



**MEDI-CAL DRUG USE REVIEW BOARD  
MEETING MINUTES  
Tuesday, May 17, 2016  
9:30 a.m. – 12 p.m.**

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

Topic	Discussion
<b>1) WELCOME/ INTRODUCTION</b>	<ul style="list-style-type: none"> <li>• The meeting was called to order by the Chair of the Board, Dr. Robert Mowers.</li> <li>• Board members present: Drs. Andrew Wong, Randall Stafford, Robert Mowers, Patrick Finley, Timothy Albertson, Janeen McBride, and Marilyn Stebbins.</li> <li>• Board members absent: none.</li> <li>• Board members and attendees introduced themselves.</li> <li>• Pauline Chan, RPh, Michael McQuiddy, PharmD, Teri Miller, PharmD, and Dorothy Uzoh, PharmD were present from DHCS Pharmacy Benefits Division.</li> <li>• Ivana Thompson, PharmD (Xerox) announced that the DUR Board meeting is being recorded and reminded everyone to sign the attendance sheet.</li> </ul>
<b>2) CALL TO ORDER/ REVIEW AND APPROVAL OF FEBRUARY 2016 MINUTES</b>	<p>The Medi-Cal Drug Use Review Board (the “Board”) reviewed the February 16, 2016 minutes. Dr. Wong noted he had minor edits and motioned that the minutes be approved with these changes. There was no discussion. The Board voted unanimously to approve the minutes as edited by Dr. Wong.</p> <p><b>ACTION ITEM:</b> Incorporate Dr. Wong’s edits into the minutes and post to the DUR website.</p>
<b>3) OLD BUSINESS</b>	<p>a. Review of Action Items from Previous Board Meeting:</p> <ul style="list-style-type: none"> <li>i. Pricing Policy for Code Z7610 – Ms. Chan provided a handout that described the current policy for the Healthcare Common Procedure Coding System (HCPCS) Code Z7610, which is used for miscellaneous drugs and supplies for non-surgical procedures. She explained this code may only be used by hospital outpatient departments, emergency rooms, surgical clinics, and community clinics. The current pricing policy links the HCPCS Code and the National Drug Code (NDC) and claims are reimbursed according to established minimum and maximum reimbursement parameters for each pair. She reported that a review of recent reimbursement data for claims involving HCPCS Code Z7610 and both acetaminophen and ibuprofen showed an average reimbursement of approximately \$8.00 per claim, inclusive of the dispensing fee. The Board did not have any further questions regarding the pricing policy.</li> <li>ii. Prospective DUR: New Generic Code Numbers (GCNs) – Due to a lack of quorum at the February 2016 Board Meeting, the Board made a motion during the May 2016 meeting to accept the recommended alert profiles for the GCN additions from the 4<sup>th</sup> quarter of 2015, which were presented in February. There was no discussion and the motion was approved.</li> <li>iii. Prospective DUR: LR Alert – Due to a lack of quorum at the February 2016 Board Meeting, the Board made a motion during the May 2016 meeting to accept the recommended changes for the late refill (LR) alert, which were presented in February. There was no discussion and the motion was approved.</li> <li>iv. Educational Outreach: Morphine Equivalent Daily Dose (MEDD) Letter – Due to a lack of quorum at the February 2016 Board Meeting, the Board made a motion during the May 2016 meeting to accept the MEDD proposal for educational outreach to providers, which was presented in February. There was no discussion and the motion was approved.</li> </ul>

	<p>v. RetroDUR: Skeletal Muscle Relaxants – Due to a lack of quorum at the February 2016 Board Meeting, the Board made a motion during the May 2016 meeting to accept the skeletal muscle relaxant retrospective DUR recommendations, which were presented in February. There was no discussion and the motion was approved.</p> <p>vi. RetroDUR: Buprenorphine – Due to a lack of quorum at the February 2016 Board Meeting, the Board made a motion during the May 2016 meeting to accept the buprenorphine retrospective DUR recommendations, which were presented in February. There was no discussion and the motion was approved.</p>
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<b>4) NEW BUSINESS</b>	<p><b>a.</b> Board Activities: Ms. Chan informed the Board that a meeting to share academic detailing best practices has been set for October 20, 2016 in Sacramento.</p> <p><b>b.</b> Managed Care Presentation by the Partnership HealthPlan: “Managing Pain Safely: A plan’s approach to combating the opioid epidemic” – Ms. Danielle Niculescu from Partnership HealthPlan was the primary presenter; she also introduced her colleagues Dr. Stan Leung and Ms. Dina Haynes. Ms. Niculescu first provided some general background information about Partnership HealthPlan of California (PHC), which is a County Organized Health System (COHS) Plan. She reported that they have a low administrative rate (less than 4 percent), which allows PHC to have a higher provider reimbursement rate and to support community initiatives through local governance that can be sensitive and responsive to the area’s healthcare needs. She also described the PHC advisory boards that participate in collective decision making.</p> <p>Ms. Niculescu summarized recent data on the opioid epidemic showing statewide and regional rates of opioid overuse and overdoses and identified the community and health plan stakeholders and how they interact through PHC liaisons to address opioid overuse.</p> <p>Ms. Niculescu then introduced PHC’s Managing Pain Safely Aim Statement, which states: “By December 31, 2016, we will improve the health of PHC members by ensuring that prescribed opioids are for appropriate indications, at safe doses, and in conjunction with other treatment modalities as measured by a:</p> <ul style="list-style-type: none"> <li>• Decrease in total number of initial prescriptions by 75%;</li> <li>• Decrease in total number of inappropriate prescription escalations by 90%; and</li> <li>• Decrease in total number of patients on inappropriate high-dose opioids (defined as &gt;120 mg MED) by 75%”</li> </ul> <p>Ms. Niculescu stated that in order to achieve the aims listed above, PHC implemented educational efforts (focused on changing the former understanding of “no maximum dose”, hyperalgesia, and decreased functioning), changed pharmacy prior authorization requirements, covered additional options for treating pain, aligned incentives for providers, and community activation.</p> <p>Changes to the pharmacy prior authorization requirements included the following:</p> <ul style="list-style-type: none"> <li>• Scrutinize justification for high doses of expensive opioids</li> <li>• Scrutinize escalation of high-dose opioids (no matter what the price)</li> <li>• Scrutinize all prescriptions for stable high doses of opioids <ul style="list-style-type: none"> <li>○ Request explanation for stable high dose</li> <li>○ Difficult cases may require supporting documentation of mental health, pain specialist, or pain medication oversight committee</li> <li>○ Track responses with PHC-level registry of patients on high dose opioids</li> </ul> </li> <li>• Implement 30 tablet maximum for short-acting opioids without prior authorization for new onset acute pain</li> </ul> <p>Ms. Niculescu presented additional options for treating pain through expanded benefits allowing for podiatry, chiropractic services, acupuncture, and osteopathic manipulation therapy; formulary changes including addition of duloxetine and other adjunctive non-opioid treatments to the formulary; and expanded access to supportive behavioral treatment and mindfulness/relaxation self-help tools.</p>
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Ms. Niculescu described the aligned incentives, including both intrinsic incentives (compliance with Medical Board and Department of Justice, increased access to care providers for patients with other conditions) and supplementary financial incentives, such as a primary care pay-for-performance program.

Ms. Niculescu then summarized the following Managing Pain Safely (MPS) outcome measures:

- Total prescriptions (rate of opioid prescriptions per member, per month)
- Initial prescriptions (rate of initial prescriptions per member, per month)
- Prescription escalations (percentage of total opioid users with escalated dose in measurement period)
- Unsafe dose (percentage of total opioid users on a dose >120 mg. morphine equivalents per day)

Ms. Niculescu presented outcomes data from January 2014 to March 2016, demonstrating:

- 49% decrease in number of opioid prescriptions per 100 members per month (P100MPM)
- 48% decrease in unsafe dose (>120 mg MED) prescriptions
- 32% decrease in initial opioid fills (P100MPM)

Keys to success included communicating a compelling need, providing a picture of success, communicating the path to success, and adding aligned incentives. Ms. Niculescu concluded by reporting the following additional health plan activities planned for 2016:

- Focusing on the reduction of over-prescribing of short-acting opioids for acute pain
- Enhancing support of local coalitions
- Planning process for creating integrated clinics for high utilizers
- Pharmacy academic detailing
- MPS provider site-level data sharing
- Promotion of naloxone distribution
- Quantity limit implementation for immediate release opioids

- c. Presentation: "Comprehensive Medication Management: California Wellness Plan Implementation"– Dr. Jessica Núñez de Ybarra, Program Chief, highlighted the chronic disease burden in California. She reported that estimated health care costs for the top five chronic conditions in 2010 (cancer, heart diseases, stroke, chronic lung conditions, and Alzheimer's disease) account for expenditures totaling \$98 Billion, or 42.4% of the total health care expenditures in the state.

The California Wellness Plan (CWP) stems from Governor's Executive Order B-19-12 to develop a 10 year plan to improve the health in California, control costs, improve quality of health care, promote personal responsibility for health, and advance health equity. The goals and strategies of CWP are to address chronic disease and promote the triple aim: better health, better care, lower cost. CWP provides a roadmap for chronic disease prevention via collective impact, objectives with baseline, benchmark & target outcomes, population health focus, and Healthy Community Indicators. The overarching goal of CWP is equity in health and wellbeing, with an emphasis on eliminating preventable chronic diseases through these focus areas:

- Healthy Communities
- Optimal Health Systems Linked with Community Prevention
- Accessible and Usable Health Information
- Prevention Sustainability and Capacity

Dr. Núñez de Ybarra then highlighted the white paper entitled, "*Comprehensive Medication Management (CMM) Programs: Description, Impacts, and Status in Southern California*", which was published in 2015. This white paper describes the current landscape, including the delivery, use, outcome, benefits, and challenges of CMM. She described how CMM is an evidence-based, physician-approved, pharmacist-led, preventive clinical service that ensures optimal use of medications effective at improving health outcomes for high-risk

patients, while decreasing health care costs.

Dr. Núñez de Ybarra then compared CMM, with Medication Therapy Management Comprehensive Medication Review (CMR) and Disease State Medication Therapy Management (dsMTM). All three programs conduct a comprehensive medication therapy review to identify all medications currently being taken and generate a personal medication record. However, she also noted some differences among the programs. For example, eligibility for CMR is determined by an anticipated annual drug spend (minimum of \$3138 in 2015) and a minimum number of drugs and conditions, no clinical data is necessary, drug therapy problems are found only related to potential drug-drug interactions, duplicative therapy, opportunities for less expensive alternatives, and suggested inappropriate medications based on age (Beers criteria). In contrast, dsMTM and CMM both include evaluating a patient to clarify or confirm medication-related problems including basic assessment, point-of-care testing, ordering medication-related tests, etc.; developing an individualized medication care plan to resolve medication-related problems and ensure successful attainment of treatment goals; the ability to add, substitute, discontinue, or modify medications/doses as needed or recommend changes, depending on state-specific scope of practice laws and in collaboration with health care team; provisions for documenting care delivered, including progress towards treatment goals, and communicating details to primary care provider and other relevant healthcare team members in a timely manner; ensuring that care is coordinated with all other team members within the broad range of services being provided to the patient; and providing follow-up care, according to individual patient needs, to determine actual outcomes from medication therapy and ensure that treatment-related goals are being achieved.

However, Dr. Núñez de Ybarra emphasized that only CMM includes an assessment of clinical status for ALL medications and medical conditions, as opposed to select medications or conditions. CMM also requires formal collaborative practice agreement between a pharmacist and a physician.

CMM pilots have been successfully implemented in six health care systems in Southern California where improvements were seen in clinical, fiscal, and quality measures. Challenges included a lack of reimbursement mechanisms, alignment of financial incentives, robust health information exchange, tracking systems for CMM impacts, and adequate staff and space.

Dr. Stebbins, one of the authors of the white paper, provided additional remarks emphasizing the holistic approach of CMM, and thanked Dr. Núñez de Ybarra for her leadership. Dr. Stafford pointed out the limitations of our current health information infrastructure, which seems to be incapable of measuring outcomes related to wellness. Dr. Núñez de Ybarra agreed and emphasized that while the overall aim of the program is for Californians to be “healthier,” these types of goals are currently very difficult to measure.

- d. Quarterly Report – 1Q2016 (January – March 2016): Ms. Fingado reported that in 2016 Q1, three drug therapeutic categories posted across-the-board 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. While NSAIDS, CYCLOOXYGENASE INHIBITOR – TYPE may be related to cold and flu season, which peaked in California during February 2016, the other two categories are related to treatment for chronic conditions: ANTIHYPERGLYCEMIC – HMG COA REDUCTASE INHIBITORS and ANTIHYPERGLYCEMIC, BIGUANIDE TYPE. She pointed out that these increases were unusual, given the shift of Medi-Cal fee-for-service beneficiaries into Medi-Cal managed care plans. She recommended continuing to monitor utilization and perhaps complete a retrospective DUR review on these categories if this trend continues.

Dr. Mowers pointed out that our population is so skewed that our pharmacy utilization reports do not match up with reports provided by the California Wellness Plan, which showed cancer, heart diseases, stroke, chronic lung conditions, and Alzheimer’s disease accounting for almost half of health care expenditures. Ms. Fingado agreed, and reminded

the group that the carved-out drugs are overrepresented in this population and may obscure other categories. She also stated that while antipsychotic medications may get a lot of attention from the DUR program, several bulletins have been written to address chronic conditions, including asthma, diabetes, and cardiovascular disease. Ms. Chan reminded the group that the goal of having the health plans come and present to the Board is to begin to open up lines of communication between fee-for-service and managed care. Ms. Fingado reported at the next meeting she will present a review on utilization of HIV antiretroviral medications, which will include data from both fee-for-service and managed care for the first time.

- e. Review of Physician Administered Drugs (PADs) – 4Q2015 (October – December): Ms. Fingado showed a summary of paid claims for physician-administered drugs for the 4<sup>th</sup> quarter of 2015, which includes paid claims with dates of services between October 1, 2015, and December 31, 2015. 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 increases in both total utilizing beneficiaries (a 23% increase) and total paid claims (a 14% increase) from 3Q2015 to 4Q2015 in the category “PHYSICIAN ADMINISTERED DRUG – NDC NOT REQUIRED,” which can be attributed to the influenza vaccine. Within this same category, Ms. Fingado pointed out large decreases in both total utilizing beneficiaries (a 52% decrease) and total paid claims (a 46% decrease) from 4Q2014 to 4Q2015. Ms. Fingado stated that this decrease is most likely due to the migration of dually-eligible beneficiaries into the Cal MediConnect program.
- f. Prospective DUR reports were presented by Amanda Fingado
  - i. Review of DUR Alerts for New GCNs in 1Q2016 (January – March 2016)
    - 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 the following eighteen GCNs:
      - GCNs # 074867 and # 074870: SOMATROPIN – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
      - GCNs #075263, #075264, and #075265: METHYLPHENIDATE HCL – High Dose (HD), Low Dose (LD)
      - GCN #075439: DICLOFENAC/BENZALKONIUM CHLOR – Drug Allergy (DA), Drug Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD)
      - GCN #075526: BUTALBITAL/ACETAMINOPHEN – Ingredient Duplication (ID), High Dose (HD)
      - GCNs #074807, #074808, #074809, #074810, and #075566: CARIPRAZINE HYDROCHLORIDE – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD)
      - GCN #075581: TESTOSTERONE MICRONIZED – Drug Pregnancy (PG), Additive Toxicity (AT), High Dose (HD), Low Dose (LD)
      - GCN #062950: FENTANYL/ROPIVACAINE/NS/PF – Drug-Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
      - GCN #075634: EMTRICITAB/RILPIVIRI/TENOF ALA – Ingredient Duplication (ID)
      - GCNs #075636 and #075637: METOPROLOL TARTRATE – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), High Dose (HD), Low Dose (LD)
      - GCN #075703: GABAPENTIN/LIDOCAINE/MENTHOL – Drug-Allergy (DA), Late Refill (LR), Ingredient Duplication (ID), 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 Prospective DUR Criteria: Update on Pregnancy (PG) Alert
- Ms. Fingado provided an update to the group after implementation of PG alert recommendations made at the November 2015 DUR Board meeting. She presented a list of drugs where the PG alert had either been turned on or turned on in test mode and stated that the DUR manual has been updated.
  - Ms. Fingado presented data on the test alerts that was collected over a ten-week period (December 25, 2015 through March 4, 2016) and showed only 20 drugs out of the 255 drugs listed in Table 3 (8%) generated PG alerts while in test mode. She reminded the group that when in test-mode, PG alerts are generated for all submitted claims (not necessarily paid claims), so data summarized using alerts from test-mode typically overestimate the number of alerts that would be generated.
  - She reported that the following four drugs were the only drugs to generate greater than 10 alerts over the 10-week period:
    - METHYLERGONOVINE MALEATE (222 alerts; 361 paid claims during this period)
    - ULIPRISTAL ACETATE (52 alerts; 743 paid claims during this period)
    - TOPIRAMATE (51 alerts; 6,172 paid claims during this period)
    - METRONIDAZOLE (21 alerts; 19,115 paid claims during this period)
  - A spot check of the PG alerts showed they seemed to be working properly. The drug generating the highest percentage of alerts, METHYLERGONOVINE MALEATE has an indication specific to pregnant women (postpartum hemorrhage), which may explain the high number of alerts among paid claims.
  - Finally, Ms. Fingado reported that First Databank (FDB) made modifications to the PG alert since December 2015. The following drugs were downgraded from a clinical significance of D, X, or 1: DABRAFENIB, ERIBULIN, EVEROLIMUS, LOMUSTINE, MEDROXYPROGESTERONE ACET (INTRAMUSC), METHOXSALEN (ORAL and TOPICAL), METHYLPREDNISOLONE, NICOTINE POLACRILEX, NINTEDANIB, NORGESTIMATE, PREDNISOLONE (SYSTEMIC), and PREDNISON.
  - The following recommendations were presented to the DUR Board for consideration:
    - Moving to active mode for all drugs currently in PG alert test-mode due to the relatively low alert burden and the potential to prevent drug-related adverse events among women with a documented pregnancy. Exceptions to this recommendation will be drugs that have since been downgraded from a clinical significance of D, X, or 1 by either the FDA or FDB since December 2015.
    - Conducting periodic evaluations of alert and claims data, in order to re-assess alert burden and whether these alerts are proving to be clinically meaningful.
    - Evaluating the PG alert on an annual basis for all changes to category and severity levels (as provided by the FDA and/or FDB), with an annual presentation of these changes to the DUR Board for review.
  - A motion was made – and seconded – to accept these recommendations. There was no further discussion. The motion was carried.

**ACTION ITEM:** The following DUR Board recommendations will be submitted to DHCS: 1) Turn on the PG alert for all drugs currently with PG alert in test-mode; 2) Conduct periodic evaluations of alert and claims data; and 3) Evaluate the PG alert on an annual basis for all changes to category and severity levels and present these changes to the DUR Board for review.

- iii. Review of Prospective DUR Criteria: Drug-Drug Interaction (DD) Alert
- Ms. Fingado reported that Medi-Cal policy in the current DUR manual (Section 20) says the following: “A list of Severity Level 1 interacting drug pairs is available upon

request. To make a request, see the contact information on the DUR: Board Meetings web page under the DUR Main Menu on the Medi-Cal website at [www.medi-cal.ca.gov](http://www.medi-cal.ca.gov).”

- However, in a different location within Section 20 of the DUR manual, Ms. Fingado stated there is a list of 53 interacting drug pairs that was not omitted when the new wording was added. According to the latest list obtained from FDB, there are currently 953 drug (or drug class) pairs with a potential for a Severity Level 1 interaction. As only 53 pairs appear in the manual, this is an outdated resource.
- Ms. Fingado suggested the DUR Board recommend removal of the existing interacting drug pairs table from Section 20 of the DUR manual and add updated instructions to Section 20 of the DUR manual for providers to consult up-to-date references for a possible Severity Level 1 interaction.
  
- A motion was made – and seconded – to accept these recommendations. There was no further discussion. The motion was carried.

**ACTION ITEM:** The DUR Board recommendations to update the Drug-Drug Interaction (DD) Alert portions of Section 20 of the DUR manual will be submitted to DHCS.

**g. Review of DUR Educational Outreach to Providers**

**i. Updated Outcomes: Antipsychotic Monitoring**

- Ms. Fingado presented updated outcomes from the provider letter aimed at increasing metabolic testing among children and adolescents in the Medi-Cal fee-for-service population taking antipsychotic medications. She reported that a total of 548 beneficiaries met inclusion/exclusion criteria for the mailing and that in the 57 cases where a beneficiary had multiple prescribers, the most recent prescriber was usually selected to receive the letter. A total of 264 prescribers were identified for educational outreach letters, although some prescribers had more than one address listed as their physical location, so a total of 274 prescriber letters were prepared for mailing.
- Ms. Fingado summarized outcome data for this mailing, including the following:
  - Rate of undeliverable letters: A total of 80 providers (out of 264 unique providers) had their letters returned to sender as undeliverable, for an undeliverable rate of 30%
  - Provider response rate (within 90 days): A total of 75 providers (out of 264 unique providers) returned 154 patient surveys within 90 days, for a provider response rate of 28%
  - A total of 154 patient surveys were returned, representing 28% of patient surveys sent to providers (a total of 548 surveys were sent)
  - If the undeliverable letters are removed from the denominator, the response rate increased to 41% (75 out of 184 unique providers)
  - Out of the 548 beneficiaries in the original study population, a total of 439 (80%) continue to be eligible in the Medi-Cal fee-for-service program. The letters for 147 of these beneficiaries were returned as undeliverable, leaving a total of 292 beneficiaries as the denominator.
    - 57 of these beneficiaries (20%) had at least one laboratory monitoring test done within 90 days of the mailing
    - 54 beneficiaries (18%) had both laboratory monitoring tests completed
    - 65 of these beneficiaries (22%) had at least one laboratory monitoring test done within 6 months of the mailing
    - 61 beneficiaries (21%) had both laboratory monitoring tests completed
    - Among the 147 beneficiaries who had letters to their providers returned as undeliverable, only one of these beneficiaries had at least one laboratory monitoring test done within 90 days of the mailing (and only three within 6 months of the mailing), for a rate of less than 1%.
  - Out of the 292 beneficiaries evaluated for the primary outcome variable, a total of 104 of these beneficiaries (36%) have not had at least two paid claims for an antipsychotic medication since the mailing (dates of service September 1, 2015

through February 29, 2016).

- She also summarized the survey responses.
    - A total of 138 surveys (90%) indicated that the patient was currently under their care, with the following responses (respondents could check more than one option):
      - “I have reviewed the information and will order metabolic testing” (n=82; 53%)
      - “I have reviewed the information and will continue without change” (n=47; 31%)
      - “however, has not seen me recently” (n=13; 8%)
      - “I have reviewed the information and will modify drug therapy” (n=3; 2%)
    - A total of 16 surveys (10%) indicated that the patient was not currently under their care, with the following responses:
      - “but has previously been a patient of mine” (n=10; 6%)
      - “however, I did prescribe medication while covering for other MD or in the ER” (n=3; 2%)
      - “and has never been a patient of mine” (n=3; 2%)
    - A total of 55 patient surveys (36%) contained written comments from providers. The majority of comments discussed lab testing recently completed (n=14) or ordered (n=14, with 11 of these comments stating this was being done in response to the letter). Some comments described barriers to completion and several comments described that the patient had not been seen for an extended period of time (n=3) or was no longer their patient (n=9)
  - Ms. Fingado suggested the Board discuss the benefit of future educational outreach to providers on this topic, including the possibility of a repeat of this intervention in the future and/or patient-specific reminders for providers to order metabolic monitoring for children and adolescents in the Medi-Cal population. The Board agreed this intervention appeared to have very successful outcomes and that it may be worthwhile repeating in some capacity in the future.
- ii. Outcomes: MEDD Letter
- Ms. Fingado reported that after the threshold for the educational letter to providers was adjusted to > 120 mg MEDD and the days’ supply filtered to only include those paid claims with a days’ supply greater than 14 days, the number of providers dropped to 380, representing 464 beneficiaries and 1,542 paid claims. Of these, a total of 218 providers had current mailing addresses listed in the Medi-Cal Master Provider File (representing 259 beneficiaries and 951 paid claims).
  - Ms. Fingado and Ms. Thompson conducted a final review of the medical and pharmacy claims for the 259 beneficiaries the week before the mailing and 101 beneficiaries who did not have a paid claim for an opioid after November 30, 2015 were excluded, as were two beneficiaries who were now listed as deceased, and one beneficiary who was found to have a cancer diagnosis. Patient profiles were developed for the remaining 155 beneficiaries and 134 letters were created for 132 prescribers (two prescribers had two separate practice locations listed).
  - Ms. Fingado stated that between March 9, 2016 and March 11, 2016 all 134 prescriber letters were mailed. Each letter contained the following:
    - Patient name, gender, and date of birth for all patients identified for the prescriber
    - Paid claims information for all opioid claims for each patient with dates of service between July 1, 2015 and February 29, 2016, including date of service, drug description, days’ supply, drug quantity, calculated MEDD, prescriber, and prescriber city
    - Any clinically relevant hospitalizations, emergency department visits, or clinic visits for each patient with dates of service between July 1, 2015 and February 29, 2016, including date of service, primary and secondary ICD-9-CM diagnostic codes and descriptions, provider or facility name, and provider or facility city
    - Medi-Cal DUR bulletin on MEDD
    - Handout with information about naloxone

- One provider response survey for each patient identified for the prescriber
  - Ms. Fingado reported the timeframe of mailing following approval of packet by DHCS:
    - Monday, February 29, 2016: packet submitted to Publications
    - Wednesday, March 2, 2016: final, edited packet approved by DHCS/Xerox
    - Friday, March 4, 2016: packet sent to printer
    - Wednesday, March 9, 2016 and Friday, March 11, 2016: packet mailed to 132 providers (134 letters total)
    - A total of 134 letters were mailed for a total estimated cost of \$138.88
  - Preliminary outcomes after 30 days were reported by Ms. Fingado, including an undeliverable rate of 25% and a provider response rate of 17%.
  - As stated in the original proposal, Ms. Fingado will assess the following outcome variables at later time points, as medical claims data become available:
    - The primary outcome variable will be the percentage of the continuously-eligible study population with a paid claim for an opioid medication exceeding > 120 mg MEDD in the 6-month period following the mailing of the intervention letter (April 1, 2016 through September 30, 2016)
    - The following secondary outcome variables will be assessed in the 6-month period following the mailing of the intervention letter (April 1, 2016 through September 30, 2016):
      - Percentage of the continuously-eligible study population identified as receiving prescription opioid medication as part of a narcotic withdrawal treatment plan
      - Percentage of the continuously-eligible study population identified with hospital or emergency department visits due to opioid overdose
      - Percentage of the continuously-eligible study population identified as having a paid claim for naloxone in the 6-month period
    - The number of days with cumulative MEDD > 120 mg in the 6-month period prior to the mailing of the intervention letter compared to the number of days with cumulative MEDD > 120 mg 6-month period following the mailing of the intervention letter, by beneficiary (in the continuously-eligible study population)
- iii. Proposal: Anticholinergic Drugs
- Ms. Fingado reported that despite the widespread use of anticholinergic medications for prophylaxis and treatment of antipsychotic-induced extrapyramidal symptoms (EPS), including tremor, rigidity, bradykinesia, and acute dystonia, there is a lack of systematic reviews and meta-analyses supporting this practice and the long-term benefits of anticholinergic use have not been established. She stated that several adverse effects have been reported from long-term use, including cognitive impairment and worsening of tardive dyskinesia, especially among persons 65 years of age and older. A recent review of the Medi-Cal fee-for-service data found that among beneficiaries with at least one paid claim for an anticholinergic medication, a total of 360 beneficiaries (1%) were age 65 years and older, with 191 of these beneficiaries having at least six paid claims for an anticholinergic medication during the measurement year.
  - Ms. Fingado proposed an educational outreach letter to providers to improve the quality of care among Medi-Cal fee-for-service beneficiaries age 65 years and older with concomitant use of second-generation antipsychotic and anticholinergic medications. A query will be done to identify any Medi-Cal fee-for-service beneficiary 65 years of age and older with regular, concomitant use of second-generation antipsychotic medications and anticholinergics. Regular use will be defined as six or more paid claims for each medication (antipsychotic and anticholinergic) during a one-year period. Beneficiaries with paid claims for antipsychotic and anticholinergic medications that amount to a total days supply > 180 days during the measurement year will also be reviewed.
  - All prescribers of anticholinergics to beneficiaries in the final study population will receive a letter with a summary of clinical recommendations. The mailing will also include patient name and date of birth (all patients identified for this prescriber), the Medi-Cal DUR article on Anticholinergics, and one provider response survey per patient.
  - The primary outcome variable will be the percentage of the continuously-eligible study population with two or more paid claims for an anticholinergic in the 6-month period

following the mailing of the intervention letter. In addition, prescriber response rates will be calculated, and response data and comments will be presented in aggregate in a report to DHCS and the DUR Board.

- A motion was made – and seconded – to accept this proposal. There was no further discussion. The motion was carried.

**ACTION ITEM:** The DUR Board recommendation to conduct an educational outreach to providers regarding Medi-Cal beneficiaries 65 years of age and older with chronic use of second-generation antipsychotic medications and anticholinergic medications will be submitted to DHCS.

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

**i. Review of Retrospective DUR Criteria: PCSK9 Inhibitors**

- The DUR Board had expressed an interest in finding out more information about the utilization of high-cost medications in the Medi-Cal fee-for-service program, including PCSK9 INHIBITORS.
- Dr. Lynch presented utilization data for all paid claims for PCSK9 INHIBITORS in the Medi-Cal fee-for-service program between August 27, 2015 (FDA-approval date) and March 31, 2016. During this time period, a total of seven beneficiaries were identified as having a paid claim for evolocumab, for a total number of 17 paid claims. All had at least one prior paid claim for ezetimibe. No paid claims for alirocumab were identified.
- Given the low utilization of these agents, no further action was recommended at this time.
- Dr. Lynch recommended conducting periodic monitoring of high-cost drug therapeutic categories, as requested by the DUR Board. The Board agreed and motioned that utilization of PCSK9 INHIBITORS be reviewed again in one year. There was no further discussion. The motion was carried.

**ACTION ITEM:** The DUR Board recommendation to review utilization of PCSK9 INHIBITORS again for the May 2017 DUR Board meeting will be submitted to DHCS.

**ii. Review of Retrospective DUR Criteria: Methadone**

- Dr. Lynch reported that in January 2016, the Centers for Medicare & Medicaid (CMS) distributed an informational bulletin entitled, “*Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction.*” Wherever possible, the bulletin provides examples of methods states can use to target the prescribing of methadone for pain relief, given the disproportionate share of opioid-related overdose deaths associated with methadone when used as a pain reliever. Suggestions included pharmacy benefit management strategies such as reassessing preferred drug list (PDL) placement of methadone, introducing clinical criteria, prior authorization, step therapy, quantity limits, and implementing drug utilization review (DUR) processes.
- Dr. Lynch stated that DHCS has discussed following the suggestion from CMS and potentially requiring an approved *Treatment Authorization Request* (TAR) for methadone. A retrospective review was conducted in order to determine the current utilization of methadone.
- Dr. Lynch stated that for this review all Medi-Cal fee-for-service paid claims for methadone with dates of service between 7/1/15 and 12/31/15 were included. During this time period, Dr. Lynch reported that a total of 1,013 Medi-Cal fee-for-service beneficiaries were identified with a paid claim for methadone, for a total of 3,223 paid claims. The majority of paid claims were for 10mg methadone. The recently published CDC MEDD calculation was utilized to approximate the MEDD. The mean MEDD for the 5mg tablets was 98 mg/day and the mean MEDD for the 10mg tablets was 609 mg/day. Discussion with the Board centered on the rationale and implications of restricting methadone to beneficiaries with an approved TAR.
- The Board requested additional evaluation of methadone claims data before making any recommendations regarding the TAR policy. Additional data points requested included diagnostic codes, and any emergency department and hospitalization data

	<p>from opioid overdose. Concomitant paid claims for naloxone were also requested, as was data regarding use of other opioids. Ms. Fingado agreed to perform additional evaluation of methadone claims data and present it at a future DUR Board meeting. Ms. Chan stated she appreciated the Board's feedback and would share comments from the discussion with Pharmacy Policy.</p> <p>i. Review of DUR Publications presented by Dr. Shalini Lynch (UCSF)</p> <ul style="list-style-type: none"> <li>i. DUR Bulletin (April, 2016): Concomitant Use of Antipsychotic and Metabolic Drugs</li> <li>ii. DUR Alert (April, 2016): Opioids</li> <li>iii. DUR Alert (April, 2016): Saxagliptin and Alogliptin</li> <li>iv. Discussion/Recommendations for Future Educational Bulletins</li> </ul> <ul style="list-style-type: none"> <li>• Due to time constraints, Dr. Lynch deferred presentation of this review to the upcoming DUR Board meeting in September 2016.</li> </ul> <p>j. Pharmacy Update</p> <ul style="list-style-type: none"> <li>i. CMS DUR Annual Report 2015 Revisions – Ms. Chan reported that updated draft of the 2015 DUR Annual Report to CMS will be presented at the next Board meeting and she plans to highlight the revisions.</li> <li>ii. Antipsychotic Drug Use in Children (ADC) Affinity Group – Ms. Chan briefly described the goals of the ADC Affinity Group and the role of the DUR program within the group.</li> <li>iii. Prescription Opioids Abuse Actions – Ms. Chan stated that the White House published a fact sheet in March 2016 that included updates on Federal actions and private sector commitments to address the opioid epidemic. Further, CMS released a guide and documents to States identifying best practices for addressing opioid overdoses, misuse, and addiction.</li> <li>iv. Proposed Medicaid Managed Care Regulation – Ms. Chan stated the final rule has just been published and she will send to the Board. She proposed a review of the final rule as an agenda item for a conference call with the Board this summer.</li> <li>v. Quality Strategy – Ms. Chan reported that states must develop a comprehensive quality strategy that applies to both MCO and FFS. The Board may have a role in recommending quality measures and setting improvement targets.</li> <li>vi. Child &amp; Adult Core Set Measures – New measures have been published for 2016, with new measures added that relate to pharmacy. Based on a review of the measures, Ms. Chan thought they may align with potential DUR bulletin topics and educational interventions.</li> <li>vii. Value Based Purchasing in Medicaid – Ms. Chan commented that value-based purchasing is likely to stay as a top agenda item for Medicaid programs.</li> <li>viii. Academic Detailing: October 20, 2016 (Sacramento) – Ms. Chan made a correction to the date that appeared on the DUR webpage and the printed copies of the agenda. The correct date of the meeting will be October 20, 2016 (not October 21, 2016).</li> </ul>
<b>5) PUBLIC COMMENTS</b>	<ul style="list-style-type: none"> <li>• None.</li> </ul>
<b>6) CONSENT AGENDA</b>	<ul style="list-style-type: none"> <li>• The next Board meeting will be held from 9:30 a.m. to 12:00 p.m. on September 20, 2016 in the Monterey Room located at Xerox State Healthcare, LLC on 840 Stillwater Road, West Sacramento, CA 95605.</li> </ul>
<b>7) ADJOURNMENT</b>	<ul style="list-style-type: none"> <li>• The meeting was adjourned at 12 p.m.</li> </ul>

Action Items	Ownership
Incorporate Dr. Wong's edits into the minutes and post to the DUR website.	Ivana
The following DUR Board recommendations will be submitted to DHCS: 1) Turn on the PG alert for all drugs currently with PG alert in test-mode; 2) Conduct periodic evaluations of alert and claims data; and 3) Evaluate the PG alert on an annual basis for all changes to category and severity levels and present these changes to the DUR Board for review.	Pauline/Ivana/Amanda

The DUR Board recommendations to update the Drug-Drug Interaction (DD) Alert portions of Section 20 of the DUR manual will be submitted to DHCS.	Ivana
The DUR Board recommendation to conduct an educational outreach to providers regarding Medi-Cal beneficiaries 65 years of age and older with chronic use of second-generation antipsychotic medications and anticholinergic medications will be submitted to DHCS.	Ivana/Amanda
The DUR Board recommendation to review utilization of PCSK9 INHIBITORS again for the May 2017 DUR Board meeting will be submitted to DHCS.	Amanda