ID alert for the 16 HIV antiretroviral drugs listed with primary ingredients available in both single and combination forms. There was no discussion. The motion was carried.

ACTION ITEM: The DUR Board recommendations for turning on the Ingredient Duplication (ID) alert for the 16 HIV antiretroviral drugs with primary ingredients available in both single and combination forms will be submitted to DHCS for review.

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

i. DUR Educational Alert (December, 2013): Asthma

- Dr. Lynch reported that current evidence-based guidelines for asthma (NAEPP 2007) outline four components to improve the quality of care and outcomes of asthma:
 1. Assessment and monitoring
 2. Patient education
 3. Control of factors contributing to asthma
 4. Medical treatment
- She described a new HEDIS® measure for 2013, which looks at the Asthma Medication Ratio (AMR), defined as the total number of controller medications divided by the total number of rescue and controller medications. The percentage of the Medi-Cal study population with an AMR \geq .50 was 57%. The AMR was found to be highest among females (60%), white, non-Hispanics (62%), and those beneficiaries with a co-morbid mental health condition (61%).
- Clinical recommendations included:
 - Review and follow the NAEPP stepwise approach for all age groups.
 - Provide a written asthma action plan in lay language to all patients.
 - Provide inhaled corticosteroids at discharge after inpatient admission or ER visit for asthma.
 - Assess patients for other conditions that may exacerbate asthma symptoms.
 - Encourage/remind patients with asthma to receive annual influenza vaccination.
 - Assist patients with asthma in smoking cessation.

ii. DUR Educational Alert (February, 2014): GLP-1 and DPP-4

- Dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors) and glucagon-like peptide-1 receptor agonists (GLP-1 agonists) are the two available incretin based therapies used to improve diabetes control and increase weight loss, either alone or in conjunction with other medications such as metformin or insulin. Recent epidemiologic studies, animal studies and autopsy studies have raised concerns that incretin-based therapies may be associated with pancreatic changes ranging from pancreatitis to premalignant lesions.
- On June 28, 2013, the American Diabetes Association, the European Association for the Study of Diabetes and the International Diabetes Federation issued recommendations for clinicians and patients with diabetes concerning the use of incretin therapy and pancreatic disease, which included the following recommendations:
 - Patients should be made aware of potential side effects of incretin-based therapy and the symptoms of pancreatitis.
 - Diabetes care providers should consider the possible adverse effects as they balance risk and benefit of particular treatment paradigms, especially in patients with other risk factors for pancreatitis.

- Discourage patients from stopping medications on their own without consulting their health care provider, since this can lead to higher levels of blood glucose that may cause serious short-term health problems and if prolonged, could increase the risk of long term diabetes-related complications.

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

i. Review of Retrospective DUR Criteria: Folic Acid

- Trends in folic acid supplement intake among women of reproductive age in California indicate that although the overall prevalence of intake of supplements containing folic acid remained stable between 2002 (40%) to 2006 (41%), use decreased among Hispanic women and women with less education.
- New research reports are finding the benefits of folic acid for additional populations, including patients with rheumatoid arthritis during treatment with methotrexate. A recent editorial suggested that policy makers and guideline developers should consider including folic acid supplementation for methotrexate users in their recommendations as a cost-effective and perhaps cost-saving treatment strategy for every rheumatoid arthritis patient starting treatment with methotrexate.
- DUR utilization reports continuously show folic acid as a top 10 drug in the Medi-Cal Fee-for-Service population, by the percentage of utilizing beneficiaries with a paid claim. During a one-month time period, approximately 5% of utilizing beneficiaries had a paid claim for folic acid, with no difference when stratified by gender. In addition, folic acid is the most frequently used drug among beneficiaries in long-term care facilities, with approximately 26% of utilizing beneficiaries in a long-term care facility having a paid claim for folic acid over a one-month time period.
- A review of Medi-Cal Fee-for-Service claims data showed the absence of a gender gap in folic acid use in the 46-64 year age group.
- A motion was made by Dr. Wong to evaluate use of folic acid in the 46-64 year age group. Ms. Fingado suggested looking at both potential overuse (in long-term care facilities and among the 46-64 year age group) and underuse among women of childbearing age (14-45 years of age). Dr. Stebbins agreed this could be a bulletin topic and the motion was seconded and carried without further discussion.

ACTION ITEM: The DUR Board recommended further evaluation of folic acid use in the Medi-Cal Fee-for-Service population, focused on 1) potential underutilization in women 14-45 years of age, and 2) potential overutilization in men and women 46-64 years of age.

ii. Review of Retrospective DUR Criteria: ADHD

- Attention deficit hyperactivity disorder (ADHD) is one of the most common childhood disorders and can continue through adolescence and adulthood. Symptoms include difficulty staying focused and paying attention, difficulty controlling behavior, and hyperactivity (over-activity).
- As more adults are being diagnosed with ADHD and are being prescribed pharmacological treatments, there remains much some uncertainty about long-term side effects.
- A review of Medi-Cal FFS claims data stratified by age showed the use of ADHD drugs in this population have remained constant since 2011, among all age groups. Although large increases in utilization have been reported in other populations, this was not present in the Medi-Cal Fee-for-Service. This may be attributed to current Medi-Cal restrictions on ADHD drugs, including both a code 1 restriction to use in Attention Deficit Disorder in individuals from 4 years through 16 years of age, with any use outside those parameters only allowed with an approved *Treatment Authorization Request (TAR)* on file.
- Dr. Mowers requested guidance for what the next steps should be for this review of

	<p>ADHD drugs. Ms. Fingado suggested if the DUR Board was interested, the recommendations stated that a prospective DUR review could be completed on this class of drugs, considering none of them currently appear on the Medi-Cal target drug list for prospective DUR review. There was no motion made for further action, although Dr. McBride suggested we should review this class of drugs again in the future.</p> <p>h. Discussion/Recommendations for Future Educational Bulletins: Ms. Fingado reported the next article would focus on the last of the DUR Board-approved topics related to the core set of health quality measures for adult Medicaid enrollees: therapeutic monitoring of persistent use of angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor blocker (ARB) drugs, diuretics, and digoxin. Dr. Mowers motioned to have a list of approved topics at each DUR Board Meeting, in order to help prioritize selection of future bulletin topics. The motion was seconded and carried without further discussion.</p> <p>ACTION ITEM: Send the DUR Board a list of potential topics for the next educational bulletin; in the future, provide this summary with each DUR Board Meeting packet.</p>
5) PUBLIC COMMENTS	None.
6) CONSENT AGENDA	<ul style="list-style-type: none"> The next Board meeting will be held on May 20, 2014 in Training Rooms B+C at 1500 Capitol Avenue, Sacramento, CA 95814.
7) ADJOURNMENT	<ul style="list-style-type: none"> The meeting was adjourned at 12:58 p.m.

Action Items	Ownership
Incorporate Dr. Wong's edits into the minutes and post to the DUR website.	Ivana/Amanda
The DUR Board recommends adding an explanation to the Prospective DUR section of the CMS Annual Report Survey (question 3, answer b).	Pauline
The DUR Board recommends asking CMS for additional guidance to states for estimating cost savings.	Pauline
The DUR Board would like more information presented for each of the 35 drugs listed, including dosage ranges, total number of alerts generated, and total number of alerts adjudicated.	Ivana/Amanda
The DUR Board recommendations for turning on the Ingredient Duplication (ID) alert for the 16 HIV antiretroviral drugs with primary ingredients available in both single and combination forms will be submitted to DHCS for review.	Ivana/Pauline
The DUR Board recommended further evaluation of folic acid use in the Medi-Cal Fee-for-Service population, focused on 1) potential underutilization in women 14-45 years of age, and 2) potential overutilization in men and women 46-64 years of age.	Amanda
Send the DUR Board a list of potential topics for the next educational bulletin; in the future, provide this summary with each DUR Board Meeting packet.	Amanda

Review of Action Items

Survey of Other States

Question from the DUR Board:

Do other states separate Fee For Service (FFS) and managed care plans in the DUR reports?

Answer:

- * DUR boards across states review **FFS data only, not managed care.**

Summary

- * In the managed care setting, the “DUR” role is done by managed care plans under contract, and various other state and federal laws.
- * That same federal and state statutory framework also prohibits State established DUR Board’s access to managed care MIS/DSS utilization data and drug cost data.

Applicable Law

- * OBRA 90, SSA Section “Payment for covered outpatient drugs” [448] Sec. 1927.[42 U.S.C.A Section 1396r-8(g), and CFR Sections 456.703-456.705.
- * As part of the program, each state was required to have a Drug Use Review Board established by the state (1396r-8(g) (3) (A).
- * 1396r-8(g)(3)(A) also describes, in detail, the membership of the DUR Board, its activities and requires that each State DUR Board prepare and submit an annual report to the U.S. Secretary of HHS.

Congressional Intent

- * The legislative history of Title 42 U.S.C.A. Section 1396r-8, and other federal legislation, make it clear why Medicaid managed care organizations are **exempt** from the DUR program requirements of Section 1396r-8, including State DUR Board oversight.

Medi-Cal Managed Care Contracts & State Law

- * Welf.& Inst. Code Sec. 14087.48(b)(3) requires that Medi-Cal managed care plans must have drug prescribing practice reviews and utilization management mechanisms.

Centers for Medicare & Medicaid Services (CMS)

- * Indicative of the limited role of State DUR Boards is the CMS website which provides a link to an “**executive summary**” of the annual reports each State is required to submit, with the title of “Executive Summary – FFY 2011 DUR Report For **Fee-For-Service (FFS)** pharmacy programs – State by State”.

Conclusion

- * The DUR board's role is defined by federal law and is **limited both statutorily and operationally to the FFS health care setting.**
- * That same federal and state statutory framework also **prohibits State established DUR Board's access to managed care utilization data and drug cost data.**