



**MEDI-CAL DRUG USE REVIEW BOARD
MEETING MINUTES
Tuesday, September 16, 2014
9:30AM – 12:00PM**

**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, Patrick Finley, Randall Stafford, and Andrew Wong • Board members absent: None • Pauline Chan introduced Dr. Randall Stafford, a new DUR Board member. All DUR Board members and attendees briefly introduced themselves. • Pauline Chan, RPh, Teri Miller, PharmD, Ron Sanui, PharmD, Dorothy Uzoh, PharmD, James Gasper, PharmD, Folashade Naku, PharmD, and Michael McQuiddy, PharmD were present from DHCS Pharmacy Benefits Division. • Ivana Thompson, PharmD (Xerox) announced that the DUR Board meeting is being recorded and reminded everyone to sign in.
2) CALL TO ORDER/ REVIEW AND APPROVAL OF MAY, 2014 MINUTES	<p>The Medi-Cal Drug Use Review Board (the "Board") reviewed the May 20, 2014 minutes. Dr. Wong noted minor typographical errors and motioned that the minutes be approved with these changes. There was no discussion. The Board voted unanimously to approve the minutes with this change.</p> <p>ACTION ITEM: Incorporate Dr. Wong's edit into the minutes and post to the DUR website.</p>
3) OLD BUSINESS	<p>a. Review of Action Items from Previous Board Meeting:</p> <ul style="list-style-type: none"> i. Retrospective DUR review of 1) metformin, 2) ACE inhibitors/ARBs, and 3) statins, and concomitant use of atypical antipsychotics: Amanda Fingado (UCSF) reported that due to time constraints at this DUR Board Meeting, this review will be presented during the next DUR Board Meeting in November. ii. Retrospective DUR review of benzotropine mesylate and concomitant use of any antipsychotic medication: Ms. Fingado reported that due to time constraints at this DUR Board Meeting, this review will also be presented during the next DUR Board Meeting in November. iii. Evaluation of diagnosis codes for beneficiaries with a paid tramadol claim for ≥ 240 tablets: Ms. Fingado will present these data later on in the meeting. iv. DUR Manual revisions: HD/LD alerts (Section 20): A motion was made – and seconded – to accept all proposed DUR Manual edits to Section 20. There was no discussion. The motion was carried. <p>ACTION ITEM: The DUR Board recommendations to approve the Section 20 DUR Manual edits for publication will be submitted to DHCS.</p> <ul style="list-style-type: none"> v. Educational bulletin on smoking cessation (publication in October 2014): Dr. Shalini Lynch (UCSF) reported the draft bulletin is being circulated for review and is on schedule for publication in October. Will present to the DUR Board at the upcoming DUR Board Meeting in November. vi. Educational bulletin on folic acid underutilization (publication in December 2014): Dr.

	<p>vii. Lynch reported that UCSF is beginning to draft this bulletin for publication in December. Further evaluate clinical guidelines for folic acid and methotrexate: Dr. Lynch will present this evaluation later in the meeting.</p> <p>viii. Educational bulletin on red flags for opioid abuse and diversion (publication in August 2014): Dr. Lynch reported this bulletin was published in August and she will present the details of this bulletin later in the meeting.</p>
<p>4) NEW BUSINESS</p>	<p>a. Board Activities: The DUR Board reported there was nothing new to report at this time.</p> <p>b. Presentation by Dr. Randall Stafford: Dr. Stafford provided a summary of his education, training, and key research/policy interests. He also presented national data reviewing antipsychotic medication prescribing from 1994 – 2007, including trends in use of antipsychotics over time. One graphic showed atypical antipsychotic utilization data stratified by both age group and whether the evidence supporting the use of antipsychotics was adequate or inadequate. In both the 0 through 18 years age group and the 65 years and older age group, the data show greater use of atypical antipsychotics based on inadequate evidence than adequate evidence.</p> <p>Dr. Finley asked if Dr. Stafford had identified any particularly problematic off-label use of antipsychotics. Dr. Stafford reiterated that all antipsychotics are not the same and that he has concern about antipsychotics being used as a first-line treatment for depression without adequate trials of antidepressant medication, including SSRIs. He also stated that the use of antipsychotics in the pediatric population for indications that are only approved in adults is problematic, as not enough research is available on the biological impact of antipsychotic use in children and adolescents.</p> <p>c. Pharmacy Update:</p> <p>i. Naloxone: Dr. Dorothy Uzoh presented a summary of the current opioid abuse and misuse epidemic, noting that in 2008 the rate of death from drug poisoning surpassed the rate of death from motor vehicle accidents for the first time and in 2007 prescription opioid overdose deaths exceeded deaths from cocaine and heroin overdose combined. In response, the Pharmacy Benefits Division (PBD) of DHCS has implemented the following strategies to help reduce the risk of death from opioid overdose:</p> <ul style="list-style-type: none"> • Improving access to naloxone, which is an antidote for opioid overdose • Utilization control of various opioid medications • Addition of naltrexone tablets to the Medi-Cal List of Contract Drugs effective February 1, 2014 • Making Vivitrol® (long-acting naltrexone) injection available for the AB 109 population • Making oral buprenorphine formulations available • Working with managed care plans to ensure that the initiatives done by DHCS are in alignment with theirs <p>Dr. Uzoh reported that as of July 1, 2013, naloxone injection (0.4 mg/ml and 1 mg/ml) is on the Medi-Cal List of Contract Drugs. Providers are able to bill naloxone as a pharmacy benefit without an approved <i>Treatment Authorization Request</i>. However, the atomization device for intranasal delivery requires an approved <i>Treatment Authorization Request</i>. In 2014, informational letters from Drs Neal Kohatsu and Ron Chapman were sent to Medi-Cal providers, encouraging them to prescribe take-home naloxone to prevent accidental deaths from opioid overdose. Dr. Kohatsu's letter was published in the April 2014 Medi-Cal Provider Bulletin. Dr. Uzoh showed that total paid claims for naloxone began to increase after the letters.</p> <p>Future plans to improve access to naloxone include:</p> <ul style="list-style-type: none"> • Purchasing materials to create naloxone kits (includes a prefilled naloxone syringe, a needle or the nasal atomization device, and instructions for use in a re-sealable bag) • Selecting pilot sites for distribution of naloxone kits • Funding academic detailing by physicians/pharmacists to visit pilot sites to introduce the kits and educate physicians and pharmacists

- Working with other payers regarding reimbursement for kits
- Working with manufacturer and CMS to establish a unique billing code for the nasal atomization device

At the conclusion of the presentation, Dr. Albertson posed the following questions to Dr. Uzoh:

1. Why is Vivitrol® (naltrexone) only available to the AB 109 population?
2. Why would the atomizer require an approved *Treatment Authorization Request*?
3. Are there numbers available on the percentage of Medi-Cal's high-risk opioid users that are being reached through naloxone outreach efforts? Dr. Albertson stated the number of paid claims for naloxone seems very low compared to the number of high-risk opioid users.

Dr. Uzoh stated that Vivitrol® is available to beneficiaries outside the AB 109 population with an approved *Treatment Authorization Request*. Dr. Albertson said he thought the *Treatment Authorization Request* process for Vivitrol® and the nasal atomizer device for naloxone might present a barrier to access for these medications and encourages DHCS to remove the *Treatment Authorization Request* requirement. Dr. Uzoh reported that the electronic TAR process has reduced the delay to approximately one business day. Dr. Uzoh did not have information available about the total number of high-risk opioid users in the Medi-Cal population or percentage of those high-risk users reached through the naloxone outreach.

- ii. CDSS/DHCS QI Project and other topics: Ms. Chan reported that effective August 18, 2014 tramadol was placed into schedule IV of the Controlled Substances Act. In addition, effective October 6, 2014, hydrocodone combination products have been moved from schedule III into schedule II of the Controlled Substances Act.

Ms. Chan reported that in June 2014 CMS released a draft quality measure for public comment to measure use of multiple concurrent antipsychotics in children and adolescents aged 1-17 years of age. She also reported on three related new measures that will be part of HEDIS® 2015:

- Use of multiple concurrent antipsychotics in children and adolescents (< 18 years)
- Metabolic monitoring for children and adolescents on antipsychotics (<18 years)
- Use of first-line psychosocial care for children and adolescents on antipsychotics (< 18 years)

Ms. Chan also informed the DUR Board of the new restriction placed on antipsychotic medication for Medi-Cal beneficiaries < 18 years of age. Effective October 1, 2014 these beneficiaries will require an approved *Treatment Authorization Request* in order to process a claim for an antipsychotic medication.

Ms. Chan provided an update of the CDSS/DHCS QI Project entitled, "Improving Psychotropic Medication Use for Children and Youth in Foster Care." The purpose of this project is to strengthen California's Medicaid and Child Welfare System by improving safe and appropriate prescribing and monitoring of psychotropic medication use. The project was initiated in July 2012 with the goals of reducing inappropriate psychotropic polypharmacy and enhancing safe use of psychotropic medications. The Clinical Workgroup of the project has created draft guidelines for improving oversight and monitoring of psychotropic medication use for children and youth in foster care and established optimal prescribing standards to engage prescribers to use a minimum number of psychotropic medications, at the lowest possible dosage, and at the appropriate age. The Clinical Workgroup is in the process of establishing monitoring parameters and meets monthly. The Expert Panel meets quarterly and has upcoming meetings in November 2014 and February 2015.

- iii. DUR Annual Report to CMS (FFY 2013): Ms. Chan presented the final draft of the FFY 2013 CMS Annual Report. As there were a number of new questions added to the CMS

Annual Report Survey this year, Ms. Chan went through all the answers given by the State of California.

A motion was made – and seconded – to approve this draft of the DUR Annual Report to CMS for FFY 2013. There was no discussion. The motion was carried.

ACTION ITEM: The DUR Board recommendations to approve the DUR Annual Report to CMS will be submitted to DHCS.

- iv. Morphine Milligram Equivalency: Dr. Ivana Thompson presented a document summarizing morphine milligram equivalency. She reported that recent studies have demonstrated that a patient's cumulative, daily morphine equivalent dose (MED) of opioids is an indicator of potential dose-related risk for adverse drug reactions. The MED calculation can be used to equate opioid drugs with different potencies via calculation of a standard morphine equivalent value. By converting the dose of an opioid to a morphine equivalent dose, clinicians can determine whether the patient's dose approaches an amount associated with an increased risk of overdose. Research data show that compared with patients receiving 1 to 20 mg MED per day, patients receiving 100 mg MED or more daily had an 8.9-fold increase in overdose risk and a 1.8% annual overdose rate.

Dr. Stafford thought that because methadone is a more difficult calculation there should be more information and guidance about calculating equivalency in this document. He also thought it would be helpful to include clinical guidelines for pain management for mild-to-moderate pain. Dr. Albertson suggested explicitly stating in the document that the equivalency is for oral morphine.

Ms. Chan stated that DHCS is asking for guidance from the DUR Board regarding the use of morphine equivalency. Dr. Stafford said it might be useful to research other state agencies in California, such as worker's compensation, and see if they are using morphine equivalency to set policy.

A motion was made – and seconded – to revise and expand the morphine milligram equivalency document to include more information as suggested by the DUR Board members, including research on the use of morphine equivalency among other state agencies in California. There was no further discussion. The motion was carried.

ACTION ITEM: The DUR Board recommendations to revise and expand the morphine milligram equivalency document will be submitted to DHCS.

- d. Quarterly Report – 2Q2014 (April – June 2014): Amanda Fingado (UCSF) presented the DUR quarterly report for the 2nd quarter of 2014. She reported that the top 20 drugs by percentage of utilizing beneficiaries with a paid claim showed ALBUTEROL SULFATE entering the top 20 (at #13), replacing LEVALBUTEROL TARTRATE, which had been ranked at #14 in the prior quarter. This shift is most likely due to recent policy changes for both of these drugs that were effective March 1, 2014. LEVALBUTEROL TARTRATE had a restriction added to the allowed dates of service and ALBUTEROL SULFATE had a restriction to the allowed dates of service removed.
- e. Review of Physician Administered Drugs (PADs) – 1Q2014 (January – March): Ms. Fingado showed a summary of paid claims for physician-administered drugs for the 1st quarter of 2014, which includes paid claims with dates of services between January 1, 2014 and March 31, 2014. These data were presented in three tables: 1) the top 20 drugs by total reimbursement paid, 2) the top 20 drugs by utilizing beneficiaries, and 3) the top 20 drugs by reimbursement paid to pharmacies per utilizing beneficiary. Ms. Fingado reported a 13% decrease in both total utilizing beneficiaries and total paid claims from 4Q2013 to 1Q2014 in the category "PHYSICIAN ADMINISTERED DRUG – NDC NOT REQUIRED," which is most likely due to rates of vaccination peaking each year in the 4th quarter.

- f. Update on the Tramadol Policy Impact Report: Ms. Fingado reported that as of August 18, 2014 tramadol has been placed into schedule IV of the Controlled Substances Act. She also presented the results of a follow-up evaluation of the 58 paid claims for 50mg tramadol that were for amounts greater than 240 tablets. Of the 28 Medi-Cal fee-for-service beneficiaries who had one or more of the 58 paid claims for greater than 240 tablets, five beneficiaries had a calculated dose of tramadol of greater than 400mg/day (the maximum recommended daily dose of 50mg tramadol), and only three had a prescribed dose of greater than 400mg/day. Ms. Fingado also presented the top ICD-9 codes for those 28 beneficiaries and found the most common diagnosis was LUMBAGO (n=10, 36%). In addition, five beneficiaries had an ICD-9 code for LONG-TERM (CURRENT) USE OF OTHER MEDICATION. All five of these beneficiaries appeared to be using tramadol as a replacement analgesic for more potent opioid medications, as their pharmacy records showed a decrease in paid claims for other opioids during the measurement year.
- g. Prospective DUR: Review of DUR Alerts for New GCNs in 2Q2014 (April – June 2014) presented by Amanda Fingado
- At each DUR Board meeting, a list of new GCN additions 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 four GCNs:
 - GCN #072215: IBUPROFEN/PHENYLEPHRINE HCL, Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Additive Toxicity (AT), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
 - GCN #061488: NITROGLYCERIN, Therapeutic Duplication (TD), Ingredient Duplication (ID), Underutilization (LR), High Dose (HD), Low Dose (LD)
 - GCN #072282: NITROGLYCERIN, Therapeutic Duplication (TD), Ingredient Duplication (ID), Underutilization (LR), High Dose (HD), Low Dose (LD)
 - GCN #072352: PROPANOLOL HCL, Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), Underutilization (LR), 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.
- h. Retrospective DUR presented by Dr. Shalini Lynch (UCSF):
- i. Retrospective DUR Educational Outreach: Tramadol
- Dr. Lynch presented a proposal to pilot-test a retrospective DUR educational outreach letter intervention to providers. The objectives of the pilot-test are to 1) educate prescribers on the statistics regarding abuse and diversion of tramadol, 2) inform prescribers that tramadol is now a schedule IV controlled substance, and 3) assess the feasibility and acceptability of a letter-writing intervention to health care providers in the Medi-Cal fee-for-service population. Dr. Lynch stated that the dataset used in writing the DUR educational bulletin on drug diversion would be used to identify the top 100 prescribers of tramadol to Medi-Cal FFS beneficiaries (by total paid claims) between April 1, 2013 and March 31, 2014. A letter and response survey will be sent to each prescriber at their service address, along with a one-page description of tramadol published by the Drug Enforcement Administration after the tramadol ruling in July 2014. In total, the mailing packet will contain two one-sided paper documents (8 ½" x 11") and one self-addressed, stamped envelope to assist providers in returning the response survey. The timing of the mailing will be no sooner than August 18, 2014 when the law placing tramadol into schedule IV of the Controlled Substances Act goes into effect.
- For this proposal, the primary outcome variables will be process-related and will include the following:
- Rate of undeliverable letters
 - Provider response rate after 30 days
 - Direct costs associated with mailing
 - Timeframe of mailing following approval of letters by DHCS

These process variables will help determine both the feasibility and acceptability of mailing educational intervention letters directly to providers. Provider response data will be presented in aggregate in a report to DHCS.

Ms. Fingado stated the goal of this particular outreach was not to impact prescribing patterns, but rather to work through the details involved in sending provider letters and to establish a protocol for sending out future letters that may have more of a quality-improvement focus. Ms. Fingado gave an example of one of the issues uncovered during this process and described how prescriber NPIs were listed for paid claims and a prescriber could prescribe a medication to a Medi-Cal beneficiary but not be registered in the Medi-Cal provider database. Dr. Thompson reported that as part of the contract between Xerox and DHCS, Xerox is only authorized to send correspondence to providers in the Medi-Cal provider database, so it was possible that not all 100 of the top prescribers of tramadol would be contacted through this educational intervention. Dr. Lee Worth (Audits and Investigations) reported that starting January 1, 2015 all prescribers must be registered with Medi-Cal in order to prescribe medications to Medi-Cal beneficiaries. Dr. Wong suggested that in light of this, we wait to send out the letters until after the first of the year. Ms. Fingado stated her opinion that since the objectives of the proposal are not to impact prescribing, but rather to establish processes for sending provider letters, delaying the letters into 2015 would delay obtaining useful information about the process even further. Dr. Stebbins said she thought DUR should move forward with sending the letters as soon as possible and not delay any further.

- A motion was made – and seconded – to accept the tramadol proposal as-is. There was no additional discussion. The motion was carried, with Dr. Wong abstaining from the vote.

ACTION ITEM: The DUR Board recommendations to approve the proposal to pilot-test a retrospective DUR educational outreach letter intervention to providers about tramadol will be submitted to DHCS.

- ii. Review of Retrospective DUR Criteria: Antipsychotics in Children and Adolescents
 - Dr. Lynch reported that antipsychotic use among children and adolescents has increased rapidly in recent decades, driven by new prescriptions and by longer duration of use. Although some evidence supports the efficacy of antipsychotics in patients under 18 years of age for certain narrowly defined conditions, according to a 2011 report by the Agency for Healthcare Research and Quality (AHRQ), children taking antipsychotic medications receive an atypical antipsychotic 90 percent of the time and in the majority of patients the use is for an off-label indication, including attention-deficit/hyperactivity disorder (ADHD) and aggressive behavior. One study found that in the Medicaid population, more than three-fourths of children and adolescents are taking antipsychotics for an indication that is not FDA approved. Antipsychotics have serious, common side effects and are the most costly drug class within the Medicaid program. Dr. Lynch presented antipsychotic medication utilization data over a one-year period (dates of service between May 1, 2013 and April 30, 2014) for Medi-Cal beneficiaries < 18 years of age. She reported 33,811 unique beneficiaries < 18 years of age had at least one paid claim for an antipsychotic medication during this time period.
 - Dr. Lynch recommended writing a DUR educational bulletin to educate providers on appropriate prescribing of antipsychotics to children and adolescents. The bulletin would include the following:
 1. An evaluation of the Medi-Cal data using a new HEDIS 2015 measure (technical specifications will be available in November 2014) that assesses the percentage of children and adolescents who are on two or more antipsychotic medications for an extended period of time.
 2. A description of the FDA-approved product labeling for the appropriate use of

	<p>atypical antipsychotics in patients < 18 years of age, including information about the potential adverse reactions and risks associated with antipsychotic therapy.</p> <ol style="list-style-type: none"> 3. A summary of current treatment guidelines, which endorse a trial of antipsychotics as a second-line treatment, after first-line psychosocial treatments, such as parent and child skills training, have been tried. 4. A statement of the current lack of evidence for using multiple, concurrent antipsychotics, especially among children and adolescents. 5. Information regarding the new Medi-Cal restriction, effective October 1, 2014, which will require an approved <i>Treatment Authorization Request</i> for any antipsychotic medication prescribed for Medi-Cal beneficiaries <18 years of age. <ul style="list-style-type: none"> • A motion was made – and seconded – to agree with the recommendation to write this bulletin. There was no further discussion. The motion was carried. <p>ACTION ITEM: The DUR Board recommendations for a DUR educational bulletin to educate providers on appropriate prescribing of antipsychotics to children and adolescents will be submitted to DHCS for publication.</p> <ol style="list-style-type: none"> iii. Update: Folic Acid <ul style="list-style-type: none"> • Dr. Lynch presented an updated folic acid review that included additional international literature supporting the use of folic acid supplementation as a cost-effective and perhaps cost-saving treatment strategy for rheumatoid arthritis patients being treated with methotrexate. Dr. Wong agreed the majority of the international community does support these findings, with a small percentage of practitioners advocating for the use of folic acid only once side effects from methotrexate are indeed present. • A motion was made – and seconded – to agree with the recommendation to write a DUR educational bulletin on this topic, focusing on both the underutilization of folic acid in women of childbearing age and patients taking methotrexate for rheumatoid arthritis. The motion was carried. <p>ACTION ITEM: The DUR Board recommendations for a DUR educational bulletin in the December Medi-Cal Pharmacy Priority Bulletin to promote folic acid use among women of childbearing age and Medi-Cal fee-for-service beneficiaries who have been prescribed methotrexate for rheumatoid arthritis will be submitted to DHCS.</p> <ol style="list-style-type: none"> i. Review of DUR Publications presented by Dr. Shalini Lynch (UCSF) <ol style="list-style-type: none"> i. DUR Educational Bulletin (August, 2014): Drug Diversion <ul style="list-style-type: none"> • Due to time constraints, Dr. Lynch was unable to present this topic. However, she reminded everyone that this bulletin has already been published and is available for review on the DUR website. ii. Discussion/Recommendations for Future Bulletins <ul style="list-style-type: none"> • Due to time constraints, there were no additional discussions or recommendations for future bulletin topics.
j. PUBLIC COMMENTS	None.
k. CONSENT AGENDA	<ul style="list-style-type: none"> • The next Board meeting will be held from 9:30 a.m. to 12:00 p.m. on November 25, 2014 in the Monterey Room located at Xerox State Healthcare, LLC on 840 Stillwater Road, West Sacramento, CA 95605.
l. ADJOURNMENT	<ul style="list-style-type: none"> • The meeting was adjourned at 1:07 p.m.

Action Items	Ownership
Incorporate Dr. Wong's edits into the minutes and post to the DUR website.	Amanda/Ivana
The DUR Board recommendations to approve the Section 20 DUR Manual edits for publication will be submitted to DHCS.	Amanda/Ivana
The DUR Board recommendations to approve the DUR Annual Report to CMS will be submitted to DHCS.	Pauline
The DUR Board recommendations to revise and expand the Morphine Milligram Equivalency document will be submitted to DHCS.	Ivana/Shalini
The DUR Board recommendations to approve the proposal to pilot-test a retrospective DUR educational outreach letter intervention to providers about tramadol will be submitted to DHCS.	Ivana/Amanda
The DUR Board recommendations for a DUR educational bulletin to educate providers on appropriate prescribing of antipsychotics to children and adolescents will be submitted to DHCS.	Amanda/Shalini
The DUR Board recommendations for a DUR educational bulletin in the December Medi-Cal Pharmacy Priority Bulletin to promote folic acid use among women of childbearing age and Medi-Cal fee-for-service beneficiaries who have been prescribed methotrexate for rheumatoid arthritis will be submitted to DHCS.	Amanda/Shalini